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FEDERAL REGISTER

BOOK 1 OF 2 BOOKS

FRIDAY, JULY 28, 1978

highlights

FEDERAL GRANT PROGRAMS

Announcing a New Weekly Feature

To assist readers wishing to keep abreast of federally funded grant programs, the FEDERAL REGISTER is adding a new listing to the weekly Reminders section published every Wednesday Beginning with the issue of August 2, 1978, the Wednesday Reminders section will include a listing of grants related documents published in the FEDERAL REGISTER during the previous week.

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federal register

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list of cfr parts affected in this issue

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A Cumulative List of CFR Sections Affected is published separately at the end of each month. The guide lists the parts and sections affected by documents published since the revision date of each title.

reminders

(The items in this list were editorially compiled as an aid to FEDERAL REGISTER users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.)

Rules Going Into Effect Today

FCC—Changes made in table of assignments: Belpre, Ohio 27536; 6-26-78
Changes made in table of assignments: Cresson, Pa 27537; 6-26-78
Changes made in table of assignments: FM broadcast station in Haines, Alaska 27535; 6-26-78
Changes made in table of assignments: Lexington, Va 27538; 6-26-78
Changes made in table of assignments: West Salem, Wis 27540; 6-26-78
USDA/AMS—Increase in payment rate for handler services on reserve tonnage raisins 27983; 6-28-78

List of Public Laws

NOTE: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's LIST OF PUBLIC LAWS.

[Last listing: July 26,1978]

The following numerical guide is a list of parts of each title of the Code of Federal Regulations affected by documents published to date during July.

FEDERAL REGISTER PAGES AND DATES—JULY

Pages	*Date*	*Pages*	*Date*	*Pages*	*Date*
28805-28963	July 3	30033-30257	13	31307-31879	21
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rules and regulations

[6325-01]

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Department of Interior, Department of Energy

AGENCY: Civil Service Commisson.

ACTION: Final rule.

SUMMARY: This amendment (1) excepts under schedule C one position in the Department of the Interior because it is confidential in nature and (2) changes the title of a position in the Department of Energy to more appropriately reflect the duties of the position.

EFFECTIVE DATES: Department of the Interior—July 18, 1978; Department of Energy—July 17, 1978.

FOR FURTHER INFORMATION CONTACT:

Michael Sherwin, 202-632-4533.

Accordingly, 5 CFR 213.3312(a)(47) and 213.3331(h)(1) are amended as set out below:

§ 213.3312 Department of the Interior.

(a) *Office of the Secretary.* * * *

(47) Four Special Assistants to the Assistant Secretary, Land and Water Resources.

§ 213.3331 Department of Energy.

* * * * *

(h) *Office of the Assistant Secretary for Conservation and Solar Application.*

(1) One Confidential Assistant (Secretary) to the Assistant Secretary.

(5 U.S.C. 3301, 3302, E.O. 10577, 3 CFR 1954-1958 comp., p. 218)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-20922 Filed 7-27-78; 8:45 am]

[6325-01]

PART 213—EXCEPTED SERVICE

Executive Office of the President

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: The Schedule A authority under 5 CFR 213.3121 for the National Security Council is transferred to 5 CFR 213.3103 to show that the National Security Council is part of the Executive Office of the President.

EFFECTIVE DATE: July 19, 1978.

FOR FURTHER INFORMATION CONTACT:

Michael D. Sherwin, 202-632-4533.

Accordingly, 5 CFR 213.3103 is amended by adding paragraph (g) and 5 CFR 213.3121 is revoked, as follows:

§ 213.3103 Executive Office of the President.

* * * * *

(g) *National Security Council.*

(1) All positions on the staff of the Council.

* * * * *

§ 213.3121 [Revoked]

5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954-1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-20957 Filed 7-27-78; 8:45 am]

[6325-01]

PART 870—REGULAR LIFE INSURANCE

PART 871—OPTIONAL LIFE INSURANCE

Reduction in Rates for Regular and Optional Federal Employees' Group Life Insurance

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: The Civil Service Commission is amending its Federal Employees' Group Life Insurance (FEGLI) regulations to effect a reduction in both regular and optional insurance rates. This action is indicated by the latest actuarial valuation of program operations as of September 30, 1977. In view of the facts that the Commission is authorized by law to determine FEGLI rates and that the amendments will effect a liberalization in benefits, the Commission finds that it is unnecessary to delay the effective date to allow for notice of proposed rulemaking and public procedure thereon.

EFFECTIVE DATE: These amendments will be effective with the first pay period which begins on or after September 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Edwin C. Hustead, Chief, Office of the Actuary, Bureau of Retirement, Insurance, and Occupational Health, U.S. Civil Service Commission, 1900 E Street NW., Room 4303, Washington, D.C. 20415, area code 202-632-4656.

SUPPLEMENTARY INFORMATION:

FEGLI RATES

By law, the Civil Service Commission is directed to determine Government and employee contributions for regular FEGLI on the basis of the level cost of each $1,000 of insurance and to determine the cost of optional FEGLI to employees, and annuitants under age 65, on the basis of such age groups as it considers appropriate (5 U.S.C. 8707, 8708, 8714a(e)). Present contributions for regular FEGLI have been in effect since March 1975, and total 53.25 cents biweekly per $1,000 of insurance, i.e., 35.5 cents from insured employees and 17.75 cents from employing Government agencies. Employees, and annuitants under age 65, must pay the full cost when optional FEGLI is elected. The current biweekly rates for optional insurance have been in effect since July 1973, and are as follows:

Age group:	*Biweekly rate for $10,000*
Under 35	$0.80
35 to 39	1.20

Age group:	Biweekly rate for $10,000
40 to 44	1.90
45 to 49	2.90
50 to 54	4.50
55 to 59	10.50
60 and over	14.00

FEGLI VALUATION

The latest actuarial valuation of the FEGLI program as of September 30, 1977, indicates that both the regular and optional FEGLI rates can be substantially reduced. This is possible for a number of reasons, among them, sharply reduced mortality rates, higher investment yields and with respect to optional FEGLI, a marked increase in employee participation since the last valuation based on program experience through June 30, 1973. Also, the current valuation includes an inflation factor in the actuarial assumptions since the high rate of inflation in recent years has established it as an important component of salary increases and interest rates, both of which have a direct impact on program costs.

Accordingly, 5 C.F.R. 870.401 (a) and (b) and 871.401(c) are amended as set out below:

§ 870.401 Withholdings and contributions.

(a) During any period in any part of which an insured employee is in a pay status there shall be withheld from the biweekly pay of such employee the sum of 25.5 cents for each $1,000 of regular insurance. The amount withheld from the pay of an employee who is paid on other than a biweekly basis is determined at a proportinate rate, adjusted to the nearest cent.

(b) The amount withheld from the pay of an insured employee whose annual pay is paid during a period shorter than 52 workweeks is the sum obtained by converting the biweekly rate of 25.5 cents for each $1,000 of regular insurance to an annual rate and prorating the annual rate over the number of installments of pay regularly paid during the year.

* * * * *

(5 U.S.C. §§ 8707, 8716(a).)

§ 871.401 Withholdings.

* * * * *

(c) The biweekly full cost of the $10,000 of optional insurance (and, for a person in receipt of annuity or compensation for work injury, of optional life insurance), until determined by the Commission on the basis of experience to be otherwise, is:

For persons under age 35	$0.60
For persons ages 35 through 39	1.00
For persons ages 40 through 44	1.70
For persons ages 45 through 49	2.40
For persons ages 50 through 54	3.50
For persons ages 55 through 59	7.50
For persons 60 or over	9.00

The amount withheld from the pay of a person paid on other than a biweekly period or insured for more than $10,000 shall be determined at a proportionate rate, adjusted to the nearest cent.

This paragraph is effective with the first pay period which begins on or after September 1, 1978.

(5 U.S.C. §§ 8714a(e), 8716(a).)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-20956 Filed 7-27-78; 8:45 am]

[3410-10]

Title 7—Agriculture

SUBTITLE A—OFFICE OF SECRETARY

PART 6—IMPORT QUOTAS AND FEES

Section 22—Import Fees; Licensing Entry of Sugar Exempt From Fees

AGENCY: Foreign Agricultural Service; USDA.

ACTION: Final rule.

SUMMARY: The rule establishes procedures and conditions for the issuance of licenses which will permit the importation of sugar exempt from the fees imposed by Presidential Proclamation 4547 of January 20, 1978, on sugar, sirups, and molasses. Sugar imported under such a license must be used solely for the production (other than by distillation) of polyhydric alcohol, except polyhydric alcohol for use as a substitute for sugar in human food consumption.

EFFECTIVE DATE: August 1, 1978. See supplementary information.

ADDRESSES: Mail comments or inquiries to the Horticultural and Tropical Products Division, Foreign Agricultural Service, USDA, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT:

Robert M. McConnell, 202-447-3423.

SUPPLEMENTARY INFORMATION: Presidential Proclamation 4547 of January 20, 1978, imposed fees on sugar, sirups, and molasses as provided for in items 956.05, 956.15, 957.15 of the Tariff Schedules of the United States (TSUS). Proclamation 4547 amended headnote 4 of part 3 of the appendix to the TSUS to read as follows:

Licenses may be issued by the Secretary of Agriculture or his designee authorizing the entry of articles exempt from the fees provided for in items 956.05, 956.15, and 957.15 of this part on the condition that such articles will be used only for the production (other than by distillation) of polyhydric alcohols, except polyhydric alcohols for use as a substitute for sugar in human food consumption. Such licenses shall be issued under regulations of the Secretary of Agriculture which he determines are necessary to insure the use of such articles only for such purposes.

Polyhydric alcohols are organic solvents containing two or more hydroxyl groups. Such alcohols are used in the production of other chemicals.

On May 15, 1978, proposed regulations for the implementation of Proclamation 4547 were published in the FEDERAL REGISTER (43 FR 20813). Interested persons were given until June 14, 1978, to submit comments. One comment was received.

The comment received was from the U.S. Customs Service. The Customs Service pointed out that the proposed regulations might create a duplication of functions with respect to the bonding requirements and use verification. The Customs Service also suggested several other technical changes in order to insure that the regulations are compatible with existing Customs practices and rules.

After consultation with the Customs Service, it was determined that the proposed regulations should be modified as follows:

1. Section 6.56 has been modified to provide that bonding shall be in conformity with all Customs bond requirements. The Customs Service shall administer the bond, including the assessment of penalties for failure to comply with the conditions of the import license and the regulations in this subpart.

2. The term "agent" (sec. 6.50(g)) has been redefined to mean a licensed customhouse broker. This change was made in order to conform with Customs regulations.

3. Section 6.58 has been modified to provide that: (1) Certificates of use are to be filed both with the Horticultural and Tropical Products Division and the appropriate Customs official; and (2) certificates of use may be filed no later than 180 days after the expiration of the import license under which the sugar in question was imported.

4. Technical and clarifying changes have been made in the regulations where necessary.

EFFECTIVE DATE

Licenses are presently needed by manufacturers in order to import sugar for the production of polyhydric alcohol exempt from the fees established by Proclamation 4547. It has therefore been determined that it is impractical and contrary to the public interest to comply with the effective date provisions of 5 U.S.C. 553.

In accordance with the above, 7 CFR Part 6 is amended by inserting the following subpart after Subpart—Section 22 Import Quotas:

Subpart—Section 22 Import Fees

Exemption From Fees—Sugar

Sec.
6.50 Definitions.
6.51 Issuance of an import license.
6.52 Transferability of an import license.
6.53 Entry of sugar.
6.54 Entry of sugar by an agent.
6.55 Appplication for an import license.
6.56 Bond requirements.
6.57 Default.
6.58 Certificate of use.
6.59 Revocation.

Authority: Sec. 22, 49 Stat. 773, as amended (7 U.S.C. 624); Presidential Proclamation 4547, January 20, 1978 (43 FR 3251).

§ 6.50 Definitions.

As used in this subpart: (a) The term "person" means an individual, partnership, corporation, association, estate, trust, or other business enterprise or legal entity, and, wherever applicable, any unit, instrumentality, or agency of a government, domestic or foreign.

(b) The term "Department" means the U.S. Department of Agriculture.

(c) The term "Secretary" means the Secretary of Agriculture or any officer or employee of the Department to whom the Secretary has delegated the authority or to whom authority may hereafter be delegated to act in his place.

(d) The term "appropriate customs official" means the district or area Director of Customs, his designee, or any other customs officer of similar authority and responsibility, for the customs district in which the port of entry is located.

(e) The term "import license" means a license issued by the Secretary permitting the entry of sugar exempt from the fees provided for in items 956.05, 956.15, and 957.15 of the tariff schedules of the United States, on condition that such sugar will be used solely for the production (other than by distillation) of polyhydric alcohols, except polyhydric alcohols for use as a substitute for sugar in human food consumption.

(f) The term "manufacturer" means a person that is engaged in the production (other than by distillation) of polyhydric alcohols from sugar.

(g) The term "agent" means a licensed customhouse broker.

(h) The term "sugar" means sugars, sirups, and molasses as defined in items 956.05, 956.15, 957.15 of the tariff schedules of the United States.

§ 6.51. Issuance of an import license.

(a) An import license may be issued to a manufacturer which complies with the provisions of this subpart. The license shall state the time period during which the license shall be effective and the maximum amount of sugar which may be imported under the license. In no case shall the effective period of a license exceed 1 year, nor shall the maximum amount of sugar which may be imported under the license exceed the anticipated requirements of the manufacturer for the 12-month period following the effective date of the license. The license may contain such other conditions as the Secretary, in his discretion, deems necessary.

(b) No more than one effective license may be issued and outstanding at any one time to any one manufacturer. In order to insure a dependable and orderly supply of sugar, a manufacturer may apply for a license prior to the expiraton of a previously issued license. The previously issued license shall be deemed to have expired on its stated expiration date, or on the effective date of the succeeding license, whichever is earlier. A succeeding license may not be issued until the previously issued license has been returned to the Horticultural and Tropical Products Division, Foreign Agricultural Service, U.S. Department of Agriculture, Washington, D.C. 20250.

§ 6.52 Transferability of an import license.

An import license may not be transfered or assigned by the manufacturer to any other person. Any attempt to transfer or assign an import license shall be null and void and shall constitute grounds for the revocation of the license by the Secretary.

§ 6.53 Entry of sugar.

(a) A manufacturer or its agent may enter sugar into the United States exempt from the fees contained in items 956.05, 956.15, 957.15 of the tariff schedules of the United States under an import license issued pursuant to this subpart. The import license must be presented to the appropriate customs official at the time of entry. Entry of the sugar exempt from fees shall be allowed only in conformity with the conditions of the import license, if any.

(b) The appropriate Customs official shall enter on the license: (1) The amount of sugar entered; (2) the date of entry; and (3) the customs entry number.

(c) A copy of the license, as marked by the appropriate customs official, shall be transmitted to the Horticultural and Tropical Products Division, Foreign Agricultural Service, U.S. Department of Agriculture, Washington, D.C. 20250, by the person entering the sugar, within 10 business days after each entry of sugar.

§ 6.54 Entry of sugar by an agent.

(a) In those cases where sugar is to be entered by an agent of the manufacturer, the agent shall produce for inspection by the appropriate customs official a written authorization by the manufacturer designating such person to act as the agent of the manufacturer for the purpose of entering sugar.

(b) A copy of such authorization shall be attached to the relevant copy of the import license that is transmitted to the Horiticultural and Tropical Products Division pursuant to § 6.53(c).

§ 6.55 Application for an import license.

(a) Only manufacturers are eligible to receive an import license.

(b) Each application for an import license shall contain the following information:

(i) Name and address of the manufacturer.

(ii) A statement of the anticipated requirements of the manufacturer for sugar to be used in the production (other than by distillation) of polyhydric alcohols, except polyhydric alcohols for use as a substitute for sugar in human food consumption, during the effective period of the license.

(iii) The anticipated amount of sugar to be imported during the specified effective period.

(iv) The effective period of the import license (but not to exceed 1 year).

(c) Each application for an import license shall contain a certification that the manufacturer shall use the quantity of sugar entered under an import license solely for the production (other than by distillation) of polyhydric alcohols, except polyhydric alcohols for use as a substitute for sugar in human food consumption.

§ 6.56 Bond requirements.

(a) Sugar entered under an import license shall be subject to all customs bond requirements (see 19 CFR Parts 113, 141, 143, and 144). The appropriate customs offical may assess liquidated damages under the customs entry bond for violation of any provision of the import license or this subpart.

(b) The appropriate customs official may release all or part of the obligation under a bond if the Secretary determines that the destruction or other disposition of a quantity of sugar entered under an import license renders performance under the bond impossible or inequitable. In such case the Secretary shall notify the appropriate customs official of his determination. The determination shall be treated as a certificate of use which has been properly and timely filed.

§ 6.57 Default.

Upon a failure to comply with the provisions of this subpart or the import license, payment of the obligation under the bond shall be made to the appropriate customs official in accordance with the conditions of the bond.

§ 6.58 Certificate of use.

(a) The certificate of use shall be a certification by the manufacturer that a quantity of sugar entered under an import license has been used for the purpose stated in § 6.50(e). Certificates of use shall be transmitted to the appropriate customs official and the Horticultural and Tropical Products Division by the manufacturer on a monthly basis. In no case shall a certificate of use be accepted more than 180 days after the expiration of the import license under which the sugar was imported, unless the Secretary, in his discretion, extends the time period in which a certificate may be filed.

(b) The certificate of use shall be signed by the manufacturer and shall contain the following certification:

The undersigned hereby certifies that between ————, 19——, and ————, 19——, the undersigned has used ——— pounds of sugar for the sole purpose of producing (other than by distillation) polyhydric alcohols, except polyhydric alcohols for use as a substitute for sugar in human food consumption. The undersigned further certifies that the quantity of sugar shown on this certificate of use does not include any sugar previously covered by another certificate of use.

§ 6.59 Revocation.

(a) If, at any time, the Secretary determines that the manufacturer has failed to comply with the requirements of this subpart or the import license, the Secretary may, in his discretion, revoke the import license.

(b) Notice of the revocation shall be given to the manufacturer and the Customs Service.

Dated: July 20, 1978.

THOMAS R. HUGHES,
Administrator.

[FR Doc. 78-20927 Filed 7-27-78; 8:45 am]

[3410-30]

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER A—CHILD NUTRITION PROGRAMS

[Amdt. I]

PART 225—SUMMER FOOD SERVICE PROGRAM FOR CHILDREN

Implementation of Special Account System for Issuing Checks for Food Service Payments to Special Accounts on Temporary Basis

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: The Department is issuing an amendment to final regulations for the Summer Food Service Program for Children. This amendment provides for the implementation of a special account system for issuing checks for food service payments to special accounts on a temporary basis. This method will be required for nongovernmental sponsors in the State of New York and will be optional in all other States. It is intended that the special account system be implemented and evaluated to determine whether it continues to be necessary to ensure that food service management companies receive payments on a timely basis.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry S. Rodriguez, Acting Director, Child Care and Summer Programs Division, 201 14th Street SW., Washington, D.C. 20250, 202-447-8211.

SUPPLEMENTAL INFORMATION: The Department believes that it is in the interest of the program to examine methods which would assist food service management companies in receiving proper payments from sponsors. The Department is, therefore, implementing a special account system on a temporary basis for nongovernmental sponsors in New York State for the 1978 summer program. In other States, the State agency may elect to implement a special account system for nongovernmental sponsors for whom program payment has been, or is expected to be, a particular problem. For other FNSRO-administered programs the special account may be established only at the request of the sponsor. Under this system, nongovernmental sponsors contracting with food service management companies must agree to establish special accounts with financial institutions for amounts intended for payments to food service management companies. The special account agreement must specify that any disbursement of monies from the account must be authorized by both the sponsor and the food service management company.

The Department is implementing the special account system on a temporary basis to assure that food service management companies will receive payment by alerting them to the time and amount of payments to the sponsors and granting them an opportunity to participate in the disbursement of monies.

Publication of proposed rules is impracticable and contrary to the public interest since the special account system is to be implemented this summer (1978).

Accordingly, 7 CFR part 225 is amended as set forth below:

(1) Subpart D of the table of contents is amended to read as follows:

Sec. 225.18a Special account payment provision.

* * * * *

(2) In § 225.2 a new paragraph (gg) is added to read as follows:

§ 225.2 Definitions.

* * * * *

(gg) "Special account" means an account with a sound and reputable recognized financial institution in which net program payments are deposited by FNS and released only in accordance with the terms of the special account agreement.

(3) A new § 225.18a is added and reads as follows:

§ 225.18a Special account payment provision.

(a) The Department shall, on a temporary basis in the State of New York for program operations undertaken in fiscal year 1978, require as a condition for participation that nongovernmental sponsors under contract with food service management companies establish special accounts for the deposit of checks for net program payments. A separate account shall be established for each food service management company under contract with the sponsor.

(b) Each sponsor shall, under its written agreement with the Department, agree to the issuance of checks payable to sponsor for net Program payments to a special account. The account agreement must specify that checks payable to the sponsor will be deposited in the special account by the financial institution and disburse-

ments from the account shall be made only with the written concurrence of both the sponsor and the food service management company. The special account agreement may contain such other terms as are agreed to by both sponsor and food service management company, *Provided, however,* That such terms are not inconsistent with the terms of the contract between the sponsor and the food service management company. A copy of the special account agreement shall be submitted to the Department and another copy maintained on file by the sponsor. Any charges by the financial institution for the accounts which are borne by the sponsor shall be considered an administrative cost.

(c) While these procedures are being used, any State agency may require the special account payment system for nongovernmental sponsors for whom proper payment has been, or is expected to be, a particular problem. Such State agency must include an appropriate provision in its written agreement with sponsors, and appropriately amend its program management and administration plan in accordance with § 225.6(c). In States where FNSRO administers the program, special accounts may be established only at the request of the sponsor.

(d) In order to assess the effectiveness of the special account payment system, the Department shall, subsequent to completion of Program operations for this fiscal year, evaluate the results of these procedures as implemented in the State of New York and in other States which so utilize the system.

(Catalog of Federal Domestic Assistance Programs No. 10.559.)

NOTE.—The Food and Nutrition Service has determined that this document does not contain significant proposals requiring preparation of an economic impact statement under Executive Order 11821 and Office of Management and Budget Circular A-107.

NOTE.—The reporting and/or recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942.

Dated: July 21, 1978.

CAROL TUCKER FOREMAN,
Assistant Secretary.

[FR Doc. 78-20710 Filed 7-27-78; 8:45 am]

[3410-02]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

PART 958—ONIONS GROWN IN CERTAIN DESIGNATED COUNTIES IN IDAHO AND MALHEUR COUNTY, OREG.

Handling Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation requires fresh market shipments of onions grown in certain designated counties in Idaho and Malheur County, Oreg., to be inspected and meet minimum quality and size requirements. The regulation should promote orderly marketing of such onions and keep less desirable qualities and sizes from being shipped to consumers.

EFFECTIVE DATE: August 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles R. Brader, Deputy Director, Fruit and Vegetable Division, AMS, U.S. Department of Agriculture, Washington, D.C. 20250, telephone 202-447-6393.

SUPPLEMENTARY INFORMATION: Marketing agreement No. 130 and order No. 958, both as amended (7 CFR Part 958), regulate the handling of onions grown in certain designated counties in Idaho and Malheur County, Oreg. It is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The Idaho-Eastern Oregon Onion Committee, established under the order, is responsible for its local administration.

Notice of rulemaking was published in the July 3, 1978, FEDERAL REGISTER (43 FR 28816). The notice afforded interested persons through July 18, 1978, to file written data, views, or arguments pertaining to that proposal. None was filed.

This regulation is based upon recommendations made by the committee at its public meeting in Ontario, Oreg., on June 20, 1978. The recommendations of the committee reflect its appraisal of the composition of the 1978 crop of Idaho-Eastern Oregon onions and the marketing prospects for this season and are consistent with the marketing policy it adopted. Harvesting of onions is expected to begin about August 1.

The grade, size, pack, maturity, and inspection requirements specified herein are necessary to prevent onions of low quality or less desirable sizes from being distributed in fresh market channels. They will also provide consumers with good quality onions consistent with the overall quality of the crop, and maximize returns to producers for the preferred quality and sizes.

Exception are provided to certain of these requirements to recognize special situations in which such requirements would be inappropriate or unreasonable. Shipments are allowed to certain special purpose outlets without regard to the grade, size, pack, maturity, and inspection requirements, *Provided,* That safeguards are met to prevent such onions from reaching unauthorized outlets.

Special purpose shipments are allowed for planting, livestock feed, charity, dehydration, extraction, and pickling since such shipments do not normally enter the commercial fresh market channels and no useful purpose would be served by regulating such shipments. Onions for canning and freezing are exempt under the legislative authority for this part.

Findings. After consideration of all relevant matters, including the proposal set forth in the aforesaid notice which was recommended by the Idaho-Eastern Oregon Onion Committee, it is hereby found that the handling regulation, as hereinafter set forth, will tend to effectuate the declared policy of the act.

It is hereby further found that good cause exists for not postponing the effective date of this regulation until 30 days after its publication in the FEDERAL REGISTER (5 U.S.C. 553) in that: (1) Shipments of onions grown in the production area will begin on or about the effective date specified herein, (2) to maximize benefits to producers, this regulation should apply to as many shipments as possible during the marketing season, (3) information regarding the provisions of this regulation, which are similar to those in effect during the previous season, has been made available to producers and handlers in the production area, (4) compliance with this regulation will not require any special preparation by handlers which cannot be completed by the effective date, and (5) notice of the proposed regulation was published in the FEDERAL REGISTER of July 3, 1978.

The regulation is as follows:

§ 958.323 Handling regulation.

During the period August 1, 1978, through April 30, 1979, no person may handle any lot of onions, except braided red onions, unless such onions are at least "moderately cured," as defined in paragraph (f) of this section, and meet the requirements of paragraphs (a) and (b) of this section, or unless such onions are handled in accordance with paragraphs (c) and (d) or (e) of this section.

(a) *Grade and size requirements.*— (1) *White varieties.* Shall be either: (i) U.S. No. 2, 1 inch minimum to 2 inches maximum diameter; or

(ii) U.S. No. 2, if not more than 30 percent of the lot is comprised of onions of U.S. No. 1 quality, and at least 1½ inches minimum diameter; or

(iii) U.S. No. 1, at least 1½ inches minimum diameter. However, none of these three categories of onions may be commingled in the same bag or other container.

(2) *Red varieties.* U.S. No. 2 or better grade, at least 1½ inches minimum diameter.

(3) *All other varieties.* Shall be either: (i) U.S. No. 2 grade, at least 3 inches minimum diameter, if not more than 30 percent of the lot is comprised of onions of U.S. No. 1 quality; or

(ii) U.S. No. 1, 1½ inches minimum to 2¼ inches maximum diameter; or

(iii) U.S. No. 1, at least 2¼ inches minimum diameter.

However, none of these three categories of onions may be commingled in the same bag or other container.

(b) *Inspection.* No handler may handle any onions regulated hereunder unless such onions are inspected by the Federal-State inspection service and are covered by a valid applicable inspection certificate, except when relieved of such requirement pursuant to paragraphs (c) or (e) of this section.

(c) *Special purpose shipments.* The minimum grade, size, maturity, and inspection requirements of this section shall not be applicable to shipments of onions for any of the following purposes: (1) Planting, (2) livestock feed, (3) charity, (4) dehydration, (5) canning, (6) freezing, (7) extraction, and (8) pickling.

(d) *Safeguards.* Each handler making shipments of onions for dehydration, canning, freezing, extraction, or pickling pursuant to paragraph (c) of this section shall:

(1) First apply to the committee for and obtain a certificate of privilege to make such shipments;

(2) Prepare, on forms furnished by the committee, a report in quadruplicate on each individual shipment to such outlets authorized in paragraph (c) of this section;

(3) Bill or consign each shipment directly to the applicable processor; and

(4) Forward one copy of such report to the committee office and two copies to the processor for signing and returning one copy to the committee office. Failure of the handler or processor to report such shipments by promptly signing and returning the applicable report to the committee office may be cause for cancellation of such handler's certificate of privilege and/or the processor's eligibility to receive further shipments pursuant to such certificate of privilege. Upon cancellation of any such certificate of privilege the handler may appeal to the committee for reconsideration.

(e) *Minimum quantity exemption.* Each handler may ship up to, but not to exceed, 1 ton of onions each day without regard to the inspection and assessment requirements of this part, if such onions meet minimum grade, size, and maturity requirements of this section. This exemption shall not apply to any portion of a shipment that exceeds 1 ton of onions.

(f) *Definitions.* The terms "U.S. No. 1" and "U.S. No. 2" have the same meaning as defined in the U.S. Standards for Grades of Onions (Other Than Bermuda-Granex-Grano and Creole Types), as amended (7 CFR 2851.2830-2851.2854), or the U.S. Standards for Grades of Bermuda-Granex-Grano Type Onions (7 CFR 2851.3195-2851.3209), whichever is applicable to the particular variety, or variations thereof specified in this section. The term "braided red onions" means onions of red varieties with tops braided (interlaced). The term "moderately cured" means the onions are mature and are more nearly well cured than fairly well cured. Other terms used in this section have the same meaning as when used in marketing agreement No. 130 and this part.

(g) *Applicability to imports.* Pursuant to § 8e of the act and § 980.117 *Import regulations; onions* (43 FR 5499); onions imported during the effective period of this section shall meet the grade, size, quality, and maturity requirements specified in the introductory paragraph and paragraph (a) of this section.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.)

Dated: July 25, 1978, to become effective August 1, 1978.

FLOYD F. HEDLUND,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 78-20962 Filed 7-27-78; 8:45 am]

[3410-02]

[Lemon Reg. 156, Lemon Reg. 155, Amdt. 1]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action establishes the quantity of California-Arizona lemons that may be shipped to the fresh market during the period July 30-August 5, 1978, and increases the quantity of such lemons that may be so shipped during the period July 23-29, 1978. Such action is needed to provide for orderly marketing of fresh lemons for the periods specified due to the marketing situation confronting the lemon industry.

DATES: The regulation becomes effective July 30, 1978, and the amendment is effective for the period July 23-29, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles R. Brader, 202-447-6393.

SUPPLEMENTARY INFORMATION: *Findings.* Pursuant to the marketing agreement, as amended, and order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, established under this marketing order, and upon other information, it is found that the limitation of handling of lemons, as hereafter provided, will tend to effectuate the declared policy of the act.

The committee met on July 25, 1978, to consider supply and market conditions and other factors affecting the need for regulation, and recommended quantities of lemons deemed advisable to be handled during the specified weeks. The committee reports the demand for lemons continues good.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting, and the amendment relieves restrictions on the handling of lemons. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

§ 910.456 Lemon regulation 156.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period July 30, 1978, through August 5, 1978, is established at 300,000 cartons.

(b) As used in this section, "handled" and "carton(s)" mean the same as defined in the marketing order.

§ 910.455 [Amended]

2. Paragraph (a) of § 910.455 Lemon regulation 155 (43 FR 31313) is amended to read as follows: "The quantity of lemons grown in California and Arizona which may be handled during the period July 23, 1978, through July 29, 1978, is established at 325,000 cartons."

(Secs. 1-19, 48 Stat. 31, as amended (7 U.S.C. 601-674).)

Dated: July 26, 1978.

CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 78-21104 Filed 7-27-78; 8:45 am]

[4410-10]

Title 8—Aliens and Nationality

CHAPTER I—IMMIGRATION AND NATURALIZATION SERVICE, DEPARTMENT OF JUSTICE

PART 231—ARRIVAL-DEPARTURE MANIFESTS AND LISTS; SUPPORTING DOCUMENTS

Submission of Aircraft/Vessel Reports (Forms I-92) for Direct Flights Between the United States and Canada; Stay of Final Rules and Request for Comments

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Stay of final rule and request for comments.

SUMMARY: The purpose of this order is to stay indefinitely the final rules published at 43 FR 30268-69 on July 14, 1978, to allow for public participation in this rule making proceeding pursuant to a request of the Air Transport Association. The Service requests comments based on the text of the rules published at 43 FR 30268-69. Full consideration will be given to all relevant representations received and the Service will reconsider the rules following an analysis of those representations.

DATES: Final rules stayed indefinitely. Interested persons are requested to submit relevant data, views and arguments concerning these stayed rules to the Commissioner of Immigration and Naturalization on or before September 26, 1978.

ADDRESSES: Please submit written representations, in duplicate, to the Commissioner of Immigration and Naturalization, Room 7100, 425 Eye Street NW., Washington, D.C. 20536.

FOR FURTHER INFORMATION CONTACT:

James G. Hoofnagle, Jr., telephone: 202-376-8373.

Dated: July 25, 1978.

LEONEL J. CASTILLO,
Commissioner of Immigration and Naturalization.

[FR Doc. 78-21067 Filed 7-27-78; 8:45 am]

[1505-01]

Title 9—Animals and Animal Products

CHAPTER III—FOOD SAFETY AND QUALITY SERVICE, MEAT AND POULTRY PRODUCTS INSPECTION, DEPARTMENT OF AGRICULTURE

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS, REINSPECTION AND PREPARATION OF PRODUCTS

Nitrates, Nitrites, and Ascorbates (or Isoacorbates) in Bacon

Correction

In FR Doc. 78-20721 appearing at page 32136 in the issue for Tuesday, July 25, 1978, on page 32137, first column, ninth line from the top, the word "nitrate" should read "nitrite".

[7590-01]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

CHANGE OF ADDRESS OF REGION II OFFICE

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is moving its Inspection and Enforcement Regional Office II to a new address in Atlanta, Ga. Parts 1, 20, and 73 of the Commission's regulations are being amended to show the new address for Region II.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Gerald L. Hutton, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone 301-492-7211.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission is moving its Inspection and Enforcement Regional Office II to a new address in Atlanta, Ga. The new address is as follows: U.S. Nuclear Regulatory Commission, Region II, 101 Marietta Street, Suite 3100, Atlanta, Ga. 30303.

Because these amendments relate solely to corrections and minor matters, the Commission has found that good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary, and for making the amendments effective on

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 1, 20, and 73 are published as a document subject to codification.

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

1. Paragraph 1.3(b) of 10 CFR Part 1 is amended by revising the address of NRC Regional Office II to read as follows:

§ 1.3 Location of principal offices and regional offices.

* * * * *

(b) * * * Region II, USNRC, 101 Marietta Street, Suite 3100, Atlanta, Ga. 30303.

* * * * *

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

2. Appendix D of 10 CFR Part 20 is amended by revising the address of NRC Regional Office II to read as follows:

APPENDIX D—U.S. NUCLEAR REGULATORY COMMISSION INSPECTION AND ENFORCEMENT REGIONAL OFFICES

* * * * *

Region II, USNRC, Office of Inspection and Enforcement, 101 Marietta Street, Suite 3100, Atlanta, Ga. 30303.

* * * * *

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

3. Appendix A of 10 CFR Part 73 is amended by revising the address of NRC Regional Office II to read as follows:

APPENDIX A—U.S. NUCLEAR REGULATORY COMMISSION INSPECTION AND ENFORCEMENT REGIONAL OFFICES

* * * * *

Region II, USNRC, Office of Inspection and Enforcement, 101 Marietta Street, Suite 3100, Atlanta, Ga. 30303.

* * * * *

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201 Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841).)

Dated at Bethesda, Md., this 20th day of July 1978.

For the Nuclear Regulatory Commission.

LEE V. GOSSICK,
Executive Director for Operations.

[FR Doc. 78-20799 Filed 7-27-78; 8:45 am]

[6210-01]

Title 12—Banks and Banking

CHAPTER II—FEDERAL RESERVE SYSTEM

SUBCHAPTER A—BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

[Reg Z; FC-0150]

PART 226—TRUTH IN LENDING

Official Staff Interpretations; Correction

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Official staff interpretation(s); correction.

SUMMARY: This notice corrects a previous FEDERAL REGISTER document published on July 17, 1978 (43 FR 30531).

FOR FURTHER INFORMATION CONTACT:

Anne Geary, Chief Staff Attorney, Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, 202-452-2761.

SUPPLEMENTARY INFORMATION: The official staff interpretation(s) published in FR Doc. 78-19506 appearing at page 30531 of the issue for Monday, July 17, 1978, paragraphs (2) and (3) of supplementary information should read as follows, with corrections in the code of Federal Regulations part number and the United States Code number:

"(2) An opportunity for public comment on an official staff interpretation may be provided upon request of interested parties and in accordance with 12 CFR Part 226.1(d)(2)(ii). As provided by 12 CFR Part 226.1(d)(3) every request for public comment must be in writing, should clearly identify the number of the official staff interpretation in question, should be addressed to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, and must be postmarked or received by the Secretary's office before the effective date of the interpretation. The request must also state the reasons why an opportunity for public comment would be appropriate.

"(3) 15 U.S.C. 1640(f)."

Board of Governors of the Federal Reserve System, July 20, 1978.

CATHY E. MINEHAN,
Assistant Secretary of the Board.

[FR Doc. 78-20885 Filed 7-27-78; 8:45 am]

[6210-01]

[Reg B; EC-0011]

PART 202—EQUAL CREDIT OPPORTUNITY

Official Staff Interpre- tations; Correction

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Official staff interpretation(s); correction.

SUMMARY: This notice corrects a previous FEDERAL REGISTER document published on July 17, 1978 (43 FR 30531).

FOR FURTHER INFORMATION CONTACT:

Anne Geary, Chief Staff Attorney, Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, 202-452-2761.

SUPPLEMENTARY INFORMATION: The official staff interpretation(s) published in FR Doc. 78-19505 appearing at page 30531 of the issue for Monday, July 17, 1978, paragraphs (2) and (3) of "Supplementary Information" should read as follows, with corrections in the code of Federal Regulations part number and the United States Code number:

"(2) An opportunity for public comment on an official staff interpretation may be provided upon request of interested parties and in accordance with 12 CFR Part 202.1(d)(2)(ii). As provided by 12 CFR Part 202.1(d)(3) every request for public comment must be in writing, should clearly identify the number of the official staff interpretation in question, should be addressed to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, and must be postmarked or received by the Secretary's office before the effective date of the interpretation. The request must also state the reasons why an opportunity for public comment would be appropriate.

"(3) 15 U.S.C. 1691(b)."

Board of Governors of the Federal Reserve System, July 20, 1978.

CATHY E. MINEHAN,
Assistant Secretary of the Board.

[FR Doc. 78-20886 Filed 7-27-78; 8:45 am]

[6210-01]

[Reg Z; FC-0151]

PART 226—TRUTH IN LENDING

Official Staff Interpretations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Official staff interpretation.

SUMMARY: The Board is publishing the following official staff interpretation of regulation Z regarding the truth in lending disclosures which must be made in connection with certain interim student credit transactions made under a federally insured program. The agency is taking this action in response to a request it has received for interpretation of this regulation.

EFFECTIVE DATE: On or after August 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Anne Geary, Chief Staff Attorney, Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, 202-452-2761.

SUPPLEMENTARY INFORMATION: (1) Identifying details have been deleted to the extent required to prevent a clearly unwarranted invasion of personal privacy. The Board maintains and makes available for public inspection and copying a current index providing identifying information for the public subject to certain limitations stated in 12 CFR Part 261.6.

(2) An opportunity for public comment on an official staff interpretation may be provided upon request of interested parties and in accordance with 12 CFR Part 226.1(d)(2)(ii). As provided by 12 CFR Part 226.1(d)(3) every request for public comment must be in writing, should clearly identify the number of the official staff interpretation in question, should be addressed to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 and must be postmarked or received by the Secretary's office before the effective date of the interpretation. The request must also state the reasons why an opportunity for public comment would be appropriate.

(3) 15 U.S.C. 1640(f).

§ 226.8(b) Under federally insured program providing credit to students for educa-

tional purposes, if student has option of receiving funds directly which may be used as the student sees fit, loan disclosures are appropriate.

§ 226.8(d) Under federally insured program providing credit to students for educational purposes, if student has option of receiving funds directly which may be used as the student sees fit, loan disclosures are appropriate.

JULY 3, 1978.

This is in response to your letter of ——, in which you request an official staff interpretation of regulation Z regarding the truth in lending disclosures which must be made in connection with certain interim student credit transactions made pursuant to a federally insured program. The staff believes that the primary issue which you raise is appropriate for an official response. Other questions asked in your letter will be addressed in a separate, unofficial staff interpretation of the regulation.

The program with which you are concerned consists of a fund from which extensions of credit are made by participating colleges and universities to students who meet the financial need criteria established by the Higher Education Act of 1965. Use of funds received under the program is restricted to expenses related to attendance at the institution which advances the funds, and the student must sign an affidavit affirming that the funds will be used only for such expenses.

Under the program, funds may be disbursed directly to the student or a credit may be made to the student's account at the educational institution. You are concerned that if a credit is made to a student's account with the institution and the student simply receives goods and services (e.g., tuition, room, board, books) from the institution, the transaction could be viewed as a credit sale rather than a loan, and credit sale disclosures rather than loan disclosures would be required under Regulation Z.

In the staff's opinion the answer to whether loan or credit sale disclosures are required in connection with the program you describe is dependent upon the ability of students participating in the program to obtain funds (e.g., cash or a check) from the institution if they so desire. As long as a student has the option of receiving funds directly which may be used as the student sees fit, the staff believes that the applicable loan disclosures under §§ 226.8(b) and (d) of Regulation Z would be appropriate. Furthermore, even though use of the loan proceeds is restricted to expenses related to attendance or continued attendance at the institution which makes the loan, as long as use of the funds is not restricted to the purchase of *particular* goods or services *from the institution* the staff feels that loan disclosures would be proper.

This is an official staff interpretation of Regulation Z, issued pursuant to § 226.1(d)(2) of the regulation. It will become effective 30 days after publication in the FEDERAL REGISTER unless a request for public comment, made in accordance with the Board's procedures, is received and granted. We will notify you if the effective date of the interpretation is suspended because such a request is received.

We also note that your client may be subject to the laws and regulations of the State of Maine which has been granted an exemption from the applicable provisions of regulation Z. Therefore, you may wish to contact Mr. Harry Giddinge, Acting Superintendent, Bureau of Consumer Protection, Department of Business Regulation, State House, Augusta, Maine, 04330, for his views on the issue addressed in this letter.

Sincerely,

NATHANIEL E. BUTLER,
Associate Director.

Board of Governors of the Federal Reserve System, July 20, 1978.

CATHY E. MINEHAN,
Assistant Secretary of the Board.

[FR Doc. 78-21032 Filed 7-27-78; 8:45 am]

[3510-08]

Title 15—Commerce and Foreign Trade

CHAPTER IX—NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 931—COASTAL ENERGY IMPACT PROGRAM

Lateral Seaward Boundaries

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Amendment to rule.

SUMMARY: This amendment to existing regulations is to clarify NOAA's intent as to what may constitute "the applicable principles of law" for purposes of establishing Coastal Energy Impact Program (CEIP) delimitation lines, when no lateral seaward boundaries between States exist, for purposed of alloting certain CEIP formula grants among States.

EFFECTIVE DATES: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

James P. Lawless, Assistant General Counsel, NOAA, Page Building 1, 3300 Whitehaven Street NW., Washington, D.C. 20235, 202-634-4245.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of Thursday, February 23, 1978, at page 7546, the National Oceanic and Atmospheric Administration (NOAA) published regulations for the Office of Coastal Zone Management to implement the Coastal Energy Impact Program (CEIP). Subpart H of those regulations, at page 7563, discusses procedures for establishing delimitation lines for calculating coastal States' shares of CEIP formula grants based on certain outer Continental Shelf activities occurring adjacent to each State.

For purposes of determining such adjacency, section 308(b)(3)(B)(ii) of the Coastal Zone Management Act of 1972, as amended (CZMA), provides: "If no lateral seaward boundaries, or any portion thereof, have been clearly defined or fixed by an interstate compact, agreement, or judicial decision. lateral seaward boundaries shall be determined according to the applicable principles of law, including the principles of the Convention on the Territorial Sea and the Contiguous Zone, and extended on the basis of such principles." In section 931.82 of the above regulations, procedures are set forth for establishment of a delimitation line when a lateral seaward boundary has not been clearly defined or fixed. The first sentence of subsection 931.82(b) reiterates the statutory provision that applicable principles of law are to be used, and was intended to provide examples of such principles. Subsequent analysis of this language has raised some question as to whether NOAA has created a presumption in favor of the principles mentioned which go beyond the statutory language. NOAA definitely did not intend to establish a presumption in favor of any principle of law over another in this regard or to change the effect of the statute. In order to clarify this intent and to avoid the possibility that someone could interpret the regulations otherwise, NOAA is hereby correcting its regulations to reiterate the language of the statute. Any other reference in Subpart H of the regulations to "applicable principles of law" also means the same principles as in section 308(b)(3)(B)(ii) of the CZMA.

Because this constitutes only a clarification of what NOAA always intended in its regulations, which was to reiterate the terms of the statute, NOAA hereby finds for good cause, in accordance with 5 U.S.C. 553 (b) and (d), that notice and public procedure on such clarification is unnecessary, and that a 30-day delay prior to the effective date of the clarification is unnecessary.

In consideration of the foregoing, part 931 should be changed as follows:

§ 931.82 [Amended]

Delete that part of the first sentence of § 931.82(b) after the words "Associate Administrator" (beginning with the sixth line), and replace it with the following:

• • • according to the applicable principles of law, including the principles of the Convention on the Territorial Sea and The Contiguous Zone.

Dated: July 18, 1978.

T. P. GLEITER,
Assistant Administrator for Administration.

[FR Doc. 78-20925 Filed 7-27-78; 8:45 am]

[6355-01]

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

Exemption From Full Compliance With Labeling Requirements of Federal Hazardous Substances Act for Cyanoacrylate-Based Glue in Containers of 3 Grams or Less

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: This document partially exempts cyanoacrylate-based glue in packages of 3 grams or less from the size of labeling requirements of the Federal Hazardous Substances Act (FHSA). This exemption is being issued because the Commission has found that, because of the size of the package involved, full compliance with the labeling requirements applicable under the FHSA is impracticable and is not necessary for the adequate protection of the public health and safety.

DATES: This exemption is effective on July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles M. Jacobson, Directorate for Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207, telephone 301-492-6400.

SUPPLEMENTARY INFORMATION:

Background

Section 2(f)(1)(A) of the Federal Hazardous Substances Act ("the Act" or "FHSA"), 15 U.S.C. 1261(f)(1)(A), provides that the term "hazardous substance" includes any substance or mixture of substances which is an irritant, if such substance or mixture of substances may cause substantial personal injury or substantial illness during, or as a proximate result of, any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

Section 2(p) of the FHSA (15 U.S.C. 1261(O)) provides that a hazardous substance which is intended, or packaged in a form suitable, for use in the household or by children is misbranded if it does not bear a label stating certain specified information.

A Commission regulation, 16 CFR 1500.121, describes in detail the placement, conspicuousness, and contrast requirements for labeling under the FHSA. Section 1500.121(d) provides that except for labeling required to be on the main panel of the label (i.e., (1) the signal word ("WARNING", "CAUTION", or "DANGER", as appropriate), (2) a statement of the principal hazard associated with the substance, and (3) instructions to read carefully any cautionary information that may be placed elsewhere on the label), the remainder of the information required under the FHSA may be placed on the label elsewhere than on the main panel. Section 1500.121(d) also provides that the type size used for the remainder of the required information must bear a reasonable relationship to the printing on the package panel involved and may be no smaller than 10 point type unless the available label space requires reductions, in which event this type size may be reduced to no smaller than 6 point type. However, because of small label space, exemptions to the 6 point type requirement may be granted under section 3(c) of the Act and 16 CFR 1500.82, 1500.83. The Consumer Product Safety Commission may exempt the substance from the full labeling requirements, to the extent consistent with the adequate protection of public health and safety, if it finds that, because of the size of a package for a hazardous substance or because of the minor hazard presented to the public by the substance, or for other good and sufficient reason, full compliance with the labeling requirements is either impracticable or unnecessary for the adequate protection of the public health and safety. Under 16 CFR 1500.83(a), any person who believes that a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from a labeling requirement otherwise applicable under the Act may submit to the Commission a request for an exemption pursuant to section 3(c) of the Act. The request must present facts in support of the view that full compliance is impracticable or is not necessary for the protection of the public health.

On May 9, 1974, the Commission issued a notice announcing information that had been obtained by testing cyanoacrylate glues (39 FR 16511). This information indicated that cyanoacrylate-based glue is a "hazardous substance" within the meaning of that term under the Act because it is an "eye irritant." Therefore, any such glue is deemed "misbranded" under section 2(p) of the Act unless it is labeled in accordance with 16 CFR 1500.121.

The information available to the Commission shows that these glues can contact the eyes in situations such as when some glue squirts out when the container is shaken to get glue to flow, when the tube ruptures when it is squeezed, when glues squirts out when the surfaces to be glued are pressed together, and when the tubes are intentionally or accidentally misused by children. In each of these types of situations, it would appear that only a small amount of glue would be likely to contact the eye.

Petition

On November 11, 1975, the Consumer Product Safety Commission received a petition from Wilhold Glues, Inc., of Santa Fe Springs, Calif., requesting an exemption from full compliance with the labeling requirements under the Federal Hazardous Substances Act for cyanoacrylate-based glue in 2-gram size tubes. The petition stated that the size of the package made it impracticable to show all of the labeling that was required by 16 CFR 1500.121 to be in at least 6 point type.

After considering this petition and the information obtained by the Commission's staff, the Commission concluded that an exemption for glues with a cyanoacrylate base sold in sizes of 2 grams or less should be proposed (42 FR 54308; October 5, 1977).

The Commission's decision to propose this exemption was based principally on the preliminary findings that full label compliance is both impracticable, due to the size of the package, and unnecessary for the adequate protection of the public health.

The Commission believes that any risk to the public of injury caused by eye irritation associated with cyanoacrylate glues can be reduced sufficiently by placing the signal word, statement of hazard, and instructions to read additional warnings on the main label panel and by placing the additional warnings elsewhere on the immediate container, and on any outer package, accompanying leaflet, and display card in accordance with the placement, conspicuousness, and contrast requirements of 16 CFR 1500.121. Accordingly, the Commission proposed that this exemption be granted under the following conditions:

(1) The signal word (in this instance, either "WARNING" or "CAUTION") must appear on the main label panel of the product and must comply with the placement, conspicuousness, and contrast requirements of 16 CFR 1500.121.

(2) The statement of the principal hazard or hazards associated with the

product, in this case "Eye Irritant" or similar wording descriptive of the hazard, must also appear on the main label panel of the product in accordance with the placement, conspicuousness, and contrast requirements of 16 CFR 1500.121. (These first two conditions merely restate requirements of § 1500.121(a), which is not affected by the exemption.)

(3) The main label panel must also bear instructions to read additional warnings elsewhere on the label and on any outer package, accompanying leaflet, and display card. Thus, any statement of precautionary measures describing the action to be followed or avoided, instructions for first-aid treatment, and the statement "keep out of the reach of children" or its practical equivalent, all required by section 2(p)(1) of the Act, need not appear on the main label panel, but instructions to read these additional warnings must be placed on the main label panel along with the required signal word and statement of hazards or hazards, in accordance with 16 CFR 1500.121. (Except for the reference to the outer package, accompanying leaflet, and display card, this condition also restates a requirement of § 1500.121(a).)

(4) The remainder of the cautionary labeling required by the Act must appear elsewhere on the immediate container and on any outer package, accompanying leaflet, and display card. These additional warnings must comply with the size, placement, contrast, and conspicuousness requirements of 16 CFR 1500.121, except that, because of small label space, the type size required for this labeling on the immediate container label may be less than six point type, provided it is legible. If there is no outer package, accompanying leaflet, or display card, then the remainder of the required cautionary labeling must be displayed by means of a tag or other suitable material that is securely affixed to the article so that the labeling will remain attached throughout the conditions of merchandising and distribution to the ultimate consumer.

Comment on Proposal

The Commission received one comment on the proposed exemption. This comment was from the original petitioner, Wilhold Glues, Inc. (Wilhold). Wilhold asked that the exemption apply to glues with a cyanoacrylate base packaged in containers of 3 grams or less, rather than the containers of 2 grams or less that were originally requested. Wilhold stated that this was necessary because since the original petition was submitted, the same size tube that had been used for 2 grams of glue was being extensively marketed with 3 grams of glue.

The Commission has evaluated this comment and has concluded that the petitioner's need for the exemption is the same for the tube containing 3 grams as for the tube containing 2 grams, since the same size tube is used to contain both amounts of glue. In addition, the additional gram of glue will not significantly increase the hazards associated with the use of cyanoacrylate-based glues. Accordingly, the Commission agrees with the comment.

Conclusion

After considering the petition, the comment received on the proposal, and information obtained by the Commission's staff, the Commission finds that, because of the size of the package involved and for the other good and sufficient reasons discussed above, full compliance with the labeling requirements otherwise applicable under the Federal Hazardous Substances Act for cyanoacrylate-based glues in packages containing 3 grams or less is impracticable and not necessary for the adequate protection of the public health and welfare and that the exemption set forth below is consistent with the adequate protection of the public health and safety.

Since this rule grants an exemption, the requirement of the Administrative Procedure Act that publication be made not less than 30 days before the effective date of the rule does not apply (5 U.S.C. 553(d)(1)), and this rule is therefore effective immediately.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (Secs. 2(f), 2(p), 3(c), 10(a); 74 Stat. 372, 374, 375, 378, as amended 80 Stat. 1304, 1305, 83 Stat. 187-189; 15 U.S.C. 1261(f), 1261(p), 1262(c), 1269(a)), and under authority vested in the Commission by the Consumer Product Safety Act (sec. 30(a), Pub. L. 92-573, 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission amends subchapter C, chapter II, of title 16 of the Code of Federal Regulations by adding to § 1500.83 a new paragraph (a)(37), reading as follows: (The text of the introductory portion of § 1500.83(a), although unchanged, is included for context.)

§ 1500.83 Exceptions for small packages, minor hazards, and special circumstances.

(a) The following exemptions are granted for the labeling of hazardous substances under the provisions of § 1500.82:

* * * * *

(37) Glues with a cyanoacrylate base in packages containing 3 grams or less are exempt from the requirement of § 1500.121(d) that labeling which is permitted to appear elsewhere than on the main label panel must be in type size no smaller than 6 point type, provided that:

(i) The main panel of the immediate container bears both the proper signal word and a statement of the principal hazard or hazards associated with this product, as provided by § 1500.121 (a) and (c);

(ii) The main panel of the immediate container also bears an instruction to read carefully additional warnings elsewhere on the label and on any outer package, accompanying leaflet, and display card. The instruction to read additional warnings must comply with the size, placement, conspicuousness, and contrast requirements of § 1500.121; and

(iii) The remainder of the cautionary labeling required by the act that is not on the main label panel must appear elsewhere on the label in legible type and must appear on any outer package, accompanying leaflet, and display card. If there is no outer package, accompanying leaflet, or display card, then the remainder of the required cautionary labeling must be displayed on a tag or other suitable material that is securely affixed to the article so that the labeling will remain attached throughout the conditions of merchandising and distribution to the ultimate consumer. That labeling which must appear on any outer package, accompanying leaflet, tag, or other suitable material must comply with the size, placement, contrast, and conspicuousness requirements of § 1500.121(d).

(Secs. 2(f), 2(p), 3(c), 10(a); 74 Stat. 372, 374, 375, 378, as amended, 80 Stat. 1304, 1305, 83 Stat. 187-189 (15 U.S.C. 1261(f), 1261(p), 1262(c), 1269(a)).)

Effective date. This amendment shall be effective July 28, 1978.

Dated: July 25, 1878.

SADYE E. DUNN,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 78-20926 Filed 7-27-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Redelegation of Grants Authority

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Commissioner of Food and Drugs is amending the regulations for delegations of authority by decentralizing the authority to approve or disapprove applications for grants and redelegating the authority to bureau level officials. The action, part of a decentralization effort to move operational functions out of the Office of the Commissioner, is being taken to increase the effectiveness of operations.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: Section 5.25 (21 CFR 5.25) is being revised by deleting the delegation of authority and reference to the Associate and Deputy Associate Commissioner for Science. Approval authority for grant applications is being delegated to bureau directors, the Executive Director of Regional Operations, and the Director, National Center for Toxicological Research, and the authority to execute and issue notices of grant awards is extended to include the Chief of the Grants Management Branch of the new Office of Management and Operations.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as "acting," or unless not legally permissible.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and secs. 301, 307, 311, and 356 of the Public Health Service Act (42 U.S.C. 241, 242l, 243, and 263d) and under authority delegated to the Commissioner (21 CFR 5.1), part 5 is amended by revising § 5.25 to read as follows:

§ 5.25 Grants.

(a) The directors of bureaus, the Executive Director of Regional Operations, and the Director of the National Center for Toxicological Research are authorized to approve or disapprove applications for grants under sections 301, 307, and 311 of the Public Health Service Act.

(b) The Director of the Bureau of Radiological Health is authorized to approve or disapprove applications for grants under section 356 of the Public Health Service Act.

(c) The Associate and Deputy Associate Commissioner for Management and Operations, the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Management and Operations, and the Chief of the Grants Management Branch of that Division and Office are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof.

Effective date. This regulation shall be effective July 28, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)) and secs. 301, 307, 311, 356 (42 U.S.C. 241, 242l, 243, 263d).)

Dated: July 24, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-20864 Filed 7-27-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of two new animal drug applications (NADA's) providing for use of 10-gram-per-pound tylosin premixes for making complete swine feeds. The applications were filed by Feed Service Co. and Illini Feeds. The list of sponsors is also amended to establish entries for these firms.

EFFECTIVE DATE: July 28, 1278.

FOR FURTHER INFORMATION CONTACT:

Jack C. Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: Feed service Co., Inc., Box 876, Mankato, Minn. 56001, and Illini Feed, Box T, Oneida, Ill. 61467, filed NADA's 111-637V and 110-202V to provide for 10-gram-per-pound tylosin (as tylosin phosphate) premixes to be used for subsequent manufacture of complete swine feeds. The complete feeds would increase rate of weight gain and improve feed efficiency. Approval of these applications relies upon safety and effectiveness data contained in Elanco Products Co.'s approved NADA 12-491V (see §558.625(f)(1)(vi)(*a*) (21 CFR 558.625(f)(1)(vi)(*a*))). The approvals do not constitute reaffirmation of Elanco Products Co.'s NADA nor do they constitute reaffirmation of the drug's safety and effectiveness.

In accordance with the freedom of information regulations and §514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Foods and Drugs (21 CFR 5.1), parts 510 and 558 are amended as follows:

1. In part 510, §510.600 is amended by adding two new sponsors alphabetically to paragraph (c)(1) and numerically to paragraph (c)(2), to read as follows:

§510.600 Names, addresses, and code numbers of sponsors of approved applications.

* * * * *

(c) * * *
(1) * * *

Firm name and address	Drug listing No.
* * * * *	
Feed Service Co., Inc., Box 876, Mankato, Minn. 56001	030841
* * * * *	
Illini Feeds, Box T, Oneida, Ill. 61467	037310
* * * * *	

(2) * * *

Drug listing No.	Firm name and address
* * * * *	
030841	Feed Service Co., Inc., Box 876, Mankato, Minn. 56001
* * * * *	
037310	Illini Feeds, Box T, Oneida, Ill. 61467.
* * * * *	

2. In part 558, §558.625 is amended by adding new paragraph (b) (54) and (55) to read as follows:

§558.625 Tylosin.

* * * * *

(b) * * *

(54) To 030841: 10 grams per pound: paragraph (f)(1)(vi)(*a*) of this section.

(55) To 037310: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

* * * * *

Effective date: This regulation is effective July 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-20720 Filed 7-27-78; 8:45 am]

[4110-03]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Piperazine Phosphate-Thenium Closylate Tablets

AGENCY. Food and Drug Adminstration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) filed by Jensen-Salsbery Laboratories, providing for use of a combination anthelmintic (drug used to destroy or expel intestinal worms) in treating weaned pups and dogs.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Jensen-Salsbery Laboratories, Division of Richardson-Merrell, Inc., 520 West 21st Street, Kansas City, Mo. 64141, filed an NADA (101-161V) providing for use of piperazine phosphate with thenium closylate tablets in weaned pups and adult dogs for removal of certain hookworms and ascarids.

In accordance with the freedom of information regulations and §514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the Office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), part 520 is amended by adding new §520.1805, to read as follows:

§520.1805 Piperazine phosphate with thenium closylate tablets.

(a) *Specifications.* Each scored tablet contains the equivalent of 250 milligams piperazine hexahydrate (as piperazine phosphate) and 125 milligrams thenium (as thenium closylate).

(b) *Sponsor.* See No. 017220 in §510.600(c) of this chapter.

(c) *Conditions of use.*—(1) *Amount.* Administer orally to dogs as follows:

Number of Tablets at Each of the Two Doses	
Animal weight (lb):	
2 but less than 5	½
5 but less than 10	1
10 or heavier	2

(2) *Indications for use.* For removal of immature (fourth stage larvae) and adult hookworms (*Ancylostoma caninum, A. braziliense,* and *Uncinaria stenocephala*) and ascarids (*Toxocara canis*) from weaned pups and adult dogs.

(3) *Limitations.* Do not use this product to treat dogs weighing less than 2 pounds, unweaned pups, or pups under 5 weeks of age. Maximum efficacy against hookworms necessitates two doses in 1 day of treatment. The interval between the doses should be not less than 4 hours or more than 24 hours. Administer the first dose in the morning before feeding. Do not permit dog to chew tablet. Feed the dog between doses. Do not feed milk or other fatty foods during treatment. Retreatment may be needed in 7 to 28 days as determined by laboratory fecal examinations or in animals kept in known contaminated quarters. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date: July 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-20723 Filed 7-27-78; 8:45 am]

[4110-03]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Uredofos Tablets; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect the change of sponsor for uredofos tablets from Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., to Beecham Laboratories, Division of Beecham, Inc. A supplemental new animal drug application (NADA) filed by Beecham Laboratories provides for this change.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc., Bristol, Tenn. 37620, filed a supplemental new animal drug application (NADA 100-745V) providing for the change of sponsor for uredofos tablets.

This intercorporate transfer of an NADA does not involve changes in manufacturing, packaging, or quality control. The approval does not require a reevaluation of the parent NADA nor does it constitute a reaffirmation of the drug's safety or effectiveness.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), §520.2645 *Uredofos tablets* is amended in paragraph (c) by deleting the number "011794" and inserting in its place the number "000029."

Effective date: This regulation is effective July 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-20725 Filed 7-27-78; 8:45 am]

[4110-03]

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

Procaine Penicillin G Aqueous Suspension (Injectable)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) providing revised labeling of injectable procaine penicillin G aqueous suspension used in treating certain infections of cattle, sheep, swine, and horses. The application was filed by Pfizer, Inc., in compliance with the National Academy of Sciences—National Research Council Drug Efficacy Study Group (NAS/NRC) evaluation of the product. This document also amends the regulations by establishing a zero residue tolerance for penicillin and its salts in sheep.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Myron C. Rosenberg, Bureau of Veterinary Medicine (HFV-125), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-1788.

SUPPLEMENTARY INFORMATION: Pfizer's product was one of several mentioned in the NAS/NRC evaluation published in the FEDERAL REGISTER of August 25, 1970 (35 FR 13544). In that document, the NAS/NRC concluded, and the Food and Drug Administration (FDA) concurred, that these products were probably effective for intramuscular use in treating infections in animals caused by pathogens sensitive to procaine penicillin. The NAS/NRC stated:

1. The dosage directions are inadequate. The dosage should be so expressed as to provide a specific quantity of the drug per unit of body weight per unit of time for each animal species.

2. The minimum allowable dosage should range from 3,000 to 10,000 units per pound body weight per day depending on the animal species. In some diseases, because of decreasing bacterial sensitivity, higher doses may be necessary.

3. Properly qualify disease entities as to those caused by pathogens sensitive to penicillin. If the disease claim cannot be so qualified the claim must be dropped.

4. The labeling should not recommend injection into open wounds, abscesses, and actinomycotic lesions, nor should the labeling recommend increasing the dose if there is no response to previous injections.

5. The labeling should state the recommended procedure for treating hyper- sensitivity reactions to penicillin and also the occasional hypersensitivity to procaine.

6. The labeling should provide a precaution statement indicating the need for sensitivity testing preceding the use of penicillin in treating staphylococcal pathogens.

7. The residue warnings should be updated.

The NAS/NRC evaluation was concerned only with the drug's effectiveness and safety to the animal being treated and did not take into account the safety of food derived from treated animals.

The evaluation was published to inform NADA holders of the findings of the NAS/NRC and FDA and to inform all interested persons that such articles may be marketed, provided they are the subject of approved NADA's and otherwise comply with the requirements of the Federal Food, Drug, and Cosmetic Act. NADA's that pertain to identical products and reflect those conditions of use as set forth in this regulation do not require efficacy data as specified by § 514.1(b)(8)(ii) or § 514.111(a)(5)(vi) of the animal drug regulations. In lieu of such data, approval may require bioequivalency or similar data as suggested in the guideline for submitting NADA's for NAS/NRC-reviewed generic drugs. The guideline is available from the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Those conditions of use are identified in this regulation by a footnote.

Pfizer, Inc., 235 East 42d Street, New York, N.Y. 10017, submitted a supplemental NADA (65-110V) which responded to the above-enumerated NASA/NRC recommendations as follows:

1. and 2. The recommended daily dosage in large animal species is now given in the product labeling as 3,000 units per pound of body weight. The indications for use of this product in all small animals have been removed from the labeling.

3. Disease entities have been qualified as to causative pathogen and these are sensitive to penicillin. Many disease claims and several animal species have been deleted from the indications of use. Indications for the use of this drug in the treatment of anthrax have been deleted from product labeling.

4. The labeling does not recommend injection into open wounds, abscesses, actinomycotic lesions nor does it suggest increasing the dose if there is no response to the previous dose. On the contrary the labeling warns against doses above those specifically recommended.

5. The revised labeling (package insert) provides a cautionary statement regarding untoward reactions that may occur in animals administered this drug and describes how they should be treated.

6. Indications for use of this product against diseases caused by *Staphylococcus spp.* have been deleted. Overgrowth of resist- ant organisms including fungi resulting from use of this product is described on the package insert.

7. Residue warnings have been updated in accordance with directions received from FDA in a letter dated April 28, 1976.

A dosage of 3,000 units per pound of body weight meets NAS/NRC efficacy requirements for treatment of the cattle, sheep, swine, and horse diseases set forth in the indications for use in this regulation.

These claim deletions and modifications in indications for use have substantiated upgrading the NAS/NRC rating from probably effective to effective.

Although this drug has been indicated for use in sheep for many years, a residue tolerance for this species has never been listed in § 556.510 (21 CFR 556.510). The FDA is currently reevaluating the tolerances for penicillins in all species. Pending completion of this evaluation, § 556.510 is being amended to include sheep among those species for which a zero tolerance is now in effect. This action does not constitute a reevaluation or reaffirmation of the underlying human safety data.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the Office of the Hearing Clerk HFA-305), at the above-named address from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 540 and 556 are amended as follows:

1. In part 540, § 540.274b is amended by adding new paragraph (c)(3) to read as follows:

§ 540.274b Procaine penicillin G aqueous suspension.

* * * * *

(c) * * *

(3)(i) *Specifications.* The drug conforms to the requirements prescribed

by § 540.274a. Each milliliter contains 300,000 units of penicillin activity.

(ii) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(iii) *Related tolerances.* See § 556.510 of this chapter.

(iv) *Conditions of use.* As an intramuscular injection for cattle, sheep, swine, and horses, used as follows:

(*a*) *Amount.* 3,000 units per pound of body weight (1 milliliter per 100 pounds body weight) daily.

(*b*) *Indications for use.* For the treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida;* swine for erysipelas caused by *Erysipelothrix insidiosa;* and horses for strangles caused by *Streptococcus equi.*[1]

(*c*) *Limitations.* Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days). Treatment should not exceed 4 consecutive days. Do not exceed 10 milliliters per injection site. Milk that has been taken during treatment and for 72 hours (six milkings) after the latest treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Cattle—10, sheep—9, and swine—7. Not for use in horses intended for food.

2. In part 556, § 556.510 is amended by revising paragraph (b) to read as follows:

§ 556.510 Penicillin.

* * * * *

(b) Zero in the uncooked edible tissues of chickens, pheasants, quail, swine, and sheep; in eggs; and in milk or in any processed food in which such milk has been used.

* * * * *

Effective date: This regulation is effective

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-20719 Filed 7-27-78; 8:45 am]

[4110-03]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Monensin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Products Co., providing for use of monensin in feed of pasture cattle.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

William D. Price, Bureau of Veterinary Medicine (HFV-123), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3442

SUPPLEMENTARY INFORMATION: Elanco Products Co., A Division of Eli Lilly & Co., 740 South Alabama Street, Indianapolis, Ind. 46206, filed a supplemental NADA (95-735V) proposing label revision of its 20-, 30-, 45-, and 60-grams per pound monensin premixes. The revision permits use of finished feeds subsequently manufactured from these premixes for increased rate of weight gain in pasture cattle. Approval of this application does not constitute reaffirmation of the safety of residues resulting from use of this drug.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360(b)(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), § 558.355 is amended by adding new paragraph (f)(3)(iii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(iii) *Amount per ton.* Monensin, 25 to 400 grams.

(*a*) *Indications for use.* Increased rate of weight gain.

(*b*) *Limitations.* Feed to pasture cattle (slaughter, stocker, and feeder) weighing more than 400 pounds. Feed at the rate of not less than 50 nor more than 200 milligrams per head per day in a minimum of 1 pound of feed, as monensin sodium. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal).

* * * * *

Effective date. This amendment is effective July 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: July 21, 1978.

FRED. J KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20718 Filed 7-27-78; 8:45 am]

[4110-03]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

MONENSIN, BACITRACIN, BACITRACIN METHYLENE DISALICYLATE, ROXARSONE

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Products Co., providing for the use of currently approved premixes in the preparation of a complete broiler feed containing a combination of monensin with bacitracin methylene disalicylate and roxarsone.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Bureau of Veterinary Medicine (HVV-147), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: Elanco Products Co., a Division of Eli Lilly and Co., 740 South Alabama Street, Indianapolis, Ind. 46206, filed an NADA (49-464V) providing for the use of approved animal drug premixes for the preparation of a complete broiler feed containing 90 to 110 grams per ton monensin sodium, 25 grams per ton bacitracin methylene disalicylate, and 11.3 to 22.7 grams per ton roxarsone for use as an aid in the prevention of certain forms of coccidiosis, for increased rate of weight gain, and for improved feed efficiency. This application is approved without reaffirmation of the underlying human safety data for use of the individual drug components: monensin sodium, bacitracin methylene disalicylate, and roxarsone in broiler feeds.

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug reglations, a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), part 558 is amended as follows:

1. In § 558.76, by adding new paragraph (e)(3)(ix) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(e) * * *
(3) * * *

(ix) Monensin and roxarsone in accordance with § 558.355.

2. In § 558.355, by adding new paragraph (f)(1)(xii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *
(1) * * *

(xii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 25 grams, and roxarsone, 11.3 to 22.7 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati;* for increased rate of weight gain and for improved feed efficiency.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600 of this chapter; as roxarsone provided by No. 011801 in § 510.600 of this chapter.

* * * * *

Effective date. This regulation is effective July 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20722 Filed 7-27-78; 8:45 a.m.]

[4110-03]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Decoquinate

AGENCY: Food and drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Hess & Clark, Division of Rhodia, Inc., providing for the use of higher concentration decoquinate-containing feed supplements for the preparation of approved decoquinate-containing cattle feeds.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-149), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: Hess & Clark, Division of Rhodia, Inc., Ashland, OH 44805, filed a supplemental NADA (39-417V) providing for the use of decoquinate-containing feed supplements containing 0.05 to 0.5 percent decoquinate for the preparation of cattle feed to be fed at the rate of 22.7 milligrams per 100 pounds of body weight per day. In addition, § 558.195 (21 CFR 558.195) is amended to include approved concentrations for complete feeds.

Approval of this supplement does not involve reevaluation of the original application or reaffirmation of the drug's safety and effectiveness.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), § 558.195 is amended in the table in paragraph (g)(2) by revising the "Limitations" column to read as follows:

§ 558.195 Decoquinate.

* * * * *

(g) * * *
(2) * * *

Decoquinate	Combination [1]	Indications for use	Limitations	Sponsor
.....	.....	.....	Administer as a complete feed containing 0.0015 pct to 0.003 pct decoquinate, or as a supplement containing 0.05 pct to 0.5 pct decoquinate. Feed for at least 28 days during periods of coccidiosis or when it is likely to be a hazard. Do not feed to breeding animals or cows producing milk for food. Complete feed should be consumed within 7 days of manufacture, supplements within 2 months.	.....

[1] In grams per ton.

Effective date: This regulation is effective July 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20724 Filed 7-27-78; 8:45 a.m.]

[4210-01]

Title 24—Housing and Urban Development

CHAPTER X—FEDERAL INSURANCE ADMINISTRATION, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

[Docket No. FI 4265]

PART 1914—AREAS ELIGIBLE FOR THE SALE OF INSURANCE

Suspension of Community Eligibility

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: This rule lists communities where the sale of flood insurance, as authorized under the National Flood Insurance Program (NFIP), will be suspended because of noncompliance with the flood plain management requirements of the program.

EFFECTIVE DATES: The third date ("Susp.") listed in the fourth column.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street, SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), administered by the Federal Insurance Administration, enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022) prohibits flood insurance coverage as authorized under the National Flood Insurance Program (42 U.S.C. 4001-4128) unless an appropriate public body shall have adopted adequate flood plain management measures with effective enforcement measures. The communities listed in this notice no longer meet that statutory requirement for compliance with program regulations (24 CFR pt. 1909 et seq.). Accordingly, the communities are suspended on the effective date in the fifth column, so that as of that date subsidized flood insurance is no longer available in the community.

In addition, the Federal Insurance Administration has identified the special flood hazard areas in these communities by publishing a flood hazard boundary map. The date of the flood map, if one has been published, is indicated in the sixth column of the table. Section 202(a) of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), as amended, provides that no direct Federal financial assistance (except assistance pursuant to the Disaster Relief Act of 1974 not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP, with respect to which a year has elasped since publication of a flood insurance map. This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Federal Insurance Administrator finds that delayed effective dates would be contrary to the public interest. The Administrator also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

In each entry, a complete chronology of effective dates appears for each listed community.

Section 1914.6 is amended by adding in alphabetical sequence new entries to the table.

§ 1914.6 List of suspended communities.

State	County	Location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Hazard area identified	Date [1]
Colorado	Arapahoe	Cherry Hills Village, city of.	080013-B	Jan. 23, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	May 10, 1974 Jan. 31, 1975	Aug. 1, 1978
Delaware	Sussex	Milton, town of	100045-A	Sept. 17, 1974, emergency; Sept. 17, 1974, regular; Aug. 1, 1978, suspended.	Sept. 13, 1974 Dec. 12, 1975	Do.
Florida	Indian River	Unincorporated areas	120119-A	July 14, 1972, emergency; July 3, 1978, regular; Aug. 1, 1978, suspended.	Dec. 20, 1974	Do.
Iowa	Hamilton	Webster, city of	190137-B	Aug. 23, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Aug. 23, 1974 Oct. 3, 1975	Do.
Kansas	Rice	Sterling, city of	200297-B	May 23, 1975, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Mar. 8, 1974	Do.
Kentucky	Jessamine	Unincorporated areas	210125-A	Apr. 16, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Dec. 6, 1974	Do.
Louisiana	Concordia	Clayton, village of	220054-B	Apr. 30, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Feb. 1, 1974 Dec. 19, 1975	Do.
Maryland	Carroll	Unincorporated areas	240015-A	Dec. 22, 1972, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Apr. 4, 1975	Do.
Massachusetts	Essex	Andover, town of	250076-A	Feb. 18, 1972, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	July 26, 1974	Do.
Michigan	St. Clair	St. Clair, township of	260205-B	Mar. 9, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Sept. 20, 1974 Sept. 24, 1976	Do.
Missouri	Texas	Cabool, city of	290439-B	Sept. 8, 1972, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	May 3, 1974 Dec. 26, 1975	Do.
Do	St. Louis	Creve Coeur, city of	290344-B	Mar. 27, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Feb. 1, 1974 Oct. 15, 1976	Do.
Do	Marion	Hannibal, city of	290233-B	Aug. 13, 1978, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	June 21, 1974	Do.
Do	St. Louis	Olivette, city of	290374-B	Feb. 19, 1974, emergency; July 3, 1978, regular; Aug. 1, 1978, suspended.	Feb. 22, 1974 Oct. 22, 1976	Do.
New Jersey	Camden	Collingswood, borough of.	340131-B	Apr. 9, 1973, emergency; July 17, 1978, regular; Aug. 1, 1978, suspended.	Nov. 23, 1973 Jan. 7, 1977	Do.
Do	Union	Cranford, township of	345291-A	June 12, 1975, emergency; June 25, 1971, regular; Aug. 1, 1978, suspended.	Sept. 2, 1970 Jan. 30, 1976	Do.
Do	Morris	Denville, township of	345392-A	July 10, 1970, emergency; June 25, 1971, regular; Aug. 1, 1978, suspended.	June 26, 1971 Dec. 5, 1975	Do.
Do	Union	Rahway, city of	345314-B	June 30, 1970, emergency; June 16, 1972, regular; Aug. 1, 1978, suspended.	June 16, 1972 Sept. 5, 1975	Do.
Do	Hunterdon	Stockton, borough of	345322-C	Apr. 23, 1971, emergency; June 16, 1972, regular; Aug. 1, 1978, suspended.	June 16, 1972	Do.
Do	Union	Union, township of	340477-A	June 2, 1972, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	May 11, 1973	Do.

State	County	Location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Hazard area identified	Date [1]
Do	Middlesex	Woodbridge, township of.	345331-B	Sept. 25, 1970, emergency; June 3, 1972, regular; Aug. 1, 1978, suspended.	June 3, 1972	Do.
New York	Livingston	Avon, village of	360379-C	Dec. 10, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	May 10, 1974 May 28, 1976	Do.
Do	Cattaraugus	Franklinville, town of	360072-A	Nov. 28, 1975, emergency; July 17, 1978, regular; Aug. 1, 1978, suspended.	May 31, 1974	Do.
Do	Livingston	Geneseo, town of	360384-A	Apr. 25, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Dec. 28, 1973	Do.
Do	Cattaraugus	Great Valley, town of	360076	Aug. 13, 1975, emergency; July 17, 1978, regular; Aug. 1, 1978, suspended.	June 28, 1974 June 25, 1976	Do.
Do	Cayuga	Mentz, town of	360115-B	Apr. 18, 1973, emergency; July 17, 1978, regular; Aug. 1, 1978, suspended.	May 3, 1974 Oct. 17, 1975	Do.
Do	Livingston	Mount Morris, town of	360387-B	Apr. 17, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	May 17, 1974 Apr. 16, 1976	Do.
Do	do	Mount Morris, village of	360969-C	Apr. 17, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Aug. 1, 1978	Do.
Do	Nassau	Oyster Bay, town of	360483-B	Sept. 5, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Nov. 29, 1974 Sept. 12, 1976	Do.
Do	Cattaraugus	Randolph, village of	360096-B	Sept. 26, 1975, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Nov. 22, 1974 Feb. 27, 1976	Do.
Do	Onondaga	Van Buren, town of	360596-B	Mar. 16, 1973, emergency; July 17, 1978, regular; Aug. 1, 1978, suspended.	May 3, 1974 June 11, 1976	Do.
Do	Schuyler	Watkins Glen, village of.	360596-B	Dec. 17, 1973, emergency; July 17, 1978, regular; Aug. 1, 1978, suspended.	Aug. 2, 1974 July 9, 1976	Do.
North Carolina	Wake	Knightdale, town of	370241-B	July 24, 1975, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Apr. 12, 1974	Do.
Oregon	Tillamook	Bay City, city of	410197-B	June 11, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	June 14, 1974	Do.
Pennsylvania	Columbia	Benton, township of	421037-B	Sept. 10, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	June 28, 1974 June 4, 1976	Do.
Do	Montour	Derry, township of	421135-A	Mar. 12, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Jan. 24, 1975	Do.
Do	Centre	Haines, township of	420261-B	Mar. 30, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Aug. 9, 1974 Sept. 24, 1976	Do.
Do	Juniata	Walker, township of	420523-A	Aug. 30, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	May 10, 1974	Do.
Rhode Island	Providence	North Smithfield, town of.	440021-B	May 6, 1975, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	June 14, 1974 Aug. 27, 1976	Do.
Tennessee	Anderson	Oak Ridge, city of	475441-B	Dec. 17, 1971, emergency; Oct. 27, 1972, regular; Aug. 1, 1978, suspended.	Oct. 27, 1972	Do.
Vermont	Chittendon	Winooski, city of	500044-B	Mar. 27, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Feb. 1, 1974	Do.
Virginia	Campbell	Altavista, town of	510029-B	Feb. 19, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	June 7, 1974 Apr. 23, 1976	Do.
Do		Buena Vista, city of	510027-A	July 23, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Nov. 12, 1976	Do.
Do	Halifax	Unincorporated areas	510188-A	Apr. 4, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Dec. 6, 1974	Do.
Do	Rockbridge	Lexington, city of	510089-B	May 14, 1975, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Feb. 15, 1974 Aug. 6, 1976	Do.
Do	Nelson	Unincorporated areas	510102	Oct. 4, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Nov. 22, 1974	Do.
Do	Pulaski	Pulaski, town of	510126-A	Nov. 8, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Aug. 2, 1974 Apr. 9, 1976	Do.
Do		Radford, city of	510127-A	Dec. 5, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	July 16, 1976	Do.
Do	Shenandoah	Unincorporated areas	510147-B	Mar. 30, 1973, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Dec. 20, 1974 Aug. 6, 1976	Do.
Washington	Whitman	Albion, town of	530206-B	Apr. 9, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	May 24, 1971 Mar. 19, 1976	Do.
Do	do	Garfield, town of	530209-B	May 7, 1975, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	June 14, 1974 Jan. 2, 1976	Do.
West Virginia	Monongalia	Star City, town of	540273-A	Apr. 18, 1975, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	Nov. 22, 1974	Do.
Do	do	Westover, city of	540274-A	Jan. 27, 1975, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	do	Do.
Do	Greenbrier	White Sulphur Springs, village of.	540045-B	Nov. 20, 1974, emergency; Aug. 1, 1978, regular; Aug. 1, 1978, suspended.	May 31, 1974 Sept. 12, 1975	Do.

[1] Certain Federal assistance no longer available in special flood hazard areas.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968); effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended, 42 U.S.C. 4001-4128; and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: July 10, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-19411 Filed 7-27-78; 8:45 am]

[4830-01]

Title 26—Internal Revenue

CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

SUBCHAPTER A—INCOME TAX

[T.D. 7555]

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Dividend Treatment for Certain Distributions by Controlled Foreign Corporations and Limitation of the Definition of Foreign Base Company Sales Income With Respect to Certain Agricultural Commodities

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations relating to dividend treatment for certain distributions by controlled foreign corporations and limitation of the definition of foreign base company sales income with respect to certain agricultural commodities. Changes to the applicable tax law were made by the Tax Reduction Act of 1975. These regulations provide necessary guidance to the public for compliance with the law.

EFFECTIVE DATES: The regulations are effective for taxable years of controlled foreign corporations beginning after December 31, 1975, and for taxable years of United States shareholders within which or with which such taxable years of controlled foreign corporations end.

FOR FURTHER INFORMATION CONTACT:

William E. Mantle, Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224. Attention: CC:LR:T, 202-566-3734.

SUPPLEMENTARY INFORMATION:

Background

On May 14, 1976, the FEDERAL REGISTER published proposed amendments to the Income Tax Regulations (26 CFR Part 1) under sections 851 and 954 of the Internal Revenue Code of 1954 (41 FR 19970). The amendments were proposed to conform the regulations to section 602 (a)(2) and (b) of the Tax Reduction Act of 1975 (89 Stat. 58). A public hearing was held on August 12, 1976. After consideration of all comments regarding the proposed amendments, those amendments are adopted as revised by this Treasury decision. In addition, this Treasury decision deletes the statutory material under sections 851 and 954.

Coffee and Bananas

The proposed rules under § 1.954-3 list coffee and bananas as agricultural commodities grown in the United States in commercially marketable quantities. Information was submitted by interested persons indicating that the amount of coffee and bananas produced in the United States is insignificant by comparison to the total world production of the two commodities. After consideration of this information, it was decided to provide in these final regulations that coffee and bananas are agricultural commodities not considered grown in the United States in commercially marketable quantities.

Crude Rubber

As proposed, the rules under § 1.954-3 do not classify crude rubber either as a commodity grown or not grown in the United States in commercially marketable quantities. It was submitted the crude rubber should be listed as an agricultural commodity not grown in the United States in commercially marketable quantities. It was concluded that crude rubber should be so listed.

Drafting Information

The principal author of this regulation was William E. Mantle of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

Adoption of Amendments to the Regulations

Accordingly, the amendments to 26 CFR Part 1 published as a notice of proposed rulemaking in the FEDERAL REGISTER on May 14, 1976 (41 FR 19970), are hereby adopted as proposed subject to the following changes:

PARAGRAPH 1. Paragraph 1 of the appendix to the notice of proposed rulemaking is revised to read as follows: "Section 1.851 is deleted."

PAR. 2. Section 1.954 is deleted.

PAR. 3. Section 1.954-3(a)(1)(ii), as set forth in paragraph 3 of the appendix to the notice of proposed rulemaking, is revised as follows:

1. Inferior subdivision (*a*) is revised by deleting the third sentence and substituting in lieu thereof the following sentence: "Bananas, black pepper, cocoa, coconut, coffee, crude rubber, and tea shall not be considered grown in the United States in commercially marketable quantities."

2. Inferior subdivision (*b*) is revised by deleting "Bananas" and "Coffee" from the list of crops in table I.

This Treasury decision is issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805).

JEROME KURTZ,
Commissioner of Internal Revenue.

Approved: July 17, 1978.

DONALD C. LUBICK,
Assistant Secretary of the Treasury.

Treasury Decision

Paragraph 1. Section 1.851 is deleted.

Par. 2. Paragraph (b) of § 1.851-2 is amended by redesignating paragraph (b) as subparagraph (1) of paragraph (b), by adding a caption to redesignated subparagraph (1), by redesignating subparagraphs (1) and (2) of existing paragraph (b) as subdivisions (i) and (ii) of redesignated subparagraphs (1), and by adding a new subparagraph (2) to paragraph (b). The redesignated and revised provisions read as follows:

§ 1.851-2 Limitations.

* * * * *

(b) *Gross income requirement*—(1) *General rule.* Section 851(b) (2) and (3) provides that (i) at least 90 percent of the corporation's gross income for the taxable year must be derived from dividends, interest, and gains from the sale or other disposition of stocks or securities, and (ii) less than 30 percent of its gross income must have been derived from the sale or other disposition of stock or securities held for less than three months.* * *

(2) *Special rules.* (i) For purposes of section 851(b)(2), there shall be treated as dividends amounts which are included in gross income for the taxable year under section 951(a)(1)(A)(i) to the extent that (*a*) a distribution out of a foreign corporation's earnings and profits of the taxable year is not included in gross income by reason of section 959 (a)(1), and (*b*) the earnings and profits are attributable to the amounts which were so included in gross income under section 951(a)(1)(A)(i). For allocation of distributions to earnings and profits of foreign corporations, see § 1.959-3. The provisions of this subparagraph shall apply with respect to taxable years of controlled foreign corporations beginning after December 31, 1975, and to taxable years of United States share-

holders (within the meaning of section 951(b) within which or with which such taxable years of such controlled foreign corporations end.

(ii) For purposes of subdivision (i) of this subparagraph, if by reason of section 959(a)(1) a distribution of a foreign corporation's earnings and profits for a taxable year described in section 959(c)(2) is not included in a shareholder's gross income, then such distribution shall be allocated proportionately between amounts attributable to amounts included under each clause of section 951(a)(1)(A). Thus, for example, M is a United States shareholder in X Corporation, a controlled foreign corporation. M and X each use the calendar year as the taxable year. For 1977, M is required by section 951(a)(1)(a) to include $3,000 in its gross income, $1,000 of which is included under clause (i) thereof. In 1977, M received a distribution described in section 959(c)(2) of $2,700 out of X's earnings and profits for 1977, which is, by reason of section 959(a)(1), excluded from M's gross income. The amount of the distribution attributable to the amount included under section 951(a)(1)(A)(i) is $900, i.e., $2,700 multiplied by ($1,000/$3,000).

Par. 3. Subparagraph (1) of § 1.954-3(a) is amended—

1. By redesignating the first five sentences thereof as subdivision (i),

2. By revising subdivision (i) as redesignated by adding a caption and by redesignating subdivisions (i), (ii), (iii), and (iv) as new inferior subdivisions (*a*), (*b*), (*c*), and (*d*).

3. By redesignating the sixth sentence of subparagraph (1) and the examples following as subdivision (iii), and

4. By adding a new subdivision (ii) immediately following redesignated subdivision (i).

The redesignated and added provisions read as follows:

§ 1.954-3 Foreign base company sales income.

(a) *Income included*—(1) *In general*—(i) *General rules.* Foreign base company sales income of a controlled foreign corporation shall, except as provided in subparagraphs (2), (3), and (4) of this paragraph, consist of gross income (whether in the form of profits, commissions, fees, or otherwise) derived in connection with (*a*) the purchase of personal property from a related person and its sale to any person, (*b*) the sale of personal property to any person on behalf of a related person, (*c*) the purchase of personal property from any person and its sale to a related person, or (*d*) the purchase of personal property from any person on behalf of a related person. * * *

(ii) *Special rule*—(a) *In general.* The term "personal property" as used in section 954(d) and this section shall not include agricultural commodities which are not grown in the United States (within the meaning of section 7701(a)(9)) in commercially marketable quantities. All of the agricultural commodities listed in table I shall be considered grown in the United States in commercially marketable quantities. Bananas, black pepper, cocoa, coconut, coffee, crude rubber, and tea shall not be considered grown in the United States in commercially marketable quantities. All other agricultural commodities shall not be considered grown in the United States in commercially marketable quantities when, in consideration of all of the facts and circumstances of the individual case, such commodities are shown to be produced in the United States in insufficient quantity and quality to be marketed commercially. The term "agricultural commodities" includes, but is not limited to, livestock, poultry, fish produced in fish farms, fruit, furbearing animals as well as the products of truck farms, ranches, nurseries, ranges, and orchards. A fish farm is an area where fish are grown or raised (artificially protected and cared for), as opposed to merely caught or harvested. However, the term "agricultural commodities" shall not include timber (either standing or felled), or any commodity at least 50 percent of the fair market value of which is attributable to manufacturing or processing, determined in a manner consistent with the regulations under section 993(c) (relating to the definition of export property). For purposes of applying such regulations, the term "processing" shall be deemed not to include handling, packing, packaging, grading, storing, transporting, slaughtering, and harvesting. Subdivision (ii) shall apply in the computation of foreign base company sales income for taxable years of controlled foreign corporations beginning after December 31, 1975, and to taxable years of U.S. shareholders (within the meaning of section 951(b)) within which or with which such taxable years of such foreign corporations end.

(*b*) *Table.*

TABLE I.—*Agricultural Commodities Grown in the United States in Commercially Marketable Quantities*

Livestock and Products	
Beeswax	Horses
Cattle and calves	Milk
Chickens	Mink
Chicken eggs	Mohair
Ducks	Rabbits
Geese	Sheep and lambs
Goats	Turkeys
Hogs	Wool
Honey	

Crops	
Alfalfa	Lettuce
Almonds	Lime
Apples	Macadamia nuts
Apricots	Maple syrup and sugar
Artichokes	Mint
Asparagus	Mushrooms
Avocadoes	Nectarines
Barley	Oats
Beans	Olives
Beets	Onions
Blackberries	Oranges
Blueberries	Papayas
Brussel sprouts	Pecans
Broccoli	Peaches
Bulbs	Peanuts
Cabbage	Pears
Cantaloupes	Peas
Carrots	Peppers
Cauliflower	Plums and prunes
Celery	Potatoes
Cherries	Potted plants
Corn	Raspberries
Cotton	Rice
Cranberries	Rhubarb
Cucumbers	Rye
Cut flowers	Sorghum grain
Dates	Soybeans
Eggplant	Spinach
Escarole	Strawberries
Figs	Sugar beets
Filberts	Sugarcane
Flaxseed	Sweet potatoes
Garlic	Tangelos
Grapes	Tangerines
Grapefruit	Tobacco
Grass seed	Tomatoes
Hay	Walnuts
Honeydew melons	Watermelons
Hops	Wheat
Lemons	

(iii) *Examples.* The application of this subparagraph may be illustrated by the following examples: * * *

[FR Doc. 78-20841 Filed 7-25-78; 9:09 am]

[4830-01]

PART 1—INCOME: TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Percentage To Be Used by Foreign Life Insurance Companies in Computing Income Tax for the Taxable Year 1977 and Estimated Tax for the Taxable Year 1978

AGENCY: Department of the Treasury.

ACTION: Proclamation.

SUMMARY: This proclamation announces the percentage to be used to compute the income tax liability of

foreign corporations carrying on life insurance business in the United States.

EFFECTIVE DATE: March 15, 1978.

FOR FURTHER INFORMATION, CONTACT:

Mr. Seymour Fiekowsky, Office of Tax Analysis, U.S. Treasury Department, Washington, D.C. 20220, 202-566-8282, not a toll-free call.

SUPPLEMENTARY INFORMATION: This proclamation modifies the proclamation made by the Secretary of the Treasury March 14, 1978, announcing the percentage to be used to compute the income tax liability of foreign corporations carrying on life insurance business in the United States. The Secretary issues a proclamation each year announcing this percentage. A modification of the earlier proclamation is being issued because further analysis of the data available for the year 1978 has revealed that the appropriate percentage is different from the percentage announced in the earlier proclamation.

PROCLAMATION: For purposes of computing the 1977 income tax of foreign corporations carrying on a life insurance business, a percentage of 15.4 shall be used in determining the "minimum figure" under section 819. The same percentage shall be used for purposes of computing the estimated tax and the installment payments of estimated tax for the taxable year 1978. No additions to tax shall be made because of any underpayment of estimated tax for the taxable year 1978 which results solely from the use of this percentage.

This proclamation is issued without notice and public procedure because the public cannot effectively participate in the determination of the percentage. It is computed from information contained in income tax returns that are not open to the public. The proclamation was not published prior to its effective date because the percentage is computed on the basis of data which were not then available.

Signed: July 11, 1978.

ROBERT H. MUNDHEIM,
General Counsel.

[FR Doc. 78-20839 Filed 7-27-78; 8:45 am]

[3810-70]

Title 32—National Defense

CHAPTER I—OFFICE OF THE SECRETARY OF DEFENSE

SUBCHAPTER R—CHARTERS

[DOD Directive 5105.36]

PART 357—DEFENSE CONTRACT AUDIT AGENCY

AGENCY: Office of the Secretary of Defense.

ACTION: Final rule—DOD Charter directive 5105.36 [1]

SUMMARY: The Secretary of Defense has assigned functions and responsibilities to the Director, Defense Contract Audit Agency (DCAA), and has delegated to his specific authorities. This directive serves as the instrument that authorizes the Director, DCAA, to carry out his charter.

EFFECTIVE DATE: June 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Arthur H. Ehlers, Director, Organizational and Management Planning, Office of the Deputy Assistant Secretary of Defense (Administration), telephone 202-695-4278.

Accordingly, a new part 357 of chapter I, title 32 of the Code of Federal Regulations is established, reading as set forth below.

Dated: July 25, 1978.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

Sec.
357.1 Purpose.
357.2 Mission.
357.3 Organization and management.
357.4 Responsibilities and functions.
357.5 Authority.
357.6 Relationships.
357.7 Administration.
357.8 Delegations of authority.

AUTHORITY: 10 U.S.C. CHAPTER 4.

§ 357.1 Purpose.

Pursuant to authority vested in the Secretary of Defense under the provisions of title 10, United States Code, this part establishes the Defense Contract Audit Agency (hereafter referred to as "DCAA") with responsibilities, functions, authorities, and relationships as outlined below.

§ 357.2 Mission.

DCAA shall: (a) Perform all necessary contract audit for the Department of Defense and provide accounting and financial advisory services regarding contracts and subcontracts to all Department of Defense components responsible for procurement and contract administration. These services will be provided in connection with negotiation, administration, and settlement of contracts and subcontracts.

(b) Provide contract audit service to other Government agencies as appropriate.

§ 357.3 Organization and management.

(a) DCAA is established as a separate agency of the Department of Defense under the direction, authority and control of the Assistant Secretary of Defense (Comptroller). It shall consist of a Director and such subordinate organizational elements as are established by the Director within resources authorized by the Secretary of Defense.

(b) No separate contract audit organization independent of the DCAA shall be established in the Department of Defense.

§ 357.4 Responsibilities and functions.

The Director, DCAA shall: (a) Organize, direct, and manage the DCAA and all resources assigned to the DCAA.

(b) Assist in achieving the objective of prudent contracting by providing DOD officials responsible for procurement and contract administration with financial information and advice on proposed or existing contracts and contractors, as appropriate.

(c) Audit, examine and/or review contrators' and subcontractors' accounts, records, documents, and other evidence; systems of internal control; accounting, costing, and general business practices and procedures; to the extent and in whatever manner is considered necessary to permit proper performance of the other functions described in (d) through (l) below.

(d) Examine reimbursement vouchers received directly from contractors, under cost-type contracts, transmitting those vouchers approved for payment to the cognizant disbursing officer and issuing DCAA Form 1, "Notice of Contract Costs Suspended and/or Disapproved," with a copy to the cognizant contracting officer, with respect to costs claimed but not considered allowable. Where the contractor disagrees with a suspension or disallowance action by DCAA, and the difference cannot be resolved, the contractor may appeal in writing to the Administrative Contracting Officer (ACO) who will make his determination in writing. In addition, the contracting officer may direct the issuance of DCAA Form 1, "Notice of Contract Costs Suspended and/or Disap-

[1] Copies may be obtained, if needed, from the U.S. Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, Pa. 19120, Attention: Code 301.

proved," with respect to any cost which he has reason to believe should be suspended or disapproved.

(e) Provide advice and recommendations to procurement and contract administration personnel on:

(1) Acceptability of costs incurred under redeterminable, incentive and similar type contracts.

(2) Acceptability of incurred costs and estimates of cost to be incurred as represented by contractors incident to the award, negotiation, modification, change, administration, termination, or settlement of contracts.

(3) Adequacy of financial or accounting aspects of contract provisions.

(4) Adequacy of contractors' accounting and financial management systems, adequacy of contractors' estimating procedures and adequacy of property controls.

(f) Assist responsible procurement or contract administration activities in their surveys of the purchasing-procurement systems of major contractors.

(g) Direct audit reports to the Government management level having authority and responsibility to take action on the audit findings and recommendations.

(h) Cooperate with other appropriate Department of Defense components on reviews, audits, analyses, or inquiries involving contractors' financial position or financial and accounting policies, procedures, or practices.

(i) Establish and maintain liaison auditors as appropriate at major procuring and contract administration offices.

(j) Review General Accounting Office reports and proposed responses thereto which involve significant contract or contractor activities for the purpose of assuring the validity of appropriate pertinent facts contained therein.

(k) In an advisory capacity, attend and participate, as appropriate, in contract negotiation and other meetings which contract cost matters, audit reports, or related financial matters are under consideration.

(l) Provide assistance, as requested in the development of procurement policies and regulations.

(m) Perform such other functions as the Assistant Secretary of Defense (Comptroller) may from time to time prescribe.

§ 357.5 Authority.

The Director, DCAA, is specifically delegated authority to:

(a) Have free and unrestricted access to and direct communication with all elements of the Department of Defense and other executive departments and agencies as necessary.

(b) Establish Defense Contract Audit Agency facilities using appropriate established physical facilities and services of other DOD components whenever practicable to achieve maximum efficiency and economy.

(c) Obtain such information, consistent with the policies and criteria of DOD directive 5,000.19,[2] advice, and assistance from DOD components as he deems necessary.

(d) Exercise the administrative authorities contained in 357.8 of this Part.

§ 357.6 Relationships.

(a) In the performance of his functions, the Director, DCAA shall:

(1) Maintain appropriate liaison with other components of the DOD, other agencies of the executive branch, and the General Accounting Office for the exchange of information and programs in the field of assigned responsibilities.

(2) Make full use of established facilities in the Office of the Secretary of Defense, other DOD components, and other governmental agencies rather than unnecessarily duplicating such facilities.

(3) The military departments and other DOD components shall provide support, within their respective fields of responsibility, to the Director, DCAA to assist in carrying out the assigned responsibilities and functions of the Agency. Programing, budgeting and financing for such support will be in accordance with policies and procedures prescribed by the Assistant Secretary of Defense (Comptroller).

(b) Procurement and contract administration activities of the DOD components shall utilize audit services of the DCAA to the extent appropriate in connection with the negotiation, administration, and settlement of contract payments and prices which are based on cost (incurred or estimated), or on cost analysis.

§ 357.7 Administration.

(a) The Director, DCAA, shall be a civilian selected by the Secretary of Defense.

(b) The apointment of other personnel to the Agency will be subject to the approval of the director, DCAA.

(c) DCAA will be authorized such personnel, facilities, funds, and other administrative support as the Secretary of Defense deems necessary.

§ 357.8 Delegations of authority.

Pursuant to the authority vested in the Secretary of Defense, and subject to his direction, authority, and control, and in accordance with DOD policies, directives, and instructions, the Director, DCAA, or, in the absence of the Director the person acting for him, is hereby delegated authority as required in the administration and operation of DCAA to:

(a) Exercise the powers vested in the Secretary of Defense by 5 U.S.C. 301, 302(b) and 3101 pertaining to the employment, direction and general administration of DCAA civilian personnel.

(b) Fix rates of pay for wage board employees exempted from Civil Service classification by 5 U.S.C. 5102(c)(7) on the basis of prevailing rates for comparable jobs in the locality where each installation is located.

(c) Establish advisory committees and employ part-time advisers pursuant to the provisions of 10 U.S.C. 173, 5 U.S.C. 3109(b), the Federal Advisory Committee Act, and the Agreement between the Department of Defense (DOD) and the Civil Service Commission on employment of experts and consultants, dated March 14, 1975.

(d) Administer oaths of office incident to entrance into the executive branch of the Federal Government or any other oath required by law in connection with employment therein, in accordance with the provisions of 5 U.S.C. 2903, and designate in writing, as may be necessary, officers and employees of DCAA to perform this function.

(e) Establish a DCAA incentive awards board and pay cash awards to, and incur necessary expenses for the honorary recognition of civilian employees of the Government whose suggestions, inventions, superior accomplishments or other personal efforts, including special acts or services, benefit or affect DCAA or its subordinate activities in accordance with the provisions of 5 U.S.C. 4503 and Civil Service Regulations.

(f) In accordance with the provisions of 5 U.S.C. 7532; Executive Order 10450, dated April 27, 1953, as amended; and DOD directive 5210.7, "Department of Defense Civilian Applicant and Employee Security Program," September 2, 1966:

(1) Designate any position in DCAA as a "sensitive" position;

(2) Authorize, in case of an emergency, the appointment of a person to a sensitive position in the Agency for a limited period of time for whom a full field investigation or other appropriate investigation, including the National Agency Check, has not been completed; and

(3) Authorize the suspension, but not to terminate the services of an employee in the interest of national security in positions within DCAA.

(g) Clear DCAA personnel and such other individuals as may be appropriate for access to classified Defense material and information in accordance with the provisions of DOD directive 5210.8, "Policy on Investigation and Clearance of DOD Personnel for Access to Classified Defense Information," February 15, 1962, and of Ex-

[2] See footnote 1.

ecutive Order 11652, dated March 8, 1972, as amended.

(h) Act as agent for the collection and payment of employment taxes imposed by chapter 21 of the Internal Revenue Code of 1954 and, as such agent, make all determinations and certifications required or provided for under section 3122 of the Internal Revenue Code of 1954 and section 205(p) (1) and (2) of the Social Security Act, as amended (42 U.S.C. 405(p) (1) and (2)) with respect to DCAA employees.

(i) Authorize and approve overtime work for DCAA civilian officers and employees in accordance with the provisions of the Federal Personnel Manual Supplement 990-1, Section 550-111.

(j) Authorize and approve:

(1) Travel for DCAA civilian officers and employees in accordance with Joint Travel Regulations, Volume 2, DOD Civilian Personnel;

(2) Temporary duty travel only for military personnel assigned or detailed to DCAA in accordance with Joint Travel Regulations, Volume 1, Members of Uniformed Services; and

(3) Invitational travel to persons serving without compensation whose consultive, advisory or other highly specialized technical services are required in a capacity that is directly related to, or in connection with DCAA activities, pursuant to the provisions of 5 U.S.C. 5703.

(k) Approve the expenditure of funds available for travel by military personnel assigned or detailed to DCAA for expenses incident to attendance at meetings of technical, scientific, professional or other similar organizations in such instances where the approval of the Secretary of Defense or his designee is required by law (37 U.S.C. 412). This authority cannot be redelegated.

(l) Develop, establish and maintain an active and continuing records management program, pursuant to the provisions of section 506(b) of the Federal Records Act of 1950 (44 U.S.C. 3102), the Freedom of Information Act program (5 U.S.C. 552) and the Privacy Act program (5 U.S.C. 552a).

(m) Establish and use imprest funds for making small purchases of material and services other than personal for DCAA when it is determine more advantageous and consistent with the best interests of the Government, in accordance with the provisions of DOD Instruction 5100.71, "Delegation of Authority and Regulations Relating to Cash Held at Personal Risk Including Imprest Funds," March 5, 1973, and the Joint Regulation of the General Services Administration/Treasury Department/General Accounting Office, entitled "For Small Purchases Utilizing Imprest Funds."

(n) Authorize the publication of advertisements, notices or proposals in newspapers, magazines or other public periodicals as required for the effective administration and operation of DCAA (44 U.S.C. 3702).

(o) Establish and maintain appropriate property accounts for DCAA and appoint boards of survey, approve reports of survey, relieve personal liability, and drop accountability for DCAA property contained in the authorized property accounts that has been lost, damaged, stolen, destroyed or otherwise rendered unserviceable, in accordance with applicable laws and regulations.

(p) Promulgate the necessary security regulations for the protection of property and places under the jurisdiction of the Director, DCAA, pursuant to subsections III.A and V.B. of DOD Directive 5200.8, "Authority of Military Commanders under the Internal Security Act of 1950 to Issue Security Orders and Regulations for the Protection of Property or Places under Their Command," August 20, 1954.

(q) Establish and maintain, for the functions assigned, an appropriate publications system for the promulgation of common supply and service regulations, instructions, and reference documents, and changes thereto, pursuant to the policies and procedures prescribed in DOD Directive 5025.1, "Department of Defense Directive System," November 18, 1977.

(r) Enter into support and service agreements with the military departments, other DOD agencies, or other Government agencies as required for the effective performance of responsibilities and functions assigned to DCAA.

The Director, Defense Contract Audit Agency, may redelegate these authorities, as appropriate, and in writing, except as otherwise specifically indicated above or as otherwise provided by law or regulation.

This delegation of authorities is effective immediately.

[FR Doc. 78-20930 Filed 7-27-78; 8:45 am]

[3810-70]

[DOD Directive 5105.41]

PART 358—DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

AGENCY: Office of the Secretary of Defense.

ACTION: Final rule—DOD Charter Directive 5105.41.[1]

SUMMARY: The Secretary of Defense has assigned functions and responsibilities to the Director, Defense Advanced Research Projects Agency (DARPA), and has delegated to him specific authorities. This Directive serves as the instrument that authorizes the Director, DARPA, to carry out his charter.

EFFECTIVE DATE: June 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Arthur H. Ehlers, Director for Organizational and Management Planning, Office of the Deputy Assistant Secretary of Defense, Administration, telephone 202-695-4278.

Accordingly, a new Part 358 of Title 32, Chapter I, of the Code of Federal Regulations is established, reading as set forth below.

Dated: July 25, 1978.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

Sec.
358.1 Purpose.
358.2 Mission.
358.3 Organization and management.
358.4 Responsibilities and functions.
358.5 Authority.
358.6 Relationships.
358.7 Administration.
358.8 Delegations of authority.

AUTHORITY: 10 U.S.C. Chapter 4.

§ 358.1 Purpose.

Pursuant to the authority vested in the Secretary of Defense under the provisions of title 10, United States Code, this Part establishes the Defense Advanced Research Projects Agency (hereafter referred to as "DARPA") with responsibilities, functions, authorities and relationships as outlined below.

§ 358.2 Mission.

DARPA shall manage and direct the conduct of selected advanced basic and applied research and development projects for the Department of Defense.

§ 358.3 Organization and management.

DARPA is established as a separate agency of the Department of Defense under the staff and operational direction of the Under Secretary of Defense for Research and Engineering. It shall consist of a Director and such subordinate organizational elements as are established by the Director within resources authorized by the Secretary of Defense.

§ 358.4 Responsibilities and functions.

The Director, DARPA shall:

(a) Organize, direct, and manage the DARPA and all resources assigned to the DARPA.

[1] Copies may be obtained, if needed, from the U.S. Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, Pa. 19120. Attention: Code 301.

(b) Provide guidance and assistance, as appropriate, to all DOD Components and other U.S. Government activities on matters pertaining to the projects assigned to the DARPA.

(c) Recommend to the Secretary of Defense, through the Under Secretary of Defense for Research and Engineering, the assignment of research projects to DARPA.

(d) Arrange for the performance of and supervise the work connected with DARPA projects assigned to the Military Departments, other U.S Government activities, individuals, private business entities, educational institutions, or research institutions, giving consideration to the primary functions of the Military Departments.

(e) Engage in assigned advanced research projects.

(f) Keep the Under Secretary of Defense for Research and Engineering, the Military Departments, the Joint Chiefs of Staff, and other DOD Agencies informed, as appropriate, on significant new developments, breakthroughs, and technological advances within assigned projects and on the status of such projects in order to facilitate early operational assignment.

(g) Prepare and submit to the Assistant Secretary of Defense (Comptroller), in accordance with established procedures, the DARPA annual program-budget estimates, to include the assignment of appropriation program priorities.

(h) Perform such other functions as may be assigned by the Under Secretary of Defense for Research and Engineering.

§ 358.5 Authority.

The Director, DARPA, is specifically delegated authority to:

(a) Place funded work orders with the Military Departments and other DOD Components or directly with subordinate echelons of the Military Departments, after clearance with the Secretary of the Military Department concerned.

(b) Authorize the allocation, as appropriate, of funds made available to DARPA for assigned advanced projects.

(c) Establish for DARPA, the Military Departments, and other research and development activities, such procedures required in connection with work being performed for DARPA consistent with policies and instructions governing the Department of Defense.

(d) Acquire or construct, through a Military Department or other U.S. Government agency, such research, development, and test facilities and equipment required to carry out his assignments and that may be approved by the Secretary of Defense in accordance with applicable statutes and DOD Directives.

(e) Exercise the administrative authorities contained in § 358.8 of this Part.

§ 358.6 Relationships.

(a) In the performance of his functions, the Director, DARPA, shall:

(1) Coordinate actions, as appropriate, with the other Components of DOD having collateral or related functions in the field of his assigned responsibility.

(2) Maintain active liaison for the exchange of information and advice in the field of his assigned responsibility with all DOD Components, non DOD research and development institutions (including private business entities), educational institutions, and other U.S. Government activities.

(3) Make full use of established facilities in the Office of the Secretary of Defense, other DOD Components, and other Governmental agencies rather than unnecessarily duplicating such facilities.

(b) Officials of all DOD Components will provide support, within their respective fields of responsibility, to the Director, DARPA as may be necessary to carry out the assigned responsibilities and functions of his Agency.

§ 358.7 Administration.

(a) The Director, DARPA, shall be a civilian selected by the Secretary of Defense.

(b) DARPA shall be authorized such personnel, facilities, funds, and other administrative support as the Secretary of Defense deems necessary.

(c) The Military Departments shall assign personnel to DARPA in accordance with approved authorizations and procedures for assignment to joint duty.

(d) Administrative support required for DARPA will be provided by the Director, Washington Headquarters Services, and other DOD Components, as appropriate.

§ 358.8 Delegations of authority.

Pursuant to the authority vested in the Secretary of Defense, and subject to his direction, authority, and control, and in accordance with DOD policies, directives, and instructions, the Director, DARPA, or, in the absence of the Director the person acting for him, is hereby delegated authority as required in the administration and operation of DARPA to:

(a) Designate any position in DARPA as a "sensitive" position, in accordance with the provisions of the Act of August 26, 1950, as amended (5 U.S.C. 7532); Executive Order 10450, dated April 27, 1953, as amended by Executive Orders 10491, 10531, 10458, 10550, and DOD Directive 5210.7, dated September 2, 1966,

(b) Authorize and approve overtime work for DARPA civilian officers and employees in accordance with the provisions of the Federal Personnel Manual Supplement 990-1, section 550.111.

(c) Authorize and approve:

(1) Travel for DARPA civilian officers and employees in accordance with the Joint Travel Regulations, volume 2, Department of Defense, Civilian Personnel;

(2) Temporary duty travel only for military personnel assigned or detailed to DARPA in accordance with the Joint Travel Regulations, volume I, members of the uniformed services; and

(3) Invitational travel to persons serving without compensation whose consultive, advisory, or other specialized technical services are required in a capacity that is directly related to, or in connection with, DARPA activities, pursuant to the provisions of United States Code 5703.

(d) Approve the expenditure of funds available for travel by military personnel assigned or detailed to DARPA for expenses incident to attendance at meetings of technical, scientific, professional, or other similar organizations in such instances where the approval of the Secretary of Defense or his designee is required by law (37 U.S.C. 412). This authority cannot be redelegated.

(e) Develop, establish, and maintain an active and continuing Records Management Program, pursuant to the provisions of Section 506(b) of the Federal Records Act of 1950 (44 U.S.C. 3102), the Freedom of Information Act Program (5 U.S.C. 552) and the Privacy Act Program (5 U.S.C. 552a).

(f) Enter into and administer contacts, through a Military Department or other U.S. Government department or agency, as appropriate, for research and development, supplies, equipment, and services required to accomplish the mission of DARPA. To the extent that any law or Executive Order specifically limits the exercise of such authority to persons at a higher level in the Department of Defense, such authority will be exercised by the appropriate Under Secretary or Assistant Secretary of Defense.

(g) Establish and use Imprest Funds for making small purchases of material and services, other than personal, when it is determined more advantageous and consistent with the best interest of the Government, in accordance with the provisions of DOD Instruction 5100.71, "Delegations of Authority and Regulations Relating to Cash Held at Personal Risk Including Imprest Funds," March 5, 1973 and the Joint Regulation of the General

Services Administration/Treasury Department/General Accounting Office, entitled "For Small Purchases Utilizing Imprest Funds."

(h) Authorize the publication of advertisements, notices, or proposals in public periodicals as required for the effective administration and operation of DARPA (44 U.S.C. 3702).

(i) Promulgate the necessary security regulations for the protection of property and places under the jurisdiction of the Director, DARPA pursuant to subsections III.A. and V.B. of DOD Directive 5200.8, "Authority of Military Commanders Under the International Security Act of 1950 To Issue Security Orders and Regulations for the Protection of Property or Places Under Their Command," August 20, 1954.

(j) Establish and maintain, for the functions assigned, an appropriate publications system for the promulgation of regulations, instructions, and reference documents, and changes thereto, pursuant to the policies and procedures prescribed in DOD Directive 5025.1, November 18, 1977.

(k) In coordination with the Deputy Assistant Secretary of Defense (Administration), enter into interservice support agreements in accordance with DOD Directive 4000.19, "Basic Policies and Principles for Interservice, Interdepartmental and Interagency Support," March 27, 1972.

(l) Establish and maintain appropriate Property Accounts for DARPA and appoint Boards of Survey, approve reports of survey, relieve personal liability, and drop accountability for DARPA property contained in the authorized Property Accounts that have been lost, damaged, stolen, destroyed, or otherwise rendered unserviceable, in accordance with applicable laws and regulations.

The Director, DARPA, may redelegate these authorities, as appropriate, and in writing, except as otherwise specifically indicated above or as otherwise provided by law or regulation.

These delegations of authority are effective immediately.

[FR Doc. 78-20928 Filed 7-27-78; 8:45 am]

[3810-70]

[DOD Directive 5105.22]

PART 359—DEFENSE LOGISTICS AGENCY

AGENCY: Office of the Secretary of Defense.

ACTION: Final rule—DOD Charter Directive 5105.22.[1]

SUMMARY: The Secretary of Defense has assigned functions and responsibilities to the Director, Defense Logistics Agency (DLA), and has delegated to him specific authorities. This Directive serves as the instrument that authorizes the Director, DLA, to carry out his charter.

EFFECTIVE DATE: June 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Arthur H. Ehlers, Director for Organizational and Management Planning, Office of the Deputy Assistant Secretary of Defense, Administration, telephone 202-695-4278.

Accordingly, a new Part 359 of Chapter I, Title 32 of the Code of Federal Regulations is established, reading as set forth below.

Dated: July 25, 1978.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

Sec.
359.1 Purpose.
359.2 Mission.
359.3 Organization and management.
359.4 Responsibilities.
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359.7 Relationships.
359.8 Administration.
359.9 Delegation of authority.
359.10 Relationship between Commanders of Unified Commands and overseas elements of the Defense Logistics Agency.

AUTHORITY: 10 U.S.C. Chapter 4.

§ 359.1 Purpose.

Pursuant to authority vested in the Secretary of Defense under the provisions of title 10, United States Code, this Part established the Defense Logistics Agency (hereafter referred to as "DLA") with responsibilities, functions, authorities, and relationships as outlined below.

§ 359.2 Mission.

DLA shall:

(a) Function as an integral element of the defense military logistics system and, as such, direct its efforts and operations toward logistics support of the mission of the military departments and the unified and specified commands under all conditions of peace and war.

(b) Provide effective and economical support to the Military Departments, other DOD Components, Federal civil agencies, foreign governments, and others as authorized, for assigned:

(1) Materiel commodities and items of supply (hereafter referenced as "items"), which are determined, through application of approved DOD criteria, to be susceptible of integrated management by a single agency for all of the military departments or as otherwise assigned.

(2) Logistics services directly associated with the supply management function and other support services as directed by the Secretary of Defense.

(c) Administer the operation of DOD programs as assigned.

§ 359.3 Organization and management.

(a) DLA is established as a separate agency of the Department of Defense under the direction, authority and control of the Assistant Secretary of Defense (Manpower, Reserve Affairs and Logistics), (hereafter referred to as "ASD(MRA&L)"). DLA activities involving acquisition policy and related matters will be closely coordinated with, and generally monitored by, the Under Secretary of Defense for Research and Engineering.

(b) DLA shall consist of a Director and such subordinate organizational elements as are established by the Director within resources authorized by the Secretary of Defense.

§ 359.4 Responsibilites.

The Director, DLA shall be responsible for:

(a) Organizing, directing, and managing the DLA and all resources assigned to the DLA.

(b) Providing responsible, effective, and economical support to:

(1) The military departments and other DOD components.

(2) Federal civil agencies.

(3) Foreign governments, and others, as authorized.

(c) Monitoring DOD supply relationships with the General Services Administration (GSA).

(d) The management (including organization, direction, procurement, administration, supervision, and control) of assigned items, services, and programs.

(e) A wholesale distribution system for assigned items.

(f) Providing assigned contract administration service in support of the military departments, other DOD components, Federal civil agencies, and when authorized, to foreign governments and others.

(g) Systems analysis and design, procedural development, and maintenance for supply and service systems.

§ 359.5 Functions.

The Director, DLA shall perform the following functions:

(a) Coordinated Procurement. (1) Administer the DOD Coordinated Procurement Program.

(2) Recommend criteria and maintain procedures for coordinated procurement assignments of all DOD components.

(3) Make recommendations on new coordinated procurement assignments

[1] Copies may be obtained, if needed, from the U.S. Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, Pa. 19120. Attention Code 301.

and changes to existing assignments for all DOD components.

(4) Review and evaluate the operation of the DOD Coordinated Procurement Program, and make changes as required and as authorized, to improve the effectiveness of the operation.

(5) Conduct coordinated procurement as assignee for designated commodities.

(b) *Cataloging.* (1) Administer the Federal catalog system.

(2) Develop, review, and control the operating procedures, rules, and regulations for the Federal catalog system pertaining to item classification, identification, Federal stock number assignment, and central file maintenance. Based upon analysis of Federal catalog system operation, recommend to the ASD(MRA&L) new and revised policies to improve the system.

(3) Develop and maintain the central, single, official record of Federal catalog data for all items of supply in the Federal catalog system, including all identification and classification data and those elements of management data appropriately contained therein.

(4) Ensure the exclusive use of Federal catalog data in the preparation, publication, distribution, and maintenance of the DOD sections of the Federal catalog, and that the publication of Identification and management data lists if fully synchronized.

(5) Furnish to the military departments, Defense Supply Centers, civil agencies, NATO countries, and other friendly foreign governments such Federal catalog data as are required and requested for item identification, classification, and maintenance of the Federal catalog system. This includes such management data as are centrally recorded and utilized by the military departments and civil agencies for the publication of management data lists.

(6) Prepare and publish on a centralized basis, for all DOD users, identification lists and cross-reference lists in a standard DOD format.

(7) Operate as the single submitting activity in the Federal supply groups and classes assigned to DLA, and prepare item identification for NATO and other friendly foreign governments, as assigned.

(8) Represent the DOD, as required, in negotiations with Federal civil agencies, NATO, and other friendly foreign governments, industry, and other nondefense activities, in matters concerning the administration of the Federal catalog system.

(c) *Excess and Surplus Disposal (Personal Property).* (1) Administer the DOD Excess, Surplus, and Foreign Excess Personal Property Disposal Program in CONUS and overseas in accordance with DOD policy.

(2) Represent the DOD as required in negotiations with other Federal departments and agencies on matters of mutual interest in the disposal of excess, surplus and foreign excess personal property.

(3) Develop, review and prescribe techniques, systems and procedures for preparation and disposal of excess, surplus and personal property, including foreign excess. Recommend to the ASD(MRA&L) as appropriate, revisions to DOD policies.

(4) In coordination with the military departments, develop and establish workload, performance and cost standards for all CONUS activities that are reimbursed from surplus sales proceeds. Exercise supervision of the program level of individual disposal activities through adherence to such established standards. Assist in establishment of the reimbursable obligation authority required for the disposal activity program of each DOD component, by recommending program levels by individual activity and changes thereto when appropriate, as a result of analyses carried out during the year.

(5) Maintain a reporting system for DOD worldwide excess and surplus personal property, including foreign excess, and prepare reports as required. Recommend to the Assistant Secretary of Defense (Comptroller) any necessary refinements to the specificity of the expenses authorized to be reimbursed from proceeds of surplus sales.

(6) Direct, manage and operate defense surplus sales offices.

(7) Administer a consolidated holding activity program within CONUS with authority to determine the disposal activities required and resolve differences.

(d) *Utilization (Personal Property and Retail Interservice Support).* (1) Administer the Defense Materiel Utilization Program in CONUS and overseas in accordance with DOD policy.

(2) Develop systems and procedures for, and recommend to the ASD(MRA&L) assignments of responsibility to the military departments to assure the cross-utilization of assets in order to minimize new procurement, stockage and transportation costs.

(3) Review and evaluate the operation of assigned utilization responsibilities and make changes as required to improve the effectiveness of operations.

(4) Administer the Defense Retail Interservice Logistic Support Program, in coordination with military departments and other DOD components, as prescribed by DOD policies.

(5) Prepare and disseminate reports on operation of the Defense Materiel Utilization Program and the Defense Retail Interservice Logistic Support Program, as required.

(e) *Systems Analysis and Design.* (1) Conduct analyses, as directed by the Secretary of Defense, of the operations of the supply and service systems of the military departments in order to recommend improvements in integrated management techniques.

(2) Design and implement improved supply and service systems for the management responsibilities assigned to DLA.

(3) Develop plans, systems, and procedures to assure a close and responsive relationship between DLA operations and the war plans and logistics requirements of the Joint Chiefs of Staff and the military departments.

(4) Design and implement DLA systems to insure effectiveness, reliability and survivability in time of war or emergencies.

(5) Review and evaluate the operation of the supply and service systems assigned to DLA and make changes, as required, to improve the effectiveness of operations.

(6) Perform analysis, design, maintenance, and surveillance of standard DOD data systems.

(f) *Item Entry Control.* (1) Administer the DOD Item Entry Control Program.

(2) Provide DOD-wide counsel and leadership in the development of techniques and systems to prevent the entry of unnecessary items into the DOD supply system; foster industry cooperation; and coordinate and monitor the direction and progress of the program to insure expeditious and effective DOD-wide implementation.

(3) Manage and conduct the DLA portion of the DOD Item Entry Control Program.

(g) *Contract Administration Services.* Within CONUS and overseas, as directed, provide assigned contract administration services to the military departments and other DOD components, Federal civil agencies and, when authorized, to foreign governments and others. Among the more significant functions performed are the following:

(1) *Industrial Security.* Administer the DOD Industrial Security Program. Establish procedures, requirements, and practices to insure effective protection of classified information (including foreign classified information) in the hands of contractors located within the United States, including Alaska and Hawaii, its possessions, trust territories, and Puerto Rico, and such other areas as are specifically authorized by the Secretary of Defense.

(2) *Contract Administration.* Perform contract administration, including plant clearance, utilization, and disposal of contract inventories, ad-

ministration of Government furnished property, financial analysis, review of contractor management systems, price and cost analysis (excluding examination of contractor's financial records), convenience termination settlements, small business and economic utilization, negotiation of contract changes pursuant to the changes clause, determination of allowability of cost, and such other functions as are delegated.

(3) *Production.* Conduct preaward surveys and surveillance of contractors' production effort and industrial resources, and arrange for packaging and transportation support.

(4) *Quality Assurance.* Evaluate contractors' quality and reliability programs for conformance with contractual provisions; perform product verification inspection and testing for acceptance or rejection of supplies and services in accordance with the quality and reliability provisions of the contracts.

(5) *Engineering Liaison.* Provide engineering liaison and assistance to system/project managers and purchasing offices.

(6) *Management Data.* Provide management data for procuring activities and inventory managers including contract shipments, fund status and contractual disbursements.

(h) *DOD/GSA Supply Relationships.* (1) Monitor supply support arrangements between DOD components and GSA concerning procurement, storage and distribution of materiel within the United States or overseas.

(2) Review and evaluate performance by GSA under approved arrangements and, in collaboration with the military departments, take steps to assure efficient use of GSA services.

(3) Recommend to the ASD(MRA&L) action on proposals to support Federal civil agencies with DLA-assigned materiel.

(4) Maintain and implement criteria for assignment of supply management responsibility between DLA and GSA in Federal supply groups, classes, and items designated for integrated management within DOD; recommend to the ASD(MRA&L) changes in criteria as required.

(i) *Industrial Plant Equipment.* (1) Administer the DOD Industrial Plant Equipment (IPE) Program to ensure the reutilization of available assets.

(2) Maintain and control a reserve of IPE to meet peacetime and mobilization needs; rebuild items in the reserve, as necessary.

(3) Review and evaluate the operation of the DOD IPE Program and recommend changes as required to improve the effectiveness of operations.

(j) *Automatic Data-Processing Equipment Reutilization Screening.* Administer the DOD-wide program for redistribution/reutilization of excess Government owned and rented automated data-processing equipment.

(k) *Warehousing Gross Performance Measurement.* Administer the DOD warehousing gross performance measurement system.

(l) *Technical (RDT&E) Report Services.* (1) Receive, store, announce, retrieve, and provide secondary distribution of scientific and technical documents.

(2) Receive, store, retrieve, and disseminate information on current research and exploratory development work.

(m) *Centralized Referral System for Displaced DOD Employees.* (1) Serve as the operating agency for the nationwide centralized referral system for displaced DOD employees.

(2) Coordinate the DOD referral and placement responsibilities within Zone 3 (Chicago and St. Louis Civil Service Regions).

(n) *Automation of the Career Program for Civilian Procurement Personnel.* Administer the automated phases of the DOD Civilian Procurement Career Development Program.

(o) *Defense Automatic Addressing System.* Administer operation of the defense automatic addressing system for logistics management data.

(p) *Civil Preparedness Materiel Support.* Administer assigned logistics operations contingent to the National Civil Defense Program within the policies and programs established by the Director of the Defense Civil Preparedness Agency.

(q) *Materiel Management.* (1) *Item Management Classification.* (i) Under policies and criteria prescribed by the ASD(MRA&L) and in coordination with the military departments, establish and maintain procedures for the coding and classification of items to be placed or maintained under integrated management and for resolving item management coding and classification conflicts between the military departments and DLA.

(ii) Determine the method of management (e.g., central stocking vs. local purchase) of assigned items.

(2) *Requirements and Supply Control (Assigned Items).* (i) Compute requirements for DLA distribution system stockage and replenishment needed for support of authorized customers.

(ii) Obtain forecasts of special program requirements (SPR's) and mobilization materiel requirements. Review for suitability and, in the case of mobilization requirements, for conformance to DOD criteria.

(iii) Compute mobilization materiel requirements, initial military department support requirements (provisioning), and/or SPR's when and in the manner mutually agreed upon between DOA and the supported military department or other customer agency.

(iv) Utilize current and projected requirements in relation to available resources for the purpose of budgeting, procurement, positioning, maintenance, retention and disposal.

(v) Provide necessary information to military departments and other authorized customers on supply capabilities in support of mobilization and peacetime program requirements.

(3) *Procurement.* (i) Conduct or direct procurement of assigned or otherwise designated items and services to meet the needs of the military departments and other authorized customers.

(ii) Administer the procurement priorities and allocation authorities as authorized by the Under Secretary of Defense for Research and Engineering.

(4) *Quality Reliability Assurance.* Take appropriate action to assure the quality and reliability of materiel procured by DLA and/or stored and maintained in the DLA distribution system.

(5) *Industrial Mobilization Planning.* (i) Conduct industrial mobilization and industrial readiness planning in assigned area of responsibility.

(ii) Maintain and publish revisions to the DOD register of planned emergency producers.

(6) *Storage.* (i) For DLA-assigned items and, as assigned, military department-managed items, civil defense items, and items managed by other Federal agencies:

(A) Determine requirements for storage space.

(B) Arrange for use of storage space and related services and facilities of the DOD, other Federal agencies, and commercial storage facilities, as necessary.

(ii) Manage, control, and operate assigned depots and storage facilities.

(iii) Administer the DOD commercial warehouse service plan for general merchandise warehouses and refrigerated storage.

(7) *Inventory and Distribution.* (i) Establish and maintain inventory procedures and distribution control, incuding reporting systems, over items owned and managed by DLA.

(ii) Control the distribution, redistribution, or disposition of assigned serviceable and reparable items of supply controlled by DLA or controlled by, but excess to the needs of, the individual installations of the military departments and other authorized customers.

(iii) Provide for stock positioning of mobilization reserve stocks, consistent with contingency, emergency, and mobilization plans.

(iv) Establish procedures for direct CONUS support of field and operating forces, and outside CONUS when mu-

tually agreed upon by DLA and the supported service.

(v) Account for control DLA-owned property in the hands of Government manufacturing plants.

(vi) Institute measures in coordination with the military departments for the use of available assets of interchangeable and substitutable DLA-managed items.

(8) *Research and Development, and Engineering Support.* (i) Recommend to the military departments, or to the Under Secretary of Defense for Research and Engineering, as appropriate, any new or changed research, development and engineering projects considered desirable, to:

(A) Improve materials, items, and methods within the commodity jurisdictions assigned; and

(B) Promote the elimination of undesirable duplication.

(ii) Arrange through the appropriate military department and the Under Secretary of Defense for Research and Engineering for support required by DLA in the performance of its mission.

(9) *Transportation.* Arrange for transportation of DLA-owned materiel for initial distribution of stocks from supplier to point of storage, from point of storage or supplier direct to consumer, and for redistribution between storage points.

(10) *Maintenance and Manufacture.* (i) Manage, control, and operate assigned maintenance and manufacturing facilities.

(ii) Develop programs, schedules, and technical guidance; and provide or arrange for the maintenance, manufacture, modification, conversion, rehabilitation, reconstitution, or assembly of DLA-owned materiel and items authorized for return to DLA from users for repair at facilities of the military departments, commercial contractors, or those assigned to DLA.

(iii) Develop technical maintenance standards for DLA-owned items, and items authorized for return from users, in coordination with the using military departments.

(iv) When requested by the using military departments and other DOD components, provide technical manuals for the operation and maintenance of items assigned to DLA.

(11) *Provisioning.* (i) Participate as a supporting inventory manager in the provisioning processes of the military departments.

(ii) Establish and maintain, in coordination with the military departments, definitive procedures for provisioning supply support of the military departments and uniform provisioning of procedural and technical documentation requirements for incorporation into DLA contracts requiring provisioning.

(12) *Technical Logistics Data and Information.* (i) Develop, administer, and maintain, as assigned, documentation governing the preparation of technical data.

(ii) Acquire, process, interchange, identify, store, and issue technical data and information adequate to support mission requirements.

(r) *Value Engineering.* (1) Initiate value engineering-type projects and studies to seek the lowest overall cost for DLA-managed/procured items, consistent with requirements for performance, reliability and maintainability.

(2) Coordinate findings with military departments, as applicable, to obtain agreement with respect to technical and engineering aspects.

(3) Make decisions with respect to value engineering changes for DLA-managed items, subject to the right of appeal to the Secretary of Defense by the military departments affected.

(s) *Standardization.* (1) Manage and conduct those portions of the Defense Standardization Program assigned to DLA.

(2) In coordination with the military departments, direct and conduct technical reviews to determine the standardization status, and develop military supply standards for all items of supply assigned to DLA. Make final standardization decisions on all items managed by DLA, subject to the right of appeal to the Secretary of Defense by the military departments affected.

(3) Determine, in coordination with the military departments, interchangeability and substitutability of items of supply managed by DLA.

(t) *Manpower Data.* Administer and manage a Defense Manpower Data Center for collection, processing, and reporting of manpower data in support of OSD, other DOD components, and other Government agencies as assigned.

(u) Such other functions as may be assigned by the ASD(MRA&L).

§ 359.6 Authority.

The Director, DLA, is specifically delegated authority to:

(a) Meet the needs of the military departments and other authorized customers by conducting, directing, supervising or controlling all procurement activities with respect to property, supplies and services assigned to DLA for procurement in accordance with applicable laws, DOD regulations and the defense acquisition regulation (DAR). To the extent that any law or Executive order specifically limits the exercise of such authority to persons at the secretarial level of a military department, such authority shall be exercised by the appropriate Under Secretary or Assistant Secretary of Defense.

(b) Have free and direct access to, and communication with, all elements of the DOD and other executive departments and agencies, as necessary.

(c) Prescribe procedures, standards, and practices for DOD, governing the execution of assigned responsibilities and functions.

(d) Obtain such reports, information, advice, and assistance from other DOD components, consistent with the policies and criteria of DOD directive 5000.19,[1] as may be necessary for the performance of assigned functions and responsibilities.

(e) Establish new DLA facilities or recommend to the ASD(MRA&L) the takeover or use of existing facilities of the military departments by DLA, as deemed necessay for improved effectiveness and economy.

(f) Provide membership on the Defense Acquisition Regulatory Council and participate with the Secretaries of the military departments in the development and promulgation of the DAR.

(g) Exercise the administrative authorities contained in § 359.9 of this part.

§ 359.7 Relationships.

(a) In the performance of his functions, the Director, DLA, shall:

(1) Maintain appropriate liaison with other DOD components and other agencies of the executive branch for the exchange of information and programs in the field of assigned responsibilities.

(2) Maintain close working relationships with weapon systems managers of the military departments to ensure integration of effort and exchange of technical programs and reference data.

(3) Make use of established facilities and services in the DOD or other governmental agencies wherever practicable to achieve maximum efficiency and economy.

(b) The Joint Chiefs of Staff, the military departments, and other DOD components shall provide support and logistical planning information, within their respective fields of responsibility, to the Director, DLA, to carry out assigned responsibilities and functions of DLA.

(c) The relationship between commanders of unified commands and overseas elements of the DLA is defined in § 359.10.

§ 359.8 Administration.

(a) The Director shall be selected by the Secretary of Defense.

(b) When the Director and the Deputy Director are both military officers, they will normally be selected from different military departments.

(c) DLA will be authorized such personnel, facilities, funds, and other ad-

[1] See footnote 1.

ministrative support as the Secretary of Defense deems necessary.

(d) The military departments will assign military personnel to DLA in acordance with approved authorizations and procedures for assignment to joint duty.

(e) Programming, budgeting, funding, auditing, accounting, pricing, and reporting activities of DLA will be in accordance with policy and procedures established by the Office of the Secretary of Defense. DLA will utilize appropriated funds to finance the operating costs of the Agency; a stock fund to finance all inventories procured for resale; and, when appropriate, an industrial fund for financing industrial-commercial type operations.

§ 359.9 Delegations of Authority.

Pursuant to the authority vested in the Secretary of Defense, and subject to his direction, authority, and control, and in accordance with DOD policies, directives, and instructions, the Director, DLA, or in the absence of the Director the person acting for him, is hereby delegated authority as required in the administration and operation of DLA to:

(a) Exercise the powers vested in the Secretary of Defense by 5 U.S.C. 301, 302(b) and 3101 pertaining to the employment, direction and general administration of DLA civilian personnel.

(b) Fix rates of pay for wage board employees exempted from civil service classification by 5 U.S.C. 5102(c)(7) on the basis of prevailing rates for comparable jobs in the locality where each installation is located.

(c) Establish advisory committees and employ part-time advisers, as approved by the Secretary of Defense for the performance of DLA functions pursuant to the provisions of 10 U.S.C. 173, 5 U.S.C. 3109(b), the Federal Advisory Committee Act, and the Agreement between the Department of Defense (DOD) and the Civil Service Commission on employment of experts and consultants, dated March 14, 1975.

(d) Administer oaths of office incident to entrance into the executive branch of the Federal Government or any other oath required by law in connection with employment therein, in accordance with the provisions of 5 U.S.C. 2903, and designate in writing, as may be necessary, officers and employees of DLA to perform this function.

(e) Establish a DLA incentive awards board and pay cash awards to, and incur necessary expenses for the honorary recognition of civilian employees of the government whose suggestions, inventions, superior accomplishments or other personal efforts, including special acts or services, benefit or affect DLA or its subordinate activities in accordance with the provisions of 5 U.S.C. 4503 and civil service regulations.

(f) In accordance with the provisions of 5 U.S.C. 7532; Executive Order 10450, dated April 27, 1953, as amended; and DOD Directive 5210.7, "Department of Defense Civilian Applicant and Employee Security Program," September 2, 1966:

(1) Designate any position in DLA as a "sensitive" position;

(2) Authorize, in case of an emergency, the appointment of a person to a sensitive position in the Agency for a limited period of time for whom a full field investigation or other appropriate investigation, including the national agency check, has not been completed; and

(3) Authorize the suspension, but not to terminate the services of an employee in the interest of national security in positions within DLA.

(g) Clear DLA personnel and such other individuals as may be appropriate for access to classified Defense material and information in accordance with the provisions of DOD Directive 5210.8, "Policy on Investigation and Clearance of DOD Personnel for Access to Classified Defense Information," February 15, 1962, and of Executive Order 11652, dated March 8, 1972, as amended.

(h) Act as agent for the collection and payment of employment taxes imposed by chapter 21 of the Internal Revenue Code of 1954 and, as such agent, make all determinations and certifications required or provided for under section 3122 of the Internal Revenue Code of 1954 and section 205(p) (1) and (2) of the Social Security Act, as amended (42 U.S.C. 405(p) (1) and (2)) with respect to DLA employees.

(i) Authorize and approve overtime work for DLA civilian officers and employees in accordance with the provisions of the Federal Personnel Manual Supplement 990-1, section 550.111.

(j) Authorize and approve:

(1) Travel for DLA civilian officers and employees in accordance with Joint Travel Regulations, Volume 2, DOD Civilian Personnel;

(2) Temporary duty travel only for military personnel assigned or detailed to DLA in accordance with Joint Travel Regulations, Volume 1, Members of Uniformed Services; and

(3) Invitational travel to persons serving without compensation whose consultive, advisory or other highly specialized technical services are required in a capacity that is directly related to, or in connection with DLA activities, pursuant to the provisions of 5 U.S.C. 5703.

(k) Approve the expenditure of funds available for travel by military personnel assigned or detailed to DLA for expenses incident to attendance at meetings of technical, scientific, professional or other similar organizations in such instances where the approval of the Secretary of Defense or his designee is required by law (37 U.S.C. 412). This authority cannot be redelegated.

(l) Develop, establish and maintain an active and continuing Records Management Program, pursuant to the provisions of section 506(b) of the Federal Records Act of 1950 (44 U.S.C. 3102), the Freedom of Information Act Program (5 U.S.C. 552) and the Privacy Act Program (5 U.S.C. 552a).

(m) Establish and use imprest funds for making small purchases of material and services other than personal for DLA when it is determined more advantageous and consistent with the best interests of the Government, in accordance with the provisions of DOD Instruction 5100.71, "Delegation of Authority and Regulations Relating to Cash Held at Personal Risk Including Imprest Funds," March 5, 1973, and the Joint Regulation of the General Services Administration/Treasury Department/General Accounting Office, entitled "For Small Purchases Utilizing Imprest Funds."

(n) Authorize the publication of advertisements, notices of proposals in newspapers, magazines or other public periodicals as required for the effective administration and operation of DLA (44 U.S.C. 3702).

(o) Establish and maintain appropriate Property Accounts for DLA and appoint boards of survey, approve reports of survey, relieve personal liability, and drop accountability for DLA property contained in the authorized property accounts that has been lost, damaged, stolen, destroyed or otherwise rendered unserviceable, in accordance with applicable laws and regulations.

(p) Promulgate the necessary security regulations for the protection of property and places under the jurisdiction of the Director, DLA, pursuant to subsections III.A. and V.B. of DOD Directive 5200.8, "Authority of Military Commanders under the Internal Security Act of 1950 to Issue Security Orders and Regulations for the Protection of Property or Places Under Their Command," August 20, 1954.

(q) Establish and maintain, for the functions assigned, an appropriate publications system for the promulgation of common supply and service regulations, instructions, and reference documents, and changes thereto, pursuant to the policies and procedures prescribed in DOD Directive 5025.1, "Department of Defense Directive System," November 18, 1977.

(r) Enter into interservice support agreements in accordance with DOD Directive 4000.19, "Basic Policies and

Principles for Interservice, Interdepartmental and Interagency Support," March 27, 1972.

(s) Enter into logistic supply and service agreements with Federal Departments and Agencies other than the DOD.

(t) Exercise the authority delegated to the Secretary of Defense by the Administrator of the General Services Administration with respect to the disposal of surplus personal property.

(u) Exercise the authority and responsibility of the ASD(MRA&L) as delegated to the Director, DLA, for the National Industrial Equipment Reserve established by the National Industrial Reserve Act of 1948, as amended (50 U.S.C. 451 et seq.).

NOTE.—The Director, DLA, may re-delegate these authorities as appropriate, and in writing, except as otherwise specifically indicated above or as otherwise provided by law or regulation.

This delegation of authorities is effective immediately.

§ 359.10 Relationship between commanders of unified commands and overseas elements of the defense logistics agency.

When the Secretary of Defense assigns mission responsibilities to the Director, Defense Logistics Agency (DLA) for the performance of integrated management functions outside of CONUS, command relationships and interfaces pertinent to DLA elements assigned overseas will be in consonance with the following:

(a) The Director, DLA, will:

(1) Ensure that DLA-assigned missions are carried out and coordinated in a manner fully responsive to, and in accordance with, the requirements of all unified and component commands concerned.

(2) Coordinate matters of significant mutual command and management interest with the unified commander and/or the Joint Chiefs of Staff (JCS), as may be appropriate. Unresolved issues between the Director, DLA, and a commander of a unified command will be referred to the JCS for resolution or forwarding to the ASD(MRA&L) for final determination when a negotiated resolution cannot be achieved.

(3) Except as otherwise provided herein, exercise operational command over DLA-assigned elements.

(4) Develop and promulgate necessary plans, policies and procedures for the efficient operation of DLA overseas activities.

(5) Develop resource requirements for DLA overseas activities and, in coordination with the applicable unified commands, establish/disestablish DLA elements as dictated by mission requirements and objectives.

(6) Comply with physical security requirements promulgated by the commander of the unified command or component commander, as appropriate.

(7) Provide for the management and direction of DLA overseas activities including budgeting, inspection and audit functions, personnel support and internal administration.

(b) The commander of a unified command is authorized to, and as appropriate, will:

(1) Exercise directive authority in the field of logistics over DLA elements within his geographic area of responsibility to ensure effectiveness and economy in operations, and the prevention or elimination of unnecessary duplication of facilities and overlapping of functions. This authority is defined as that required to ensure the coordination, as necessary, of:

(i) Acquisition, storage, movement, distribution, maintenance, evacuation and disposition of materiel.

(ii) Movement and evacuation of personnel.

(iii) Acquisition or construction, maintenance, operation and disposition of facilities.

(iv) Acquisition or furnishing of services.

The commander will exercise such authority, after prior coordination locally with the pertinent DLA overseas activity, directly with the Director, DLA, or through the JCS, as appropriate.

(2) In the event of a major emergency which necessitates use of all available forces, assume temporary operational control of all DLA elements in his area of responsibility. The determination of the existence of such an emergency is the responsibility of the commander concerned who, on assuming temporary operational control of DLA elements, shall immediately advise the following of the nature and estimated duration of employment:

(i) The JCS.

(ii) The appropriate operational commander.

(iii) The Director, DLA.

(3) Exercise administrative direction over DLA elements in their area of responsibility in a manner consistent with, and comparable to that which he exercises over assigned forces and elements of other DOD components within his command. This will include, without being limited to, matters relating to status of forces agreements and other agreements with host nations, standards for dress and conduct, general theatre regulations applicable to all U.S. Forces, and war and emergency plans.

(4) Provide, in accordance with existing DOD policy for interservice support, guidance on support between DLA overseas elements and service components.

(5) Advise the Director, DLA, of any recommended changes to, or dis-satisfactions with, the type, adequacy and responsiveness of logistic support provided by DLA to and within his command. Unresolved issues between the Director, DLA, and a commander of a unified command will be referred to the JCS for resolution or forwarding to the ASD(MRA&L) for final determination when a negotiated resolution cannot be achieved.

(c) Commanders of component commands will:

(1) Exercise such responsibilities and authorities pertinent to DLA elements as may be assigned or otherwise delegated to them by the commander of their unified command.

(2) Provide for the physical security and administrative and logistic support of DLA elements as agreed to by DLA and component commands concerned under host/tenant agreements.

[FR Doc. 78-20929 Filed 7-27-78; 8:45 am]

[6560-01]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER D—WATER PROGRAMS

[FRL 933-1]

PART 118—DETERMINATION OF HARMFUL QUANTITIES FOR HAZARDOUS SUBSTANCES

Intention To Reinstate Effective Date Deferral

AGENCY: Environmental Protection Agency.

ACTION: Notice regarding effective date and guidance.

SUMMARY: On March 13, 1978, EPA published regulations under the Clean Water Act to control the discharge of hazardous substances (43 FR 10474). The regulations apply in part to discharges from facilities holding permits under the national pollution discharge elimination system (NPDES) of the act. On June 5, 1978, EPA deferred for 60 days the regulations' effective date for discharges subject to NPDES permits (43 FR 24309). On June 8, 1978, the District Court for the Western District of Louisiana enjoined EPA from enforcing and implementing the regulations pending a final determination on the merits or until further order of the court. EPA has received a number of inquiries regarding the relationship between the court injunction and EPA's 60 day deferral for NPDES-permitted discharges. EPA's

intent is to reinstate this 60-day deferral period whenever the court's injunction is terminated, in order to allow permittees sufficient time to test their effluents and submit permit applications. EPA will publish notice in the FEDERAL REGISTER stating the new effective date for NPDES-permitted discharges whenever the injunction is terminated.

Guidance regarding testing and reporting procedures to be used in NPDES permit applications with respect to hazardous substances is now being developed. Copies of this guidance may be obtained by requesting it in writing from Edward A. Kramer at the address listed below.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Edward A. Kramer (EN-336), Office of Water Enforcement, Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.

Dated: July 13, 1978.

JEFFERY G. MILLER,
Acting Assistant Administrator for Enforcement.

[FR Doc. 78-21024 Filed 7-27-78; 8:45 am]

[6820-24]

Title 41—Public Contracts and Property Management

CHAPTER 101—FEDERAL PROPERTY MANAGEMENT REGULATIONS

SUBCHAPTER E—SUPPLY AND PROCUREMENT

[FPMR Amendment E-226]

PART 101-26—PROCUREMENT SOURCES AND PROGRAMS

Submitting Requisitions to GSA

AGENCY: Final rule.

ACTION: General Services Administration.

SUMMARY: This regulation changes the Federal Property Management Regulations (FPMR) to require that Federal agencies submit requisitions for security equipment, certain types of data processing tape, and tabulating machine cards to the GSA regional office supporting the area in which the requisitioning agency is located rather than to selected GSA regions as is presently required. This change will simplify the requisitioning process by providing that agencies submit requisitions for these items to the same GSA regional office from which they normally order other items.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. John I. Tait, Director, Regulations and Management Control Division, Office of the Executive Director, Federal Supply Service, General Services Administration, Washington, D.C. 20406, 703-557-1914.

The table of contents for part 101-26 is amended to revise the following entries:

AUTHORITY: Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).

Subpart 101-26.5—GSA Procurement Programs

1. Section 101-26.507-1 is revised as follows:

§ 101-26.507-1 Submission of requisitions.

Requisitions for security equipment covered by the latest edition of Federal specifications AA-F-357, AA-F-358, AA-F-363, AA-S-1518, and AA-D-600, and interim Federal specifications AA-F-00364 and AA-C-001697 shall be submitted in FEDSTRIP format to the GSA regional office supporting the geographic area in which the requisitioner is located. GSA will consolidate requisitions for these items from all regions for procurement on a definite quantity basis.

2. Section 101-26.507-2 is revised as follows:

§ 101-26.507-2 Procurement time schedule.

Requisitions for security equipment will be consolidated by GSA on January 31, April 30, July 31, and October 31 of each year. The consolidated requisitions will be used in executing definite quantity contracts. To ensure inclusion in the invitation for bids, requisitions shall be submitted to GSA on or before January 1, April 1, July 1, or October 1 as appropriate. Requisitions received after any of these dates normally will be carried over to the subsequent consolidation date. Approximately 180 calendar days following the consolidation dates should be allowed for initial delivery. Requisitions shall include a required delivery date which reflects anticipated receipt under the time schedule.

3. Section 101-26.507-3 is revised as follows:

§ 101-26.507-3 Purchase of security equipment from Federal Supply Schedules.

To ensure that a readily available source exists to meet unforeseen demands for security equipment, indefinite quantity Federal Supply Schedule contracts will remain in effect to satisfy urgent requirements which are not appropriate for consolidated procurement and do not exceed the maximum order limitations. Items of security equipment are available through Federal Supply Schedule, FSC group 71, part XI, sections A and B, for agencies to order direct from the contractor. These sources may also be used by Government contractors and subcontractors (at any tier) meeting the requirements of §§ 1-5.902 and 101-26.407, as applicable, for purchases within the specified maximum order limitation.

4. Section 101-26.508-1 is revised as follows:

§ 101-26.508-1 Requisitioning data processing tape available through Federal Supply Schedule contracts.

Federal Supply Schedules, FSC group 70, part XI, and FSC group 58, part V, section C, include contracts to satisfy Government requirements for those types of EDP tape and instrumentation tape (wide and intermediate band) which are most widely used. Federal agencies located within the 48 contiguous United States, Washington, D.C. and Hawaii (applicable to EDP tape only for Hawaii) shall procure these tapes in accordance with the provisions of the current schedules and this § 101-26.508-1. Orders not exceeding the maximum order limitations of the Federal Supply Schedules and prepared directly by activities located outside the geographical areas referenced above shall, to the extent possible, be consolidated and submitted in FEDSTRIP format to the GSA regional office supporting the geographic area in which the requisitioner is located.

5. Section 101-26.508-2 is amended to revise paragraphs (a), (b), and (d) as follows:

§ 101-26.508-2 Requisitioning data processing tape not available from Federal Supply Schedule contracts.

(a) Requisitions for types of EDP tape and instrumentation tape (wide and intermediate band) covered by Federal Supply Schedule contracts which exceed the maximum order limitations of the schedule shall be submitted to the GSA regional office supporting the geographic area in which the requisitioner is located.

(b) Requisitions for all types of EDP tape and instrumentation tape (wide and intermediate band) not covered by Federal Supply Schedule contracts shall be submitted to GSA for purchase action when the dollar value of the requisitions exceeds, or is estimated to exceed, $2,500 for EDP tape and $5,000 for instrumentation tape. However, regardless of the amount involved (including requisitions estimated to be less than the dollar limitations referenced above), purchase action shall not be taken by GSA or an agency unless a waiver of the requirement for using items of tape available from Federal Supply Schedule contracts has been furnished in accordance with § 101-26.100-2. Requests for waivers shall be submitted to the Commissioner, Federal Supply Service (F), General Services Administration, Washington, D.C. 20406. The requests shall fully describe the type of tape required and state the reasons Federal Supply Schedule items will not adequately serve the agency's needs. GSA will notify the requesting agency in writing of the action taken on the requests. To reduce leadtime, requisitions may be submitted in FEDSTRIP format with the requests for waivers. Requisitions for which a waiver has first been obtained shall be submitted with a copy of the waiver to the GSA regional office supporting the geographic area in which the requisitioner is located. GSA will either arrange for procurement of the items or authorize the requesting agency to procure them.

* * * * *

(d) When an agency submitting a purchase request in accordance with this § 101-26.508-2 has a need for scheduled deliveries, minimum or maximum order quantities, or other special arrangements, GSA will develop specific provisions to accommodate the needs. The provisions will be based on information furnished by the agency concerned and will be included in solicitations for offers and resultant contracts.

6. Section 101-26.508-3 is revised as follows:

§ 101-26.508-3 Consolidation of requisitions.

To the maximum extent feasible, agencies shall develop procedures which will permit planned consolidated requisitioning of EDP tape and instrumentation tape (wide and intermediate band) on an agencywide basis. When agencywide consolidation is not feasible, consideration shall be given to the consolidation of individual requisitions for small quantities at any agency level. This will enable the Government to benefit from lower prices generally obtainable through large volume procurements.

7. Section 101-26.509-1 is revised as follows:

§ 101-26.509-1 Requisitioning tabulating machine cards available from Federal Supply Schedule contracts.

Federal Supply Schedule, FSC group 75, part VIII, includes contracts for tabulating cards applicable to electrical and mechanical contact tabulating machines, including aperture cards and copy cards. Federal agencies shall procure these cards in accordance with the provisions of the current schedule. Orders not exceeding the maximum order limitation of the Federal Supply Schedule and prepared directly by activities located outside the geographical delivery areas specified in the schedule shall be submitted in FEDSTRIP format to the GSA regional office supporting the geographic area in which the requisitioner is located.

8. Section 101-26.509-2 is amended to revise paragraphs (a) and (b) as follows:

§ 101-26.509-2 Requisitioning tabulating machine cards not available from Federal Supply Schedule contracts.

(a) Requisitions for tabulating machine cards covered by Federal Supply Schedule contracts which exceed the maximum order limitation of the schedule shall be forwarded in FEDSTRIP format to the GSA regional office supporting the geographic area in which the requisitioner is located.

(b) Requisitions for tabulating machine cards not covered by Federal Supply Schedule contracts shall be submitted to GSA for purchase action if the dollar value of the cards exceeds or is estimated to exceed $2,500. However, regardless of the amount involved (including requisitions estimated to be $2,500 or less), purchase action shall not be taken by GSA or an agency unless a waiver of the requirement for the use of tabulating cards available from Federal Supply Schedule contracts has been furnished in accordance with § 101-26.100-2. Requests for waivers shall be submitted to the Commissioner, Federal Supply Service (F), General Services Administration, Washington, D.C. 20406. The requests shall fully describe the items required and state the reasons the tabulating machine cards covered by the Federal Supply Schedule contracts will not adequately serve the end-use purpose. GSA will notify the requesting agency in writing of the action taken on the waiver request. To reduce leadtime, requisitions may be submitted in FEDSTRIP format with the requests for waivers. A requisition for items for which a waiver has first been obtained shall be submitted with a copy of the waiver to the GSA regional office supporting the geographic area in which the requisitioner is located. GSA will either arrange for procurement of the items or authorize the requesting activity to procure them.

* * * * *

9. Section 101-26.509-3 is revised as follows:

§ 101-26.509-3 Consolidation of requisitions.

To the maximum extent feasible, agencies shall consolidate their requisitions for tabulating machine cards on an agencywide basis. If agencywide consolidation is not feasible, consideration shall be given to the consolidation of requisitions at any agency level when the Government will benefit from lower prices through large-volume procurement.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).)

Dated: July 14, 1978.

ROBERT T. GRIFFIN,
Acting Administrator of General Services.

[FR Doc. 78-20932 Filed 7-27-78; 8:45 am]

[6820-24]

[FPMR Amendment E-227]

PART 101-26—PROCUREMENT SOURCES AND PROGRAMS

Procurement of Automobiles

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: This regulation changes the identification of the various categories of vehicles available through the GSA motor vehicle procurement program; includes a reference to the GSA Handbook, Discrepancies or Deficiencies in GSA or DOD Shipments, Material, or Billings; prescribes the use of GSA Form 6317, Instructions to Consignee Receiving New Motor Vehicles Purchased by General Services Administration; and includes minor editorial and procedural changes. This regulation has been developed to update the provisions relating to procurement of new motor vehicles.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. John I. Tait, Director, Regulations and Management Control Division, Office of the Executive Director, Federal Supply Service, General Services Administration, Washington, D.C. 20406, 703-557-1914.

The table of contents for part 101-26 is amended to revise the following entry:

101-26.501-3 Submission of orders.

Subpart 101-26.5—GSA Procurement Programs

1. Section 101-26.500 is revised as follows:

§ 101-26.500 Scope and applicability of subpart.

(a) This subpart prescribes policies and procedures relating to GSA procurement programs other than the GSA stock and the Federal supply schedule programs. Also excluded are the policies and procedures relating to the procurement of automatic data processing equipment and services set forth in part 101-36.

(b) The policies and procedures in this subpart 101-26.5 are applicable to executive agencies except as otherwise specifically indicated. Federal agencies other than executive agencies may participate in these programs and are encouraged to do so.

2. Section 101-26.501 is amended to revise the introductory material in paragraph (a) and revise paragraph (b) and subparagraph (d)(2), as follows:

§ 101-26.501 Purchase of new motor vehicles.

(a) With respect to the procurement of new sedans, station wagons, and light trucks other than those to be used for law enforcement, it shall be the policy to procure standard vehicles (unless other than standard vehicles are specifically required) as follows: Sedans, class IA-small, class IB-subcompact, or class II-compact; station wagons, class IB-subcompact or class II-compact vehicles, as described in Federal standard No. 122; and light trucks as defined in Federal standard Nos. 292 and 307. (Federal standard Nos. 122, 292, and 307 as used in this section mean the latest editions and include any interim standard being used temporarily as a replacement.) Requisitions submitted to GSA for motor vehicles shall be in conformance with the requirements of subpart 101-38.13.

* * * * *

(b) Requisitions submitted to GSA for new passenger vehicles shall contain a certification by the agency head or a designee that the acquisition is in conformance with Pub. L. 94-163 and Executive Order 12003. The certification may be placed on the requisition or on an appropriate attachment thereto. Agency passenger vehicle requisitions omitting this certification will not be processed until such certification is received. Agencies requiring other than standard sedans and station wagons shall justify the need for these vehicle requirements and retain the justification in their files.

* * * * *

(d) * * * (2) Additional systems or equipment requested to be purchased by GSA will be construed to have been determined essential for the effective operation of the vehicle involved by the agency head or a designee. When systems or equipment other than those listed in Federal standards are requested, these systems or equipment shall be considered and treated as deviations under § 101-26.501-3(b).

3. Section 101-26.501-1 is amended to revise the introductory paragraph and paragraph (a) as follows:

§ 101-26.501-1 General.

Except as provided for the Department of Defense (DOD) in paragraph (a) of this section, each executive agency shall submit to GSA for procurement its orders for purchase in the United States of all new passenger motor vehicles (FSC 2310), trucks or truck tractors (FSC 2320), trailers (FSC 2330) van type (with payload of not less than 5,000 nor more than 50,000 pounds), and firetrucks and firefighting trailers (FSC 4210). Specifically included are sedans, station wagons, carryalls, ambulances, buses, and trucks, including trucks with specialized mounted equipment, truck chassis with special purpose bodies, and all van-type trailers (with payload of not less than 5,000 nor more than 50,000 pounds).

(a) DOD shall submit to GSA for procurement its orders for purchase in the United States of all commercial-type passenger motor vehicles (FSC 2310), including buses and trucks (FSC 2320) up to 10,000 pounds gross vehicle weight (GVW) except the following:

(1) Buses, convertible to ambulances;

(2) Trucks, convertible to ambulances; and

(3) Trucks, 4 x 4, dump, 9,000 GVW with cut-down cab.

* * * * *

4. Section 101-26.501-2(a) is revised as follows:

§ 101-26.501-2 Consolidated purchase program.

(a) To achieve maximum benefits and economies, GSA makes monthly consolidated procurements of all motor vehicle types plus four volume procurements each year as follows:

(1) One volume procurement of sedan and station wagons of the types covered by Federal standard No. 122 and related specifications for civilian agencies and for DOD activities; and

(2) Three volume procurements of light trucks of the types covered by Federal standard No. 307 for civilian agencies and of similar types covered by military specifications for DOD activities.

* * * * *

5. Section 101-26.501-3 is amended to revise the introductory paragraph and paragraph (c) as follows:

§ 101-26.501-3 Submission of orders.

Orders for all motor vehicles shall be submitted on GSA Form 1781, Motor Vehicle Requisiton—Delivery Order—Invoice, or DD Form 448, Military Interdepartmental Purchase Request (MIPR), to the General Services Administration (FY), Washington, D.C. 20406, and shall contain required FEDSTRIP data for mechanized processing. The Department of Defense shall ensure that appropriate MILSTRIP data are entered on DD Form 448.

* * * * *

(c) GSA Form 1781, Motor Vehicle Requisition—Delivery Order—Invoice (illustrated at § 101-26.4902-1781), has been specifically designed for agency use to expedite ordering of all vehicles. GSA Form 1781 is also used by GSA as a purchase order and by the consignee as a receiving report. Agencies are requested to use GSA form 1781 as a single-line-item requisition for nonstandard as well as standard vehicles. When ordering standard vehicles, the appropriate item number for passenger vehicles equipped to meet specific operational needs may be selected from the applicable table in Federal standard No. 122. Additional systems and equipment may be added by inserting in the "Standard Option(s)" portion of block 9 of the form the appropriate code for the selected items from the table in the standard. When a vehicle equipped as listed in Federal standard No. 122 includes items which are not required, the item number of the standard vehicle representing the minimum wheelbase required should be selected. All additional systems or equipment required should be identified by inserting in the appropriate portion of block 9 of GSA form 1781 the applicable codes from the table in the standard listing the additional systems or equipment. When ordering nonstandard vehicles or options, the instructions on the reverse of GSA form 1781 shall be followed. Submission of GSA form 1781, properly completed, will satisfy the requirements regarding the submission of requisitions as set forth in paragraph (a) of this section.

* * * * *

6. Section 101-26.501-4 is amended to revise paragraph (a) and subparagraph (b)(3) as follows:

§ 101-26.501-4 Procurement time schedules.

(a) *Volume consolidated purchases.* Requisitions covering vehicle types included in Federal standard No. 122 or Federal standard No. 307 received before the consolidation dates shown in the time schedule of this paragraph (a) will be consolidated for volume procurement unless there is included a statement justifying the need for delivery earlier than the delivery times indicated in § 101-26.501-4(d). Requisitions containing a statement of justification will be handled on a monthly basis in accordance with § 101-26.501-4(b)(1).

TIME SCHEDULE FOR VOLUME CONSOLIDATION

Vehicle category	Standard sedans and station wagons	Standard light trucks (4 x 2)
Sedans, station wagons, and trucks of types covered by Federal Standard No. 122 or Federal Standard No. 307.	End of model year availability to Nov. 15.	July 1 to Aug. 15. Aug. 16 to Dec. 31. Jan. 1 to Apr. 15.

NOTE.—Requirements not included on the above volume consolidated solicitations or optional increase provisions thereto will, upon request of the requisitioning agency, be purchased on a monthly consolidated basis where possible. Included in this category are requirements held over from 1 fiscal year to another because of manufacturer model year changeover.

(b) * * * (3) With respect to categories (i) and (ii) of § 101-26.501-4(b)(1), no assurance can be given as to price and time of delivery of vehicles on requisitions received by GSA after the 15th of April. This is because of the industry practice of closing out the production of the current year's model and retooling for new models. Agencies should bear this in mind when programing their requirements. Agencies submitting requisitions for sedans and station wagons that cannot be placed on contract before the end of the fiscal year in which submitted will be notified by GSA.

* * * * *

7. Section 101-26.501-6 is amended to revise paragraph (b) and add a new paragraph (c) as follows:

§ 101-26.501-6 Forms used in connection with delivery of vehicles.

* * * * *

(b) *Standard Form 368, Quality Deficiency Report (Category II).* GSA is constantly striving to improve customer service and the quality of motor vehicles for which it contracts. To inform contractors of the deficiencies noted during the life of the vehicles, Standard form 368 shall be prepared by the consignee and sent to GSA describing details of vehicle deficiency and action taken for correction. Procedures for documenting and reporting quality deficiencies are set forth in the GSA Handbook, Discrepancies or Deficiencies in GSA of DOD Shipments, Material, or Billings (FPMR 101-26.8). Standard form 368 replaced GSA form 1718, Unsatisfactory Equipment Report, for reporting deficiencies and repetitive failures of motor vehicles. Agencies are urged to report all deficiencies to GSA irrespective of satisfactory corrective action taken by the manufacturer's authorized dealer. If the dealer refuses to take corrective action on any vehicle within its warranty period, the report shall so state and include an explanation of the circumstances. Standard form 368 shall also be used to report all noncompliance with specifications or other requirements of the purchase order.

(c) *GSA Form 6317, Instructions to Consignee Receiving New Motor Vehicles Purchased by General Services Administration.* This form is furnished to each consignee with copies of GSA form 1781, Motor Vehicle Requisition—Delivery Order—Invoice. Personnel responsible for receipt and operation of Government motor vehicles should be familiar with the instructions and information contained in GSA form 6317.

8. Section 101-26.501-7 is revised as follows:

§ 101-26.501-7 Sale of vehicles.

GSA will not solicit trade-in bids when purchasing new motor vehicles for replacement purposes under the consolidated purchase program because experience has shown that suppliers (manufacturers) are unwilling to accept used vehicles in part payment for new ones. Accordingly, used vehicles that are being replaced will be disposed of by sale as set forth in part 101-46.

Subpart 101-26.49—Illustrations of Forms

Section 101-26.4902-1781 is revised to illustrate the February 1978 edition of GSA form 1781, Motor Vehicle Requisition—Delivery Order—Invoice.

NOTE.—The form illustrated in § 101-26.4902-1781 is filed as part of the original document and does not appear in the FEDERAL REGISTER.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).)

Dated: July 14, 1978.

ROBERT T. GRIFFIN,
Acting Administrator of General Services.

[FR Doc. 78-20931 Filed 7-27-78; 8:45 am]

[6820-24]

[FPMR Temp. Reg. E-52]

APPENDIX—TEMPORARY REGULATIONS

Returning Items to GSA for Credit

AGENCY: Federal Supply Service, General Services Administration.

ACTION: Temporary regulation.

SUMMARY: This regulation changes the minimum line item dollar values required for certain stock items to be eligible for return to GSA for credit and provides revised policy on the granting of credit for material returned to GSA with packing or packaging deficiencies. These changes will reduce the losses incurred by GSA in the repacking and repackaging of these materials.

DATES: Effective date: July 28, 1978. Expiration date: December 31, 1978. Comments due: On or before August 31, 1978.

ADDRESS: General Services Administration (FAF), Washington, D.C. 20406.

FOR FURTHER INFORMATION CONTACT:

John Tait, Director, Regulations and Management Control Division, 703-557-1914.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).)

In 41 CFR Chapter 101, the following temporary regulation is listed in the appendix at the end of subchapter E.

GENERAL SERVICES ADMINISTRATION

WASHINGTON, D.C.

FEDERAL PROPERTY MANAGEMENT REGULATIONS TEMPORARY REGULATION E-52

To: Heads of Federal agencies.
Subject: Returning items to GSA for credit.

1. *Purpose.* This temporary regulation changes the minimum line item dollar values required for certain stock items to be

eligible for return to GSA for credit and provides revised policy on the granting of credit for material returned to GSA with packing or packaging deficiencies.

2. *Effective date.* This regulation is effective upon publication in the FEDERAL REGISTER.

3. *Expiration date.* This regulation expires December 31, 1978, unless revised or superseded sooner.

4. *Background.* a. The costs incurred in returning items to GSA and placing them in stock have increased significantly in the past several years. When the line item dollar value of items returned is relatively low, these costs frequently exceed the value of the items returned. This results in a net loss to the Government. To reduce these losses, it is necessary to eliminate the return of items when it is uneconomical for them to be returned to stock. This can be accomplished by revising FPMR 101-27.502(a) to increase the minimum line item dollar values required for items to be eligible for return to GSA for credit.

b. When material is returned to GSA for credit with packing or packaging deficiencies which were not the fault of GSA, GSA frequently must repack or repackage the material before it can be reissued. The costs associated with repacking or repackaging material can be considerable. These costs are presently absorbed by GSA although it is appropriate that they be borne by the agency returning the material. Accordingly, a decision has been made to revise FPMR 101-27.503-2 to include a provision that will allow a reduction in the credit granted for material returned to GSA with significant packing or packaging deficiencies. A sampling of the cost involved in correcting these deficiencies indicates that a 60 percent credit would be sufficient for GSA to recover the costs.

5. *Criteria for return of stock items to GSA for credit.* When an agency determines that it has no current or future requirements for GSA stock items in that agency's possession, the items may be eligible for return to GSA for credit if the dollar value per line item (based on the current GSA selling price) is at least:

a. $50 for hand tools, FSG 51, and measuring tools, FSG 52;

b. $300 for:

(1) Household furniture, FSC 7105; office furniture, FSC 7110; cabinets, lockers, bins, and shelving, FSC 7125; and miscellaneous furniture and fixtures, FSC 7195;

(2) Cleaning and polishing compounds and preparations, FSC 7930; and

(3) Paints, dopes, varnishes, and related products, FSC 8010; preservatives and sealing compounds, FSC 8030; and adhesives, FSC 8040; and

c. $100 for items in all other Federal supply groups and classes except for standard forms, FSC 7540; and boxes, cartons, and crates, FSC 8115, which are not returnable and shall be considered excess and processed in accordance with part 101-43.

6. *Credit for stock items returned with deficiencies.* a. After acceptance by GSA of items with deficiencies which were not the fault of GSA, credit will be granted for the items at a percentage of the current GSA selling price in accordance with the following:

(1) Sixty percent for items which involve limited expenses or effort to restore to serviceable condition (specifically, a deficiency in packing or packaging which restricts the issue or requires repacking or repackaging) (condition code E);

(2) Thirty percent when it is economically feasible to repair, overhaul, or recondition the items for return to issuable condition (condition code F); or

(3) Thirty percent when these items require additional parts or components to complete the end item prior to issue (condition code G).

b. No credit will be given for material returned to GSA which does not meet the above criteria or which was returned to GSA without prior approval.

7. *Agency comments.* Comments concerning the effect or impact of this regulation on agency operations or programs should be submitted to the General Services Administration (FAF), Washington, D.C. 20406, no later than August 31, 1978, for consideration and possible incorporation into a permanent regulation.

8. *Effect on other directives.* This regulation supersedes FPMR 101-27.502(a) and 101-27.503-2.

ROBERT T. GRIFFIN,
Acting Administrator of General Services.

JULY 14, 1978.

[FR Doc. 78-20933 Filed 7-27-78; 8:45 am]

[6820-35]

Title 45—Public Welfare

CHAPTER XVI—LEGAL SERVICES CORPORATION

PART 1606—PROCEDURES GOVERNING TERMINATION OF FINANCIAL ASSISTANCE AND DENIAL OF REFUNDING

AGENCY: Legal Services Corporation.

ACTION: Final regulation.

SUMMARY: The Legal Services Corporation issues a final regulation establishing procedures to insure a fair hearing before any application for refunding will be denied or financial assistance terminated. This regulation is required by the Legal Services Corporation Act, as amended.

EFFECTIVE DATE: August 28, 1978.

ADDRESS: Legal Services Corporation, 733 15th Street NW., Suite 700, Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113

SUPPLEMENTARY INFORMATION: Section 1011 of the Legal Services Corporation Act, 42 U.S.C. 2996j, requires the Corporation to establish procedures to insure that no application for refunding will be denied and financial assistance will not be terminated unless the recipient has been afforded an opportunity for a fair hearing. A temporary regulation, published on April 30, 1976 (41 FR 18081), is now in effect. A proposed final regulation was published for comment on January 26, 1977 (42 FR 4864), and a revised version was published for comment on January 3, 1978 (43 FR 16), following final amendment of the Legal Services Corporation Act. Full consideration of written comments,and extended discussion with interested persons, preceded the decision made by the Board of Directors of the Corporation on July 6, 1978 to adopt the following regulation.

There is little functional difference between a decision to deny refunding and a decision to terminate a recipient's grant or contract. Both are serious actions to be taken only as necessary to achieve the purpose of the Act. In the vast majority of cases, the Corporation will seek to ensure that service will continue to the community affected without regard to whether financial assistance has been terminated or refunding denied. The single difference between the two types of action is the equitable consideration that, having made a grant or contract to a particular recipient, the Corporation should not be permitted to terminate on the basis of a rule, regulation, guideline, or instruction that did not exist at the time financial assistance was extended. That principle is reflected in section 1606.4 of the regulation.

Section 1606.3, enumerating the grounds for denial of refunding, has been revised to provide more specificity than existed in previous drafts. The final version is designed to provide a satisfactory balance between the need for fairness to recipients and the need to protect the Corporation's ability to meet its statutory responsiblities and to respond to anticipated contingencies.

Section 1606.11, dealing with burden of proof, has been revised. The final version assigns to the corporation the burden of proving any disputed fact relied upon as a basis for denying refunding. In addition, the "substantial basis" language in section 1606.11(b) indicates that, even if the Corporation proves its case, refunding should not be denied for an insubstantial or trivial reason. Consistent with that meaning of section 1606.11(b), section 1616.13 gives the presiding officer authority to recommend continuation of funding if the grounds for denying it—though proven—are unreasonable, insubstantial, or trivial. The same discretion is conferred on the President of the Corporation by section 1606.14.

Accordingly, 45 CFR Part 1606 is revised to read as follows:

PART 1606—PROCEDURES GOVERNING TERMINATION OF FINANCIAL ASSISTANCE AND DENIAL OF REFUNDING

Sec.
1606.1 Purpose.
1606.2 Definitions.
1606.3 Grounds for Denial of Refunding.
1606.4 Grounds for Termination.
1606.5 Preliminary Determination.
1606.6 Informal Conference.
1606.7 Initiation of Proceedings.
1606.8 Presiding Officer.
1606.9 Pre-hearing Conference.
1606.10 Conduct of Hearing.
1606.11 Obligations of the Corporation.
1606.12 Briefs and Argument.
1606.13 Recommended Decisions.
1606.14 Final Decision.
1606.15 Time Extension and Waiver.
1606.16 Right to Counsel.
1606.17 Reimbursement.
1606.18 Interim Funding.
1606.19 Termination Funding.
1606.20 Notice.

AUTHORITY: Sec. 1006(b)(1) and (3), 1007(a)(1), 1007(a)(3), 1007(a)(9), 1007(d), 1008(e), 1011 (42 U.S.C. 2996e(b)(1) and (3), 2996f(a)(1), 2996f(a)(3), 2996f(a)(9), 2996f(d), 2996g(e), 2996j).

§ 1606.1 Purpose.

By affording a recipient the opportunity for a timely, full, and fair hearing that will promote informed deliberation by the Corporation when there is reason to believe a grant or contract should be terminated or refunding denied, this part seeks to avoid unnecessary disruption in the delivery of legal assistance to eligible clients.

§ 1606.2 Definitions.

(a) "Termination" means a decision that financial assistance to a recipient will be permanently terminated in whole or in part prior to expiration of the recipient's current grant or contract.

(b) "Denial of refunding" means a decision that, after expiration of its current grant or contract, a recipient:

(1) Will not be provided with financial assistance; or

(2) Will have its annual level of financial support reduced to an extent that is not required either by a change of law or by a reduction in the Corporation's appropriation that is apportioned among all recipients of the same class in proportion to their current level of funding, and is either more than 10 percent or more than $20,000 below the recipient's annual level of financial assistance under its current grant or contract; or

(3) Will be provided with financial assistance subject to a new condition or restriction that is not generally applicable to all recipients of the same class, and that would significantly reduce the ability of a recipient to maintain the quality and quantity of its current legal assistance to eligible clients.

(c) "Director of a recipient" means the person who has overall day-to-day responsibility for management of operations by the recipient.

(d) "Presiding Officer" means the person appointed by the President to recommend a decision that a grant or contract should be continued or terminated, or that refunding should be granted or denied.

§ 1606.3 Grounds for denial or refunding.

Refunding may be denied when (a) Denial is required by, or will implement, a provision of law, a Corporation rule, regulation, guideline, or instruction that is generally applicable to all recipients of the same class, or a funding policy, standard, or criterion approved by the Board; or

(b) There has been substantial failure by a recipient to comply with a provision of law, or a rule, regulation, or guideline issued by the Corporation, or a term or condition of a current or prior grant from or contract with the Corporation. In the absence of unusual circumstances, refunding shall not be denied for this cause unless the Corporation has given the recipient notice of such failure and an opportunity to take effective corrective action; or

(c) There had been substantial failure by a recipient to use its resources to provide economical and effective legal assistance of high quality as measured by generally accepted professional standards, the provisions of the act, or a rule, regulation or guideline issued by the Corporation. In the absence of unusual circumstances, refunding shall not be denied for this cause unless the Corporation has given the recipient notice of such failure and an opportunity to take effective corrective action.

§ 1606.4 Grounds for termination.

A grant or contract may be terminated on any of the grounds and under the circumstances stated in § 1606.3, except that termination shall not be based on a Corporation rule, regulation, guideline, or instruction that was not in effect when the current grant was made or when the current contract was entered into.

§ 1606.5 Preliminary determination.

(a) When there is reason to believe that a grant or contract should be terminated or that refunding should be denied, the Corporation shall serve a written preliminary determination upon the receipient, which shall state the grounds for the proposed action, and shall identify, with reasonable specificity, any facts or documents relied upon as justification for that action.

(b) The preliminary determination shall advise the recipient that it may, within 10 days of receipt of the preliminary determination, make written request for

(1) a hearing under this part, or

(2) an informal conference under § 1606.6 of this part, with a subsequent right as there provided to request a hearing.

(c) The preliminary determination shall also advise the recipient of its right to receive interim, and to request termination, funding, under § 1606.18 or § 1606.19 of this part.

(d) If the recipient advises the Corporation that it will not request review, or if it fails to request review within the time prescribed in § 1606.5(b) or § 1606.6, the preliminary determination shall become final.

§ 1606.6 Informal conference.

On timely request by the recipient, the Corporation employee who made the preliminary determination shall promptly conduct an informal conference with the recipient at a time and place designated by the employee. The parties thereto shall exchange views, seek to narrow the issues, and explore the possibilities of settlement or compromise. At the conclusion of the conference, which may be adjourned for deliberation or consultation, the Corporation employee may, in writing, modify, withdraw, or affirm the preliminary determination. The recipient may, within 5 days thereafter, make written request for a hearing under § 1606.9 through § 1606.15 of this part.

§ 1606.7 Initiation of proceedings.

Within 10 days after receipt of a request for a hearing made under § 1606.5(b) or § 1606.6, the Corporation shall notify a recipient in writing of

(a) The name of the presiding officer, and of the attorney who will represent the Corporation;

(b) The date, time and place scheduled for a prehearing conference, if any should be requested or ordered; and

(c) The date, time and place scheduled for the hearing.

§ 1606.8 Presiding officer.

(a) The presiding officer shall be appointed by the President, and shall be a person who is familiar with legal services and supportive of the purposes of the Act, who is independent, and who is not an employee of the Corporation.

(b) Within 5 days of receipt of the notice required under § 1606.7, the recipient shall notify the Corporation if it objects to the presiding officer on the grounds that the person does not satisfy the criteria stated in § 1606.8(a), or is personally biased. The notice shall state the specific facts and documents that the recipient contends

support its objection, and, if a pre-hearing conference has not been scheduled, shall request a pre-hearing conference for the purpose of presenting the objection. At the pre-hearing conference, the recipient and the Corporation may question the presiding officer for a reasonable period of time on matters relevant to the recipient's objection.

(c) The recipient shall, within 5 days following the pre-hearing conference, notify the Corporation of any further facts that it contends support its objections. The President shall, within 10 days following the pre-hearing conference, either sustain the objection and appoint a new hearing officer or overrule the objection.

(d) No objection to the appointment of a presiding officer may be made unless presented in the manner specified by this section.

§ 1606.9 Pre-hearing conference.

(a) A pre-hearing conference may be ordered by the presiding officer, and shall be ordered if requested by either the recipient or the Corporation. The matters to be considered at the conference shall include:

(1) Proposals to define and narrow the issues;

(2) Efforts to stipulate the facts, in whole or in part;

(3) The probable number, identity, and order of presentation of exhibits and witnesses;

(4) On the agreement of the parties, the possibility of presenting the case on written submission or oral argument;

(5) The desirability of advance submission of some or all of the direct testimony in writing;

(6) Any necessary variation in the date, time and place of the hearing;

(7) Discussion of settlement; and

(8) Such other matters as may be appropriate.

(b) In advance of the pre-hearing conference, the presiding officer may require a party to submit a written statement discussing any matter described in subparagraph (a). After the pre-hearing conference, the presiding officer may establish the procedures, consistent with this part, to be followed at the hearing.

(c) The presiding officer may, at the pre-hearing conference or at any subsequent appropriate time prior to completion of the hearing, require the Corporation or the recipient, on sufficient notice, to produce a relevant document in its possession, to make a report not unduly burdensome to prepare, or to produce a person in its employ to testify, if any might offer a relevant and substantial addition to the accuracy or completeness of the record. With the consent of the presiding officer, a party may make a written submission before the hearing.

§ 1606.10 Conduct of hearing.

(a) The hearing shall be scheduled to commence at the earliest appropriate date, ordinarily not later than 45 days after the notice required by § 1606.7, and, whenever practical, shall be held at a place convenient to the recipient and the community it serves. A hearing affecting more than one community or recipient shall be held in a single centrally located place unless the presiding officer determines that an additional hearing place is required.

(b) The presiding officer shall preside, conduct a full and fair hearing, avoid delay, maintain order, and insure that a record sufficient for full disclosure of the facts and issues is made. The hearing shall be open to the public unless, for good cause and in the interests of justice, the presiding officer shall determine otherwise.

(c) The presiding officer may allow any interested person or organization to participate in the hearing if such participation will not broaden the issues unduly or cause delay, and will aid in proper determination of the issues.

(1) A person or organization wishing to participate in a hearing shall request permission from the presiding officer, stating the reason for the request, and the nature of the evidence or argument to be offered; and shall notify the Corporation and the recipient of its request.

(2) The presiding officer shall notify the Corporation, the recipient, and the person or organization requesting participation whether the request has been granted, and in case of denial shall include a brief statement of the reasons therefor.

(3) The presiding officer may limit the scope or form of participation authorized under this paragraph.

(d) The Corporation and the recipient each may present its case by oral or documentary evidence, conduct examination and cross-examination of witnesses, examine any document submitted by another party, and submit rebuttal evidence.

(e) If a party fails, without good cause, to produce a person or document required under § 1606.9(c), the presiding officer may make an adverse finding on the fact or issue with respect to which production was required.

(f) Technical rules of evidence shall not apply. The presiding officer shall make any procedural or evidentiary ruling that may help to insure full disclosure of the facts, to maintain order, or to avoid delay. Irrelevant, immaterial, repetitious or unduly prejudicial matter may be excluded.

(g) Official notice may be taken of published policies, rules, regulations, guidelines, and instructions of the Corporation, of any matter of which judicial notice may be taken in a Federal court, or of any other matter whose existence, authenticity, or accuracy is not open to serious question.

(h) A stenographic or electronic sound record, or a summary of the hearing shall be made in a manner determined by the presiding officer, and a copy shall be made available to a party upon payment of its cost.

§ 1606.11 Burden of proof.

At a hearing under § 1606.10:

(a) The Corporation shall have the obligation of proving, by a preponderance of the evidence, the existence of any disputed fact relied upon as justification for termination or denial of refunding; and

(b) On all other issues, the Corporation shall have the obligation of establishing a substantial basis for terminating the grant or contract or denying refunding.

§ 1606.12 Briefs and argument.

(a) Within 10 days after the close of the hearing, each party may, and, upon request of the presiding officer, shall, submit to the presiding officer, with service upon all other parties, proposed findings of fact and argument on matters of law or policy.

(b) The presiding officer may direct or permit oral argument at the close of the hearing or after submission of briefs.

§ 1606.13 Recommended decision.

(a) As soon as practicable after the hearing, and normally within 20 days after its conclusion, the presiding officer shall issue a written recommended decision.

(1) Continuing the recipient's current grant or contract, or granting refunding subject to any modification or condition that may be deemed necessary on the basis of information adduced at the hearing; or

(2) Terminating financial assistance to the recipient as of a particular date, or denying refunding.

(b) The recommended decision shall contain findings of the significant and relevant facts and shall state the reasons for the decision. Findings of fact shall be based solely on the evidence adduced at the hearing or on matters of which official notice was taken.

§ 1606.14 Final decision.

(a) If neither the Corporation nor the recipient requests review by the President, a recommended decision shall become final 10 days after receipt by a recipient.

(b) The recipient or the Corporation may seek review by the President of a

recommended decision. A request shall be made in writing within 10 days after receipt by the party of the recommended decision, and shall state in detail the reasons for seeking review.

(c) As soon as practicable after receipt of a request for review of a recommended decision, and normally within 30 days, the President shall adopt, modify, or reverse the recommended decision, or direct further consideration of the matter. In the event of modification or reversal, the President's decision shall conform to the requirements of section 1606.13(b).

(d) A decision by the President shall become final upon receipt by a recipient.

§ 1606.15 Time and extension and waiver.

(a) Any period of time provided in these rules may, upon good cause shown and determined, be extended:

(1) By the person making the preliminary determination, prior to the time the presiding officer is designated;

(2) By the presiding officer, prior to the issuance of a recommended decision; or

(3) By the President at any time.

(b) Requests for extensions of time shall be considered in light of the overall objective that the procedures prescribed by this part ordinarily shall be concluded within 90 days of the preliminary determination.

(c) Any other provision of these rules may be waived or modified:

(1) By the presiding officer with the assent of the recipient and of counsel for the Corporation; or

(2) By the President upon good cause shown and determined.

§ 1606.16 Right to counsel.

At a hearing under section 1606.10, the Corporation and the recipient each shall be entitled to be represented by counsel, or by another person. The attorney designated may be an employee, or may be outside counsel retained for the purpose. Unless prior written approval is received from the Corporation, the fee paid to outside counsel shall not exceed the hourly equivalent of the rate of level V of the executive schedule specified in section 5316 of title 5, United States Code.

§ 1606.17 Reimbursement.

If the recipient's grant or contract is continued or refunding is granted after a preliminary determination has been issued under section 1606.5, a recipient shall receive reimbursement by the Corporation, to the extent it has prevailed, for reasonable and actual expenses that were required in connection with proceedings under this part.

§ 1606.18 Interim funding.

Failure by the Corporation to meet a time requirement of this part shall not entitle a recipient to continuation of its grant or contract or to refunding. Pending a final determination under this part, the Corporation shall provide the recipient with interim funding necessary to maintain its current level of legal assistance activities under the act.

§ 1606.19 Termination funding.

After a final determination to terminate a recipient's grant or contract or to deny refunding, and without regard to whether a hearing has occurred, the Corporation may authorize temporary funding if necessary to enable a recipient to close or transfer current matters in a manner consistent with the recipient's professional responsibility to its present clients.

§ 1606.20 Notice.

A notice required to be sent to a recipient under this part shall be sent to the director of the recipient, and may be sent to the chairperson of its governing body.

ALICE DANIEL,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-21010 Filed 7-27-78; 8:45 am]

[6820-35]

PART 1607—GOVERNING BODIES

Amendments to the Regulations

AGENCY: Legal Services Corporation.

ACTION: Final regulation.

SUMMARY: These regulations require that at least one-third of the members of a recipient's governing board be eligible clients. These amendments implement the new statutory requirement in the Legal Services Corporation Act Amendments of 1977. Although the statute provides only that eligible clients on a program board may be representatives of their communities, the regulation makes that requirement mandatory. The new regulations attempt to insure that programs will be accountable to the communities they serve.

DATE: Effective date: August 28, 1978.

ADDRESS: Legal Services Corporation, 733 15th Street NW., Suite 700, Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION: Section 11 of the Legal Services Corporation Act Amendments of 1977, Pub. L. 95-222, amended section 1007(c) of the act to require that at least one-third of a recipient's governing body consist of "persons who are, when selected, eligible clients who may also be representatives of associations or organizations of eligible clients." The effective date of this provision was delayed until July 1, 1978, "to afford local boards time, if needed to comply * * *." Sen. Rep. No. 95-172, 95th Cong., 1st sess. (1977), at 8. These amendments to part 1607 implement the new statutory requirement. The Amendment follows the approach of the current regulation by requiring that most members of a program board be selected by appropriate associations or groups. That requirement is at the heart of the Corporation's attempt to insure that programs will be accountable to the communities that they serve. Although the statute provides only that eligible clients on a program board may be representatives of their communities, the regulation makes that requirement mandatory.

The regulation contains a new section 1607.7, concerning compliance with the board composition requirements. Immediate compliance is required, but recipients may apply for an extension of time in which to comply with the new statutory language. This approach should help to avoid disruption of programs that have recently restructured their boards to comply with the current regulation or for which immediate compliance would otherwise be unduly burdensome. Given the importance of the issue, however, extensions should not be granted lightly, and all recipients must be in compliance by July 1, 1979.

The regulation was published for comment on May 22, 1978 (43 FR 21904). All comments received were considered by the Regulations Committee of the Corporation at its meeting on July 5, 1978.

Following is the complete regulation, as amended. The comment that appeared in the June 23, 1976 (41 FR 25901), final publication of part 1607 remains in effect.

Accordingly, 45 CFR Part 1607 is revised to read as follows:

Sec.
1607.1 Purpose.
1607.2 Definition.
1607.3 Composition.
1607.4 Functions of a governing body.
1607.5 Waiver.
1607.6 Compensation.
1607.7 Compliance.

AUTHORITY: Sec. 1007(c); 42 U.S.C. 2996f(c).

§ 1607.1 Purpose.

This part is designed to insure that the governing body of a recipient will be well qualified to guide a recipient in its efforts to provide high-quality legal

assistance to those who otherwise would be unable to obtain adequate legal counsel, and to insure that the recipient is accountable to its clients.

§ 1607.2 Definition.

"Eligible client," as used in this part, means a person eligible to receive legal assistance under the act, without regard to whether the person is receiving assistance at the time of selection for membership on a governing body.

§ 1607.3 Composition.

(a) A recipient shall be incorporated in a State in which it provides legal assistance, and shall have a governing body that reasonably reflects the interests and characteristics of the eligible clients in the area served.

(b) At least sixty (60) percent of a governing body shall be attorneys admitted to practice in a State in which a recipient is to provide legal assistance, who are supportive of the purposes of the act and have interest in, and knowledge of, the delivery of quality legal services to the poor.

(c) The attorney shall be selected from, or designated by, appropriate Bar Associations and other groups, including, but not limited to, law schools, civil rights or antipoverty organizations, and organizations of eligible clients.

(d) At least one-third of a governing body shall be, when selected, eligible clients.

(e) The members who are eligible clients shall be selected from, or designated by, a variety of appropriate groups including, but not limited to, client and neighborhood associations and organizations.

(f) The remaining members of a governing body, whatever the method of selection, shall be individuals interested in and supportive of legal services to the poor.

(g) No category of governing board membership shall be dominated by persons serving as the representatives of a single association, group, or organization.

(h) Members of a governing body may be selected by appointment, election, or other means. The method of selection and composition shall be subject to approval by the Corporation.

§ 1607.4 Functions of a governing body.

(a) A governing body shall have at least four meetings a year. Timely and effective prior public notice of all meetings shall be given, and all meetings shall be public except for those concerned with matters properly discussed in executive session.

(b) A governing body shall establish and enforce broad policies governing the operation of a recipient, but shall not interfere with any attorney's professional responsibilities to clients.

§ 1607.5 Waiver.

(a) Upon application, the President shall waive the requirements of this part to permit a recipient that was funded under section 222(a)(3) of the Economic Opportunity Act of 1964 and, on July 25, 1974, had a majority of persons who were not attorneys on its governing body, to continue such nonattorney majority.

(b) The President may waive the requirements of this part upon application of a recipient that demonstrates that it cannot comply with them because of:

(1) The nature of the population or area served; or

(2) Special circumstances, including, but not limited to, conflicting requirements of the recipient's major funding source.

(c) A recipient seeking a waiver shall demonstrate that it has made diligent efforts to comply with the requirements of this part.

§ 1607.6 Compensation.

While serving on the governing body of a recipient, no member shall receive compensation from the recipient, but a member may receive payment for normal travel and other out-of-pocket expenses required for fulfillment of the obligations of membership.

§ 1607.7 Compliance.

(a) A recipient whose current governing body does not satisfy the requirements of this part shall submit a plan for achieving compliance to the relevant Regional Director immediately.

(b) The President may, upon application, extend the time in which a recipient must comply with the requirements of section 1607.3 (d) and (e). The application shall state:

(1) The current composition of the recipient's governing body, and the date upon which the composition was achieved;

(2) The date upon which the term of each current member of the recipient's governin body will expire;

(3) The recipient's plan for complying with the requirements of section 1607.3 (d) and (e) with all possible speed; and,

(4) The reasons why complying immediately would be unduly burdensome to the recipient.

(c) An application for an extension of time under subsection (b) must be received by the Corporation no later than 30 days after the effective date of the regulation. A copy of the application shall also be sent to the National Clients Council, which shall transmit its comments on the application, if any, to the Corporation. An extension may be granted for no more than 6 months, and no more than two extensions may be granted to any recipient. In no event may the time for compliance be extended beyond July 1, 1979.

ALICE DANIEL,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-21017 Filed 7-27-78; 8:45 am]

[6820-35]

PART 1608—PROHIBITED POLITICAL ACTIVITIES

Amendments to the Regulations

AGENCY: Legal Services Corporation.

ACTION: Final regulation.

SUMMARY: Section 7(a) of the Legal Services Corporation Act Amendments of 1977, Pub. L. 95-222, applies the current provisions of the Hatch Act, relating to the political activities of State and local employees, to staff attorneys, as well as Corporation employees. Other, more restrictive, provisions of the LSC Act, affecting the political activities of staff attorneys on their own time, were repealed. The revisions of part 1608 reflect these changes.

EFFECTIVE DATE: August 28, 1978.

ADDRESS: Legal Services Corporation, 733 15th Street NW., Suite 700, Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION: The amendment to this regulation was published for comment on March 17, 1978 (43 FR 11241). Following is the complete regulation, as amended. The Comment on this regulation that appeared in the June 23, 1976 (41 FR 25900) final publication of part 1608 remains in effect.

Accordingly, 45 CFR part 1608 is revised to read as follows:

PART 1608—PROHIBITED POLITICAL ACTIVITIES

Sec.
1608.1 Purpose.
1608.2 Definition.
1608.3 Prohibitions applicable to the Corporation and to recipients.
1608.4 Prohibitions applicable to all employees.
1608.5 Prohibitions applicable to Corporation employees and staff attorneys.
1608.6 Prohibitions applicable to attorneys and to staff attorneys.
1608.7 Attorney-client relationship.
1608.8 Enforcement.

AUTHORITY.—Secs. 1001(5), 1005(b)(2), 1006(b)(3), 1006(b)(5)(B), 1006(d)(3), 1006(d)(4), 1006(e)(1), 1006(e)(2), 1007(a)(6), 1007(b)(2); 42 U.S.C. 2996(5), 2996d(b)(2), 2996e(b)(3), 2996e(b)(5)(B), 2996e(d)(3), 2996e(d)(4), 2996e(e)(1), 2996e(e)(2), 2996f(a)(6), 2996(b)(2).

§ 1608.1 Purpose.

This part is designed to insure that the Corporation's resources will be used to provide high quality legal assistance and not to support or promote political activities or interests. The part should be construed and applied so as to further this purpose without infringing upon the constitutional rights of employees or the professional responsibilities of attorneys to their clients.

§ 1608.2 Definition.

"Legal assistance activities," as used in this part, means any activity.

(a) Carried out during an employee's working hours;

(b) Using resources provided by the Corporation or by a recipient; or

(c) That, in fact, provides legal advice, or representation to an eligible client.

§ 1608.3 Prohibitions applicable to the Corporation and to recipients.

(a) Neither the Corporation nor any recipient shall use any political test or qualification in making any decision, taking any action, or performing any function under the act.

(b) Neither the Corporation nor any recipient shall contribute or make available Corporation funds, or any personnel or equipment

(1) To any political party or association;

(2) To the campaign of any candidate for public or party office; or

(3) For use in advocating or opposing any ballot measure, initiative, or referendum.

§ 1608.4 Prohibitions applicable to all employees.

(a) No employee shall intentionally identify the Corporation or a recipient with any partisian or nonpartisan political activity, or with the campaign of any candidate for public or party office.

(b) No employee shall use any Corporation funds for activities prohibited to attorneys under section 1608.6; nor shall an employee intentionally identify or encourage others to identify the Corporation or a recipient with such activities.

§ 1608.5 Prohibitions applicable to Corporation employees and to staff attorneys.

While employed under the act, no Corporation employee and no staff attorney shall, at any time,

(a) Use official authority or influence for the purpose of interfering with or affecting the result of an election or nomination for office, whether partisan of nonpartisan;

(b) Directly or indirectly coerce, attempt to coerce, command or advise an employee of the Corporation or of any recipient to pay, lend, or contribute anything of value to a political party, or committee, organization, agency or person for political purposes; or

(c) *Be a candidate for partisan elective public office.*

§ 1608.6 Prohibitions applicable to attorneys and to staff attorneys.

While engaged in legal assistance activities supported under the act, no attorney shall engage in

(1) Any political activity,

(2) Any activity to provide voters with transportation to the polls, or to provide similar assistance in connection with an election, or

(3) Any voter registration activity.

§ 1608.7 Attorney-client relationship.

Nothing in this Part is intended to prohibit an attorney or staff attorney from providing any form of legal assistance to an eligible client, or to interfere with the fulfillment of any attorney's professional responsibilities to a client.

§ 1608.8 Enforcement.

This part shall be enforced according to the procedures set forth in § 1612.5.

ALICE DANIEL,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-21011 Filed 7-27-78; 8:45 am]

[6820-35]

PART 1612—RESTRICTIONS ON CERTAIN ACTIVITIES

Amendments to the Regulations

AGENCY: Legal Services Corporation.

ACTION: Final regulation.

SUMMARY: The current regulations restrict the availability of Corporation funds which are used to influence legislation. This rule clarifies and revises these restrictions. One of the effects of the new regulations is to restrict the use of Corporation funds for activities designed to influence the outcome of State proposals by initiative petition. The rule is being adopted to reflect new language in the Legal Services Corporation Act Amendments of 1977. In addition, the regulations are revised to reflect the Corporation's new procedures governing suspension and termination proceedings. Thus, it is no longer necessary to rely on OEO regulations for enforcement of certain of the Corporation's regulations.

DATES: Effective date: August 28, 1978.

ADDRESS: Legal Services Corporation, 733 15th Street NW., Suite 700, Washington, D.C. 20005

FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION: Section 9(c) of the Legal Services Corporation Act Amendments of 1977, Pub. L. 95-222, expanded the restriction in section 1007(a)(5) of the Act regarding legislative representation to include activities designed to influence the outcome of State proposals by initiative petition, expanded the exceptions to the prohibition to include lobbying regarding measures directly affecting the activities of the recipient or the Corporation, and clarified the restriction on soliciting clients for purposes of legislative representation to include only activities that violate the Code of Professional Responsibility. Section 1612.4(a) of the regulations has been revised to include the new language. In addition, section 1612.5(a) has been revised to reflect the fact that the Corporation has prescribed procedures governing suspension and termination proceedings. Thus, it is no longer necessary to rely on OEO regulations for enforcement of part 1612.

It bears emphasis that the new exception for matters "directly affecting" a recipient does not permit lobby on poor people's issues generally. To the contrary, an amendment in the House bill that would have permitted such lobbying was dropped in conference. The exception extends only to appropriations or other measures directed to the Corporation, or the recipient or its employees, as opposed to eligible clients. See Conf. Rep. 95-825, 95th Cong., 1st Sess. (1977), at 13.

The amendment to this regulation was published for comment on March 17, 1978 (43 FR11241). Following is the complete regulation, as amended. The comment that appeared in the May 5, 1976 final publication of part 1612 remains in effect (41 FR 18514).

Accordingly, 45 CFR Part 1612 is revised to read as follows:

Sec.

AUTHORITY: Secs. 1006(b)(5), 1007(a)(5), 1011, 1008(e), Public Law 93-355, 88 Stat. 378 (42 U.S.C. 2996e(b)(5), 2996f(a)(5), 2996j, 2996g(e)).

§ 1612.1 Definition.

"Legal assistance activities," as used in this part, means any activity

(a) Carried out during an employee's working hours;

(b) Using resources provided by the Corporation or by a recipient; or

(c) That, in fact, provides legal advice, or representation to an eligible client.

§ 1612.2 Public demonstrations and other activities.

(a) While carrying out legal assistance activities under the Act no employee shall

(1) Knowingly participate in any public demonstration, picketing, boycott, or strike, except as permitted by law in connection with the employee's own employment situation; or

(2) Intentionally exhort, direct, or coerce others to engage in such activities, or otherwise usurp or invade the rightful authority of a client to determine what course of action to follow.

(b) While employed under the Act, no employee shall, at any time,

(1) Knowingly participate in any

(i) Rioting or civil disturbance;

(ii) Activity in violation of an outstanding injunction of any court of competent jurisdiction; or

(iii) Any other illegal activity that is inconsistent with an employee's responsibilities under the Act, Corporation regulations, or the Code of Professional Responsibility; or

(2) Intentionally exhort, direct, or coerce others to engage in such activities, or otherwise usurp or invade the rightful authority of a client to determine what course of action to follow.

§ 1612.3 Attorney-client relationship.

Nothing in this part shall prohibit an attorney from

(a) Informing and advising a client about legal alternatives to litigation or the lawful conduct thereof;

(b) Attending a public demonstration, picketing, boycott, or strike for the purpose of providing legal assistance to a client; or

(c) Fulfilling the professional responsibilities of an attorney to a client.

§ 1612.4 Legislative and administrative representation.

(a) No funds made available to a recipient by the Corporation shall be used, directly or indirectly, to support activities intended to influence the issuance, amendment, or revocation of any executive or administrative order or regulation of a Federal, State or local agency, or to influence the passage or defeat of any legislation by the Congress of the United States or by any State or local legislative body or State proposals by initiative petition.

(1) An employee may engage in such activities in response to a request from a govenmental agency or a legislative body, committee, or member made to the employee or to a recipient; and

(2) An employee may engage in such activities on behalf of an eligible client of a recipient, if the client may be affected by a particular legislative or administrative measure but no employee shall solicit a client in violation of professional responsibilities for the purpose of making such representation possible; and,

(3) An employee may engage in such activities if a governmental agency, legislative body, committee, or member thereof is considering a measure directly affecting the activities under the Act of the recipient or the Corporation.

(b) Nothing in this section is intended to prohibit an employee from

(1) Communicating with a governmental agency for the purpose of obtaining information, clarification, or interpretation of the agency's rules, regulations, practices, or policies; or

(2) Informing a client about a new or proposed statute, executive order, or administrative regulation; or

(3) Communicating with the Corporation for any purpose.

§ 1612.5 Enforcement.

(a) The Corporation shall have authority in accordance with the procedures set forth in part 1606 and part 1623 of these regulations:

(1) To suspend or terminate the employment of an employee of the Corporation who violates the provisions of this part; and

(2) To suspend or terminate financial assistance to a recipient who fails to insure that its employees refrain from activities prescribed by the Act or by this part.

(b) A recipient shall

(1) Advise employees about their responsibilities under this part; and

(2) Establish procedures, consistent with the notice and hearing requirements of section 1011 of the Act, for determining whether an employee has violated a provision of this part; and shall establish a policy for determining the appropriate sanction to be imposed for a violation, including

(i) Administrative reprimand if a violation is found to be minor and unintentional, or otherwise affected by mitigating circumstances;

(ii) Suspension and termination of employment; and

(iii) Other sanctions appropriate for the enforcement of this regulation; and

(3) Consult the General Counsel of the Corporation before suspending or terminating the employment of any person for violation of this part.

ALICE DANIEL,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-21018 Filed 7-27-78; 8:45 am]

[6820-35]

PART 1613—RESTRICTIONS ON LEGAL ASSISTANCE WITH RESPECT TO CRIMINAL PROCEEDINGS

Amendments to the Regulations

AGENCY: Legal Services Corporation.

ACTION: Final regulation.

SUMMARY: Current Legal Services Corporation regulations provide for circumstances under which legal assistance may be provided in criminal proceedings involving juvenile cases. The Legal Services Corporation Act Amendments of 1977 repealed the provision on which the current regulations are based. Therefore, the regulations are being revised to reflect the change in the law. Now that juvenile cases are no longer subject to special treatment, the general provisions relating to authorized criminal representation will apply.

EFFECTIVE DATE: August 28, 1978.

ADDRESS: Legal Services Corporation, 733 15th Street NW., Suite 700, Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION: Section 10 of the Legal Services Corporation Act Amendments of 1977, Pub. L. 95-222, repealed the restriction on juvenile representation formerly contained in section 1007(b)(4) of the act. Currently, § 1613.4(b) refers to juvenile cases as instances when representation may be provided in criminal proceedings. Now that such cases are no longer subject to special treatment, however, the general provisions relating to authorized criminal representation should apply. Section 1613.4 has been modified accordingly.

The amendment to part 1613 was published for comment on March 17, 1978 (43 FR 11241). Following is the complete regulation, as amended. The comment on this regulation that appeared in the September 10, 1976, (41 FR 38506) final publication of part 1613 remains in effect.

Accordingly, 45 CFR part 1613 is revised to read as follows:

PART 1613—RESTRICTIONS ON LEGAL ASSISTANCE WITH RESPECT TO CRIMINAL PROCEEDINGS

Sec.
1613.1 Purpose.
1613.2 Definition.
1613.3 Prohibition.
1613.4 Authorized representation.

AUTHORITY.—Sec. 1007(b)(1); 42 U.S.C. 2996f(b)(1).

§ 1613.1 Purpose.

This part is designed to insure that Corporation funds will not be used to provide legal assistance with respect to criminal proceedings unless such assistance is required as part of an attorney's responsibilities as a member of the bar.

§ 1613.2 Definition.

"Criminal proceeding" means the adversary judicial process prosecuted by a public officer and initiated by a formal complaint, information, or indictment charging a person with an offense denominated "criminal" by applicable law and punishable by death, imprisonment, or a jail sentence. A misdemeanor or lesser offense tried in an Indian tribal court is not a "criminal proceeding".

§ 1613.3 Prohibition.

Corporation funds shall not be used to provide legal assistance with respect to a criminal proceeding, unless authorized by this part.

§ 1613.4 Authorized representation.

Legal assistance may be provided with respect to a criminal proceeding.

(a) Pursuant to a court appointment made under a statute or a court rule or practice of equal applicability to all attorneys in the jurisdiction, if authorized by the recipient after a determination that it is consistent with the recipient's primary responsibility to provide legal assistance to eligible clients in civil matters; or

(b) When professional responsibility requires representation in a criminal proceeding arising out of a transaction with respect to which the client is being, or has been, represented by a recipient.

ALICE DANIEL,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-20784 Filed 7-27-78; 8:45 am]

[6730-01]

Title 46—Shipping

CHAPTER IV—FEDERAL MARITIME COMMISSION

[General Order 4; Docket No. 77-53]

PART 510—LICENSING OF INDEPENDENT OCEAN FREIGHT FORWARDERS

Surety Bond

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: This rule increases the amount of the surety bond required for Commission licensed independent ocean freight forwarders engaged in the business of forwarding in the United States export trade from $10,000 to $30,000. The rule further provides for return of the application for failure to submit such required bond within a specified period. The rule also deletes certain provisions rendered obsolete or unnecessary by the passage of time. The changes are designed to add a greater degree of protection to the shipping public in the event of a forwarder default.

DATES: To become effective September 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Francis C. Hurney, Secretary, Federal Maritime Commission, Room 11101, 1100 L Street NW., Washington, D.C. 20573, 202-523-5725.

SUPPLEMENTAL INFORMATION: This proceeding was instituted by Notice of Proposed Rulemaking published in the FEDERAL REGISTER on October 21, 1977 (42 FR 56139-56140) to: (1) Amend § 510.5(g)(3) of the Commission's General Order 4 (46 CFR 510.5(g)(3)), by raising the amount of the surety bond required for Commission licensed independent ocean freight forwarders engaged in carrying on the business of forwarding in the export commerce of the United States from $10,000 to $50,000; (2) provide for the return of an application for a freight forwarders license to the applicant for failure to submit surety bond in the required amount; and (3) make other modifications to § 510.5.

In its notice the commission explained that while the bonding requirement was intended to offer some degree of protection to the shipping public in the event a forwarder should cause financial loss to the shipper, experience has demonstrated that in many instances of forwarder default, the present amount of the bond does not reasonably afford the degree of protection originally intended. In this regard, it was noted that inflationary spiral since 1963, the date of the original $10,000 bond, requires that more financial protection be afforded shipper clients of freight forwarders. This, the Commission pointed out, is demonstrated by the fact that freight rates, the moneys received by forwarders from shippers to be paid to carriers, have doubled and tripled since the original bond was established. The Commission also noted that to obtain such a bond would require the applicant forwarder to demonstrate a substantial degree of financial responsibility and that the surety companies would require a higher degree of financial responsibility from the forwarder.

In addition to increasing the amount of the required surety bond, the Commission also proposed to amend the existing provisions of § 510.5 by: (1) Providing for the return of the application to the applicant for failure to submit required bond; (2) establishing a time period within which existing licensees would be required to file the increased bond; (3) eliminating those provisions pertaining to "grandfather" rights of forwarders and temporary bonding which have been rendered unnecessary by the passage of time; and (4) redesignating certain provisions and making other editorial revisions necessitated by the above changes.

The stated reason for additional amendment (1) above was to terminate the existing procedure of issuing a notice of intent to deny an application and affording the applicant an opportunity for hearing where such applicant has failed to file the required bond. The Commission reasoned that because the filing of a bond by an applicant prior to licensing is mandatory under General Order 4 and section 44 of the Shipping Act, 1916, to require a hearing under circumstances where no bond has been furnished is unnecessary and time consuming.

Comments to the proposed rule were received from 134 parties, 122 forwarders, four forwarder associations, two congressmen, two shippers, one insurance association, one Government agency, one surety company, and one group of ocean freight agents. The Commission's Bureau of Hearing Counsel replied to the comments and answers to Hearing Counsel's replies were also submitted.

All of the comments address the proposal to raise the amount of the bond from $10,000 to $50,000. Most of these oppose the proposed increase in the amount of bond. Those opposed, including Hearing Counsel, agree, however, that some change in the present bonding requirement is necessary and a variety of alternatives is suggested.

Several reasons are advanced by those commentators supporting the proposed increase; the increased bond would better protect the shipping public, help "professionalize" an industry in which, at present, an individual may enter with relatively little capital, reduce malpractices and deter undercapitalized individuals from entering the field.

Those opposing changes in the present bonding requirements take the position that the increase would impose a severe burden on small forwarders; that small forwarders would be forced from the business, leaving the field entirely in the hands of large forwarders. Several of these parties, including an insurance association and the Small Business Administration, submit that forwarders will be unable to: (1)

Afford the premium on such a bond; and/or (2) establish to the bonding companies that a small forwarder has sufficient financial strength to be eligible to receive a bond of the proposed size.[1] While most of those opposing the Commission proposal believe that the present bond is sufficient, some argue that no bond should be required.

A large number of comments was received favoring some change in the present bond, but opposing the proposed increase to $50,000. This group, which includes hearing counsel, states that small forwarders will be unable to secure a $50,000 bond due to the size of their forwarding operations and inability to pledge the required collateral, thus driving small forwarders from the trade, leaving ocean freight forwarding entirely in the hands of a limited number of large forwarders.

Many of these parties urge that the size of the bond be based upon the volume of the forwarder's business. Other comments suggest that recently licensed forwarders, or those licensed in the future, should be required to maintain a large bond while forwarders with several years of experience should be permitted to operate under the current bond requirements.

Certain of the commentators in favor of some change recommend that the amount of the bond be raised to $20,000; hearing counsel suggest $25,000. Some suggest that the public would be better served by rigorous Commission enforcement of existing regulations governing the conduct of forwarders in addition to imposing stricter requirements on forwarders seeking a Commission license. Several parties believe that the amount of credit extended by carriers to forwarders should be limited and that the bond requirement be replaced by a yearly license fee.

Hearing counsel suggest the initiation of a further rulemaking proceeding to strengthen the Commission's regulation of the forwarding industry by establishing experience requirements for new forwarders and requiring financial data reporting by existing forwarders in order to identify those with potential problems.

Finally, one commentator suggests that the Commission give consideration to allowing the submission of security other than a bond. In this regard, it is noted that while section 44(c) of the Shipping Act, 1916, provides for a bond, "or other security," § 510.5(g)(3), of Commission general order 4, allows only for the filing of a surety bond.

In this proceeding the Commission must weigh the consequences of the following alternatives. An increase in the amount of the forwarder bond to $50,000 could impose hardship on small forwarders and be detrimental to the interests of the shipping public and possibly reduce the number of forwarders with a corresponding lessening of competition. Conversely, requiring a $50,000 bond could enhance the level of protection to the shipping public by holding forwarders to a higher degree of financial responsibility.

After carefully considering and evaluating all arguments advanced in support of these conflicting propositions, we have decided to increase the amount of the forwarder bond to $30,000.[2] This not only should act to temper the fears of those who believe the existing $10,000 bond is inadequate to protect the shipping public, but also appears to be within the range which many of those opposing an increase to $50,000 would find reasonable.

No comments were made on the remaining proposed amendments to § 510.5 and subject to one minor change in redesignated paragraph (h)(2), will be adopted as proposed.[3]

Hearing counsel have suggested various changes in the Commission's freight forwarder regulations which are outside the scope of this rulemaking and, accordingly, are not addressed here. However, these comments will be considered for possible inclusion in any future rulemaking.

§ 510.5 [Amended]

Therefore, pursuant to sections 43 and 44 of the Shipping Act, 1916 (46 U.S.C. 841a, 841b); and section 4 of the Administrative Procedure Act (5 U.S.C. 553), § 510.5, Title 46 CFR, is hereby amended as follows:

1. Paragraphs (g)(1) and (g)(2) are deleted.

2. Paragraph (g)(3) is redesignated paragraph (g)(1) and revised as follows:

* * * * *

(g) * * *

(1) No license shall be issued to a person to whom this paragraph is applicable unless such person has filed with the Commission a surety bond in the amount of $30,000 on form FMC-59 as set forth below.

3. New paragraph (g)(2) is added as follows:

* * * * *

(g) * * *

(2) Every licensee shall file with the Commission on or before December 1, 1978, a surety bond in the amount of $30,000 on form FMC-59 as set forth below; otherwise such license issued to the licensee shall be revoked in accordance with § 510.9.

* * * * *

4. Paragraph (h)(1) is deleted.

5. Paragraph (h)(2) is redesignated as paragraph (h)(1) and revised as follows:

* * * * *

(h) * * *

(1) The Commission shall notify applicants for license of their qualification for the issuance of a license. Within 30 days of such notice the applicant shall file with the Commission a surety bond in the form and amount prescribed in paragraph (g) of this section. The Commission may, upon a showing of good cause, extend the time within which to file said surety bond.

* * * * *

6. Paragraph (h)(3) is redesignated as paragraph (h)(2) and revised as follows:

* * * * *

(h) * * *

(2) If the applicant shall not have submitted the surety bond required under paragraph (g)(1) of this section, within the period specified in paragraph (h)(1), or otherwise authorized, the Commission shall return the application to the applicant.

By order of the Federal Maritime Commission.

FRANCIS C. HURNEY,
Secretary.

[FR Doc. 78-20867 Filed 7-27-78; 8:45 am]

[1] This is contravened in an answer submitted by another commentator engaged in the bonding of forwarders which submits that the $50,000 bond would not have an adverse impact on the forwarding company. This commentator claims that $50,000 is not beyond the ability of forwarders, even small forwarders, to secure.

[2] Commissioner Karl E. Bakke dissents on this point. He does not find the proposed $50,000 figure to be unreasonable and would hold to that amount.

[3] The phrase "for failure to prosecute its application in accordance with this section" has been deleted from final paragraph (h)(2) as unnecessary.

[6712-01]

Title 47—Telecommunication
CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION

PART 1—PRACTICE AND PROCEDURE

PART 81—STATIONS ON LAND IN THE MARITIME SERVICES AND ALASKA-PUBLIC FIXED STATIONS

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

PART 87—AVIATION SERVICES

PART 89—PUBLIC SAFETY RADIO SERVICES

PART 91—INDUSTRIAL RADIO SERVICES

PART 93—LAND TRANSPORTATION RADIO SERVICES

PART 94—PRIVATE OPERATIONAL FIXED MICROWAVE SERVICE

PART 95—PERSONAL RADIO SERVICE

Permitting Corporate Officers or Duly Authorized Employees of Corporations To Sign Applications, Amendments Thereto, and Related Statements of Fact Required by the Commission; Correction

AGENCY: Federal Communications Commission.

ACTION: Erratum.

SUMMARY: The FCC is changing the effective date of a rule amendment it recently adopted concerning the signing of applications for station licenses in the Safety and Special Radio Services.

EFFECTIVE DATE: August 2, 1978.

ADDRESS: FCC, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Joseph Johnson, 202-632-7280.

SUPPLEMENTARY INFORMATION:

In the matter of amendment of parts 1, 81, 83, 87, 89, 91, 93, 94, and 95 of the Commission's rules to permit corporate officers or duly authorized employees of corporations to sign applications, amendments thereto, and related statements of fact required by the Commission. Erratum (43 FR 27990).

Released: July 24, 1978.

(1) On June 7, 1978, the Commission adopted an order, FCC 78-392, amending parts 1, 81, 83, 87, 89, 91, 93, 94, and 95 of its rules to permit an authorized employee of a corporation to sign certain station license applications in the Safety and Special Radio Services.

(2) By this action, the Commission is correcting the effective date of its order from July 31, 1978 to August 2, 1978.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

[FR Doc. 78-20856 Filed 7-27-78; 8:45 am]

[6712-01]

[FCC 78-502]

PART 73—RADIO BROADCAST SERVICES

Reregulation of Television and Radio Broadcasting

AGENCY: Federal Communications Commission.

ACTION: Order.

SUMMARY: As a result of its continuing study of reregulation of broadcasting, the Commission initiated the restructuring of part 73 of its rules into a more concise and orderly form by beginning the transfer to subpart H of all rules the subject matter of which is common to AM, FM, and TV broadcasting but are repeated in each of the present subparts for those services. Revisions are made in the rules where needed. Rules which are unique to a particular service will remain in their respective subparts.

EFFECTIVE DATE: August 1, 1978.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Phil Cross, Steve Crane, or John Reiser, Broadcast Bureau, 202-632-9660.

SUPPLEMENTARY INFORMATION:

Adopted: July 12, 1978.

Released: July 21, 1978.

Order. In the matter of reregulation of radio and television broadcasting.

By the Commission:

1. As a result of its continuing study concerning the reregulation of radio and TV, the Commission has under consideration the matter of amending certain provisions of its broadcasting rules as described herein.

2. In the public notice in which the broadcast reregulation study and the formation of the reregulation staff were announced, the Commission stated that one of the staff's goals would be a simpler, more readily understandable set of rules, organized in a manner to more clearly identify those regulations which apply to the various types and classes of broadcast stations.

3. As the reregulation work has progressed, reviewing rules, determining their validity with relation to the present state of the art, and deciding whether they should be retained, modified or deleted, continuing thought has been given to the optimum form the broadcast rule book should take.

4. In developing a reorganized and reformatted rule book, we have concluded that a basic purpose thereof is to facilitate a better understanding of our rules by broadcasters and practitioners through simple and quick access to them. The first step to easy access was the development and the adoption of the alphabetical index (FCC 76-1042, adopted November 9, 1976). It is an alphabetical index of rule titles in part 73, volume III, and provides ready reference to most, but not absolutely all, of the subject matter in the rules, inasmuch as a rule title, while it is indicative, may not be all-inclusive of the subject matter therein. A complete alphabetical index of all subject matter in our rules is to be an integral and continuing part of this overall reorganization and rewriting (where needed) which begins with this order.

5. The FCC rules and regulations are grouped into 11 volumes and sold by the Superintendent of Documents, Washington, D.C. volume III, parts 73 and 74, "Radio Broadcast Services," contain the bulk of the broadcast rules. Other rules exclusively applicable to broadcasting are contained in volume I, part 1, subpart D, "Broadcast Applications and Proceedings." Also, rules applicable to broadcasting, and to other communications services as well, are found in volume I, part 1, subpart G, "Schedule of Fees Filed with the Commission" (suspended January 1, 1977, pending further Commission action), subpart H, "Ex Parte Presentations"; subpart I, "Procedures Implementing the National Environmental Policy Act of 1969"; part 13, "Commercial Radio Operators"; and part 17, "Construction, Marking and Lighting of Antenna Structures."

6. We are looking toward a rule book setting forth, in part 73 of volume III, all rules applicable to the broadcast services. Rules in volume I which are applicable exclusively to broadcasting would be removed therefrom and consolidated into part 73, volume III. Rules which are applicable to other communications services, as well as to broadcasting, would be left in volume I, but restated in pertinent part and in condensed form and added to the broadcast services rule book in part 73, volume III. Thus, volume I would be

undisturbed except for removal of subpart D, "Broadcast Applications and Proceedings."

7. Part 73, volume III, is presently subdivided into subparts A, "Standard Broadcast Stations" (to be changed to "'AM' Broadcast Stations" in this title and throughout the rules as review and revision proceeds); B, "FM Broadcast Stations"; C, "Noncommercial Educational FM Broadcast Stations"; E, "Television Broadcast Stations" (to be changed to "TV Broadcast Stations" as revision take place); F, "International Broadcast Stations"; G, "Emergency Broadcast System"; and H, "Rules Applicable in Common to Broadcast Stations". Subparts F and G will remain as they are for now. Subpart H will be expanded to include all rules applying in common to AM, FM, and TV stations. (See par. 8, below.) Thought is being given to adding subpart D for rules exclusively applicable to noncommercial educational AM, FM, and TV stations. An alternate plan being considered is the inclusion of rules exclusively applicable to noncommercial educational stations in the subparts for the separate AM, FM, and TV services. They could be included as separate subdivisions of the AM, FM, and TV subparts, or as separate subparagraphs in subpart H sections (i.e., "Commercial applicability" and "Noncommercial educational applicability.") In the immediate future, we seek more experience in testing the alternatives as the reformatting and reorganization progresses, and our findings will dictate our final decision.

8. Part 73, volume III, as presently structured, includes, in the separate subparts, rules which are applicable to that particular service only, as well as approximately 215 rules which apply in common to all broadcast stations. They constitute the bulk of the non-engineering regulations in the separate subparts. There is, of course, subpart H, containing rules common to all broadcast stations, but only a small number of such rules, "in common", have been included there (13 at present). With this order initiating the restructuring of the rule book, we begin the transfer to subpart H of all rules, the subject matter of which is common to AM, FM, and TV (at the same time reviewing each rule and making certain revisions as hereinafter indicated.) At the completion of this part of our reorganizational task, we will have included, in one place in our rule book, regulations applicable in common to all broadcast licensees. These common rules will, of course, provide for any necessary variations between AM, FM, and TV services, where appropriate. The resultant separate subparts for AM, FM, and TV will contain certain technical/engineering requirements and non-technical rules which are unique to that particular sevice.

9. As a further refinement of volume III into the "total information center" for broadcast operations, we look toward the inclusion of references and sources for policies and procedures not presently in our rules (or there only in part) but which direct the actions and conduct of our licensees. Included would be such policies as those pertaining to renewals, ascertainment, minority hirings, program length commercials, loud commercials, payola, and plugola, to name a few.

10. Volume III also contains part 74, "Experimental, Auxiliary and Special Broadcast and Other Program Distributional Services." As a result of earlier reregulation undertakings a large number of revisions have already been made in this part, including a complete recreation of subpart D (Remote Pickup Broadcast Stations). A complete retooling and reorganization of the part, including separate alphabetical indexing, can be delayed until the part 73 project is completed, or at least well along the way. Of course, the staff will give quick attention to any rule matters that require immediate attention without delay in this part, or in any of the broadcast rules, wherever located.

11. Thus, a restructured volume III, with its two parts, will give to licensees and others concerned with broadcasting, a new and complete ready-reference handbook of rules and regulations. This order takes the first steps in implementing the changes. As these changes are made, the table of contents, and more importantly, the alphabetical index, will reflect each step, assuring the user of the rule book instant directions to any rule being sought.

12. Following are the changes to the rules to be effected in this order:

(a) The subpart H title is revised, the first section of subpart H (§ 73.1001) is retitled "SCOPE" and the entire section is rewritten for clarity.

(b) Rules pertaining to broadcast station license periods, renewal dates and terms of licenses are presently titled "Normal license period" and found in § 73.34 for AM stations, § 73.218 for FM stations, § 73.518 for NCE-FM stations and § 73.630 for TV stations. The separate sections are deleted from their respective subparts and the rule is reassigned to subpart H as § 73.1020 and retitled "Station license period." Renewal dates which have been passed (1977 and thus far in 1978) have been revised to the next appropriate triennial renewal date.

(c) Broadcast licensees have traditionally been allowed by the Commission to use their stations for purposes of research and experimentation which had a reasonable promise of contributing to the development and the improvement of the technical phases of broadcasting. Additionally, licensees have used their stations for the "housekeeping chores" of testing and maintaining their equipment at optimum operating levels. These two procedures have been inextricably entwined in our rules and with this order they will be separately stated, newly titled and reassigned to subpart H from subpart A (§ 73.10, Experimental period; and § 73.32, Special experimental authorizations), subpart B (§ 73.262 Experimental operation), subpart C (§ 73.562, Experimental operation) and subpart E (§ 73.666, Experimental operation). These present rules will be designated § 73.1510, Experimental authorizations, and § 73.1520, Operation for tests and maintenance in subpart H. Section 73.10 will become the definition of the term "experimental period" as it applies to AM broadcast stations and section 73.72 will be expanded to include all conditions of operation during the experimental period.

(d) The rules pertaining to transmitting equipment tests, during the construction of a broadcast station, are titled "Equipment tests", and are found in § 73.95 (AM stations), § 73.216 (FM stations), § 73.516 (NCE-FM stations) and § 73.628 (TV stations). These separate sections are herein deleted from their respective subparts and the rule is relocated in subpart H as § 73.1610 with the same section headnote.

(e) After completing construction of a broadcast station and the filing of the application for station license, the permittee may request authority to conduct program tests. The rules pertaining to program tests for the separate broadcast services are titled as such and are found in § 73.96 for AM, § 73.217 for FM, § 73.517 for NCE-FM and § 73.629 for TV. These separate sections will be deleted in this order and the rule will be reassigned to subpart H as § 73.1620, "Program tests".

(f) Applicants for construction of new or changed facilities must consider the matter of possible harmful interference to the National Radio Astronomy Observatory in Pendleton County, W. Va., and the Table Mountain Radio Receiving Zone in Boulder County, Colo., and notify the former at the time the application is filed. The rules pertaining thereto are titled, "Notification of filing of applications," and are designated as §§ 73.18, 73.215, 73.515, and 73.624 in subparts A (AM), B (FM), C (NCE-FM), and E (TV), respectively. They are consolidated and moved into subpart H as § 73.1030. Also, the section headnote is retitled to make clear that radio astronomy,

research and receiving installations are all included in this provision.

(g) An identical section on "Cross reference to rules in other parts" is presently contained in each of the AM (§ 73.17), FM (§ 73.214), NCE-FM (§ 73.514) and TV (§ 73.602) subparts of part 73. These are deleted from the respective subparts and consolidated in subpart H as § 73.1010.

(h) The terms "AM broadcast station" and "standard broadcast station," are both used in part 73. They are synonymous. The term "standard" was used at the outset for the only broadcast stations then licensed, i.e., those transmitting with amplitude modulation. When broadcast stations using frequency modulation were developed and licensed, the term "FM" was applied to the new service. The term "TV" is generally applied to television broadcast stations. In the context of the three services, the term "AM" has come into general use as a more accurate and definitive description of that service than "standard." As amendments have been made to rules which used the term "standard," changes to "AM" have been made. The term "standard" still appears in a substantial number of rules. The most practical and orderly way of converting the remaining ones is to make changes as those rules are subsequently worked into this new format. With this Order, the headnote of subpart A is changed to "AM broadcast stations," and §§ 73.1, 73.2, 73.3 and 73.21 of the subpart are amended to define an "AM broadcast station," "AM broadcast band," "AM broadcast channel" and "Classes of AM broadcast channels and stations," respectively. Section 73.1 also points out that "AM broadcast" is synonymous with the term "standard broadcast" as contained elsewhere (for the time being) in this chapter.

(i) The separate service rules on "Frequency measurements," as contained in §§ 73.60, 73.252, 73.552, and 73.690, are combined into one rule section in subpart H, § 73.1540, "Carrier frequency measurements." The addition of the word "carrier" in the section headnote clarifies the scope of the rule since there are now other types of frequency measurements required in the broadcast services such as measurement of the FM stereophonic pilot signal. The restructured rule, while recognizing that the primary standard for all radio frequency measurements is that maintained by the National Bureau of Standards, also makes it clear that the actual procedure or method used for measuring or determining the station carrier frequency of each main transmitter used may be selected by the station licensee.

(j) Special field test authorizations may be granted for use in making field strength measurements for transmitter site selection, propagation studies and other specialized AM, FM, and TV broadcast signal analysis work. Low power portable transmitters are frequently used in making these measurements. The term "portable transmitter," as used in connection with special field tests, is only defined in the AM subpart of the rules in § 73.12. Since these portable facilities, more correctly called "Portable Test Stations," are used for field tests in all broadcast services, the definition "Portable Test Station" is set forth in subpart H as § 73.1530.

(k) The part 73 alphabetical index is revised to reflect the rule changes described below.

13. We conclude that, for the reasons set forth above, adoption of these revisions will serve the public interest and inasmuch as these amendments impose no additional burdens and raise no issue upon which comments would serve any useful purpose, prior notice of rulemaking, effective date provisions and public procedure thereon are unnecessary pursuant to the Administrative Procedure and Judicial Review Act provisions of 5 U.S.C. (b)(3)(B).

14. Therefore, *it is ordered,* That pursuant to Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, the Commission's rules and regulations are amended as set forth below, effective August 1, 1978.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303.)

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

1. In part 73, the title headnote of subpart A is changed to the following:

Subpart A—AM Broadcast Stations

2. Section 73.1 and headnote are amended to read as follows:

§ 73.1 AM broadcast station (Definition).

The term "AM broadcast station" means a broadcast station licensed for the dissemination of radio communications intended to be received by the public and operated on a channel in the band 535-1605 kilohertz (kHz). The term "AM broadcast" is synonymous with the term "standard broadcast" as contained elsewhere in this chapter.

3. Section 73.2 and headnote are amended to read as follows:

§ 73.2 AM broadcast band (Definition).

The term "AM broadcast band" means the band of frequencies extending from 535 to 1605 kHz.

4. Section 73.3 and headnote are amended to read as follows:

§ 73.3 AM broadcast channel (Definition).

The term "AM broadcast channel" means the band of frequencies occupied by the carrier and two sidebands of a broadcast signal with the carrier frequency at the center. Channels shall be designated by their assigned carrier frequencies. The 107 carrier frequencies assigned to AM broadcast stations shall begin at 540 kHz and be in successive steps of 10 kHz.

5. Section 73.10 headnote and text are amended to read as follows:

§ 73.10 Experimental period (Definition).

The term "experimental period" in reference to AM station operation means that time between 12 midnight local time and local sunrise.

6. Section 73.12 is amended to read as follows:

§ 73.12 Portable transmitters.

See § 73.1530.

7. Section 73.17 is amended to read as follows:

§ 73.17 Cross reference to rules in other parts.

See § 73.1010.

8. Section 73.18 is amended to read as follows:

§ 73.18 Notification of filing of applications.

See § 73.1030.

9. The headnote of section 73.21 is amended to read as follows:

§ 7321 Classes of AM broadcast channels and stations.

10. Section 73.32 is amended to read as follows:

§ 73.32 Special experimental authorizations.

See § 73.1510 and § 73.1520.

11. Section 73.34 is amended to read as follows:

§ 73.34 Normal license period.

See § 73.1020.

12. Section 73.60 is amended to read as follows:

§ 73.60 Frequency measurements.

See § 73.1540.

13. Section 73.72, the headnote and text are amended to read as follows:

§ 73.72 Operating during the experimental period.

(a) An AM station may operate during the experimental period on its assigned frequency and with its authorized power for the routine testing and maintenance of its transmitting system, and for conducting experimentation under an experimental authori-

zation; provided no interference is caused to other stations maintaining a regular operating schedule within such period.

(b) No station licensed for "daytime" or "specified hours" of operation may broadcast any regular or scheduled program during this period.

(c) The licensee of an AM station shall operate or refrain from operating its station during the experimental period as directed by the FCC to facilitate frequency measurements or for the determination of interference.

14. Section 73.95 is amended to read as follows:

§ 73.95 Equipment tests.

See § 73.1610.

15. Section 73.96 is amended to read as follows:

§ 73.96 Program tests.

See § 73.1620.

16. The undesignated headnote immediately preceding § 73.181 is changed to read as follows:

AM TECHNICAL STANDARDS

17. The undesignated headnote, "Administrative Procedures," preceding section 73.214 is deleted in its entirety.

18. Section 73.214 is amended to read as follows:

§ 73.214 Cross reference to rules in other parts.

See § 73.1010.

19. Section 73.215 is amended to read as follows:

§ 73.215 Notification of filing of applications.

See § 73.1030.

20. Section 73.216 is amended to read as follows:

§ 73.216 Equipment tests.

See § 73.1610.

21. Section 73.217 is amended to read as follows:

§ 73.217 Program tests.

See § 73.1620.

22. Section 73.218 is amended to read as follows:

§ 73.218 Normal license period.

See § 73.1020.

23. Section 73.252 is amended to read as follows:

§ 73.252 Frequency measurements.

See § 73.1540.

24. Section 73.262 is amended to read as follows:

§ 73.262 Experimental operation.

See § 73.1510 and § 73.1520.

25. The undesignated headnote, "FM Technical Standards," following § 73.295 in the "Contents—Part 73" is relocated to follow § 73.301 and precede § 73.310.

26. The undesignated headnote, "Administrative Procedures", preceding § 73.514 is deleted in its entirety.

27. Section 73.514 is amended to read as follows:

§ 73.514 Cross reference to rules in other parts.

See § 73.1010.

28. Section 73.515 is amended to read as follows:

§ 73.515 Notification of filing of applications.

See § 73.1030.

29. Section 73.516 is amended to read as follows:

§ 73.516 Equipment tests.

See § 73.1610.

30. Section 73.517 is amended to read as follows:

§ 73.517 Program tests.

See § 73.1620.

31. Section 73.518 is amended to read as follows:

§ 73.518 Normal license period.

See § 73.1020.

32. The undesignated headnote, "Equipment," preceding § 73.550 is relocated to precede § 73.540.

33. Section 73.552 is amended to read as follows:

§ 73.552 Frequency measurements.

See § 73.1540.

34. Section 73.562 is amended to read as follows:

§ 73.562 Experimental operation.

See § 73.1510 and § 73.1520.

35. Section 73.602 is amended to read as follows:

§ 73.602 Cross reference to rules in other parts.

See § 73.1010.

36. Section 73.624 is amended to read as follows:

§ 73.624 Notification of filing of applications.

See § 73.1030.

37. Section 73.628 is amended to read as follows:

§ 73.628 Equipment tests.

See § 73.1610.

38. Section 73.629 is amended to read as follows:

§ 73.629 Program tests.

See § 73.1620.

39. Section 73.630 is amended to read as follows:

§ 73.630 Normal license period.

See § 73.1020.

40. Section 73.666 is amended to read as follows:

§ 73.666 Experimental operation.

See § 73.1510 and § 73.1520.

41. Section 73.690 is amended to read as follows:

§ 73.690 Frequency measurements.

See § 73.1540.

42. the title headnote of subpart H, part 73, is amended to read as follows:

Subpart H—Rules Applicable to all Broadcast Stations

43. Section 73.1001 and headnote are amended to read as follows:

§ 73.1001 Scope.

(a) The rules in this subpart are common to all AM, FM, and TV broadcast services, commercial and noncommercial.

(b) Rules in part 73 applying exclusively to a particular broadcast service are contained in the following: AM, subpart A; FM, subpart B; Noncommercial Educational FM, subpart C; and TV, subpart E.

(c) Certain provisions in this subpart apply to International Broadcast Stations (subpart F, part 73) and Television Broadcast Translator Stations (subpart G, part 74) where the rules for those services so provide.

(d) The provisions of this part applying to licensees also apply to holders of construction permits (permittees).

44. New § 73.73.1010 is added to subpart H, part 73, as follows:

§ 73.1010 Cross reference to rules in other Parts.

Certain rules applicable to broadcast services, some of which are also applicable to other services, are set forth in the following Volumes and Parts of the Commission's Rules and Regulations:

(a) Part 1 (Volume I), "Practice and Procedure."

(1) Subpart A, "General Rules of Practice and Procedure" (§§ 1.1 to 1.120).

(2) Subpart B, "Hearing Proceedings" (§§ 1.201 to 1.363).

(3) Subpart C, "Rule Making Proceedings" (§§ 1.399 to 1.430).

(4) Subpart D, "Broadcast Applications and Proceedings" with subheadings of "General Filing Requirements," "Application Forms and Particular Filing Requirements," "Application Processing Procedures," "Action on Applications," "Forms and Information To Be Filed With The Commission" and "Forfeitures Relating to Broadcast Licensees and Permittees" (§§ 1.501 to 1.621).

(5) Subpart G, "Schedule of Fees" (§§ 1.1101 to 1.1120).

(6) Subpart H, "Ex Parte Presentations" (§§ 1.1201 to 1.1251).

(7) Subpart I, "Procedures Implementing the National Environmental policy Act of 1969" (§§ 1.1301 to 1.1319).

(b) Part 2 (volume II), "Frequency Allocations and Radio Treaty Matters: General Rules and Regulations," including subparts A, "Definitions," B, "Allocation, Assignments, and Use of Radio Frequencies," C, "Emissions," D, "Call Signs and Other Forms of Identifying Radio Transmissions," G, "Treaties and Other International Agreements," and J, "Equipment Authorization Procedures—Type Approval; Type Acceptance; Certification."

(c) Part 13 (volume I), "Commercial Radio Operators."

(d) Part 17 (volume I), "Construction, Marking, and Lighting of Antenna Structures."

(e) Part 74 (volume III), "Experimental, Auxiliary and Special Broadcast, and Other Program Distributional Services," including subparts on the following stations: A, "Experimental Television—," B, "Experimental Facsimile—," C, "Developmental—," D, "Remote Pickup—," E, "Aural STL and Intercity Relay—," F, "Television Auxiliary—," G, "Television Broadcast Translator—," H, "Low Power Auxiliary—," I, "Instructional Television Fixed Service," L, "FM Translator and Booster—."

45. New § 73.1020 is added to subpart H, part 73, to read as follows:

§ 73.1020 Station license period.

(a) Initial licenses for broadcast stations will ordinarily be issued for a period running until the date specified in this section for the State or Territory in which the station is located. If issued after such date, it will run to the next renewal date determined in accordance with this section; and, when renewed, will normally be renewed for 3 years. If the FCC finds that the public interest, convenience, and necessity will be served thereby, it may issue either an initial license or a renewal thereof for a lesser term. The time of expiration of normally issued initial and renewal licenses will be 3 a.m., local time, on the following dates and at 3-year intervals thereafter for stations located in:

(1) Delaware and Pennsylvania, August 1, 1978.

(2) Maryland, District of Columbia, Virginia and West Virginia, October 1, 1978.

(3) North Carolina and South Carolina, December 1, 1978.

(4) Florida, Puerto Rico and Virgin Islands, February 1, 1979.

(5) Alabama and Georgia, April 1, 1979.

(6) Arkansas, Louisiana and Mississippi, June 1, 1979.

(7) Tennessee, Kentucky and Indiana, August 1, 1979.

(8) Ohio and Michigan, October 1, 1979.

(9) Illinois and Wisconsin, December 1, 1979.

(10) Iowa and Missouri, February 1, 1980.

(11) Minnesota, North Dakota, South Dakota, Montana and Colorado, April 1, 1980.

(12) Kansas, Oklahoma and Nebraska, June 1, 1980.

(13) Texas, August 1, 1980.

(14) Wyoming, Nevada, Arizona, Utah, New Mexico and Idaho, October 1, 1980.

(15) California, December 1, 1980.

(16) Washington, Oregon, Alaska, Guam and Hawaii, February 1, 1981.

(17) Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont, April 1, 1981.

(18) New Jersey and New York, June 1, 1981.

NOTE.—For the cutoff date for the filing of applications mutually exclusive with, and petitions to deny, renewal applications, see § 1.516(e) of this chapter.

46. New § 73.1030 is added to subpart H, part 73, as follows:

§ 73.1030 Notifications concerning interference to radio astronomy, research and receiving installations.

(a) *Radio astronomy and radio research installations.* In order to minimize harmful interference at the National Radio Astronomy Observatory site located at Green Bank, Pocahontas County, W. Va., and at the Naval Radio Research Observatory at Sugar Grove, Pendleton County, W. Va., an applicant for authority to construct a new broadcast station or for authority to make changes in the frequency, power, antenna height, or antenna directivity of an existing station within the area bounded by 39°15′ N on the north, 78°30′ W on the east, 37°30′ N on the south, and 80°30′ W on the west shall, at the time of filing such application with the FCC simultaneously notify the following:

Director, National Radio Astronomy Observatory, P.O. Box No. 2, Green Bank, W. Va. 21911.

The notification shall be in writing and set forth the particulars of the proposed station, including the geographical coordinates of the antenna, antenna height, antenna directivity if any, proposed frequency, type of emission and power. In addition, the applicant shall indicate in his application to the FCC the date notification was made to the observatory. After receipt of such applications, the FCC will allow a period of 20 days for comments or objections in response to the notifications indicated. If an objection to the proposed operation is received during the 20-day period from the National Radio Astronomy Observatory for itself or on behalf of the Naval Radio Research Observatory, the FCC will consider all aspects of the problem and take whatever action is deemed appropriate.

(b) *Radio receiving installations.* Protection for Table Mountain Radio Receiving Zone, Boulder County, Colo.: Applicants for a station authorization to operate in the vicinity of Boulder County, Colo., under this part are advised to give due consideration, prior to filing applications, to the need to protect the Table Mountain Radio Receiving Zone from harmful interference. These are the Research Laboratories of the Department of Commerce, Boulder County, Colo. To prevent degradation of the present ambient radio signal level at the site, the Department of Commerce seeks to ensure that field strenghts at 40°07′50″ N latitude, 105°14′40″ W longitude, resulting from new assignments (other than mobile stations) or from the modification or relocation of existing facilities do not exceed the following values:

Frequency range	Field strength [1]	Power flux density [2] [3]
Below 540 kHz	10	−65.8
540 to 1600 kHz	20	−59.8
1.6 to 470 MHz	10	−[4][4]65.8
470 to 890 MHz	30	−[4][4]56.2
Above 890 MHz	1	−[4][4]85.8

[1] (mV/m) in authorized bandwidth of service.

[2] (dBW/m [2]) in authorized bandwidth of service.

[3] Equivalent values of power flux density are calculated assuming a free-space characteristic impedance of 376.7=120 π ohms.

[4] Space stations shall conform to the power flux density limits at the Earth's surface specified in appropriate parts of the FCC rules, but in no case should exceed the above levels in any 4 kHz band for all angles of arrival.

(1) Advance consultation is recommended particularly for those applicants who have no reliable data which indicate whether the field strength or power flux density figures in the above table would be exceeded by their proposed radio facilities (except mobile stations). In such instances, the following is a suggested guide for determining whether coordination is recommended:

(i) All stations within 1.5 miles;

(ii) Stations within 3.0 miles with 50 watts or more effective radiated power (ERP) in the primary plane of polarization in the azimuthal direction of the Table Mountain Radio Receiving Zone;

(iii) Stations within 10 miles with 1 kW or more ERP in the primary plane of polarization in the azimuthal direction of Table Mountain Receiving Zone;

(iv) Stations within 50 miles with 25 kW or more ERP in the primary plane of polarization in the azimuthal direction of Table Mountain Receiving Zone.

(2) In advance of filing their applications with the FCC, applicants concerned are urged to communicate with the following:

Radio Frequency Management Coordinator, Department of Commerce, Research Support Services NOAA/R5X3, Boulder Laboratories, Boulder, Colorado 80302, telephone, 303-499-1000, extensions 6548 or 6549.

(3) The FCC will not screen applications to determine whether advance consultation has taken place. However, applicants are advised that such consultation can avoid objections from the Department of Commerce of proceedings to modify any authorization which may be granted which, in fact, delivers a signal at the reference point in excess of the field strength specified herein.

47. New § 73.1510 is added to Subpart H, Part 73, as follows:

§ 73.1510 Experimental authorizations.

(a) Licensees of broadcast stations may obtain experimental authorizations to conduct technical experimentation directed toward improvement of the technical phases of operation and service, and for such purposes may use a signal other than the normal broadcast program signal.

(b) Experimental authorizations may be requested by filing an informal application with the FCC in Washington, D.C., describing the nature and purpose of the experimentation to be conducted, the nature of the experimental signal to be transmitted, and the proposed schedule of hours and duration of the experimentation. Experimental authorizations shall be posted with the station license.

(c) Experimental operations are subject to the following conditions:

(1) The authorized power of the station may not be exceeded, except as specifically authorized for the experimental operations.

(2) Emissions outside the authorized bandwidth must be attenuated to the degree required for the particular type of station.

(3) The experimental operations may be conducted at any time the station is authorized to operate, but the minimum required schedule of programming for the class and type of station must be met. AM stations also may conduct experimental operations during the experimental period (12 midnight local time to local sunrise) and at additional hours if permitted by the experimental authorization provided no interference is caused to other stations maintaining a regular operating schedule within such period(s).

(4) If an experimental authorization permits the use of additional facilities or hours of operation for experimental purposes, no sponsored programs or commercial announcements may be transmitted during such experimentation.

(5) The licensee may transmit regularly scheduled programming concurrently with the experimental transmission if there is no significant impairment of service.

(6) No charges may be made, either directly or indirectly, for the experimentation; however, normal charges may be made for regularly scheduled programming transmitted concurrently with the experimental transmissions.

(d) The FCC may request a report of the research, experimentation and results at the conclusion of the experimental operation.

48. New § 73.1520 is added to Subpart H, Part 73, as follows:

§ 73.1520 Operation for tests and maintenance.

(a) Broadcast stations may be operated for tests and maintenance of their transmitting systems on their assigned frequencies using their licensed operating power and antennas during their authorized hours of operation without specific authorization from the FCC.

(b) Licensees of AM stations may operate for tests and maintenance during the hours from 12 midnight local time to local sunrise, if no interference is caused to other stations maintaining a regular operating schedule within such period. No AM station licensed for "daytime" or "specified hours" of operation may broadcast any regular or scheduled programs during this period of test and maintenance operation.

(c) Licensees of AM stations must obtain a special antenna equipment test authorization using the procedures described in § 1.544(a) in order to operate with authorized nighttime power and directional antenna system during daytime hours when necessary to conduct monitor point field strength measurements and antenna proof of performance measurements.

49. New § 73.1530 is added to subpart H, part 73, as follows:

§ 73.1530 Portable test stations. [Definition]

A portable test station is one that is moved from place to place for making field strength and ground conductivity measurements, for selecting station transmitter sites, and conducting other specialized propagation tests. Portable test stations are not normally used while in motion, and may not be used for the transmission of programs intended to be received by the public.

50. New § 73.1540 is added to subpart H, part 73, as follows:

§ 73.1540 Carrier frequency measurements.

(a) The carrier frequency of each AM and FM station and the visual carrier frequency and difference between the visual carrier and the aural carrier or center frequency of each TV station shall be measured or determined as often as necessary to insure that they are maintained within the prescribed tolerances. In any event, each station with an authorized operating power greater than 10 watts shall make at least one measurement or determination each calendar month with intervals not exceeding 40 days between successive measurements for each main transmitter in use.

(b) In measuring the carrier frequency, the licensee may use any method or procedure that has sufficient precision to establish that the carrier frequency is within the prescribed departure limits.

(c) The primary standard of frequency for radio frequency measurements is the standard frequency maintained by the National Bureau of Standards or the standard signals of Stations WWV, WWVB, and WWVH of the National Bureau of Standards.

51. New § 73.1610 is added to subpart H, part 73, as follows:

§ 73.1610 Equipment tests.

(a) During the process of construction of a broadcast station, the permittee, after notifying the FCC in Washington, D.C. and engineer in charge of the radio district in which the station is located may, without further authority of the FCC, conduct equipment tests for the purpose of such adjustments and measurements as may be necessary to assure compliance with the terms of the construction permit, the technical provisions of the application therefor, the rules and regulations and the applicable engineering standards. For AM stations, tests must be conducted during the experimental period, 12 midnight local time to local sunrise. The FCC may authorize equipment tests other than during the experimental period for AM stations, if such operation is shown to be desirable to the proper completion of construction and adjustment of the transmitting equipment and antenna system. An informal application for such authority, giving full details regarding the need for such tests, shall be filed with the FCC in Washington, D.C. at least 2 days (not including Saturdays, Sundays, and legal holidays when the offices of the FCC are not open) prior to the date on which it is desired to begin such operation.

(b) The FCC may notify the permittee not to conduct tests or may cancel, suspend, or change the date for the beginning of equipment tests if and when such action may appear to be in

the public interest, convenience, and necessity.

(c) Equipment tests may be continued so long as the construction permit shall remain valid.

(d) Inspection of a station will ordinarily be required during the equipment test period and before the commencement of program tests. After construction and after adjustments and measurements have been completed to show compliance with the terms of the construction permit, the technical provisions of the application therefor, and the rules and regulations, the permittee shall notify the engineer in charge of the radio district in which the station is located that it is ready for inspection.

(e) The authorization for tests embodied in this section shall not be construed as constituting a license to operate but as a necessary part of construction.

52. New § 73.1620 is added to subpart H, part 73, as follows:

§ 73.1620 Program tests.

(a) Upon completion of construction of an AM, FM, or TV station in accordance with the terms of the construction permit, the technical provisions of the application, the rules and regulations and the applicable engineering standards, and when an application for station license has been filed showing the station to be in satisfactory operating condition, the permittee may request authority to conduct program tests. Such request shall be filed with the FCC in Washington, D.C. at least 10 days prior to the date on which it is desired to begin such operation. All data necessary to show compliance with the terms and conditions of the construction permit must be filed with the license application.

(1) An AM station, using directional antennas, must also file an antenna proof of performance.

(b) Program tests shall not commence until specific FCC authority is received. The FCC reserves the right to change the date of the beginning of such tests or to suspend or revoke the authority for program tests.

(c) Unless sooner suspended or revoked, the program test authority continues valid during FCC consideration of the application for license, and during this period further extension of the construction permit is not required. Program test authority shall be automatically terminated by final determination upon the application for station license.

(d) All operation under program test authority shall be in strict compliance with the rules governing broadcast stations and in strict accordance with representations made in the application for license pursuant to which the tests were authorized.

(e) The granting of program test authority shall not be construed as approval by the FCC of the application for station license.

(f) The licensee of a UHF TV station which is not in operation on, but assigned to, the same allocated channel which a 1000 watt UHF translator station is authorized to use (see § 1.516(c), Specifications of facilities), shall notify the licensee of the translator station, in writing, at least 10 days prior to commencing or resuming operation. The TV station licensee shall also certify to the FCC in Washington, D.C. that such advance notice has been given to the translator station licensee.

53. Part 73 is amended with the following revised "Alphabetical Index of Rules Titles—Part 73" to follow after the last page of "Contents—Part 73:"

ALPHABETICAL INDEX OF RULES TITLES—PART 73

SUBPART A—AM BROADCAST STATIONS

ALPHABETICAL INDEX OF RULES TITLES—PART 73—Continued

ALPHABETICAL INDEX OF RULES TITLES—PART 73—Continued

ALPHABETICAL INDEX OF RULES TITLES—PART 73—Continued

SUBPART B—COMMERCIAL FM BROADCAST STATIONS

SUBPART B—COMMERCIAL FM BROADCAST STATIONS—Continued

SUBPART B—COMMERCIAL FM BROADCAST STATIONS—Continued

SUBPART B—COMMERCIAL FM BROADCAST STATIONS—Continued

SUBPART B—COMMERCIAL FM BROADCAST STATIONS—Continued

SUBPART C—NONCOMMERCIAL EDUCATIONAL FM BROADCAST STATIONS

SUBPART C—NONCOMMERCIAL EDUCATIONAL FM BROADCAST STATIONS—Continued

SUBPART C—NONCOMMERCIAL EDUCATIONAL FM BROADCAST STATIONS—Continued

SUBPART E—TV BROADCAST STATIONS

SUBPART E—TV BROADCAST STATIONS—Continued

SUBPART E—TV BROADCAST STATIONS—Continued

SUBPART E—TV BROADCAST STATIONS—Continued

SUBPART F—INTERNATIONAL BROADCAST STATIONS

SUBPART F—INTERNATIONAL BROADCAST STATIONS—Continued

SUBPART G—EMERGENCY BROADCAST SYSTEM (EBS)

[FR Doc. 78-20855 Filed 7-27-78; 8:45 am]

[6712-01]

[BC Docket No. 78-103; FCC 78-503]

PART 73—RADIO BROADCAST SERVICES

PART 76—CABLE TELEVISION SERVICE

Broadcasts and Cablecasts by Legally Qualified Candidates for Public Office

AGENCY: Federal Communications Commission.

ACTION: Final rules.

SUMMARY: The FCC is amending its rules on political broadcasting and cablecasting to clarify them and resolve uncertainties in their application; also, to make certain paragraphs fully interpretative of applicable sections of the Communications Act as amended by Congress in 1972, 1974, and 1976. We believe our action will make it much easier for broadcast licensees, cable television system operators, and political candidates to understand the law in this area.

EFFECTIVE DATE: August 28, 1978.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

William B. Ray, Broadcast Bureau, 202-632-5414, this is not a toll-free telephone number.

In the matter of amendment of parts 73 and 76 of the Commission's rules relating to broadcasts and cablecasts by legally qualified candidates for public office, BC docket No. 78-103, FCC 78-503; *Report and order* (43 FR 13402).

Adopted: July 12, 1978.

Released: July 27, 1978.

1. The Commission has before it for consideration the Notice of Proposed Rule Making adopted March 16, 1978, and released March 24, 1978 (FCC 78-205) and comments filed in response thereto on proposed amendments to the rules relating to broadcasts and cablecasts by legally qualified candidates for public office. Additionally, the Commission considers herein certain other amendments to the political broadcasting and cablecasting rules to make them fully interpretative of section 315 of the Communications Act of 1934, as amended.

2. Timely comments on the Notice of Proposed Rule Making were filed by eight parties: American Broadcasting Co., Inc. (ABC); Belo Broadcasting Corp. (Belo); CBS, Inc.; the firm of Jorgensen, Johnson & Northrop on behalf of eight licensees (Jorgensen); National Association of Broadcasters (NAB); National Broadcasting Co., Inc. (NBC); National Radio Broadcasters Association (NRBA), and Public Broadcasting Service (PBS). After the announced closing date for comments, the National Cable Television Association (NCTA) and the National Black Media Coalition (NBMC) each filed comments on a single but different aspect of the proposed rulemaking. Despite the late filing, both comments have been considered. No reply comments were filed.

PRESENT DEFINITIONS OF CANDIDATES

3. The particular parts of the political broadcasting and cablecasting rules to which our notice was directed are those defining a "legally qualified candidate for public office" for the purposes of the Communications Act. The definitions in the present broadcast rules, which are almost identical to those in the cable television rules, are as follows:

(a) *Definitions.*—A "legally qualified candidate" means any person who has publicly announced that he is a candidate for nomination by a convention of a political party or for nomination or election in a primary, special, or general election, municipal, county, State, or national, and who meets the qualifications prescribed by the applicable laws to hold the office for which he is a candidate, so that he may be voted for by the electorate directly or by means of delegates or electors, and who either:

(1) Has qualified for a place on the ballot, or

(2) Has publicly committed himself to seeking election by the write-in method, and is eligible under the applicable law to be voted for by sticker, by writing in his name on the ballot, or other method; and makes a substantial showing that he is a bona fide candidate for nomination or office.

We were concerned about three aspects of these rules: (1) They permit write-in candidates to become legally qualified for purposes of sections 312 and 315 of the act earlier than candidates who seek to qualify for places on the ballot; (2) with respect to candidates seeking nomination by convention, caucus, or similar means other than a primary election, they specify no requirement for becoming "legally qualified" candidates for nomination

except public announcement of candidacy and eligibility to hold the office that is sought; (3) with respect to candidates seeking nomination to the offices of President or Vice President of the United States, the rules not only suffer from the deficiency set forth in (2) above, but leave unanswered the question of the number of States in which one must qualify for nomination to be considered a candidate nationwide.

PROPOSED NEW DEFINITIONS

4. In order to eliminate these problems, we proposed to adopt the following revised definition of a legally qualified candidate:

(a) *Legally qualified candidate.* (1) A legally qualified candidate for public office is any person who:

(i) Has publicly announced his or her intention to run for nomination or office;

(ii) Is qualified under the applicable local, State, or Federal law to hold the office for which he or she is a candidate; and,

(iii) Has met the qualifications set forth in either subparagraphs (2), (3), or (4), below.

(2) A person seeking election to any public office, or nomination for any public office except that of President or Vice President of the United States, by means of a primary, general, or special election, shall be considered a legally qualified candidate if, in addition to meeting the criteria set forth in subparagraph (1), above, that person:

(i) Has qualified for a place on the ballot, or

(ii) Publicly announces his or her intention to be a write-in candidate and makes a substantial showing that he or she is a bona fide candidate for nomination or office: Except, that no person shall be considered a legally qualified write-in candidate prior to the time that candidates for the same nomination or office are able, under applicable local, State, or Federal law, to qualify for a place on the ballot.

(3) A person seeking nomination to any public office, except that of President or Vice President, by means of a convention, caucus, or similar procedure, shall be considered a legally qualified candidate if, in addition to meeting the criteria set forth in subparagraph (1), above, that person makes a substantial showing that he or she is a bona fide candidate for such nomination.

(4) A person seeking nomination for the offices of President or Vice President of the United States shall be considered a legally qualified candidate in all States and territories of the United States if, in addition to meeting the criteria set forth in subparagraph (1), above,

(i) He or she, or proposed delegates on his or her behalf, have qualified for the primary or Presidental preference ballot in any State or territory of the United States, or

(ii) He or she has made a substantial showing that he or she is a bona fide candidate for such nomination.

PROPOSED CHANGES

5. The significant changes thus proposed in the new definitions may be summarized as follows:

(a) Subparagraph (2)(ii) seeks to equalize the time prior to an election in which write-in and ballot candidates may be considered legally qualified for purposes of the Communications Act;

(b) Subparagraph (3) adds the requirement that candidates seeking nomination by convention or any means other than a primary election make a "substantial showing" of bona fide candidacy, which would eliminate from the "legally qualified candidate" category those who seek equal opportunities and other statutory benefits by merely stating that they are candidates. We also requested comments on whether there should be a limit to the period in which those seeking nomination by means of a convention or similar proceeding to any office except that of President or Vice President might be considered legally qualified candidates for purposes of the act. For example, under subparagraph (3) should anyone be considered a legally qualified candidate for nomination more than a certain number of days prior to the convention or other event which will name the nominee?

(c) In subparagraph (4) we proposed to incorporate into our rules the holding in the *Pat Paulsen* case [1] that a person who has legally qualified as a candidate for a political party's nomination for President or Vice President in one State must be considered such a candidate nationwide. We also proposed to provide an alternative method of achieving nationwide candidacy status—making "a substantial showing that he or she is a bona fide candidate for such nomination."

COMMENTS ON WRITE-IN CANDIDATE RULES

6. The proposal to equalize the time during which write-in and ballot candidates may be considered legally qualified for purposes of the Communications Act was supported, either in detail or in principle, by seven of the nine parties filing comments on it. ABC, NAB, and Jorgensen supported it without reservation. Belo also endorsed it but suggested slight language changes in the proposed rule. CBS favored the concept of a time limit but stated that the laws of some States set no date before which one cannot qualify for a place on the ballot and suggested that we establish a date, perhaps 90 days before the State's final date for ballot qualification, before which no candidate can be considered legally qualified.[2] To this end, CBS suggested revisions in the "Except" clause of proposed subparagraph (2)(ii). NBC suggested that in States which have no definite opening date for filing for ballot status the time for allowing write-in candidates to become legally qualified be set as the last date, under State law, to qualify for a place on the ballot. NRBA supported the Commission's proposal but suggested that for the ake of uniformity we set our own date before which a candidate will not be considered legally qualified, rather than relying on each State to set its date. PBS and NBMC were the only ones to oppose the time limitation. PBS asserted that this is not a substantial problem, since stations have the right to determine when to make their facilities available to candidates and if a problem does exist with respect to Federal candidates under the "reasonable access" provisions of section 312(a)(7), the Commission can deal with it by setting a date on which "reasonable access" rights vest. PBS also argued that the proposed limit is unnecessary because under the present rules, if a write-in candidate "uses" broadcast facilities prior to the time a ballot candidate can qualify, the intended ballot candidate "can secure equal opportunity rights by declaring that he or she will pursue the office as a write-in candidate, if they fail to obtain ballot status * * *" Finally, PBS stated that the proposal does not defer to State laws as the commission's policies generally do in this area. PBS thinks that if State law allows a write-in candidate to qualify as a legally qualified candidate before a ballot opponent, the Commission should do likewise.

7. NBMC's opposition was based on broader grounds. It stated that write-in candidates already are at a disadvantage because they are not as well known as major party candidates, and that even if under the present rules they are able to qualify as candidates and obtain some broadcast coverage, "the result could only be to lessen the disparity between write-ins and ballot candidates." NBMC asserted that under the 1959 amendments to section 315 creating four categories of exempt "nonuses," licensees cover the major party candidates in exempt programs during an election but the write-in candidate "is not only not entitled to equal time, but may not even be able to rely on the fairness doctrine," citing *Benjamin Spock*, 44 FCC 2d 12 (1973). NBMC also quoted from the U.S. Supreme Court decision in *Williams* v. *Rhodes*, 393 U.S. 23 (1968):

> Write-ins are no substitute for a place on the ballot * * * to force a candidate to rely on write-ins is to burden him with a disability. It makes it more difficult for him to get elected and for the voters to elect him.

NBMC stated that if the rationale for the proposed rule change "is to put all candidates on an equal footing as to

[1] *Walt Disney Productions, Inc.*, 33 FCC 2d 297 (1972); aff'd, 33 FCC 2d 835 (1972); aff'd sub. nom. *Paulsen* v. *FCC*, 491 F. 2d 887 (9th Cir. 1974).

[2] In response to staff inquiry, CBS later cited five States as being among those specifying no starting date for qualifying for ballot status: Connecticut, Delaware, Michigan, Missouri, and New Jersey.

when they are legally qualified, then the major party primary dates are also unfair. Often, third-party candidates qualify after the Democratic-Republican primary. Therefore, to be consistent, no candidate should qualify until all can qualify." Like PBS, NBMC maintained that in adopting this proposal the Commission would be abandoning its policy of basing the qualifications of a candidate on the law of the State in which the election is held. NBMC asserted that the States are in a better position to determine when write-in candidates will be considered to be bona fide candidates, and that "The Commission should refrain from restricting write-in candidates' access rights where State law puts no such restriction * * *"

3. After carefully considering all of the comments on this aspect of the proposed rulemaking, we have decided not to amend the rules to limit the time in which a write-in candidate shall be considered legally qualified. We are inclined to agree with PBS that this is not a major problem. In fact, it has rarely arisen. When it does, as PBS suggests, it can be dealt with under the "reasonable access" provisions of section 312(a)(7) so far as Federal candidates are concerned. With respect to local and State candidates, licensees are under no specific statutory obligation to grant access, and they may exercise their reasonable, good faith judgment as to when to make time available. We believe that the present rules on this subject are adequate for most purposes and that the "reasonable access" requirement for Federal candidates and the exercise of licensee discretion regarding all others appear sufficient to cope with future problems in this area. If the problems become major, we shall deal with them at that time. Accordingly, we are leaving unchanged the "Definition" portions of our rules as they relate to write-in candidates.

Candidates for Nomination by Convention

9. All parties commenting on it supported the proposal in subparagraph 3 to require that persons seeking nomination by convention or caucus to an office other than the Presidency or Vice Presidency make a substantial showing that they are bona fide candidates for nomination. The parties differed as to the extent to which the Commission should define "substantial showing" rather than leaving the determination of the meaning of that term in specific cases to licensees, and whether the Commission should incorporate guidelines in its rules. ABC and Jorgensen suggested a concept similar to that approved for one write-in candidate in *Socialist Workers*, 26 FCC 2d 244 (1970), i.e., evidence of the issuance of press releases, maintenance of a campaign committee, delivering addresses to political meetings, and distribution of campaign literature. However, ABC recommended "considerable flexibility as to such elements." Belo believed it "preferable to give greater certainty to the meaning of [substantial showing] on case by case administrative interpretations than to undertake the unsuitable task of fixing that meaning by rule definition." NBC and NAB also recommended not defining the phrase in the rules or, at most, merely annexing to the rules illustrative examples of the types of activities contemplated. NBC urged that the initial determination be left to the licensee, since factual situations may vary so much, and that the Commission review the licensee's judgment only for good faith and reasonableness. However, NRBA believed that the definition should be as specific as possible and that an outline of "substantial showing" should be included in the rules rather than restricted to other FCC documents, since it says almost all broadcasters have copies of the rules but "few, if any, maintain copies of the official reports." CBS did not "object" to this provision, but urged reliance on licensee judgments in determinations under the standard. PBS stated that while the guidelines mentioned in *Socialist Workers* are helpful, "they still leave substantial areas of uncertainty * * *." It urged that the Commission make it clear that "mere nominal compliance with the four criteria mentioned [in *Socialist Workers*] are not sufficient to establish that a candidate is legally qualified * * * they should be required to establish that they have some public support for their candidacy, that their campaign committee reflects a real organization * * * that they have election headquarters and that they have addressed not only political meetings or groups in the past but that they have a reasonable schedule of such campaign efforts in the future."

10. As for setting a limit on the period during which candidates covered by subparagraph (3) may become legally qualified, ABC believed there was no practical way for the Commission to set a limit since "typically there is no local law establishing a time limit for candidacy in the non-electoral process." It and NAB both believed this problem could best be dealt with in the "reasonable access" inquiry in BC docket No. 78-102. Belo also believed that "there are practical difficulties in fixing a specific limitation * * *." It suggested that if any limit were adopted it correspond to the 45-day prenomination period prescribed by section 315 for application of the lowest-unit-charge requirement.[3] CBS suggested a cutoff date consistent with what it suggested for write-in candidate (apparently, 90 days before opening of the convention or caucus). NBC suggested 45 days before the convention as the date on which candidacy should commence for purposes of the rule. NRBA suggested that the Commission itself fix the number of days before a convention during which a candidate for nomination could become legally qualified. Jorgensen stated that candidates competing for nomination by convention for caucus normally need less widespread publicity for their candidacies "since they will be chosen not by the public at large but by a smaller number of known delegates * * *. The convention or caucus candidate will succeed or fail more as a result of his direct contacts with the delegates than as a result of broadcast publicity." For this reason, Jorgensen recommended a time limit of no more than 1 month for such candidacies. PBS made no suggestions for a pre-convention time limitation.

11. After considering the comments and reviewing our experience over the years in dealing with inquiries and complaints in this area, we have determined to adopt subparagraph (3) as set forth in the notice and to add thereto the following time limitation clause:

> Except, that no person shall be considered a legally qualified candidate for nomination by the means set forth in this subparagraph prior to 90 days before the beginning of the convention, caucus or similar procedure in which he or she seeks nomination.

We believe the "substantial showing" requirement should be applied here for the same reason that we long ago established the requirement for persons claiming to be write-in candidates; namely, to deny to those who do no more than state that they are candidates the benefits which Congress intended to accord serious candidates for public office. The absence of laws in many States setting standards for eligibility of write-in candidates and of such laws in most if not all States with respect to eligibility to seek nomination to local or State office by convention or caucus, leads us to the conclusion that we must establish some criteria for distinguishing between serious candidates and those who may be mere publicity seekers trying to take advantage of Federal laws which were enacted to assure equal opportunities to those genuinely contending for election to public office. As for the time limitation of 90 days before opening of the convention or caucus, we believe it a reasonable period for all except na-

[3] However, the lowest unit charge requirements of section 315 apply only to primary, special, and general elections, not to conventions or caucuses.

tional conventions (which are not covered in subparagraph (3)) and that adoption of a limitation representing a period twice that specified in section 315 of the act for lowest unit charges preceding a primary election will give certainty as to their rights and obligations to candidates, broadcast licensees, and cable system operators alike. We are adopting NRBA's suggestion that at least an outline of the meaning of "substantial showing" be included in the rules by adding subparagraph (5) to the "definitions" paragraph. It states the general meaning of the term and gives some examples of activities normally involved in such a showing, while stating that there may be still other activities which would contribute to such a showing.

CANDIDATES FOR PRESIDENT AND VICE PRESIDENT

12. All parties commenting on the subject opposed the proposal in subparagraph (4) to codify the ruling in *Pat Paulsen* that a person who has legally qualified as a candidate for his party's nomination for President or Vice President in one State must be considered such a candidate nationwide. Because of the complexity of the issue and the fact that the next Presidential election is 2 years away, NRBA suggested allowing more time for considering this question and separating it from the current rulemaking. PBS also urged that this question be considered in a separate future proceeding and that the Commission at that time also consider the definition of a Presidential candidate for purposes of the general election. It believed that the two definitions are closely related and the definition for purposes of the general election is a most important one. NAB and NBC likewise raised the question of defining Presidential candidacy for purposes of the general election.

13. With respect to the general election question, proposed subparagraph (2) already defines a legally qualified candidate in all general elections. To make this fact more clear, we have inserted language to the effect that the provisions of subparagraph (2) apply to general elections to the Presidency and Vice Presidency, although not to nomination for these two offices. There remains, however, the question of whether a person who is a legally qualified candidate in one, two, three, or any number of States and territories less than all of them, is to be accorded nationwide status as a Presidential candidate in the general election for purposes of equal opportunities, freedom from censorship, reasonable access, etc. This question has rarely if ever been raised concerning a general election for President and Vice President. We agree, however, that it should be settled and we shall consider it along with the *Pat Paulsen* issue. In fact, we see no reason why the requirements for gaining nationwide status as a legally qualified candidate for election to the Presidency should be different from those for achieving similar status as a legally qualified candidate for nomination for that office.

14. Although all commenting parties agreed that the 1-State candidacy illustrated in the *Paulsen* ruling was insufficient to gain nationwide status as a candidate, their recommendations ranged all the way from "more than 1" State to as many as 20 States in which the candidate would be required to become legally qualified or make a substantial showing before being considered legally qualified nationwide. NAB pointed out that some States have minimal requirements for voter signatures in order to get on a primary ballot. It urged that "localized political activities" not entitle a person to "automatic nationwide" status, and that it is "an unfair imposition upon both the broadcaster and the electorate to entitle frivolous candidated [to] 'equal time' and access rights." In urging a more extensive showing by a candidate, CBS stated that, according to its information, there were 30 Presidential primaries or preference ballots in 1976 and many persons were on the ballot in only 1 Democratic or Republican primary, including Rick Lowenherz, Stanley Arnold, Shorty Price, Billy Joe Clegg, Bernard Schecter, Lar Daly, Frank Ahern, Abram Eisenman, George Roden, H. R. H. Fifi Rockefeller, Tommy Klein, Jesse Gray, John H. Gonas, Henry Lomento, and Floyd Lunger. Under the *Paulsen* ruling, each was entitled to reasonable access and to opportunities equal to those accorded the Democratic and Republican Presidential candidates in all 50 States, the District of Columbia, and the territories.

15. NBC suggests that we require a candidate to qualify for the ballot or make a substantial showing of bona fide candidacy in at least 20 States in order to achieve nationwide recognition. It points out that under the 1974 revisions of the Federal Election Campaign Act, candidates for nomination to the Presidency are required to make a showing of financial support in at least 20 States in order to be considered candidates for purposes of eligibility for Federal campaign funds. Pub. L. 93-442, 92d Cong., 1st sess., 88 Stat. 1263. As for the general Presidential election, NBC states that in 1976, 15 candidates were on the ballot in at least 1 State or the District of Columbia; 10 were on the ballot in at least 10 States.

16. PBS urges that we require that candidates for Presidential or Vice Presidential nomination "demonstrate that they are seeking the nomination on a meaningful, realistic and nationwide basis before according them national rights under section 315(a) and section 312(a)(7)* * *." PBS favors a requirement "that he or she is on the ballot in primaries or make a substantial showing of a bona fide candidacy in at least 10-States." It takes the 10-State standard from the Presidential Election Campaign Fund Act, 26 U.S.C. §§ 9001, et seq., which requires a candidate in the general election, other than a major party candidate, to demonstrate that he or she is on the ballot in at least 10-States to be eligible for matching Federal funds. 26 U.S.C. § 9002. PBS says "Congress established that standard as a reasonable measure of whether a candidate has national support* * *." PBS states that under its proposed 10-States standard, 8 of the candidates in 1976 for Democratic nomination would have been considered national candidates on the basis of their ballot candidacies and 4 more who were on the ballot in 6 or more States might well have qualified under the "substantial showing" standard.

17. Although NAB stated that some States "have very minimal requirements for voter signatures, so that qualifying as a candidate is a relatively easy task," none of the parties furnished specific information on this subject. Inquiry by our staff into the requirements of a sampling of States indicates that it is easy to attain ballot status in Presidential primaries in some States, although others make the task much more difficult. In many States, the Secretary of State or a board of State officials selects ballot candidates on the basis of their being "generally advocated and nationally recognized as candidates." Persons not so chosen may get on the ballot by petition or, in at least 1 State, by merely filing an announcement of candidacy. The minimum number of signatures required on petitions ranges from an apparent low of 200 to a percentage of the total State vote for Governor or President in the last general election.

18. After considering the comments and our own experience and research we have decided to overturn one part of the *Paulsen* ruling and to require that a candidate for either nomination or election to the Presidency gain ballot status or make a substantial showing of bona fide candidacy in at least 10 States in order to achieve nationwide status as a candidate so as to entitle him or her to such rights as "reasonable access," "equal opportunities," and "lowest unit charge" in all States, territories, and the District of Columbia, regardless of whether he or she is on the ballot or has made a substantial showing of candidacy in a particular State. Persons qualifying in

fewer than 10 States still will be accorded all of their section 312(a) and 315 rights in the States in which they are on the ballot or have made a substantial showing of bona fide candidacy. We believe this is a reasonable standard for determining national candidacy. According to PBS, it would have permitted between 8 and 14 persons to achieve nationwide candidate status in the 1976 Democratic nomination campaign. According to NBC, 10 candidates were on the ballot in 10 or more States in the 1976 general Presidential election and 3 more who were on the ballot in from 6 to 9 States might also have qualified under the "substantial showing" requirement.

19. It should be noted that the ruling in *Paulsen* that he should be considered a legally qualified candidate for Presidential nomination in all States because he had qualified as such in New Hampshire was only one part of a ruling which was principally concerned with the definition of a "use" by a candidate, and that neither the petition for Commission review of the staff ruling nor the appeal to the courts was based on the part of the decision we are overruling here. Thus, neither the Commission nor any Federal appellate court has ruled specifically on the point at issue in subparagraph (4). The requirement that a candidate gain ballot status or make a substantial showing in 10 States in order to gain candidate status in all States does not mean that a candidate failing to reach the 10-State minimum is automatically denied broadcast time in States where he has not qualified. Broadcasters in these States may give or sell time to such a candidate if they so desire. Our new requirement does mean that stations are not required to grant equal opportunities or reasonable access to candidates outside the areas in which they have qualified unless they have met the 10-State test. In some cases, such as *Paulsen*, it may even be to the advantage of the "one-State" Presidential candidate not to be considered a legally qualified candidate nationwide. Regardless of that consideration, we believe it unreasonable and contrary to the intent of Congress to hold, for example, that because a person has obtained a ballot position in one State merely filing an announcement of candidacy or obtaining 200 signatures on a petition, he is entitled to all of the rights of a candidate for Presidential nomination in all other States.

Other Rule Amendments

20. In addition to the foregoing amendments, additional ones are necessary to bring other parts of our rules into conformity with amendments to the Communications Act adopted by Congress in recent years. Since the amendments are interpretative of statute or, in one other instance, merely serve to clarify requirements already inherent in the rule, notice of proposed rulemaking need not be published nor comments solicited. 5 U.S.C. § 553(b) (A) and (B).

21. In 1972 Congress adopted the Federal Election Campaign Act of 1971 (FECA), amending section 315 of the Communications Act in order, among other things, to limit the charges made for use of broadcast stations and cable systems by political candidates during certain periods. The Federal Election Campaign Act was amended in 1974 and again in 1976 but the above provision relating to charges made to candidates was not affected.

22. The Commission issued a public notice on March 16, 1972, 37 FR 5796, 34 FCC 2d 510, interpreting FECA as it amended the Communications Act and another public notice on June 10, 1975, 40 FR 28664, 55 FCC 2d 279, on the effect of the 1974 amendments. The 1972 public notice called attention to the fact that the guidelines set forth therein for compliance with the Federal Election Campaign Act were inconsistent with some parts of the Commission's existing rules on political broadcasts and cablecasts. The notice stated that "such inconsistencies are to be resolved in favor of the guidelines" and stated that the Commission would amend the rules in the future to conform to the guidelines. Some of the guidelines in the 1972 public notice were made obsolete by the 1974 amendments to FECA. It is essential to amend our political broadcasting and cablecasting rules without further delay to make them consistent with present statutory provisions.

Broadcast Rules

23. For the reasons set forth above, we are amending our rules on political broadcasting as set forth in appendix A. In line with our present policy of consolidating the rules governing operation of the different broadcast services as they apply to the same subject, we are substituting for present sections 73.120, 73.290, 73.590, and 73.657 a consolidated section to be designated section 73.1940.

24. The specific changes in the broadcast rules are as follows: Par. (a) "Definitions" is amended as explained above and set forth fully in appendix A. Par. (b) "General requirements" is deleted, since it merely paraphrases section 315(a) of the act as it read before the 1972 and 1974 amendments. Former par. (c)(1) "Rates and practices" becomes new par. (b) under the heading "Charges for use to stations." Par. (b) will consolidate references to rates charged to candidates, including the provisions of former par. (c)(1) and the "lowest unit charge" and "comparable charge" provisions of section 315(b) of the act as amended. Former par. (c)(2) becomes new par. (c) and is titled "Discrimination between candidates." Par. (d) "Records, inspection" is being revised to clarify its meaning. The present language of the first sentence of the rule refers to "requests" for broadcast time made by or on behalf of candidates for public office. It also refers to "the charges made, *if any*, if the request is granted." [Emphasis added.] Thus, the sentence indicates that the rule refers to both paid and free time. We believe that additional language should be added to make clear the fact that gifts of political time, whether or not "requested" by candidates, must be entered in the political file and that all requests and time provided by the licensee without charge should be entered as soon as possible during the entire campaign. We believe such clarification is consistent with the inherent requirements of the rule and the purposes for which it was adopted and later amended. This is particularly evident in light of the relationship of this paragraph to par. (e) the "7-day rule" since a candidate may be unable to make his request for equal opportunities within the specified 7-day period unless he can learn by inspection of station political files what time has been either sold or provided free to opposing candidates, regardless of whether they make "requests" for it. It is equally evident that unless all such gifts or sales of time are entered in the political file as soon as possible throughout the campaign, opposing candidates may not be able to file their requests for equal opportunity within the required period. Accordingly, we are revising the language of par. (d) to clarify its requirements and resolve any uncertainties as to its meaning that may have existed previously. Since the revisions are only of this nature, publication of a notice of proposed rulemaking is unnecessary. See 5 U.S.C. 553(b)(B). In order to eliminate any uncertainty as to the possible scope of the rule we also should explain that it refers to time used by supporters of candidates, as well as that used by candidates themselves. Pars. (e) and (f) of the present rules remain unchanged.

Origination Cablecast Rules

25. The National Cable Television Association's comments did not address the specific rule changes proposed in our notice, and we believe that this is not the appropriate proceeding in which to rule on the questions raised therein regarding the Commission's authority to adopt rules relating to cablecasts by political candidates.

26. For the same reasons set forth above for amending our rules on broadcasts by candidates for public office, we are making similar amendments to our rules on origination cablecasts by candidates for public office, as set forth in appendix B hereto.

27. Authority for the adoption of the amendments herein is contained in section 4(i) of the Communications Act of 1934, as amended (47 U.S.C. 154(i)).

28. Accordingly, *it is ordered*, That, effective August 28, 1978, §§ 73.120, 73.290, 73.590, and 73.657 are amended as set forth below, and new § 73.1940 as set forth below is adopted. Further, *it is ordered*, That, effective August 28, 1978, §§ 76.5(y) and 76.205 are amended as set forth below.

29. *It is further ordered*, That, this proceeding is terminated.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

Part 73 of Chapter 1, Title 47, Code of Federal Regulations, is amended as follows:

1. Section 73.120 is amended to read as follows:

§ 73.120. Broadcasts by candidates for public office.

See § 73.1940.

2. Section 73.290 is amended to read as follows:

§ 73.290. Broadcasts by candidates for public office.

See § 73.1940.

3. Section 73.590 is amended to read as follows:

§ 73.590. Broadcasts by candidates for public office.

See § 73.1940.

4. Section 73.657 is amended to read as follows:

§ 73.657. Broadcasts by candidates for public office.

See § 73.1940.

5. New section 73.1940 is added as follows:

§ 73.1940. Broadcasts by candidates for public office.

(a) *Definitions.* (1) A legally qualified candidate for public office is any person who

(i) Has publicly announced his or her intention to run for nomination or office;

(ii) Is qualified under the applicable local, State or Federal law to hold the office for which he or she is a candidate; and

(iii) Has met the qualifications set forth in either subparagraphs (2), (3), or (4), below.

(2) A person seeking election to any public office including that of President or Vice President of the United States, or nomination for any public office except that of President or Vice President, by means of a primary, general or special election, shall be considered a legally qualified candidate if, in addition to meeting the criteria set forth in subparagraph (1) above, that person:

(i) Has qualified for a place on the ballot, or

(ii) Has publicly committed himself or herself to seeking election by the write-in method and is eligible under applicable law to be voted for by sticker, by writing in his or her name on the ballot or by other method, and makes a substantial showing that he or she is a bona fide candidate for nomination or office.

Persons seeking election to the office of President or Vice President of the United States shall, for the purposes of the Communications Act and the rules thereunder, be considered legally qualified candidates only in those States or territories (or the District of Columbia) in which they have met the requirements set forth in paragraph (a) (1) and (2) of this rule: Except, that any such person who has met the requirements set forth in paragraph (a) (1) and (2) in at least 10 States (or 9 and the District of Columbia) shall be considered a legally qualified candidate for election in all States, territories, and the District of Columbia for purposes of this Act.

(3) A person seeking nomination to any public office, except that of President or Vice President of the United States, by means of a convention, caucus or similar procedure, shall be considered a legally qualified candidate if, in addition to meeting the requirements set forth in paragraph (a)(1) above, that person makes a substantial showing that he or she is a bona fide candidate for such nomination: Except, that no person shall be considered a legally qualified candidate for nomination by the means set forth in this paragraph prior to 90 days before the beginning of the convention, caucus or similar procedure in which he or she seeks nomination.

(4) A person seeking nomination for the office of President or Vice President of the United States shall, for the purposes of the Communications Act and the rules thereunder, be considered a legally qualified candidate only in those States or territories (or the District of Columbia) in which, in addition to meeting the requirements set forth in paragraph (a)(1) above,

(i) He or she, or proposed delegates on his or her behalf, have qualified for the primary or Presidential preference ballot in that State, territory or the District of Columbia, or

(ii) He or she has made a substantial showing of bona fide candidacy for such nomination in that State, territory or the District of Columbia; Except, that any such person meeting the requirements set forth in paragraph (a) (1) and (4) in at least 10 States (or nine and the District of Columbia) shall be considered a legally qualified candidate for nomination in all States, territories and the District of Columbia for purposes of this act.

(5) The term "substantial showing" of bona fide candidacy as used in paragraphs (a) (2), (3), and (4) above means evidence that the person claiming to be a candidate has engaged to a substantial degree in activities commonly associated with political campaigning. Such activities normally would include making campaign speeches, distributing campaign literature, issuing press releases, maintaining a campaign committee, and establishing campaign headquarters (even though the headquarters in some instances might be the residence of the candidate or his campaign manager). Not all of the listed activities are necessarily required in each case to demonstrate a substantial showing, and there may be activities not listed herein which would contribute to such a showing.

(b) *Charges for use of stations.* The charges, if any, made for the use of any broadcasting station by any person who is a legally qualified candidate for any public office in connection with his campaign for nomination for election, or election, to such office shall not exceed

(1) during the 45 days preceding the date of a primary or primary runoff election and during the 60 days preceding the date of a general or special election in which such person is a candidate, the lowest unit charge of the station for the same class and amount of time for the same period, and

(2) at any other time the charges made for comparable use of such station by other users thereof. The rates, if any, charged all such candidates for the same office shall be uniform and shall not be rebated by any means direct or indirect. A candidate shall be charged no more than the rate the station would charge if the candidate were a commercial advertiser whose advertising was directed to promoting its business within the same area as that encompassed by the particular office for which such person is a candidate. All discount privileges otherwise offered by a station to commercial advertisers shall be available upon equal terms to all candidates for public office.

(3) This paragraph shall not apply to any station which is not licensed for commercial operation.

(c) *Discrimination between candidates.* In making time available to candidates for public office, no licensee shall make any discrimination between candidates in practices, regulations, facilities, or services for or in connection with the service rendered pursuant to this part, or make or give any preference to any candidate for public office or subject any such candidate to any prejudice or disadvantage; nor shall any licensee make any contract or other agreement which shall have the effect of permitting any legally qualified candidate for any public office to broadcast to the exclusion of other legally qualified candidates for the same public office.

(d) *Records, inspection.* Every licensee shall keep and permit public inspection of a complete record (political file) of all requests for broadcast time made by or on behalf of candidates for public office, together with an appropriate notation showing the disposition made by the licensee of such requests, and the charges made, if any, if the request is granted. When free time is provided for use by or on behalf of such candidates, a record of the free time provided shall be placed in the political file. All records required by this paragraph shall be placed in the political file as soon as possible and shall be retained for a period of 2 years. See sections 1.526-27 of this chapter.

(e) *Time of request.* A request for equal opportunities must be submitted to the licensee within 1 week of the day on which the first prior use, giving rise to the right of equal opportunities, occurred: *Provided, however,* That where the person was not a candidate at the time of such first prior use, he shall submit his request within 1 week of the first subsequent use after he has become a legally qualified candidate for the office in question.

(f) *Burden of proof.* A candidate requesting equal opportunities of the licensee, or complaining of noncompliance to the Commission shall have the burden of proving that he and his opponent are legally qualified candidates for the same public office.

Part 76 of Chapter I, Title 47, Code of Federal Regulations, is amended as follows:

Section 76.5(y) is amended to read as follows:

§ 76.5 Definitions

* * * * *

(y) *Legally qualified candidate.* (1) Any person who

(i) Has publicly announced his or her intention to run for nomination or office;

(ii) Is qualified under the applicable local, State or Federal law to hold the office for which he or she is a candidate; and,

(iii) Has met the qualifications set forth in either subparagraphs (2), (3) or (4), below.

(2) A person seeking election to any public office including that of President or Vice President of the United States, or nomination for any public office except that of President or Vice President, by means of a primary, general or special election, shall be considered a legally qualified candidate if, in addition to meeting the criteria set forth in subparagraph (1) above, that person:

(i) Has qualified for a place on the ballot, or

(ii) Has publicly committed himself or herself to seeking election by the write-in method and is eligible under applicable law to be voted for by sticker, by writing in his or her name on the ballot or by other method, and makes a substantial showing that he or she is a bona fide candidate for nomination or office.

Persons seeking election to the office of President or Vice President of the United States shall, for the purposes of the Communications Act and the rules thereunder, be considered legally qualified candidates only in those States or territories (or the District of Columbia) in which they have met the requirements set forth in paragraphs (y) (1) and (2) of this rule; Except, That any such person who has met the requirements set forth in paragraph (y) (1) and (2) in at least 10 States (or nine and the District of Columbia) shall be considered a legally qualified candidate for election in all States, territories and the District of Columbia for purposes of this Act.

(3) A person seeking nomination to any public office except that of President or Vice President of the United States, by means of a convention, caucus or similar procedure, shall be considered a legally qualified candidate if, in addition to meeting the requirements set forth in paragraph (y)(1) above, that person makes a substantial showing that he or she is a bona fide candidate for such nomination: Except, That no person shall be considered a legally qualified candidate for nomination by the means set forth in this paragraph prior to 90 days before the beginning of the convention, caucus or similar procedure in which he or she seeks nomination.

(4) A person seeking nomination for the office of President or Vice President of the United States shall, for the purposes of the Communications Act and the rules thereunder, be considered a legally qualified candidate only in those States or territories (or the District of Columbia) in which, in addition to meeting the requirements set forth in paragraph (y)(1), above.

(i) He or she, or proposed delegates on his or her behalf, have qualified for the primary or Presidential preference ballot in that State, territory or the District of Columbia, or

(ii) He or she has made a substantial showing of bona fide candidacy for such nomination in that State, territory or the District of Columbia. Except, That such person meeting the requirements set forth in paragraph (y) (1) and (4) in at least 10 States (or nine and the District of Columbia) shall be considered a legally qualified candidate for nomination in all States, territories and the District of Columbia for purposes of this Act.

(5) The term "substantial showing" of bona fide candidacy as used in paragraphs (y) (2), (3) and (4) above means evidence that the person claiming to be a candidate has engaged to a substantial degree in activities commonly associated with political campaigning. Such activities normally would include making campaign speeches, distributing campaign literature, issuing press releases, maintaining a campaign committee, and establishing campaign headquarters (even though the headquarters in some instances might be the residence of the candidate or his campaign manager). Not all of the listed activities are necessarily required in each case to demonstrate a substantial showing, and there may be activities not listed herein which would contribute to such a showing.

* * * * *

Section 76.205 is amended to read as follows:

§ 76.205. Origination cablecasts by candidates for public office.

(a) *General requirements.* If a cable television system operator shall permit any legally qualified candidate for public office to use the system's origination channel(s) and facilities therefor, the system operator shall afford equal opportunities to all other such candidates for that office: *Provided, however,* That such cable television system operator shall have no power of censorship over the material cablecast by any such candidate: *And provided further,* That an appearance by a legally qualified candidate on any:

(1) Bona fide newscast,

(2) Bona fide interview,

(3) Bona fide news documentary (if the appearance of the candidate is incidental to the presentation of the subject or subjects covered by the news documentary), or

(4) On-the-spot coverage of bona fide news events (including but not limited to political conventions and activities incidental thereto), shall not be deemed to be use of the facilities of the system within the meaning of this paragraph.

NOTE.—The Fairness Doctrine is applicable to these exempt categories. See § 76.209.

(b) *Charges for use of cable systems.* The charges, if any, made for the use of any cable television system by any person who is a legally qualified candidate for any public office in connection with his campaign for nomination for election, or election, to such office shall not exceed:

(1) During the 45 days preceding the date of a primary or primary runoff election and during the 60 days preceding the date of a general or special election in which such person is a candidate, the lowest unit charge of the cable television system for the same class and amount of time for the same period, and

(2) At any other time, the charges made for comparable use of such system by other users thereof. The rates, if any, charged all such candidates for the same office shall be uniform and shall not be rebated by any means direct or indirect. A candidate shall be charged no more than the rate the cable television system would charge if the candidate were a commercial advertiser whose advertising was directed to promoting its business within the same area as that encompassed by the particular office for which such person is a candidate. All discount privileges otherwise offered by a cable television system to commercial advertisers shall be available upon equal terms to candidates for public office.

(c) *Discrimination between candidates.* In making time available to candidates for public office, no cable television system operator shall make any discrimination between candidates in practices, regulations, facilities, or services for or in connection with the service rendered pursuant to this part, or make or give any preference to any candidate for public office or subject any such candidate to any prejudice or disadvantage; nor shall any cable television system operator make any contract or other agreement which shall have the effect of permitting any legally qualified candidate for any public office to cablecast to the exclusion of other legally qualified candidates for the same public office.

(d) *Records, inspection.* Every cable television system operator shall keep and permit public inspection of a complete record (political file) of all requests for cablecast time made by or on behalf of candidates for public office, together with an appropriate notation showing the disposition made by the cable television system operator of such requests, and the charges made, if any, if the request is granted. When free time is provided for use by or on behalf of such candidates, a record of the free time provided shall be placed in the political file. All records required by this paragraph shall be placed in the political file as soon as possible and shall be retained for a period of 2 years.

(e) *Time of request.* A request for equal opportunities for use of the origination channel(s) must be submitted to the cable television system operator within one (1) week of the day on which the first prior use, giving rise to the right of equal opportunities occurred: *Provided, however,* That where a person was not a candidate at the time of such first prior use, he shall submit his request within one (1) week of the first subsequent use after he has become a legally qualified candidate for the office in question.

(f) *Burden of proof.* A candidate requesting such equal opportunities of the cable television system operator, or complaining of noncompliance to the Commission, shall have the burden of proving that he and his opponent are legally qualified candidates for the same public office.

[FR Doc. 78-20854 Filed 7-27-78; 8:45 am]

[6712-01]

[Docket No. 21255; FCC 78-483]

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

Permitting Aircraft To Use Maritime Mobile VHF Frequencies Under Certain Conditions

AGENCY: Federal Communications Commission.

ACTION: Report and order amending the rules.

SUMMARY: The Commission's rules are being amended to permit aircraft stations to use certain VHF maritime mobile frequencies. These changes are a result of changes made in the international radio regulations at the 1974 World Maritime Administrative Radio

Conference. This action will make the Commission's rules consistent with the international radio regulations.

EFFECTIVE DATE: August 28, 1978.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Kemp J. Beaty, Safety and Special Radio Services Bureau, 202-632-7197.

SUPPLEMENTARY INFORMATION:

In the matter of amendment of the rules to permit aircraft to use maritime mobile VHF frequencies under certain conditions, docket No. 21255, FCC 78-488; report and order (proceeding terminated) (42 FR 28164).

Adopted: July 12, 1978.

Released: July 26, 1978.

By the Commission.

1. A notice of proposed rulemaking in the above-captioned matter was released May 27, 1977, and published in the FEDERAL REGISTER on June 2, 1977 at 42 F.R. 28164. The specified time for filing comments and reply comments has passed.

2. The proposed rule amendment was designed to incorporate into the Commission's rules certain changes to the international radio regulations which were adopted at the 1974 Maritime World Administrative Radio Conference (WARC). Those changes would permit aircraft stations to use maritime frequencies in the VHF band 156-158 MHz under certain limited circumstances.

3. Comments were filed by the Lorain Electronics Corp. (Lorain), the Helicopter Association of America (HAA), the U.S. Coast Guard (USCG), the North Pacific Marine Radio Council (NPMRC), the Pacific Towboat & Salvage Co. (PT&S), Northwest Instrument (Northwest), the Lake Carriers Association (LCA), the County of Los Angeles Department of Communications (Los Angeles), the Central Committee on Telecommunications of the American Petroleum Institute (API), the American Institute of Merchant Shipping (AIMS), the St. Philip Towing & Transportation Co. (St. Philip), the Southern California Marine Radio Council itself and its San Diego and Point Conception Divisions separately (SCMRC). There were no reply comments, HAA, Northwest, Los Angeles and St. Philip generally favored the proposal. Lorain, USCG, NPMRC, PT&S, LCA, API, AIMS, and SCMRC were opposed to certain of the changes proposed.

4. Lorain and LCA were concerned about interference to marine VHF public correspondence channels if aircraft were permitted access to these frequencies, especially in an automated system as exists on the Great Lakes. Possible interference to United States Coast Guard VTS communications on channels 11, 12 and 14 were cited by the USCG and API. USCG suggested a further condition of prohibiting use by aircraft within 60 miles of a VTS area. API felt that aircraft should not be authorized the use of VTS frequencies. NPMRC, Northwest, API and AIMS all commented about the difficulty of enforcing the 1,000-foot altitude limitation. NPMRC, PT&S and API also pointed out that an aircraft at 1,000 feet with a 5-watt transmitter would have a substantially greater coverage area than a vessel with a 25-watt transmitter. SCMRC and PT&S felt aircraft should be prohibited from using the "already overcrowded" port operations frequencies. Both commentors point out that a "loss of communications when moving and docking a supertanker in a crowded port area could result in serious collision causing severe damage to property and the environment along with the attendant possible loss of life". NPMRC, Northwest, API and SCMRC all said if aircraft were permitted the use of marine VHF frequencies they should be limited to a few specific intership frequencies. NPMRC and SCMRC were of the opinion that aircraft should not be licensed "automatically" on these frequencies but should have to submit a detailed "showing of need". In addition SCMRC felt aircraft should be required to monitor channel 16 just as a vessel is required to do so.

5. St. Philip in their comments supporting the proposal requests that the altitude restriction be raised to 2,500 feet and transmitter power increased to 25 watts. Los Angeles favors the proposal because of their large area of coastline but they also request that aircraft be permitted the use of the U.S. Coast Guard liaison frequency 157.1 MHz to allow communications between private aircraft and the U.S.

Coast Guard for search and rescue purposes. Northwest supports the proposal but, as indicated in paragraph 4, feels that a few specific frequencies should be assigned for this use. HAA submitted their comments indicating support for our proposal.

6. In view of the comments received it appears that the Commission's proposal is too broad. The concerns of many of the commentors regarding the interference potential of aircraft operating on these frequencies are valid. However, only a small number of aircraft will be authorized the use of these frequencies and particular types of aircraft, mainly seaplanes, have a legitimate need for communications on marine VHF frequencies. Furthermore, aircraft communications are restricted to those in support of maritime activities in which maritime stations are primarily involved.

7. St. Philip's request that the altitude restrictions be raised and the maximum power be increased cannot be accommodated. To do so would intolerably increase interference to maritime communications as well as violate the international radio regulations which limits aircraft use to 5 watts power and 1,000 feet of altitude. Los Angeles provides no information to support their request to include 157.1 MHz as one of the frequencies aircraft may use. Further, this is a U.S. Coast Guard frequency and its use by non-Government entities, other than vessels, has been authorized only after careful examination and coordination with the Coast Guard. Since the Coast Guard has made no request to have this frequency included for use by non-Government aircraft we do not feel it is appropriate to permit this usage. SCMRC's suggestion that aircraft be required to monitor 156.8 MHz (channel 16) does not contain any information that such a requirement would contribute to the safety system's operation. Accordingly, we are not adopting any of the requested changes discussed in this paragraph.

8. Our original proposal, if adopted, would permit aircraft to use all maritime mobile VHF frequencies except for four specific frequencies. For the reasons raised in the comments and discussed herein, we are modifying our proposal as follows:

a. The use of channel 6 (156.3 MHz), the intership safety frequency, will be limited to use by aircraft for safety communications only.

b. Aircraft will not be authorized the use of VHF public correspondence or port operations frequencies as these frequencies are less tolerable to interference, already overcrowded with maritime usage, and public correspondence frequencies normally would not be frequencies used in direct support of maritime activities. In addition, interference by an aircraft using a port operations frequency could disrupt communications at a critical time during the movement or docking of a vessel. This could create a situation that could lead to widespread damage, pollution and the possible loss of life.

c. Aircraft will be permitted the use of channel 67 (156.375 MHz), 8 (156.4 MHz), 68 (156.425 MHz), 9 (156.45 MHz), 70 (156.525 MHz), 72 (156.625 MHz), and 18 (156.9 MHz) as working frequencies.

Under this modification it is anticipated that aircraft and vessels will be equipped and operational procedures established so that most contacts will be on the appropriate working frequencies. In those cases where an aircraft cannot raise the vessel on the working frequency; channel 16 (156.8 MHz) which will be monitored by the vessel may be used to establish initial contact and a selection of a working frequency.

9. Accordingly, *it is ordered*, That, pursuant to the authority contained in sections 4(i) and 303 (c), (h) and (r) of the Communications Act of 1934, as amended, the Commission's rules are amended, as set forth below, effective August 28, 1978.

10. *It is further ordered*, That this proceeding is terminated.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

Part 83 of chapter I of title 47 of the Code of Federal Regulations is amended as follows:

Part 83—Stations on Shipboard in the Maritime Services

1. In section 83.351, paragraph (a) is amended by adding numeral "76" to the table, and paragraph (b) is amended by adding a new footnote, numbered 76, to read as follows:

§ 83.351 Frequencies available.

(a) • • •

Carrier frequency (MHz)	Conditions of use	
	Section	Limitations
• • •	• • •	•
156.300	83.106, 83.359	34, 40, 44, 76.
• • •	• • •	•
156.375	83.359	40, 49, 76.
156.400	83.359	40, 49, 76.
156.425	83.359	40, 41, 56, 54, 76.
156.450	83.359	40, 41, 49, 50, 76.
• • •	• • •	•
156.525	83.359, 83.361	40, 50, 52, 76.
• • •	• • •	•
156.625	83.359	40, 50, 52, 76.
• • •	• • •	•
156.800	83.106, 83.233, 83.359	40, 41, 43, 76.
• • •	• • •	•
156.900	83.359	40, 41, 49, 76.
• • •	• • •	•

(b) • • •

(76) These frequencies may be used by aircraft subject to the limitations on such usage set forth in section 83.359 of this part.

2. Section 83.359 is amended as follows:

§ 83.359 Frequencies in the band 156–162 MHz available for assignment.

(a) The frequencies in the following table are available for assignment to stations as indicated.

• • • • •

(b) In addition to the limitations contained in § 83.351 (b)(34) and (b)(55), aircraft may use certain of these frequencies under the following circumstances and subject to the following limitations:

(1) The altitude of aircraft stations shall not exceed 1,000 feet, except for reconnaissance aircraft participating in icebreaking operations where an altitude of 1,500 feet is allowed;

(2) The mean power of aircraft station transmitters shall not exceed five watts; however, a power of one watt or less shall be used to the maximum extent possible;

(3) Aircraft stations shall use intership frequencies only;

(4) Communications of an aircraft station shall be brief and limited to operations in which stations of the maritime mobile service are primarily involved and where direct communications between the aircraft and the ship or coast station is required;

(5) The frequency 156.3 MHz may be used by aircraft stations for safety purposes only and the frequency 156.8 MHz may be used for distress, safety and calling purposes only.

[FR Doc. 78-20853 Filed 7-27-78; 8:45 am]

[4310-55]

Title 50—Wildlife and Fisheries

CHAPTER I—U.S. FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

Listing and Protecting Loggerhead Sea Turtles as "Threatened Species" and Populations of Green and Olive Ridley Sea Turtles as Threatened Species or "Endangered Species"

CROSS REFERENCE: For a regulation on the above entitled matter, issued jointly by the Department of Commerce/National Oceanic and Atmospheric Administration/National Marine Fisheries Service and the Department of the Interior/Fish and Wildlife Service, see FR Doc. 78-21047 in the rules and regulations section of this issue of the FEDERAL REGISTER.

[3510-22]
[4310-55]

CHAPTER I—U.S. FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

CHAPTER II—NATIONAL MARINE FISHERIES SERVICE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

Listing and Protecting Loggerhead Sea Turtles as "Threatened Species" and Populations of Green and Olive Ridley Sea Turtles as Threatened Species or "Endangered Species"

AGENCIES: National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce, and U.S. Fish and Wildlife Service, Department of the Interior.

ACTION: Final rule.

SUMMARY: The National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (FWS), Department of the Interior, determine the loggerhead sea turtle (*Caretta caretta*) to be a threatened species under the Endangered Species Act of 1973 (the Act). In addition, the green sea turtle (*Chelonia mydas*, which includes the subspecies *C. mydas agassizii*, and *C. mydas carrinegra*) and the olive (Pacific) ridley sea turtle (*Lepidochelys olivacea*) (hereinafter referred to as the Pacific ridley) are determined to be threatened species under the Act except that the Florida and Mexican Pacific coast breeding populations of green sea turtles and the Mexican Pacific coast breeding population of Pacific ridley sea turtles are determined to be endangered species. This rulemaking also contains protective regulations for threatened species of sea turtles. The primary differences as a result of listing these populations as endangered instead of threatened are that incidental catch by commercial fishermen is prohibited and there are no exceptions for zoological exhibition or educational purposes, taking of injured, dead, or stranded specimens, taking of species under State-Federal Cooperative Agreements for research or conservation, or subsistence taking of green turtles in the water by residents of certain U.S. territories in the Pacific.

DATES: This rule becomes effective 30 days after publication in the FEDERAL REGISTER by Environmental Protection Agency of availability of the final Environmental Impact Statement.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard B. Roe, Acting Chief, Division of Marine Mammal and Endangered Species, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Washington, D.C. 20235, 202-634-7287.

Mr. Keith M. Schreiner, Associate Director—Federal Assistance, Fish and Wildlife Service, U.S. Department of the Interior, Washington, D.C. 20240, 202-343-4646.

SUPPLEMENTARY INFORMATION:

BACKGROUND

On December 28, 1973, FWS published a proposal to list green and loggerhead sea turtles as endangered species under the Endangered Species Conservation Act of 1969. On that same day the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) was enacted into law and superseded the Endangered Species Conservation Act of 1969. The 1973 act provides legal authority for this action.

On April 23, 1974, F. Wayne King, Director of Conservation and Environmental Education for the New York Zoological Society, submitted a formal petition under the new law to list the green sea turtle as an endangered species and the loggerhead and Pacific ridley sea turtles as threatened species. Following a NMFS preliminary status review of these three species, NMFS and FWS sent letters on August 8, 1974, to the Governors of the States, Territories, Possessions, and the Commonwealth of Puerto Rico, where green, loggerhead, and Pacific ridley sea turtles are resident, announcing a NMFS/FWS status review of these species and requesting views and data relevant to the status of these species. On August 9, 1974, Wayne King petitioned the Secretary of Interior to have the green sea turtle listed under the "similarity of appearance" provision of the act. Mariculture, Ltd. (now known as Cayman Turtle Farm, Ltd. and hereinafter referred to as Cayman Farm), Grand Cayman Island, British West Indies, a business involved in the raising and marketing of captive green sea turtles, submitted a formal petition on August 15, 1974, to list the green sea turtle as a threatened species, but to exempt turtles bred or raised in captivity from this classification. A formal review by NMFS/FWS of the status of green, loggerhead, and Pacific ridley sea turtles was announced on August 16, 1974, in the FEDERAL REGISTER (39 FR 29605; 39 FR 29607).

On May 20, 1975, the NMFS/FWS determination to propose listing green, loggerhead, and Pacific ridley sea turtles as threatened species was published in the FEDERAL REGISTER (40 FR 21982, 40 FR 21974) (corrected 40 FR 26043 and 40 FR 25217). That proposal summarized the factors thought to be contributing to the likelihood that these sea turtles could become endangered within the foreseeable future, specified the regulations which would be applicable to conserve these species if such a determination were made, and solicited comments, suggestions, objections, and factual information from any interested person. In July 1975, NMFS and FWS sent a telegram to all diplomatic and consular posts soliciting comments on the proposed action and information on sea turtles found in their jurisdiction. On July 17, 1975, Robert Nordstrom, Director of the Fisheries Divisions, National Canners Association, requested that NMFS hold a public hearing on the proposed regulations regarding sea turtles. On August 20, 1975, notice was published in the FEDERAL REGISTER of the NMFS decision to prepare an environmental impact statement and to hold a public hearing on the proposal to list green, loggerhead, and Pacific ridley sea turtles as threatened, the proposed protective regulations for these species, and the draft environmental impact statement (DEIS) (40 FR 36401). On November 14, 1975, notice was published in the FEDERAL REGISTER postponing the NMFS public hearing from December 3, 1975, to February 25, 1976 (40 FR 53051). The National Marine Fisheries Service submitted its DEIS on January 30, 1976, to the Council on Environmental Quality (CEQ). On February 6, 1976, CEQ announced in the FEDERAL REGISTER the availability of the DEIS and opening of the 45 day comment period on the DEIS (41 FR 5426). Also on February 6, 1976, notice by NMFS was published in the FEDERAL REGISTER extending the comment period on the proposed listing and protective regulations, DEIS, and public hearing from March 8, 1976 to March 22, 1976 (41 FR 5413). On February 25-26, 1976, an informal, fact-finding public hearing was held in Washington, D.C., on the proposed listing of the three species of sea turtles and the DEIS. Scientists, conservationists, businessmen, shrimpers, and representatives from State and foreign governments participated in this hearing. On March 19, 1976, CEQ published notice in the FEDERAL REGISTER extending the public comment period on the DEIS until April 5, 1976 (42 FR 11602).

On June 16, 1976, NMFS/FWS proposed regulations to list green, loggerhead, and Pacific ridley sea turtles as threatened species under the "similarity of appearance" provisions were published in the FEDERAL REGISTER (41 FR 24378). Once these final listing regulations (on the proposal of May 20, 1975) are effective, the proposed "similarity of appearance" regulations will be withdrawn as indicated in the June 16, 1976 proposal. Cayman Farm requested on July 22, 1976, that a public hearing be held on the proposed regulations treating these three species of sea turtles as threatened under the "similarity of appearance" provisions. On October 15, 1976, denial of the hearing requested by Cayman Farm was published by the Department of the Interior in the FEDERAL REGISTER (41 FR 45573).

On July 18, 1977, a Memorandum of Understanding (MOU) concerning the jurisdiction of sea turtles between NMFS and FWS was signed. This MOU established sole agency jurisdiction with NMFS while the turtles are in the water and with FWS while they are on land.

The Environmental Defense Fund submitted a request on February 28, 1978, to reopen the public comment period in light of the long time that had elapsed since publication of proposed regulations and to submit newly acquired evidence and related data. On March 27, 1978, NMFS and FWS announced in the FEDERAL REGISTER that the public comment period was reopened until April 17, 1978 (43 FR 12735; corrected 43 FR 13906). Suggestions by a number of parties to extend this comment period were denied because of the need to expedite the listing.

Comments were received from Governors Ricardo Bordallo of Guam, Ella Grasso of Connecticut, Sherman Tribbitt of Delaware, Marvin Mandel of Maryland, George Wallace of Alabama, George Ariyoshi of Hawaii, and Jonn Haydon of American Samoa. Governor Bordallo supported listing the loggerhead and Pacific ridley as threatened, but recommended limited harvesting of green sea turtles be allowed. Governors Grasso and Tribbitt supported listing all three species as threatened. Governors Mandel and Wallace supported listing the green and loggerhead as threatened. Governor Wallace also supported an exception for incidental catch believing that incidental catch is not a major cause of decline in turtle stocks in the Alabama area. Governor Ariyoshi opposed prohibiting incidental catch in "areas of substantial breeding and feeding" unless "substantial" was clarified since the waters of the entire Hawaiian Archipelgo are feeding areas for the green sea turtle. Governor Ariyoshi also supported an exemption for subsistence fishing of the Hawaiian green sea turtle population. Governor Haydon supported the listing of the loggerhead and Pacific ridley, but expressed concern about listing the green since it would deprive many people of a means of living and food. In addition, representatives or agencies from New Jersey, California, Texas, South Carolina, North Caroli-

na, Georgia, Mississippi, Florida, New York, Puerto Rico, and the Trust Territory of the Pacific expressed their views.

SUMMARY OF COMMENTS AND RECOMMENDATIONS

Section 4(b)(1)(C) of the act requires that a summary of comments and recommendations relating to a proposed listing be published in the FEDERAL REGISTER prior to adding the species to the endangered or threatened list. A press release on the proposal was issued by the Department of Commerce on May 30, 1975. Public comment periods were open from May 20, 1975 to July 18, 1975; from February 6, 1976 to April 5, 1976; and from March 27, 1978 to April 17, 1978. Due to the great number of comments received during these periods, only those offering substantive comments have been summarized and enumerated here. However, all public comments were considered in the preparation of final regulations.

All comments are available for review between 9 a.m. and 5 p.m. at the Marine Mammal and Endangered Species Division, National Marine Fisheries Service, 3300 Whitehaven Street NW., Washington, D.C.

The majority of comments concerned the following issues, and are summarized below by category: (1) whether or not to list these three species of sea turtles, or populations thereof, as threatened or endangered; (2) whether or not to allow an exception for mariculture; (3) whether or not to allow an exception for the incidental catch of sea turtles by commercial fishermen; and (4) whether or not to allow the subsistence taking of threatened sea turtles.

(1) The majority of comments received concerned the appropriate listing categories for these species. All three species were proposed to be listed as threatened. Hundreds of cards and letters were received supporting the listing of the sea turtles, most of which favored an endangered classification. However, many supported a threatened listing and many others favored listing, but made no recommendations as to the appropriate category. As indicated above, those comments which offered no rationale or other information have not been enumerated. Substantive comments were received from 73 parties: 24 supported a threatened listing for all three species; 12 favored an endangered listing for all species; 17 supported a population approach to the listing; and various comments were received from 20 others (4 to list the green as endangered and the loggerhead and Pacific ridley as threatened; 4 to list the green and loggerhead as threatened; 1 to list the green and loggerhead as endangered; 1 to list the loggerhead as threatened; 2 to list the green as endangered; 4 to list the green as threatened; 2 not to list the green; and 2 not to list the loggerhead).

Of those 24 comments supporting a threatened classification for the 3 sea turtles under consideration, 10 were received from the States and territories (New Jersey, California, Texas, Connecticut, South Carolina, New York, Delaware, Guam, and Puerto Rico), 5 from researchers/biologists, 2 from the environmental community, 2 from industry, 2 from the Federal Government (regional offices of the Army Corps of Engineers), and 3 from other interested parties. These parties expressed a belief there was a serious decline in sea turtle stocks, but the stocks were not in present danger of extinction. Commentors felt that protective regulations would be adequate for the conservation of these species. Some believed an endangered classification would be unduly restrictive. One biologist believed the existing data to be too fragmentary to warrant an endangered listing. State comments expressed views that the proposed regulations would strengthen existing State regulations protecting sea turtles.

Those 12 who supported an endangered classification for these species included 8 from the environmental community, 1 researcher/biologist, and 3 other interested parties. They expressed the belief that current data indicated that all three species of sea turtles are in danger of extinction throughout all or a significant portion of their ranges, and further that they are extinct in parts of their former ranges. Commentors provided additional data to support this viewpoint. In addition, an environmental group argued that since certain geographic populations are endangered and since they are indistinguishable from other populations, the species as a whole must be listed as endangered to insure adequate protection.

Those 17 favoring a population approach to listing (i.e., evaluating each population and, based on the best available information, determining whether they are endangered or threatened or neither) included 7 from the environmental community, 3 from researchers/biologists, 3 from industries, 1 from the Federal Government (CEQ), 1 from Nicaragua, 1 from the Trust Territory of the Pacific, and 1 other interested individual. The act defines "species" to include "any subspecies of fish or wildlife or plants and any other group of fish or wildlife of the same species or smaller taxa in common spatial arrangement that interbreed when mature." Some commentors pointed out that sea turtles aggregage into intraspecific populations which are spatially and functionally independent of other populations within the same species. Therefore, they argued that based on existing evidence, certain populations are endangered and should be so listed. These commentors also indicated that data for the remaining populations are insufficient to support an endangered listing and therefore these populations should be listed as threatened.

Recommendations for listing populations of green sea turtles as endangered included the Gulf of Thailand, Sri Lanka, Indonesia, Philippines, certain of the Western Indian Ocean, Sarawak, Caroline Islands, Hawaii, Costa Rica, Mexico, Bermuda, Florida, and Caribbean populations. The following populations of Pacific ridleys were recommended as endangered: The Gulf of Thailand, Sri Lanka, Mexico, certain of the Western Indian Ocean, and Surinam populations. The Mexican population of loggerhead turtles was also recommended for endangered listing.

RESPONSE

In determining how to list these sea turtles, NMFS and FWS scientists analyzed the status of individual populations. This task was complicated by two factors. First: Although our listing was based on the best available scientific and commercial data and there are obvious and in many cases significant declines in the populations of these species, the data base for many populations is poor. Statistically valid data are available only for a few populations and much of the available information for all three species is qualitative rather than quantitative.

The status of sea turtle populations is poorly known though generally thought to be declining worldwide (with some exceptions). Because sea turtles spend only a small fraction of their life on the land, little information has been obtained on their populations. Most population estimates are based on beach counts of nesting females (the males do not generally return to land after entering the sea as hatchlings) from which extrapolations are made of total population size based on sex ratios of 1:1. Population declines are suggested by repetitive, decreasing counts of nesting females on known accessible beaches.

Sea turtles inhabit much of the tropical and subtropical seas of the world. The species addressed in this rulemaking have circumglobal distributions. Nesting sites for each of these species are numerous, scattered, and have not been counted accurately. Generally, wherever suitable nesting beaches occur there has been evidence of sea turtle utilization. Although studies have been made on some geo-

graphical areas, the extent of sea turtle habitation in many areas is virtually unknown. The difficulty in determining the status of many turtle populations is complicated by interbreeding, sharing of feeding grounds, and other conditions that cloud the identification of discrete populations.

A second problem arose from the difficulty in determining discrete populations. Some areas which were once populated by large numbers of sea turtles are now barren or have greatly reduced stocks. It is uncertain whether these populations are extinct or have relocated to a new area. Factors such as interbreeding and sharing of feeding grounds make population identification difficult.

Some species of sea turtles have individuals which utilize several different beaches during a nesting season. Green sea turtle populations are identified by scientists by their nesting beach origin. There is a strong nesting site fixation of the Caribbean green sea turtles, whose females are believed to return voluntarily only to particular sections of a nesting beach. However, loggerhead sea turtles seem to have a less developed sense of nest site fixation.

Green turtles are herbivorous, gregarious, herding animals which are highly migratory and susceptible to exploitation. Consequently the number of turtles within a population is of greater significance in evaluating the status of green turtles than in other species. For example, the loggerhead is a solitary, carnivorous species with localized distribution. The species tends to live in proximity to the nesting grounds.

Whether a species over its entire range or individual populations should be listed as endangered or threatened under the terms of the act was difficult to determine. The point at which any species becomes in danger of extinction is not clear from the act. Since the definition of "threatened" refers to the foreseeable future and of "endangered" refers to the present, it is apparent that an endangered species is one that is in more immediate danger of extinction than a threatened species. The National Marine Fisheries Service and U.S. Fish and Wildlife Service determined that the data base for any of the three species or individual populations was not sufficient to determine any identifiable populations are in imminent danger of extinction with the exception of the Florida and Pacific Mexican breeding populations of green turtles and the Pacific Mexican breeding population of Pacific ridleys.

Although evidence on individual populations is fragmentary, we know that these three species of sea turtles have suffered drastic reductions in abundance from historical levels throughout most of their ranges. The major reasons for these declines are overexploitation, loss of habitat, and predation. In certain areas population decreases are caused by the loss of turtles in commercial fishing operations. It is highly probable that, if the factors causing declines in some species of sea turtles remain unchanged, these sea turtles will be facing extinction throughout significant portions of their ranges in the foreseeable future.

After a thorough review and consideration of all the scientific and commercial data available, NMFS and FWS have determined that the green, loggerhead, and Pacific ridley sea turtles are at least threatened throughout all or a significant portion of their ranges, as herein specified, due to one or more of the five factors described in section 4(a) of the act.

(a) *Factor: The present or threatened destruction, modification, or curtailment of habitat or range of the species.* Human population expansion has been instrumental in reducing available nesting habitat for green and loggerhead sea turtles. Land reclamation, road and seawall construction, beach development, and recreational utilization, have seriously affected beach habitat. In many areas, the encroachment of human habitation with its attendant rise in beach traffic and artificial light seriously discourages turtles seeking suitable nesting sites and disorients hatchlings. For example, green turtle rookeries in Bermuda, the Bahamas, and beaches along the Greater Antilles have all been lost. A small nesting population of green turtles (less than 50 female individuals) still is active along the Florida coast, a remnant of a once-abundant population. Development of beaches into seaside resorts has also reduced the loggerhead nesting population. This factor is not known to be significant in the decline of Pacific ridleys.

(b) *Factor: Overutilization for commercial, sporting, scientific, or educational purposes.* Sea turtles (eggs and adults) are utilized worldwide as a food item and are particularly desired in some nations as a source of protein. Harvesting for subsistence and commercial trade is widespread because of the desirability and high value of sea turtles and their products. The green turtle is prized as a food item (stew, soups, steaks, and other meat products) and commercial fisheries harvesting for sea turtles occurs in Costa Rica, Mexico, Nicaragua, and other Central American countries. The Pacific ridley is utilized primarily for leather and to a lesser extent for food. The loggerhead is used for food in some areas such as the Indian Ocean. These turtles are also taken for shell products and curios.

Little sport fishing seems to occur for sea turtles though there is evidence some turtles have been taken or harassed by skindivers and sport fishermen in Florida waters and elsewhere. The use of hatchlings for bait by sport fishermen has also been reported.

(c) *Factor: Disease or predation.* The incidence of parasitism and disease in wild sea turtles is unknown. No data are available to support such agents as being a major contributing factor to the decline in sea turtle abundance.

Predation is a major cause of mortality at all stages in the life cycle of sea turtles. Both human and wild carnivores (raccoons, coyotes, weasels, etc.) prey heavily on turtle nests. Hatchlings are consumed on the beach by birds and in the water by fish. Subadults and adults are taken by man and large fish. In some coastal areas of the United States and other countries, the available habitat for many turtle predators has become constricted due to human habitation. Because many turtle nesting beaches share this constricted space, the incidence of animal predation has increased.

(d) *Factor: The inadequacy of existing regulatory mechanisms.* Most mainland coastal States within the United States where these turtles occur have legislation protecting sea turtles from commercial exploitation. While nesting females, eggs, and young are often protected, there is a lack of uniformity in State and local controls.

Hawaii allows the capture of green sea turtles for home consumption if the carapace length equals or exceeds 36 inches. The U.S. Pacific Trust Territory loosely controls the take of sea turtles as does American Samoa. Subsistence fisheries exist throughout these areas for sea turtles. Puerto Rico and the Virgin Islands prohibit the taking of turtles on the beach but not in the water.

The United States and other parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora control international trade in green, loggerhead, and Pacific ridley sea turtles, and their parts and products. Generally, international trade for commercial purposes is prohibited as is importing sea turtles harvested outside the U.S. territorial sea (3 miles). However, not all countries trading in turtles are parties to the convention. Various foreign countries have national laws protecting sea turtles but protection is not uniform.

(e) *Factor: Other natural or man-made factors affecting the continued existence of the species.* Sea turtles are taken incidentally in many commercial fisheries such as the shrimp and industrial fish trawl, purse seine, and gill net fisheries in various parts of the

world. In the United States, this problem is most serious in the trawl fisheries of the South Atlantic and Gulf of Mexico regions. Incidental capture occurs in the shrimp trawl fisheries off Mexico, Central America, and the northeastern coast of South America but this is undocumented. In some areas and at certain times of the year the incidental take may be a significant contribution to subadult and adult sea turtle mortality. There is evidence that sea turtles are taken occasionally in the Pacific tuna purse seine fishery.

The Florida breeding population of green sea turtles is recognized as a discrete breeding group. In the 19th century, this population was abundant and reportedly nested in large numbers on Florida beaches. Due to commercial exploitation and loss of habitat, the population was decimated. No nests were known in the twentieth century until recently when a small amount of nesting activity was discovered along the southeast coast of Florida. National Marine Fisheries Service scientists believe that this population currently contains less than 100 mature adults. Because of the size of this stock, the status of the population is fragile and any adverse activity such as commercial or uncontrolled scientific exploitation, incidental take or loss of habitat could result in the immediate extinction of this stock. Therefore, the Florida green turtle population is listed as endangered.

Evidence submitted during the last comment period documents the loss of green sea turtle nesting populations along the Pacific coast of Mexico and the overharvest of green sea turtles in the Baja California area which led to the conclusion that this population would be in danger of extinction within 3 years. For these reasons, NMFS and FWS determined that population to be endangered.

Evidence was also supplied on the Pacific ridley on the Pacific coast of Mexico indicating that the annual take of this species since the early 1960's to the present is estimated to be 500,000 to 1,000,000 turtles. Specifically, in Oaxaca State in 1977, 70,000 female Pacific ridleys were reportedly taken from a nesting population estimated to number 150,000. This Pacific ridley stock is beginning to show the same signs of stress that existed with the Atlantic ridley, an endangered species, in the 1950's. Scientists have estimated that this stock may be beyond recovery in 8 years.

While the available data clearly indicated drastic reductions in certain populations of green, loggerhead, and Pacific ridley sea turtles, there were no data available to show that these species as a whole are endangered throughout a significant portion of their ranges. Estimates of populations indicate that statuses of the species as a whole are not so fragile in contrast to the Florida green sea turtle that a reasonable expectation of the loss of habitat, and/or commercial exploitation or incidental take will result in extinction of the species throughout a significant portion of their ranges. Moreover, the species as a whole are not believed to be subject to the type of pressure being exerted on the Mexican breeding populations of green and Pacific ridley sea turtles. Thus, the evidence does not indicate that these species as a whole should be listed as endangered nor that additional populations shoud be presently listed as endangered.

(2) Another issue for which considerable comments were received was the proposed exception for commercial mariculture operations. The proposed regulations provided an exception for importation, exportation, taking, and transporting of sea turtles (and their parts and products) derived from mariculture operations, with the provision that after 2 years the exception would apply only to turtles derived from captive-bred parents. Comments were received from 44 parties concerning this issue.

Approximately 24 of these were opposed to this exception. These included 12 from the environmental community, 6 from researchers/biologists, 2 from State agencies of New York, 3 from industries, and 1 from another interested party. Opponents argued that little progress has been made in achieving "self-sufficiency," and questioned the possibility of ever achieving a completely closed-cycle operation. It was argued that mariculture is accompanied by ecological and pathological problems due to holding turtles in tanks on land. Also argued was that mariculture is heavily dependent on wild stocks for eggs and brood stock, and that such removal from the wild would further jeopardize the condition of wild sea turtle stocks. Some asserted that the high price of turtle products negates their value as a significant contribution to the world supply of protein. Further, they contended that mariculture will stimulate the exploitation of wild turtles by creating an increased demand for turtle products which could not be supplied by captive-bred stocks. During the recent comment period, it was argued that 3 years have elapsed since the proposed regulations, and therefore, mariculture operations have had more than the 2 years originally proposed and still have not become self-sufficient. Opponents also argued that to allow trade in products from turtles which were not truly "bred in captivity" would be inconsistent with the meaning of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (the convention). The convention prohibits trade in appendix I species (which includes all sea turtles except the flatback and Australian population of green) except in the case of animals which were "bred in captivity."

About 20 comments were received in support of an exception for mariculture. These included four from a commerical mariculture operation, one from the Cayman Island Government, two from State agencies (California and Texas), two from industry, two from biologists/researchers, one from the British Embassy, one from the Federal Government (Environmental Protection Agency), and seven from other interested parties. Advocates of mariculture contended that the research conducted on the culture, diseases, food habits, and rearing of sea turtles benefits the care of maintenance of other captive stocks (e.g., commercial seaquariums and research pools) and would benefit headstart operations (i.e., rearing turtles from transplanted eggs to subadults for release to the wild to avoid the vulnerable period of hatchling mortality). In addition, they argued that mariculture can help to conserve wild stocks by providing superior but cheaper turtle products from captive animals and thus reduce pressure on wild populations. Further, they asserted that mariculture can provide a dependable source of protein for human consumption. They claimed that cultured turtles could be used to restore depleted wild stocks. A mariculture operation purports to buy green turtle eggs from Surinam which are considered "doomed" because the eggs are taken from eroding beaches and, if left in the nest, would be destroyed. In addition, this operation anticipates a final taking of eggs in 1979, and indicated it would become a closed-cycle operation by 1980. It also provided evidence of increasing success of eggs being laid by turtles which mated in captivity.

RESPONSE

After much consideration, NMFS and FWS decided not to provide an exception for mariculture. The primary reasons for this decision were a belief that little or no scientific benefit would be received, that the mariculture operations could not be monitored adequately, and that increased worldwide demand for sea turtles and sea turtle products would be encouraged. This condition could lead to increased exploitation of wild stocks including the stimulation of poaching which would be inconsistent with our mandate under the act to adopt regulatory measures to bring threatened species to the point where they no longer need to be listed under the act.

No evidence has been received that Cayman Farm, or any other mariculture operation has made significant research contributions in the 3 years since the proposed regulations were published (May 1975). Cayman Farm is the only known mariculture operation of significant size in the world. Evidence provided for the 1976 NMFS hearing by Cayman Farm, indicated three turtles which were born in captivity had successfully nested in captivity. No information has been received since then on additional captive-bred nesting success. However, Cayman Farm did provide evidence of increasing success with eggs being laid by turtles which mated in captivity. Many scientists knowledgeable in sea turtles, take the view that this operation will not provide much useful information for conserving sea turtles.

Monitoring Cayman Farm would require observers to be stationed at the facility on a regular basis. Otherwise, NMFS and FWS would have to require periodic reports from Cayman Farm which would be difficult to verify.

Cayman Farm had 3 years to demonstrate their ability to raise sea turtles under a closed-cycle system. In that we do not have sufficient evidence to indicate progress has been made, it is questionable that they will reach the goal of 1980 indicated in a April 17, 1978, letter received from Cayman Farm. Sea turtle mariculture may indeed stimulate additional commercial interest in sea turtles and the small prospect of research benefits is insufficient to merit an exception in light of the current status of sea turtle stocks.

(3) The proposed exception for the incidental catch of sea turtles received a total of 46 comments. The proposed regulations contained an exception for incidental catch if: (a) the sea turtle was caught by fishing gear incidental to fishing effort or research not directed toward these sea turtles; (b) the person responsible was not fishing in an area of substantial breeding or feeding of these sea turtles; and (c) any captured sea turtle was immediately returned to the water, whether dead or alive, and with due care to minimize injuries to live sea turtles.

Of those, 13 comments opposed an exception, of which 9 were from the environmental community and 4 were from biologists/researchers. Some commentators felt that the incidental capture of sea turtles is a major factor in their decline, and should be prohibited. Others felt that although in itself incidental catch may not have contributed directly to the current status of sea turtles, due to the serious status of stocks incidental catch was further jeopardizing these species.

Support for an exception for incidental catch was included in eight comments from the States of North Carolina, Mississippi, Georgia, Alabama, Texas, and South Carolina, four from industries, one from a fishery commission, one U.S. Senator, one researcher/biologist, and four other individuals. They expressed the belief that incidental catch is not a major cause of the decline in sea turtle stocks or, at worst, no more of a detriment than predation on eggs and hatchlings or man-induced destruction of nesting habitats. Some felt that if incidental catch were prohibited, it would destroy the domestic shrimp industry. Some expressed views that measures, other than prohibiting incidental catch, would better serve to conserve sea turtles. Some of the measures suggested included predator control, nest protection, and strengthening enforcement activities.

Many comments were received objecting to the language "areas of substantial breeding and feeding" in the proposed regulations. Some felt the phrase was too general and could not be enforced. Others feared that a strict interpretation could put many shrimpers out of business. Many were opposed to the immediate return of comatose turtles to the water without attempting to revive them prior to release.

Others, although not opposed to an exception, believed that incidental catch should be controlled and substantially reduced. Suggestions made included developing a net to exclude turtles, designating critical habitat, eliminating fishing in breeding areas, setting limits on incidental captures, and having a permit system for incidental catch.

RESPONSE

The act prohibits taking of any endangered species incidental to commercial fishing operations. Therefore, the incidental catch of the Florida and Mexican Pacific coast green sea turtle populations and the Mexican Pacific coast Pacific ridley population will be prohibited because of this endangered status.

Conservation measures for threatened species however, may be promulgated which will allow an incidental catch. Most incidentally taken sea turtles are caught inadvertently by shrimp trawls. Presently, there is no way to avoid accidental capture of turtles in shrimp trawls, however, NMFS has been developing an "excluder panel" to be fitted across the mouth of standard shrimp trawls that would prevent, or substantially reduce, the incidental capture of sea turtles. Although preliminary designs have been tested, these need to be comparatively tested with conventional trawls under commercial shrimping conditions. The National Marine Fisheries Service has accelerated its 1978 gear program and is testing the excluder panels on shrimp grounds this year with the aid of the shrimp industry. The objective of this program is, in part, to obtain as much experimental gear, research, and habitat data as possible so that acceptable net design can be achieved by the end of the 1978 shrimping season. Our goal is to promulgate regulations requiring the use of the panel to prevent, or substantially reduce, incidental catch of sea turtles without significantly reducing shrimp production. Sea turtles are occasionally caught inadvertently in other fisheries (e.g., pet food fishery, menhaden fishery, tuna fishery). The incidental catch and mortality of sea turtles in these fisheries is believed to be much smaller than in the shrimp fishery. The excluder panel under development is not adoptable to non-trawl fisheries.

The National Marine Fisheries Service and the U.S. Fish and Wildlife Service are considering candidate areas where turtles are concentrated for designation as Restricted Fishing Areas and/or Critical Habitat. A Restricted Fishing Area is an area where incidental catch is prohibited or otherwise controlled. Controls may include proper gear usage, fishing methods or procedures, or other regulatory controls to reduce or eliminate incidental catch of sea turtles. Prior to the designation of any Restricted Fishing Area within State waters, the Assistant Administrator shall consult, as he deems appropriate, with the Governor(s) and the Marine Conservation Department(s) of the affected State(s). The Assistant Administrator shall also consult with the appropriate Regional fishery Management Councils and with affected fishing industries with regard to these designations. The National Marine Fisheries Service discovered in the winter of 1977-78 hibernating loggerhead and Atlantic ridley sea turtles in the Cape Canaveral ship channel. This area will be proposed in August 1978 as Critical Habitat and will be proposed as a Restricted Fishing Area at a later date.

The proposed regulations would have prohibited incidental catch in areas of substantial breeding or feeding. The National Marine Fisheries Service agreed with commentators who believed that "areas of substantial breeding or feeding" was too vague, unenforceable, and under strict interpretation, could unnecessarily put shrimpers out of business. Hence, those terms were deleted and a provision was added for designating Restricted Fishing Areas. Our accelerated gear program and anticipated designation of Restricted Fishing Areas are believed adequate to protect sea turtles and, at the same time, not close fisheries. The recommendation

for á prohibition of all incidental catch was rejected because the data to indicate shrimping was detrimental to sea turtles throughout the geographical range of the fishery were not available.

Setting limits on incidental captures and establishing a permit system for incidental catch were rejected as difficult to enforce and administer. Catch limits may be imposed in selected areas designated as Restricted Fishing Areas.

We agreed with commentators who were opposed to the immediate return of comatose turtles to the water. The regulations provide that resuscitation be attempted before a comatose turtle is returned to the water.

(4) A limited number of comments were received on whether or not to allow subsistence taking of threatened sea turtles. The proposed regulations did not provide an exception for subsistance. Comments from 10 parties were received addressing this issue.

Of these, nine were in support of allowing subsistence taking, the majority of these being from State and Territorial governors or State agencies where subsistence fishing occurs. These included Hawaii, Guam, American Samoa, and the Trust Territory of the Pacific. Their comments were mainly restricted to the green sea turtle and stressed the need to consider social and economic factors. They related the importance of the green sea turtle as a source of food for many of the island's inhabitants. Evidence was provided indicating the importance of turtles in the cultural way of life in some areas. It was also argued that enforcement would be nearly impossible. Hawaii expressed the opinion that existing State regulations provided adequate protection and that Federal regulations should not be more restrictive. Comment was received in support of subsistence taking provided it is adequately researched and enforced, only allowed where stocks are plentiful, and not allowed on nesting beaches. Two individuals believed it should be allowed by natives in the Pacific Trust Territory for local consumption. One biologist supported subsistence fishing in the Trust Territory if it were carefully monitored, and in Hawaii only after comprehensive investigations indicate that subsistence taking would not be detrimental to that population.

One comment was received from the environmental community, and was endorsed by others, specifically addressing support of a prohibition on subsistence taking on the basis that alternative sources of food are available. It should also be noted that comments were received in general support of the proposed regulations which contained no exception for subsistence.

RESPONSE

Subsistence fisheries for sea turtles exist within U.S. territorial waters. Most are opportunistic in nature, though there are directed fisheries for eggs and adults in the Trust Territory. Some turtles, primarily green, are taken in Puerto Rican and U.S. Virgin Island waters by local fishermen. Hawaii permits the take of green turtles in excess of 36 inches for home use. A limited opportunistic take of turtles (probably green turtles) occurs near Guam. In the Trust Territory, turtle eggs and meat are a traditional food source.

Although the record provides no evidence of subsistence turtle fishing in the Caribbean, NMFS believes increased "subsistence" taking of green turtles has substantially contributed to the decline in Western Caribbean nesting groups. The absence of indigenous natives in Puerto Rico and the Virgin Islands precludes the establishment of long "cultural" ties to the taking of sea turtles for subsistence purposes such as is found in the Pacific Islands. Localized "subsistence" fishing for sea turtles does occur but the motivating factor is esthetic rather than nutritional. The green turtle does not contribute significantly to the food needs of Puerto Rican or Virgin Island residents and prohibiting taking would not have a major nutritional impact. Lastly, because of the close proximity of other breeding groups and the high volume of Caribbean inter-island commerce, it would be impossible to control the flow of turtle products through the Puerto Rican and Virgin Islands nesting area. It would be difficult to effectively stop the illegal trade of sea turtles consumed in Puerto Rico or the Virgin Islands as "subsistence taken." Because of the increase in human impact on Caribbean sea turtles and the absence of a documented subsistence food need for turtle meat, NMFS and FWS decided that no subsistence taking for green turtles or other species of sea turtles should be allowed in Puerto Rico or the Virgin Islands.

Hawaii referenced State regulations that permit the taking of green turtles only in excess of 36-inch carapace length for home consumption. In the State's opinion, such protection was adequately protecting the population. However, NMFS and FWS have concern over increased takings and sale of turtle shell and other products to tourists in Hawaii. For these reasons and because there are alternative food sources available in Hawaii, no exception is allowed for taking green sea turtles in that area.

Sea turtles reportedly provide a major food source for many Pacific island inhabitants, and in areas such as the Yap Islands, play a major role in traditional culture.

The available information on the Western Pacific green turtle population is, at best, incomplete. Reports indicate increased harvesting of eggs and adults have occurred in some areas due to improved native transportation to remote islands. These activities may be instrumental in causing the population declines reported in some areas. However, information submitted showed certain nesting colonies were healthy. There was no strong evidence to support a seriously declining green turtle population which could not support historical harvest levels conducted in a traditional manner.

Because of the condition of the western Pacific population (other than Hawaii), allowing a subsistence take at historical levels is believed consistent with our obligation to conserve threatened species. Therefore, NMFS and FWS decided to allow a traditional subsistence taking of green turtles by residents of the Trust Territory. No subsistence taking will be allowed in other areas. Turtles may be taken only in the water and must be necessary for the sustenance of the individual or immediate family of the individual taking the turtle.

The National Marine Fisheries Service and the U.S. Fish and Wildlife Service will proceed to obtain data on the extent of subsistence fishing and the status of the populations affected by that activity. Further decisions on regulating subsistence fishing will be based on those data.

SUMMARY OF FINAL REGULATIONS

Generally, the proposed regulations would have prohibited (with some exceptions) take, importation, exportation, and interstate and foreign commerce of green, loggerhead, and Pacific ridley turtles. These activities are essentially the same as prohibited activities for endangered species, except interstate commerce prohibition does not take effect for 1 year and the proposed regulations included more exceptions than allowed for endangered species. These final regulations contain the same prohibitions, as were in the proposed regulations. There are however, changes in the exceptions. Other than allowing more exceptions, these regulations governing threatened species are the same as would be promulgated for an endangered listing for all three species.

An exception for scientific, propagation, or survival purposes was authorized under permit in the proposed regulations. The final regulations provide this exception but include a more detailed description of the procedures for the submission and approval of applications for permits. A transition period (in which to obtain permits) for

ongoing sea turtle activities falling in this category is also provided.

The proposed regulations did not except public display, zoological exhibition, or educational purposes from taking prohibitions. The final rulemaking authorizes exception under permit for zoological exhibition or educational purposes.

An exception for taking of injured, dead, or stranded specimens was contained in the proposed regulations for certain Federal and State agency employees. This exception is repeated in the final regulations. An exception for research or conservation program takings under Cooperative Agreement was contained in the proposed regulations. This exception is also repeated in the final regulations.

The proposed regulations contained an exception for incidental catch provided that: (a) The specimen was caught by fishing gear incidental to fishing effort or research not directed toward these sea turtles; (b) the person responsible was not fishing in an area of substantial breeding or feeding of these sea turtles; and (c) any captured sea turtle is immediately returned to the water, whether dead or alive, and with due care to minimize injuries to live turtles. The final regulations provide an exception for incidental taking, subject to any future controls on gear and Restricted Fishing Areas, provided that: (a) The taking was by fishing gear during fishing or research activities conducted at sea and not directed toward sea turtles; (b) any sea turtle so taken must be handled with due care to prevent injury to live sea turtles and must be returned to the water immediately whether it is dead or alive; if it is alive and unconscious, before returning it to the water, resuscitation must be attempted by turning the turtle on its back and pumping its plastron by hand or foot; and (c) any sea turtle so taken must not be consumed, landed, offloaded, transshipped, or kept below deck.

The proposed regulations contained a 2-year exception for mariculture operations dependent on taking from the wild. Thereafter, the exception was limited to mariculture operations independent of taking from the wild. The exception was to be under permit conditioned on, among other things, a marking or other identification system for mariculture products, Government certification that collection of wild eggs would not be detrimental to survival of the species in the wild, and during the first 2 years demonstrating progress toward becoming self-sufficient. No exception for any mariculture is provided by the final regulations.

The proposed regulations contained an exception (grandfather clause) for turtles held in captivity or in a controlled environment on the date of publication of final regulations and not held in the course of a commercial activity on such date. This exception has been deleted from the final regulations because the long period during which the proposal was pending should have been sufficient notice to the public that controls on sea turtles, and their parts and products were forthcoming. Also, the grandfather clause in the act is available to cover items such as jewelery or antiques which were held for non-commercial purposes on December 28, 1973 (the effective date of the act).

The proposed regulations did not contain an exception for subsistence taking. The final regulations provide an exception to take turtles in the water for home consumption only by residents of the Trust Territory of the Pacific Islands. Taking of nesting females and eggs is prohibited.

The proposed regulations contained a 1-year exemption to minimize undue economic hardship tied to a prior contract commitment. No exception for economic hardship is provided in the final regulations since more than 1 year has transpired since the turtles were formally proposed for listing.

Lastly, the final regulations provide procedures for processing permit applications based on the MOU between NMFS and FWS on sea turtle jurisdiction.

Effect of the Rulemaking

Section 7 of the act provides:

> The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this act. All other Federal departments and agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this act by carrying out programs for the conservation of endangered species and threatened species listed pursuant ot section 4 of this act and by taking such action necessary to insure that actions authorized, funded, or carried out by them do not jeopardize the continued existence of such endangered species and threatened species or result in the destruction or modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with the affected States, to be critical.

The National Marine Fisheries Service and the U.S. Fish and Wildlife Service prepared, in consultation with an ad hoc interagency committee, guidelines for Federal agencies for the application of section 7 of the act. These guidelines were superseded by final regulations governing Interagency Cooperation published by NMFS and FWS and January 4, 1978, in the Federal Register (43 FR 870) to assist Federal agencies in complying with section 7.

The National Marine Fisheries Service will propose in, August 1978, the Cape Canaveral ship channel as Critical Habitat for loggerhead and Atlantic ridley sea turtles. Other areas may be considered as a result of the gear research program currently in progress.

Sections 9 and 10 of the act and endangered species regulations already published in title 50 of the Code of Federal Regulations set forth a series of general prohibitions and exceptions which apply to all endangered species. The regulations which pertain to the threatened sea turtles are now contained in parts 220 and 227 of title 50 and are set forth below.

International Effects

All three species of sea turtles are listed on Appendix I of the Convention with the exception of the Australian population of green sea turtles. The Convention prohibits international trade in Appendix I species (with limited exceptions) conducted primarily for commercial purposes. Appendix I species taken on the high seas cannot be landed commercially under the provisions of the Convention. However, the Convention does not apply to the taking of sea turtles within any nation's jurisdiction. Many countries (e.g., Mexico, Japan, and a number of European countries where markets exist) have not ratified the Convention. Mexico has protective legislation of green turtles but adequate enforcement is questionable. Further, because Mexico has signed but not ratified the Convention it can engage in unregulated trade in sea turtles or sea turtle products with other countries not formally implementing the Convention (nonmember or nonratifying members). United States-Mexican trade primarily in these sea turtles for commercial purposes is prohibited.

The National Marine Fisheries Service and the U.S. Fish and Wildlife Service will continue to encourage international Cooperation in the conservation of these species.

National Environment Policy Act

Both a draft and a final EIS have been prepared by NMFS and are on file in the offices of the Division of Marine Mammal and Endangered Species, NMFS, Washington, D.C.

Because this final rulemaking lists green, loggerhead, and Pacific ridley sea turtles in their own right, the similarity of appearance proposal of June 16, 1976, by NMFS and FWS (41 FR 24378) is withdrawn.

The primary author of this rule is Robert B. Gorrell, Acting Endangered Species Program Manager, Division of Marine Mammal and Endangered Species, NMFS, 202-634-7471.

Regulation Promulgation

Accordingly, 50 CFR § 17.11, 17.42(b) and 50 CFR Chapter II are amended as follows:

1. The list of Endangered and Threatened Wildlife in 50 CFR § 17.11 is amended by adding the green, loggerhead and olive (Pacific) ridley sea turtles to the list, alphabetically, under "Reptiles" as indicated below:

SPECIES			RANGE				
Common Name	Scientific Name	Population	Known Distribution	Portion of range where threatened or endangered	Status	When Listed	Special rules
Reptiles:							
Turtle, Leatherback sea ***							
Turtle, Green Sea	Chelonia mydas	Wherever found except in those areas where it is listed as endangered as set forth below	Circumglobal in tropical and temperate seas and oceans	Entire	T		50 CFR § 17.42(b) and Parts 220 and 227
Turtle, Green Sea	Chelonia mydas	Breeding colony populations in Florida and on the Pacific coast of Mexico	All State waters of Florida including Hutchinson and Jupiter Islands; and Pacific coast of Mexico including the Gulf of California	Entire	F		
Turtle, Loggerhead Sea	Caretta caretta	N/A	Circumglobal in tropical and temperate seas and oceans	Entire	T		50 CFR § 17.42(b) and Part 220 and 227
Turtle, Olive (Pacific) Ridley Sea	Lepidochelys olivacea	Wherever found except in those areas where it is listed as endangered as set forth below	Circumglobal in tropical and temperate seas and oceans	Entire	T		50 CFR § 17.42(b) and Part 220 and 227
Turtle, Olive (Pacific) Ridley Sea	Lepidochelys olivacea	Breeding colony population in Pacific Coast of Mexico	Pacific coast of Mexico including the Gulf of California	Entire	E		

* * * *

2. A new special rule § 17.42(b) is added to 50 CFR reading as follows:

§ 17.42 Special rules—reptiles.

* * * * *

(b) Green sea turtle (*Chelonia mydas*), loggerhead sea turtle (*Caretta caretta*), olive ridley sea turtle (*Lepidochelys olivacea*) (these do not include the populations listed as endangered in § 17.11).

(1) *Prohibitions.* Subject to the permits allowable under the following paragraph (b)(2) of this section, all of the provisions set forth in § 17.31 (which incorporate portions of § 17.21) shall apply to this wildlife with the following exceptions:

(i) Section 17.21(c)(2) (self-defense) is not applicable.

(ii) In § 17.21(c)(3)(i), the word "orphaned" is replaced by the word "stranded."

(iii) Delete § 17.21(c)(3)(iv) (Wildlife threatening human safety).

(iv) Sections 17.21 (e) and (f) do not apply to any delivery, receipt, carriage, transportation, shipment, sale or offer for sale in interstate commerce which takes place within 1 year after the effective date of this regulation and which involves specimens taken prior to such effective date.

(v) The prohibition against taking shall not apply to incidental catches, as specified in 50 CFR 227.72(e).

(vi) The prohibition against taking within the United States or the territorial sea of the United States shall not apply to subsistence taking, as specified in 50 CFR 227.72(f).

(2) *Permits.* (i) For those activities which come under the jurisdiction of the Service, only permits for scientific purposes, enhancement of propagation or survival, zoological exhibition or educational purposes, are available under § 17.32. Procedures for issuance of permits are found in § 17.32 and, for those activities which come under the jurisdiction of the National Marine Fisheries Service, Subpart E of Part 220. All the provisions of § 17.32 apply to permits issued by the Service.

(ii) Activities which are ongoing on the effective date of this regulation and which are for scientific purposes or for enhancement of propagation or survival may continue without permit for up to 90 days as specified in 50 CFR 227.72(a).

3. 50 CFR Part 220 is amended by adding the following new Subpart E:

Subpart E—Permits Involving Endangered or Threatened Sea Turtles

Sec.
220.50 Purpose.
220.51 Permit applications.
220.52 Issuance of permits.
220.53 Other requirements.

AUTHORITY: Endangered Species Act of 1973, section 11(f), 87 Stat. 884, Pub. L. 93-205; act of August 31, 1951.

Subpart E—Permits Involving Endangered or Threatened Sea Turtles

§ 220.50 Purpose.

This subpart establishes procedures for issuance of permits for scientific purposes or to enhance the propagation or survival of "endangered" or "threatened" sea turtles and zoological exhibition or educational purposes for "threatened" sea turtles.

§ 220.51 Permit applications.

Applications for permits to take, import, export or engage in any other prohibited activity involving any species of sea turtle listed in 50 CFR § 17.11 shall be submitted to the Wildlife Permit Office (WPO) of the U.S. Fish and Wildlife Service in accordance with either, 50 CFR § 17.22(a) (Endangered Species) or 50 CFR § 17.32(a) (Threatened Species) as appropriate. Applications involving activities under the jurisdiction of the National Marine Fisheries Service (NMFS) as defined in 50 CFR § 222.23(a) and 50 CFR § 227.4 shall be forwarded by the WPO to NMFS.

§ 220.52 Issuance of permits.

(a) Applications under the jurisdiction of the WPO shall be reviewed and acted upon in accordance with 50 CFR § 17.22 or 50 CFR § 17.32 as appropriate.

(b) NMFS shall make a complete review of applications forwarded to it by the WPO in accordance with § 220.51 and determine the appropriate action to be taken in accordance with 50 CFR § 220.21(b) and § 222.23(c). In instances where the application involves activities solely within NMFS jurisdiction, NMFS shall issue permits or letters of denial and provide WPO with copies of its actions.

(c) Where a permit application involves activities under both NMFS and FWS jurisdiction, each agency will process the application for activities under its jurisdiction. WPO will issue either a permit or a letter of denial.

(d) Where a permit application for activities under NMFS jurisdiction also requires a permit under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (TIAS 8249, July 1, 1975) (CITES) (50 CFR Part 23), NMFS will process the application for activities under its jurisdiction. WPO will issue the final document by means of a combination ESA/CITES permit or a letter of denial.

§ 220.53 Other requirements.

Permits issued by NMFS under this Subpart shall be administered and comply with the provisions of 50 CFR § 217-§ 227 as appropriate.

§ 222.23 [Amended].

4. 50 CFR § 222.23(a) is amended by deleting the period after the words, "Atlantic ridley sea turtle (*Lepidochelys kempii*)" and inserting the following: Green sea turtle (*Chelonia mydas*) breeding colony populations in Florida and on the Pacific coast of Mexico, and the olive ridley sea turtle (*Lepidochelys olivacea*) breeding colony population on the Pacific coast of Mexico."

5. Sections 222.23(a), 222.23(b), and 222.23(c)(13) of 50 CFR Chapter II are amended by deleting the following language set off by quotation marks—

(a) * * * "Of these, the National Marine Fisheries Service and the U.S. Fish and Wildlife Service presently share endangered species jurisdictional responsibility for sea turtles." * * *

(b) * * * "A copy of each application for a permit involving sea turtle(s) will be forwarded by the National Marine Fisheries Service to the U.S. Fish and Wildlife Service." * * *

(c) * * *

(13) "If the permit application involves a sea turtle(s), both the National Marine Fisheries Service and the U.S. Fish and Wildlife Service must concur prior to issuance since these two agencies presently share jurisdiction on sea turtles."

Substitute the following language for that deleted above in section 222.23(a), and amend paragraph (b) by adding the material set forth below to the end of the first full sentence:

§ 222.23 Permits for scientific purposes or to enhance the propagation or survival of the affected endangered species.

(a) * * * Of these, the National Marine Fisheries Service has sole agency jurisdiction for sea turtles while the turtles are in the water and the U.S. Fish and Wildlife Service has jurisdiction for sea turtles while the turtles are on land.

* * * * *

(b) * * * except for permits involving sea turtles in which case the applicant shall follow the procedures set out in 50 CFR Part 220 Subpart E. * * *

6. 50 CFR Chapter II is amended by adding a new Part 227, as follows:

PART 227—THREATENED FISH AND WILDLIFE

Subpart A—General Provisions

Sec.
227.1 Purpose.
227.2 Scope.
227.3 Definitions.
227.4 Enumeration of threatened species.
227.5-227.10 [Reserved]

AUTHORITY: Endangered Species Act of 1973 (as amended), Pub. L. 93-205, 16 U.S.C. 1531 et seq.

Subpart A—General Provisions

§ 227.1 Purpose.

The regulations contained in this part identify the species, subspecies, or any other group of fish and wildlife of the same species or smaller taxa in common spatial arrangement that interbreed when mature, under the jurisdiction of the Secretary of Commerce which have been determined to be threatened species under the Endangered Species Act of 1973 and provide for the conservation of such species by establishing rules and procedures to govern activities involving the species.

§ 227.2 Scope.

(a) The regulations contained in this part apply only to the threatened species enumerated in § 227.4.

(b) The provision of this part are in addition to, and not in lieu of other regulations of Parts 217-222 and Part 225 of this Chapter II which prescribe additional restrictions or conditions governing threatened species.

(c) Certain of the threatened fish or wildlife listed in 50 CFR 17.11 and enumerated in 50 CFR 227.4 are included in Appendix I or II to the Convention on International Trade in Endangered Species of Wild Fauna and Flora. The importation, exportation, and reexportation of such species are subject to additional regulations provided in Part 23, Chapter I (Title 50).

§ 227.3 Definitions.

In addition to the definitions contained in the Act, and in Parts 217 and 225 of this Chapter, and unless the context otherwise requires, in this Part 227:

(a) "Act" means the Endangered Species Act of 1973, as amended, 16 U.S.C. § 1531-1547;

(b) "Assistant Administrator" means the Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration, Department of Commerce, or his authorized delegate. The Assistant Administrator for Fisheries is in charge of the National Marine Fisheries Service;

(c) "Ongoing project(s)" means an activity for scientific purposes or to enhance the propagation or survival of such species which are not conducted in the course of a commercial activity initiated before the listing of the effected species;

(d) "Plastron" means the ventral part of the shell of a sea turtle consisting typically of nine symmetrically placed bones overlaid by horny plates; and

(e) "Sea Turtle(s)" means those sea turtle species enumerated in § 227.4 and any part(s), product(s), egg(s) or offspring thereof, or the dead body or part(s) thereof.

§ 227.4 Enumeration of Threatened Species.

The species listed as threatened under the act which are under the jurisdiction of the Secretary of Commerce are:

(a) Green sea turtle (*Chelonia mydas*) except for those populations listed under 50 CFR § 222.23(a).[1]

(b) Loggerhead sea turtle (*Caretta caretta*).[1]

(c) Pacific ridley sea turtle (*Lepidochelys olivacea*) except for those populations listed under 50 CFR 222.23(a).[1]

§§ 227.5-227.10 [Reserved]

Subpart B—Threatened Marine Mammals

§§ 227.11-227.30 [Reserved]

Subpart C—Threatened Marine Fish

§§ 227.31-227.70 [Reserved]

Subpart D—Threatened Marine Reptiles

§ 227.71 Prohibitions.

Except as provided in § 227.72 it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit or to cause to be committed in any of the following acts with respect to any species enumerated in § 227.4:

(a) import any such species into, or export any such species from, the United States;

(b) take any such species within the United States or the territorial sea of the United States;

(c) take any such species upon the high seas;

(d) possess, sell, deliver, carry, transport, or ship by any means whatsoever, any such species taken in violation of the prohibitions in paragraphs (b) and (c) of this section;

(e) deliver, receive, carry, transport, or ship in foreign commerce by any means whatsoever, and in the course of a commercial activity, any such species;

(f) sell, or offer for sale, in foreign commerce any such species;

(g) deliver, receive, carry, transport, or ship in interstate commerce, by any means whatsoever, and in the course of commercial activity; provided that this paragraph (g) shall not apply to any such species taken prior to the effective date of the listing of the species for 1 year after such listing; or

(h) sell, or offer for sale, in interstate commerce any such species; provided that this paragraph (h) shall not apply to any such species taken prior to the effective date of the listing of the species for 1 year after such listing.

§ 227.72 Exceptions to prohibitions.

(a) *Scientific, propagation, or survival permits.* (1) The Assistant Administrator may issue permits authorizing activities which would otherwise be prohibited under § 227.71 for scientific purposes or to enhance the propagation or survival of such species. Applications for these permits are subject to the provisions of Part 220 of this Chapter II.

(2) Ongoing scientific, propagation, or survival projects, which would otherwise be prohibited by § 227.71 may continue without a permit until an application for a permit has been denied or 90 days from the effective date of the listing of the effected species, whichever comes first. If a permit has not been denied, ongoing projects may continue beyond this 90-day period provided that the individual responsible for such project(s) has applied for a permit and receives a letter from the Assistant Administrator stating that the application is complete and sufficient for processing within the 90-day period. Projects not receiving a permit or letter indicating sufficiency by the 90th day must cease. Within 30 days of receipt of an application, the Assistant Administrator will determine the completeness and sufficiency of the application for processing. If an application is deemed complete and sufficient for processing, a permit will be issued or denied within the next 90 days beginning with the date of the letter informing the applicant that the application is sufficient. Approved projects shall continue in accordance with the conditions of the permit.

(b) *Permits for Zoological Exhibition or Educational Purposes.* The Assistant Administrator may issue permits authorizing activities which would be otherwise prohibited under § 227.71 for zoological exhibition or educational purposes. Applications for these permits are subject to the provisions of Part 220 of this Chapter II.

(c) *Exceptions for injured, dead, or stranded specimens.* If any member of any threatened species listed in § 227.4 is found injured, dead, or stranded,

[1] Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service, jurisdiction for sea turtles is limited to turtles while in the water.

any agent or employee of the National Marine Fisheries Service, the Fish and Wildlife Service, the U.S. Coast Guard, or any other Federal land or water management agency, or any agent or employee of a State agency responsible for fish and wildlife who is designated by his or her agency for such purposes, may, when acting in the course of his or her official duties, take such specimens without a permit if such taking is necessary to aid a sick, injured, or stranded specimen or dispose of a dead specimen or salvage a dead specimen which may be useful for scientific study. Wherever possible, live specimens shall be returned to their aquatic environment as soon as possible. Every action shall be reported in writing to the Assistant Administrator within 30 days, and reports of further occurrence shall be made as deemed appropriate by the Assistant Administrator until the specimen is either returned to its environment or disposed of. Reports shall be mailed by registered or certified mail, return receipt requested, to the Assistant Administrator for Fisheries, National Marine Fisheries Service, Washington, D.C. 20235, and shall contain the following information:

(1) Name and position of the official or employee involved;

(2) Description of the specimen(s) involved;

(3) Date and location of disposal;

(4) Circumstances requiring the action;

(5) Method of disposal;

(6) Disposition of the specimen(s), including, where the specimen(s) has been retained in captivity, a description of the place and means of confinement, and the measures taken for its maintenance and care; and

(7) Such other information as the Assistant Administrator may require.

(d) *Exception for research or conservation.* Any employee or agent of the National Marine Fisheries Service, the Fish and Wildlife Service, or a State fish and wildlife agency operating a conservation program pursuant to the terms of a Cooperative Agreement with the National Marine Fisheries Service or the Fish and Wildlife Service in accordance with Section 6(c) of the Act, designated by his or her agency for such purposes, may, when acting in the course of his or her official duties, take any threatened species to carry out scientific research or conservation programs. All such takings shall be reported within 30 days of the taking to the Assistant Administrator who may request additional reports of the taking and research at his discretion.

(e) *Exception for incidental taking*—(1) *General.* Except as provided in paragraphs (e)(2) and (e)(3) of this section, the incidental taking of any member of any species listed in § 227.4 during fishing or scientific research activities not directed toward such members of such species is allowed under the following conditions:

(i) any specimen so taken must be handled with due care to prevent injury to live specimens, and must be returned to the water immediately whether it is dead or alive unless it is a sea turtle which is alive and unconscious, in which case before returning it to the water, resuscitation must be attempted by turning the turtle on its back and pumping its plastron by hand or foot; and

(ii) any specimen so taken must not be consumed, sold, landed, offloaded, transshipped, or kept below deck.

(2) *Restricted Fishing Areas.* [Reserved]

(3) *Gear.* [Reserved]

(f) *Subsistence.* The prohibition in § 227.71(b) shall not apply with respect to the taking of any member of the species of green sea turtle (*Chelonia mydas*) in waters seaward of mean low tide for personal consumption by residents of the Trust Territory of the Pacific Islands if such taking is customary, traditional and necessary for the sustenance of such resident and his immediate family. Sea turtles so taken cannot be transferred to non-residents or sold.

NOTE.—The National Marine Fisheries Service and the U.S. Fish and Wildlife Service have determined that this document does not contain a major action requiring preparation of an economic impact statement under Executive Order 11949 and OMB Circular A-107.

Dated: July 25, 1978.

TERRY L. LEITZELL,
Assistant Administrator for Fisheries.

Dated: July 25, 1978.

LYNN A. GREENWALT,
Director, U.S. Fish and Wildlife Service.

[FR Doc. 78-21047 Filed 7-27-78; 8:45 am]

proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

[1620-01]

COST ACCOUNTING STANDARDS BOARD

[4 CFR Parts 403, 410, 422]

ACCOUNTING FOR INDEPENDENT RESEARCH AND DEVELOPMENT AND BID AND PROPOSAL COSTS

AGENCY: Cost Accounting Standards Board.

ACTION: Proposed rule.

SUMMARY: The Cost Accounting Standards Board is proposing a standard which, if adopted, would be one of a series of cost accounting standards which the Board is promulgating to achieve increased uniformity and consistency in the cost accounting principles followed by defense contractors and subcontractors under Federal contracts. This proposed rule would provide criteria for the accumulation of costs of independent research and development (I.R. & D.) and bid and proposal (B. & P.) projects and the allocation of such costs to cost objectives, based on the beneficial or causal relationship between such costs and cost objectives. The application of these criteria should increase the probability that I.R. & D. and B. & P. costs are allocated to final cost objectives in a uniform and consistent manner.

DATE: Written comments must be received on or before October 2, 1978.

ADDRESS: Written comments should be sent to the Cost Accounting Standards Board, 441 G Street NW., Room 4836, Washington, D.C. 20548.

FOR FURTHER INFORMATION CONTACT:

Clark G. Adams, Project Director, Cost Accounting Standards Board, 441 G Street NW., Room 4836, Washington, D.C. 20548, 202-275-5418.

SUPPLEMENTARY INFORMATION: In addition to the proposed standard, related amendments to standards 4 CFR Part 403 and 4 CFR 410 are being proposed.

The Board solicits comments on the proposed cost accounting standard and related amendments. During the course of research, comments were received stating objections to the prohibition of allocating deferred I.R. & D. costs. Those voicing objections, however, did not provide sufficient criteria to determine when an I.R. & D. project's costs should be deferred and when they should not. The Board, therefore, requests that anyone objecting to the prohibition in this standard provide to the Board objective criteria for making this determination.

Also, in addition to your comments and suggestions relative to the proposed standard, we would appreciate your providing us with the following information:

(1) To what extent would the provisions of the proposed standard affect the dollar amount of I.R. & D. and B. & P. costs allocable to Government contracts for 1 year as compared to present practices and regulations? To the extent practical, please relate any such differences in allocable costs to the specific section of the standard.

(2) Would the implementation of the proposed standard result in increased or decreased administrative costs? If so please provide details as to the nature of such costs and show how much of any increased or decreased costs would be one-time and how much would be continuing. By increased or decreased costs, we mean incremental costs.

(3) What function(s), if any, would be added or deleted from the contractor's activities as a result of this standard?

NOTE.—All written submissions made pursuant to this notice will be made available for public inspection at the Board's office during regular business hours.

(Sec. 719, Defense Production Act of 1950, as amended, Pub. L. 91-379, 50 U.S.C. app. 2168.)

ARTHUR SCHOENHAUT,
Executive Secretary.

It is proposed to amend 4 CFR Part 403, *Allocation of home office expense to segments,* by deleting paragraph (b)(5) of § 403.40 and inserting the following in lieu thereof.

§ 403.40 Fundamental requirement.

* * * * *

(b) * * *

(5) *Independent research and development and bid and proposal costs.* The costs of independent research and development and bid and proposal efforts allocated by a home office shall be allocated in accordance with the provisions of 4 CFR Part 422.

* * * * *

It is proposed to amend 4 CFR Part 410, *Allocation of business unit general and administrative expenses to final cost objectives,* by deleting paragraph (d) of § 410.40 in its entirety and inserting the following in lieu thereof.

§ 410.40 Fundamental requirement.

* * * * *

(d) Any costs which do not satisfy the definition of G. & A. expense in this standard, but which have been classified by a business unit as G. & A. expenses, can remain in the G. & A. expense pool unless they can be allocated to business unit cost objectives on a beneficial or causal relationship which is best measured by a base other than a cost input base.

It is proposed to amend 4 CFR chapter III by adding a new Part 422 to read as follows:

PART 422—COST ACCOUNTING STANDARD ACCOUNTING FOR INDEPENDENT RESEARCH AND DEVELOPMENT AND BID AND PROPOSAL COSTS

Sec.
422.10 General applicability.
422.20 Purpose.
422.30 Definitions.
422.40 Fundamental requirement.
422.50 Techniques for application.
422.60 Illustrations.
422.70 Exemption.
422.80 Effective date.

AUTHORITY: Sec. 719, Defense Production Act of 1950, as amended, Pub. L. 91-379, 50 U.S.C. app. 2168.

§ 422.10 General applicability.

General applicability of this cost accounting standard is established by § 331.30 of the Board's regulations on applicability, exemption, and waiver of the requirement to include the cost accounting standards contract clause in negotiated defense prime contracts and subcontracts. (§ 331.30 of this chapter.)

§ 422.20 Purpose.

The purpose of this cost accounting standard is to provide criteria for accumulation of independent research and

development and bid and proposal costs and for the allocation of such costs to cost objectives based on the beneficial or causal relationship between such costs and cost objectives. Consistent application of these criteria will improve cost allocation.

§ 422.30 Definitions.

(a) The following are definitions of terms prominent in this standard.

(1) *Allocate.* To assign an item of cost, or a group of items of cost, to one or more cost objectives. This term includes both direct assignment of cost and the reassignment of a share from an indirect cost pool.

(2) *Bid and proposal (B. & P.) costs.* The costs incurred in the effort of preparing, submitting, and supporting bids and proposals (whether or not solicited) on potential contracts which effort is neither sponsored by a grant, nor required in performance of a contract and which falls within the following:

(i) Administrative costs including the cost of the nontechnical effort for the physical preparation of the technical proposal documents and also the cost of the technical and nontechnical effort for the preparation and publication of the cost data and other administrative data necessary to support the contractor's bids and proposals, and

(ii) Technical costs incurred to specifically support a contractor's bid or proposal, including the costs of system and concept formulation studies and the development of engineering and production engineering data.

(3) *Business unit.* Any segment of an organization, or an entire business organization which is not divided into segments.

(4) *Cost input.* The cost, except G. & A. expenses, which for contract costing purposes is allocable to the production of goods and services during a cost accounting period.

5. *General and administrative (G. & A.) expenses.* Any management, financial, and other expense which is incurred by or allocated to a business unit and which is for the general management and administration of the business unit as a whole. G. & A. expense does not include those management expenses whose beneficial or causal relationship to cost objectives can be more directly measured by a base than a cost input base representing the total activity of a business unit during a cost accounting period.

(6) *Home office.* An office responsible for directing or managing two or more, but not necessarily all, segments of an organization. It typically establishes policy for, and provides guidance to the segments in their operations. It usually performs management, supervisory, or administrative functions, and may also perform service functions in support of the operations of the various segments. An organization which has intermediate levels, such as groups, may have several home offices which report to a common home office. An intermediate organization may be both a segment and a home office.

(7) *Independent research and development (I.R. & D.) costs.* The costs of effort which is neither sponsored by a grant, nor required in performance of a contract of the organization, and which falls within any of the following three areas: (i) Basic and applied research, (ii) Product or service development, and (iii) Systems and other concept formulation studies.

(8) *Indirect cost.* Any cost not directly identified with a single final cost objective, but identified with two or more final cost objectives or with at least one intermediate cost objective.

(9) *Segment.* One of two or more divisions, product departments, plants, or other subdivisions of an organization reporting directly to a home office, usually identified with responsibility for profit and/or producing a product or service. The term includes Government-owned contractor-operated (GOCO) facilities, and joint ventures and subsidiaries (domestic and foreign) in which the organization has a majority ownership. The term also includes those joint ventures and subsidiaries (domestic and foreign) in which the organization has less than a majority of ownership, but over which it exercises control.

§ 422.40 Fundamental requirement.

(a) I.R. & D./B. & P. projects shall be treated as if they were final cost objectives, except that business unit general and administrative expenses are not allocable to such projects.

(b) Each IR&D/B&P project shall be accounted for separately, and the costs of all such projects shall in turn be accumulated in a separate pool(s) apart from other costs.

(c) (1) Costs incurred clearly and exclusively for a particular IR&D/B&P project shall be allocated only to that project and shall be accounted for as a direct cost of that project,

(2) The IR&D/B&P cost pool(s) at the home office shall be allocated to segments by means of a base representing the total activity of all the segments reporting to that home office.

(3) The IR&D/B&P cost pool(s) of a segment shall be allocated to final cost objectives of that segment by means of a base representing the total activity of that segment. The base selected shall be the one that best represents the total activity of a typical cost accounting period.

§ 422.50 Techniques for application.

(a) IR&D/B&P cost pool(s) of a home office or segment shall include any IR&D/B&P costs incurred in that home office or segment less any such costs that are directly allocated from a home office or segment.

(b) Only those types of cost which would be treated as direct costs of a final cost objective shall be treated as direct costs of IR&D/B&P projects.

(c) The costs of IR&D/B&P projects performed at a segment at the request of another segment or a home office shall be directly allocated to the requesting organization. The cost of such projects shall include an allocation of the general and administrative expenses of the performing segment, in accordance with the provisions of 4 CFR Part 410. The cost of IR&D/B&P projects performed at a home office at the request of a segment shall be directly allocated to the requesting segment.

(d) IR&D/B&P costs accumulated in a home office pool(s) shall be allocated to all segments under the home office by means of a cost input base representative of the total activity of such segments except where paragraph (e) below applies.

(e) Where a particular segment receives significantly more or less benefit from IR&D/B&P costs than would be reflected by the allocation of such costs to the segment on a cost input base, the Government and the contractor may agree to a special allocation of IR&D/B&P costs to such segment commensurate with the benefits received. The amount of a special allocation to any segment made pursuant to such an agreement shall be excluded from the pool(s) of IR&D/B&P costs to be allocated to the segment and the cost input data of any such segment shall be excluded from the base used to allocate the IR&D/B&P pool(s).

(f) The base used to allocate the IR&D/B&P cost pool(s) of a business unit to cost objectives shall be the same base used by the business unit to allocate its general and administrative expense in accordance with 4 CFR 410.50.

(g) The IR&D/B&P cost pool(s) may be combined with the G&A expense pool for allocation to final cost objectives provided that provision is made to identify the IR&D/B&P cost separately from the G&A expenses in the combined pool.

(h) IR&D/B&P costs incurred in a cost accounting period shall not be allocated to cost objectives of any other cost accounting period.

§ 422.60 Illustrations.

(a) Segment A receives a request to provide support for an IR&D project of Segment B. Segment A performs

the requested project but does not directly allocate the costs for such project to Segment B. As a result, the costs are included in the IR&D pool of Segment A and allocated to final cost objectives of Segment A. This accounting practice is not in compliance with the requirements of § 422.50(a).

(b) Segment C, in accordance with its established accounting practice, charges administrative efford including typing to an indirect cost pool. The costs of typing are included as an indirect cost of the department assigned to prepare the proposal. In submitting a major proposal, Segment C assigns several typists to the proposal project on a full-time basis and charges the typists' time direct to the proposal project, rather than to the departmental overhead pool. Because the segment charges the cost of the typing effort incurred for this one proposal on a different basis from that used to charge typing effort in the department, the accounting practice is not in compliance with the requirements of § 422.50(b).

(c) Segment D requests that Segment E provide support for an IR&D project. Segment E allocates to the project requested by Segment D all the incurred direct and related indirect costs, including an allocation of the performing segments' G&A expense. Segment E then directly allocates the cost of the project to Segment D. Since Segment D requested Segment E's support and Segment E directly allocated the direct and related indirect costs (including G&A) to Segment D, Segment E's accounting practice is in compliance with the requirements of § 422.50(c) and 4 CFR Part 410.

(d) (1) Contractor F has six operating segments and a research laboratory, which is not part of the home office but is a separate segment. The research laboratory performs effort under R&D contracts, performs IR&D projects for the benefit of the contractor as a whole, and performs IR&D for the advancement of its own technical expertise. It also performs work on IR&D projects as specifically requested by any one of the six segments. The laboratory directly allocates the IR&D costs of the requested project to the requesting segment. The IR&D costs incurred for the advancement of its own technical expertise is allocated to the final cost objectives of the laboratory. The remaining IR&D costs of the laboratory are for the general benefit of the research laboratory and of the six operating segments and are accumulated at the home office, and allocated to the segments on a cost input base representing the total activity of all the segments. This accounting practice is in compliance with the requirements of § 422.50(d).

(2) Company G has two research laboratories; one established as an integral part of a group home office and a second established as a segment reporting to the group home office. Both laboratories only perform IR&D which is for the general benefit of the other segments of the company. The IR&D costs incurred by the group home office and the segment (laboratory) are pooled at the group home office for allocation purposes to the other segments reporting to that home office. The group home office uses a total cost input base which consists of the total cost input of the other segments to allocate the pooled IR&D costs. This accounting practice is in compliance with the requirements of § 422.50(d).

(e) Company H has a research laboratory established at the home office which performs primarily applied research. All segments reporting to the home office are reseach-oriented except one. The nature of the business activity of the one segment is such that the applied research performed by the home office laboratory provides no benefit to that segment. The company uses a total cost input base which is representative of the total activity of all the segments for allocation purposes. The company, however, removes the total cost input of the non-research segment from the base for allocation of the applied research costs as there is no beneficial or casual relationship between the applied research costs and that segment. This accounting practice is in compliance with the requirements of § 422.50(e).

(f) Business Unit I allocates its G&A expense pool by means of a total cost input base in accordance with the provisions of 4 CFR Part 410. The Business Unit, however, establishes a base for the allocation of its IR&D/B&P cost pool by removing certain major subcontracts. The base with the subcontracts removed is not the same base used to allocate its G&A expense pool, and therefore is not representative of the total activity of the cost accounting period. The accounting practice is not in compliance with the requirements of § 422.50(f).

§ 422.70 Exemption.

This Standard shall not apply to contractors who are subject to the provisions of Federal Management Circular 74-4 (Principles for Determining Cost Applicable to Grants and Contracts with State and Local Governments).

§ 422.80 Effective date.

(a) The effective date of this Cost Accounting Standard is [reserved].

(b) This Cost Accounting Standard shall be followed by each contractor on or after the start of his next fiscal year beginning after the receipt of a contract to which this Cost Accounting Standard is applicable.

[FR Doc. 78-20999 Filed 7-27-78; 8:45 am]

[6740-02]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[18 CFR Parts 1, 2]

[Docket No. RM78-16]

REVIEW OF SETTLEMENT AGREEMENTS

Proposed Rule

JULY 24, 1978.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: This rule amends the Federal Energy Regulatory Commission's (Commission) regulations to facilitate Commission review of settlement agreements. It provides that, once a hearing has been ordered, settlement agreements will be received by the Commission only upon certification by the presiding administrative law judge, who is to determine whether the settlement is in the public interest or, if contested, whether the contested issues can be decided on their merits on the basis of substantial evidence.

DATE: Comments must be received on or before August 31, 1978.

ADDRESSES: Send comments to the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426. Written submissions will be available for public inspection at the Commission's Office of Public Information, Room 1000, 825 North Capitol Street NE., Washington, D.C., during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Kenneth F. Plumb, 202-275-4166.

SUPPLEMENTARY INFORMATION:

A. BACKGROUND

It has been the policy of the Federal Power Commission and the Federal Energy Regulatory Commission[1] to accept for filing, both directly and by way of certification by a presiding administrative law judge, settlement agreements containing wholly and partially settled matters, 18 CFR 1.18. The submittal and consideration of settlement agreements permits expeditious resolution of cases where those

[1] The "Commission" when used in the context of an action taken prior to October 1, 1977, refers to the FPC; when used otherwise, the reference is to the FERC.

settlements are found to be in the general interest of the public. Consideration of settlements to which the parties have not unanimously agreed but which are supported by substantial evidence on the record and meet the standards enunciated in the Federal Power Act or Natural Gas Act also permits a more expeditious resolution of an ongoing proceeding. *Mobil Oil Corporation* v. *F.P.C.*, 417 U.S. 283 (1973).

Nevertheless, the need for more fully developed records, or records on which a reasoned decision can be made, has become apparent in recent cases in which offers of settlement with certain contested issues were submitted to the Commission before the parties had the opportunity, or having been presented the opportunity chose not to exercise it, to submit testimony or to cross-examine those witnesses who submitted testimony.[2]

In an effort to alleviate this problem, and, more importantly, to expedite the issuance of final decisions and to provide the assurance that participants are afforded due process of law in presenting and litigating their views before this Commission, the Commission is hereby proposing new procedures for certifying settlement agreements to the Commission once a hearing has been ordered. Before that time, the parties may submit an offer of settlement to the Commission. The Commission invites interested persons to comment on this proposed rulemaking.

B. Summary of the Commission's Proposed Regulations

The proposed procedures are intended to assure that offers of settlement certified to the Commission are either unanimously supported or, if contested by any participants to the proceedings, that the presiding administrative law judge has determined that all parties have had an opportunity to present evidence or have waived their right to do so, as to issues which they contest. The Commission may thereby render a decision on contested issues on the basis of substantial record evidence, consistent with the requirements of due process.

In cases where a hearing has been ordered by the Commission, the Commission proposes to review offers of settlement only upon certification of the offer of settlement and all pertinent documents, testimony, and exhibits by the presiding administrative law judge. If the offer of settlement is contested, the judge shall certify the offer of settlement together with his finding that the contested issues are severable and either his decision on the merits of contested issues, or, if a waiver of the initial decision is requested, his determination that the record contains substantial evidence to enable the Commission to reach a decision on the merits of contested issues. The participants shall outline the scope of the offer of settlement, including applicable contracts, schedules, or documents filed with the Commission in current and, if applicable, prior proceedings.

Comments. The Commission currently receives comments from the parties upon the filing of an offer of settlement with the Commission. The Commission proposes that, where a hearing has been ordered by the Commission, the settlement shall be filed with the presiding officer. The Secretary shall thereupon issue a notice of the offer of settlement and provide for the filing of initial comments (and reply comments, if deemed appropriate by the presiding officer) with the presiding officer. The purpose of filing comments with the presiding officer is to allow him to determine prior to certification whether an offer of settlement is unanimously supported and ripe for Commission review as a settlement, or, if portions of it are contested, to determine if the participants wish to present further evidence on the record, and to render a decision on the contested portions of the offer of settlement in the absence of a request for waiver of the initial decision.

Contested issues. If there are contested issues, the presiding officer shall provide the participants an opportunity to present evidence or to cross-examine opposing witnesses. He may defer certification until he concludes the hearing and renders a decision on the contested issues, or he may certify the uncontested portion of the agreement to the Commission, or, as a third alternative, if waiver of his decision is requested, he may certify the record together with his determination that the record contains substantial evidence from which the Commission may reach a reasoned decision on the contested issues and that the disposition of the contested issues will not affect the settled issues.

The Commission will, by the proposed rule, no longer accept offers of settlement certified by the presiding officer which are accompanied by contested issues, unless the parties have either exhausted or waived their rights to further proceedings before the presiding officer, including the introduction of evidence in support of their positions, and the presiding officer has either determined that substantial evidence has been presented to support the settlement offer or rendered an initial decision on the merits of the severable contested issues. Briefs on exceptions and briefs opposing exceptions would be submitted to the Commission upon an initial decision.

The participants may request a waiver of the requirement for an initial decision on the contested portions of the offer of settlement. (See 18 CFR 1.30(c).) In that event, the presiding officer shall certify to the Commission the motion for waiver of his initial decision, the entire offer of settlement, with pertinent documents and supporting portions of the record, and the comments of the participants, upon his determination that the disposition of the contested issues will not affect the settlement, that the record contains substantial evidence from which the Commission may reach a reasoned determination on the merits of the contested issues, and that the participants have either exhausted or waived their rights to present additional evidence in the proceeding before the presiding officer. The participants will be bound by the Commission's ultimate decision on the merits of the contested issues. This does not preclude any party from seeking rehearing of the Commission's order on the contested issues, nor does anything in the rule preclude any party from requesting a hearing in the event that the Commission rejects or substantially alters the terms of the settlement agreement by accepting it subject to conditions.

In consideration of the foregoing, it is proposed to amend Part I, Subchapter A, Chapter I of Title 18, Code of Federal Regulations, as set forth below.

Any interested person may submit to the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, to be received no later than August 31, 1978, views, comments, and suggestions in writing concerning all or part of the amendments proposed herein. Written submittals will be placed in the Commission's public files and will be available for public inspection at the Commission's Office of Public Information, Room 1000, 825 North Capitol Street NE., Washington, D.C. 20426, during regular business hours. The Commission will consider all such written submittals before acting on the matters herein proposed. An original and 14 conformed copies should be filed with the Secretary of the Commission. Submittals to the Commission should indicate the name, title, mailing address,

[2] See, for example, *North Penn Gas Co.*, docket No. RP76-158, order granting rehearing, establishing procedures, and granting motion to vacate order, issued on Nov. 30, 1977. After the Commission completed its analysis of the record before it and issued a decision based on the evidence presented, a certain party requested a hearing on the contested issues, thereby withdrawing unilaterally from the agreements. The Commission therefore was required to remand the proceeding to the presiding administrative law judge.

and telephone number of the person to whom communications concerning the proposal should be addressed.

Comments on all aspects of the proposal are solicited.

Issued in Washington, D.C., on July 24, 1978.

By order of the Commission.

KENNETH F. PLUMB,
Secretary.

1. Code of Federal Regulations, chapter I of title 18, part 1, subchapter A, § 1.1(f), is amended by adding new subparagraph (23) reading as follows:

§ 1.1 The Commission.

* * * * * *

(f) *Definitions.* * * *

(23) *Offer of settlement.* For the purpose of this paragraph and §§ 1.18, 1.36, and 1.4(d)(2)(v), an offer of settlement shall include all documents, testimony, and exhibits, which provide support for the offer of settlement, a list of all schedules, contracts, documents, or data within the scope of the settlement, and a proposed notice suitable for publication in the FEDERAL REGISTER.

2. Code of Federal Regulations, chapter I of title 18, part 1, Subchapter A, § 1.18(e), is revised to read as follows:

§ 1.18 Conferences; offers of settlement.

* * * * *

(e) *Procedures for submission of offers of settlement to Commission.*— (1) *General rule.* Any participant to a proceeding may submit an offer of settlement, as defined by § 1.1(f)(23) to all participants and to the presiding officer, and may request a conference for such purpose. If the Commission has ordered a hearing at the time the offer of settlement is submitted, the offer of settlement shall be filed with the presiding officer. The participant submitting the offer of settlement shall state whether the settlement is a package, with no severable parts, or whether any specific issues may be separated from the settlement for separate decision, should the need for a separate decision arise. An unaccepted offer of settlement shall be privileged and shall not be admissible in evidence against any person claiming such privilege.

(2) *Comments.* The presiding officer shall fix the time and order for filing comments with him, and may permit the filing of reply comments. These procedures shall be set forth in a notice to be published in the FEDERAL REGISTER by the Commission Secretary.

(3) *Unopposed offer of settlement.* If the offer of settlement is unopposed, the presiding officer shall certify to the Commission the offer of settlement, his statement that the offer of settlement is unopposed, and the evidentiary record, which shall include support for the offer of settlement.

(4) *Contested offers of settlement.* If the offer of settlement is opposed in whole or in part, the presiding officer shall either: (i) Defer his certification of the offer of settlement until he has reached a decision supported by substantial record evidence on the remaining contested issues; or (ii) upon a determination that the disposition of the remaining contested issue or issues will not affect the settlement, certify to the Commission the uncontested portion of the offer of settlement, as provided in subparagraph (3) of this paragraph, specifying issues which are contested and are severable from the offer of settlement, and proceed with hearing procedures on the remaining contested issue or issues; (iii) in lieu of the procedures set forth in § 1.30(c), the participants may file with the presiding officer a motion for waiver of an initial decision on the contested portions of the offer of settlement, with the request that he certify the motion to the Commission. The presiding officer shall only certify to the Commission the motion, the entire offer of settlement, including the contested portions, the record, and the comments of the parties if he determines that: (*a*) The disposition of the contested issues will not affect the uncontested portions of the settlement, (*b*) the record contains substantial evidence from which the Commission may reach a reasoned decision on the merits of the contested issues, and (*c*) all participants either have had or have waived the opportunity to present evidence and/or cross-examine opposing witnesses. If these three conditions are not met, the presiding officer shall establish such further procedures as he deems appropriate.

(5) *Reservation of rights.* Any participant may reserve its right to a hearing if the Commission does not accept and approve the unopposed portion of the offer of settlement, or approves it subject to conditions which substantially alter the result of the offer of settlement or the underlying intent of the participants.

3. Code of Federal Regulations, Chapter I of Title 18, Part 1, Subchapter A, § 1.30(c)(1) and § 1.30(c)(3) are amended to read as follows:

§ 1.30 Decisions.

* * * * *

(c) *Waiver and omission of intermediate decision procedure.* (1) In lieu of any intermediate decision (initiated by presiding officer, recommended by presiding officer or designated responsible officer, or tentative by the Commission), any party or staff counsel in any proceeding may request that the Commission forthwith render the final decision. Except as provided in § 1.18(e)(4)(iii), if all other parties and staff counsel join or concur in such request, it shall be deemed to have been granted unless the Commission denies such request within 10 days next following its submission or filing. Except as provided in § 1.18(e)(4)(iii), such requests for omitting the intermediate decision procedure shall specify:

(i) The concurrence of the other parties and staff counsel;

(ii) Whether opportunity for presenting oral argument of filing briefs before the presiding officer or Commission is desired or waived;

(iii) Whether opportunity for presenting proposed findings and conclusions with supporting reasons therefor, is desired or waived; and

(iv) Whether the parties reserve only their rights to apply to the Commission for rehearing and to petition for judicial review of the Commission's decision or order as may be provided for by the statute under which the proceeding was initiated and conducted.

* * * * *

(3) Except as provided in § 1.18(e)(4)(iii), requests for waiver and omission of the intermediate decision procedure shall be by motion filed with the Commission at any time during, but not later than five days next following, the conclusion or adjournment sine die of the hearing; shall be in writing under oath, subscribed and verified; and shall in all other respects conform to the requirements of §§ 1.12 and 1.15 to 1.17, inclusive: *Provided, however,* That during sessions of hearings in proceedings, motions for such waiver and omission may be made orally on the record before the presiding officer, who shall forthwith report the same to the Commission.

§ 2.1 [Amended]

4. Code of Federal Regulations, Chapter I of Title 18, CFR Part 2, § 2.1(a)(1)(i)(H) is deleted.

[FR Doc. 78-20868 Filed 7-27-78; 8:45 am]

[4810-22]

DEPARTMENT OF THE TREASURY

Customs Service

[19 CFR Part 123]

CUSTOMS RELATIONS WITH CANADA AND MEXICO

Proposed Rulemaking-Amending the Customs Regulations Relating to Violations in Manifests for Vehicles and Certain Vessels Arriving From Canada or Mexico

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish uniform procedures for handling discrepancies in the manifests of vehicles and certain vessels arriving from Canada or Mexico. The proposed rule is intended to provide instructions for the public and Customs officers to insure uniform treatment of all cases involving a discrepancy in a manifest.

DATES. Comments must be received on or before: August 28, 1978.

ADDRESSES: Written comments should be addressed to the Commissioner of Customs, Attention: Regulations and Legal Publications Division, 1301 Constitution Avenue NW., Washington D.C. 20229.

Comments submitted will be available for public inspection in accordance with §103.8(b) of the Customs regulations (19 CFR 103.8(b)) during regular business hours at the Regulations and Legal Publications Division, Headquarters, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT:

Donald H. Reusch, Carriers, Drawback and Bonds Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, 202-566-5706.

SUPPLEMENTARY INFORMATION: The U.S. Customs Service proposes to amend §123.9 of the Customs regulations (19 CFR 123.9). The present regulations do not satisfactorily state the applicable statutory provisions or outline the procedures to be followed in situations involving incorrect manifests. The proposed amendment is designed to promote uniform treatment in cases involving discrepancies in minifests for vessels of less than 5 net tons arriving otherwise than by sea from Canada or Mexico and all vehicles arriving from Canada or Mexico.

For the purposes of the Customs regulations, vessels which arrive in the United States "otherwise than by sea" generally are those which arrive via the Great Lakes or via rivers or other inland waters. However, no precise definition of the term "otherwise than by sea" governs every case. The Customs Service has ruled that a vessel arriving from Mexico via the Falcon Reservior arrives "otherwise than by sea." On the other hand, in "Border Line Transportation Co. v. Haas," 128 F. 2d 192 ninth circuit 1942), cert. den. 318 U.S. 763, the court held that a vessel arriving from British Columbia via the Strait of Juan de Fuca arrived "by sea."

Interested parties desiring specific information with regard to whether a particular arrival will be considered as "otherwise than by sea" may contact the district director of Customs in the customs district where the intended port of arrival is located. A list of customs districts and ports is found in §101.3 of the Customs regulations (19 CFR 101.3). A ruling with respect to a particular arrival also may be obtained from Customs Service Headquarters, Attention: Carriers, Drawback and Bonds Division, Washington, D.C. 20229, by following the procedures outlined in Part 177 of the Customs regulations (19 CFR Part 177).

DISCUSSION OF PROPOSED CHANGES

CHANGING THE SECTION HEADING

The heading of §123.9 of the Customs regulations (19 CFR 123.9) entitled "Correction of manifest" implies that the filing of the descrepancy report and declaration, Customs form 5931, corrects a manifest so as to relieve a person from a penalty. The proposed amendment would change the heading to read "Explanation of a discrepancy in a manifest." This change is intended to avoid creating any implication that the filing of the discrepancy report and declaration, Customs form 5931, corrects the manifest and cancels any liability arising under section 460 or 584, Tariff Act of 1930, as amended (19 U.S.C. 1460, 1584).

STATUTORY BASIS OF A VIOLATION

Section 123.9 of the Customs regulations (19 CFR 123.9) applies to vessels of less than 5 net tons arriving otherwise than by sea from Canada or Mexico and to all vehicles arriving from Canada or Mexico. Those vessels and vehicles are required to file a correct manifest with the U.S. Customs Service on arrival in the United States. Paragraph (a) of §123.9 cites section 440 of the Tariff Act of 1930, as amended (19 U.S.C. 1440), as prescribing the penalty for failing to correct a manifest by a post entry and section 584 of the Tariff Act of 1930, as amended (19 U.S.C. 1584), as prescribing the penalty for filing an incorrect manifest. The citation of section 440 is incorrect, and the citation of section 584 is misleading, for the following reasons.

Section 440 concerns the filing of a post entry to correct a manifest on a vessel from a foreign port required to make entry. That section does not apply to vessels of less than 5 net tons arriving otherwise than by sea from Canada or Mexico or to vehicles arriving from Canada or Mexico. Accordingly, the reference to section 440 is deleted from proposed §123.9.

Section 460 of the Tariff Act of 1930, as amended (19 U.S.C. 1460) is applicable to vessels of less than 5 net tons arriving otherwise than by sea from Canada or Mexico and to vehicles arriving from Canada or Mexico. For violations involving those vehicles and vessels, section 460 rather than section 584 is the proper authority for violations that are covered by both statutes because section 460 is more specific in scope. Paragraph (a) of proposed §123.9 details the specific situations covered by sections 460 and 584.

Penalties should be assessed under section 460 if a manifest is not filed or if it fails to include all of the merchandise imported or brought in on those vessels or vehicles. On the other hand, a penalty would be assessed under section 584 if a manifest listed merchandise that is not found on board a vehicle or a vessel of less than 5 net tons arriving otherwise than by sea from Canada or Mexico.

REPORT OF DISCREPANCY

Paragraph (b) of §123.9 of the Cusoms regulations (19 CFR 123.9(b)) establishes a procedure for reporting discrepancies in a manifest to the Customs Service. The present procedure is limited to the situation where a private individual discovers the discrepancy.

Proposed §123.9(b) is divided into two parts. The first part concerns the situation where a private individual discovers the discrepancy. The proposal states the 60-day time period from the date of arrival for a private individual to report the discrepancy to the district director of Customs who received the original manifest. Previously, §123.9 referred to the time limits set in §4.12 of the Customs regulations (19 CFR 4.12). Stating the time limit in the proposed section will eliminate the need to refer to another section. The second part of proposed §123.9(b) concerns the situation where a Customs officer discovers the discrepancy before it is reported to the Customs Service. In this part of the proposed section there is a requirement for the district director concerned to notify the private individual of the discrepancy. The proposal also requires the private individual to exlain the discrepancy within 30 days of the district director's notification or within 60 days after arrival, whichever is later.

ACTION ON DISCREPANCY REPORT

The proposal would add a new paragraph (d) to § 123.9 of the Customs regulations (19 CFR 123.9). This new paragraph establishes guidelines for remitting a penalty assessed for violation of section 460 of the Tariff Act of 1930, as amended (19 U.S.C. 1460). These guidelines would also be used in determining whether to assess a penalty under section 584 of the Tariff Act of 1930, as amended (19 U.S.C. 1584).

SETTING PENALTY AMOUNT

Proposed new paragraph (e) of § 123.9 of the Customs regulations (19 CFR 123.9) provides instructions for setting the amount of the penalty. The proposed paragraph cross-references § 162.43 of the Customs regulations (19 CFR 162.43) which establishes rules for appraising merchandise subject to a penalty under the Customs laws. The cross-reference to § 162.43 is used because the appraisement rules themselves are too lengthy to repeat in proposed paragraph (e). Previously, § 123.9(a) contained a reference to § 4.12 of the Customs regulations (19 CFR 4.12) which, in turn, referred to § 162.43. The new paragraph would reduce the amount of cross-referencing.

EFFECT OF LACK OF KNOWLEDGE

Proposed new paragraph (f) of § 123.9 of the Customs regulations (19 CFR 123.9) makes it clear that lack of knowledge of a discrepancy by a private individual does not relieve that individual from a penalty. This concept is a carryover from present § 123.9(a). Previously § 123.9(a) referenced § 4.12 of the Customs regulations (19 CFR 4.12) which contained the concept. The proposed paragraph would eliminate the need for that cross-reference.

DEFINITION OF CLERICAL ERROR OR OTHER MISTAKE

The proposed amendment provides a definition of the term "clerical error or other mistake". That term is already defined in §§ 4.12(a)(5) and 6.7(h)(5) of the Customs regulations (19 CFR 4.12(a)(5), 6.7(h)(5)). However, although the definition of clerical error or other mistake is important with respect to handling cases involving discrepancies in manifests, the term has not been defined in § 123.9 of the Customs regulations (19 CFR 123.9). The proposed amendment would add a new paragraph (g) to § 123.9 that would contain the definition of "clerical error or other mistake" used in §§ 4.12(a)(5) and 6.7(h)(5).

Accordingly, the U.S. Customs Service proposes to amend § 123.9 of the Customs regulations (19 CFR 123.9) and the heading of that section to read as follows:

§ 123.9 Explanation of a discrepancy in a manifest.

(a) *Provisions applicable*—(1) *Failure to file a manifest; overages.* If there is a failure to file a manifest in accordance with § 123.5 or merchandise is found that is not listed on the manifest filed in accordance with § 123.5 (an overage), the merchandise and the vessel or vehicle in which it was brought or imported into the United States are subject to forfeiture and the master of the vessel or the person in charge of the vehicle is liable, in addition to any other penalty equal to the value of the merchandise under section 460, Tariff Act of 1930, as amended (19 U.S.C. 1460).

(2) *Shortages.* If merchandise is manifested but not found on board (a shortage), the master of the vessel or other person in charge or the owner of that vessel or vehicle shall be subject to a penalty of $500 under section 584, Tariff Act of 1930, as amended (19 U.S.C. 1584).

(b) *Report of discrepancies.*—(1) *Discrepancies discovered by master or person in charge.* The master, person in charge, or agent of the vessel or vehicle shall report all discrepancies to the district director within 60 days after the date of arrival by completion of a report for an overage or a declaration for a shortage. The overage report or shortage declaration may be made on the appropriate manifest form, as listed in § 123.4, or on Customs form 5931, discrepancy report and declaration. If no manifest had been filed, an original copy of the appropriate form, as listed in § 123.4 should be used. In each case where a manifest form is used, it shall be marked or stamped "Overage Report" or "Shortage Declaration," as appropriate. The form used shall list the merchandise involved and state the reasons for the discrepancy.

(2) *Discrepancies discovered by Customs.* The district director shall immediately advise the master, person in charge, owner, or agent of any discrepancies discovered by Customs officers which have not been reported by the master, person in charge, owner, or agent. Thereafter, such master, person in charge, owner, or agent shall file an explanation of the discrepancy as required by paragraph (b)(1) of this section within 30 days of that notification or within 60 days after arrival of the vessel or vehicle, whichever is later. The district director may notify the master, person in charge, owner, or agent of a discrepancy by furnishing a copy of Customs form 5931 to that person, or by any other appropriate means.

(c) *Statement on report of discrepancy required.* The overage report or shortage declaration shall bear the following statement signed by the master of the vessel, the person in charge of the vehicle, the owner of the vessel or vehicle or an authorized agent:

I declare to the best of my knowledge and belief that the discrepancy described herein occurred for the reasons stated. I also certify that evidence to support a claim of nonimportation or proper disposition of merchandise will be retained in the carrier's files for a period of at least 1 year from the date of this report of discrepancy and will be made available to Customs upon demand.

(d) *Action on the discrepancy report.* Any penalty or liability to forfeiture incurred under 19 U.S.C. 1460 shall be remitted under section 618, Tariff Act of 1930, as amended (19 U.S.C. 1618), and in accordance with the proviso of 19 U.S.C. 1584, no penalty or liability to forfeiture shall be incurred under 19 U.S.C. 1584, if—

(1) There is a timely filing of the manifest discrepancy report;

(2) There has been no loss of revenue;

(3) The district director is satisfied that the discrepancy resulted from clerical error or other mistake; and

(4) In the case of a discrepancy not initially reported by the master, person in charge, owner, or agent, the district director is satisfied that there was a valid reason for the failure to so report.

Otherwise, applicable penalties under 19 U.S.C. 1460 and 1584 shall be assessed and the vessel or vehicle shall be liable to forfeiture (see § 162.31 of this chapter).

(e) *Penalty assessment.* For the purpose of assessing penalties under 19 U.S.C. 1460 or 1584, the value of the merchandise shall be determined as prescribed in § 162.43 of this chapter.

(f) *Lack of knowledge does not relieve liability.* The fact that the master of the vessel, the person in charge of the vehicle, or the owner of the vessel or vehicle had no knowledge of a discrepancy shall not relieve the master, the person in charge, or the owner from a penalty, or the vessel or vehicle from liability to forfeiture, incurred under 19 U.S.C. 1460 and 1584.

(g) *Clerical error or other mistake defined.* For the purpose of this section, the term "clerical error or other mistake" is defined as a non-negligent, inadvertent, or typographical mistake in the preparation, assembly, or submission of manifests. However, repeated similar manifest discrepancies by the same individuals may be considered the result of negligence and not clerical error or other mistake.

This amendment is proposed under the authority of R.S. 251, as amended

(19 U.S.C. 66), and section 624, 46 Stat. 759 (19 U.S.C. 1624).

R. E. CHASEN,
Commissioner of Customs.

Approved: July 18, 1978.

RICHARD J. DAVIS,
Assistant Secretary of the Treasury.

[FR Doc. 78-20884 Filed 7-27-78; 8:45 am]

[4810-22]

[19 CFR Part 141]

ENTRY OF MERCHANDISE

Proposed Amendment to the Customs Regulations Relating to Additional Information Required on Invoices for Footwear

AGENCY: United States Customs Service, Treasury.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Customs Regulations by consolidating and updating the information required on invoices of imported footwear. Customs has determined that much of the information now required, which generally is descriptive of footwear, no longer is necessary, and other information, relating to the construction of footwear, is necessary. The information is used to establish the correct tariff classification of imported footwear and to assist in its appraisement.

DATE: Comments must be received on or before September 26, 1978.

ADDRESS: Comments (preferably in triplicate) may be addressed to the Commissioner of Customs, Attention: Regulations and Legal Publications Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT:

Benjamin J. Mahoney, Entry Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, 202-566-5778.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Invoices of merchandise imported into the United States are required by section 481 of the Tariff Act of 1930 (19 U.S.C. 1481) to include certain specified information and "any other facts deemed necessary to a proper appraisement, examination, and classification of the merchandise that the Secretary of the Treasury may require." Section 141.89, Customs Regulations (19 U.S.C. 141.89), requires additional information on invoices of footwear classifiable under schedule 7, part 1A, Tariff Schedules of the United States (19 U.S.C. 1202).

The additional information enables the Customs Service to establish the correct tariff classification of imported footwear and assists Customs in determining whether or not an imported article of footwear is like or similar to footwear made in the United States for purposes of appraisement under the American selling price procedure described in section 152.24, Customs Regulations (19 CFR 152.24).

Because footwear manufacturing methods have changed since the additional reporting requirements were established, much of the information now required, which generally is descriptive of footwear, no longer is necessary, and other information, relating to the construction of footwear, is needed. It is proposed to amend section 141.89 to reflect these changes and to consolidate and simplify the information reporting requirements.

COMMENTS

The Customs Service invites written comments from all interested parties on the proposed amendment. Comments submitted will be available for public inspection in accordance with § 103.8(b), Customs Regulations (19 CFR 103.8(b)), during regular business hours at the Regulations and Legal Publications Division, room 2335, Headquarters, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229.

DRAFTING INFORMATION

The principal author of this document was Paul G. Hegland, Regulations and Legal Publications Division, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

AUTHORITY

This amendment is proposed under the authority of R.S. 251, as amended (19 U.S.C. 66), sections 481, 484, 624, 46 Stat. 719, 722, as amended, 759 (19 U.S.C. 1481, 1484, 1624), and 77A Stat. 14 (19 U.S.C. 1202 (General Headnote 11, Tariff Schedules of the United States)).

PROPOSED AMENDMENT

It is proposed to amend § 141.89 of the Customs Regulations (19 CFR 141.89) by substituting a new paragraph for footwear, in appropriate alphabetical order, to read as follows:

Part 141—Entry of Merchandise

§ 141.89 Additional information for certain classes of merchandise.

• • • • •

Footwear classifiable under schedule 7, part 1A, Tariff Schedules of the United States—

(1) The manufacturer's style number.

(2) The importer's style number.

(3) Component materials of upper with percentage (value) of each component (if fiber, and if fiber plus rubber and/or plastic is less than 50 percent, state the percentage by weight and value of each fiber used).

(4) Component materials of entire article with percentage (value) of each component. If the materials in (3) and (4) are primarily of leather, answer only (10) and (11). Otherwise answer all questions.

(5) Component materials of sole with percentage (value) of each component.

(6) Percentage of weight of entire article.

(a) Fiber.

(b) Rubber and/or plastic.

(c) Other (specify material).

(7) Percentage of exterior surface area of upper:

(a) Leather.

(b) Rubber and/or plastic.

(c) Other (specify material).

(8) Whether there is a foxing-like band around bottom of upper.

(9) Whether the upper extends over the ankle.

(10) Type of construction:

(a) Cement.

(b) Molded or vulcanized.

(c) Turned.

(d) Unsoled moccassin.

(e) Welt.

(f) Other.

(11) If the component material of chief value of the entire article is leather, state if made on a male or female last. Customs Form 5523 may be used for furnishing the additional information.

Approved: July 17, 1978.

G. R. DICKERSON,
Acting Commissioner of Customs.

RICHARD J. DAVIS,
Assistant Secretary of the Treasury.

[FR Doc. 78-20937 Filed 7-27-78; 8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 172 and 182]

[Docket No. 78N-0153]

GUM GUAIAC

Removal as a Gras Ingredient and Regulated Food Additive for Direct Human use in Foods

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposal would remove gum guaiac from the list of direct human food ingredients that are generally recognized as safe (GRAS) and from the list of approved direct food additives. The safety of this substance has been evaluated as part of the comprehensive review of all GRAS ingredients currently being conducted by FDA. There is no evidence to indicate that gum guaiac is used in foods at this time, and it is therefore impossible to evaluate fully potential food uses.

DATE: Comments by September 26, 1978.

ADDRESSES: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: A comprehensive safety review of human food ingredients classified as generally recognized as safe (GRAS) or subject to a prior sanction is being conducted by the Food and Drug Administration. The Commissioner of Food and Drugs has issued several notices and proposals initiating this review (see the FEDERAL REGISTER of July 26, 1973 (38 FR 20040)). The safety of gum guaiac has been evaluated as part of this review. In accordance with the provisions of § 170.35 (21 CFR 170.35), the Commissioner proposes to remove this ingredient from the GRAS list and from food additive regulations permitting direct food uses of the ingredient.

Gum guaiac is obtained from *Guaiacum officinale L.* (lignum vitae) and *G. Sanctum L.* (bastard lignum vitae or holywood). The gum is found as an exudate on the trunks of the trees which are native to tropical America. Gum guaiac was used extensively in the 1930's and 1940's as an antioxidant in lard. However, it was reported in the 1951 edition of Bailey's Industrial Oil and Fat Products[1] that use of gum guaiac as an antioxidant in lard had been discontinued.

Gum guaiac is listed in § 182.3336 (21 CFR 182.3336) as GRAS for use in edible fats and oils as a chemical preservative under a regulation published in the FEDERAL REGISTER of November 20, 1959 (24 FR 9368). It is also listed in § 172.510 (21 CFR 172.510) as a natural flavoring substance.

The indirect uses of gum guaiac are listed in § 181.24 (21 CFR 181.24) as a prior-sanctioned substance for use as a antioxidant in the manufacture of food-packaging material, and in § 175.300 (21 CFR 175.300) as an antioxidant in the production of resinous and polymeric coatings.

A representative cross section of food manufacturers was surveyed by the National Academy of Sciences/National Research Council (NAS/NRC) to determine the specific food in which gum guaiac was used and the levels of usage. This survey showed no indication that gum guaiac was used in food products in 1970.

Gum guaiac has been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) any reported carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavorial effects, (12) detection and (13) processing. A total of 49 abstracts on gum guaiac was reviewed, and 7 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

The scientific literature review shows the following information as summarized in the report of the select committee on GRAS Substances (the select committee), selected by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology:

Most of the pertinent biological data on gum guaiac was reported in 1938 by Johnson et al. and in 1951 by Lehman et al. This information was reviewed in 1962 by the Joint FAO/Who Expert Committee on Food Additives.

According to Johnson et al., little if any ingested gum guaiac is absorbed into the blood of rats, dogs, and man. Much is passed out in the feces, although an appreciable quantity may be destroyed in the colon. For example, in one experiment with 4 dogs fed 2, 29, or 40 g of gum guaiac mixed in the food, 67 to 99 percent was recovered in the feces over the ensuing 2 to 4 days. Other in vitro experments showed that no destruction of gum guaiac occurred in gastric or pancreatic juice but most of the gum guaiac added feces was not recoverable after 24 hours of incubation.

The LD_{50} of gum guaiac in three species of animals has been reported as follows:

Animal	Route	LD_{50} (mg/kg body weight)
Rats	Oral	>5000
Rats	Oral	>2000
Mice	Oral	>2000
Mice	i.p.	>2000
Guinea pigs	Oral	1120

Six human subjects were given a total of 10 doses of 2 or 3 grams of gum guaiac at a time, over an unspecified period. In some instances, one or two loose stools were passed; otherwise, there were no untoward effects.

Lehman et al. reported that when young male rats were fed gum guaiac as 0.5 percent of the diet (about 500 mg per kg body weight) for 6 months, the mean growth rate was 80 to 85 percent of the rate for control rats.

The effect of gum guaiac ingestion was studied in 11 adult dogs over a period of 62 to 103 weeks. Five dogs received 0.5 to 1 g of gum guiac daily, in addition to a standard diet. Three dogs received 1 g daily (about 100 mg per kg body weight), and three dogs served as controls. At the end of the test, all but one dog had gained weight, and in the exception, the loss apparently was not significant. Histological examination of intestines, lungs, kidneys, livers, and spleens from three dogs fed 1 g gum guaiac daily for 75 weeks showed that these tissues and organs were normal. Red cell and white cell counts were normal, as were hemoglobin levels.

A similar experiment was conducted with eight adult cats for 34 to 117 weeks. Three received no gum guaiac, and five were fed 0.5 to 1.0 g of gum guaiac daily (about 600 mg per kg body weight). Only one cat, receiving 1 g of gum guaiac daily, failed to gain weight. Gross and histological examination of the lungs, kidneys, livers, and spleens revealed no untoward effects. The intestinal mucosa was not inflamed.

Four women and seven men ingested 0.05 of 0.10 g of gum guaiac (about 1 to 2 mg per kg of body weight) mixed in chocolate pellets, daily for periods of 18 to 104 weeks; five subjects continued for another 90 weeks. Red and white blood cell counts, hemoglobin determinations, and Fishberg's (1930) modification of Volhard's urine-concentration test for kidney function were performed each month. Stool consistency and body weight were noted. No abnormalities in these parameters were detected and all subjects remained healthy.

Lehman at al cited an unpublished 2-year study of R.N. Bieter in which one group of 10 rats was fed a diet containing 0.5 percent gum guaiac (about 500 mg per kg of body weight), and another group of 10 rats received no gum guaiac. There was no discernable difference between the two groups as determined by mortality and pathological examination.

In a lifetime study, four groups of 10 rats each were fed a basal diet containing 0.005, 0.05, 0.5 percent (estimated to be in range of 5 to 500 mg per kg body weight) of gum guaiac. The second and third generation descendants (80 in number) of the original rats were maintained throughout their lives on the same diet as their parents. No differences were observed between the experimental groups and the controls in regard to body weight, growth rate, life span, reproduction, or pathological examination. In all three generations, there were no significant differences between the treated and control groups with respect to number of pregnancies, number of young born, and number of young weaned.

[1] Bailey, A. E., "Gum guaiac" in "Industrial Oil and Fat Products," 2d ed., Interscience Publishers, Inc., New York, pp. 230-232, 308, and 309, 1951.

No reports on the teratogenicity, mutagenicity, carcinogenicity, or allergic reactions due to gum guaiac have come to the attention of the Select Committee.

All the available safety information on gum guaiac has been carefully evaluated by qualified scientists of the Select Committee. It is the opinion of the Select Committee that:

The literature on the biological activity of gum guaiac indicated that it is a substance of very low acute toxicity. A number of short- and long-term feeding studies in experimental animals at levels orders of magnitude greater than those to which humans might be exposed indicate the absence of chronic effects. Daily ingestion by human subjects for nearly four years resulted in no observable adverse effects.

It is the conclusion of the Select Committee that there is no evidence in the available information on gum guaiac that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public if it is used as an antioxidant at levels compatible with current limitations. Based upon the Commissioner's own evaluation of all available information on gum guaiac, the Commissioner concurs with this conclusion.

However, the Commissioner is not aware of any current direct food uses of gum guaiac. In the absence of such use information, it is not possible to evaluate fully the safety of present or potential food uses of this ingredient. Because of the lack of knowledge concerning the uses of gum guaiac in food, the Commissioner concludes that affirmation of the GRAS status of this ingredient would not be appropriate.

Also, on April 13, 1973 (38 FR 9310), the Commissioner proposed to delete gum guaiac and 51 other GRAS substances from the GRAS list because the NAS/NRC survey of food manufacturers indicated that these substances were not being used in food. No comments were received on gum guaiac in response to that proposal, thus confirming that gum guaiac is not used in human foods. The proposal was withdrawn on July 26, 1973 (38 FR 20041) because many of the other GRAS substances included in the proposal elicited a large enough response to retain the entire group in the current GRAS review.

If evidence of direct food use of gum guaiac (foods to which it is added, intended technical effects as defined in § 170.3 (21 CFR 170.3), and amounts added to food) is submitted during the comment period, however, further consideration will be given to affirming the GRAS status of gum guaiac. Alternatively, the substance may be considered for GRAS affirmation on the basis of a petition submitted in accordance with § 170.35 (21 CFR 170.35). Food uses of gum guaiac not specifically authorized by regulations will result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act.

The prior-sanctioned use of gum guaiac as an antioxidant in food-packaging materials (21 CFR 181.24) and the specific regulated indirect use of the substance (21 CFR 175.300) are not affected by this proposal. This proposal also does not affect the present use of gum guaiac in pet food or animal feed.

Copies of the scientific literature review of gum guaiac and the report of the Select Committee are available for review at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22151, as follows:

Title	Order No.	Price code	Price*
Gum guaiac (scientific literature review).	PB-228-547/AS	A02	$4.00
Gum guaiac (Select Committee report).	PB-274-474/AS	A02	$4.00

*Price subject to change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that parts 172 and 182 be amended as follows:

§ 172.510 [Amended]

1. In part 172 by deleting the entry for "guaiac" from the table in paragraph (b) of § 172.510 *Natural flavoring substances and natural substances used in conjunction with flavors.*

§ 182.3336 [Deleted]

2. In part 182 by deleting § 182.3336 *Gum guaiac.*

The Commissioner hereby gives notice that he is unaware of any prior sanction for the use of this ingredient in food under conditions different from those stated in part 181 (21 CFR part 181). Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The proposed regulation will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act (21 U.S.C. 342), and the failure of any person to come forward with proof of such an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on such sanction at any later time. This notice also contitutes a proposal to establish a regulation under part 181, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to this proposal.

Interested persons may, on or before September 26, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this proposal will not have a major economic impact as defined by Executive Order 11821 (amended by Executive Order 11949) and OMB Circular A-107.

Dated: July 18, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-20626 Filed 7-27-78; 8:45 am]

[4110-03]

[21 CFR Parts 369 and 429]

[Docket No. 78N-0181]

INSULIN PRODUCTS

Withdrawal and Reissuance of Proposal to Discontinue Certification of all 80-Unit Insulin Products

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This agency is withdrawing its original proposal and is reproposing to discontinue the certification of all 80-unit (U-80) insulin products. In addition, it is requesting comments on (1) the suitability of 100-unit (U-100) insulin as the only standard strength, and (2) the need for the continued certification of a low-potency insulin product for pediatric use. The purpose of this proposal is to reduce the potential for patient errors that results from having insulin available in two high concentrations and syringes calibrated for use with more than one concentration.

DATES: Comments by November 27, 1978. The agency proposes that the final rule based on this proposal become effective 180 days after date of publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Marc H. Hoffman, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of November 15, 1974 (39 FR 40301), the Commissioner of Food and Drugs proposed to discontinue certification of all insulin products containing 80 USP units per milliliter (ml) (U-80 insulin). None of the comments responding to the original proposal objected to its intent. Some of the comments, however, questioned the proposed discontinuance of U-80 insulin at a time when sufficient supplies of suitable syringes for administration of U-100 insulin were not available. In addition, some comments questioned whether diabetics using U-80 insulin and their physicians had sufficient knowledge of the proposed action to effect an orderly transition to U-100 usage.

Statistics compiled by the Food and Drug Administration's (FDA's) Certification Services Branch, on file in the office of the Hearing Clerk, reveal that in the past few years, there has been a definite trend toward greater acceptance of U-100 insulin and away from use of U-80 insulin. The most current figures available, those for January 1975 through October 1977, show that significantly more batches of U-100 insulin have been and are currently being certified (and consequent vials produced) than is the case with U-80 insulin.

In view of this wide acceptance of U-100 insulin, and with the understanding that sufficient supplies of syringes are available for the administration of U-100 insulin, the Director of the Bureau of Drugs to whom the Commissioner has delegated the authority to amend the insulin regulations believes it appropriate to propose discontinuance of the certification of U-80 insulin products. Because of the length of time since the November 15, 1974 proposal, and because of the changes referred to above, the Director has decided to issue another proposal on this matter. Accordingly, the November 15, 1974 proposal is withdrawn and replaced by this document.

Also in the FEDERAL REGISTER of November 15, 1974 (39 FR 40284), the Commissioner issued a final regulation providing for the certification of modified insulin products in the 100-unit strength (U-100 insulin). This was done with the intention of later phasing out the U-80 insulin concentrations already on the market and possibly phasing out the U-40 concentrations, also at some later date.

Section 506(a) of the Federal Food, Drug, and Cosmetic Act states that a batch of insulin shall be certified if it has such characteristics of identity, strength, quality, and purity as prescribed in the regulations as necessary to adequately insure safety and efficacy of use. Insulin products are presently available over-the-counter in the United States in concentrations of 40, 80, and 100 units of insulin per ml. (This proposal does not affect the status of 500-unit insulin, available only on a prescription basis.) It should be noted that "insulin" is used throughout this document to refer to both regular and modified insulin products available over-the-counter.

There have been reports of adverse reactions as a result of patient errors due to confusion in matching the prescribed concentration to the correct syringe or to the correct calibration. A single concentration of U-100 for general use would be expected to eliminate such patient errors. The advantage of the 100-unit concentration is that its numerical relationship to the decimal system makes the dosage easier to calculate and measure. In addition, with the higher concentration, a smaller volume per injection is needed, which can reduce the discomfort of the injection.

This proposal does not call for revoking the certification of any batches of U-80 insulin certified prior to the effective date of the final rule. Batches certified prior to that date would remain on the market until they became outdated. The agency is proposing that the final rule become effective 180 days after publication in the FEDERAL REGISTER. Such a delay in the effective date is intended to provide a sufficient phase-over and adjustment period for the insulin and syringe manufacturers involved, as well as for the affected public. Because many diabetics and private physicians who may be affected by the final order do not normally have access to the FEDERAL REGISTER, FDA plans to distribute this proposal as widely as possible through an educational program conducted in cooperation with trade and professional groups.

It should be noted that American manufacturers export U-80 insulin for sale abroad. Under the provisions of section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)), shipments of uncertified insulin to foreign countries are lawful. Consequently, discontinuance of certification for U-80 used in this country would still permit production of that insulin concentration for sale abroad.

U-100 insulin is now available only in the United States and Canada. The lack of U-100 insulin available outside of North America, however, should pose virtually no problem for Americans traveling abroad as the increased concentration of insulin, combined with its stability at room temperature, make it possible for most travelers to take along an adequate supply. The main concern would be to protect the vials from extremes of heat and cold.

Revoking the provisions for certifying U-80 insulin, as proposed here, could be an action taken on its own or could be the first step toward making insulin available in only one high concentration. Although the Director is not now proposing to stop the certification of U-40 insulin, such a proposal may be published in the future. First, however, the Director would like to receive comments from interested persons, particularly insulin users and their physicians, pertaining to the basic policy of stopping the certification of U-80 and, perhaps, U-40 insulin. In particular, the Director is interested in obtaining comments on the suitability of having only one strength of insulin available as well as the need for the continued certification of a low concentration insulin product for pediatric use. Responses to the following questions will be especially valuable:

1. Should the ultimate goal be to have only one strength of insulin available?

2. If only one strength of insulin is available, should it be insulin containing 100 units per milliliter?

3. Is there a demonstrated need for a low-potency insulin, such as U-10, U-20, or U-40, for pediatric use?

The Director of the Bureau of Drugs has determined that this document does not contain an agency action covered by § 25.1(b) (21 CFR 25.1(b)); therefore, consideration by the agency of the need for preparing an environmental impact statement is not required.

Accordingly, under the Federal Food, Drug, and Cosmetic Act (sec. 506, 55 Stat. 851 (21 U.S.C. 356)) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director of the Bureau of Drugs (21 CFR 5.73), the Director proposes to amend parts 369 and 429 by removing all references to 80-unit insulin as follows:

§ 369.21 [Amended]

1. In part 369, § 369.21 *Drugs; warning and caution statements required by regulations* is amended in the entry for insulin by deleting the number "80" and the commas immediately preceding and following it.

§ 429.11 [Amended]

2. In part 429, § 429.11 *Labeling* is amended in paragraph (c) by deleting the number "80" and the commas immediately preceding and following it.

§ 429.12 [Amended]

3. Section 429.12 *Distinguishing colors on packages* is amended:

(a) In paragraph (a) by deleting the phrases "Green, if it contains 80 U.S.P. Units of insulin per milliliter" and "Green and gray, if it contains 80 U.S.P. Units of insulin per milliliter."

(b) In paragraph (b) by deleting the phrase "Green and white, if it contains 80 U.S.P. Units of insulin per milliliter."

(c) In paragraph (c) by deleting the phrase "Green and brown, if it contains 80 U.S.P. Units of insulin per milliliter."

(d) In paragraph (d) by deleting the phrase "Green and blue, if it contains 80 U.S.P. Units of insulin per milliliter."

(e) In paragraph (e) by deleting the phrase "Green and lavender, if it contains 80 U.S.P. Units of insulin per milliliter."

§ 429.40 [Amended]

4. Section 429.40 *Requests for certification; samples; storage; approvals preliminary to certification* is amended in paragraph (g)(1) by deleting the phrase "80 or" preceding the number "100" each time it appears.

Interested persons may, on or before November 27, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: July 24, 1978.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc. 78-20865 Filed 7-27-78; 8:45 am]

[4830-01]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 1]

[LR-152-76]

INTEREST RELATED TO EXEMPT-INTEREST DIVIDENDS

Proposed Rulemaking

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations concerning interest related to exempt-interest dividends. Changes to the applicable law were made by the Tax Reform Act of 1976. The regulations would provide the public with the guidance needed to comply with that Act and would affect certain taxpayers who own shares of stock in certain regulated investment companies.

DATES: Written comments and requests for a public hearing must be delivered or mailed by September 26, 1978. The amendments are proposed to be effective for taxable year beginning after December 31, 1975.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (LR-152-76), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT:

Robert H. Waltuch of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224, Attention: CC:LR:T 202-566-3328, not a toll-free number).

SUPPLEMENTARY INFORMATION:

BACKGROUND

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 265 of the Internal Revenue Code of 1954. These amendments are proposed to conform the regulatons to section 2137(e) of the Tax Reform Act of 1976 (90 Stat. 1932) and are to be issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805).

The Tax Reform Act of 1976 added a new paragraph (4) to section 265. This new paragraph denies a deduction to a taxpayer for interest in indebtedness incurred or continued to purchase or carry shares of stock of a regulated investment company which during the taxable year of the holder thereof distributes exempt-interest dividends.

COMMENTS AND REQUESTS FOR A PUBLIC HEARING

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably six copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the FEDERAL REGISTER.

DRAFTING INFORMATION

The principal author of these regulations was Robert H. Waltuch of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

PROPOSED AMENDMENTS TO THE REGULATIONS

The proposed amendments to 26 CFR Part 1 are as follows:

Paragraph 1. The following new section is added immediately after § 1.265-2:

§ 1.265-3 Nondeductibility of interest relating to exempt-interest dividends.

(a) *In general.* No deduction is allowed for the interest on indebtedness that relates to exempt-interest dividends distributed by a regulated investment company.

(b) *Interest relating to exempt-interest dividends.* (1) If an indebtedness is either incurred or continued to purchase or carry shares of stock in a regulated investment company which during the shareholder's taxable year distributes exempt-interest dividends (as defined in section 852(b)(5) of the Code), then all or a portion of the interest on the indebtedness relates to the exempt-interest dividends. If the regulated investment company distributes only exempt-interest dividends to the shareholder during that shareholder's taxable year, then all of the interest paid or accrued relates to exempt-interest dividends. If the regulated investment company distributes exempt-interest dividends in addition to taxable dividends (excluding captial gain dividends distributed or captial gains required to be included in the shareholder's computation of long-term capital gains under section 852(b)(3)(D)) to the shareholder during the shareholder's taxable year, then a portion of the interest paid or

accrued by the shareholder during that shareholder's taxable year relates to exempt-interest dividends.

(2) To determine the portion of the interest that relates to the exempt-interest dividends the total amount of interest paid or accrued on the indebtedness is multiplied by a fraction. The numerator of the fraction is the amount of exempt-interest dividends received. The denominator of the fraction is the sum of the exempt-interest dividends and taxable dividends received (excluding capital gain dividends received or capital gains required to be included in the shareholder's computation of long-term capital gains under section 852(b)(3)(D)).

JEROME KURTZ,
Commissioner of Internal Revenue.

[FR Doc. 78-20840 Filed 7-27-78; 8:45 am]

[4830-01]

[26 CFR Part 1]

[LR-2-78]

REQUIREMENTS RELATING TO CERTAIN EXCHANGES INVOLVING A FOREIGN CORPORATION

Extension of comment period; hearing request

AGENCY: Internal Revenue Service, Treasury.

ACTION: Extension of time for comments and requests for a public hearing.

SUMMARY: This document provides notice of an extension of time for submitting comments and requests for a public hearing concerning the notice of proposed rulemaking with respect to requirements relating to certain exchanges involving a foreign corporation. The extended deadline for submission of comments and requests for a public hearing is October 2, 1978.

DATES: Written comments and requests for a public hearing must be delivered or mailed by October 2, 1978.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (LR-2-78), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT:

Katherine A. Newell of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224, CC:LR:T, 202-566-3289, not a toll-free call.

SUPPLEMENTARY INFORMATION: By a notice of proposed rulemaking published in the FEDERAL REGISTER for Friday, December 30, 1977 (42 FR 65152 and 65204), comments and requests for a public hearing with respect to the proposed rules were to be delivered or mailed to the Commissioner of Internal Revenue, Attention: CC:LR:T (LR-2-78), Washington, D.C. 20224, by February 28, 1978. By a notice published in the FEDERAL REGISTER for Tuesday, February 21, 1978 (43 FR 7245), this date was extended to May 1, 1978, and was additionally extended to August 1, 1978, by a notice published in the FEDERAL REGISTER for Monday, May 1, 1978 (43 FR 18570). The date by which such comments and requests must be delivered or mailed is hereby further extended to October 2, 1978.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the proposed Treasury directive appearing in the FEDERAL REGISTER for Wednesday, May 24, 1978.

ROBERT A. BLEY,
Director, Legislation and Regulations Division.

[FR Doc. 78-21028 Filed 7-27-78; 8:45 am]

[4510-26]

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1956]

CONNECTICUT

Notice of the Connecticut State Plan for Public Employees Only and Its Availability for Public Comment

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Proposed rule.

SUMMARY: This document gives notice of the submission by Connecticut of a State plan for the enforcement of occupational safety and health standards applicable to public-sector employment only. After an opportunity for public comment, the Assistant Secretary of Labor for Occupational Safety and Health will approve the plan if it meets the criteria set forth in the Occupational Safety and Health Act of 1970 and applicable regulations.

DATES: Interested person(s) are hereby given until August 24, 1978, to submit in writing data, views, and arguments concerning the plan.

ADDRESSES: Written comments and requests for a hearing should be submitted to the Director, Federal Compliance and State Programs, Occupational Safety and Health Administration, Department of Labor, room N3101, Third and Constitution Avenue NW., Washington, D.C. 20210.

FOR FUTHER INFORMATION CONTACT:

Ms. Rrencie V. McGlown, Project Officer, U.S. Department of Labor, Occupational Safety and Health Administration, 2100 M Street NW., room 149, Washington, D.C. 20210, phone 202-653-5377.

LOCATION OF PLAN FOR INSPECTION AND COPYING

A copy of the plan may be inspected and copied during normal business hours at the following locations: Office of State Programs, 2100 M Street NW., room 149, Washington, D.C. 20210; Office of the Regional Administrator, Occupational Safety and Health Administration, room 1804, John F. Kennedy Federal Building, Boston, Mass. 02203; Connecticut Department of Labor, 200 Folly Brook Boulevard, Wethersfield, Conn. 06109.

SUPPLEMENTARY INFORMATION:

AUTHORITY

Section 18 of the Occupational Safety and Health Act of 1970 ("the Act," 29 U.S.C. 667) provides that a State which desires to assume reponsibility for the development and enforcement of standards relating to any occupational safety and health issue with respect to which a Federal standard has been promulgated may submit a plan to the Assistant Secretary of Labor for Occupational Safety and Health ("Assistant Secretary") describing in detail the proposed program. Regulations promulgated pursuant to the act at 29 CFR part 1956 provide that a State may submit a State plan for the development and enforcement of occupational safety and health standards applicable only to employees of the State and its political subdivisions ("public employees"). Under these regulations the Assistant Secretary will approve a State plan for public employees if, in her judgement, the plan provides for the development and enforcement of standards relating to hazards in employment covered by the plan which are or will be at least as effective in providing safe and healthful employment and places of employment for public employees as standards promulgated and enforced under section 6 of the Federal act. In making this determination the Assistant Secretary will consider, among other things, the criteria and indices of effectiveness set forth in 29 CFR 1956, subpart B.

BACKGROUND

A State plan for the enforcement of occupational safety and health standards in Connecticut was approved by the Assistant Secretary on December 28, 1973 (39 FR 1013; 29 CFR 1952.300 et seq.). This plan included coverage of

private workplaces as well as a program for public employees. By an act of the Connecticut General Assembly, effective July 1, 1978 (P.A. 77-610), the Connecticut Occupational Safety and Health Act was amended to exclude coverage of private sector employees. This change in the extent of State safety and health coverage necessitates withdrawal of the original State plan and submission for the Assistant Secretary's approval of a State plan for public employees only. In a letter from Gov. Ella Grasso to the Assistant Secretary, dated September 19, 1977, the State has agreed to withdraw the existing State plan upon approval of the plan for public employees only.

DESCRIPTION OF THE PLAN

The plan designates the Connecticut Department of Labor as the State agency responsible for administering the plan throughout the State. The State has adopted all Federal standards promulgated as of September 1977 and pledges to continue to adopt all Federal standards, revisions, and amendments. The plan includes legislation, Public Act 73-379, passed by the Connecticut Legislature in 1973 and amended as follows: P.A. 74-176, P.A. 75-285, P.A. 77-107, and P.A. 77-610. Under the legislation the Connecticut Department of Labor, Occupational Safety and Health Division, has full authority to enforce and administer all laws and rules protecting the safety and health of employees of the the State and its political subdivisions. In addition, the legislation is accompanied by a statement of the Governor's support and a legal opinion that it meets the requirements of the Occupational Safety and Health Act of 1970 and is in accord with the constitution of the State.

The plan establishes procedures for variances and the protection of employees from hazards under a variance; insures inspection in response to complaints; provides employer and employee representatives an opportunity to accompany inspectors and to call attention to possible violations before, during, and after inspections; notification to employees of their representatives when no compliance action is taken as a result of alleged violations, including informal review; notification of employees of their protection; protection of employees against discharge or discrimination in terms and conditions of employment; adequate safeguards to protect trade secrets; provision for prompt notices to employers and employees of violations of standards and abatement requirements; sanctions against employers for violation of standards and orders; employers' right to appeal citations for violations, abatement periods and proposed penalties; employees' right to appeal abatement periods; and employee participation in review proceedings. Also included are provisions for right of entry for inspection, prohibition of advance notice of inspection, and the requirement for both employers and employees to comply with the applicable rules, standards, and orders, and employer obligations to maintain records and provide reports as required. Further, the plan provides assurances of a fully trained adequate staff and sufficient funding.

Any interested person(s) may request an informal hearing concerning the proposed plan or any part thereof. If the Assistant Secretary finds that substantial objections are filed, she may hold a hearing on the subjects and issues involved.

DECISION

The Assistant Secretary will consider all relevant comments, arguments, and requests submitted in accordance with this notice or any hearing afforded pursuant to 29 CFR part 1902.11. She will thereafter issue her decision on the approvability of the plan, which decision will be published in the FEDERAL REGISTER.

Signed at Washington, D.C., this 20th day of July 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

[FR Doc. 78-20645 Filed 7-27-78; 8:45 am]

[1410-01]

COPYRIGHT ROYALTY TRIBUNAL

[37 CFR Part 302]

FILING OF CLAIMS TO CABLE ROYALTY FEES; PROOF OF FIXATION

Proposed Rule With Respect to Proof of Fixation of Copyrighted Works

AGENCY: Copyright Royalty Tribunal.

ACTION: Proposed rule.

SUMMARY: The proposed rule establishes the policy and procedures of the Copyright Royalty Tribunal concerning the submission to the Tribunal during proceedings for the distribution of cable royalty fees of evidence of the fixation of works in a tangible medium as required by section 102(a) of the Copyright Act. Under the proposed rule, the filing of tangible fixations would not be required, and controversies concerning the fixation of works would be resolved on the basis of other appropriate evidence. It is necessary that the proposed rule be adopted so that claimants to cable royalty fees will have timely knowledge of the evidence of fixation that may be required by the Tribunal.

DATES: Comments must be received on or before August 21, 1978.

ADDRESS: Interested persons should submit 10 copies of their comments to Chairman, Copyright Royalty Tribunal, 1111 20th Street NW., Washington, D.C. 20036.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Brennan, Chairman, Copyright Royalty Tribunal, 202-653-5175.

SUPPLEMENTARY INFORMATION: Section 111(d)(5) of the act for General Revision of the Copyright Law directs the Copyright Royalty Tribunal to provide for the distribution of cable royalty fees, and to resolve controversies concerning the distribution of such fees among copyright owner claimants. Section 102(a) establishes as one of the conditions of copyright protection that a work be fixed in a tangible medium of expression.

Shortly after the constitution of the Copyright Royalty Tribunal, the agency was requested to establish a policy concerning the evidence that may be required to resolve disputes as to whether a particular work which is the subject of a claim was fixed in a tangible medium. In an advisory letter of January 31, 1978, the Copyright Royalty Tribunal stated that participation in the royalty distribution proceedings does not require copyright owners to preserve and submit to the Copyright Royalty Tribunal simultaneous fixations of live transmissions. Subsequently in the FEDERAL REGISTER of May 5, 1978 (43 FR 19424), in connection with the publication of the proposed rule as to the filing of claims to cable fees, the Copyright Royalty Tribunal invited comments as to "what proof of fixation, other than the actual video tape or film, should be required in a royalty distribution proceeding." Comments were requested to consider "such form of proof as affidavits from authorized personnel, and the technical feasibility of preserving an identifiable frame or frames from each program." Seven comments were received by the Copyright Royalty Tribunal.

The majority of the comments expressed the view that any requirement that fixation of live transmissions be established by submission of frames, although technically feasible, would be burdensome, expensive, and of limited value as proof of actual fixation. However, the Motion Picture Association of America believes that "some material evidence should be required as independent affirmative proof of fixation."

The proposed rule provides that in the event of a controversy as to whether a work was fixed in a tangible medium, the CRT will not require the

submission of tangible fixations in whole or in part. Any such controversy would be resolved on the basis of affidavits, other documentary evidence, and such oral testimony as may be necessary.

Such proposed rule reads as follows:

Under 17 U.S.C. 111(d)(5)(A), 37 CFR Chapter III, Part 302 is amended by adding a new § 302.9, as follows:

§ 302.9 Proof of fixation of works.

The Copyright Royalty Tribunal shall not require in any proceeding for the distribution of cable royalty fees the filing by claimants of tangible fixations of works in whole or in part. In the event of a controversy concerning the actual fixation of a work in a tangible medium as required by the Copyright Act, the Copyright Royalty Tribunal shall resolve such controversy for purposes of the distribution proceeding solely on the basis of affidavits and other appropriate documentary evidence, and such oral testimony as the Copyright Royalty Tribunal may deem necessary. Affidavits submitted by claimants should establish that the work for which the claim is submitted was fixed in its entirety, and should state the nature of the work, the title of the program, the duration of the program, and the date of fixation. No such affidavits need be filed with the Copyright Royalty Tribunal unless requested by the Tribunal.

THOMAS C. BRENNAN,
Chairman, Copyright Royalty Tribunal.

[FR Doc. 78-20935 Filed 7-27-78; 8:45 am]

[1410-01]

[37 CFR Part 305]

CLAIMS TO PHONORECORD PLAYER (JUKEBOX) ROYALTY FEES

AGENCY: Copyright Royalty Tribunal.

ACTION: Proposed rule.

SUMMARY: The proposed rule prescribes procedures whereby persons claiming to be entitled to compulsory license fees for public performances of nondramatic musical works by coin-operated phonorecord (jukebox) players shall file claims with the Copyright Royalty Tribunal. The rule prescribes the content and time of filing of such claims. The rule is necessary to implement provisions of the Act for General revision of the Copyright Law.

DATES: Comments must be received on or before August 21, 1978.

ADDRESS: Interested persons should submit 10 copies of their comments to Chairman, Copyright Royalty Tribunal, 1111 20th Street NW., Washington, D.C. 20036.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Brennan, Chairman, Copyright Royalty Tribunal, 202-653-5175.

SUPPLEMENTARY INFORMATION: Section 116(c)(2) directs the Copyright Royalty Tribunal to adopt regulations whereby persons claiming to be entitled to compulsory license fees for the performance of nondramatic musical works by coin-operated phonorecord players may file claims to such fees. The Tribunal in the FEDERAL REGISTER of February 14, 1978 (43 FR 6262), published an advance notice of proposed rulemaking. The proposed rule is to be distinguished from the proposed rule published on May 12, 1978 (43 FR 20513), concerning access to establishments in which phonorecord players are located.

Such proposed rule reads as follows:

Under 17 U.S.C. 116(c)(2), 37 CFR Chapter III is amended as follows:

By adding a new Part 305, to read as follows:

PART 305—CLAIMS TO PHONORECORD PLAYER (JUKEBOX) ROYALTY FEES

Sec.
305.1 General.
305.2 Time of filing.
305.3 Content of claims.
305.4 Justification of claims.
305.5 Forms.

AUTHORITY: 17 U.S.C. 116(c)(2).

§ 305.1 General.

This regulation prescribes procedures pursuant to 17 U.S.C. 116(c)(2), whereby persons claiming to be entitled to compulsory license fees for public performances of nondramatic musical works by means of coin-operated phonorecord players shall file claims with the Copyright Royalty Tribunal.

§ 305.2 Time of filing.

During the month of January in each year every person claiming to be entitled to phonorecord player fees for performances of nondramatic musical works during the preceding calendar year shall file a claim with the Copyright Royalty Tribunal. Claimants may file jointly or as a single claim. A performing rights society shall not be required to obtain from its affiliates separate authorizations, apart from their standard affiliation agreements, for purposes of this filing and fee distribution.

§ 305.3 Content of claims.

The claims filed shall include the following information:

(a) The full legal name of the person or entity claiming compulsory license fees. Performing rights societies are not required to include lists of affiliates to whom distributions would be made by such societies.

(b) The full address, including a specific number and street name or rural route, of the place of business of the person or entity.

(c) A specific agreement to accept as final the determination of the Copyright Royalty Tribunal in any controversy concerning the distribution of royalty fees, except for the judicial review provided in 17 U.S.C. 810.

§ 305.4 Justification of claims.

(a) Not later than the first day of November of each year, every person or entity which has filed a claim pursuant to § 305.2 shall file with the Copyright Royalty Tribunal a statement claiming the proportionate share of compulsory license fees to which such person or entity believes it is entitled. The statement shall include a detailed justification for the requested entitlement and shall also include such specific information as the Copyright Royalty Tribunal may require by regulation or order.

(b) The entitlement justification statement required by subsection (a) need not be filed with the Copyright Royalty Tribunal if it has been determined by the Tribunal that there is no controversy as to the distribution of royalty fees.

§ 305.5 Forms.

The Copyright Royalty Tribunal does not provide printed forms for the filing of claims.

THOMAS C. BRENNAN,
Chairman, Copyright Royalty Tribunal.

[FR Doc. 78-20936 Filed 7-27-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 65]

[FRL 933-2]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Approval of an Administrative Order Issued by the State of Idaho Department of Health and Welfare to FMC Corp.

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the State of Idaho Department of Health and Welfare to FMC Corp. The order requires the company to bring air emissions from its elemental phospho-

rus plant in Pocatello, Idaho, into compliance with certain regulations contained in the federally approved Idaho State implementation plan (SIP) by July 1, 1979. Because the order has been issued to a major source and permits a delay in compliance with provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the Federal enforcement or citizen suit provisions of the act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before August 28, 1978.

ADDRESSES: Comments should be submitted to Director, Enforcement Division, EPA, Region X, 1200 Sixth Avenue, Seattle, Wash. 98101. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

John Pfander, EPA, Idaho Operations Office, 422 West Washington, Boise, Idaho 83702, 208-384-1450.

SUPPLEMENTARY INFORMATION: FMC Corp. operates an elemental phosphorus plant at Pocatello, Idaho. The order under consideration addresses emissions from the furnace stack scrubbers, the burden level, and ore crusher at the facility, which are subject to regulations E and F, rules and regulations for the control of air pollution in Idaho. The regulations limit the emissions of particulate matter, visible emissions, and fugitive dust, and is part of the federally approved Idaho State implementation plan. The order requires final compliance with the regulation by July 1, 1979, through installation of secondary scrubbers on the furnace stacks. A medusa crossover system is to be installed for control of fugitive emissions. The source has consented to the terms of the order and has satisfied all increments due at this time.

Because this order has been issued to a major source of particulate emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before it becomes effective as a delayed compliance order under section 113(d) of the Clean Air Act (the act). EPA proposes to approve the order because it satisfies the appropriate requirements of this subsection.

If the order is approved by EPA, source compliance with its terms would preclude Federal enforcement action under section 113 of the act against the sources for violations of the regulation covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provisions of the act (section 304) would be similarly precluded. If approved, the order would also constitute an addition to the Idaho SIP.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order. After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the order in 40 CFR Part 65.

The provisions of 40 CFR Part 65 will be promulgated by EPA soon, and will contain the procedure for EPA's issuance, approval, and disapproval of orders under section 113(d) of the act. In addition, part 65 will contain sections summarizing orders issued, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 14876 (April 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

(42 U.S.C. 7413, 7601.)

Dated: July 5, 1978.

DONALD P. DUBOIS,
Regional Administrator,
Region X.

[FR Doc. 78-20859 Filed 7-27-78; 8:45 am]

[6820-35]

LEGAL SERVICES CORPORATION

[45 CFR Part 1602]

FREEDOM OF INFORMATION ACT

Amendments to the Regulations

AGENCY: Legal Services Corporation.

ACTION: Proposed amendment.

SUMMARY: The Legal Services Corporation proposes to amend regulations issued in accordance with the Freedom of Information Act. The only substantive change would be in the fees charged for locating and reproducing materials requested under the act. The fees have been adjusted to reflect actual cost to the Corporation. Other changes are technical or stylistic in nature.

DATES: Comments must be received on or before September 11, 1978.

ADDRESS: Legal Services Corporation, 733 15th Street NW., Suite 700, Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION: Section 1005(g) of the Legal Services Corporation Act, 42 U.S.C. 2996d(g) provides that the Corporation shall be subject to the provisions of the Freedom of Information Act, 5 U.S.C. 552.

A final regulation was published in the FEDERAL REGISTER on November 13, 1975 (40 FR 52847). The only substantive change the proposed amendment is in section 1602.13, *Fees.* These have been adjusted to reflect the actual charge to the Corporation of locating and reproducing materials requested under the Freedom of Information Act. The provisions of section 1602.13 authorizing waiver of fees under certain conditions remain in effect. Section 1602.6, *Regional Records Rooms* has been revised to show the addresses of the Corporation's regional offices as of June 15, 1978. The phrases to be deleted from the Definitions section are now included in Part 1600, the general Definitions section that was published on May 5, 1976 (41 FR 18511), and applies to all the regulations. The other changes are stylistic.

Accordingly, it is proposed that 45 CFR Part 1602 be revised to read as follows:

PART 1602—PROCEDURES FOR DISCLOSURE OR PRODUCTION OF INFORMATION UNDER THE FREEDOM OF INFORMATION ACT

Sec.

AUTHORITY: Section 1005(g); 42 U.S.C. 2996d(g).

§ 1602.1 Purpose.

This Part prescribes the procedures by which records of the Legal Services Corporation may be made available pursuant to section 1005(g) of the Legal Services Corporation Act, 42 U.S.C. § 2996d(g), and the Freedom of Information Act, as amended in 1974, 5 U.S.C. 552

§ 1602.2 Definitions.

As used in this Part—

(a) "FOIA" means the Freedom of Information Act, as amended in 1974, 5 U.S.C. 552;

(b) "Records" means books, papers, maps, photographs, or other documentary materials, regardless of physical form or characteristics, made or received by the Corporation in connection with the transaction of the Corporation's business and preserved by the Corporation as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Corporation, or because of the informational value of data in them. The term does not include books, magazines, or other materials acquired solely for library purposes and available through any officially designated library of the Corporation.

§ 1602.3 Policy

The Corporation will make records concerning its operations, activities, and business available to the public to the maximum extent reasonably possible. Records will be withheld from the public only in accordance with the FOIA and this regulation. Records that may be exempt from disclosure may be made available as a matter of discretion when disclosure is not prohibited by law, and it does not appear adverse to legitimate interests of the public, the Corporation, or any individual.

The Corporation will attempt to provide assistance to requesting parties, including information about how a request may be submitted. The Corporation will act on requests for records in a timely manner.

§ 1602.4 Index of Records.

The Corporation will maintain a current index identifying any matter within the scope of section 1602.5(b)(1)-(3) which has been issued, adopted, or promulgated by the Corporation, and other information published or made publicly available. The index will be maintained and made available for public inspection and copying at the Corporation's headquarters in Washington, D.C., and at each regional office. The Corporation will provide a copy of the index on request, at a cost not to exceed the direct cost of duplication.

§ 1602.5 Central records room.

(a) The Corporation will maintain a central records room at its headquarters at 733 15th Street NW., Suite 700, Washington, D.C. 20005, 202-376-5100. This room will be supervised by a Records Officer, and will be open during regular business hours of the Corporation for the convenience of members of the public in inspecting and copying records made available pursuant to this Part. Certain records, described in paragraph (b) of this section, will be regularly maintained in or in close proximity to the records room, to facilitate access thereto by any member of the public.

(b) Subject to the limitation stated in paragraph (c) of this subsection, there will be available in the central records room the following:

(1) All final opinions, including concurring and dissenting opinions, and orders made in the adjudication of cases;

(2) Statements of policy and interpretations adopted by the Corporation;

(3) Administrative staff manuals and instructions to the staff that affect the public;

(4) To the extent feasible, guidelines, forms, published regulations, notices, program descriptions, and other records considered to be of general interest to members of the public in understanding activities of the Corporation or in dealing with the Corporation in connection with those activities;

(5) The current index required by § 1602.4.

(c) Certain types of staff manuals or instructions, such as instructions to auditors or inspection staff, or instructions covering certain phases of contract negotiation, that deal with the performance of functions that would automatically be rendered ineffective by general awareness of the Corporation's techniques or procedures, may be exempt from mandatory disclosure even though they affect or may affect the public. These records will not be maintained in the central records room.

(d) Certain records maintained in the records room or otherwise made available pursuant to this Part may be "edited" by the deletion of identifying details concerning individuals, to prevent a clearly unwarranted invasion of personal privacy. In such cases, the record shall have attached to it a full explanation of the deletion.

§ 1602.6 Regional Records Rooms.

(a) Each regional office shall have either a specially designated records room similar to the central records room described in § 1602.5 or, if that is not feasible, a designated area within the office, a principal function of which is to serve the public in accordance with this Part. The Corporation will endeavor to maintain and have readily available in its regional offices the records described in § 1602.5(b), and will designate a records officer in each regional office to receive and process requests submitted pursuant to this Part.

(b) The regional records rooms as of June 15, 1978, are located at the following addresses:

Boston Regional Office, 84 State Street, Room 520, Boston, Mass. 02101.
New York Regional Office, 10 East 40th Street, Room 2010, New York, N.Y. 10016.
Philadelphia Regional Office, 101 North 33d Street, Suite 404, Philadelphia, Pa. 19104.
Northern Virginia Regional Office, 1730 North Lynn Street, Suite 600—Rosslyn, Arlington, Va. 22209.
Chicago Regional Office, 310 South Michigan Avenue, 24th Floor, Chicago, Ill. 60604.
Atlanta Regional Office, 615 Peachtree Street NE., Ninth Floor, Atlanta, Ga. 30308.
San Francisco Regional Office, 177 Post Street, Suite 890, San Francisco, Calif. 94104.
Denver Regional Office, 1726 Champa Street, Suite 500, Denver, Colo. 80202.
Seattle Regional Office, 506 Second Avenue, Room 1621, Seattle, Wash. 98104.

§ 1602.7 Use of records rooms.

(a) Any member of the public who wishes to inspect or copy records regularly maintained in the central or a regional records room may secure access to these records by presenting himself or herself at the records room during business hours. No advance notice or appointment is required, although persons wishing to make extended use of regional office facilities should take account of the possible limitations in these facilities.

(b) Each records room will also be available to any member of the public to inspect and copy records which are not regularly maintained in such room. To obtain such records a person should present his or her request identifying the records to the records officer. Because it will sometimes be impossible to produce these records or copies of them on short notice, a person who wishes to use records room facilities to inspect or copy such records is advised to arrange a time in advance, by telephone or letter request made to the records officer of the facility which he or she desires to use. Persons submitting requests by telephone will be advised by the records officer or another designated employee whether a written request would be advisable to aid in the identification and expeditious processing of the records sought. Persons submitting written requests should identify the records sought in the manner provided in § 1602.8(b) and should indicate whether they wish to use the records room facilities on a specific date. The records officer will endeavor to advise the requesting party as promptly as possible if, for any reason, it may not be possible to make the records sought available on the date requested.

§ 1602.8 Availability of records on request.

(a) In addition to the records made available through the records rooms, the Corporation will make such records available to any person in accord-

ance with paragraphs (b) and (c) of this section, unless it is determined that such records should be withheld and are exempt from mandatory disclosure under the FOIA and § 1602.9 of these regulations.

(b) *Requests.*

(1) A request will be acceptable if it identifies a record with sufficient particularity to enable officials of the Corporation to locate the record with a reasonable amount of effort. Requests seeking records within a reasonably specific category will be deemed to conform to the statutory requirement of a request which "reasonably describes" such records if professional employees of the Corporation who are familiar with the subject area of the request would be able, with a reasonable amount of effort, to determine which particular records are encompassed within the scope of the request, and to search for, locate, and collect the records without unduly burdening or materially interfering with operations because of the staff time consumed or the resulting disruption of files. If it is determined that a request does not reasonably describe the records sought as specified in this paragraph, the response denying the request on that ground shall specify the reasons why the request failed to meet the requirements of this paragraph and shall extend to the requesting party an opportunity to confer with Corporation personnel in order to attempt to reformulate the request in a manner that will meet the needs of the requesting party and the requirements of this paragraph.

(2) To facilitate the location of records by the Corporation, a requesting party should try to provide the following kinds of information, if known: (i) the specific event or action to which the record refers; (ii) the unit or program of the Corporation which may be responsible for or may have produced the record; (iii) the date of the record or the date or period to which it refers or relates; (iv) the type of record, such as an application, a grant, a contract, or a report; (v) personnel of the Corporation who may have prepared or have knowledge of the record; (vi) citations to newspapers or publications which have referred to the record.

(3) The Corporation is not required to create a record to satisfy a request for information. When the information requested exists in the form of several records at several locations, the requesting party should be referred to those sources if gathering the information would unduly burden or materially interfere with operations of the Corporation.

(4) All requests for records under this section shall be made in writing, with the envelope and the letter clearly marked: "Freedom of Information Request." All such requests shall be addressed to the records officer at the headquarters of the Corporation or at any regional records office. Any request not marked and addressed as specified in this sub-paragraph will be so marked by Corporation personnel as soon as it is properly identified, and forwarded immediately to the records officer. A request improperly addressed will not be deemed to have been received for purposes of the time period set forth in paragraph (c) of this section until forwarding to the appropriate office has been effected. On receipt of an improperly addressed request, the records officer shall notify the requesting party of the date on which the time period commenced to run.

(5) A person desiring to secure copies of records by mail should write to the records officer at the headquarters in Washington, D.C. The request must identify the records of which copies are sought in accordance with the requirements of this paragraph, and should indicate the number of copies desired. Fees may be required to be paid in advance in accordance with § 1602.13. The requesting party will be advised of the estimated fee, if any, as promptly as possible. If a waiver of fees is requested, the grounds for such request should be included in the letter.

(c) The records officer, upon request for any records made in accordance with this Part, shall make an initial determination of whether to comply with or deny such request and dispatch such determination to the requesting party within 10 days (excepting Saturdays, Sundays, and legal public holidays) after receipt of such request, except for unusual circumstances in which case the time limit may be extended for not more than 10 working days by written notice to the requesting party setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. In determining whether to issue a notice of extension of time for a response to a request beyond the 10-day period, Corporation officials shall consult with the Office of the General Counsel. As used herein, "unusual circumstances" are limited to the following, but only to the extent reasonably necessary to the proper processing of the particular request:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the Corporation having substantial subject matter interest therein.

(d) If no determination has been dispatched at the end of the 10-day period, or the last extension thereof, the requesting party may deem his request denied, and exercise a right of appeal in accordance with § 1602.12. When no determination can be dispatched within the applicable time limit, the records officer shall nevertheless continue to process the request. On expiration of the time limit, he shall inform the requesting party of the reason for the delay, of the date on which a determination may be expected to be dispatched, and of his right to treat the delay as a denial and to appeal to the President in accordance with § 1602.12; and he may ask the requesting party to forego appeal until a determination is made.

(e) After it has been determined that a request will be granted, the Corporation will act with diligence in providing a substantive response.

§ 1602.9 Invoking Exemptions to Withhold a Requested Record.

(a) A requested record of the Corporation may be withheld from public disclosure only if one or more of the following categories exempted by the FOIA apply:

(1) Matter which is related solely to the internal personnel rules and practices of the Corporation;

(2) Matter which is specifically exempted from disclosure by statute;

(3) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(4) Inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the Corporation;

(5) Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(6) Investigatory records compiled for enforcing the Act or any other law, but only to the extent that the production of such records would (i) interfere with enforcement proceedings, (ii) deprive a person of a right of a fair trial or an impartial adjudication, (iii) constitute an unwarranted invasion of personal privacy, (iv) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful

national security intelligence investigation, confidential information furnished only by the confidential source, (v) disclose investigative techniques and procedures, or (vi) endanger the life or physical safety of law enforcement personnel;

(b) In the event that one or more of the above exemptions applies, any reasonably segregable portion of a record shall be provided to the requesting party after deletion of the portions that are exempt. In appropriate circumstances, subject to the discretion of Corporation officials, it may be possible to provide a requesting party with: (1) A summary of information in the exempt portion of a record or (2) an oral description of the exempt portion of a record. In determining whether any of the foregoing techniques should be employed in accordance with this paragraph or whether an exemption should be waived in accordance with paragraph (c) of this section, Corporation officials shall consult with the Office of General Counsel. No requesting party shall have a right to insist that any or all of the foregoing techniques should be employed in order to satisfy a request.

(c) Records that may be exempted from disclosure pursuant to paragraph (a) of this section may be made available as a matter of discretion when disclosure is not prohibited by law, if it does not appear adverse to legitimate interests of the Corporation, the public, or any person.

§ 1602.10 Official authorized to grant or deny requests for records.

The General Counsel shall furnish necessary advice to Corporation officials and staff as to their obligations under this Part and shall take such other actions as may be necessary or appropriate to assure a consistent and equitable application of the provisions of this Part by and within the Corporation. Other officials of the Corporation shall consult with the General Counsel before denying request under this Part, or before granting requests for waiver or modified application of an exemption or for categories of documents which the General Counsel determines may present special or unusual problems. The General Counsel and, subject to consultation with him where required, the Records Officer, each Regional Director, and each Regional Records Officer are authorized to grant or deny requests under this Part.

§ 1602.11 Denials.

(a) A denial of a written request for a record that complies with the requirements of § 1602.8 shall be in writing and shall include the following:

(1) A reference to the applicable exemption or exemptions in § 1602.9(a) upon which the denial is based;

(2) An explanation of how the exemption applies to the requested records;

(3) A statement explaining why it is deemed unreasonable to provide segregable portions of the record after deleting the exempt portions;

(4) The name and title of the person or persons responsible for denying the request; and

(5) An explanation of the right to appeal the denial and of the procedures for submitting an appeal, including the address of the official to whom appeals should be submitted.

(b) Whenever the Corporation makes a record available subject to the deletion of a portion of the record, such action shall be deemed a denial of a record for purposes of paragraph (a) of this section.

(c) All denials shall be treated as opinions and shall be maintained and indexed accordingly, subject only to the necessity of deleting identifying details the release of which would constitute a clearly unwarranted invasion of personal privacy.

§ 1602.12 Appeals of denials.

(a) Any person whose written request has been denied is entitled to appeal the denial within 90 days by writing to the president of the Corporation at the headquarters in Washington, D.C. The envelope and letter should be clearly marked: "Freedom of Information Appeal." An appeal need not be in any particular form, but should adequately identify the denial, if possible, by describing the requested record, identifying the official who issued the denial, and providing the date on which the denial was issued.

(b) No personal appearance, oral argument, or hearing will ordinarily be permitted on appeal of a denial. Upon request and a showing of special circumstances, however, this limitation may be waived and an informal conference may be arranged with the president, or the president's specifically designated representative, for this purpose.

(c) The decision of the president on an appeal shall be in writing and; in the event the denial is in whole or in part upheld, shall contain an explanation responsive to the arguments advanced by the requesting party, the matters described in § 1602.11(a)(1)-(4), and the provisions for judicial review of such decision under section 552(a)(4) of the FOIA. The decision shall be dispatched to the requesting party within 20 working days after receipt of the appeal, unless an additional period is justified pursuant to § 1602.8(c) and such period taken together with any earlier extension does not exceed 10 days. The president's decision shall constitute the final action of the Corporation. All such decisions shall be treated as final opinions under § 1602.5(b).

§ 1602.13 Fees.

(a) Information provided routinely in the normal course of doing business will be provided at no charge.

(b) The records officer may waive or reduce fees where special circumstances, including but not limited to the benefit of the general public, warrant. A records officer shall waive fees where the requesting party is indigent unless the fees would exceed $25 and may waive or reduce fees for the request of an indigent where the fees would exceed $25. These provisions will be subject to appeal in the same manner as appeals from denial under § 1602.12.

(c) There shall be no fee charged for services rendered by the Corporation pursuant to this part, unless the charges, as calculated in paragraph (e) of this section, exceed $6.50. Where the charges are calculated to exceed $6.50, the fee shall be the difference between $6.50 and the calculated charges.

(d) Ordinarily, no fee shall be levied where the records requested are not provided or made available. However, if the time expended in processing the request is substantial, and if the requesting party has been notified of the estimated cost pursuant to paragraph (f) of this section, and has been specifically advised that it cannot be determined in advance whether any records will be made available, fees may be charged.

(e) The schedule of charges for services regarding the production or disclosure of the Corporation's records is as follows:

(1) Search for records and production of information based on the following schedule of direct labor charges: (a) Programer=$6.25/quarter hour; (b) Analyst=$3.50/quarter hour and (c) Processor=$1.50/quarter hour

(2) Computer time: Actual charge as incurred.

(3) Reproduction, duplication, or copying of records: $0.10 per page.

(4) Reproduction, duplication, or copying of microfilm: Actual charge as incurred.

(5) Certification of true copies: $ each.

(f) Where it is anticipated that the fee chargeable under this part will amount to more than $25, and the requesting party has not indicated in advance his willingness to pay so high a fee, the requesting party shall be notified of the amount of the anticipated fee or such portion thereof as can readily be estimated. In such cases, the request will not be deemed to have

been received until the requesting party is notified of the anticipated cost and agrees to bear it. Such a notification shall be transmitted as soon as possible, but in any event within 5 working days, giving the best estimate then available. The notification shall offer the requesting party the opportunity to confer with appropriate representatives of the Corporation for the purpose of reformulating the request so as to meet his needs at a reduced cost.

(g) Where the anticipated fee chargeable under this part exceeds $25, an advance deposit of 25 percent of the anticipated fee may be required. Where a requesting party has previously failed to pay a required fee, an advance deposit of the full amount of the anticipated fee together with the fee then due and payable may be required.

(h) The Corporation reserves the right to limit the number of copies that will be provided of any document to any one requesting party, or to require that special arrangements for duplication be made in the case of bound volumes or other records representing unusual problems of handling or reproduction.

ALICE DANIEL,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-21009 Filed 7-27-78; 8:45 am]

[6820-35]

[45 CFR Part 1620]

PRIORITIES IN ALLOCATION OF RESOURCES

AGENCY: Legal Services Corporation.

ACTION: Proposed amendment.

SUMMARY: The Corporation proposes to revise its regulation concerning the priority-setting procedures for recipients who provide legal assistance. This proposal would require that recipients set priorities in a more systematic way and involve clients in every step. This rule is being proposed after the Corporation has considered public comments which were received in response to a previously published proposed rule.

DATES: Comments must be received on or before September 11, 1978.

ADDRESS: Legal Services Corporation, 733 15th Street NW., Suite 700, Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION: Section 1007(a)(2)(C) of the Legal Services Corporation Act requires the Corporation to insure that recipients adopt procedures for determining and implementing priorities in the allocation of their resources for the provision of legal assistance. Section 9(b)(1) of the 1977 amendments to the Legal Services Corporation Act requires that, in setting and implementing priorities, recipients take into account the relative needs of eligible clients "including particularly the needs for service on the part of significant segments of the population of eligible clients with special difficulties of access to legal services or special legal problems * * *.". The elderly and handicapped are cited as examples of groups with such problems. The legislative history of this provision makes clear that it was not intended to establish a preference for certain groups of eligible clients. Rather, it is intended to insure that the needs of all significant segments of the client community are considered, and that the consideration addresses the need for expanded access to service as well as substantive problems.

A proposed amendment to part 1620 was published for comment on March 17, 1978 (43 FR 11241). Many of the comments received urged revision of the regulation to require recipients to approach the setting of priorities in a more systematic way, and to involve clients in every step. The Corporation recognizes the validity of these concerns and has made substantial revisions in response to them.

Some comments urged that an additional step be added to the priority-setting process, that is, a requirement that the views of clients be documented and a written statement of reasons be prepared whenever those reasons are departed from. Others view such a requirement as inconsistent with the draft's attempt to set out only the basic elements of priority-setting, leaving the details to be worked out by individual recipients in light of their particular needs. The documentation requirement is set forth in the bracketed provision 1620.2(d). The Corporation is particularly interested in receiving comments on the wisdom and helpfulness of including or excluding that section.

At present, Part 1620 reads as follows:

Sec.
1620.1 Purpose.
1620.2 Procedure.

AUTHORITY: Sec. 1007(a)(2); 42 U.S.C. 2996(a)(2).

Section 1620.1 *Purpose.* This Part is designed to insure that a recipient will allocate its resources in an economical and effective manner.

Section 1620.2 *Procedure.* (a) A recipient shall adopt procedures for establishing priorities in the allocation of its resources. The procedures adopted shall insure participation by clients and employees of the recipient, and shall provide opportunity for comment by interested members of the public. Priorities shall be reviewed periodically.

(b) The following factors shall be among those considered in establishing priorities:

(1) The resources of the recipient;

(2) The population of eligible clients in the geographic area served by the recipient;

(3) The availability of another source of free or low-cost legal assistance in a particular category of cases or matters;

(4) The urgency of particular legal problems of the clients of the recipient; and

(5) The general effect of the resolution of a particular category of cases or matters on persons least able to afford legal assistance in the community served.

* * * * *

The proposed revision of Part 1620 reads as follows:

PART 1620—PRIORITIES IN ALLOCATION OF RESOURCES

Sec.
1620.1 Purpose.
1620.2 Procedure.
1620.3 Review.

AUTHORITY: Sec. 1007(a)(2); 42 U.S.C. 2996(a)(2).

§ 1620.1 Purpose.

This Part is designed to insure that a recipient, through policies adopted by its governing body, takes into account the views of eligible clients, staff and other interested persons in establishing priorities for allocating its resources in an economical and effective manner, consistent with the purposes and requirements of the act and other provisions of Federal law.

§ 1620.2 Procedure.

(a) A recipient shall adopt procedures for establishing priorities in the allocation of its resources. The procedure adopted shall:

(1) Provide for an assessment of the needs of eligible clients in the geographic area served by the recipient, and their relative importance, based on comments from eligible clients solicited in a manner reasonably calculated to reflect the attitudes of all significant segments of the eligible client population. The assessment shall determine the need for outreach, training of the recipient's employees, and support services, as well as substantive legal problems; and

(2) Insure participation by all significant segments of the client community and the recipient's employees in the setting of priorities, in the development of the work plan required by subsection (c), and in the review required by section 1620.3, and provide the opportunity for comment by interested members of the public.

(b) The following factors shall be among those considered by the recipient in establishing priorities:

(1) The needs assessment described in subsection (a)(1) above;

(2) The population of eligible clients in the geographic area served by the recipient, including all significant segments of that population with special legal problems, or with special difficulties of access to legal services;

(3) The resources of the recipient;

(4) The availability of another source of free or low-cost legal assistance in a particular category of cases or matters;

(5) The relative importance of particular legal problems of the clients of the recipient;

(6) The general effect of the resolution of a particular category of cases or matters on eligible clients in the area served; and

(7) The availability of other sources of training, support, and outreach services.

(c) The recipient shall develop a work plan describing each of its priorities in detail and the manner in which those priorities will be implemented. The plan shall be available to the public, and the recipient shall report on its success in achieving the plan prior to its next review of priorities, but in no event less often than annually.

[(d) The recipient shall record the results of the needs assessment, the priorities, the reasons for adopting priorities which are different from the needs assessment, the work plan and the review of priorities, all of which shall be available to the public.]

§ 1620.3 Review.

Priorities shall be reviewed regularly. The following factors shall be among those considered in determining whether the recipient's priorities should be changed:

(a) The extent to which the objectives of the recipient's work plan have been accomplished;

(b) Changes in the resources of the recipient; and,

(c) Changes in the size or needs of the eligible client population.

ALICE DANIEL,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-21019 Filed 7-27-78; 8:45 am]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 1]

[Gen. Docket No. 78-167; FCC 78-517]

POLICIES AND PROCEDURES REGARDING EX PARTE COMMUNICATIONS DURING INFORMAL RULEMAKING PROCEEDINGS

Proposed Rulemaking and Extension of Time

AGENCY: Federal Communications Commission.

ACTION: Further Notice of Inquiry.

SUMMARY: In the June 27, 1978 issue of the FEDERAL REGISTER (43 FR 27868), the FCC published a Notice of Inquiry and Interim Policy Statement permitting ex parte communications in most informal (notice and comments) rulemaking proceedings, but requiring that such contacts be publicly disclosed. This document gives further notice of inquiry and contains five minor modifications or clarifications of the original notice: Those clarifications or modifications are:

1. The reference to "channel allocations" is changed to "channel assignments".

2. The definition of participants in rulemaking is changed to "all interested persons".

3. Memoranda from outsiders must include the substance of proposed discussion, not just lists of topics, and

4. No date certain for response to ex parte presentation will be established.

5. No prior notice of cut off.

DATES: Non-applicable.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Keith H. Fagan, Office of General Counsel, 202-632-7112.

ORDER AND FURTHER NOTICE OF INQUIRY

Adopted: July 17, 1978.

Released: July 18, 1978.

In the matter of: Policies and procedures regarding Ex Parte Communications during informal rulemaking proceedings, Gen. Docket No. 78-167.

In reviewing our original Notice of Inquiry in this docket, FCC 78-405, released June 14, 1978, some matters have come to our attention which we believe require clarification or modification. These are as follows:

1. In paragraphs 3, 10, and 15, we referred to cases involving FM or TV channel allocations. We should have said channel assignments. Both under our former procedures and our proposed new procedures, ex parte contacts are prohibited only in the those rulemakings involving changes in the FM or TV table of assignments. Such contacts are not barred (although they must now be disclosed) in rulemakings involving spectrum allocation.

2. In paragraph 17, we stated that the persons outside the Commission to be governed by the new procedures included "Participants in the rulemaking, i.e., those filing or intending to file formal comments." It has been pointed out that this definition is too narrow, since not all participants in rulemakings do file formal comments. Accordingly, we are substituting for the above language the words "Participants in the rulemaking, i.e., all interested persons." It should be noted, however, that this category still includes public as well as private entities. Also, the representatives of these interested persons, as well as interceders on their behalf, are still covered by the new procedures.

3. In paragraph 18, we stated that a person wishing to discuss the merits of a proceeding with a Commissioner or staff member should bring with him a "memorandum of the subjects he wishes to discuss." One of the purposes of this requirement is to make it possible for other interested persons to comment on the matters discussed at such meetings. Therefore, this memo should not simply be a list of the topics to be discussed; rather, it should reflect the substance of what the writer actually intends to say about these topics.

4. In paragraph 23, we said that we would give notice of a "date certain" by which responses to ex parte presentations should be made. Upon further reflection, we have decided that it is unnecessary to require that responses be made within a certain time. Accordingly, responses to ex parte presentations will be permissible at any time prior to cut-off.

5. In paragraph 24, we said that there would be "short prior notice" of the date after which ex parte contact would be cut off. Upon reconsideration, we have determined that any prior notice would defeat the purpose of the cut-off requirement. Therefore, our notice for each docket will simply state that ex parte contacts have been cut off as of the date of the notice.

It is ordered, That the Notice of Inquiry, FCC 78-405, released June 14, 1978, is amended in accordance with the preceding paragraphs.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

[FR Doc. 78-20888 Filed 7-27-78; 8:45 am]

[6712-01]

[47 CFR PART 73]

[BC Docket No. 78-220; RM-3063]

FM BROADCAST STATIONS IN MAYFLOWER, CONWAY AND JACKSONVILLE, ARKANSAS

Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Action taken herein proposes the assignment of a class A FM channel to Conway, Ark. It also de-

letes a class C channel from Conway and reassigns it to Jacksonville, Ark., to reflect the fact that it already is being used there.

DATES: Comments must be received on or before September 15, 1978, reply comments must be received on or before October 5, 1978.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Mildred B. Nesterak, Broadcast Bureau, 202-632-7792.

SUPPLEMENTARY INFORMATION: In the matter of amendment of § 73.202(b), table of assignments, FM broadcast stations. (Mayflower and Conway, Ark. BC Docket No. 78-220, RM-3063. Notice of Proposed Rulemaking.

Adopted: July 17,1978.

Released: July 24, 1978.

By the Chief, Broadcast Bureau:

1. *Petitioner, proposal, comments.* (a) Notice of Proposed Rulemaking is given concerning amendment of section 73.202(b) of the Commission's rules as concerns Mayflower, and Conway, Ark.

(b) Petition for rulemaking[1] was filed by Michael D. Harrison ("petitioner"), requesting the assignment of FM channel 224A to Mayflower, Ark. No responses to the petition were made.

2. *Community Data.* (a) *Location*—Mayflower, in Faulkner County, is located approximately 27 kilometers (17 miles) northwest of Little Rock, Ark.

(b) *Population*—Mayfower—469; Faulkner County—31,578.[2]

(c) *Present local aural service*—There is no local aural broadcast service in Mayflower.

3. *Economic data.* Petitioner states that Mayflower is primarily an agricultural area whose major industries are food packaging, microfilm and manufacturing. He asserts that there is a particular need for providing local weather information to the farmers and workers. In addition, he states that a locak facility would fill an important need for coverage of general events in the community such as nighttime sports, musical programs, school announcements, and discussion of controversial subjects of interest and importance to the community. We are told that Mayflower is served by no local newspapers.

4. *Preclusion study.* Preclusion would occur only on the cochannel in two areas: one small area contains the proposed transmitter site and Conway which has an FM assignment; the other is a larger area surrounding Hot Springs, Ark., which has three FM stations.

5. *Other considerations.* In order to avoid short-spacing to station KOTN-FM, channel 222, Pine Bluff, Ark., a channel 224A station at Mayflower would have to use a site 12.8 kilometers (8 miles) north of Mayflower. This would place the station 1.6 kilometers (1 mile) southwest of Conway, Ark. (pop. 15,510), which has two class C assignments (channels 262, 286) with one of the assignments used at Jacksonville, Ark., some 38 kilometers (24 miles) distant.

6. Although petitioner proposes the assignment of channel 224A to the small community of Mayflower, Conway, seat of Faulkner County, is clearly the population center for this area. It appears that, with transmitter site restriction, the proposed channel's principal service area is Conway rather than Mayflower. We believe, therefore, that it might be more appropriate to assign channel 224A to Conway. This, however, does not foreclose use of the channel at Mayflower, since the proximity of the two communities would permit the channel to be licensed as a Mayflower facility under the provisions of § 73.203(b), the "10-mile rule."

7. The proposed assignment appears to raise the question of whether a third assignment to a community of 15,510 population would be warranted. However, since one of the presently assigned channels is used at Jacksonville, Conway only really has one FM station. Therefore, we are proposing to amend the FM table to reflect the current usage of the channel at Jacksonville. Conway is large enough to qualify for assignment of a second channel under the Commission's population guidelines. However, assignment of the proposed class A channel would result in the intermixture in classes of assignments. In the absence of availability of class C assignments, the Commission has permitted such intermixture if an interest has been shown to operate under such conditions. Yakima, Wash., 45 FCC 2d 548, 550 (1973); Key West, Fla., 45 FCC 2d 142, 145 (1974). Petitioner should indicate his willingness to operate a class A FM station.

8. Since a second FM assignment is being proposed for Conway, petitioner should submit in his comments a Roanoke Rapids, 9 FCC 2d 672 (1967) study showing the number of people who would receive a first or second FM service. In addition, petitioner should show the extent of nighttime service provided by standard broadcast stations so that we can determine whether any first and second aural service would be provided. Anamosa-Iowa City, Iowa, 46 FCC 520 (1974).

9. Comments are invited on the proposal to amend the FM table of assignments (§ 73.202(b) of the rules), as follows:

City and Channel No.

Conway, Ark.: Present: 262, 286; Proposed: 224A, 286.
Jacksonville, Ark.: Present: —; Proposed: 262.

10. The Commission's authority to institute rulemaking proceedings; showings required; cutoff procedures used; and filing requirements are set forth below and are incorporated herein. *NOTE:* A showing of continuing interest is required by paragraph 2 below before a channel will be assigned.

11. Interested parties may file comments on or before September 15, 1978, and reply comments on or before October 5, 1978.

FEDERAL COMMUNICATIONS COMMISSION,
WALLACE E. JOHNSON,
Chief, Broadcast Bureau.

1. Pursuant to authority found in sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and § 0.281(b)(6) of the Commission's rules, it is proposed to amend the FM table of assignments, § 73.202(b) of the Commission's rules and regulations, as set forth in the Notice of Proposed Rulemaking to which this appendix is attached.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rulemaking to which this appendix is attached. Proponent(s) will be expected to anwer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cutoff procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rulemaking which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and public notice to this

[1] Public Notice of the petition was given on March 7, 1978, report No. 1106.

[2] Population figures are taken from the 1970 U.S. Census.

effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rulemaking to which this appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b), and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street NW., Washington, D.C.

[FR Doc. 78-20857 Filed 7-27-78; 8:45 am]

[6712-01]

[47 CFR Part 73]

[BC Docket No. 78-221; RM-3060]

FM BROADCAST STATION IN ATLANTA, MICH.

Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Action taken herein proposes the assignment of a class C FM channel to Atlanta, Mich. Petitioner, Wilderness Broadcasting, Inc., states the proposed channel would bring the first local aural broadcast service to a three county area.

DATES: Comments must be filed on or before September 15, 1978, reply comments must be filed on or before October 5, 1978.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Mildred B. Nesterak, Broadcast Bureau, 202-632-7792.

SUPPLEMENTARY INFORMATION: In the matter of amendment of § 73.202(b), table of assignments, FM broadcast stations. (Atlanta, Mich.), BC Docket No. 78-221, RM-3060. Notice of Proposed Rulemaking.

Adopted: July 17, 1978.

Released: July 24, 1978.

1. *Petitioner, proposal, comments.* (a) Petition for rulemaking [1] filed January 5, 1978, by Edward S. Solomon d.b.a. Wilderness Broadcasting, Inc. ("petitioner"), proposing the assignment of class C FM channel 223 to Atlanta, Mich.

(b) This channel could be assigned without affecting any existing FM assignments.

(c) Petitioner, the only responding party, states it will apply for the channel, if assigned.

2. *Demographic data.* (a) *Location*—Atlanta, seat of Montmorency County, is located in the northeastern part of Michigan's lower peninsula, 300 kilometers (188 miles) northwest of Detroit.

(b) *Population*—Atlanta—800; Montmorency County—5,247.[2]

(c) *Local aural service*—There is no local aural broadcast service in Atlanta.

3. *Economic considerations.* Petitioner states that, according to the Northeast Michigan Council, Atlanta's economy is primarily devoted to governmental activities and related services. We are informed that forest related activities, tourism, and some minimal agricultural activity are also factors in the area's economy. Petitioner adds that the largest industrial enterprise in the Atlanta area is Essex Wire Corp. which employs about 400 employees.

4. *Additional considerations.* Petitioner asserts that the counties of Montmorency, Oscoda, and Alcona have no local aural broadcast service. It claims that the proposed station would cover the news and community affairs of this area.

5. *Preclusion study.* Assignment of class C channel 223 to Atlanta, Mich., would cause preclusion to two communities in Michigan with populations greater than 1,000, namely, St. Ignace (pop. 2,892) and Onaway (pop. 1,262). St. Ignace has an FM station on its own assignment. Onaway does not have an assigned channel. Petitioner should indicate in its comments whether an alternate FM channel is available for assignment to Onaway.

[1] Public notice of the petition was given on March 7, 1978, report No. 1106.

[2] Population figures are taken from the 1970 U.S. Census.

6. In this case where the community has a population of only 800 persons, it would be the usual practice to assign a class A channel. However, the petitioner requested a class C channel. Such an exception has been made where the class C proposal woud bring service to unserved or underserved areas. However, before the Commission is able to determine whether the requested assignment would be in the public interest, additional information is needed. Petitioner should submit in its comments a Roanoke Rapids-Goldsboro, N.C., 9 FCC 2d 672 (1967), study showing the figures for the area and number of people who would receive a first and second FM service from a class C station in Atlanta. In addition, petitioner should show the extent of nighttime service provided by standard broadcast stations in the context of first and second aural service. Anamosa-Iowa City, Iowa, 46 FCC 2d 520 (1974). Both first and second FM and first and second aural services should be shown apart from any noncommercial educational FM stations.

7. Comments are invited on the following proposal to amend the table of assignments with regard to the community of Atlanta, Mich.

City and Channel No.

Atlanta, Mich.; Present: —; Proposed: 223.

8. The Commission's authority to institute rulemaking proceedings; showings required; cut-off procedures used; and filing requirements are set forth below and are incorporated herein.

NOTE.—A showing of continuing interest is required by paragraph 2 below before a channel will be assigned.

7. Interested parties may file comments on or before September 15, 1978, and reply comments on or before October 5, 1978.

FEDERAL COMMUNICATIONS COMMISSION,
WALLACE E. JOHNSON,
Chief, Broadcast Bureau.

1. Pursuant to authority found in sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and § 0.281(b)(6) of the Commission's rules, it is proposed to amend the FM table of assignments, § 73.202(b) of the Commission's rules and regulations, as set forth in the Notice of Proposed Rulemaking to which this appendix is attached.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rulemaking to which this appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also

expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cut-off procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rulemaking which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and public notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rulemaking to which this appendix is attached. All submissions by parties to this proceeding or persons action on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b), and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street NW., Washington, D.C.

[FR Doc. 78-20858 Filed 7-27-78; 8:45 am]

[6712-01]

[47 CFR Parts 81 and 83]

[Gen. Docket No. 78-208; FCC 78-487]

PROVIDING FOR THE USE OF SINGLE SIDEBAND EMISSION A3J (SUPPRESSES CARRIER) ON THE MARITIME MOBILE SERVICE RADIOTELEPHONE FREQUENCY 2182 kHz

Proposed Rulemaking

AGENCY: Federal Communications Commission.

ACTION: Proposed rulemaking.

SUMMARY: Amendment of the rules to provide for the use of single sideband (SSB) emission A3J (suppressed carrier) on the maritime mobile service radiotelephone frequency 2182 kHz, effective November 1, 1978. This action completes a Commission program to shift from double sideband (DSB) to single sideband emission in the band 2000-2850 kHz, initiated in 1968, except for certain communications (see supplementary information). This amendment also provides improvement in the maritime mobile service radio distress system.

DATES: Comments must be received on or before August 28, 1978, and reply comments must be received on or before September 8, 1978.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Walter E. Weaver, Safety and Special Radio Services Bureau, 202-632-7197.

SUPPLEMENTARY INFORMATION:

Adopted: July 12, 1978.

Released: July 21, 1978.

In the matter of amendment of parts 81 to 83 to provide for the use of single sideband emission A3J (suppressed carrier) on the maritime mobile service radiotelephone frequency 2182 kHz, effective November 1, 1978, Gen. Docket No. 78-208.

1. Notice of proposed rulemaking in the above-captioned matter is hereby given.

2. In this notice of proposed rulemaking the Commission is proposing amendment of parts 81 and 83 to provide for the use of single sideband (SSB) emission A3J (suppressed carrier) on the maritime mobile service radiotelephone frequency 2182 kHz, effective November 1, 1978. Effective on that date use of SSB emission A3H (full carrier) on 2182 kHz will be discontinued, except for communications: (1) Between a coast station and vessels of foreign registry; (2) between a ship station and foreign coast stations; (3) between a ship station and vessels of foreign registry; and (4) between survival craft and coast or ship stations. Matters pertinent thereto are discussed in the paragraphs which follow:

BACKGROUND—CURRENT STATUS

3. In the proceedings in dockets Nos. 17295, 18307, 18632, and 18633 [1] the Commission, in 1967 and 1968, initiated a two-part program to effect needed improvements in radio- telephony communications in the maritime mobile service. One part concerned the use of VHF, replacing 2 MHz for short distance communications, and channel splitting to approximately double the number of VHF channels. The second part concerned conversion of the 2 MHz frequencies from double sideband (DSB) to single sideband (SSB).

4. The objectives of the 2 MHz part of the program were concisely stated by the Commission in its notice of proposed rulemaking (docket No. 18307, FCC 68-894, 33 FR 14121), excerpted as follows:

> 14. * * * to increase the number of channels, to reduce congestion and interference, to establish VHF as the short-distance communication system in U.S. waters, to effect needed improvements in communications, to enhance the maritime radio safety system, and to provide for future use of radiotelephony by vessels unable to fulfill their communication needs by use of VHF * * *"

5. In the proceedings of docket 21089 to implement an Inter-Governmental Maritime Consultative Organization's (IMCO) resolution pertaining to the Safety of Life at Sea Convention, the continued use of A3 emission was authorized for distress and safety purposes of 2182 kHz under certain conditions. These conditions provided for portable survival craft equipment, and DSB transmitters authorized prior to January 1, 1972, as described in §§ 83.106(a), 83.132(c)(3), and 83.132(c)(4). The continued use of A3 emission is primarily responsive to emergency needs when beyond range of VHF communications, and where outdated DSB equipment may be available only for distress and safety communications.

6. In the intervening 9 years since implementing the objectives of the 2 MHz and VHF programs, substantial improvements have been achieved particularly by enhanced service provided through VHF and the shift of users to VHF for coastal and inland communications. In addition, an engineered safety system has been installed by

[1] Docket No. 17295, report and order, released July 25, 1968, FCC 68-740, 33 FR 10849. Docket No. 18307, first report and order, released June 16, 1970, FCC 70-608, 35 FR 10212. Docket No. 18632, report and order, released October 26, 1971, FCC 71-1044, 36 FR 20949. Docket No. 18633, first report and order, released June 28, 1971, FCC 71-663, 36 FR 12502.

the U.S. Coast Guard to provide VHF coverage around the periphery of the United States, and on the Great Lakes and major U.S. waterways. The serious congestion on 2 MHz radiotelephone which made it literally ineffective in 1968 has been greatly alleviated by this two-part program, and the longer range capabilities of 2 MHz frequencies made more dependable for those maritime users beyond VHF range who require 2 MHz coverage.

7. While these programs have substantially improved 2 MHz operations, they are not in our opinion satisfactory as concerns the maritime radio system on 2182 kHz. The current difficulty results from transitional measures in using SSB with carrier (A3H) in order to permit intercommunications between various configurations of received and transmitted emissions and receiver detectors. This compromise solution was necessary during the period of SSB implementation, and to satisfy the requirement to intercommunicate with those foreign ships in U.S. coastal areas and survival equipment that still employ A3 emission. The current difficulties affect 2182 kHz safety service through two impacts:

(1) Decreased communications range.
(2) Decreased intelligibility where one station transmits on DSB and the other receives on a SSB receiver.

It is our view that measures must be implemented to correct these difficulties as early as practicable.

CURRENT DIFFICULTIES

8. In examining the two general type complaints referred to above, it is appropriate to note that they both occur when the transitional (A3H) mode of operation is in use, that is, to effect the shift from DSB to SSB it was necessary to provide a mode of operation (A3H) whereby a vessel fitted with SSB can communicate with vessels fitted with DSB. The A3H SSB mode was selected because the DSB receiver can demodulate the A3H SSB signal and, conversely, the SSB receiver, set in the A3H mode, can demodulate the DSB signal. (The DSB signal must be on frequency, or close thereto.) The A3H SSB mode is not relatively efficient, as compared to the A3A or A3J modes, nor are there any merits to its use other than that it provides a necessary technical vehicle to effect transition from DSB to SSB. An analysis conducted by the Coast Guard indicated that A3H transmissions on 2182 kHz suffer severe degradations at even moderate distances. For example, if a ship is capable of transmitting 80 nautical miles by SSB (A3J), the corresponding predicted coverage by A3H would be 26 nautical miles. These coverage estimates are being validated by the Coast Guard during day-to-day operations. Thus, if confined to A3H emission, the resulting service range of 2182 kHz merely duplicates the distress and safety coverage being provided by VHF instead of serving those intended users beyond VHF range in the offshore area.

9. In the first case listed above, decreased communications range, transmission on SSB (A3H), reception on a DSB receiver;

The SSB signal suffers in excess of a 3 dB noise power degradation in the DSB receiver. (The DSB receiver bandwidth is more than twice that required to pass the SSB signal.) The SSB (A3H) signal is demodulated by the envelope detector in the DSB receiver, resulting in a 3 dB power loss over that of the DSB signal. In summary, reception of A3H SSB on a DSB receiver suffers at least a 6 dB degradation, as compared to reception of DSB on the same receiver.

10. In the second case listed above, lack of or decrease in intelligibility, transmission on DSB, reception on a SSB (A3H) receiver:

With voice communications, when the DSB carried is off-frequency (different from the reinserted carrier), there is an equal and corresponding shift in voice register;

Frequency tolerances, ITU radio regulations, permit ship stations to depart from 2182 kHz by ±436.4 Hz, or survival craft and EPIRB's to depart ±654.6 Hz;

Speech will be unintelligible when DSB carrier is off-frequency by a value of substantially less than 436 Hz. A departure of this magnitude may be beyond the range of the receiver "clarifier" control, or, if provided, circuitry in receivers for automatic frequency control. Distortion and unintelligibility occur also under a number of other conditions, dependent upon the selectivity, detection, and audio systems employed in the particular receiver under consideration, for example: When the DSB sideband is only partially within the pass band of the SSB receiver; or when the DSB carrier falls within the SSB receiver pass band; etc.

In summary, in order to be intelligible on a SSB (A3H) receiver, the carrier of the DSB transmission on 2182 kHz must be within reasonable proximity to the frequency 2182 kHz.

It is apparent that both of the above types of difficulty will disappear once all ships employ the same mode of operation. While this was not possible prior to January 1, 1977, due to the large number of DSB users, it will be possible to do so now as concerns U.S. registry vessels operating in the U.S. coastal areas.

11. The major impediment to U.S. implementation of A3J operation on 2182 kHz is the impact this action may have upon those remaining users not yet converted (waivered U.S. vessels (FCC docket 21089), non-SSB equipped foreign vessels, survival craft radios, and emergency position indicating radio beacons (EPIRB's)). It should be noted that SSB (A3J)[2] emission is authorized on all other MF and HF maritime radiotelephone frequencies. Further, those vessels that transmit A3H (single sideband with carrier) as presently authorized on 2182kHz do so by electrically reinserting the carrier to the output of the single sideband circuits internal to the equipment. This connection is included in the channel selection switch that automatically provides for reinsertion when set to 2182 kHz, or by any emission mode switch. At issue is whether to proceed with full implementation of single sideband in U.S. waters to realize its improved performance in distress and calling coverage on 2182 kHz, or to continue to delay this achievable improvement in U.S. waters until all potential foreign and U.S. DSB users are fully converted. In this respect, the final dates for which A3 or A3H may continue to exist pursuant to international agreement are interpreted as final targets in the international improvement program rather than a prohibition to orderly implementation. The decisions are influenced by the extent of non-SSB equipment in U.S. waters, and the relative risks in detection of emergency non-SSB transmissions. In any case, the ultimate world conversion to SSB (A3J) on 2182 kHz is being pursued. The following subsections discuss the rationale and impacts pertinent to implementing A3J operation on 2182 kHz.

U.S. WATERS

GENERAL

12. The rule amendments adopted by the Commission in the above referenced proceedings[1] provide: (1) That the use of DSB on 2182 kHz, and on other 2 MHz frequencies, be discontinued aboard U.S. registry vessels effective January 1, 1977; and (2) that all coast and shipboard transmitters typed accepted for SSB radiotelephony be capable of operation in all three SSB modes, that is for A3A, A3H, and A3J emissions. Thus, with the exception of DSB equipment retained for emergency and safety use within the provisions of docket 21089, equipment fitted aboard any U.S. registry vessel for use on 2 MHz after January 1, 1977, is capable of SSB operation and of adjustment to one or the other of all three SSB modes. As of the implementation date of this rulemaking, shore stations of the U.S. Coast Guard and Federal Communications Commission licensed public coast stations[3] will be fitted with SSB equipment (receivers) capable of receiving the SSB operating modes.

13. The rule amendments in the above-reference proceedings[1] also pro-

[2] Further, SSB emission A3A (reduced carrier) is also authorized for use for public correspondence.

[3] Not applicable to those public coast stations which have outstanding a rule waiver of the requirement to guard 2182 kHz.

vide, generally, the vessels within VHF range of shore will use VHF and that vessels at greater distances will use the 2 MHz frequencies. The communication range over which VHF is usable is subject to a number of variables, however, a rounded figure of 20 nautical miles is used here to coincide with the distance designed into VHF shore facilities to the U.S. Coast Guard (USCG), which serve the VHF maritime radio safety system on 156.8 MHz. With the VHF maritime radio safety system extending out from shore for a distance of 20 nautical miles, it is reasonable to assume that any vessel in need of assistance will call the USCG on VHF if less than 20 nautical miles from shore or on 2182 kHz if more than 20 nautical miles from shore.

COAST

14. Population estimates of civil ships and vessels beyond 20 nautical miles but within 200 nautical miles offshore of the continental United States on an average day approximate 1750. The statistical distribution[4] of this population by class and flag is estimated as follows:

Type/class	Total	United States	Foreign
Commercial ships	750	500	250
Fishing vessels	900	700	200
Recreational and party	100	100	
Totals	1,750	1,300	450
Percent		.74	26

These estimates may vary by season, geography, and operational research methodology; however, they are considered generally valid as an average projection. For example, fishing vessels move widely in following particular fish species and foreign fishing vessels may concentrate offshore of New England to increase observed populations in particular areas. Recreational boating similarly may concentrate in offshore races but normally only 0.1 percent are beyond approximately 20 nautical miles of shore. Commerical ships in international transit generally are outfitted to utilize high frequency voice and/or telegraph because of extended ranges of movement. Foreign commercial ships primarily call at major ports such as Boston, New York, Norfolk/Baltimore, New Orleans, Galveston/Houston, Los Angeles, San Francisco, and Seattle. As a result, predominant commercial carriage along the U.S. coasts in the zone of interest is by U.S. ships.

15. Whereas essentially all U.S. ships and vessels are SSB equipped pursuant to the program covered by these rules, the population in the offshore zone that may have DSB-only capabilities is unknown other than the assumption that the majority are foreign ships. Based on the 26 percent estimated foreign flags within the offshore zone, some rationale may be applied to estimate the actual DSB population. Commercial foreign ships by nature of their extended voyage may be assumed to be outfitted with HF in a significant majority. Where this is voice, SSB equipment has been installed for the HF spectrum area in consonance with high seas telephone and regulatory patterns. Further, foreign-flag ships include those owned by U.S. parent companies (total estimated as 660) where the company, for standardization, outfits to conform with U.S. communication trends. With regard to foreign fishing vessels in the zone of consideration, it is observed that they operate by groups within range of supporting logistics or processing ships. The communications aboard supporting ships are sophisticated and it is assumed that SSB capabilities for 2182 kHz distress or guard is again in a significant majority. In examination of all 2182 kHz calls to the USCG in 1975 concerning emergencies, only 1.1 percent of all calls were from foreign flag ships or vessels.[5] Further, through informal discussions with a major operator of 2 MHz public correspondence stations, no calls were received on DSB in the last year. Accordingly, the DSB-equipped population offshore of the U.S. coasts is indeed a low percentage and considered less than 5 percent.

16. Accordingly, as we assess the situation at this time, an overwhelming majority (95 percent) of the vessels involved are capable of operating in the SSB A3J mode and the remaining 5 percent are not capable of operating in that mode. If we continue to retain the DSB watch on 2182 kHz for the minority, the majority will receive an inferior service from decreased range and intelligibility difficulties discussed in paragraphs 8, 9, and 10, above. On the other hand, if we shift to the SSB A3J mode on November 1, 1978,[6] improved service will be provided to the majority, the decreased range and intelligibility difficulties will be removed, and the technical benefits of SSB can be realized. In brief, it is our opinion that regardless of the approach taken to solve the needs of the minority, the public interest cannot be served by disregarding the needs of, or by forcing an inferior service upon, the majority. We believe that the public interest demands that first consideration be given to providing a satisfactory service to the large majority of 95 percent. We are, therefore, proposing that effective November 1, 1978, all FCC licensed coast stations involved shift the guard on 2182 kHz to the SSB A3J mode. The DSB user situation (foreign vessels, waivered U.S. vessels, etc.) in the 20-200 nautical mile area is discussed below.

17. A coast station fitted with an SSB A3J mode receiver will be able to satisfactorily demodulate DSB transmissions on 2182 kHz from a ship station if the carrier of the DSB transmission is on frequency, or close thereto. This condition ceases when the DSB transmission is excessively displaced from 2182 kHz. A ship station fitted with a DSB receiver will not, however, be able to receive the SSB A3J mode transmissions from the coast station. In general, we expect that the majority (about 62 percent) of foreign registry vessels will be close enough to 2182 kHz (within approximately 45 Hz) to be clearly demodulated by an SSB A3J mode receiver. Most of the remaining 40 percent also will be within an acceptable range and can be satisfactorily demodulated by the SSB A3J mode receiver. In regard to waivered U.S. vessels, the provisions of docket 21089 that permit retention of DSB equipment authorized prior to January 1, 1972, do not include means to evaluate the compatibility of such equipment with an SSB (A3J) system. Accordingly, the Coast Guard will accept short communication checks on 2182 kHz from boaters who continue to rely upon DSB equipment for emergency purposes.[7] Moreover, it should be noted that in 2-month evaluation of watchkeeping using only A3J reception concluded September 30, 1977, by the Third and Fifth Coast Guard Districts, no major problem were detected or reported. Similar tests show that autoalarm signals are totally recognizable from DSB transmitters noting that the Coast Guard uses operator guards rather than autoalarm receivers. In regard to EPIRB's of foreign vessels, the Coast Guard has never experienced a 2182 kHz EPIRB case in U.S. responsible waters. However, tests have shown them to be extremely stable and therefore detectable with SSB systems. In tests with DSB (A3) signals as detected by Coast Guard receivers, signals are either understandable or provide sufficient alerting to permit receiver shifts as appropriate.

[4] Provided by the U.S. Coast Guard.

[5] The trend in the use of 2182 kHz by foreign vessels to the Coast Guard is as follows: Year and Number of distress calls—1971, 164; 1972, 148; 1973, 100; 1974, 94; 1975, 56; and 1976, 25.

[6] The U.S. Coast Guard suggests the shift be made on May 1, 1978. To provide time in which to complete the rulemaking process, we have changed that date to November 1, 1978.

[7] We are amending § 83.365(a)(4) to bring that section into accord with this revised USCG policy, as set forth in the attached appendix.

INTERNATIONAL WATERS AND NATIONAL WATERS OF OTHER COUNTRIES

18. The situation in international waters is expected to differ from the situation in U.S. waters in regard to the proportion of foreign registry to U.S. registry vessels, that is, the number of foreign registry vessels will substantially increase as compared to the number of U.S. registry vessels. Thus, the number of vessels fitted with DSB may be proportionally greater than the number of SSB-fitted vessels. As far as intership communications and the capability to communicate is concerned, the situation will be unchanged from that described in paragraph 17, above.

19. In national waters of other countries, the situation in regard to intership communications is unchanged from that described in paragraph 17, above. As concerns communication between U.S. registry vessels fitted with SSB and the coast stations of the concerned foreign administration, fitted probably with SSB A3H mode transmitters and DSB receivers, we doubt that any such station will be off-frequency from 2182 kHz by a sufficient amount to present difficulty in demodulating the coast SSB transmission in the ships SSB A3J receiver. As discussed above, it will be necessary that the ship station transmit to these coast stations using the SSB A3H mode.

INTERNATIONAL RADIO REGULATION

20. The radio regulations in No. 1323.1 permit where coast stations provide a watch on 2182 kHz for receiving A3A and A3J emissions, that ship stations may call for safety purposes on A3A and A3J after first calling using A3 or A3H emission. In this proceeding we are recommending that A3J be used for all calling, whether for safety purposes or otherwise, in U.S. waters. This would not be in conformity with the procedures set forth in No. 1323.1 of the radio regulations. This is based on a choice between two basic situations: First, whether to serve the needs of the majority of affected vessels using a system which is technically capable of providing communications over the range (20 to 200 miles); or second, to attempt to serve the minority of affected vessels using a system which is technically not capable of providing effective communications. The Commission, of course, does not take lightly international procedures; however, when a situation is clearly inimical to safety we must choose a course of action which will provide greater safety. As discussed herein the U.S. Coast Guard also recognizes the need for our present proposed changes. It must be recognized that the Commission in its MF radiotelephone conversion program to SSB starting in 1968 and completed in 1977, except for 2182 kHz, has been keeping pace with the state of the art while international procedures reflect something less than current technology and were not intended for an SSB environment.

RELATED MATTERS

21. The International Radio Consultative Committee (CCIR), of the International Telecommunication Union, prepared document 8/1063-E which was adopted at the CCIR XIII Plenary Assembly, 1974, on the subject of "Equivalent Powers of Double-Sideband and Single-Sideband Radiotelephone Emissions (Maritime Mobile Service)." This document represents the first internationally coordinated and agreed opinion on the relative merits of the various DSB and SSB emissions. The benefits from use of SSB emission A3J, as compared to DSB emission A3 and SSB emission A3H, are readily apparent. It is also apparent that if the maritime mobile service is to have a first class safety system on 2182 kHz, that system must be converted to SSB emission A3J.

22. The 1974 WMARC adopted resolution MAR 2-20 which includes the following:

Resolves (1) That study of the use of class A3A and A3J emissions for distress and safety purposes is required;

(2) That this study should be completed in time for a decision on the date for the final conversion to class A3A and A3J emissions on the carrier frequency 2182 kHz to be made by the next competent World Administrative Radio Conference;

Requests the C.C.I.R. to study the abovementioned subject as a matter of urgency and, if possible, to issue Recommendations sufficiently in advance of the above mentioned conference;

Invites the Inter-Governmental Maritime Consultative Organization to consider the matter as part of the study currently being undertaken of the maritime distress and safety system.

23. It will be noted that the matter of emissions and frequencies to be provided in survival craft equipment has not been treated in the proposed rule amendments. That matter is under continuing study and will be treated at a future date.

24. The proposed amendments to the rules, as set forth in the appendix are issued pursuant to the authority contained in section 303 (c), (f), (g), and (r) of the Communications Act of 1934, as amended.

25. Pursuant to applicable procedures set forth in § 1.415 of the Commission's rules, interested persons may file comments on or before August 28, 1978, and reply comments on or before September 8, 1978. All relevant and timely comments and reply comments will be considered by the Commission before final action is taken in this proceeding, the Commission may also take into account other relevant information before it, in addition to the specific comments invited by this notice.

26. In accordance with the provisions of § 1.419 of the Commission's rules, an original and five copies of all statements, briefs, or comments filed shall be furnished to the Commission. Responses will be available for public inspection during regular business hours in the Commission's public reference room at its headquarters in Washington, D.C.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

Parts 81 and 83 of chapter I of title 47 of the Code of Federal Regulations are amended as follows:

PART 81—STATIONS ON LAND IN THE MARITIME SERVICES AND ALASKA-PUBLIC FIXED STATIONS

1. Section 81.104, paragraphs (b) and (d) are amended to read as follows:

§ 81.104 Facilities required for coast stations.

* * * * *

(b) Each coast station using telephony on frequencies in the band 1605-3500 kHz shall be equipped and licensed to transmit on the frequency 2182 kHz and at least one working frequency in that band.

* * * * *

(d) Each coast station licensed to transmit on frequencies in the band 1605-3500 kHz shall be capable of receiving A3J emission on the frequency 2182 kHz and at least one working frequency in that band.

* * * * *

2. In § 81.132, paragraph (a)(2)(i) is amended to read as follows:

§ 81.132 Authorized classes of emission.

* * * * *

Frequency Band and Classes of Emission

(a) * * *

(2) Coast stations using radiotelephony:

(i) For frequencies below 23 MHz in § 81.304(a): 2182 kHz—A3J as specified in § 81.304 (c) and (d).

* * * * *

3. In § 81.304, paragraphs (c)(5) and (d)(5) are amended to read as follows:

§ 81.304 Frequencies available.

* * * * *

(c) * * *

(5) Public coast stations are required to have the capability to receive A3J emission on 2182 kHz.

* * * * *

(d) * * *

(5) Public coast stations are required to have the capability to receive A3J emission on 2182 kHz.

* * * * *

4. In § 81.360, paragraphs (a)(1) (iii) and (v) are amended to read as follows:

§ 81.360 Frequencies available below 4000 kHz.

(a) * * *

(1) * * * (iii) Except as provided in § 81.142(d), the capability of using A3J emission;

* * * * *

(v) Limited coast stations are required to have the capability to receive A3J emission;

* * * * *

5. In § 81.708, paragraph (b)(7) is amended to read as follows:

§ 81.708 Frequencies available.

* * * * *

(b) * * * (7) Except as provided in § 81.142(d), the capability of using A3J emission is required on frequencies shared with the maritime mobile service below 4000 kHz.

* * * * *

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

§ 83.104 [Amended]

1. In § 83.104, paragraph (h)(2)(i) is deleted.

2. In § 83.106, paragraph (a) is amended to read as follows:

§ 83.106 Required frequencies for radiotelephony.

(a) Each ship radiotelephone station licensed to operate in the band 1605 to 3500 kHz shall be able to transmit and receive A3J[1] emission on the carrier frequency 2182 kHz, and, if the station is used for other than safety communication, it shall be capable also of transmitting and receiving class A3J[1] emission on at least two other frequencies within that band.

* * * * *

[1]Ship stations are, additionally, authorized to receive and transmit using emission A3H for communication with foreign coast stations and with vessels of foreign registry.

3. In § 83.132, paragraph (a)(2)(i) is amended to read as follows:

§ 83.132 Authorized classes of emission.

* * * * *

Frequency Band and *Classes of Emission*

(a) * * *

(2) Stations using radiotelephony:

(i) For frequencies below 23 MHz designated in § 83.351(a): 2182 kHz A3J.[2]

* * * * *

4. In § 83.201, paragraph (b) is amended to read as follows:

§ 83.201 Watch required during silence periods.

* * * * *

(b) Except for stations on board vessels required by law to be fitted with radiotelegraph equipment, each ship station licensed to transmit by telephony on one or more frequencies within the band 1605 to 3500 kHz shall, during its hours of service for telephony, maintain an efficient watch for the reception of A3J emissions on the authorized carrier frequency 2182 kHz, whenever such station is not being used for transmission on that frequency or for communication on other frequencies in this band. Such watch shall, insofar as is possible, be maintained at least twice each hour for 3 minutes commencing at x h. 00 and x h. 30, Greenwich mean time. Except for messages of distress, urgency, and vital navigational warnings, ship stations shall not transmit on 2182 kHz during the silence periods.

5. In § 83.233, the table is amended to read as follows:

§ 83.233 Frequencies for use in distress.

In case of distress, mobile stations shall, in the bands set forth below, use the frequencies specified when requesting assistance from the maritime service. The preferred types of emission are shown. When a ship station cannot transmit on the designated frequency, it shall use any available frequency on which attention might be attracted.

Frequency band	Emission	Carrier frequency
405-535 kHz	A2	[3]500 kHz.
1605-3500 kHz	A3H, A3J	2182 kHz.
118-135 MHz	A2, A3, A9	121.5 MHz.
	A3	123.1 MHz
156-162 MHz	F3	156.8 MHz.
225-399.9 MHz	A9	243 MHz.

[3]The maximum transmitter power obtainable shall be used.

[2]Ship stations are, additionally, authorized to receive and transmit using emission a3H for communication with foreign coast stations and with vessels of foreign registry.

6. In § 83.242, paragraph (b) is amended to read as follows:

§ 83.242 Transmission of distress message by a station not itself in distress.

(a) * * *

(b) The transmission of a distress message under the conditions prescribed in paragraph (a) of this section shall be made on either or all of the international distress frequencies (500 kHz radiotelegraph; 2182 kHz or 156.8 MHz radiotelephone) or on any other available frequency on which attention might be attracted.

* * * * *

7. In § 83.248, paragraph (a) is amended to read as follows:

§ 83.248 Urgency message.

(a) The urgency signal and call, and the message following it, shall be sent on one of the international distress frequencies (500 kHz radiotelegraph; 2182 kHz or 156.8 MHz radiotelephone). However, stations which cannot transmit on a distress frequency may use any other available frequency on which attention might be attracted.

* * * * *

8. In § 83.249, paragraph (d) is amended to read as follows:

§ 83.249 Safety signals.

* * * * *

(d) The safety signal and call shall be sent on one of the international distress frequencies (500 kHz radiotelegraph; 2182 kHz or 156.8 MHz radiotelephone). However stations which cannot transmit on a distress frequency may use any other available frequency on which attention might be attracted.

9. In § 83.365, subparagraph (4) of paragraph (a) is amended to read as follows:

§ 83.365 Procedure in testing.

(a) * * *

(4) Testing of transmitters shall, insofar as practicable be confined to working frequencies without two-way communications; however, 2182 kHz and 156.8 MHz may be used to contact other ship or coast stations when signal reports are necessary. U.S. Coast Guard stations may be contacted on 2182 kHz for test purposes only:

(i) When tests are being conducted during inspections by Commission representatives or when qualified radio technicians are installing equipment or correcting deficiencies in the station radiotelephone equipment. In these cases the test shall be identified

as "FCC" or "technical" and logged accordingly; or

(ii) (As an interim measure pending final resolution in Docket No. 21089). When short tests, by vessels which continue to rely upon the use of DSB equipment for distress and safety purposes, are required as a means to evaluate the compatibility of that equipment with an SSB emission A3J system.

10. In § 83.484, paragraphs (a) and (d)(2) are amended to read as follows:

§ 83.484 Radiotelephone transmitter.

(a) The transmitter shall be capable of effective transmission of A3H and A3J emissions on 2182 kHz, 2638 kHz, in accordance with § 83.351, and at least two other frequencies within the band 1605 to 3500 kHz available for ship-to-shore or ship-to-ship communication.

* * * * *

(d) The transmitter shall be considered as capable of complying with the range requirement specified in paragraph (c) of this section when:

(1) * * *

(2) The transmitter has been demonstrated, or is of a type which has been demonstrated, to the satisfaction of the Commission as capable, with normal operating voltages applied, of delivering not less than 50 watts peak envelope power for A3H and A3J emissions on each of the frequencies 2182 and 2638 kHz into either an artificial antenna consisting of a series network of 10 Ohms effective resistance and 200 picofarads capacitance or an artificial antenna of 50 Ohms nominal impedance: *Provided, however,* That an individual demonstration of the power output capability of the transmitter, with the radiotelephone installation normally installed on board ship, may be required whenever in the judgment of the Commission this is deemed necessary.

* * * * *

11. In § 83.488, paragraph (a) is amended to read as follows:

§ 83.488 Radiotelephone receivers.

(a) The receiver used for maintaining the watch required by §§ 83.202(b) and 83.203(b) shall be capable of effective reception of A3H and A3J emissions, shall be connected to the antenna system specified by § 83.494, and shall be present to, and capable of accurate and convenient selection of, the frequencies 2182 kHz, 2638 kHz, and the receiving frequencies associated with the transmitting frequencies provided pursuant to § 83.484(a).

* * * * *

12. In § 83.514, paragraph (a)(1) is amended to read as follows:

§ 83.514 Radiotelephone installation.

(a)(1) The radiotelephone installation shall include a transmitter capable of effective transmission of A3H and A3J emissions and a receiver capable of effective reception of A3H and A3J emissions within the band 1605 to 2850 kHz; or alternatively, if the vessel is within communication range of a public coast station or U.S. Coast Guard station operating in the band 156 to 162 MHz which maintains an efficient watch for the reception of F3 emission on 156.8 MHz at all times while the vessel is navigated in waters specified in § 83.511, and the vessel while so navigated is never more than 20 nautical miles from a 156.800 MHz receiving location of such station, the radiotelephone installation may, in lieu of medium frequency equipment, include a transmitter and receiver capable of effective transmission and reception of F3 emission within the band 156 to 162 MHz.

* * * * *

13. In § 83.517, paragraphs (a) and (c)(2) are amended to read as follows:

§ 83.517 Medium frequency transmitter.

(a) The transmitter shall have a peak envelope output power of at least 50 watts for A3H and A3J emissions on 2182 kHz, in accordance with § 83.351, and at least one ship-to-shore working frequency within the band 1605 to 2850 kHz enabling communication with a public coast station serving the region in which the vessel is navigated.

* * * * *

(c) * * *

(2) The transmitter has been demonstrated, or is of a type which has been demonstrated, to the satisfaction of the Commission as capable, with normal operating voltages applied, of delivering not less than 50 watts peak envelope power for A3H and A3J emissions on each of the frequencies 2182 and 2638 kHz into either an artificial antenna consisting of a series network of 10 Ohms effective resistance and 200 picofarads capacitance or an artificial antenna of 50 Ohms nominal impedance: *Provided, however,* That an individual demonstration of the power output capability of the transmitter, with the radiotelephone installation normally installed onboard ship, may be required whenever in the judgment of the Commission this is deemed necessary.

14. In § 83.519, paragraph (a) is amended to read as follows:

§ 83.519 Radiotelephone receiver.

(a) If a medium frequency radiotelephone installation is provided, the receiver used for maintaining the watch required by § 83.202(c) shall be capable of effective reception of A3H and A3J emissions, shall be connected to the antenna system specified by § 83.526, and shall be present to, and capable of accurate and convenient selection of, the frequencies 2182 kHz, 2638 kHz, and the receiving frequency(s) associated with the ship-to-shore transmitting frequency(s) provided pursuant to § 83.517(a).

* * * * *

[FR Doc. 78-20866 Filed 7-27-78; 8:45 am]

[3510-22]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[50 CFR Part 656]

ATLANTIC BILLFISHES AND SHARKS

Final Environmental Impact Statement/Preliminary Fishery Management Plan; Hearings

AGENCY: National Oceanic and Atmospheric Administration (NMFS), Commerce.

ACTION: Notice of public hearings.

SUMMARY: The National Marine Fisheries Service will conduct a series of hearings on the proposed amendment to the Final Environmental Impact Statement/Preliminary Fishery Management Plan for Atlantic Billfishes and Sharks that was published in the FEDERAL REGISTER on January 27, 1978 (43 FR 3818).[1] The preliminary fishery management plan governs foreign fishing for billfishes and sharks within the U.S. Fishery Conservation Zone of the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. The plan prohibits the retention of bill fishes and other nontarget species taken incidental to directed fisheries for tunas and sharks, and identifies a surplus of 1,150 metric tons of sharks for allocation among foreign nations. The amendment proposes to extend the preliminary fishery management plan into the 1979 fishing season, and to institute procedures for minimizing the capture and subsequent mortality of nontarget species in directed foreign shark fisheries. No change is proposed in the surplus of sharks (1,150 metric tons) for allocation to foreign nations in 1979. No significant adverse economic or environmental effects are anticipated as a result of the proposed amendment.

[1] This document appeared in the Notices section of the FEDERAL REGISTER. Future documents of this type will appear in the Proposed Rules section.

DATES AND ADDRESSES: Hearings are open to the public and will be held in accordance with the following schedule:

1978 Date, Location and Time

August 14, Marine Resources Center, Pine Knoll Shores, Morehead City, N.C., 7:30 p.m.-9 p.m.

August 15, Downtowner Motor Inn, 201 West Oglethorpe Ave., Savannah, Ga., 7:30 p.m.-9 p.m.

August 16, Ramada Inn, Highway A1A, Treasure Island, Fort Pierce, Fla., 7:30 p.m.-9 p.m.

August 21, Texas A&M University, Agriculture Research and Extension Center, Texas Highway 44, 5 miles west of Corpus Christi, Corpus Christi, Tex., 7-10 p.m.

August 21, Quality Inn, Lake Wright, 6280 Northampton Boulevard, Box 2048, Norfolk, Va. 23502, 7:30 p.m.

August 22, City Council Chambers, City Hall, 1300 Perdido, New Orleans, La., 7-10 p.m.

August 23, City Commission Meeting Room, City Hall, 9 Harrison Ave., Panama City, Fla., 7-10 p.m.

August 23, South Carolina Wildlife and Marine Resources, Department Building, Fort Johnson Rd., Charleston, S.C., 7:30 p.m.-9 p.m.

August 23, Asbury Avenue Pavillion, South Asbury and Ocean Ave., Asbury Park, N.J. 07712, 7:30 p.m.

August 24, Marathon High School (Cafeteria), Sombrero Rd., Marathon, Fla., 7-10 p.m.

August 24, Narragansett Laboratory, National Marine Fishery Service, RR 7A, Box 522A, Narragansett, R.I. 02882, 7:30 p.m.

Written comments should be submitted to the contact person listed below prior to September 2, 1978, to receive full consideration in the amendment process.

FOR FURTHER INFORMATION CONTACT:

Jack T. Brawner, Chief, Fisheries Management Division, National Marine Fisheries Service, Southeast Regional Office, 9450 Koger Boulevard, St. Petersburg, Fla. 33702, telephone 813-893-3721.

Dated: July 21, 1978.

WINFRED H. MEIBOHM,
Associate Director,
National Marine Fisheries Service.

[FR Doc. 78-20345 Filed 7-27-78; 8:45 am]

notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

[3410-02]

DEPARTMENT OF AGRICULTURE

Federal Grain Inspection Service

GRAIN STANDARDS

Request for Transfer of Designation by the Cedar Rapids Chamber of Commerce Grain Service, Inc., Cedar Rapids, Iowa

AGENCY: Federal Grain Inspection Service.

ACTION: Notice.

SUMMARY: Notice that the Cedar Rapids Chamber of Commerce Grain Service, Inc., Cedar Rapids, Iowa, has requested transfer of its designation as an official agency to perform grain inspection services under the authority of the U.S. Grain Standards Act, as amended, to Mr. Florian E. Polaski, who has filed an application for such designation. This notice also requests comments on the proposed transfer and invites other interested persons to make application for designation as an official agency at Cedar Rapdis.

DATE: Comments and/or applications must be received by August 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Edith A. Christensen, Federal Grain Inspection Service, Compliance Division, Delegation and Designation Branch, 201 14th Street SW., Room 2405, Auditors Building, Washington, D.C. 20250, 202-447-8525.

SUPPLEMENTARY INFORMATION: The U.S. Grain Standards Act, as amended (7 U.S.C. 71 et seq.) (hereinafter the "act"), has been amended to extensively modify the official grain inspection system. Pursuant to sections 7 and 7A of the act, the Administrator of the Federal Grain Inspection Service (FGIS) has the authority to designate any State or local governmental agency, or any person, as an official agency for the conduct of all or specified functions involved in official inspection (other than appeal inspection), weighing and supervision of weighing of grain, at inland locations where the Administrator determines there is a need for such services (7 U.S.C. 79 and 7 U.S.C. 79a). Under the act, such designation shall terminate triennially but may be renewed in accordance with the criteria and procedure prescribed (7 U.S.C. 79(g)(1) and 79a(c)).

The Cedar Rapids Chamber of Commerce Grain Service, Inc. (Chamber of Commerce), Cedar Rapids, Iowa, has requested that its designation under the act to operate as an official agency at Cedar Rapids, Iowa, be transferred to Mr. Florian E. Polaski, the present Chief Inspector of the Chamber of Commerce. Mr. Florian E. Polaski has applied for designation in accordance with section 7(f)(1) of the act (7 U.S.C. 79(f)(1)) to operate as the official agency at Cedar Rapids, Iowa, to be known as the Cedar Rapids Grain Service, Inc. This application does not preclude other interested persons from making similar application.

NOTE.—Section 7(f)(2) of the act (7 U.S.C. 79(f)) provides that not more than one official agency shall be operative at one time for any geographic area as determined by the Administrator.

Interested persons are hereby given opportunity to submit written views or comments with respect to the requested transfer of official agency designation. All views or comments should be submitted in writing, in duplicate, and mailed to the Director's Office, Compliance Division, Federal Grain Inspection Service, 201 14th Street SW., Room 2405, Auditors Building, Washington, D.C. 20250, not later than August 28, 1978.

Under the provisions of section 7(f)(1), interested persons are also given opportunity to make application for designation to operate as an official agency at Cedar Rapids, Iowa, pursuant to the requirements in section 7(f)(1)(A) of the act, as amended (7 U.S.C. 79(f)(1)(A)) and § 26.96 of the regulations (7 CFR 26.96). Persons wishing to apply for designation to operate as an official agency at Cedar Rapids should contact the Compliance Division, Federal Grain Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, for the appropriate forms and mail their applications to the Director's Office at the above cited address, not later than August 28, 1978.

Consideration will be given to the views and comments filed and to any applications submitted and to all other information available to the U.S. Department of Agriculture before a final determination is made with respect to the official agency designation. All views, comments and applications submitted pursuant to this notice will be made available for public inspection at the above office of the Director during regular business hours (7 CFR 1.27(b)).

(Sec. 8, Pub. L. 94-582, 90 Stat. 2870 (7 U.S.C. 79); sec. 9, Pub. L. 94-582, 90 Stat. 2875 (7 U.S.C. 79a); sec. 27, Pub. L. 94-582, 90 Stat. 2889 (7 U.S.C. 74 note).)

Done in Washington, D.C. on: July 24, 1978.

L. E. BARTELT,
Administrator.

[FR Doc. 78-20944 Filed 7-27-78; 8:45 am]

[3410-11]

Forest Service

BURLINGTON NORTHERN INC. LAND EXCHANGE PROPOSAL OFFERED LANDS; BEAVERHEAD AND GALLATIN NATIONAL FOREST'S SELECTED LANDS; WESTERN MONTANA

Northern Region—U.S.F.S.; Intent to Prepare an Environmental Statement

Pursuant to 102(2)(c) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture, will prepare an environmental statement for Burlington Northern Inc. (BN) proposal to offer its approximately 177,000 acres of land within the Gallatin and Beaverhead National Forests in exchange for national forest lands in western Montana.

In an April 1977 news release, BN Vice President Bud Merryman says the trade is sought since BN is inhibited from developing its timber resources because of its checkboard pattern of ownership mingled with public lands mainly in the Madison and Gallatin Mountain ranges of southwest Montana. Issues and concerns identified thus far are: effect on programed allowable timber harvest; effect on county revenues, effect on resources; effect on existing rights (mining claims, special uses, etc.); effect on public use; and social effects.

Forest Service Chief John McGuire is the responsible official; Robert Torheim is the regional forester, northern region; and Vic Standa is the project leader working with personnel from the Bitterroot, Custer, Gallatin, Beaverhead, Lolo, Flathead, and Kootenai National Forests.

The draft environmental statement is scheduled for completion by July 1979, with a 60-day review period, and the final environmental statement is scheduled for filing in December 1979.

Comments on the notice of intent or on the land exchange proposal should be sent to Robert Torheim, Regional Forester, Northern Region, Federal Building, Missoula, Mont. 59807.

JAMES E. REID,
Acting Regional Forester,
Forest Service, Northern Region.

JULY 21, 1978.

[FR Doc. 78-20869 Filed 7-27-78; 8:45 am]

[3410-01]

Office of the Secretary

PRIVACY ACT OF 1974

Notice of Systems of Records

Notice is hereby given that the Department of Agriculture, in accordance with 5 U.S.C. 552a(e) (4) and (11), intends to amend the notice of an existing system of records as set forth below.

This notice was originally published in the FEDERAL REGISTER 40 FR 38919 (August 27, 1975). All the proposed amendments are administrative and are based on operational experience under the Privacy Act. The changes will provide more accurate information for the public.

The amendments to the notice will be adopted July 28, 1978.

System USDA/FS-14, Grazing Permittees, Individual, National Forest System, is amended to adequately describe system location, category of records in the system, policies and practices for storing and retrieving records in the system, and record source categories.

The paragraphs are amended to read:

Security location: The records in this system are maintained in the Regional Foresters's office as pertains to special limits of some grazing permittees, in the headquarters offices of the Forest Supervisors for all permittee records, and offices of District Rangers for duplicate records of those kept by Forest Supervisors. Records are also stored on magnetic tape at the Fort Collins Computer Center. The addresses for Regional Foresters and Forest Supervisors are listed in 36 CFR 200.2, Subpart A, and the addresses for District Rangers are in the telephone directory of the applicable locality under the heading, U.S. Government, Department of Agriculture, Forest Service.

Categories of records in the system: The system contains information on names and post office addresses of permittees; number, kind, and brands of livestock owned; acres, by kind, of land owned which is declared as base property; number and kinds of livestock permitted; race and sex of permittee; type of permits, periods of use, grazing allotments (areas) involved, and whether or not an escrow waiver of term permit privileges exists.

Also included are acres of land owned or leased in addition to base property; tons of dry feed produced or purchased, Bureau of Land Management permits held by Forest Service permittees (number and kind of livestock, periods of use), names of other parties who own an interest in permitted livestock, identification of other grazing permits on National Forest System lands in which the permittee holds an interest. For private land permits, system identifies owned or leased property offered as a basis for grazing permits, specifying legal subdivision, section, township, range, and number of acres.

Storage: Records are maintained in file folders and on magnetic tape.

Retrievability: Records in file holders are indexed by name of permittee; records on magnetic tape are retrievable by name, by identification number assigned by Forest Supervisor, characteristics of permittee, or type of grazing use.

Safeguards: Records are kept in locked government offices. Magnetic tape files are available only to persons having authorized access codes.

Record source categories: Information in the system comes from individual grazing permittees, or grazing associations, and from Forest Service records concerning grazing allotments and permitted livestock. Race and sex of permittee is included by District Ranger based on observation.

In consideration of the foregoing, notice is hereby given that the revised system will read as set forth below.

Dated: July 24, 1978.

BOB BERGLAND,
Secretary.

USDA/FS-14

System name:

Grazing Permittees, Individual, National Forest System, USDA/FS.

Security location:

The records in this system are maintained in the Regional Forester's office as pertains to special limits of some grazing permittees, in the headquarters offices of the Forest Supervisors for all permittee records, and offices of District Rangers for duplicate records of those kept by Forest Supervisors. Records are also stored on magnetic tape at the Fort Collins Computer Center. The addresses for Regional Foresters and Forest Supervisors are listed in 36 CFR 200.2, Subpart A, and addresses for District Rangers are in the telephone directory of the applicable locality under the heading, U.S. Government, Department of Agriculture, Forest Service.

Categories of individuals covered by the system:

Parties who hold permits to graze livestock on Forest Service administered lands are included in this system of records.

Categories of records in the system:

The system contains information on names and post office addresses of permittees; number, kind, and brands of livestock owned; acres, by kind, of land owned which is declared as base property; number and kinds of livestock permitted; race and sex of permittee; type of permits, periods of use, grazing allotments (areas) involved, and whether or not an escrow waiver of term permit privileges exists.

Also included are acres of land owned or leased in addition to base property, tons of dry feed produced or purchased, Bureau of Land Management permits held by Forest Service permittees (number and kind of livestock, periods of use), names of other parties who own an interest in permitted livestock, identification of other grazing permits on National Forest System lands in which the permittee holds an interest. For private land permits, system identifies owned or leased property offered as a basis for grazing permits, specifying legal subdivision, section, township, range, and number of acres.

Authority for maintenance of the system:

5 U.S.C. 301; 36 CFR 222.3.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

None.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

Records are maintained in file folders and on magnetic tape.

Retrievability:

Records in file folders are indexed by name of permittee; records on magnetic tape are retrievable by name, by indentification number assigned by Forest Supervisor, characteristics of permittee, or type of grazing use.

Safeguards:

Records are kept in locked government offices. Magnetic tape files are available only to persons having authorized access codes.

Retention and disposal:

Records are maintained in current file while permit is active, transferred to closed files for 3-year period following cancellation, and then sent to Federal Records Center for permanent retention.

System manager(s) and address:

Director of Range Management, USDA-Forest Service, P.O. Box 2417, Washington, D.C. 20013; and/or the appropriate Regional Forester or Forest Supervisor.

Notification procedure:

Any party may request information as to what the system contains pertaining to himself/herself from the appropriate System Manager. If specific locations are known, requests should be made to the Forest Supervisor involved.

Record access procedures:

Use the same procedure as for requesting Notification.

Contesting record procedures:

Use the same procedure as for requesting Notification.

Record source categories:

Information in the system comes from individual grazing permittees, or grazing associations, and from Forest Service records concerning grazing allotments and permitted livestock. Race and sex of permittee is included by District Ranger based on observation.

[FR Doc. 78-20882 Filed 7-27-78; 8:45 am]

[6320-01]

CIVIL AERONAUTICS BOARD

[Docket No. 32162]

DALLAS/FORT WORTH-TUCSON INVESTIGATION

Hearing

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that a hearing in the above-entitled proceeding will be held on Tuesday, August 22, 1978, at 10 a.m. (local time) at the ballroom of the Doubletree Inn, 445 South Alvernon Way, Tucson, Ariz. 85711, before the undersigned. For information concerning the issues involved and other details in this proceeding, interested persons are referred to the documents which are in the docket of this proceeding on file in the Docket Section of the Civil Aeronautics Board.

Dated at Washington, D.C., July 24, 1978.

BURTON S. KOLKO,
Administrative Law Judge.

[FR Doc. 78-20939 Filed 7-27-78; 8:45 am]

[6320-01]

[Order No. 78-7-96; Docket Nos. 32617, 32618]

PAN AMERICAN WORLD AIRWAYS, INC.

Order To Show Cause and Granting Exemption

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 21st day of July 1978. Application of Pan American World Airways, Inc. for Detroit-Washington fill-up authority. Application of Pan American World Airways, Inc. for an exemption under section 416(b) for Detroit-Washington fill-up authority.

By application dated May 5, 1978, Pan American seeks authority to carry local traffic between Detroit and Washington, D.C., on flights serving London. On the same date, it asked for exemption authority to carry fill-up passengers on one daily round trip pending final action on its 401 application. Pan American has also petitioned for an order to show cause why its certificated application should not be granted.

In support of its applications, Pan American asserts that on May 1, 1978, it inaugurated one daily Detroit-Washington (Dulles)-London round trip, and that it is economically inefficient to operate the Detroit-Washington portion of the flights without carrying local traffic; it can no longer route its Detroit-London flights over Boston, as it has done in the past, because it no longer has Boston-London authority; [1] in order to continue its Detroit-London one-stop service economically it must operate over a strong intermediate point and the new routing insures continuation of a service greatly benefiting Detroit-London/Europe passengers; since there is no Detroit service to Washington's Dulles International Airport, the proposed fill-up service will fill a gap in the existing Detroit-Washington/Northern Virginia service pattern and will cause little or no diversion from the incumbents, all of whom serve National Airport or BWI; and it will offer a range of stimulative low fares in the market.

The Commonwealth of Virginia supports the application.

United Air Lines opposes our grant of the application by means of show-cause proceedings, alleging that the Board cannot legally act on it in this way. United also opposes Pan American's request for exemption, stating that it would not be in the public interest; the proposed operations are not of limited extent since they will increase the frequency of service in the market by approximately 10 percent; and Pan American has not demonstrated any unusual circumstances indicating a need for the requested exemption.

Pan American filed a motion for leave to file an unauthorized document, accompanied by a reply to United's answer. Because Pan American has not provided adequate justification for our receiving the reply, we have decided to deny the motion. [2]

We tentatively conclude that the public convenience and necessity require the issuance of an order to show cause why we should not grant Pan American fill-up authority in this market. We will also grant the carrier an exemption to carry fill-up passengers on one daily round trip pending our final action on the section 401 application.

Our tentative conclusion to issue a show cause order is supported by the following tentative findings. The requested authority will benefit Pan American by enabling it to fill some of its empty seats. It will also benefit the traveling public by providing them with first Detroit service to and from Dulles International Airport, and at low fares. We recognize that Pan American does not have a history of Detroit-Washington operations, and most of our previous orders have considered fill-up rights only in markets in which the applicants have provided service for a sustained period of time. [3] On the basis of Pan American's previous Detroit-Boston-London operations, [4] however, we are confident that the carrier is providing Detroit-London one-stop service primarily to serve the needs of international traffic rather than Detroit domestic passengers. As a result of circumstances beyond its control, Pan American can no longer serve the Boston-London

[1] We recently recommended that TWA be designated by the President as the sole Boston-London carrier (see our opinion in 78-5-146, May 24, 1978).

[2] In its motion, Pan American did not raise any new facts nor did it demonstrate that United's answer contained new material it could not have anticipated.

[3] See Orders 77-10-16, October 6, 1977 and 77-4-153, April 29, 1977. See, however, Order 78-1-135, January 31, 1978 (made final by Order 78-5-25, May 5, 1978) where we granted Delta local fill-up rights between Houston and New Orleans, on flights serving Venezuela, in advance of Delta's inauguration of the Houston extension of its New Orleans-Venezuela flights. We based our decision on the facts that Delta already had domestic authority between Houston and New Orleans and that the extension of its New Orleans-Venezuela flights to include Houston would primarily serve the needs of international traffic.

[4] Pan American has served the Detroit-Boston-London market for approximately three decades.

market, so it must find another intermediate point for its Detroit-London operations. Accordingly, we believe that we should extend to it this fill-up authority.[5]

Our decision to grant an exemption is justified by the unusual circumstances surrounding the loss of Pan American's Detroit-Boston-London routing. We find that enforcement of section 401 of the act, to the extent it would otherwise prevent Pan American from providing the services authorized here, would be an undue burden on it by reason of the unusual circumstances surrounding its operations and is not in the public interest.

We will give interested persons 30 days following adoption of this order to show cause why the tentative findings and conclusions we have stated here should not be made final. We expect such persons to support their objections with detailed economic analysis. Any objector requesting an oral evidentiary hearing should state, in detail, why such a hearing is necessary and what relevant and material facts it would expect to establish through such a hearing that it cannot establish by written pleadings. We will not entertain general, vague, or unsupported objections.[6]

Accordingly, *it is ordered*, That:

1. All interested persons be directed to show cause why the Board should not issue an order making final the tentative findings and conclusions we have reached in this order and authorize Pan American World Airways to transport persons, property, and mail in interstate air transportation between Detroit and Washington, D.C., on flights in overseas or foreign air transportation;

2. Any interested persons who object to the issuance of an order making final the proposed findings, conclusions, and certificate amendments set forth here shall, within 30 days after the date of adoption of this order, file and serve on all persons listed in paragraph 7 below a statement of objections together with a summary of testimony, statistical data, and such evidence they expect to rely on to support the stated objections; answers may be filed 10 days after that;

3. If timely and properly supported objections are filed, we will consider fully the matters and issues raised in them before taking further action;[7]

4. In the event no one files objections, all further procedural steps will be deemed to have been waived, and the case will be submitted to the Board for final action;

5. Pan American be exempted from section 401 of the Act and the terms, conditions, and limitations of its certificate for Route 132 to the extent necessary to permit it to transport persons, property, and mail in interstate air transportation between Detroit and Washington, D.C., on one daily round trip in overseas or international air transportation;

6. The authority granted in paragraph 5 above shall be effective immediately and continue until 60 days after final Board decision in Docket 32617;

7. The motion of Pan American for leave to file an unauthorized document be denied; and

8. This order shall be served on Pan American World Airways, United Air Lines, and the Commonwealth of Virginia.

This order shall be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board.[8]

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-20940 Filed 7-27-78; 8:45 am]

[5] In past orders (e.g., 78-3-43, March 9, 1978, at 2; 77-11-10, November 3, 1977 at 3-4, 77-4-153, April 29, 1977, at pp. 3 and 7, and 75-1-77, January 17, 1975, at 2), we have rejected the general arguments made by United against our use of show-cause procedures for grant of fill-up rights, and United has presented no new arguments on this point.

[6] We also tentatively find that Pan American is a citizen of the United States within the meaning of the Act and is fit, willing and able within the intent of the Act.

We have considered Pan American's environmental evaluation of Detroit-Washington fill-up authority. We tentatively find that our action does not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969 and will not constitute a major regulatory action under the Energy Policy and Conservation Act of 1975 as defined in Part 313 of the Board's Regulations.

[7] All motions or petitions for reconsideration shall be filed within the period allowed for filing objections and we will entertain no further motions, requests, or petitions for reconsideration of this order.

[8] All Members concurred.

[6325-01]

CIVIL SERVICE COMMISSION

DEPARTMENTS OF HEALTH, EDUCATION AND WELFARE, TRANSPORTATION, HOUSING AND URBAN DEVELOPMENT

Grant of Authority to Make Noncareer Executive Assignment

Under authority of § 9.20 of Civil Service rule IX (5 CFR 9.20), the Civil Service Commission authorizes the following agencies to fill by noncareer executive assignment in the excepted service the positions listed below:

Department of Health, Education, and Welfare—(1) Deputy Assistant Secretary for Health Policy, Research and Statistics, Immediate Office, Office of Health Policy, Research and Statistics, Office of the Assistant Secretary for Health, Public Health Service; (2) Director, Office of Bilingual Education, Office of Education.

Department of Transportation—Engineer and Science Adviser (Deputy Under Secretary), Office of the Deputy Secretary, Office of the Secretary.

Department of Housing and Urban Development—Deputy Assistant Secretary for Urban Policy, Immediate Office of the Assistant Secretary, Office of the Assistant Secretary for Community Planning and Development.

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-20920 Filed 7-27-78; 8:45 am]

[6325-01]

DEPARTMENT OF THE TREASURY

Title Change in Noncareer Executive Assignment

By notice of April 13, 1973, FR Doc. 73-7184 the Civil Service Commission authorized the Department of the Treasury to fill by noncareer executive assignment the position of Special Assistant to the Secretary (Debt Management), Office of the Assistant Secretary (Capital Markets and Debt Management), Office of the Secretary. This is notice that the title of this position is now being changed to Deputy Assistant Secretary (Debt Management), Office of the Assistant Secretary (Domestic Finance), Office of the Secretary.

For the U.S. Civil Service Commission.

JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-20921 Filed 7-27-78; 8:45 am]

[3510-07]

DEPARTMENT OF COMMERCE

Bureau of the Census

NUMBER OF EMPLOYEES, PAYROLLS, RECEIPTS, GEOGRAPHIC LOCATION, CURRENT STATUS, AND KIND OF BUSINESS FOR THE ESTABLISHMENTS OF MULTIESTABLISHMENT COMPANIES

Consideration for Surveys

Notice is hereby given that the Bureau of the Census is considering a proposal under the provisions of title 13, United States Code, sections 182, 224, and 225, to conduct a 1978 company organization survey. It is designed to collect information on the number of employees, payrolls, receipts, geo-

graphic location, current status, and kind of business for the establishments of multiestablishment companies. The information will be used to update company and establishment changes to the multiestablishment companies in the Standard Statistical Establishment List. The data will have significant application to the needs of the public and to governmental agencies, and are not publicly available from nongovernmental or governmental sources.

The survey, if conducted, shall begin not earlier than December 1, 1978.

Copies of the proposed forms are available on request to the Director, Bureau of the Census, Washington, D.C. 20233.

Any suggestions or recommendations concerning the subject matter of the proposed survey submitted to the Director in writing on or before August 28, 1978, will receive consideration.

Dated: July 25, 1978.

MANUEL D. PLOTKIN,
Director,
Bureau of the Census.

[FR Doc. 78-20890 Filed 7-27-78; 8:45 am]

[3510-25]

Industry and Trade Administration

DARTMOUTH COLLEGE, ET AL.

Applications for Duty Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Statutory Import Programs Staff, Bureau of Trade Regulation, U.S. Department of Commerce, Washington, D.C. 20230, on or before August 17, 1978.

Regulations (15 CFR 301.9) issued under the cited act prescribed the requirements for comments.

A copy of each application is on file, and may be examined between 8:30 a.m. and 5 p.m., Monday through Friday, in Room 6886C of the Department of Commerce Building, 14th and Constitution Avenue NW., Washington, D.C. 20230.

Docket No. 78-00287. Applicant: Dartmouth College, Chemistry Department, Steele Hall, Hanover, N.H. 03755. Article: Temperature Jump Apparatus, Model 120-S. Manufacturer: Hartley Measurements, Ltd., United Kindgom. Intended use of article: The article will be used in the course Chem 72—Chemical Dynamics to train chemistry major juniors and seniors in theory and practice of chemical kinetics. Application received by Commissioner of Customs: June 26, 1978.

Docket No. 78-00288. Applicant: University of California, San Diego Scripps Institute of Oceanography, Deep Sea Drilling Project A-031, La Jolla, Calif. 92093. Article: ROCK-EVAL Source Rock Analyzer, IFP-FINA Process and Spare Parts. Manufacturer: Technip Geoproduction, France, Intended use of article: The article is intended to be used to determine the genetic potential of sampled rocks to produce hydrocarbons thereby providing a measure useful for safety considerations which are primary in those drilling operation areas which are deemed to have a geologic setting conducive to hydrocarbon generation and/or accumulation. Application received by Commissioner of Customers: June 26, 1978.

Docket No. 78-00289. Applicant: Cornell University, 161 Day Hall, Ithaca, N.Y. 14853. Article: Scanning Transmission Electron Microscope, Model HB5 and accessories. Manufacturer: Vacuum Generators, United Kingdom. Intended use of article: The article is intended to be used for the study of polymeric resists, silicon based and compound semiconductor structures, superconductors (niobium, lead), insulators (oxides) and structures at the submicrometer scale. The phenomena to be investigated will include chemical and electronic structure at spatial structures at patterns down to 5A and interaction of electrons with meterials as preparatory to electron beam lithography. Application received by Commissioner of Customs: June 26, 1978.

Docket No. 78-00290. Applicant: Professional Staff Association of the L.A. County Harbor General Hospital, 1124 West Carson Street, Torrance, Calif. 90502. Article: HN A200 Electrophoretic Apparatus Safety Model complete with accessories. Manufacturer: V. Holm, Denmark. Intended use of article: The article is intended to be used to separate serum and brain protein in an electric field during the study of immunological response to the nervous system to viral infection. Application received by Commissioner of Customs: June 21, 1978.

Docket No. 78-00293. Applicant: Bureau of Biologics Food and Drug Administration, Building 29, Room 514, 8800 Rockville, Pike, Bethesda, Md. 20014. Article: H-5010 Scanning Attachment for Electron Microscope. Manufacturer: Hitachi Ltd., Japan. Intended use of article: The article is an accessory to an electron microscope which is being used in conducting ultrastructural studies pertinent to control and research activities concerned with biological products including viral, rickettsial and bacterial vaccines, allergenic products, blood and blood fractions and diagnostic reagents. Application received by Commissioner of Customs: June 23, 1978.

Docket No. 78-00304. Applicant: University of California, Los Angeles, 405 Hilgard Avenue, Los Angeles, Calif. 90024. Article: Gas Chromatograph Mass Spectrometer, Model MS25 and accessories. Manufacturer: KRATOS Inc., United Kingdom. Intended use of article: The foreign article is intended to be used in research studies in environmental chemistry and insect pheromones. This article will also be used by graduate students in their educational advance toward a Ph. D. degree. Application received by Commissioner of Customs: June 26, 1978.

Docket No. 78-00305. Applicant: College of Medicine and Dentistry of New Jersey, P.O. Box 10146, Newark, N.J. 07101. Article: LKB 2128-010 Ultrotome IV Ultramicrotome and Accessories. Mamufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to cut sections for electron microscopy of biological material including plant, animal and fungal specimens. Normal and disease biological tissues will be embedded in hardened epoxy resins, and other resins and embedding materials for sectioning. Investigations will include chiefly ultrastructural studies of the morphology of normal and diseased plant and animal tissues, and electron cytochemical studies aimed at detecting and localizing certain proteins in diseased tissue. The major cytochemical studies proposed are designed to: (a) Detect vascular damage and (b) precisely localize immunoglobulins in natural and experimental autoimmune disorders of the kidney and central nervous system using the immuno-peroxide technique. The article will also be used in the courses Ultrastructure and Cytochemistry which will involve a study of general principles on techniques and the use of the electron microscope to study the fine structure of cells and various cellular organelles and the employment of cytochemical staining methods to localize various enzymes. The objetives of these courses will be to train students in the use and application of electron microscopy and to use the electron microscope in solving individual research problems. Application received by Commissioner of Customs: June 28, 1978.

Docket No. 78-00306. Applicant: University of California, Los Angeles, School of Engineering and Applied Science, 405 Hilgard Avenue, Los Angeles, Calif. 90024. Article: Lumonics

TEA 600A, CO_2 Laser. Manufacturer: Lumonics Research Ltd., Canada. Intended use of article: The article is intended to be used for far-infrared lasers development, a program which consists of using CO_2 lasers to optically pump molecular gases such as Methyl Fluoride, Deuterium Oxide and obtain laser action around 5mm. These far-infrared lasers are to be used for Takomak plasmas diagnostics. This is part of a line of research in an attempt to find an alternative to oil and other fossil fuels as a source of electrical power. Application received by Commissioner of Customs: June 28, 1978.

Docket No. 78-00307. Applicant: University of Chicago, Operator of Argonne National Lab., 9700 South Cass Avenue, Argonne, Ill. 60439. Article: No. 512 Eulerian Cradle (Huber) with offset Phi circle, and accessory. Manufacturer: Robert Huber, Dissrakpionspechnick, West Germany. Intended use of article: The article is intende to be used for measurement of Bragg intensities during studies of single crystal inorganic and organic materials, e.g., platinocyanide complexes, TCNQ derivatives, etc. Application received by Commissioner of Customs: June 28, 1978.

Docket No. 78-00308. Applicant: University of Washington, Department of Ophthalmology RJ-10, RR 735 HSB, Seattle, Wash. 98195. Article: Ultramicrotome, Model LKB 8800A and accessories. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to prepare brain, nerve and eye specimens for ultrastructural studies on normal physiological tissues, developmental studies on animal systems, cyto and histochemical studies on enzyme and subcellular organelle localization in cells and tissues, morphology, interfaces, and subcellular changes in cells induced by changes in their biochemical and physical environments. The article will also be used in courses to train students in the use and application of electron microscopy and to use the electron microscope in solving individual research problems. Application received by Commissioner of Customs: June 29, 1978.

Docket No. 78-00309. Applicant: Indiana University, Department of Biology, Bloomington, Ind. 47401. Article: Ultramicrotome, Model LKB 2128-010 and accessories. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used for ultrastructural studies on normal and pathologic plant tissues, developmental studies on laticifer cell systems, cyto and histochemical studies on enzyme and subcellular organelle localization in laticifer cells and gland tissues, membrane interactions at organelle-cytoplasm interfaces, and subcellular changes in cells induced by changes in their biochemical and physical environments. This research will be conducted to further basic knowledge on cell and tissue ultrastructure and to reveal, at the ultrastructural level, the enzyme localization and distribution of alkaloids and terpenoids in cells and tissues developing under normal and pathological conditions. In addition, the article will be used in the courses Cell Ultrastructure and Cell Cytochemistry which will involve a study of general principles on techniques and the use of the electron microscope to study the fine structure of cells and various subcellular organelles and the employment of cytochemical staining methods to localize various enzymes and other cellular compounds. Application received by Commissioner of Customs: June 29, 1978.

Docket No. 78-00310. Applicant: St. Francis Hospital, 2230 Liliha Street, Honolulu, Hawaii 96817. Article: Electron Microscope, Model EM 9S-2. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used as an integral part of a training program for undergraduate, graduate, and medical students as well as pathology residents. The article is needed for electron microscopic instruction in the following courses: Courses 601 and 602 in Human Pathology which provide a comprehensive review of the pathologic basis of disease, and Course 699 entitled "Directed Research" provides an in-depth study of the pathology of aging, nutrition, alcoholism, and immunology. Application received by Commissioner of Customs: June 29, 1978.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Director, Statutory Import Programs Staff.

[FR Doc. 78-20943 Filed 7-27-78; 8:45 am]

[3510-25]

JOHNS HOPKINS UNIVERSITY

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 a.m. and 5 p.m. in Room 6886C of the Department of Commerce Building, at 14th and Constitution Avenue NW., Washington, D.C. 20230.

Docket No. 76-00410. Applicant: The Johns Hopkins University, Department of Anatomy, 725 North Wolfe Street, Baltimore, Md. 21205. Article: Scanning Electron Microscope, Model JSM-35U and accessories. Manufacturer: JEOL, Japan. Intended use of article: The article is intended to be used to study biological specimens drawn from the blood, blood producing tissues, and immune system tissues in experiments to be conducted on animals in which these tissues will be selectively treated with drugs, chemicals, and irradiation. In addition, diseased tissues from humans and animals will be studied to gain an understanding of the structure and function of these tissues and to obtain information necessary for treatment and cure of leukemia, anemia, multiple myeloma, and related diseases. The article will also be used in graduate and medical courses in cell biology and histology. Comments: No comments have been received with respect to this application. Decision: Application denied. An instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, was being manufactured in the United States at the time the foreign article was ordered (August 28, 1975). Reasons: This application is a resubmission of Docket No. 76-00195-33-46070 which was denied without prejudice to resubmission on April. 1, 1976, for informational deficiencies. In reply to question 8 in this application the applicant alleged that the foreign article provides the following pertinent features:

I. A new standard option Lanthanum Hexaboride (LaB_6) electron gun source which provides a guaranteed resolution of 50A resolution;

II. A longlife LaB_6 electron source (500+ hours) with an ability to be easily changed (filament change takes about half an hour and can be done by most users) and aligned by students;

III. Electronic systems for astigmatism, focusing, and brightness and contrast control which enables users with varying expertise to obtain maximum performance from the article; and

IV. Reliability.

The National Bureau of Standards (NBS) advises in its memoranda dated February 8, 1977, and January 25, 1978, respectively that only resolution (feature I above) is pertinent to the applicant's intended purposes within the meaning of subsection 301.2(n) of the regulations. In addition, NBS advises that the domestic Model 50A Scanning Electron Microscope (SEM) manufactured by Coates and Welter Instrument Corp. (CWIC) is of equivalent scientific value to the foreign article for the applicant's intended use. As to the specific allegations of the appli-

cant in response to question 8, in the order listed above, the following is noted:

I. *Resolution.* The CWIC Model 50A provides a guaranteed resolution of 50Å *with its brighter field emission gun which more than matches the foreign article.* In its recommendation NBS discusses the resolution for the foreign article because such a resolution is very close to the theoretical limit of a thermionic instrument (as opposed to a field emission system) and upon researching the issue, found no evidence of 50Å resolution being obtained through the use of an LaB_6 source on biological material. We know of no evidence to the contrary. Based on the foregoing the Department finds that the CWIC Model 50A matches the foreign article with respect to this pertinent feature.

II. *Longlife LaB_6 Source.* In the initial submission, Docket No. 76-00195 33-46070, the applicant alleged that the article's long tip life (500+ hrs) is a definite teaching aid, because "students cannot be expected to be able to change the tip" and must summon the technician to replace it. In this submission (Docket No. 76-00410) the applicant repeats verbatim his response to question 7 in the first submission and in his response to question 8 states, "* * * A point which was made in the original application but which must be emphasized here is that we require an instrument which can be heavily used by both advanced researchers and by medical and veterinary students, graduate students, clinicians, and post-doctoral fellows. From our own experience with the Coates and Welter machine we learned that a filament change and subsequent realignment takes about 7 hours and can only be performed by highly trained personnel. This is due to the bake time and cooling period required by the Vac-Ion pumps and the complex tip installation procedure. [The article] does not employ Vac-Ion pumps and tip alignment is electromagnetic, and so that equivalent procedure takes about half an hour and can be done by most users." Further, in response to question 8 the applicant alleges that "the extraordinary lifetime of the LaB_6 tip (500+ hours) and *its ability to be easily changed and aligned by students*" [emphasis added] is an important advantage of the article.

The Department notes that in the denial without prejudice to resubmission of the initial submission the applicant was informed that the CWIC Model 50A provided a matching guaranteed resolution and that other features cited were not shown to be pertinent, because although they might relate to the operation of the SEM they were not related to the scientific requirements for performance of the work. As noted above, the applicant in this second submission did not add any additional details to the description of his purposes, for example, how the intended research cannot be performed on the CWIC, in support of justification for duty-free entry. Moreover, the Department notes a significant difference in the applicant's two submissions. In the second submission, the applicant no longer alleges that a technician is necessary to replace the article's long life tip but now states that it can be easily changed and aligned by students.

In accordance with subsection 301.11(a) of the regulations, the determination of scientific equivalency is based on a comparison of the guaranteed specifications of the article and the most closely comparable domestic instrument for those specifications found to be pertinent. Neither the article nor the model 50A specify guaranteed times for a filament change and subsequent realignment or specify that these operations can be done by most users. However, the Department has learned that these functions can be performed in both instruments in 15 to 20 minutes with the help of convenient external tip alignment controls for the X, Y, Z, axis by personnel who are not highly trained (i.e., prior demonstration is sufficient training for skill in tip replacement). The domestic instrument's literature also indicates that automatic bakeout for convenient tip replacement is provided. Since signs of tip breakdown precede actual failure by a significant period of time, users can usually plan for an automatic overnight pumpdown with bakeout.

The Department also notes that both instruments provide built-in features which are conducive to usage by large numbers of investigators. The domestic Model 50A provides a prealigned permanent "stay clean" aperature, permanent scintillator, ultra-clean ultra-high vacuum system which provides a three minute pumpdown time with normal specimens, and a long life (2 months to 1 year) field emission gun which operates at room temperature. The article provides a heated aperture, vacuum system which pumps down in 10 minutes, and a long life LaB_6 gun (500+hours). NBS advises that the life expectancy of any electron source is essentially a factor based on many variables such as vacuum, current saturation, temperature control, alignment, quality of materials and aperture control. NBS advises and the Department concurs that the service and maintainability of the LaB_6 tip in the article is a convenience feature within the meaning of Subsection 301.2 (n) of the regulations and not pertinent for the described work.

Finally, the applicant's claims concerning an SEM loaned by CWIC must be addressed. The applicant states that "while the Coates and Welter Co. offered the same resolution, their microscope was consistently unable to perform to specifications even with constant maintainence by the company." This statement implies that the applicant was loaned a CWIC Model 50A SEM (the only CWIC instrument with a 50Å guarantee available at that time). The Department has determined that the applicant was actually loaned a Model 104A, a less expensive instrument with lower capability than the article and a guaranteed resolution of 90Å. Apparently, this particular instrument had seen much use (and possible abuse) as a demonstrator in various areas of the country. It was in the applicant's possession for less than 2 months.

Although the applicant's experience (7 hour filament change with realignment) has been covered above, it must be noted that this experience was gained on an instrument that might not be expected to perform nearly so well as one that has been accepted as meeting specifications after purchase (as had been the case with many CWIC instruments). In any event, while an institution's previous experience with the products of a particular manufacturer may enter into its buying decisions, such experience is not an objective criterion that the Department can rely on in making the requisite equivalency determination under Pub. L. 89-651.

III. *Astigmatism, Focus, Brightness and Contrast.*

A. *Astigmatism and Focus.*—The CWIC Model 50A provides for rapid correction of changes in astigmatism, tip x and y position, and focus which are immediately observable on a 12-inch CRT monitor. This feature helps enable users with varying expertise to obtain maximum performance from the Model 50A. Further, NBS advises that an electronic system for astigmatism control is helpful (but not essential and, therefore, not pertinent within the meaning of Subsection 301.2(n) of the regulations) in adjusting astigmatism to an acceptable level for high quality micrographs (high resolution). In this connection, NBS points out that the ability to correct the causes of astigmatism is more important and that such causes of astigmatism as aperture contamination, applied kilovolts, working distance, specimen interaction, and lens adjustment are all factors which may relate to astigmatism under operator control. But aside from the question of pertinency, NBS advises that the CWIC Model 50A is a precision instrument which is capable of providing a high depth of focus and astigmatism control matching that of the foreign article. NBS reinforces this advice by pointing out that micrographs of biological material available from CWIC show excellent quality, which is directly related to astigmatism and focusing. Thus, the Department finds that the astigmatism and focusing aspects of feature III are not grounds for duty-free entry.

B. *Brightness and Contrast.*—The Model 50A provides an Automatic Gain Control (AGC) amplifier that automatically sets the brightness and contrast to accommodate a wide range of specimen characteristics, manual overrides on the gamma control, edge enhancer as well as brightness and contrast controls which provide the operator with the capability to optimize desired micrograph parameters. Thus, the Department finds that the Model 50A matches the article with respect to brightness and contrast control. Moreover, the Department notes that the optional automatic contrast and brightness (ACB) control the only system for controlling brightness and con-

trast in the literature supplied by the applicant, was not ordered with the foreign article. Therefore, in accordance with Subsections 301.2(d) and 301.6(a)(3) of the regulations, this feature cannot be a factor in our deliberation.

IV. *Reliability.*—In response to Question 8, the applicant describes his "on loan" use for about 2 months before the article was ordered of a CWIC SEM on which he could not get publication quality pictures. The applicant summarizes this experience by stating that while CWIC offered the same resolution [as the article] the CWIC SEM was consistently unable to perform to specifications, even with constant maintenance by the domestic firm which was unable to correct serious problems with the loan instrument's photographic and stage assemblies. As noted in our coverage of feature II above the loan instrument was the Model 104A. As previously stated, the loan instrument which had poorer guaranteed resolution than the article, might be expected to have problems not found in a new instrument accepted after purchase as meeting its guaranteed specifications. In this connection, it is noted that this has been the case with many CWIC SEM's, including the Model 50A. Also, NBS advises that micrographs of biological materials available from the domestic manufacturer show excellent quality.

In a prior case, Docket No. 75-00213-65-46070, in which that applicant similarly claimed that domestic manufacturers (including CWIC) were not reliable, NBS advised that the applicant's claims regarding the unreliability of domestic manufacturers' SEM's are not found in fact and are not a matter of general understanding in the field of scanning electron microscopy. In connection with this prior case, our scientific consultants at HEW pointed out that reliability is a cost of ownership associated with the level of maintenance and is not a pertinent specification within the meaning of Subsection 301.2(n) of the regulations. This position is one which has been consistently followed by the Department over the years.

In general, information which can lead to a direct quantitative comparison of the reliability (i.e., ability to conform to specifications without excessive breakdown) of two instruments is seldom available. When a specification is "guaranteed" the manfucturer is stating, in effect, that necessary steps have been taken to verify ability to meet this obligation. Thus a guaranteed specification presupposes a determination of reliability to some "engineered-in" degree. Customarily, manufacturers neither issue quantitative specifications on reliability nor guaranteed reliability.

Without strong and substantive supporting evidence in the record, which is not available here, that the reliability of the two instruments were measurably different and the difference in reliability precluded performance of the work intended, reliability cannot be considered a justifiable basis for duty-free entry under Pub. L. 89-651. While reputations with respect to reliability which are derived from personal experience or word-of-mouth claims may enter into a person's decision to buy a particular instrument, such cannot serve as objective basis for duty-free entry.

Based on the foregoing considerations, the NBS advice and our own review of the application, as well as other factual information in our possession (specifications, textbooks, etc.), we find that at the time the foreign article was ordered the CWIC Model 50A was of equivalent scientific value to the foreign article for such purposes as the foreign artilce is intended to be used.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Director, Statutory Import Programs Staff.

[FR Doc. 78-20941 Filed 7-27-78; 8:45 am]

[3510-25]

NORTH CAROLINA STATE UNIVERSITY, ET AL.

Applications for Duty-Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Statutory Import Programs Staff, Bureau of Trade Regulation, U.S. Department of Commerce, Washington, D.C. 20230, on or before August 17, 1978.

Regulations (15 CFR 301.9) issued under the cited act prescribe the requirements for comments.

A copy of each application is on file, and may be examined between 8:30 a.m. and 5 p.m., Monday through Friday, in Room 6886C of the Department of Commerce Building, 14th and Constitution Avenue NW., Washington, D.C. 20230.

Docket No. 78-00311. Applicant: North Carolina State University, Department of Geosciences, 228 Withers Hall, Raleigh, N.C. 27650. Article: Five (5) recording current meters, model 4. Manufacturer: Aanderaa Instruments Co., Norway. Intended use of article: The article is intended to be used for studies of Gulf Stream meanders and eddies along the North Carolina continental sheld and slope. The phenomena to be investigated will include dominant periods and wavelengths of Gulf Stream fluctuations, and their relation to satellite surface infrared and altimetric images of the stream. These investigations will be conducted to understand the cause(s) of the wave-like Gulf Stream meanders off the Carolinas. Application received by Commissioner of Customs: July 5, 1978.

Docket No. 78-00312. Applicant: Indiana University, Purchasing Department, 1101 East 17th Street, Bloomington, Ind. 47401. Article: Universal Camera for Elmiskop 1 Electron microscope. Manufacturer: Siemens AG, West Germany. Intended use of article: The article is an accessory to an existing electron microscope manufactured by the same manufacturer which will be used in research and teaching applications. Specifically, the article will be used for (a) examination of fine structural changes in various experimental ocular disease conditions, (b) recognition of fine tissue changes in experimental animal retina research, and (c) the teaching of graduate students and residents in advanced training. Application received by Commissioner of Customs: July 5, 1978.

Docket No. 78-00313. Applicant: Purdue University, ADMS Building, West Lafayette, Inc. 47907. Article: Superconducting 8.5 T solenoid with power supply. Manufacturer: Oxford Instrument, Ltd., United Kingdom. Intended use of article: The article is intended to be used to apply state-of-the art NMR instrumentation for the solution of certain well-defined problems in protein chemistry. The general goals are two-fold: (i) To learn more about the structure and function of particular proteins and (ii) to refine and develop NMR techniques along with other methods of protein chemistry for use in future studies. Five specific problems under investigation are: (1) The active sites of serine proteinases, (2) the mechanisms of interactions between protein proteinase inhibitors and proteinases, (3) the structures of glycoproteins, (4) the mechanism of folding of staphylococcal nuclease, and (5) the mechanism of electron transport in photosynthesis.

The article will also be used for educational purposes in the course—Chemistry 696B which is designed as an introduction to the theory of NMR spectroscopy and its applications to biochemical problems. Application received by Commissioner of Customs: July 5, 1978.

Docket No. 78-00314. Applicant: Veterans Administration Hospital, 500 Foothill Boulevard, Salt Lake City, Utah 84148. Article: Electron microscope, model JEM 100CX and accesso-

ries. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used for diagnosis of most renal glomerular diseases, for identification of certain poorly differentiated neoplastic cells of origin, and for identification of viral particles, certain liver diseases, certain diseases of hematopoetic cells and certain environmental elements in lungs of the affected patients. The article will also be used to study and identify the light and heavy element in clinical cases of environmental lung diseases and in experimentally induced pulmonary lesions as well as to study and trace beryllium in cellular immunity, both in vivo and in vitro experimental models. In addition, the article will be used to familiarize the student or resident with the principles, operation and applications of the techniques of TEM, SEM, STEM, and X-ray microanalysis. Application received by Commissioner of Customs: July 5, 1978.

Docket No. 78-00315. Applicant: Yale University, Biology Department, Kline Biology Tower, New Haven, Conn. 06520. Article: LKB 8800A Ultrotome III Ultramicrotome and Accessories. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to section specimens of plant and animal tissues which have been frozen in liquid freon. Investigations to be conducted will include studies of cell ultrastructure and intracellular localization of elements in: (a) Plant cells that undergo large rhythmic and light-regulated changes in turgor; (b) protoplasts isolated from cereals and regenerating new walls; (c) cells of plants subjected to environmental pollutants; (d) cells of plants subjected to gravitational stimulation; and (e) pathological and normal tissue from animals and plants. The article will also be used in a course entitled Cell Biology in which students will be taught standard electron microscopy. Application received by Commissioner of Customs: July 5, 1978.

Docket No. 78-00316. Applicant: The Medical College of Wisconsin, 561 North 15th Street, Milwaukee, Wis. 53233. Article: LKB 2128-010 Utrotome IV Ultramicrotome. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used for the development of sets of slides of a variety of animal and human tissues for class use in histology. Studies will be conducted to learn about cell structure and function. Students will be trained in the use and application of electron misroscopy and learn light and electron microscopy of human tissue in courses entitled Histology and Ultrastructure Technique. Application received by Commissioner of Customs: July 5, 1978.

Docket No. 78-00317. Applicant: Ellis Fischel State Cancer Hospital, 115 Business Loop 70 West, Columbia, Mo. 65201. Article: LKB 8800A Ultrotome III Ultramicrotome. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to prepare tissue specimens for the study of cellular structure of various cancer tumors. Application received by Commissioner of Customs: July 5, 1978.

Docket No. 78-00318. Applicant: Southern California College of Optometry, 2001 Associated Road, Fullerton, Calif. 92631. Article: Nagel Anomaloscope. Manufacturer: Schmidt and Haensch, West Germany. Intended use of article: The article is intended to be used to identify persons with deficiencies of color vision through quantitative assessment of the type and degree of severity of a color vision deficiency. The article will be used in Visual Science 322, a course devoted to the theories, experimental basis, and testing of human color vision. In addition, the article will be used in the teaching clinics of the college for diagnosis of color vision anomalies. Application received by Commissioner of Customs: July 5, 1978.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Director,
Statutory Import Programs Staff.

[FR Doc. 78-20942 Filed 7-27-78; 8:45 am]

[3510-25]

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

BILATERAL TEXTILE NEGOTIATIONS WITH THE GOVERNMENT OF INDIA

Soliciting Public Comment

JULY 25, 1978.

On April 21, 1974, the Committee for the Implementation of Textile Agreements published a notice in the FEDERAL REGISTER (39 FR 13307) conveying the Committee's intention to announce, and solicit comment on, U.S. Government actions implementing the GATT Arrangement Regarding International Trade in Textiles and the bilateral textile agreements entered into thereunder.

Pursuant to the terms of the Arrangement and the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of December 30, 1977, as amended, between the Governments of the United States and India, the Committee anticipates holding consultations with the Government of India beginning early in September 1978. Any party wishing to express a view or provide data or information with regard to the treamtment of any product under the bilateral agreement and any other aspects thereof, or comment on production or availability of domestic textile products, is invited to submit such in ten copies to Mr. Robert E. Shepherd, Chairman of the Committee for the Implementation of Textile Agreements and Deputy Assistant Secretary for Domestic Business Development, U.S. Department of Commerce, Room 3826, 14th Street and Constitution Avenue NW., Washington, D.C. 20230.

Views, data or information submitted under this procedure will be available for public inspection in the Office of Textiles, Room 2815, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, D.C. 20230, and may be obtained upon written request. Whenever practicable, public comment may be invited concerning views, comments or information received from the public which the Committee for the Implementation of Textile Agreements considers appropriate for further consideration.

The solicitation of comments on any negotiation, consultation, market disruption or any other matter pursuant to this notice is not a waiver in any respect of the exemption contained in 5 U.S.C. 553(a)(1) and 554(a)(4) relating to matters which constitute "a foreign affairs function of the United States."

ROBERT E. SHEPHERD,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Domestic Business Development.

[FR Doc. 78-20912 Filed 7-27-78; 8:45 am]

[6820-33]

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

PROCUREMENT LIST 1978

Proposed Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to Procurement List 1978 commodities to be produced by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: August 30, 1978.

ADDRESS: Committee for Purchase from the Blind and Other Severely

Handicapped, 2009 14th Street North, Suite 610, Arlington, Va. 22210.

FOR FURTHER INFORMATION CONTACT:

C. W. Fletcher, 703-557-1145.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2), 85 Stat. 77.

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodities listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities to Procurement List 1978, November 14, 1977 (42 FR 59015):

Class 6510
Bandage, Muslin, Compressed
6510-00-201-1755
Class 7210
Pillow, Bed, Feather
7210-01-015-5190
Class 8415
Apron, Food Handler's
8415-01-04500587

C. W. FLETCHER,
Executive Director.

[FR Doc. 78-20892 Filed 7-27-78; 8:45 am]

[3810-71]

DEPARTMENT OF DEFENSE

Department of the Navy

BOARD OF VISITORS TO THE U.S. NAVAL ACADEMY

Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. app. 1), notice is hereby given that the Board of Visitors to the U.S. Naval Academy will meet on September 27, 1978, in room 301, Rickover Hall, at the U.S. Naval Academy, Annapolis, Md. The meeting will commence at 8:30 a.m. and terminate at approximately 4 p.m.

The purpose of the meeting is to make such inquiry as the Board shall deem necessary into the state of morale and discipline, the curricuium, instruction, physical equipment, fiscal affairs, and academic methods of the U.S. Naval Academy.

For further information concerning this meeting contact: Rear Ad. Robert W. McNitt, U.S. Navy (retired), Secretary to the Board of Visitors, Dean of Admissions, U.S. Naval Academy, Annapolis, Md. 21402. Telephone 301-267-2188.

Dated: July 21, 1978.

P. A. WILLE,
Captain, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (Administrative Law).

[FR Doc. 78-20870 Filed 7-27-78; 8:45 am]

[3128-01]

DEPARTMENT OF ENERGY

ISSUANCE OF DECISIONS AND ORDERS BY THE OFFICE OF HEARINGS AND APPEALS

Week of June 5 through June 9, 1978

Notice is hereby given that during the week of June 5 through June 9, 1978, the decisions and orders summarized below were issued with respect to appeals and applications for exception or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions which were dismissed by the Office of Hearings and Appeals and the basis for the dismissal.

APPEALS

R. D. Bowerman d.b.a. Executive Center Gulf, San Antonio, Tex., FRA-1354, motor gasoline

R. D. Bowerman d.b.a. Executive Center Gulf (Bowerman) appealed from a Remedial Order which was issued to the firm by FEA Region VI on May 23, 1977. In the Remedial Order, FEA Region VI found that during the period November 1, 1973 through July 24, 1974 Bowerman sold motor gasoline to its customers at prices which exceeded the maximum permissible levels calculated in accordance with 10 CFR 212.93. In its Appeal, Bowerman challenged the Remedial Order on several procedural grounds. Bowerman's first claim was that any action by the DOE to collect the overcharges was barred by the Texas statute of limitations. The DOE found that although the Emergency Petroleum Allocation Act (EPAA) did not contain a relevant statute of limitations, the application of a State statute of limitations to enforcement action of this type would be inconsistent with the national policy expressed in the EPAA. In this connection, the DOE found that its enforcement activities, a crucial element of the regulatory program which was intended to achieve the EPAA's policy objectives, would be seriously jeopardized if the agency were precluded from instituting compliance actions as a result of peculiarities and differences arising under local law. In this regard, the DOE found that the enforcement proceeding against Bowerman was part of a program which was designed to further the objective of promoting equitable distribution of petroleum products at equitable prices among all regions of the country. Moreover, the DOE noted that the public itself would be the direct beneficiary of the enforcement action inasmuch as the Remedial Order required Bowerman to offer for sale all grades of gasoline at reduced prices. Consequently, the DOE held that the Texas statue of limitations was not applicable to the enforcement action against Bowerman. Bowerman also claimed that he never received the Notice of Probable Violation (NOPV) which was issued to him by the FEA prior to the issuance of the Remedial Order and as a result was not accorded the full procedural safeguards to which he was entitled. The DOE rejected this contention, noting that the agency possessed a signed written United States Postal Service receipt indicating that Bowerman had received the NOPV. Finally, Bowerman contended that the DOE previously made a determination not to proceed against him for violating the price regulations and therefore should be barred from reopening this matter in the absence of a showing that the agency now possessed new information regarding those violations. This argument was similarly rejected. The DOE determined that even though an investigation of a firm's compliance with the price regulations during a particular period may have been closed, the agency's regulations permitted a further investigation at any time that circumstances so warranted. The DOE concluded that in the present proceeding the circumstances justified the reissuance of the NOPV. Accordingly, the Bowerman Appeal was denied.

Gulf Oil Corp., Tulsa, Okla., DEE-0612, crude oil

Gulf Oil Corp. filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D which, if granted, would permit Gulf to sell the crude oil produced from the Kiefer Unit located in Creek County, Okla., at upper tier ceiling prices. In considering the exception application, the DOE found that the cost of producing crude oil from the Kiefer Unit had increased to a level where it now exceeds the revenue that the firm can obtain from the sale of the crude oil at the lower tier ceiling price. The DOE therefore concluded that Gulf had no economic incentive to continue to produce crude oil from the property, and that it was highly unlikely that the crude oil from the reservoir underlying the Kiefer Unit could be recovered by any other firm in the absence of exception relief. The DOE therefore concluded that the application of the ceiling price rule resulted in a gross inequity to Gulf and the other working interest owners. In order to provide the working interest owners with an incentive to continue to produce, the DOE granted exception relief which permits Gulf to sell 34.88 percent of the crude oil produced from the Kiefer Unit for the benefit of the working interest owners at upper tier ceiling prices for a six month period of time.

Texaco, Inc., Westchester, N.Y., DFA-0177, Freedom of Information

Texaco, Inc. (Texaco) appealed from a partial denial by the Information Access Officer of a Request for Information which the firm had submitted under the Freedom of Information Act (FOIA). In its Appeal, Texaco requested that the DOE order the release of six documents which the Information Access Officer had withheld from the firm. The Information Access Officer denied the firm access to those documents on the grounds that they are intra-agency memoranda which are exempt from mandatory public disclosure under the provisions of 5 U.S.C. 552(b)(5). In considering the Appeal, the DOE found that the documents which were withheld from the firm generally summarize and analyze a number of problems associated with the application of the Mandatory Petroleum Price Regulations to crude oil producers and that the material was predecisional in nature. The DOE also determined that the material which was withheld is precisely the type of information which Exemption 5 of the FOIA was designed to protect from disclosure. In addition, the DOE determined that there were no portions of the documents which contain

purely factual material which could be easily segregated from the policy discussions contained in the documents and released to Texaco. Finally, the DOE determined that the Information Access Officer's response to the Texaco Request for Information adequately set forth the grounds upon which the six documents were withheld. Accordingly, the Texaco Appeal was denied.

Texas Gas Exploration Corp., Washington, D.C., FEE-4460, propane

Texas Gas Exploration Corp. (Exploration) filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart K, which if granted, would permit the firm to increase the banks of unrecovered product costs which it is generally permitted to reflect in price increases in future months. In its Application, Exploration stated that because of the ambiguity surrounding the correct application of the definition of "transaction" prior to the issuance of Ruling 1977-5, it incorrectly calculated its May 15, 1973, weighted average selling price for propane produced at its Eunice, Louisiana gas plant. According to the firm, this resulted in its adoption of a maximum permissible selling price for propane which was lower than its correct maximum price under the Price Regulations, and a consequent loss of substantial revenues on its sales of this product during the period from 1975 through 1977. Exploration requested that its banks of unrecovered product costs be increased by an amount equal to the revenues which it lost during the 1975-1977 period.

In considering the Exploration request, the DOE noted that in *Quincy Oil Co., Inc.*, 1 DOE Par. 81,030 (November 23, 1977), it had held that due to the confusion surrounding the proper application of the term "transaction" to variable-price contracts, the standard for retroactive relief should not be applied in evaluating applications for exception from the definition of transaction set forth in Ruling 1977-5. The DOE determined that the application of the transaction definition to the fixed-price contract in the present case was ambiguous as well. The DOE further found that Exploration had adopted a conservative interpretation of the Price Regulations and had thereby charged lower prices than it was lawfully permitted to charge under the Regulations. The DOE also determined that market conditions during the relevant period would have permitted the firm to charge the lawful higher prices. Under these circumstances, the DOE concluded that the firm should be permitted to recover the revenues which it had foregone. However, since only one customer was undercharged as result of the firm's interpretation of transaction, the exception relief approved was limited to the prospective prices charged to that customer.

REQUESTS FOR EXCEPTION

Charter Oil Co., Jacksonville, Fla., DXE-0491, Crude oil

Charter Oil Co. (Charter) filed an Application for Exception from the provisions of 10 CFR 211.67 (the Entitlements Program) which, if granted, would relieve the firm of its obligation to purchase entitlements beginning with the month of March 1978. In support of its Application Charter submitted projected financial and operating material for its current fiscal year ending Dec. 31, 1978. Based on the Charter submission, the DOE determined that Charter would incure an obligation to purchase entitlements during its current fiscal year which would prevent it from achieving either its historical profit margin or its historical return on invested capital (ROIC). The DOE therefore concluded that exception relief was warranted under the criteria set forth in *Delta Refining Co.*, 2 FEA Par. 83,275 (Sept. 11, 1975), and *Beacon Oil Co.*, 3 FEA Par. 83,209 (June 8, 1976). The DOE found that Charter's projections indicated that even if the firm were relieved of its entire entitlement purchase obligation for the current fiscal year it would still not attain either its historical profit margin or ROIC. Accordingly, in a Proposed Decision and Order issued to the firm on Mar. 20, 1978, the DOE tentatively granted Charter an exception which relieved it of any obligation to purchase entitlements during the 6-month period Mar. 31 through Aug. 31, 1978. Since no Notice of Objection was filed to the Proposed Decision in accordance with the regulations which govern exception matters, the Decision and Order was issued to Charter in final form on Mar. 20, 1978.

Standard Oil Co. (Indiana), Chicago, Ill., FXE-4813, Natural Gas Liquids

On Oct. 28, 1977, the DOE issued a Proposed Decision and Order to the Standard Oil Co. (Indiana) (Standard) which denied the firm's request for exception from the provisions of 10 CFR 212.165. The Proposed Decision refused to extend the exception relief which Standard had previously been granted which permitted it to increase its selling prices for the natural gas liquids produced at its Elmwood natural gas processing plant. *See Standard Oil Co.* (Indiana), 5 FEA Par. 82,057 (Jan. 25, 1977). The determination in the Proposed Decision was based on a comparison of the non-product costs which the firm incurred at its Elmwood plant during the calendar quarter including May 15, 1973 and the three calendar quarters ending June 30, 1977. On Dec. 8, 1977, Standard filed a Statement of Objections to the Proposed Decision. Standard contended that it did not seek an extension of the Jan. 25, 1977 exception determination prior to its expiration on June 1, 1977 because the firm's costs would not have justified an extension of relief at that time. Consequently, Standard claimed that its current application should have been construed by DOE as an initial request for exception and that the calculation of the amount of relief therefore should have been based upon a comparison of only the most recently completed quarter's costs with those of the base period. In considering the firm's contention, the DOE noted that it had previously considered and rejected a virtually identical argument in *Shell Oil Co.*, 1 DOE Par. 80,222 (Mar. 13, 1978). As indicated in the *Shell* Decision, if the DOE permitted firms to selectively utilize their costs from interim periods to justify the magnitude of the exception relief which they seek, the amount of relief granted could be unrepresentatively high because of factors such as the timing of accounting record entries. In order to avoid this result, the DOE typically determines the amount of unrecovered nonproduct costs which have been incurred at a particular plant on the basis of a comparison of base quarter costs with those incurred during a current period which encompasses all of the quarters which have elapsed since a previous grant of exception relief. Since Standard failed to present any convincing evidence that the principles of *Shell* should be reversed or that their application would be inappropriate in this case, the Proposed Decision and Order was issued in final form.

Sun Co., Inc., Dallas, Tex., FXE-4780, FXE-4785, FXE-4806, FXE-4823, FXE-4826, FXE-4833, FXE-4847, Natural Gas Liquids

On Sept. 30, 1978, the Sun Co., Inc. (Sun) was issued a Proposed Decision and Order which tentatively extended previously granted exception relief permitting Sun to increase its selling prices above maximum levels permitted under 10 CFR 212.165 for natural gas liquids and natural gas liquid products which it produces at several of its natural gas processing plants. On Nov. 15, 1977, Sun filed a Statement of Objections to the Proposed Decision and Order. In its Statement of Objections, Sun contended that the DOE erred in utilizing the most recently completed six month period for purposes of comparison with May 15, 1973, cost levels in order to determine the level of exception relief. Instead, Sun argued that only the most recently completed 3-month period should have been used to calculate the level of relief. In this regard, Sun contended that utilization of the most recent 3-month period results in a better approximation of the plants' future nonproduct cost levels which the relief is intended to defray. In considering Sun's contentions, the DOE noted that it had previously rejected an identical argument which Sun had raised in an Appeal involving exception relief granted to other of its plants. *See Sun Company, Inc.*, 6 FEA 80,557 (Sept. 19, 1977). In that Decision the DOE stated that the utilization of a 6-month period is rational since it takes into consideration all of the data which has become available since the previous grant of exception relief. Since Sun failed to present any convincing evidence that the use of a 6-month period is erroneous or that its application to this case is inappropriate, the DOE issued the Proposed Decision and Order in final form on June 5, 1978.

SUPPLEMENTAL ORDERS

Arizona Fuels Corp., Salt Lake City, Utah, DEX-0075, Crude Oil

On Jan. 16, 1978, the DOE issued a Proposed Decision and Order to the Arizona Fuels Corp. (Arizona Fuels) which tentatively concluded that an Application for Exception which the firm had submitted from the provisions of 10 CFR 211.67 (the Entitlements Program) should be granted. On Jan. 17, 1978, the DOE issued a further Decision and Order to the firm staying its obligation to purchase entitlements to the extent specified in the Proposed Decision and Order. Arizona Fuels subsequently filed a Statement of Objections to the January 16 Proposed Decision. No final determination had as yet been issued with respect to the Proposed Decision. However, under the specific terms of the January 17 Stay Order Arizona Fuels would continue to receive stay relief even though the 6-month exception relief period specified in the Proposed Decision and Order had expired. Accordingly, the January 17 Stay Order was amended to specify that the stay relief was applicable only to the 6-month period January

through June 1978 pending the issuance of a final determination with respect to the Proposed Decision and Order.

Laketon Asphalt Refining, Inc., Evansville, Ind., DEX-0076, Crude Oil

On Feb. 10, 1978, the DOE issued a Proposed Decision and Order to Laketon Asphalt Refining, Inc. (Laketon) which tentatively concluded that an Application for Exception which the firm had submitted from the provisions of 10 CFR 211.67 (the Entitlements Program) should be granted. On Feb. 10, 1978, the DOE issued a further Decision and Order to the firm staying its obligation to purchase entitlements to the extent specified in the Proposed Decision and Order. Laketon subsequently filed a Statement of Objections to the February 10 Proposed Decision. No final determination has as yet been issued with respect to the Proposed Decision. However, under the specific terms of the February 10 Stay Order, Laketon would continue to receive stay relief even though the 6-month exception relief period specified in the Proposed Decision and Order had expired. Accordingly, the February 10 Stay Order was amended to specify that the stay relief was applicable only to the six month period February through July 1978 pending the issuance of a final determination with respect to the Proposed Decision and Order.

Newhall Refining Co., Inc., Dallas, Tex., DEX-0077, Crude Oil

On February 10, 1978, the DOE issued a Proposed Decision and Order to Newhall Refining Co., Inc. (Newhall) which tentatively concluded that an Application for Exception which the firm had submitted from the provisions of 10 CFR 211.67 (the Entitlements Program) should be granted. On Feb. 10, 1978, the DOE also issued a Decision and Order to the firm staying its obligation to purchase entitlements to the extent specified in the Proposed Decision and Order. Newhall subsequently filed a Statement of Objections to the February 10 Proposed Decision. No final determination had as yet been issued with respect to the Proposed Decision. However, under the specific terms of the February 10 Stay Order, Newhall would continue to receive stay relief even though the 6-month exception relief period specified in the Proposed Decision and Order had expired. Accordingly, the February 10 Stay Order was amended to specify that the stay relief was applicable only to the 6-month period February through July 1978 pending the issuance of a final determination with respect to the Proposed Decision and Order.

No. 2 (Home) Heating Oil, Washington, D.C., DEH—0050 through DEH—0056, Evidentiary Hearing Home Heating Oil

The Office of Hearings and Appeals of the Department of Energy recently received 11 Petitions to Intervene submitted by organizations that wish to participate as parties in an evidentiary hearing which will be held in August 1978 concerning No. 2 (home) heating oil. Those Petitions were filed pursuant to Rule 2 of the rules of procedure which the Office of Hearings and Appeals adopted on an interim basis on Apr. 18, 1978. In a previous Decision and Order, the Office of Hearings and Appeals granted the Petitions of three organizations, the Energy Policy Task Force of the Consumer Federation of America, the American Petroleum Institute, and the Antitrust Division of the Department of Justice. Accordingly, these petitioners were designated as parties to the August 1978 evidentiary hearing. The Office of Hearings and Appeals also held a conference on June 6, 1978 in order to allow the remaining petitioners to comment further on the reasons why they should be accorded party status. After considering the views which were presented at the June 6 conference and reviewing the eight pending Petitions to Intervene, the DOE determined that two of the petitioners, the National Oil Jobbers Council (NOJC) and the Atlantic Richfield Company (ARCO), should be accorded party status in this proceeding. In this regard, the DOE found that the written petitions and oral presentations made by NOJC and ARCO at the June 6 conference indicated that their participation in the evidentiary hearing would contribute substantially to the purpose and scope of the hearing. With respect to the remaining petitioners, the Office of Hearings and Appeals determined that they should not be accorded party status at the evidentiary hearing.

SUMMARY DECISIONS

In the following case, stay relief from the provisions of 10 CFR, Part 212 which had previously been granted to sellers of Gasohol in the State of Illinois and to members of FS Services and Affiliated Companies that sell Gasohol in the States of Iowa and Wisconsin was extended to all sellers of Gasohol in the State of Iowa: Iowa Development Commission, Des Moines, Iowa. DES-0064.

DISMISSALS

The following submissions were dismissed following a statement by the applicant indicating that the relief requested was no longer needed: City of Long Beach Dept. of Oil Properties, Long Beach, Calif., FMR-0124; Lewtex Oil & Gas Co., Austin, Tex., DEE-0435 & DEE-0437.

Copies of the full text of these Decisions and Orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1 p.m. and 5 p.m., e.d.t., except Federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

RICHARD T. TEDROW,
Acting Director,
Office of Hearings and Appeals.

JULY 24, 1978.

[FR Doc 78-20871 Filed 7-27-78; 8:45]

[3128-01]

CASES FILED WITH THE OFFICE OF HEARINGS AND APPEALS

Week of July 7 Through July 14, 1978

Notice is hereby given that during the week of July 7 through July 14, 1978, the appeals and applications for exception or other relief listed in the appendix to this notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under the DOE's procedural regulations, 10 CFR, part 205, any person who will be aggrieved by the DOE action sought in this case may file with the DOE written comments on the application within 10 days of service of notice, as prescribed in the procedural regulations. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.

JULY 19, 1978.

THOMAS L. WIEKER,
Acting Director, Office of Hearings and Appeals.

APPENDIX.—*List of cases received by the Office of Hearings and Appeals*

[Week of July 7 through July 14 1978]

Date	Name and location of applicant	Case No.	Type of submission
July 7, 1978	Pennzoil Producing Co., Houston, Tex	DEX-0092	Supplemental order. If granted: The decision and order issued to Pennzoil Producing Co. on May 15, 1978, would be modified in certain technical respects (case No. FXE-4776).
Do	Warrior Asphalt Co. of Alabama, Washington, D.C.	DEX-0093	Supplemental order. If granted: The DOE would review the entitlements exception relief granted to Warrior Asphalt Co. of Alabama during its 1978 fiscal year in order to determine whether the level of relief accorded the firm was appropriate.
July 10, 1978	L. W. Babcock, Bakersfield, Calif	DEE-1408	Price exception (sec. 212.73). If granted: L. W. Babcock would be permitted to sell the crude oil produced from the Union Avenue field at upper-tier ceiling prices.
Do	Cities Service Co., Tulsa, Okla	DEE-1410 through DEE-1412.	Price exception (sec. 212.165). If granted: Cities Service Co. would be permitted to increase its prices to reflect nonproduct cost increases in excess of $0.005 per gallon for natural gas liquid products produced at the Natomas, Seiling, and Thunder Creek plants.
Do	Eastern Shore Gas Co., Philadelphia, Pa	DES-0086	Stay request. If granted: Eastern Shore Gas Co. would be granted a stay of the provisions of 10 CFR 212.93 pending a determination on an application for exception which the firm had filed (case No. DRC-0009).
Do	Keener Oil Co., Tulsa, Okla	DXE-1407	Extension of relief granted in *Keener Oil Company*, 1 DOE Par. 81,008 (Mar. 7, 1978). If granted: Keener Oil Co. would be permitted to sell the crude oil produced from its Lizzie-Orwig well No. 1 located in Seminole County, Okla., at upper-tier ceiling prices.
Do	Lerner Oil Co., Inc., Gardena, Calif	DSG-0024	Request for special redress. If granted: An NOPV which was issued to MacMillan Ring-Free Oil Co. by DOE region IX and subsequently withdrawn would be reissued.
Do	Sidney E. Pinkston, Jr., Adams County, Miss.	DEE-1409	Price exception (sec. 212.73). If granted: Sidney E. Pinkston, Jr., would be permitted to sell the crude oil produced in the Beaver Branch field at upper-tier ceiling prices.
Do	Wyoming Refining Co., Denver, Colo	DED-0495	Motion for discovery. If granted: Wyoming Refining would be entitled to discovery in connection with its statement of objections to a proposed decision and order issued to Little America Refining Co.
July 11, 1978	A. Johnson & Co., New York, N.Y.	DES-0087	Request for stay. If granted: A. Johnson & Co. would receive a stay of the provisions of 10 CFR 211.67 pending a final determination on its application for exception.
Do	Allied Chemical Corp., Houston, Tex	DEE-1413 through DEE-1415.	Price exception (sec. 212.165). If granted: Allied Chemical Corp. would be permitted to increase its prices to reflect nonproduct cost increases in excess of $0.005 per gallon for natural gas liquid products produced at the Burnell-N. Pettus, N. Terrebonne-Tebone, and S. Fullerton plants.
Do	Econ-o-Gas, Inc., Temple, Tex	DEE-1416	Exception to change supplier. If granted: Econ-O-Gas, Inc., would be assigned a new, lower priced supplier of motor gasoline to replace its base period supplier, Foremost.
Do	Powerine Oil Co., Los Angeles, Calif	DMR-0027	Request for modification of *Powerine Oil Co.*, 6 FEA Par. 87,013 (July 7, 1977). If granted: The decisions and order issued to Powerine Oil Co. on April 11, 1977, and July 7, 1977, would be modified with respect to the level of relief from purchases of entitlements to be afforded the firm during 1975.
July 12, 1978	E. C. Johnson Co., Longview, Tex	DXE-1418	Price exception (sec. 212.165). If granted: E. C. Johnson Co. would be permitted to increase its prices to reflect nonproduct cost increases in excess of $0.005 per gallon for natural gas products produced at the R. M. Stephens plant.
Do	No. 2 (Home) Heating Oil (Wisconsin), Washington, D.C.	DEH-0060	Request for evidentiary hearing. If granted: The State of Wisconsin would be permitted to submit written comments to the Office of Hearings and Appeals in connection with an evidentiary hearing being held with respect to No. 2 (home) heating oil.
July 13, 1978	Arizona Fuels Corp., Salt Lake City, Utah	DEX-0094	Supplemental order. If granted: Arizona Fuels Corp. would receive a stay of a portion of its entitlement purchase obligations pending a final determination on its application for exception.
Do	DeMartin Truck Lines, Inc., Bakersfield, Calif.	DRA-0198 and DRS-0198.	Appeal of revised remedial order issued June 29, 1978. Stay request. If granted: The June 29, 1978, revised remedial order issued by DOE region IX would be rescinded and DeMartin Truck Lines, Inc., would not be required to refund overcharges made in its sales of propane and butane.
Do	Northland Oil & Refining Co., Tulsa, Okla.	DES-0089	Stay request. If granted: Northland Oil & Refining Co. would be granted a stay of any entitlements purchase obligations pending a decision on its application for exception.
Do	John Wight, Billings, Mont	DEE-1417	Allocation exception (sec. 214.21). If granted: The firm would be granted an allocation of crude oil under the provisions of 10 CFR 214.21.
July 14, 1978	Champlin Petroleum Co., Fort Worth, Tex	DRZ-0012	Interlocutory order. If granted: The DOE would establish procedures with regard to an evidentiary hearing which might be held with respect to the remedial order issued to Champlin Petroleum Co.
Do	Norco Oil Co., Cheboygan, Mich	DRH-0064	Request for evidentiary hearing. If granted: An evidentiary hearing would be convened in connection with the Norco Oil Co.'s objections regarding the March 20, 1978, proposed remedial orders issued to the firm.
Do	Texas City Refining, Inc., Washington, D.C.	DEE-1418	Exception to entitlements program. If granted: Texas City Refining, Inc., would receive an exception from the provisions of 10 CFR 211.67 with respect to its entitlements purchase obligations.

Notices of objection received

[Week of July 7 through July 16, 1978]

Date	Name and location of applicant	Case No.
July 7, 1978	McCulloch Gas Processing Plant, Washington, D.C	DXE-1087 through DXE-1091
Do	Lunday-Thagard Oil Co. Washington, D.C.	DXE-1057
Do	San Joaquin Refining Co. Bakersfield, Calif	DXE-1049

Notices of objection received—Continued

[Week of July 7 through July 16, 1978]

Date	Name and location of applicant	Case No.
July 10, 1978	Robert E. Hanson, Riverton, Wyo	DEE-0320
Do	New England Petroleum Corp., New York, N.Y	DEE-0361
Do	The Glenrock Refinery, Inc., Washington, D.C	FEE-4853
Do	Commonwealth Oil Refining Co., Inc., San Antonio, Tex	DEE-1369
July 12, 1978	Jack Halbert, Tyler, Tex	FEE-4844 and FEE-4845
July 13, 1978	Saber Refining Co., Houston, Tex	DEE-0425

Proposed remedial orders

July 7, 1978	Ford Oil Co., Washington, D.C	DRO-0078
July 10, 1978	Woodward Drilling Co., Columbus, Ohio	DRO-0079
Do	Monterrey Petroleum Corp., San Antonio, Tex	DRO-0030
Do	Crystal Petroleum Co., Corpus, Christi, Tex	DRO-0031
July 12, 1978	Gene L. Bolin, d.b.a. Gene Bolin's Chevron Station Philomath, Oreg	DRO-0032
Do	Chevron U.S.A., Inc., San Francisco, Calif	DRO-0033

[FR Doc. 78-20872 Filed 7-27-78; 8:45 am]

[3128-01]

PRIVACY ACT OF 1974

Proposed Amendments to System of Records

AGENCY: Department of Energy.

ACTION: Notice of Proposed Amendments to a System of Records.

SUMMARY: Notice is hereby given that the Department of Energy (DOE) is proposing to amend the categories of individuals and type of information covered by the system of records heretofore designated as FEA-23, Telephone Numbers of FEA Officials. Concurrent with the publication of this Notice, a Report on New Systems is being submitted to Congress and the Office of Management and Budget, in accordance with 5 U.S.C. 552a(o) with respect to these proposed amendments, since they alter the number and types of individuals on whom records are maintained and expand the categories of information maintained in the referenced system.

Written comments are invited with respect to this proposal; however, it is the intent of DOE to operate the existing system as proposed at the expiration of the advance notice period if no comments to the contrary are received.

DATES: Comments by August 28, 1978.

FOR FURTHER INFORMATION CONTACT:

John Treanor, Acting Director, Division of Freedom of Information and Privacy Acts Activities, Federal Building, Room 2121, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461, 202-566-9840.

Laura Rockwood, Office of General Counsel, Federal Building, Room 6144, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461, 202-566-9653.

SUPPLEMENTARY INFORMATION:

I. Narrative statement describing FEA-23, as required by the Privacy Act of 1974 and OMB Circular A-108.

II. Comment Procedures.

I. Narrative statement as required by the Privacy Act of 1974 and OMB Circular A-108:

Background: This Report on New Systems is submitted by the Department of Energy (DOE), as required by the Privacy Act of 1974, 5 U.S.C. 552a(o), and paragraph 2a(2) of Transmittal Memorandum No. 1 to Office of Management and Budget (OMB) Circular A-108. OMB Circular A-108 required that a government agency publish a Report on New Systems whenever a new system of records is proposed or there occurs a change in the number or types of individuals about whom information is maintained; an expansion in the type or categories of information maintained; an alteration in the manner in which the records are organized, indexed, or retrieved so as to change the nature or scope of those records; an alteration in the purposes for which the information is used; or a change in the equipment configuration on which the system is operated so as to create the potential for either greater or easier access. In this case, the amendments would alter the number of individuals covered and the types of information contained, as more fully described below.

The DOE was estimated by the Department of Energy Organization Act (Pub. L. 95-91) (the Act), which was made effective October 1, 1977, by Executive Order 12009, dated September 13, 1977 (42 FR 46267, September 15, 1977). The act transfers to, and vests in, the DOE and the independent collegial body within the DOE, the Federal Energy Regulatory Commission (FERC), the functions of the former Federal Energy Administration, the former Energy Research and Development Administration, the former Federal Power Commission, and certain functions previously performed by several other departments and programs.

The departments, agencies, and commissions, or components thereof, which, prior to the act, discharged the functions which the act vests in the DOE, established and proposed certain systems of records in accordance with the Privacy Act of 1974 and other authority vested in them. Those systems of records (or portions thereof) either in existence or proposed prior to October 1, 1977, which relate to the functions of any entity which was transferred to the DOE by the act to either the Secretary or to the FERC (or delegated to the FERC by the Secretary) were formally transferred to the Secretary and to the FERC, as appropriate to their respective functions (42 FR 54856, October 11, 1977).

The system designated as FEA-23, telephone numbers of FEA officials, is a system of records created and noticed in 42 FR 52485, September 30, 1977. The system contains the home telephone numbers of senior staff officials of the Federal Energy Administration (FEA). The proposed amendments to FEA-23 would expand both the number and types of individuals covered by the system and the type of information contained therein. These proposed amendments to FEA-23 are therefore being noticed in the FEDERAL REGISTER in accordance with section 3(e)(11) of the Privacy Act of 1974, 5 U.S.C. 552a(e)(11).

B. *Purpose:* The system designated as FEA-23 was originally established as a necessary precaution to guard against an emergency situation during which the appropriate senior FEA official could not otherwise be contacted. The proposed amendments reflect the expansion of the system to include all DOE senior staff. The proposed amendments would also expand the employees covered to include support staff. This reflects the recognition of the necessity of having such personnel available to support senior officials by

carrying out secretarial and administrative duties arising as a result of emergency situations. Additionally, the home addresses of all of the individuals covered are proposed to be included to aid in determining the relative availability and accessability of officers and employees in the event of an emergency. As a result of these changes, the system will be renamed FEA-23, telephone numbers and addresses of DOE senior and support staff.

C. *Authority:* Section 641 of the Department of Energy Organization Act authorizes the Secretary, to the extent necessary or appropriate in performing any function transferred by that act, to exercise any authority or part thereof available by law to the official or agency from which such function was transferred. Section 301 of the act transfers to the Secretary, among other functions, all of the functions vested by law in the Administrator of FEA. The authority for the FEA Administrator to amend systems of records was based upon the authority vested in him pursuant to Section 7(a) of the Federal Energy Administration Act of 1974 (Pub. L. 93-275) to promulgate such rules, regulations, and procedures as necessary to carry out his functions. Therefore, as a result of the transfer of functions pursuant to Section 301 of the DOE Organization Act, the Secretary of DOE is vested with that authority to amend systems of records which was previously vested in the FEA Administrator.

Additionally, 5 U.S.C. 301 and section 644 of the Department of Energy Organization Act authorize the Secretary of the DOE to prescribe such procedural and administrative rules and regulations as he may deem necessary or appropriate to adminster and manage functions vested in him. Therefore, these provisions are also authority for the proposed amendments.

D. *Potential consequences on individual privacy.* Although the amendments would expand the categories of individuals and the type of information under this system, DOE does not deem that the maintenance of the amended FEA-23 will have any substantial effect on the privacy and other personal or property rights of individuals. No information is or will be retained in the system other than that which is given voluntarily to the agency by an individual. The use of FEA-23 is totally internal to DOE operations, with no access to information contained therein allowed to any persons other than those with a need to know for the purpose of conducting official DOE business. With DOE's stringent access controls and limited use of the records contained in the FEA-23, the operation of the system will have minimal effect on individual privacy and other personal or property rights.

E. *Safeguards against unauthorized access.* The risk of unauthorized access has been minimized by locating FEA-23 in a lockable container within a room secured when neither authorized users nor the system manager is present. Control over these facilities is given only to the system manager and those qualifying for access under the routine uses listed in the accompanying proposed amended system notice. The lower risk alternative of maintaining the system in a locked cabinet within secured rooms was considered; however, the presence of responsible DOE personnel was considered to be sufficient to prevent unauthorized access to the systems. No higher risk alternatives were considered.

II. Comment Procedures:

As provided by section 3(e)(11) of the Privacy Act of 1974 (5 U.S.C. 552a(e)(11)), interested persons are invited to submit written data, views, or arguments related to these proposals to Public Hearing Management, Department of Energy, Box SW, 2000 M Street, Room 2313, Washington, D.C. 20461. Hand carried comments may be delivered to that same office between the hours of 8 a.m. to 4:30 p.m., Monday through Friday, except on legal public holidays.

Comments should be identified on the outside of the envelope and on the documents submitted to DOE with the designation "FEA-23, Privacy Act System of Records". Fifteen copies should be submitted. All comments received on or before August 28, 1978, will be available for public inspection in the DOE Reading Room, Room 2107, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except on legal public holidays. These comments and all other relevant information will be considered by DOE before the amended system is adopted in its final form.

Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The DOE reserves the right to determine the confidential status of the information or data and to treat it according to that determination.

It is the intent of DOE to operate the amended system of records as proposed at the expiration of the comment period if no comments to the contrary are received.

The DOE has determined that this document does not contain a proposal requiring preparation of a regulatory analysis under Executive Order 12044.

(Privacy Act of 1974, Pub. L. 93-579; Department of Energy Organization Act, Pub. L. 95-91; Executive Order 12009, 42 FR 46267; Federal Energy Administration Act of 1974, Pub. L. 93-275, as amended; Executive Order 11790, 39 FR 23185.)

In consideration of the foregoing, the amendments to FEA-23 as described above are proposed. An amended system description incorporating the proposed amendments is set forth below.

Issued in Washington, D.C., July 25, 1978.

WILLIAM P. DAVIS,
Deputy Director of Administration.

FEA-23

System name:

Telephone numbers and addresses of DOE officials and support staff.

Security classification:

Unclassified.

System location:

Office of the Secretary, Department of Energy, Forrestal Building, Washington, D.C. 20585.

Categories of individuals covered by the system:

DOE senior staff officials and support staff.

Categories of records in the system:

Name, home telephone number, and home address.

Authority for maintenance of the system:

5 U.S.C. 301; Federal Energy Administration Act of 1974; Executive Order 11790; Department of Energy Organization Act; Executive Order 12009.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

The records are available only to DOE staff within the office of the Secretary and the energy policy staff within the Executive Office of the President. Telephone numbers will be given out on an individual basis from the list to those DOE officials or energy policy staff with a demonstrated need for the information in the course of their duties.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

Paper records.

Retrievability:

Name of DOE official or support staff.

Safeguards:

Records are located in lockable drawers in secured rooms with access limited to those whose official duties require access.

Retention and disposal:

Records are revised when appropriate, at which point the older records are destroyed.

System manager and address:

Director, Office of the Secretary, Department of Energy, Forrestal Building, Washington, D.C. 20585.

Notification procedure:

Requests by an individual to determine if a system of records contains information about him should be directed to the Privacy Act Officer, Department of Energy, Washington, D.C. 20461, in accordance with DOE's Privacy Act Regulations

Record access procedures:

Requests by an individual for access to a system of records that contains information about him should be directed to the Privacy Act Officer, Department of Energy, Washington, D.C. 20461, in accordance with DOE's Privacy Act Regulations (10 CFR 206.3, 40 FR 45610 (October 2, 1976)).

Contesting record procedures:

Requests by an individual to correct or amend the content of a record containing information about him should be directed to the Privacy Act Officer, Department of Energy, Washington, D.C. 20461, in accordance with Privacy Act Regulations (10 CFR 206.7, 40 FR 45613 (October 2, 1975)).

Record source categories:

The subject individuals.

System exempted from certain provisions of the act:

None.

[FR Doc. 78-20881 Filed 7-27-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 910-6]

IDENTIFICATION OF CONVENTIONAL POLLUTANTS

Publication

Notice is hereby given that the Environmental Protection Agency is publishing on this date a list of four conventional pollutants in accordance with subsection 304(a)(4) of the Clean Water Act, 33 U.S.C. 1251 et seq. These four pollutants are required to be listed by the act and are therefore published as a final list. Three additional pollutants are proposed today as conventional pollutants and public comment is invited.

Pursuant to section 304(a)(4) of the act, the Administrator is required within 90 days to publish information identifying conventional pollutants including but not limited to, pollutants classified as biological oxygen demanding, suspended solids, fecal coliform bacteria and pH. The thermal component of any discharge is not to be identified as a conventional pollutant under section 304(a)(4).

For conventional pollutants, the applicable technology-based limitations for point sources are defined on the basis of the "best conventional pollution control technology" (BCT) pursuant to section 304(b)(4)(B) and section 301(b)(2)(E) of the act, and section 301(b)(2)(E) provides that such limitations must be achieved not later than July 1, 1984. The reasonableness assessment required under section 304(b)(4)(B) of the act for the determination of BCT may, in some cases, result in effluent limitations less stringent than those established based upon "best available technology economically achievable." However, in no case shall BCT limitations be less stringent than those based on "best practicable technology currently available."

The act and its legislative history state that the economic and water quality waivers provided in sections 301(c) and 301(g) will not be available for BCT limitations. It should be stressed that loss of these waivers by addition of a pollutant to the conventional pollutant list will result in limitation of the Agency's authority to provide a permittee with effluent limitations less stringent than BCT based on a case-by-case evaluation of economic or water quality concerns. Thus establishment of BCT may result in some cases in the imposition of effluent limitations which are more stringent than necessary for protection of local water quality. Since BCT will always be equal to or less stringent than BAT, BCT may be less protective of water quality. Such cases would result in a greater reliance on water quality standards.

Criteria Considered and Accepted

Because the act is silent on the definition of conventional pollutants, the Agency was allowed a great deal of discretion in determining criteria factors. However, the Agency tried to determine the act's intent and used the act and the legislative history as a guide to establishing criteria which were used in the selection of conventional pollutants. Based on these considerations the Agency has identified three classes of substances which may contain conventional pollutants: oxygen demanding substances, solids and nutrients.

The overriding consideration in the Agency's selection process is the environmental effects of classes of pollutants. The legislative history indicates that conventional pollutants are generally those pollutants which are naturally occurring, biodegradable, oxygen demanding materials, and solids and which have similar characteristics to naturally occurring biodegradable substances. This criterion is supported by Congress' designation of BOD and TSS as conventional pollutants. These classes of pollutants impact water quality and aquatic life and therefore are an appropriate criterion to be used in the selection of conventional pollutants.

The second criterion the Agency established concerned those classes of pollutants that traditionally have been the primary focus of wastewater control. This criterion is supported in the act's designation of pH and fecal coliform as conventional pollutants, neither of which is oxygen demanding or a solid. The Agency believes this is an appropriate criterion and is in keeping with the intent of the act.

Using these criteria, three classes of conventional pollutants have been identified: oxygen demanding substances, solids, and nutrients.

Criteria Considered and Rejected

There were two other criteria that were considered in the selection process, but ultimately rejected.

First, although the cost and level of reduction of conventional pollutants from the discharge of publicly owned treatment works (POTW) is one factor used to establish the "reasonableness" of BCT limitations, the Agency concluded that this does not require that a pollutant be regulated at secondary treatment levels in POTW in order to be identified as conventional.

Although most of the pollutants that Congress specified are treated by the secondary treatment, this is not true for every pollutant. For example, fecal coliform was included by Congress although EPA does not require the control of fecal coliform as part of secondary treatment standards. Additionally, there is not necessarily a direct link between secondary treatment levels and environmental impacts, thus the criterion is inappropriate.

Further, the concept of secondary treatment is nowhere identified by Congress as a requirement in defining this reasonableness test. If a pollutant is normally treated beyond secondary treatment by POTW, the Agency can use those costs and effluent reduction benefits as the basis of comparison for establishing BCT limitations.

If the three pollutants that EPA is proposing to add to the conventional pollutant list, phosphorus is the only pollutant which is not commonly treated by secondary treatment technology. It should be emphasized that in determining the "reasonableness" of BCT limitations for phosphorus, the Agency intends to use POTW tertiary control costs and reduction as the basis for comparison to industrial point source dischargers of phosphorus, while for BOD and TSS, secondary treatment costs and reductions will be the basis for comparison.

Finally, although the act specifies that one factor in determining BCT limitations is the cost and effluent reductions of conventional pollutants at POTW; it does not prohibit the Agency from using other tests to determine the reasonableness of BCT limitations. Thus, if a pollutant is not commonly treated by POTW technology but would otherwise meet the criteria for a conventional pollutant, it may be designated as a conventional pollutant. The Agency believes that the treatability of a conventional pollutant by a POTW should not be a factor in the selection of conventional pollutants.

The second criterion that the Agency considered and rejected was that the conventional pollutants are those not identified as toxic. Although the legislative history indicates that conventional pollutants are not toxic, the Agency does not interpret this to mean that because pollutants have toxic properties that they are precluded from being on the conventional pollutant list. If a pollutant meets the criteria for conventional pollutants and incidentally is toxic, the Agency believes that it has the flexibility to weigh the pollutant's toxic properties against its conventional properties and assign the pollutants to the list (conventional pollutant list or toxic list) which the Agency deems more appropriate.

The major impact of assigning a pollutant to the conventional list rather than the toxic list is that the BCT limitations for conventional pollutants must meet the added test of reasonableness, while the limitation for a toxic pollutant must meet BAT. Therefore, the control of a conventional may be less than that of a toxic.

Because the selection criteria are the major factors in the choice of conventional pollutants, other than those mandated by the act, the Agency encouraes interested parties to comment on these and other criteria and their appropriateness in selecting conventional pollutants. It must be emphasized that these criteria are the essential elements in the selection process. Public comments should emphasize the appropriateness of the criteria as well as the appropriateness of a candidate pollutant.

Conventional Pollutant List

The act identifies four pollution parameters as conventional:

Biochemical oxygen demand (BOD) is a standardized laboratory test which is a measure of the quantity of dissolved oxygen used in the biochemical oxidation of organic matter in a specified time, at a specified temperature, and under other specified conditions. The test is a measure used to determine waste loadings to wastewater treatment plants and to evaluate the efficiency of such treatment systems.

Total suspended solids (TSS) (nonfilterable residue) is a laboratory measure of the organic and inorganic particulate matter in wastewater which does not pass through a specified glass filter disk. The test does not differentiate specific types or sources of suspended solids. TSS is also used as a parameter in characterizing wastewaters and in determining the efficiency of wastewater treatment works.

Fecal coliform bacteria are measured to identify the bacteria which are normally present in the intestinal tract of warm-blooded animals including humans and are recognized universally as indicators of sanitary water quality. Fecal coliform bacteria are conventionally held to indicate the potential presence of pathogenic intestinal organisms.

The term pH is a designation for the negative logarithm of the hydrogen ion concentration in water and is a measure of acidity and alkalinity achieved by various dissolved compounds, salts and gases. It is an important factor in chemically characterizing water systems since changes in pH affect the degree of dissociation of weak acids or bases. This in turn affects the toxicity and solubility of many compounds including metals and metallic salts. Biological systems are affected by the pH of the water. pH is widely recognized as a necessary measurement in the control of chemical and biological wastewater treatment systems.

Section 304(a)(4) authorizes the Administrator to specify conventional pollutants in addition to the four parameters identified as conventional by the act, and the Agency is now proposing chemical oxygen demand (COD), phosphorus, and oil and grease as candidates for designation as conventional pollutants.

Chemical oxygen demand (COD) is a standard test typically used to characterize certain industrial waste loads and for control of wastewater treatment works. This determination provides a measure of the carbonaceous portion of the organic matter present that is susceptible to oxidation by a strong chemical oxident such as potassium dichromate. Thus, like BOD, COD is a measure of an oxygen demanding fraction in wastewater streams. However, with certain waste containing chemical substances, COD provides a means of determining the organic demand for oxygen where BOD may not provide such data.

Phosphorus also is a pollutant which traditionally has been of concern in wastewater control and treatment. It is a nutrient and the growth enhancing properties of phosphorus on aquatic plants and the resultant environmental degradation are well recognized. Phosphorus is regarded as a controlling factor in accelerating nuisance aquatic plant growths and eutrophication, particularly in fresh water. Phosphorus means total phosphorus as defined at 40 CFR 136.

Oil and grease is defined by the measurement method used. The method measures groups of oils of petroleum, animal and vegetable origin having similar physical characteristics based upon their mutual solubility in the organic solvent used (trichloro- trifluoroethane). It is common practice to install oil and grease removal equipment for by-product recovery purposes or to prevent disruption of subsequent wastewater treatment. Substances found in this group of pollutants also represent oxygen demanding material and are of concern in wastewater treatment.

Concentrations of BOD, COD, TSS, and oil and grease may in some cases reflect the pollutional load of toxic pollutants in a wastewater. Where available data support this relationship, it is the Agency's intent that it may specify one or more of these parameters as an indicator of a toxic pollutant. Effluent limitations for such indicators of toxic pollutants will be established pursuant to the provisions of best available treatment technology, pretreatment, new source performance standards, and best management practices of the act. When a conventional pollutant is used as an indicator for a toxic pollutant or for a group of toxic pollutants in effluent limitations, such conventional pollutant will be treated as a toxic pollutant for purposes of effluent limitation.

In high concentrations some conventional pollutants may adversely affect the biological treatment process in publicly owned wastewater treatment plants. Thus, there is no intent to supersede any local ordinances for control of any of these conventional pollutants through pretreatment requirements.

In summary, the pollutants and measurements of pollutants listed and proposed today as conventional pollutants include:

LIST OF CONVENTIONAL POLLUTANTS

biochemical oxygen demand (BOD);
total suspended solids (nonfilterable) (TSS);
fecal coliform bacteria;
pH (hydrogen ion);

PROPOSED ADDITIONS TO THE LIST OF CONVENTIONAL POLLUTANTS

chemical oxygen demand (COD);
phosphorus;
oil and grease.

Comments on the proposed list of conventional pollutants are invited and all comments received on or before September 26, 1978, will be considered in developing a final notice identifying conventional pollutants. Suggestions for additions or deletions to this list accompanied by a rationale should be directed to Mr. Kenneth M. Mackenthun, Director, Criteria and Standards Division (WH-585), 401 M Street SW., Washington, D.C. 20460, 202-755-0100.

Dated: July 21, 1978.

BARBARA BLUM,
Acting Administrator.

[FR Doc. 78-20850 Filed 7-27-78; 8:45 am]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

[BC Docket Nos. 78-37, 78-38; File Nos. BPH-9,964; BPH-10,048]

KALTRIM BROADCASTING CO. AND PENINSULA BROADCASTING, INC.

Memorandum Opinion and Order Designating Applications for Consolidated Hearing on Stated Issues

Adopted: July 6, 1978.

Released: July 25, 1978.

In re Applications of: Kaltrim Broadcasting Co., Kalkaska, Mich., BC Docket No. 78-37; File No. BPH-9,964; Requests: 97.7 MHz, Channel No. 249A, 3 kW (H&V), 300 feet (H&V) Peninsula Broadcasting, Inc., Kalksaska, Mich., BC Docket No. 78-38, File No. BPH-10,048; Requests: 97.7 MHz, Channel No. 249A, 1 kW (H&V), 500 feet (H&V) for construction permits.

By the Chief, Broadcast Bureau:

1. The Commission, by the Chief, Broadcast Bureau, acting pursuant to delegated authority, has before it the above-captioned applications of Kaltrim Broadcasting Co. (hereinafter "Kaltrim") and Peninsula Broadcasting, Inc. (hereinafter "Peninsula"), which are mutually exclusive in that they seek the same FM broadcast channel in Kalkaska, Mich.[1]

2. Analysis of Kaltrim's financial data reveals that $64,328[2] will be required to construct the proposed facility and operate for one year, without revenue, itemized as follows:

Down payment on equipment	$3,234
Lease payments on equipment (including interest)	9,494
Building	3,600
Miscellaneous	2,000
Working capital (first year)	46,000
Total	64,328

To attempt to meet this requirement, Kaltrim relies upon a stockholder loan of $55,000 from George E. Benko. However, the loan commitment does not state the rate of interest, the collateral required, if any, or the terms of repayment as required by section III, Paragraph 4(a) of the application. Therefore, the Commission is unable to find that the proposed loan is available. Moreover, Mr. Benko's balance sheet submitted in support of his ability to honor the loan commitment is more than one year old. Without a current balance sheet, we are unable to determine whether Mr. Benko has the financial ability to comply with loan agreement.[3] Accordingly, since Kaltrim has not shown any funds available, a financial issue will be specified.

3. Kaltrim has failed to comply with the Commission's Primer on Ascertainment of Community Problems by Broadcast Applicants, 27 FCC 2d 650, 21 RR 2d 1501 (1971). Question and Answer 9 of the Primer requires that applicants show that they have determined the composition of their communities by submitting "such data as is necessary to indicate the minority, racial, or ethnic breakdown of the community, its economic activities, governmental activities, public service organizations, and any other factors or activities that make the particular community distinctive." Kaltrim has failed to provide information relating to Kalkaska's public service organizations. Evaluation of the applicant's list of community leaders in light of the demographic information submitted shows that not all signifcant groups have been consulted. *Voice of Dixie, Inc.*, 45 FCC 2d 1027, 29 RR 2d 1124 (1974). For example, Kaltrim's list of community leaders contacted includes no identifiable leaders of industry, labor, recreation, public service organizations, the elderly, and the professions. Furthermore, the applicant has not provided a sufficient description of the methodology it employed in its sample of the general public for the Commission to determine whether genuinely random sample was achieved, in compliance with Question and Answer 13(b) of the Primer. An ascertainment issue will therefore be specified.

4. Analysis of Peninsula's financial data reveals that it will require, $76,650 to construct its proposed facility and operate for 1 year, without revenue, itemized as follows:

Equipment	$29,650
Building	1,500
Miscellaneous	6,000
Working capital (first year)	39,500
Total	76,650

To meet this requirement, Peninsula plans to rely on $10,000 in stock subscriptions and $80,000 in loans from two of its principals, Roy Henderson and Roger Watson.[4] Peninsula has not satisfactorily established the availability of the proposed commitment from Roy Henderson. Mr. Henderson relies on two bank loans from the Cadillac State Bank to support his $40,000 commitment. Since the bank commitment letter has expired, the Commission is unable to find these funds available. Moreover, the Commission notes that while the Cadillac State Bank commitment letter requires Mrs. Henderson's cosignature for the loans and contemplates the pledge of certain assets of the corporate applicant and its stockholders, no indication of Mrs. Henderson's agreement to co-sign the note or of any agreement to the collateralization requirements have been presented. Since Peninsula has, therefore, shown the availability of only $50,000 to meet a $76,650 requirement, a financial issue will be specified.

5. Peninsula proposes independent programing, while Kaltrim, should its pending AM application be granted, proposes to duplicate the programing of that station during 62 percent of its broadcast time. Therefore, evidence regarding program duplication will be admissible under the standard comparative issue in the event that the AM application is granted before the hearing in this proceeding has been terminated. When duplicated programing is proposed, the showing per-

[1] Kaltrim also has pending before the Commission an application for a construction permit for a new commercial AM station in Kalkaska, Mich. (file No. BP-20,329).

[2] Kaltrim's financial proposal states, in part, that the FM station will utilize the proposed AM station's program origination equipment. However, no amount has been specified in the FM application for this cost. Since this application is being processed prior to the AM application, the cost of this equipment has been included in our calculation of Kaltrim's first year costs. Moreover, the first year operating costs for the proposed AM station have been added to the FM operating cost estimate in light of Kaltrim's intention to duplicate all of the programming of its proposed AM station.

[3] Mr. Benko's balance sheet suffers from a further infirmity for Mr. Benko proposes to loan $25,000 to Gladwin Broadcasting Co. for the construction and operation of an FM station in Gladwin, Mich. However, his balance sheet fails to reflect this current liability.

[4] Each stockholder has subscribed to $5,000 of stock. Furthermore, Roy Henderson and Roger Watson have committed to loan the applicant $35,000 and $45,000, respectively.

mitted under the standard comparative issue will be limited to evidence concerning the benefits to be derived from the proposed duplication which would offset its inherent inefficiency. *Jones T. Sudbury,* 8 FCC 2d 360, 10 RR 114 (1967).

6. Data submitted by the applicants indicates that there would be a significant difference in the size of the areas and populations which would receive service from the proposals. Consequently, for the purposes of comparison, the areas and populations which would receive FM service of 1 mV/m or greater intensity, together with the availability of other primary aural services in such areas will be considered under the standard comparative issue, for the purpose of determining whether a comparative preference should accrue to either of the applicants.

7. Except as indicated by the issues specified below, the applicants are qualified to construct and operate as proposed. However, because the proposals are mutually exclusive, they must be designated for hearing in a consolidated proceeding on the issues specified below.

8. *It is ordered,* That, pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, at a time and place to be specified in a subsequent order, upon the following issues:

1. To determine whether Kaltrim Broadcasting Co. is financially qualified to construct and operate its proposed station.

To determine the efforts made by Kaltrim Bradcasting Co. to ascertain the community needs and interests of the area to be served and the means by which the applicant proposes to meet those needs and interests.

3. To determine with respect to the application of Peninsula Broadcasting, Inc.:

(a) The availability of additional funds in excess of the $50,000 indicated; and

(b) Whether, in light of the evidence adduced pursuant to (a) above, the applicant is financially qualified to construct and operate as proposed.

4. To determine which of the proposals would, on a comparative basis, better serve the public interest.

5. To determine in light of the evidence adduced pursuant to the foregoing issues, which, if either, of the applications for a construction permit should be granted.

9 *It is further ordered,* That no avail themselves of the opportunity to be heard, the applicants, pursuant to § 1.221(c) of the Commission's rules, in person or by attorney shall, within 20 days of the mailing of this order, file with the Commission in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this order.

10. *It is further ordered,* That the applicants herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 1.594 of the Commission's rules, give notice of the hearing, either individually or, if feasible and consistent with the rules, jointly, within the time and in the manner prescribed in such rule, and shall advise the Commission of the publication of such notice as required by section 1.594(g) of the rules.

FEDERAL COMMUNICATIONS COMMISSION,
WALLACE E. JOHNSON,
Chief, Broadcast Bureau.

[FR Doc. 78-20846 Filed 7-27-78; 8:45 am]

[6712-01]

TV BROADCAST APPLICATIONS READY AND AVAILABLE FOR PROCESSING

Adopted: July 17, 1978.

Released: July 21, 1978.

By the Chief, Broadcast Facilities Division.

Notice is hereby given, pursuant to § 1.572(c) of the Commission's rules, that on September 8, 1978, the TV broadcast applications listed in the attached appendix will be considered as ready and available for processing. Pursuant to § 1.227(b)(1) and § 1.591(b) of the Commission's rules, an application in order to be considered with any application appearing on the attached list or with any other application on file by the close of business on September 7, 1978, which involves a conflict necessitating a hearing with any application on this list, must be substantially complete and tendered for filing at the offices of the Commission in Washington, D.C., by the close of business on September 7, 1978.

The attention of any party in interest desiring to file pleadings concerning any pending TV broadcast application, pursuant to section 309(d)(1) of the Communication's Act of 1934, as amended, is directed to § 1.580(i) of the Commission's rules for provisions governing the time for filing and other requirements relating to such pleadings.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

BPCT-5171 (new), Tulsa, Okla., Oklahoma City Broadcasting Co. Channel 23. ERP. Vis. 2838 kW, HAAT: 1,480 ft.

BPCT-5172 (new), Tulsa, Okla., Western Area Bureau of Information Broadcasting Division, Channel 41. ERP. Vis. 2100 kW, HAAT: 291 ft.

BPCT-5173 (new), Galveston, Tex., The Old Time Religion Hour, Inc. (The O.T.R.H., Inc.) Channel 48. ERP. Vis. 2500 kW, HATT: 1,151 ft.

BPCT-5175 WTVX-TV, Ft. Pierce, Fla., Indian River Television, Inc. Channel 34. Change ERP. to Vis. 2846 kW, HAAT: 1,486 ft.; change transmitter location.

BPCT-5176 (new), Newark, Ohio., Christian Television of Ohio, Inc. Channel 52. ERP. Vis. 21.5 kW, HAAT: 395 ft.; request waiver of § 73.610 of the Commission's rules.

BPCT-5179 (new), Tulsa, Okla., David Livingstone Missionary Foundation. Channel 47. ERP. Vis. 344 kW, HAAT: 638 ft.

BPCT-5183 (new), Hardin, Mont., KOUS TV, Inc. Channel 4. ERP. Vis. 91.45 kW, HAAT: 1,062 ft.

BPCT-5185 (new), West Chicago, Ill., Lago Grande Television Co. Channel 60. ERP. Vis. 2390 kW, HAAT: 1,460 ft.

BPCT-5199 (new), Miami, Fla., Contemporary Television Broadcasting, Inc. Channel 39. ERP. Vis. 2858 kW, HAAT: 649 ft.; request for waiver of § 73.610(d) of the Commission's rules.

BPET-610 (new), Bismarck, N. Dak., Prairie Public Television, Inc. Channel *3. ERP. Vis. 100 kW, HAAT: 1,393 ft.

BPET-611 (new), Minot, N. Dak., Prairie Public Television, Inc. Channel *6. ERP. Vis. 100 kW, HAAT: 1,111 ft.

Application deleted from public notice released May 26, 1978, mimeo No. 1196, 43 FR 24132.

BPET-600 (WNJB-TV), New Brunswick, N.J., New Jersey Public Broadcasting Authority. Channel *58. Change transmitter location; change ERP. Vis. 3040.9 kW, HAAT: 1,410.3 ft.; and request for waiver of § 73.610(d) of the Commission's rules.

[FR Doc. 78-20848 Filed 7-27-78; 8:45 am]

[6210-01]

FEDERAL RESERVE SYSTEM

GUARANTY CORPORATION

Formation of Bank Holding Co.

Guaranty Corporation, Denver, Colorado, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of Guaranty Bank & Trust Company, Denver, Colorado. The factors that are considered in acting on the application are set forth in § 3(c) of the act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than August 15, 1978.

Board of Governors of the Federal Reserve System, July 25, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-20897 Filed 7-27-78; 8:45 am]

[4110-89]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Assistant Secretary for Information

COMMENTS ON COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY

Pursuant to Section 406(g)(2)(B), General Education Provisions Act, notice is hereby given as follows:

The U.S. Office of Education has proposed collections of information and data acquisition activities which will request information from educational agencies or institutions.

The purpose of publishing this notice in the FEDERAL REGISTER is to comply with paragraph (g)(2)(B) of the "Control of Paperwork" amendment which provides that each educational agency or institution subject to a request under the collection of information and data acquisition activity and their representative organizations shall have an opportunity, during a 30-day period before the transmittal of the request to the Director of the Office of Management and Budget, to comment to the Administrator of the National Center for Education Statistics on the collection of information and data acquisition activity.

These data acquisition activities are subject to review by the HEW Education Data Acquisition Council and the Office of Management and Budget.

Descriptions of the proposed collections of information and data acquisition activities follow below.

Written comments on the proposed activities are invited. Comments should refer to the specific sponsoring agency and form number and must be received on or before August 28, 1978 and should be addressed to Administrator, National Center for Education Statistics, ATTN: Manager, Information Acquisition, Planning, and Utilization, Room 3001, 400 Maryland Avenue SW., Washington, D.C. 20202.

Further information may be obtained from Elizabeth M. Proctor of the National Center for Education Statistics, 202-245-1022.

MARIE D. ELDRIDGE,
Administrator, National Center for Education Statistics.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY

1. TITLE OF PROPOSED ACTIVITY

Program Financial Status Report and Performance Reports for the Emergency School Aid Act and Title IV of the Civil Rights Act of 1964.

2. AGENCY/BUREAU/OFFICE

U.S. Office of Education, Bureau of Elementary and Secondary Education, Equal Educational Opportunity Programs.

3. AGENCY FORM NUMBER

OE Forms 257, 116-2, -2-1, -2-2.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY

"(16) provides (A) that the applicant will make periodic reports at such time, in such form, and containing such information as the Assistant Secretary may require by regulation, which regulation may require at least—

(i) In the case of reports relating to performance, that the reports be consistent with specific criteria related to the program objectives, and

(ii) That the reports include information relating to educational achievement of children in the schools of the applicant, and (B) that the applicant will keep such records and afford such access thereto as—

(i) Will be necessary to assure the correctness of such reports and to verify them, and

(ii) Will be necessary to assure the public adequate access to such reports and other written materials.

(b) No application under this section may be approved which is not accompanied by the written comments of a committee established pursuant to clause (2)(B) of subsection (a). The Assistant Secretary shall not approve an application without first affording the committee an opportunity for an informal hearing if the committee requests such a hearing. (Pub. L. 92-318, section 710(a)(16) and section 710(b)); (20 U.S.C. 1609(a)(16) and 1609(b)); (45 CFR 185.13(k)). (Office of Education General Provisions for Programs, 45 CFR Part 100a, Subparts P, Q, and R.)

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSES REQUIRED

Required of grantees.

6. HOW INFORMATION TO BE COLLECTED WILL BE USED

Performance reports (OE 257, OE 116-2, -2-1, -2-2)—information will be used to measure the effectiveness of programs in meeting the objectives.

Financial status report (SF 269)—information will be used to determine the amount of unspent funds that must be returned to the U.S. Treasurer.

7. DATA ACQUISITION PLAN

a. Method of collection: Mail.

b. Time of collection:

Program Progress Report, OE 257: 180 days after beginning of the budget period.

Financial Status Report, SF 269: Within 90 days after completion of the grant.

Districtwide Advisory Committee Report, OE 116-2-1: Within 90 days after completion of the grant.

Student Advisory Committee Report, OE 116-2-2: Within 90 days after completion of the grant.

Frequency: Annually.

8. RESPONDENTS

a. Type: Local educational agencies, institutions of higher education, other public agencies and organizations, and private nonprofit organizations.

b. Number:

Program Progress Report: 1344.

Financial Status Report: 1344.

Districtwide Advisory Committee Report: 935.

Student Advisory Committee Report: 1150.

c. Estimated average man-hours per respondent:

Program Progress Report: 12 hours.

Financial Status Report: 2 hours.

Districtwide Advisory Committee Report: ½ hour.

Student Advisory Committee Report: ½ hour.

9. INFORMATION TO BE COLLECTED

Program Progress Report: The grantee shall provide for each type of project a list of major events and for each event, provide the planned and actual starting and completion dates, a brief description of actual accomplishments, and the difference between proposed and actual accomplishments (where applicable).

Financial Status Report: Provide financial data for each program, function, and activity in the approved budget. Provide the total Federal and non-Federal gross outlays, the total Federal and non-Federal unliquidated obligations, the total cumulative amount of Federal funds authorized and the unobligated balance of Federal funds.

Districtwide Advisory Committee Report: The chairperson of the committee shall provide information about the frequency of committee meetings and visits to the program, the opportunity to make recommendations to school officials, frequency with which recommendations were carried out, and a description of any advisory committee activity that made a significant contribution to the success of the program.

Student Advisory Committee Final Report: The chairperson of the committee shall provide information about the frequency of committee meetings, the opportunity to make recommendations to school officials, the frequency with which recommendations were carried out, and a description of any advisory committee activity that made a significant contribution to the success of the program. Also, the chairperson is requested to indicate participation in a list of activities suggested in the ESAA Student Advisory Committee Handbook and to rate the success of those activities.

Description of a Proposed Collection of Information and Data Acquisition Activity

1. TITLE OF PROPOSED ACTIVITY

National direct student loan program semi-annual default loan report.

2. AGENCY/BUREAU/OFFICE

U.S. Office of Education/Bureau of Student Financial Assistance/Division of Program Operations.

3. AGENCY FORM NUMBER

OE form 574.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY

Section 463. (a) "An agreement with any institution of higher education for the payment of Federal capital contributions under this part shall: Provide that where a note or written agreement evidencing a note has been in default for (A) one hundred and twenty days, in the case of a loan which is repayable in monthly installments, or (B) one hundred and eighty days, in the case of a loan which is repayable in less frequent installments, notice of such default shall be given to the Commissioner in a report describing the total number of loans from

such fund which are in such default, and made to the Commissioner at least semi-annually."

(Pub. L. 92-318, Sec. 137(b), 20 U.S.C. 1087cc, as amended under Sec. 130(c), Pub. L. 94-482, Education Amendments of 1976.)

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSE

Required to obtain or maintain benefits.

6. HOW INFORMATION TO BE COLLECTED WILL BE USED

Program management: This report will serve to provide information about the capability of the institutions to establish and administer effective collections programs. The data will be used to determine the effectiveness of the loan activities and to determine whether the institutions are following the steps necessary in the performance of due diligence as stipulated in the regulations. It will also be used in the formula to compute delinquence percentages and potential default rates.

Evaluation: (1) Compliance with established regulations pertaining to collection practices, such as regular billing and follow-up procedures, and collection activities; (2) institutional administrative capability; (3) practices and policies established to carry out due diligence.

Research: The data collected may be used for the purposes of (1) establishing default trends in various types of institutions by repayment method; (2) analysis and studies of defaulted loans by educational organizations and OE; (3) comparison of default ratios.

Condition of education: (1) Summaries of categorical information for OE and organizations associated with the Education Community; (2) response to Congressional inquiries; (3) public dissemination.

7. DATA ACQUISITION PLAN

(a) Method of collection: Mail.
(b) Time of collection: Winter (December 31) of each year.
(c) Frequency: Annually.

8. RESPONDENTS

(a) Type: Colleges and universities—vocational/technical and proprietary institutions of postsecondary education.
(b) Number: 4,000.
(c) Estimated average man-hours per respondent: 5.

9. INFORMATION TO BE COLLECTED

(1) Number of borrowers in default status.
(2) Principal amount outstanding.
(3) Principal amount in default.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY

1. TITLE OF PROPOSED ACTIVITY

Survey of individual educational program plans.

2. AGENCY/BUREAU/OFFICE

U.S. Office of Education/Bureau of Education for the Handicapped/Division of Innovation and Development.

3. AGENCY FORM NUMBER

OE-631.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY

"* * *the Commissioner shall conduct a statistically valid survey for assessing the effectiveness of individualized education programs." Section 618, Pub. L. 94-142, 20 U.S.C. 1418.

5. VOLUNTARY OBLIGATORY NATURE OF RESPONSE

Voluntary.

6. HOW INFORMATION COLLECTED WILL BE USED

Evaluation: The Survey is one of several evaluation studies authorized under Section 618, Pub. L. 94-142. This section specifically mandates the survey, "* * * the Commissioner shall conduct a statistically valid survey for assessing the effectiveness of individualized education programs."

The primary but not only objective of all the evaluation studies is to provide information for a annual congressional report. The objective of this report is to describe who, where, and how the beneficiaries of Pub. L. 94-142 are served; what administrative mechanisms are used to provide these services; what the consequences are of the law; and the extent the intent of the law is being met.

The specific objective of the survey is to assess the effectiveness of the individualized education program by surveying the mandated program document. First, section 613 mandates that several aspects of a good plan must be included in the program document. Thus, the survey will describe the nature, prevalence, and variety of plans to serve handicapped children. Second, the survey will describe the characteristics of the children and associate these characteristics with their plans. Third, the survey will describe the characteristics of schools and associate these characteristics with the plans they have for the handicapped children they serve. And forth, the survey will discuss the adequacy of the public document to account for and communicate the program to all those interested in the education of that handicapped child.

7. DATA ACQUISITION PLAN

a. Method of collection: Site visit.
b. Time of collection: November 1978 through the end of February 1979.
c. Frequency: Biennial.

8. RESPONDENTS

a. Type: Teachers, elementary/secondary.
b. Number: 6,600.
c. Estimated average man-hours per respondent: 20 minutes.

a. Type: Principals, elementary/ secondary.
b. Number: 480.
c. Estimated average man-hours per respondent: 30 minutes.

a. Type: Superintendent of State institutions.
b. Number: 100.
c. Estimated average man-hours per respondent: 30 minutes.

9. INFORMATION TO BE COLLECTED

The teachers will be asked about the child characteristics, the nature of the plan as she/he is currently using it, and his/her involvement in the development of the plan.

The principal will be asked about the school characteristics and the nature of the program the school has for handicapped children.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY

1. TITLE OF PROPOSED ACTIVITY

Fiscal-operations report 1977-1978 award period (July 1, 1977 through June 30, 1978) and application to participate—1979-1980 award period (July 1, 1979 through June 30, 1980)—national direct student loan, supplemental educational opportunity grants, and college work-study programs.

2. AGENCY-BUREAU-OFFICE

Office of Education—Bureau of Student Financial Assistance—Division of Program Operations.

3. AGENCY FORM NUMBER

OE Form 646 (This form is a combination of the fiscal-operations report, EO form 1152-1-4, and the tripartite application, OE form 1036).

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY

A."Include such other provisions as may be necessary to protect the financial interest of the United States and promote the purposes of this part as are agreed to by the Commissioner and the institution." (Pub. L. 92-318, 20 U.S.C. 1087 cc section 137(b), CFR, section 144.18) national direct student loan program; "include such other provisions as may be necessary to protect the financial interest of the United States and promote the purposes of this subpart." (Pub. L. 92-318, 20 U.S.C 1070b-2, section 131(b), CFR section 176.23) supplemental educational opportunity grants program; "include such other provisions as the Commissioner shall deem necessary or appropriate to carry out the purposes of this part." (Pub. L. 89-329, 42 U.S.C. 2754, section 444(8), CFR section 175.29) college work-study program.

B. "Any institution of higher education desiring to receive payments of Federal capital contributions from the apportionment of the State in which it is located for any fiscal year shall make an agreement under section 463 and shall submit an application therefore to the Commissioner, in accordance with the provisions of this part. The Commissioner shall, from time to time, set dates before which such institutions must file applications under this section." (Pub. L. 92-318, Section 137(b), 20 U.S.C. 1087bb, CFR 144.5) national direct student loan program; "The Commissioner shall, from time to time, set dates before which institutions in any State must file applications for allocation, to such institution, of supplemental grant funds from the apportionment to that State for any fiscal year pursuant to subsection (a)(1)." (Pub. L. 92-318, section 131(b)(1), 20 U.S.C. 1070b-3, CFR 176.5) supplemental educational opportunity grants program; "include such other provisions as the Commissioner shall deem necessary or appropriate to carry out the purposes of this part" (Pub. L. 89-329, section 444(8), 42 U.S.C. 2754, CFR section 175.5, 6, 7) college work-study program.

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSE

Fiscal-operations portion required of all institutions which participated in the pro-

grams during 1977-1978. Application portion required only if institution wishes to participate in the programs during 1979-1980.

6. HOW INFORMATION COLLECTED WILL BE USED

Program management: The information contained in this form will be used to determine a standard measurement of relative institutional financial need which will be the basis to compute the amount of funds needed by applicant institutions to operate one or more of the campus-based programs during the 1979-1980 award period. Previous fiscal utilization and historical data, as provided by each institution, will be used as a base to determine relative need and the final institutional allocations. The data will also be used to assess program effectiveness and accountability of fund expenditures to OE under the authority previously cited. In addition, the data will be used in conjunction with institutional program reviews to assess the administrative capability of the applicant and compliance enforcement.

Evaluation: (1) Data collected will allow a standard measure of relative institutional need culminating in a level of funding for institutions requesting participation in one or more of the programs; (2) Data will also be used to develop a data base sufficiently comprehensive and reliable to drive funding formulas based on verifiable data input; (3) Expenditure data will be used to calculate past utilization of funds awarded; (4) Data regarding collection activities relating to the NDSL program will be used for the computation of institutional default rates and the identification of poorly administered operations which may require on site monitoring and additional training of institutional personnel.

Research: The data collected will be used for the purposes of (1) evaluation of the new funding process; (2) initiation of a specific procedure which will enable institutions to determine long-range disbursement needs; and (3) development of a nationwide data base to evaluate future funding alternatives.

Condition of Education: (1) Summarize and categorize information for the Office of Education and Organizations associated with the education community, (2) response to Congressional inquiry; and (3) public dissemination.

7. DATA ACQUISITION PLAN

a. Method of collection: Mail.
b. Time of collection: Fall—1978.
c. Frequency: Annually.

8. RESPONDENTS

a. Type: Colleges and universities vocational/technical and proprietary institutions of postsecondary education.
b. Number: 4,400 Universe.
c. Estimated average man-hours per respondent. 30.

9. INFORMATION TO BE COLLECTED

(a) Fiscal data regarding all programs for the period ending June 30, 1978. (1) Number of students receiving financial aid by ethnic, sex, and income categories; (2) amount spent by type of student and income categories; and (3) funds authorized and expended by program.

(b) Application data: (1) Funds needed to operate programs; (2) historical information regarding total enrollment, cost of attendance, revenues, and other sources of financial aid; (3) number of eligible students by type and income category for the 1977-1978 award period; and (4) "first time" applicant information such as number and status of students enrolled and length of course.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION

1. TITLE OF PROPOSED ACTIVITY

Evaluation of the OE criteria for the recognition of accrediting and State approval agencies.

2. AGENCY/BUREAU/OFFICE

Office of Education/Office of Planning, Budgeting, and Evaluation/Postsecondary Programs Division.

3. AGENCY FORM NUMBER

663.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY

"* * * the Secretary shall transmit to (appropriate congressional committees) an annual evaluation report which evaluates the effectiveness of applicable programs * * * such report shall * * * contain information on the progress being made * * * describe the cost and benefits of the applicable program * * * identify which sectors of the public receive the benefits of such program * *.*" (20 U.S.C. 1226C) Pub. L. 93-380, Sec. 417.

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSE

Voluntary.

6. HOW INFORMATION COLLECTED WILL BE USED

The U.S. Office of Education (USOE) is required by law to identify those accrediting and state approval agencies that are "reliable authorities as to the quality of training" offered by the institutions or programs accredited. In determining which agencies to recognize as "reliable authority", USOE examines the organization and functioning of the agencies with respect to a published list of criteria. The primary purpose of the study for which the proposed questionnaires have been designed is to evaluate the criteria and procedures followed by USOE in relation to its congressional charge.

The major concerns of the study are for the reliability and validity of the recognition process. The following purposes are directed to those two concerns and to recommendations for modifying the process. The proposed questionnaires are related to the first four of the following six purposes.

1. Assess the validity of the procedures and criteria used to recognize accrediting and state approval agencies, or the observable basis for the inferences drawn from them.

2. Assess the reliability, or the absence of error, in the application of the recognition process.

3. Assess the impact of the recognition process on the functions and procedures of the accrediting and state approval agencies.

4. Suggest modifications for the recognition process that will provide for:

a. Weights to be assigned to the different criteria in arriving at a recognition decision;

b. Periodic review of the procedures, criteria, and their weights.

5. Review, through an examination of appropriate documents and correspondence,

a. The functions and responsibilities of the private accrediting associations, State agencies, and USOE;

b. The history of the recognition process and the development of the present set of criteria.

6. Assess the relationships between the present procedures and criteria.

7. DATA ACQUISITION PLAN

a. Method of collection: Mail.
b. Time of collection: October 15, 1978 to November 30, 1978.
c. Frequency: One-time. ge

8. RESPONDENTS

a. Type: Heads of accrediting and State approval agencies for postsecondary education.
b. Number: 100 (Universe).
c. Estimated average man-hours per respondent: 2 hours.

a. Type: Chairpersons of accrediting agencies or commissions.
b. Number: 100 (Universe).
c. Estimated average man-hours per respondent: One-half hour.

a. Type: State education agencies (members of licensing agencies, coordinating boards for postsecondary education, State boards of education, directors of vocational education, State directors of student financial aid, legislators and aids).
b. Number: 50 (total).
c. Estimated average man-hours per respondent: 2 hours.

a. Type: Federal agency and congressional staff members.
b. Number: 50.
c. Estimated average man-hours per respondent: 2 hours.

a. Type: College and university faculty members who have been involved with the accrediting or State approval process.
b. Number: 50.
c. Estimated average man-hours per respondent: 2 hours.

a. Type: Experts on accreditation (not presently directly involved with accreditation).
b. Number: 25.
c. Estimated average man-hours per respondent: 2 hours.

a. Type: Critics of accreditation.
b. Number: 25.
c. Estimated average man-hours per respondent: 2 hours.

9. INFORMATION TO BE COLLECTED

Heads of accrediting and State approval agencies for postsecondary education:

Evidence on the reliability and validity of the OE recognition process.

Evidence on the accessibility to observation of the OE recognition criteria.

Changes in accrediting or approval practices over the past ten years; when such changes occurred; was the change

attributable to the recognition process or independent of it.

Suggestions for modification of the recognition process: extent of agreement within the accreditation community on about 50 suggested changes in the recognition process.

Expert judges of accreditation (State agencies and legislators, Federal agency and congressional staff members, postsecondary school administrators and faculty members, independent experts and critics of accreditation):

Comparative importance of accrediting agency characteristics.

Evidence on the reliability and validity of the OE recognition process.

Chairpersons of accrediting agency commissions or boards:

Evidence on the reliability and validity of the OE recognition process.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY

1. TITLE OF PROPOSED ACTIVITY

Institutional release of funds/request for additional funds under the supplemental educational opportunity grants and/or college work-study programs.

2. AGENCY/BUREAU/OFFICE

Office of Education/Bureau of Student Financial Assistance/Division of Program Operations.

3. AGENCY FORM NUMBER

OE form 1286.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY

The supplemental educational opportunity grants statue states that, "funds allocated to an institution for initial grants which the institution anticipates will not be used by the end of the period for which such funds were made available may be reallocated on an equitable basis to other institutions in that State." Pub. L 95-205 (20 U.S.C. 10706-3), CFR section 176.4(b).

"Provided further, that funds contained herein for work-study grants shall remain available through September 30, 1979 * * *" Pub. L. 95-26 (42 U.S.C. 2756), CFR section 175.4(b).

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSE

Required to obtain benefit.

6. HOW INFORMATION COLLECTED WILL BE USED

The information will be used to identify those institutions that are unable to utilize all of their Federal funds in either the supplemental educational opportunity grants and/or college work-study programs during the award period, and the amounts, if any, that they are willing to release. The information will also be used to identify those institutions with additional need for funds in either or both programs.

7. DATA ACQUISITION PLAN

a. Method of collection: Mail.
b. Time of collection: Fall.
c. Frequency: Annually.

8. RESPONDENTS

a. Type: Institutions of higher education.
b. Number: Estimated 2,500.
c. Estimated average man-hours per respondent: 5.

9. INFORMATION TO BE COLLECTED

The amount of Federal funds to be released, for the supplemental educational opportunity grants and/or college work-study programs. The amount of additional Federal funds requested for the SEOG and/or CWS programs.

[FR Doc. 78-20893 Filed 7-27-78; 8:45 am]

[4110-02]

Office of Education

NATIONAL ADVISORY COUNCIL FOR CAREER EDUCATION

Meeting

AGENCY: Office of Education, National Advisory Council for Career Education.

ACTION: Notice..

SUMMARY: This notice sets forth the schedule and proposed agenda of forth coming meeting of the National Advisory Council for Career Education. It also describes the functions of the Council. Notice of the meeting is required pursuant to Section 10 (a) (2) of the Federal Advisory Committee Act (Pub. L. 92-463.) This document is intended to notify the general public of their opportunity to attend.

DATE: August 28, 1978.

ADDRESS: Room 300, FOB No. 6, 400 Maryland Avenue, SW., Washington, D.C.20202.

FOR FURTHER INFORMATION CONTACT:

Dr. Joseph Scherer, Office of Education, Office of Career Education, Seventh and D Streets SW., Room 3100, FOB No. 3, Washington, D.C. 20202, 202-245-2547.

The National Advisory Council for Career Education is established under section 406 of the Education Amendments of 1974, Pub. L. 93-380 (88 Stat. 552, 553.) The Council is directed to:

Advise the Commissioner of Education on the implementation of Section 406 of the Education Amendments of 1974, sections 331-336 of the Education amendments of 1976, and the Career Education Incentive Act and carry out such advisory functions as it deems appropriate, including reviewing the operation of these sections and all other programs of the Division of Education pertaining to the development and implementation of career education, evaluating their effectiveness in meeting the needs of career education throughout the United States, and in determining the need for further legislative remedy in order that all citizens may benefit from the purpose of career education as described in section 406 and in the Career Education Incentive Act.

The Council with the assistance of the Commissioner conducted a survey and assessment of the current status of career education programs, projects, curricula and meterials in the United States and submitted to Congress a report on such survery.

The Assistant Secretary shall, to the extent practicable, seek the advice and assistance of the Council concerning the lifelong learning activities authorized by section 133, Part B, Title I of the Higher Education Act of 1965, as amended.

The meeting of the Council shall be open to the public. The meeting will be held on Monday, August 28, 1978 and will begin at 9 a.m. and end at 4:30 p.m. The meeting will be held at the Federal Office Building No. 6 (FOB No. 6), located at 400 Maryland Avenue SW. (room 3000), Washington, D.C. 20202.

The proposed agenda includes:

(1) Current Issues and Collaboration in Career Education.
(2) Legislative Update.
(3) Recent Developments in Career Education.
(4) Subcommittee and Task Force Reports.
(5) New Business.

Records shall be kept of all Council proceedings and shall be available 14 days after the meeting for public inspection at the Office of Career Education located at Seventh and D Streets SW., room 3100, FOB No. 3, Washington, D.C. 20202.

Signed at Washington, D.C., on July 25, 1978.

JOHN LINDIA,
Delegate, National Advisory Council for Career Education.

[FR Doc. 78-20891 Filed 7027-78; 8:45 am]

[4110-03]

Food and Drug Administration

[Docket No. 78G-0195]

ASPEN FIBER CORP.; FIBER FOR, INC.

Petition for Affirmation of Gras Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Aspen Fiber Corp. and Fiber For, Inc., have jointly filed a petition (GRASP MF-3714) proposing affirmation that ground whole aspen and ground aspen parts used as a feedstuff for livestock are generally recognized as safe (GRAS).

DATE: Comments by September 26, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and

Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

William D. Price, Bureau of Veterinary Medicine (HFV-123), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and the regulations for affirmation of GRAS status (§ 570.35 (21 CFR 570.35)), notice is given that Aspen Fiber Corp., Box 14, Marcell, Minn. 56657, and Fiber For, Inc., R.D. No. 4, Box 207, Prior Lake, Minn. 55372, have jointly filed a petition for GRAS affirmation (GRASP MF-3714) which has been placed on public display at the Office of the Hearing Clerk. The petition proposes affirmation that ground whole aspen and ground aspen parts are GRAS as an animal feed.

The petition states that ground whole aspen is composed of the entire tree, including leaves, branches, trunk, and bark, but excluding roots and stump. Aspen parts may likewise include leaves, branches, trunk, and bark, but not in the precise ratio as in the harvested whole tree, whose parts also vary somewhat with tree age and size. Roots and stump are excluded to avoid possible contamination of dirt and rocks in the product. No processing other than that which physically changes the final particle size shall change the product. A mature harvestable aspen tree with a normal ratio of plant parts as occurring in the forest should contain no less than 0.6 percent crude protein and 2.0 percent fat, and no more than 60.0 percent fiber.

Any petition that meets the format requirements outlined in § 570.35 is filed by the Food and Drug Administration. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for affirmation.

Interested persons may, on or before September 26, 1978, review the petition and/or file comments, preferably four copies, with the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Comments should be identified with the Hearing Clerk docket number found in brackets in the heading of this document and should include any available information helpful in determining whether the substance is, or is not, generally recognized as safe. A copy of the petition and received comments may be seen in the office of the Hearing Clerk, address given above, from 9 a.m. to 4 p.m., Monday through Friday.

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-20714 Filed 7-27-78; 8:45 am]

[4110-03]

CIRCULATORY SYSTEM DEVICES PANEL

Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meeting is announced:

Committee name	Date, time, and place	Type of meeting and contact person
Circulatory System Devices Panel.	Aug. 11, 9 a.m., room 1409, FB-8, 200 C Street SW., Washington, D.C.	Open public hearing 9 a.m. to 10 a.m.; open committee discussion 10 a.m. to 11 a.m.; closed committee deliberations 11 a.m. to 4 p.m.; Glenn A. Rahmoeller (HFK-450), 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7559.

General function of the committee. Reviews and evaluates available data concerning the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

Agenda.—Open public hearing. Interested persons are encouraged to present information pertinent to the classification of cardiovascular devices to the executive secretary. Submission of data relative to tentative classification findings is also invited. Those desiring to make formal presentations should notify the executive secretary by July 28, 1978, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, references to any data to be relied on, and also an indication of the approximate time required to make their comments.

Open committee discussion. The Panel members will discuss the development of product development protocol guidelines for prosthetic heart valves, vascular graft prostheses, oxygenators, and pacemakers. This will be a continuation of the discussions on product development protocols which were held at the Panel's June 30, 1978 meeting.

Closed committee deliberations. The Panel members will review new drug applications and premarket approval applications for cardiovascular devices. This portion of the meeting will be closed to permit discussion of trade secret data (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this FEDERAL REGISTER notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed

above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be obtained from the Public Records and Documents Center (HFC-18), 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94-409), permit such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably, deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

Dated: July 20, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 78-20622 Filed 7-27-78; 8:45 am]

[4110-03]

[Docket No. 78N-0179]

KAHLE TURKEY FARMS & HATCHERY

Applications For Animal Feeds Bearing or Containing New Animal Drugs; Opportunity For Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This is a notice of opportunity for hearing on the proposal by the Director of Bureau of Veterinary Medicine to withdraw approval of all applications for animal feeds bearing or containing new animal drugs (form FD-1800) for Kahle Turkey Farms & Hatchery, R.F.D. No. 1, Fort Jennings, Ohio 45844. The reason for the proposed withdrawal is that new information shows that the firm's methods and controls used for manufacturing and processing such feeds are not adequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein nor were they made adequate within a reasonable time after receipt of written notice specifying the deficiencies.

DATE: A written appearance requesting a hearing and data and analysis upon which a request for a hearing relies must be submitted by August 28, 1978.

ADDRESS: Written requests to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockeville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Frank Pugliese, Bureau of Veterinary Medicine (HFV-234), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockeville, Md. 20857, 301-443-3460.

SUPPLEMENTARY INFORMATION: Kahle Turkey Farms & Hatchery raises turkeys and also manufactures medicated feeds to be fed to the turkeys that it raises. The firm holds three approved medicated feed applications (form FD-1800) for the manufacture of medicated feeds bearing or containing a new animal drug as required by section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)) as follows:

1. F 39-529V for animal feeds containing 0.0375 percent carbarsone (not U.S.P.); approved August 1, 1968.

2. F 43-568V for animal feeds containing 0.0375 percent carbarsone (not U.S.P.) and 0.01875 percent zoalene; approved March 9, 1970.

3. C 49-338V for animal feeds containing 0.0375 percent carbarsone (not U.S.P.) and 0.0011 percent bacitracin (as bacitracin methylene disalicylate); approved March 15, 1972.

For a feed manufacturer to obtain approval of the Food and Drug Administration (FDA) for the manufacture of a medicated feed bearing or containing a new animal drug, it must submit a form FD-1800 for each medicated feed that it wishes to produce. Such application requires, among other things, that certain assays be performed at periodic intervals and that the sponsor comply with the current good manufacturing practice regulations as set forth in part 225 (21 CFR pt. 225).

The current good manufacturing practice regulations in part 225 are criteria for the manufacturing of medicated feeds to assure that such drugs meet the requirements of the act as to safety and that they have the identity and strength and meet the quality and purity characteristics they purport or are represented to possess.

On March 14 through 17, 1977, FDA conducted an inspection of the Kahle Turkey Farm. A copy of the findings of the investigator, which were given to Mr. Kahle, manager of the farm, included the following:

1. No. production records were maintained for the manufacture of feeds containing the drug carbarsone.

2. No production records were maintained for other medications used as water or feed additives.

3. No assay results of finished carbarsone medicated feeds were available for observation.

4. No assay results of finished medicated feeds using other medications were performed.

In a regulatory letter, dated May 13, 1977, FDA notified the firm that the

conditions and practices noted during the March inspection were violations of section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) as follows:

1. Failure to maintain daily inventory records for each drug used, as required by § 225.42 (21 CFR 225.42).

2. Failure to perform periodic assays of the drug components in the medicated feeds manufactured, as required by § 225.58 (21 CFR 225.58).

3. Failure to maintain a master record file and production records of medicated feeds manufactured, as required by § 225.102 (21 CFR 225.102).

The Food and Drug Administration requested that the firm take prompt action to correct the violations.

As a followup to the regulatory letter, FDA inspected Kahle Turkey Farms on August 3 and 4, 1977. A copy of the investigator's findings, which were given to Mr. Kahle, included the following:

1. No daily inventory record for each drug used was maintained.

2. No periodic assays were run on medicated feeds for drug components.

3. Neither a master record file nor production records for medicated feeds manufactured were maintained.

4. No receipt record was maintained for incoming lots of drugs received.

The Director of the Bureau of Veterinary Medicine notified the firm by letter, dated October 26, 1977, that because of its continuing violations of the Federal Food, Drug, and Cosmetic Act for conditions previously brought to the attention of the firm, the agency intended to withdraw the firm's medicated feed applications unless the violations were promptly corrected. The Director requested that the firm reply within 10 days with a plan as to what it intended to do to correct the violations noted. The firm responded on or about November 18, 1977 that it was keeping records and was trying to comply with the agency's demands.

On February 9 through 14, 1978, FDA reinspected the firm and the investigators noted the following:

1. Daily inventory record for each drug used was not maintained.

2. Master record files or production records for medicated feeds manufactured were not maintained.

3. No periodic assays were run for medicated feeds for drug components.

The investigators stated that although the firm had started to keep inventory records and production records, such recordkeeping was discontinued on October 15, 1977.

Therefore, notice is given to the above-listed firm and to any other interested persons who may be adversely affected that the Director proposes to issue an order under section 512(m)(4)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)(4)(B)(ii)), withdrawing approval of the listed applications and all amendments and supplements thereto on the grounds that new information shows that the methods used in, and the controls used for, the manufacture and processing of animal feeds bearing or containing new animal drugs are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs contained therein, and were not made adequate within a reasonable time after receipt of written notice specifying such deficiencies.

If the holder of the approvals or any other interested person elects to avail himself or herself of an opportunity for hearing under section 512(m)(4)(B) of the act and § 514.200 (21 CFR 514.200), that person must file with the hearing clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, a written appearance requesting such a hearing and giving the reason why the applications should not be withdrawn, i.e., show that the required records were being kept and that the required assays were being done, by August 28, 1978.

The failure of the holder of the approvals to file timely written appearance and request for hearing as required by § 514.200 constitutes an election not to avail himself or herself of the opportunity for a hearing, and the Director of the Bureau of Veterinary Medicine will summarily enter a final order withdrawing the approvals.

A request for hearing may not rest upon mere allegations or denials, but it must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing.

If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests a hearing, making findings and conclusions, denying a hearing.

If review of the data or information submitted by the applicant or any other interested persons warrants the conclusion that there exists substantial evidence demonstrating the firm was in compliance with the requirements of current good manufacturing practice, the Commissioner will rescind this notice of opportunity for hearing for that product. The Commissioner reserves the right to verification of such data and information before reaching a decision to rescind the notice.

If a hearing is requested and is justified by the applicant's response to this notice of opporuntity for hearing, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will commence will be issued as soon as practicable.

Four copies of all submissions pursuant to this notice must be filed with the hearing clerk, Food and Drug Administration. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, responses to this notice may be seen in the office of the hearing clerk (HFA-305), Food and Drug Administration, between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512(m), 82 Stat. 343-351 (21 U.S.C. 360b(m))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84).

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20712 Filed 7-27-78; 8:45 am]

[4110-03]

[Docket No. 77N-0245]

RECYCLED ANIMAL WASTE

Request for Data, Information, and Views; Extension of Time for Submissions

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice extends to September 25, 1978 the time for submitting data, information, and views concerning a notice regarding use of animal waste as animal feed.

DATE: Written submissions by September 25, 1978.

ADDRESS: Written submissions to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Veterinary Drugs: Jack Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-5247.

Foods: William Horwitz, Bureau of

Foods (HFF-101), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1301.

SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER of December 27, 1977 (42 FR 64662), the Commissioner of Food and Drugs requested data, information, and views regarding use of animal waste as animal feed. The notice provided that written submissions be submitted by June 26, 1978.

A joint annual meeting of the American Dairy Science Association and the American Society of Animal Science was held July 9-13, 1978 at Michigan State University, East Lansing, Mich. As part of this meeting, a symposium was held on the management and utilization of animal waste, including use of processed animal waste products as feed. To include the information obtained at the symposium and to enable persons attending the symposium to submit their views on the December 1977 FEDERAL REGISTER notice, the Commissioner concludes that a 90-day extension for submitting data, information, and views is justified. Therefore, the period of time for submitting comments is extended to September 25, 1978.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b)) and under authority delegated to the Commissioner (21 CFR 5.1).

Dated: July 21, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner, Regulatory Affairs.

[FR Doc. 78-20713 Filed 7-27-78; 8:45 am]

[4110-03]

SCHERING CORP.

Utonex (Ethinyl-Estradiol and Nitro- furathiazide) Suspension and Suppositories; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice withdraws approval of new animal drug applications (NADA's) 13-003 and 13-660, that provided for use of Utonex Metritis Suspension and Utonex Metritis Suppositories, respectively. These products are intended for treating metritis in cows. This action is taken in response to a request by Schering Corp., the sponsor.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Frank Pugliese, Bureau of Veterinary Medicine (HFV-234), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3460.

SUPPLEMENTARY INFORMATION: Schering Corp., Galloping Hill Road, Kenilworth, N.J. 07033, is the sponsor of NADA 13-003 that covers Utonex Metritis Suspension intended for intrauterine use in bovine animals for the treatment of metritis and metritis complicated by retained placenta. Each milliliter of the product contains 0.1 milligram (mg) of ethinyl estradiol and 1 mg of nitrofurathiazide. The applications became effective on March 5, 1962. The firm is also the sponsor of NADA 13-660 covering Utonex Metritis Suppositories. Each suppository contains 3 mg of ethinyl estradiol and 30 mg of nitrofurathiazide. The product is used in the same manner as the suspension. This NADA was originally approved on February 1, 1963.

Utonex Metritis Suspension was subject to review by the National Academy of Sciences-National Research Council (NAS/NRC) Drug Efficacy Study Group, and the findings of that review and the Food and Drug Administration's conclusions were published in the FEDERAL REGISTER of August 25, 1970 (35 FR 13544). The NAS/NRC review evaluated the products as probably effective for the treatment of metritis and metritis complicated by retained placenta in the bovine. The sponsor was also notified that tissue residue data might be needed. On December 17, 1971, the agency informed the firm that because the nitrofurathiazide component was a potential carcinogen, either a suitable analytical method or data showing the drug not to be a carcinogen was necessary. The firm agreed to provide the essential data by their letter of May 10, 1972. The firm subsequently initiated a 2-year study in rats and a 1½-year study in mice to establish safety of the products. The final report of the rat study, submitted on April 15, 1977, was found inadequate, and the firm was so notified on February 8, 1978. The final report of the mouse study was submitted February 9, 1978, and was also found inadequate. On May 25, 1978, the agency informed the firm that to permit the continued marketing of the drug in view of unresolved questions regarding the safety of the drugs was not in the public interest. The firm replied by letter of June 8, 1978, advising that distribution of the products had been discontinued and requesting withdrawal of approval of the applications.

Therefore under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360(b))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 of the new animal drug regulations (21 CFR 514.115), notice is given that approval of NADA's 13-003 and 13-660 and all supplements for Utonex Metritis Suspension and Utonex Metritis Suppositories is hereby withdrawn, effective July 28, 1978.

Dated: July 21, 1978.

FRED J. KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20711 Filed 7-27-78; 8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 77N-0333]

HEARING AIDS

Opportunity for Oral Hearing on Proposed Action on State Applications for Exemption from Preemption of State and Local Requirements

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces an opportunity for interested persons to request an oral hearing on a proposed rule on State applications for exemption from preemption of State and local requirements governing the labeling and conditions of sale of hearing aids. This action is being taken in accordance with section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k). The proposed rule is published elsewhere in this issue of the FEDERAL REGISTER.

DATES: Requests for an oral hearing by August 28, 1978.

ADDRESS: Written requests (preferably four copies) to the Hearing Clerk (HFC-20), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FURTHER INFORMATION CONTACT:

Joseph M. Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration announces an opportunity for oral hearing on its proposal on the State applications for exemption from preemption of State and local require-

ments governing the labeling and conditions of sale of hearing aids. The proposal affects the applications of the following State and local governments: Arizona, California, Connecticut, District of Columbia, Florida, Kentucky, Maine, Minnesota, Mississippi, Nebraska, New Jersey, New Mexico, New York, Ohio, Oregon, Pennsylvania, Texas, Washington, and West Virginia. Interested persons may request an oral hearing on or before August 28, 1978.

Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner of Food and Drugs is proposing to grant or to deny each State application requesting an exemption from Federal preemption for certain State laws and regulations pertaining to hearing aids, allowing 60 days for comment. To enable expeditious review of any request for an oral hearing, the Commissioner has limited the period for requesting an oral hearing to the first 30 days of the comment period. Upon a determination that an oral hearing should be held, the Commissioner shall publish a notice in the FEDERAL REGISTER of the time, date, and place of the hearing. The procedures to govern any such oral hearing are those applicable to a public hearing before the Commissioner under Part 15 (21 CFR Part 15).

Interested persons may on or before August 28, 1978, submit requests for an oral hearing on the subject matter to the Hearing Clerk, address above. All requests should be identified with the Hearing Clerk docket number found in brackets in the heading of this notice.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 521, 90 Stat. 574 (21 U.S.C. 360k)) and under authority delegated to the Commissioner (21 CFR 5.1).

Dated: July 6, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 78-20860 Filed 7-27-78; 8:45 am]

[4110-03]

[Docket Nos. 76N-0184 and 76N-0112; DESI 3590]

PARENTERAL PROTEIN SUPPLEMENTS CONTAINING PROTEIN HYDROLYSATE

Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Applications

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice.

SUMMARY: This notice proposes to withdraw approval of the new drug applications for all parental protein hydrolysate solutions on the basis that the drugs are not shown to be safe for use as a dietary supplement of protein. Protein hydrolysate solutions are sterile parenteral solutions of amino acids and short-chain peptides, derived from natural protein sources such as fibrin or casein, and are administrered intravenously.

DATE: Hearing requests due on or before August 28, 1978.

ADDRESS: Communications forwarded in response to this notice should be identified with the reference number DESI 3590, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

Requests for Hearings (identify with the appropriate Docket number appearing in the heading of this notice): Hearing Clerk, Food and Drug Administration (HFA-305), room 4-65.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT:

Ronald L. Wilson, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice (DESI 3590; Docket No. 76N-0184) published in the FEDERAL REGISTER of September 21, 1976 (41 FR 41132), the Director of the Bureau of Drugs announced his conclusion that the following single-entity 5-percent protein hydrolysate parenteral solutions are effective for use as an adjunct in the prevention of nitrogen loss or in the treatment of a negative nitrogen balance:

1. That part of NDA 3-590 pertaining to Amigen injection containing 5 percent protein hydrolysate; Mead Johnson Laboratories, Division Mead Johnson & Co., 2404 Pennsylvania Street, Evansville, Ind. 47721.

2. That part of NDA 5-932 pertaining to Aminosol injection containing 5 percent protein hydrolysate (modified); Abbott Laboratories, Inc., 14th and Sheridan Rd., N. Chicago, Ill. 60064.

3. That part of NDA 6-170 pertaining to Hyprotigen injection containing 5 percent protein hydrolysate (modified); McGaw Laboratories, 1015 Grandview Avenue, Glendale, Calif. 91201.

4. That part of NDA 6-726 pertaining to the C.P.H. injection containing 5 percent protein hydrolysate (modified); Cutter Laboratories, Inc., 4th and Parker Streets, Berkeley, Calif. 94710.

5. That part of NDA 5-419 pertaining to Travamin injection containing 5 percent protein hydrolysate; Travenol Laboratories, Inc., Morton Grove, Ill. 60053.

In a notice of opportunity for hearing (NOH) (DESI 3590; Docket No. 76N-0112), also published in the FEDERAL REGISTER of September 21, 1976 (41 FR 41133), the Director announced his conclusion that all combination products containing protein hydrolysates and single-entity products containing other than 5 percent protein hydrolysates lack substantial evidence of effectiveness. In response to the NOH, Travenol Laboratories submitted a hearing request for the products described below. Since no other hearing request was received, approval of the other drug products listed in the September 21, 1976 NOH (Docket No. 76N-0112) was withdrawn in the FEDERAL REGISTER of February 4, 1977 (42 FR 6908).

That part of NDA 5-419 pertaining to Travamin Injection containing 5 percent protein hydrolysate and 5 percent dextrose; Travenol Laboratories, Inc.

Travamin Injection containing 10 percent protein hydrolysate (no NDA); Travenol Laboratories, Inc.

Travamin Injection containing 5 percent protein hydrolysate, 12.5 percent fructose, and 2.4 percent alcohol (no NDA); Travenol Laboratories, Inc. The September 21, 1976 NOH (Docket No. 76N-0112) proposed to withdraw approval of the new drug applications on the basis that substantial evidence of effectiveness is lacking for the drugs. The Director is hereby amending that notice to include the additional ground of a lack of evidence of safety. This amendment applies only to the two combination products and one single-entity product that are the subject of the hearing request submitted by Travenol Laboratories in response to the NOH. In addition, the Director concludes that all the single-entity products containing 5 percent protein hydrolysate that were the subject of the other September 21, 1976 notice (Docket No. 76N-0184) also lack evidence of safety. The Director therefore proposes to withdraw approval of the new drug applications for all protein hydrolysates on the ground that new evidence, not contained in the applications or not available to the Food and Drug Administration until after the applications were approved, evaluated together with the evidence available when the applications were approved, shows that the drug products are not shown to be safe for use under the conditions for use upon the basis of which the applications were ap-

proved. Specifically, the Director refers to the following adverse effects, which give an unfavorable benefit-to-risk ratio for these drugs, and the fact that a more effective alternative drug product having less potential for risk is readily available.

A. Studies have conclusively demonstrated that protein hydrolysates contain large amounts of ammonia (Refs. 1, 3, 7). Although hyperammonemia is usually clinically asymptomatic, it may nevertheless damage the liver (Ref. 3).

B. Fever (Refs. 5, 9) and elevation of liver enzymes have been observed in patients infused with protein hydrolysates (Refs. 3, 14, 17).

C. Fungi and bacteria proliferate rapidly at room temperature in parenteral mixtures prepared from casein hydrolysates and dextrose, while they fail to multiply or grow very slowly in similar solutions of synthetic amino acids (Ref. 6).

D. Thirty to fifty percent of the content is peptides (Refs. 4, 13), and hypersensitivity has been reported on several occasions (Refs. 4, 9).

E. The titratable acidity of protein hydrolysates is high and this may contribute to the potential to cause metabolic acidosis (Ref. 19).

F. The high levels of acidic amino acids in protein hydrolysates, were associated with hypothalamic lesions in immature mice (Ref. 10).

G. The crystalline amino acid solutions for parenteral use are alternative drug products that have less potential for risk. In addition, studies have shown that about 2 times more of the hydrolysates are necessary to achieve the same level of nitrogen balance as compared to the crystalline solutions (Ref. 11), as 30 to 50 percent of the peptides are excreted in the urine (Refs. 13, 15). The amino acid solutions also have the advantage of increased effectiveness because they can be tailored to the patient's needs.

H. The casein hydrolysates are imbalanced in their composition, being poor in aromatic and S-containing amino acids (Refs. 4, 16) and arginine, and containing excessive amounts of glutamic acid (Ref. 12), which can cause vomiting (Ref. 12) and, in immature mice, brain damage (Ref. 10). Moreover, their composition is not reproducible (Refs. 8, 15), since it is difficult to standardize the hydrolytic process. The poor nutritional effectiveness and the high ammonia content of the hydrolysates may be the reason that studies have shown that there is no increase in the survival rate of infants who received hydrolysates as compared to infants supplemented with only 10 percent glucose (Ref. 2). The fact that protein hydrolysates cost less than the crystalline amino acid solutions is far outweighed by their lesser nutritional effectiveness and high ammonia content.

REFERENCES

1. Webster, L. T. and C. S. Davidson, "Cirrhosis of the Liver; Impending Hepatic Coma and Increased Blood Ammonium Concentrations During Protein Hydrolystate Infusion," *The Journal of Laboratory and Clinical Medicine*, 50:1-10, July 1957.

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3. Johnson, J. D., et al., "Hyperammonemia Accompanying Parenteral Nutrition in Newborn Infants," *The Journal of Pediatrics*, 81:154-161, 1972.

4. Heller, L., "Clinical and Experimental Studies on Complete Parenteral Nutrition," *Scandinavian Journal of Gastroenterology*, 4:Suppl. 3:7-16, 1969.

5. Shohl, A. T., et al., "Nitrogen Metabolism During the Oral and Parenteral Administration of the Amino Acids of Hydrolyzed Casein," *The Journal of Pediatrics*, 15:469-475, October 1939.

6. Goldman, D. A., et al., "Growth of Bacteria and Fungi in Total Parenteral Nutrition Solutions," *The American Journal of Surgery*, 126:314-318, September 1973.

7. Gahadimi, H., et al., "Biochemical Aspects of Intravenous Alimentation," *Pediatrics*, 48:955-965, December 1971.

8. Shaw, J. C. L., "Parenteral Nutrition in the Management of Sick Low Birthweight Infants," *Pediatric Clinics of North America*, 20:333-358, May 1973.

9. Ruberg, R. L., "Hospital Practice of Total Parenteral Nutrition," *in* "Total Parenteral Nutrition," edited by White, P. L., M. E. Nagy, and D. C. Fletcher, Publishing Sciences Group, Inc., Acton, Mass., 1974, p. 347.

10. Olney, J. W., et al., "Brain-Damaging Potential of Protein Hydrolysates," *The New England Journal of Medicine*, 289:391-395, August 23, 1973.

11. Anderson, G. H., et al., "Design and Evaluation by Nitrogen Balance and Blood Aminograms of an Amino Acid Mixture for Total Parenteral Nutrition of Adults with Gastrointestinal Disease," *The Journal of Clinical Investigation*, 53:904-912, March 1974.

12. Levey, S., et al., "Serum Glutamic Acid Levels and the Occurrence of Nausea and Vomiting After the Intravenous Administration of Amino Acid Mixtures," *The Journal of Laboratory and Clinical Medicine*, 34:1238-1248, 1949.

13. Long, C. L., et al., "Parenteral Nutrition in the Septic Patient: Nitrogen Balance, Limiting Plasma Amino Acids, and Calorie to Nitrogen Ratios," *The American Journal of Clinical Nutrition*, 29:380-391, April 1976.

14. Garnica, A. D., "The Hepatotoxicity of Parenteral Protein Hydrolysate-containing Solutions," *Annals of Clinical and Laboratory Science*, 6:446-454, 1976.

15. Fleming, C. R., et al., "Total Parenteral Nutrition," *Mayo Clinic Proceedings*, 51:187-199, 1976.

16. Patel, D., et al., "Amino Acid Adequacy of Parenteral Casein Hydrolysate and Oral Cottage Cheese in Patients with Gastrointestinal Disease as Measured by Nitrogen Balance and Blood Aminogram," *Gastroenterology*, 65:427-437, 1973.

17. Cohen, M. I., "Changes in Heptatic Function," *in* "Intravenous Nutrition in the High Risk Infant," edited by Winters, R. W. and E. G. Hasselmeyer, John Wiley & Sons, New York, 1975, pp. 293-305.

18. Wei, P., et al., "A Clinical and Metabolic Study of an Intravenous Feeding Technique Using Peripheral Veins as the Initial Infusion Site," *The Canadian Medical Association Journal*, 106:969-979, 1972.

19. Alvear, D. T. and L. A. Somers, "Parenteral Nutrition in Seriously Ill Neonates; Search for the Ideal Mixture," *American Journal of Surgery*, 127:696-699, 1974.

Copies of these references are available for public examination in the office of the Hearing Clerk, and may be seen during working hours Monday through Friday.

Therefore, notice is given to the holder(s) of the new drug application(s) and to all other interested persons that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application(s) and all amendments and supplements thereto on the ground that new evidence of clinical experience, not contained in such application(s) or not available to the Director until after such application(s) was approved, evaluated together with the evidence available to the Director when the application(s) was approved, shows that such drug(s) is not shown to be safe for use under the conditions of use upon the basis of which the application(s) was approved.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product that is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing to determine whether it covers any drug product that the person manufactures or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

In addition to the ground(s) for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6) e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of

the act, or pursuant to section 107(c) of the Drug Amendments of 1962, or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310, 314), the applicant(s) and all other persons subject to this notice pursuant to 21 CFR 310.6 are hereby given an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and of all identical, related, or similar drug products.

An applicant or any other person subject to this notice pursuant to 21 CFR 310.6 who decides to seek a hearing shall file (1) on or before August 28, 1978, a written notice of appearance and request for hearing, and (2) on or before September 28, 1978, the data, information and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other peson subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by the person not to make use of the opportunity for a hearing concerning the action proposed with respect to the product and constitutes a waiver of any contentions concerning the legal status of any such drug product. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will intitate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 5.82).

Dated: July 20, 1978.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc. 78-20363 Filed 7-27-78; 8:45 am]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

MEXICAN STANDARD BROADCAST STATIONS

Notification List

List of New Stations, proposed changes in existing stations, deletions, and corrections in assignments of Mexican standard broadcast stations modifying the assignments of Mexican broadcast stations contained in the appendix to the recommendations of the North American Regional Broadcasting Agreement Engineering Meeting, January 30, 1941.

JUNE 1, 1978.

MEXICAN LIST NO. 284

Call letters	Location	Power watts	Antenna radiation mv/m/kw	Schedule	Class	Antenna height (feet)	Ground systems: Number of radials	Ground systems: Length (feet)	Proposed date of change or commencement of operation
				550 kHz					
XETNC	Tepic, Nay., *N. 21°31'10", W. 104°52'28"*	10.000D/ .150N	DA-D ND-N-190	U	III	446	120	445	Immediately.
				650 kHz					
XEEJ	Puerto Vallarta, Jal., N. 20°36'40", W. 105°14'50", (proposal deleted, PO 0.250 kWD, ND-D175, 108/90/100)	5.000	DA-D	D	II				
				770 kHz					
(New)	Cordoba, Ver., N. 18°54'02", W. 96°55'32"	.250	ND-D-175	D	II	226	120	294	12.1.78.
				870 kHz					
XEAMO	Irapuato, Gto., *N. 20°38'00", W. 101°21'42"*	1.000	DA-D	D	II				Immediately.
				910 kHz					
XEHO	Cd Obregon, Son. *N. 27°34'22", W. 109°57'04"* (*shares antenna with XEHX on 1460 kHz*)	1.000D/ .250N	ND-U-*183*	U	III	*205*	*120*	*233*	Do.
				920 kHz					
XELCM	Lazaro Cardenas, Mich., *N. 17°04'21", W. 102°13'32"*	.500	ND-D-190	D	III	267	120	267	Do.
				920 kHz					
XEÇQ	Culiacan, Sin. N. 24°51'24", W. 107°23'47", (*shares antenna with XESA on 1360 kHz*)	5.000D/ .100N	ND-U-*183*	U	III	246	120	*246*	Do.

MEXICAN LIST No. 284—Continued

Call letters	Location	Power watts	Antenna radiation mv/ m/kw	Schedule	Class	Antenna height (feet)	Ground systems: Number of radials	Ground systems: Length (feet)	Proposed date of change or commencement of operation
				930 kHz					
XEGEM	Toluca, Mex., N. 19°17'33", W. 99°39'38"	2.000N	DA-N.....	N	III	.....	.....	.....	Do.
				950 kHz					
XEZB	Oazaca, Oax., N. 17°03'52", W. 96°43'06", (PO 1120 kHz, 0.500 kWD, ND-D-175)	1.000D/ .100N	ND-U-175.....	U	III	220	90	180	12.1.78.
				990 kHz					
XEUM	Valladolid, Yuc. N. 20°40'40", W. 88°12'32"	1.000D/ .250N	ND-U-190.....	U	II	249	120	249	Immediately.
				1010 kHz					
XEEB	Esperanza, Son. N. 27°33'29", W. 109°56'15", *(PO 0.250 kWU, ND-U-175)*	.500D/ .250N	ND-U-175.....	U	II	194	90	236	12.1.78.
				1060 kHz					
XEEP	Mexico, D.F., N. 19°21'43", W. 99°01'4", *(PO 20 kWU, ND-U-231)*	50.000D/ 50.000N	ND-D-*231* ..... DA-N.....	U	I-B	*440*	120	*246*	Immediately.
				1120 kHz					
XEZB	Oaxaca, Oax., N. 17°03'52", W. 93°43'06", (change in frequency to 950 kHz)	.500	ND-D-175	D	II	220	90	180	12.1.78.
				1120 kHz					
XEGV	Villa Del Puebl, Qro., N. 20°32'09", W. 100°25'54"	.500	ND-D-190	D	II	220	120	220	Immediately.
				1120 kHz					
XEZAZ	Zacatecas, Zac., *N. 22°44'41", W. 102°31'31"*	.250	ND-D-175	D	II	220	90	180	Do.
				1130 kHz					
XEZL	Jalapa, Ver., *N. 19°32'51", W. 96°52'21"*, (PO 10 kWD, ND-D-180)	10.000D/ 10.000N	ND-D-180 ..... DA-N.....	U	II	*215*	120	197	Do.
				1180 kHz					
XEYI	Cancun, Q. R., *N. 21°06'58", W. 86°56'11"*	1.000	DA-D	D	II	.....	.....	.....	Do.
				1270 kHz					
XEYM	Uman, Yuc., *N. 20°52'12", W. 89°44'41"*	2.500D/ .500N	ND-U-190.....	U	III	194	120	194	Do.
				1280 kHz					
XELK	Zacatecas, Zac., *N. 22°46'21", W. 102°37'39", (PO 0.250 kW, ND-U-181)*	5.000D/ .250N	ND-U-*190*.....	U	III	*192*	*120*	*192*	12.1.78.
				1330 kHz					
XEUAS	Culiacan, Sin., *N. 24°48'34", W. 107°23'58"*	5.000D/ 1.000N	ND-D-190 ..... DA-N.....	U	III	185	120	185	Immediately.
				1340 kHz					
XEOS	Cd Obregon, Son., *N. 27°29'37", W. 109°55'40"*	.250D/ .250N	ND-U-*168*.....	U	IV	*197*	*120*	*91*	Do.
				1360 kHz					
XEIK	Piedras Negras, Coah., *N. 28°41'55", W. 100°31'35"*	.500D/ .250N	ND-U-*187*.....	U	III	*223*	*120*	*133*	Do.
				1360 kHz					
XEEJ	Puerto Vallarta, Jal., N. 20°36'40", W. 105°14'50" (see assignment on 650 kHz)	1.000	ND-D-199	D	III	295	120	131	12.1.78.
				1360 kHz					
XESA	Culiacan, Sin., *N. 24°51'24", W. 107°23'47", (shares antenna with XECQ on 920 kHz)*	1.000D/ .500N	ND-U-*219*.....	U	III	*246*	*120*	*246*	Immediately.
				1360 kHz					
XEXM	Jerez, Zac., N. 22°38'51", W. 102°59'48" (PO 1 kWD, ND-D-190)	1.000D/ .100N	ND-U-190.....	U	III	180	120	180	Do.
				1380 kHz					
XEKOK	Las Cruces, Gro., *N. 16°56'55", W. 99°49'54"*	1.000	ND-D-190	D	III	*197*	120	*180*	Do.
				1450 kHz					
XEBP	Torreon, Coah., N. 25°32'18", W. 103°27'55"	1.000D/ .250N	ND-U-175.....	U	IV	230	90	230	Do.
				1520 kHz					
XEUAA	Aguascalientes, Ags., *N. 21°54'44", W. 102°19'01"*	.250	ND-D-190	D	II	161	120	161	Do.
				1540 kHz					
XEHOS	Hermosillo, Son., N. 29°04'29", W. 110°57'36"	5.000D/ 5.000N	ND-U-175.....	U	II	213	120	213	Do.

WALLACE E. JOHNSON,
Chief, Broadcast Bureau,
Federal Communications Commission.

[FR Doc. 78-20847 Filed 7-27-78; 8:45 am]

[4110-12]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

SOCIAL SECURITY ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

Part S (formerly Part 4) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health, Education, and Welfare contains the Statement of Organization, Functions, and Delegations of Authority for the Social Security Administration (SSA). Notice is hereby given that the organization of the Office of Family Assistance published in the FEDERAL REGISTER (p. 32846-7) of June 28, 1977, is amended to reflect organizational changes necessary to permit the Associate Commissioner, OFA to devote more of his time and energy to interfaces with other components of SSA, to active leadership in program direction and program development in the regions, and to working with other Federal agencies as well as non-government bodies toward more effective and efficient income maintenance programs in the States and other jurisdictions.

The changes made establish a second Deputy Associate Commissioner and eliminate the two positions of Office Director. These changes affect section SF-10 and section SF-20 as indicated below.

Section SF-10 *Office of Family Assistance* (Organization) The Office of Family Assistance, under the leadership of the Associate Commissioner for Family Assistance consists of the:

A. Associate Commissioner for Family Assistance
B. Deputy Associate Commissioner for Family Assistance
C. Deputy Associate Commissioner for Family Assistance
D. Immediate Office of the Associate Commissioner for Family Assistance which includes the: 1. Regional Liaison Staff
E. The Special Programs Staff
F. The Division of Policy
G. The Division of Procedures
H. The Division of Financial Management
I. The Division of Management Support
J. The Division of Planning, Evaluation and Statistical Analysis

Section SF-20 *Office of Family Assistance* (Functions)

A. 1. The Associate Commissioner for Family Assistance is directly responsible to the Commissioner of Social Security (the Commissioner) for performance of OFA's mission and provides general supervision to the principal components of OFA.

2. During the absence or disability of the Associate Commissioner for Family Assistance (the Associate Commissioner) the Deputy Associate Commissioner designated by the Associate Commissioner shall act as Associate Commissioner. In the event of a vacancy in the position of Associate Commissioner, the Deputy Associate Commissioner designated by the Commissioner shall act as Associate Commissioner.

3. In the event of the absence or disability of the Associate Commissioner and both Deputy Associate Commissioners an OFA executive designated by the Associate Commissioner shall serve as acting head of OFA.

4. Should the positions of Associate Commissioner and both Deputy Associate Commissioners become vacant, an SSA official designated by the Commissioner shall serve as acting head of OFA.

B. *The Deputy Associate Commissioner for Family Assistance* Assists the Associate Commissioner in carrying out his responsibilities and performs such other duties as the Associate Commissioner may prescribe. In addition has specialized duties in day-to-day program policy activities. Such specialized duties would not lessen the deputy's OFA-wide responsibility.

C. *The Deputy Associate Commissioner for Family Assistance:*

Assists the Associate Commissioner in carrying out his responsibilities and performs such other duties as the Associate Commissioner may prescribe. In addition, has specialized duties in day-to-day program implementation activities. Such specialized duties would not lessen the deputy's OFA-wide responsibility.

D. *The Immediate Office of the Associate Commissioner for Family Assistance:*

1. *The Regional Liaison Staff*

a. Assures continuous and effective communications between central and regional offices on program and management concerns.

b. Assures that regional concerns and needs are given attention for resolution by central office components and/or the regional offices.

E. *The Special Program Staff (SFP-1):*

1. Administers the Cuban and Indochinese Refugee Programs including the development of regulations, policies and procedures and making arrangements for: financial assistance, resettlement services, emergency health services, assistance to public schools in impacted areas, loans to refugee students and protective care of minors. Develops regulations and guidelines pertaining to these programs.

2. Directs Federal program activities relating to the repatriation of U.S. citizens from foreign countries. Coordinates the return of repatriates with Department of State. Coordinates the provision of services to repatriates with regional offices. Approves claims by State agencies for reimbursement, and makes determinations whether repayment by the repatriate is appropriate. Develops regulations and guidelines pertaining to the program.

F. *The Division of Policy (SFP-2):*

1. Develops regulations and policies to implement laws governing family assistance programs and coordinates with the SSA Office of Policy and Regulations (OPR) on the issuance of such regulations. These regulations govern Federal/State income maintenance programs including policies to safeguard the rights of individuals and families; i.e., dependent and needy children in their own homes, in protective care in AFDC family foster homes, in child care institutions, and for emergency assistance to needy families with children.

2. Develops, analyzes, and recommends concepts for new legislation concerning family assistance programs and coordinates these activities with the SSA Office of Program Evaluation and Planning.

3. Evaluates State plan materials for consistency with Federal policies and recommends revisions to assure consistency with Federal law and regulations. Reviews and evaluates program management and quality control reports to determine program policy effectiveness and develops proposals for policy changes, proposed regulatory and/or legislative changes.

4. Supports office of general counsel and other legal authorities in litigation involving family assistance programs.

5. Conducts review of identified compliance and reconsideration issues; recommends and manages appropriate action.

6. Provides technical assistance and consultation to regions and States concerning Federal policies.

G. *The Division of Procedures (SFP-3):*

1. Develops, issues and interprets operational procedures, relative to income maintenance regulations and which are designed to provide States with leadership and guidance in the most efficient and effective techniques of administering OFA programs.

2. Review proposed income maintenance legislation and regulations for procedural implementation impacts and feasibility.

3. Reviews and approves applications from States for Federal financial participation in the acquisition of ADP equipment or the design of automated information systems in support of OFA programs.

4. Reviews amd evaluates the utilization of State and local agency manpower devoted to OFA program administration.

5. Provides technical assistance and consultation to the States concerning such matters as operational procedures, systems analysis, program training and establishing models and guides for States regarding income maintenance methods.

H. *The Division of Financial Management (SFM-1):*

1. Reviews State budget forecast and expenditure reports and related financial management activities and analyzes the consequences of these reports for the Federal budget.

2. Exercises financial control over grants to States for public assistance provided under OFA programs.

3. Provides training, technical assistance, and guidance to OFA regional components on matters pertaining to Federal/State financial management activites.

4. Establishes and issues program fiscal and accounting policies and procedures.

5. Prepares, presents, and executes the total OFA budget.

6. Analyzes and present cost data for activities funded under OFA programs.

I. *The Division of Management Support (SFM-2):*

1. Plans, organizes, and directs OFA's internal manpower utilization, organization, and training programs, in accordance with Federal, HEW, and SSA personnel management regulations, policies, and procedures.

2. Analyzes the organizational effectiveness of OFA components and insures uniform and effective manpower utilization and position management.

3. Manages the OFA repository of State plans for AFDC programs and periodically prepares and publishes "Characteristics of State AFDC Plans" and related analyses and reports.

4. Prepares the program budget for the U.S. repatriate program and performs related financial management activities.

5. Prepares and executes the salaries and expenses budget for the OFA.

6. Analyzes OFA facilities, space, and equipment needs and initiates necessary actions to provide same. Provides management services in the areas of forms; issuances; mail; reports; travel; safety; records; and property management.

7. Coordinates the review, preparation, and publication of OFA operational instructions to insure consistency, lack of duplication, receipt, and access to such material by OFA audiences. Coordinates the issuance process of the OFA regulations and program policies with the SSA Office of Policy and Regulations.

J. *The Division of Planning, Evaluation, and Statistical Analysis (SFM-3):*

1. Develops OFA emergency, long-range, and short-range plans to assure effective continuity of OFA activities. Prepares trend analyses and reports, and energy and environmental impact statements.

2. Specifies program information needs and provides program input to SSA research efforts. Assesses the practical application of research findings to OFA program administration.

3. Develops statistical information relative to State, regional, and national program administration. Based upon such information, data developed by the Office of Research and Statistics, and other reports, evaluates program effectiveness, identifies potential program abuse, reports findings and recommends actions aimed at improving program administration and integrity.

4. Develops projects concerning client populations and program activities to meet the needs of OFA components and State agencies.

5. Develops a coordinated and comprehensive program for identifying major OFA operational planning objectives and monitors the implementation of such goals.

6. Coordinates external audits and audit reporting requirements with the SSA Office of Management and Administration.

7. Provides technical assistance and consultation to regions and States concerning planning, evaluation, statistical analyses, and related matters.

Dated: July 18, 1978.

LEONARD D. SCHAEFFER,
Assistant Secretary for Management and Budget.

[FR Doc. 78-20938 Filed 7-27-78; 8:45 am]

[4110-88]

Alcohol, Drug Abuse, and Mental Health Administration

MINORITY ADVISORY COMMITTEE, ADAMHA

Meeting Cancellation

In FR Doc. 78-19146 appearing on page 29989 in the issue of Wednesday, July 12, 1978, the August 2-4, 1978 meeting of the Minority Advisory Committee, ADAMHA was announced. This meeting has been postponed and will be rescheduled at a later date.

Dated: July 26, 1978.

CAROLYN T. EVANS,
Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 78-21143 Filed 7-27-78; 10:03 am]

[4310-84]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

OUTER CONTINENTAL SHELF, GULF OF MEXICO

Proposed Oil and Gas Lease Sale No. 65

In connection with oil and gas leasing on the Outer Continental Shelf, the Secretary of the Interior has established a new policy relating to sale notices to further and enhance consultation with the affected coastal States. That policy includes providing the affected States with the opportunity to review the draft proposed sale notice prior to its final publication in the FEDERAL REGISTER. The following is a draft sale notice for proposed sale No. 65 in the offshore waters of the eastern Gulf of Mexico area. This notice is hereby published as a matter of information to the public.

ARNOLD E. PETTY,
Acting Director, Bureau of Land Management.

Approved: July 24, 1978.

CECIL D. ANDRUS,
Secretary of the Interior.

PROPOSED SALE NOTICE

1. *Authority.* This notice is published pursuant to the Outer Continental Shelf Lands Act (43 U.S.C. 1331-1343) and the regulations issued thereunder (43 CFR 3300).

2. *Filing of Bids.* Sealed bids will be received by the Manager, New Orleans Outer Continental Shelf (OCS) Office, Bureau of Land Management, Hale Boggs Federal Building, 500 Camp Street, Suite 841, New Orleans, La. 70130. Bids may be delivered, either by mail or in person, to the above address until 4:15 p.m., c.s.t., October —, 1978; or by personal delivery to the Tulane

Room, Grand Hotel, 1500 Canal Street, New Orleans, La. 70140, between the hours of 8:30 a.m., c.s.t., and 9:30 a.m., c.s.t., October —, 1978. Bids received by the Manager later than the times and dates specified above will be returned unopened to the bidders. Bids may not be modified or withdrawn unless written modification or withdrawal is received by the Manager prior to 9:30 a.m., c.s.t., October —, 1978. All bids must be submitted and will be considered in accordance with applicable regulation, including 43 CFR 3300. The list of restricted joint bidders which applies to this sale was published in 43 FR 15500, April 13, 1978, as corrected in 43 FR 16427, April 18, 1978.

3. *Method of Bidding.* A separate bid in a sealed envelope labeled "Sealed Bid for Oil and Gas Lease (insert number of tract), not to be opened until 10 a.m., c.s.t., October —, 1978," must be submitted for each tract. A suggested form appears in paragraph 17 of this notice. Bidders are advised that tract numbers are assigned solely for administrative purposes and are not the same as block numbers found on official protraction diagrams. All bids received shall be deemed submitted for a numbered tract. Bidders must submit with each bid one fifth of the cash bonus in cash or by cashier's check, bank draft, certified check, or money order payable to the order of the Bureau of Land Management. No bid for less than a full tract as described in paragraph 13 will be considered. Bidders submitting joint bids must state on the bid form the proportionate interest of each participating bidder, in percent to a maximum of five decimal places, as well as submit a sworn statement that the bidder is qualified under 43 CFR 3302. The suggested form for this statement to be used in joint bids appears in paragraph 18. Other documents may be required of bidders under 43 CFR 3302.4. Bidders are warned against violation of 18 U.S.C. 1860, prohibiting unlawful combination or intimidation of bidders.

4. *Bonus Bidding With a Fixed Sliding Scale Royalty.* Bids on tracts 65-25, 65-26, 65-27, 65-28, 65-30, 65-31, 65-79, 65-80, 65-81, 65-82, 65-89, 65-90, 65-91, 65-92, 65-93, 65-94, 65-95, 65-96, 65-97, 65-107, 65-109, and 65-110 must be submitted on a cash bonus bid basis with the percent royalty due in amount or value of production saved, removed or sold fixed according to the sliding scale formula described below. This formula fixes the percent royalty at a level determined by the value of lease production during each calendar quarter. For purposes of determining the royalty percent due on production during a quarter, the value of production during the quarter will be adjusted for inflation as described below. The determination of the value of the production on which royalty is due will be made pursuant to 30 CFR 250.64.

The fixed sliding scale formula operates in the following way: when the quarterly value of production, adjusted for inflation, is less than or equal to $13.236229 million, a royalty of 16.66667 percent in amount or value of production saved, removed, or sold will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $13.236230 million, but less than or equal to $1662.854082 million, the royalty percent due on the unadjusted value or amount of production is given by

$$R_j = b[\mathrm{Ln}\,(V_j/S)]$$

where

R_j = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter j.
b = 10.0.
Ln = natural logarithm.
V_j = the value of production in quarter j, adjusted for inflation, in millions of dollars.
S = 2.5.

When the adjusted quarterly value of production is equal to or greater than $1662.854083 million, a royalty of 65.00000 percent in amount or value of production saved, removed or sold will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of quarterly production saved, removed or sold.

In determining the quarterly percent royalty due, R_j, the calculation will be carried to five decimal places (for example, 20.17329 percent). This calculation will incorporate the adjusted quarterly value of production, V_j, in millions of dollars, rounded to the sixth digit; i.e., to the nearest dollar (for example, 15.392847 millions of dollars).

The form of the sliding scale royalty schedule is illustrated in Figure 1. Note that the effective quarterly royalty rate depends upon the inflation adjusted quarterly value of production. However, this rate is applied to the unadjusted quarterly value of production to determine the royalty payments due.

In adjusting the quarterly value of production for use in calculating the percent royalty due on production during the quarter, the actual value of production will be adjusted to account for the effects of inflation by dividing the actual value of production by the following inflation adjustment factor. The inflation adjustment factor used will be the ratio of the GNP fixed weighted price index for the calendar quarter preceding the quarter of production to the value of that index for the quarter preceding the issuance of the lease. The GNP fixed weighted price index is published monthly in the Survey of Current Business by the Bureau of Economic Analysis, U.S. Department of Commerce. The percent royalty will be due and payable on the actual amount or value of production saved, removed, or sold as determined pursuant to 30 CFR 250.64. The timing of procedures for inflation adjustments and determinations of the royalty due will be specified at a later date. Table 1 provides hypothetical examples of quarterly royalty calculations using the sliding scale formula just described under two different values for the quarterly price index.

Leases awarded on the basis of a cash bonus bid with fixed sliding scale royalty will provide for a yearly rental or minimum royalty payment of $3 per acre or fraction thereof.

Bidders for these tracts should recognize that the Department of Energy is authorized, under section 302 (b) and (c) of the Department of Energy Organization Act, to establish production rates for all Federal oil and gas leases.

Figure 1
Form of the Sliding Royalty Schedule

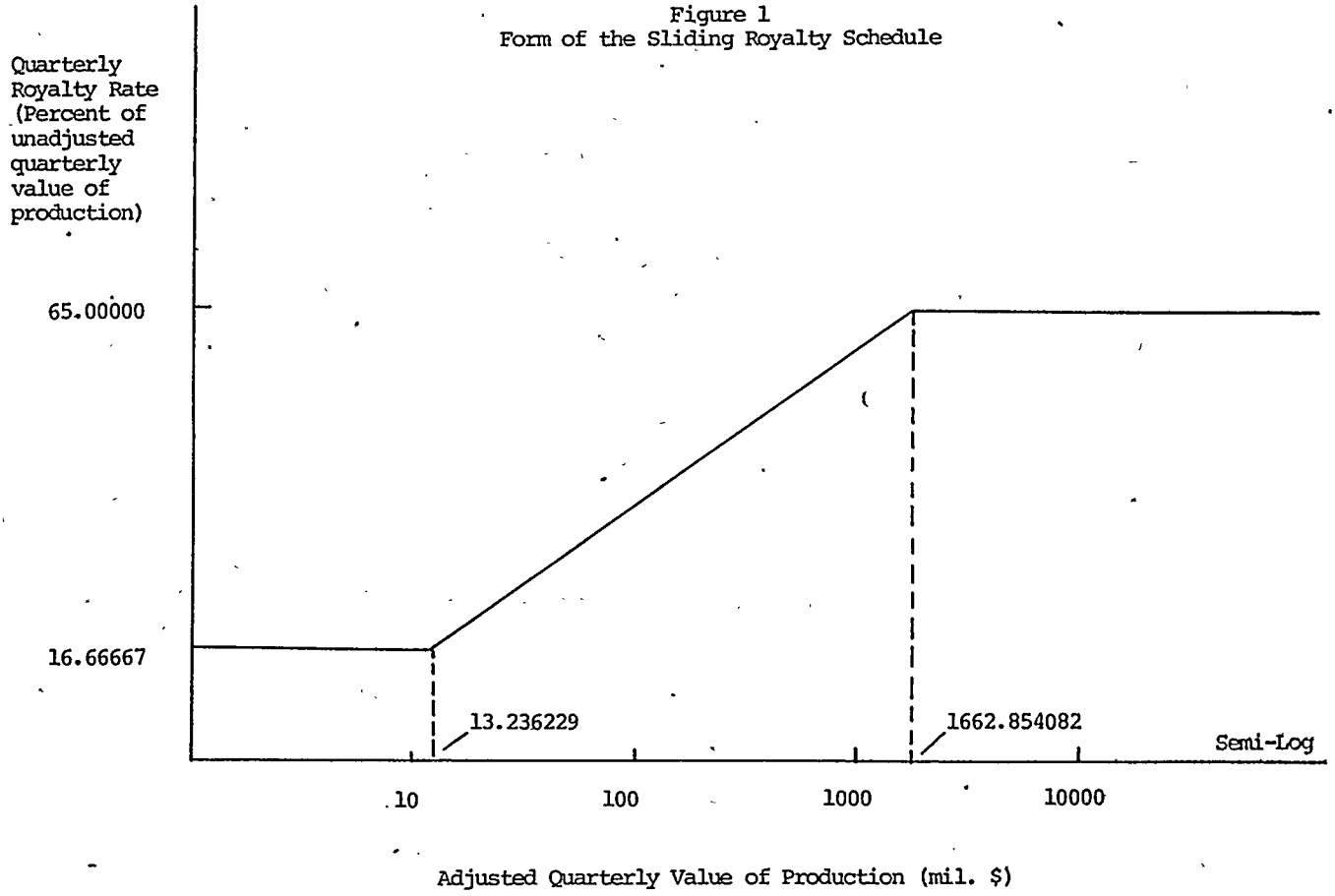

TABLE 1. HYPOTHETICAL QUARTERLY ROYALTY CALCULATIONS

(1) Actual Value of Quarterly Production (Millions of dollars)	(2) GNP Fixed Weighted Price Index	(3) Inflation Factor[1]	(4) Adjusted Value of Quarterly Production[2] (V_j, mil. $)	(5) Percent Royalty Rate (R_j)	(6) Royalty Payment[3] (millions of dollars)
10.000000	200.0	4/3	7.500000	16.66667	1.666667
30.000000	200.0	4/3	22.500000	21.97225	6.591675
90.000000	200.0	4/3	67.500000	32.95837	29.662533
270.000000	200.0	4/3	202.500000	43.94449	118.650123
810.000000	200.0	4/3	607.500000	54.93061	444.937941
10.000000	250.0	5/3	6.000000	16.66667	1.666667
30.000000	250.0	5/3	18.000000	19.74081	5.922243
90.000000	250.0	5/3	54.000000	30.72693	27.654237
270.000000	250.0	5/3	162.000000	41.71306	112.625262
810.000000	250.0	5/3	486.000000	52.69918	426.863358

1 Column (2) divided by 150.0 (assumed value of GNP fixed weighted price index at time leases are issued).

2 Column (1) divided by Inflation Factor.

3 Column (1) times Column (5); All values are rounded for display purposes only.

5. *Bonus bidding with a fixed constant royalty.* Bids on the remaining tracts to be offered at this sale must be on a cash bonus basis with a fixed royalty of 16⅔ percent. Leases which may be issued will provide for a yearly rental payment or minimum royalty payment of $3 per acre or fraction thereof. A suggested cash bonus bid form is shown in paragraph 17.

6. *Equal opportunity.* Each bidder must have submitted by 9:30 a.m., c.s.t., October —, 1978, the certification required by 41 CFR 60-1.7(b) and Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, on the compliance report certification form, form 1140-8 (November 1973), and the affirmative action representation form, form 1140-7 (December 1971).

7. *Bid opening.* Bids will be opened on October —, 1978, beginning at 10 a.m., c.s.t., at the address stated in paragraph 2. The opening of the bids is for the sole purpose of publicly announcing and recording bids received and no bids will be accepted or rejected at that time. If the Department is prohibited for any reason from opening any bid before midnight, October —, 1978, that bid will be returned unopened to the bidder, as soon thereafter as possible.

8. *Deposit of payments.* Any cash, cashier's checks, certified checks, bank drafts, or money orders submitted with a bid may be deposited in a suspense account in the Treasury during the period the bids are being considered. Such a deposit does not constitute and shall not be construed as acceptance of any bid on behalf of the United States.

9. *Acceptance or rejection of bids.* The United States reserves the right to reject any and all bids for any tract. In any case, no bid for any tract will be accepted and no lease for any tract will be awarded to any bidder unless:

(a) The bidder has complied with all requirements of this notice and applicable regulations;

(b) The bid is the highest valid cash bonus bid; and

(c) The amount of the bid has been determined to be adequate by the Secretary of the Interior.

No bid will be considered for acceptance unless it offers a cash bonus in the amount of $25 or more per acre or fraction thereof.

10. *Withdrawal of tracts.* The United States reserves the right to withdraw any tract from this sale prior to issuance of a written acceptance of a bid for that tract.

11. *Successful bidders.* Each person who has submitted a bid accepted by the Secretary of the Interior will be required to execute copies of the lease specified below, pay the balance of the cash bonus bid together with the first year's annual rental, and satisfy the bonding requirements of 43 CFR 3304.1 within the time provided in 43 CFR 3302.5.

12. *Protraction diagrams.* Tracts offered for lease may be located on the following official protraction diagrams which are available from the manager, New Orleans Outer Continental Shelf Office, at the address stated in paragraph 2. They sell for $2 each.

OUTER CONTINENTAL SHELF OFFICIAL PROTRACTION DIAGRAMS

(1) NH 16-5, Pensacola.
(2) NH 16-8, Destin Dome.
(3) NH 16-12, Florida Middle Ground.
(4) NG 16-3, The Elbow.
(5) NG 16-6.
(6) NH 17-10, Tarpon Springs.
(7) NG 17-1, St. Petersburg.
(8) NG 17-4, Charlotte Harbor.

13. *Tract descriptions.* The tracts offered for bid are as follows:

NOTE: There may be gaps in the sequence of the numbers of the tracts listed. Some of the blocks identified in the final environmental statement may not be included in this notice.

OCS OFFICIAL PROTRACTION DIAGRAM, PENSACOLA NH 16-5

[Approved Oct. 10, 1972; revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-1	882	All	5760
65-2	883	All	5760
65-3	884	All	5760
65-4	885	All	5760
65-5	886	All	5760
65-6	926	All	5760
65-7	927	All	5760
65-8	928	All	5760
65-9	929	All	5760
65-10	930	All	5760
65-11	970	All	5760
65-12	971	All	5760
65-13	972	All	5760
65-14	973	All	5760
65-15	974	All	5760

OCS OFFICIAL PROTRACTION DIAGRAM, DESTIN DOME NH 16-8

[Approved Oct. 10, 1972; revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-21	313	All	5760
65-22	314	All	5760
65-23	357	All	5760
65-24	358	All	5760
65-25	473	All	5760
65-26	474	All	5760
65-27	518	All	5760
65-28	519	All	5760
65-29	529	All	5760
65-30	562	All	5760
65-31	563	All	5760
65-32	573	All	5454.72
65-33	574	All	5760
65-34	618	All	5760
65-35	661	All	5760
65-36	662	All	5760

OCS OFFICIAL PROTRACTION DIAGRAM, FLORIDA MIDDLE GROUND NH 16-12

[Approved Oct. 10, 1972; revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-41	358	All	5760
65-42	359	All	5760
65-48	402	All	5760
65-49	403	All	5760
65-50	404	All	5760
65-51	405	All	5760
65-57	446	All	5760
65-58	447	All	5760
65-63	490	All	5760
65-64	491	All	5760
65-69	534	All	5760
65-70	535	All	5760

OCS OFFICIAL PROTRACTION DIAGRAM, THE ELBOW NG 16-3

[Approved Oct. 10, 1972; revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-71	567	All	5134.56
65-72	609	All	5760
65-73	696	All	5760
65-74	697	All	5760
65-75	739	All	5760
65-76	783	All	5760
65-77	827	All	5760
65-78	871	All	5760

OCS OFFICIAL PROTRACTION DIAGRAM, NG 16-6

[Approved June 5, 1974; revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-79	258	All	5760
65-80	259	All	5760
65-81	302	All	5760
65-82	303	All	5760
65-83	609	All	5760
65-84	610	All	5760
65-85	611	All	5760
65-86	653	All	5760
65-87	654	All	5760
65-88	697	All	5760

OCS OFFICIAL PROTRACTION DIAGRAM, TARPON SPRINGS NH 17-10

[Approved Oct. 10, 1972; revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-89	233	All	5760
65-90	234	All	5760
65-91	277	All	5760
65-92	278	All	5760
65-93	279	All	5760

OCS OFFICIAL PROTRACTION DIAGRAM, ST. PETERSBURG NG 17-1

[Approved Oct. 10, 1972; revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-94	661	All	5760
65-95	662	All	5760
65-96	705	All	5760
65-97	706	All	5760
65-98	753	All	5760
65-99	754	All	5760
65-100	797	All	5760
65-101	798	All	5760

OCS OFFICIAL PROTRACTION DIAGRAM, CHARLOTTE HARBOR NG 17-4

[Approved Oct. 10, 1972; revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-102	143	All	5760
65-103	144	All	5760
65-104	145	All	5760
65-105	187	All	5760
65-106	188	All	5760
65-107	221	All	5760
65-108	231	All	5760
65-109	265	All	5760
65-110	266	All	5760
65-111	627	All	5760
65-112	628	All	5760
65-113	671	All	5760
65-114	672	All	5760
65-115	715	All	5760
65-116	716	All	5760

14. *Lease Terms and Stipulations.* Leases issued as a result of this sale will be on Form 3300-1 (December 1976), available from the Manager, New Orleans Outer Continental Shelf Office, at the address stated in paragraph 2. For leases resulting from this sale for tracts offered on a cash bonus basis with fixed sliding scale royalty listed in paragraph 4 of this Notice of Sale, Form 3300-1, will be amended as follows:

SEC. 3(b)(1) *Royalty on Production.* To pay the lessor a royalty of that percent in amount or value of production saved, removed or sold from the leased area as determined by the sliding scale royalty formula as follows. When the quarterly value of production, adjusted for inflation, is less than or equal to $13.236229 million, a royalty of 16.66667 percent in amount or value or production saved, removed or sold will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $13.236230 million, but less than or equal to $1662.854082 million, the royalty percent due on the unadjusted value or amount of production is given by

$$R_j = b[\mathrm{Ln}\,(V_j/S)]$$

where

R_j= the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter j.
b= 10.0.
Ln= natural logarithm.
V_j= the value of production in quarter j, adjusted for inflation, in millions of dollars.
S= 2.5

When the adjusted quarterly value of production is equal to or greater than $1662.854083 million, a royalty of 65.00000 percent in amount or value of production saved, removed or sold will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of quarterly production saved, removed or sold.

In determining the quarterly percent royalty due, R_j, the calculation will be carried to five decimal places (for example, 20.17329 percent). This calculation will incorporate the adjusted quarterly value of production, V_j, in millions of dollars, rounded to the sixth digit, i.e., to the nearest dollar (for example, 15.392847 millions of dollars).

SEC. 3(b)(3). When paid in value, royalties on production shall be due and payable monthly on the last day of the month next following the month in which the production is obtained, *except* that the Secretary may establish such other requirements for the timing of royalty payments as he determines are necessary. In no case will the royalty payments be required prior to the last day of the month next following the month in which production is obtained. Each such determination regarding the timing of royalty payments shall be made only after due notice to the Lessee and a reasonable opportunity has been afforded to the Lessee to be heard. When paid in production, * * *.

In the following stipulations the term "Supervisor" refers to the Gulf of Mexico area oil and gas Supervisor for operations of the Geological Survey and the term "Manager" refers to the Manager of the New Orleans OCS Office of the Bureau of Land Management. Except as otherwise noted, the following stipulations will be included in each lease resulting from this sale.

STIPULATION NO. 1

a. The lessee agrees that if any site, structure, or object of historical or archaeological significance should be discovered during the conduct of operations on any leased area, he shall report immediately such findings to the Supervisor, and make every reasonable effort to preserve and protect the cultural resource from damage until the Supervisor has given directions as to its preservation.

b. (To apply only to the leases resulting from this proposed sale for tracts 65-1 through 65-21 and 65-89 through 65-93.)

For these lease tracts, falling within Cultural Resource Zones 1 and 2 as defined and plotted in the final report Cultural Resources Evaluation of the Northern Gulf of Mexico Continental Shelf (Coastal Environments, Inc., 1977), and tracts falling outside the Zones 1 and 2 in which there is reason to believe a cultural resource exists, the Supervisor shall require the lessee to comply with the following:

Prior to any drilling activity or the construction or placement of any structure for exploration or development on the lease, including but not limited to, well drilling and pipeline and platform placement, hereinafter in this stipulation referred to as "operation," the lessee shall conduct remote sensing surveys to determine the potential existence of any cultural resource that may be affected by such operations. All data produced by such remote sensing surveys as well as other pertinent natural and cultural environmental data shall be examined by a qualified marine survey archaeologist to determine if indications are present suggesting the existence of a cultural resource that may be adversely affected by any lease operation. A report of this survey and assessment prepared by the marine survey archaeologist shall be submitted by the lessee to the Supervisor and to the Manager.

If such cultural resource indicators are present the lessee shall: (1) Locate the site of such operations so as not to adversely affect the identified location; or (2) establish, to the satisfaction of the Supervisor, on the basis of further archaeological investigation conducted by a qualified marine survey archaeologist or underwater archaeologist using such survey equipment and techniques as deemed necessary by the Supervisor, either that such operations will not adversely affect the location identified or that the potential cultural resource suggested by the occurence of the indicators does not exist.

A report of this identification investigation prepared by the marine survey archaeologist or underwater archaeologist shall be submitted to the Supervisor and the Manager, for their review. Should the Supervisor determine that the existence of a cultural resource which may be adversely affected by such operation is sufficiently established to warrant protection, the lessee shall take no action that may result in an adverse effect on such cultural resource until the Supervisor has given directions as to its preservation.

STIPULATION NO. 2

For the purpose of this stipulation, "Live Bottom Areas" are defined as those areas which contain biological assemblages consisting of such sessile invertebrates as sea fans, sea whips, hydroids, anemones, ascidians, sponges, bryozoans, or corals living upon and attached to naturally occurring hard or rocky formations with rough, broken, or smooth topography; or whose lithotope favors the accumulation of turtles and fishes.

a. (To apply only to leases resulting from this proposed sale for tracts 65-1 through 65-20.)

Prior to any drilling activity or placement of any fixed structures or pipelines or any other exploration or production activity, the lessee will submit to the Supervisor as part of his exploration and/or development plan a bathymetry map, prepared utilizing remote sensing survey techniques. This map will include interpretations for the presence of live bottom areas within a minimum one-mile radius of the proposed exploration or production activity site.

b. (To apply to all leases resulting from this proposed sale.)

If it is determined that remote sensing data indicate the possibility of live bottom areas, the lessee will submit to the Supervisor photo or other documentation of the sea bottom of the proposed exploratory drilling sites or proposed platform locations or points as determined by the Supervisor.

If it is determined that live bottom areas might be adversely impacted by the proposed activities, then the Supervisor will require the lessee to undertake any measures deemed economically, environmentally, and technologically feasible to protect live bottom areas. These measures may include, but are not limited to, the following:

1. The relocation of operations to avoid live bottom areas.

2. The shunting of all drilling fluids and cuttings in such a manner as to avoid live bottom areas.

3. The transportation of drilling fluids and cuttings to approved disposal sites.

4. The monitoring of live bottom areas to assess the adequacy of any mitigating measures taken and the impact of lessee-initiated activities.

STIPULATION No. 3

a. (To apply only to the leases resulting from this proposed sale for tracts 65-6, 65-11, 65-16, 65-17, 65-18, 65-21 through 65-28, 65-30, 65-31, 65-37 through 65-70, 65-73 through 65-78, and 65-94 through 65-116.)

Whether or not compensation for such damage or injury might be due under a theory of strict or absolute liability or otherwise, the lessee assumes all risks of damage or injury to persons or property, which occur in, on, or above the Outer Continental Shelf, to any persons or to any property of any person or persons who are agents, employees or invitees of the lesses, its agents, independent contractors or subcontractors doing business with the lessee in connection with any activities being performed by the lessee in, on, or above the Outer Continental Shelf, if such injury or damage to such person or property occurs by reason of the activities of any agency of the U.S. Government, its contractors or subcontractors, or any of their officers, agents or employees, being conducted as a part of, or in connection with the programs and activities of the Gulf Test Range, the Pensacola Naval Air Station, Eglin Air Force Base, MacDill Air Force Base, Tyndall Air Force Base or Naval Air Advance Training Command, Naval Air Station, Corpus Christi, Tex. The lessee assumes this risk whether such injury or damage is caused in whole or in part by any act or omission, regardless of negligence or fault, of the United States, its contractors or subcontractors, or any of their officers, agents, or employees. The lessee further agrees to indemnify and save harmless the United States against and to defend at its own expense the United States against all claims for loss, damage, or injury sustained by the lessee, and to indemnify and save harmless the United States against, and to defend at its own expense the United States against, all claims for loss, damage, or injury sustained by the agents, employees, or invitees of the lessee, its agents, or any independent contractors or subcontractors doing business with the lessee in connection with the programs and activities of the aforementioned military installations, whether the same be caused in whole or in part by the negligence or fault of the United States, its contractors, or subcontractors, or any of their officers, agents, or employees and whether such claims might be sustained under theories of strict or absolute liability or otherwise.

The lessee agrees to control his own electromagnetic emissions and those of his agents, employees, invitees, independent contractors or subcontractors emanating from individual designated defense warning areas in accordance with requirements specified by the commander of the appropriate onshore military installation, i.e., Pensacola Naval Air Station, Eglin Air Force Base, MacDill Air Force Base, or Tyndall Air Force Base, to the degree necessary to prevent damage to, or unacceptable interference with, Department of Defense flight, testing or operational activities, conducted within individual designated warning areas. Necessary monitoring control, and coordination with the lessee, his agents, employees, invitees, independent contractors or subcontractors, will be effected by the commander of the appropriate onshore military installation conducting operations in the particular warning area: *Provided, however,* That control of such electromagnetic emissions shall in no instance prohibit all manner of electromagnetic communication during any period of time between a lessee, its agents, employees, invitees, independent contractors or subcontractors and onshore facilities.

The lessee, when operating or causing to be operated on its behalf boat or aircraft traffic into the individual designated warning areas shall enter into an agreement with the commander of the appropriate onshore military installation, i.e., Pensacola Naval Air Station, Eglin Air Force Base, MacDill Air Force Base, Tyndall Air Force Base, utilizing an individual designated warning area prior to commencing such traffic. Such agreement will provide for positive control of boats and aircraft operating into the warning areas at all times.

b. (To apply only to the leases resulting from this proposed sale for tracts 65-25 through 65-28, 65-30, and 65-31.)

When the activities of the Armament Development and Test Center at Eglin Air Force Base may endanger personnel or property, the lessee agrees, upon receipt of a directive from the Secretary, to evacuate all personnel from all structures on the lease and to shut-in and secure all wells and other equipment, including pipelines on the lease, within forty-eight (48) hours or within such longer period as may be specified by the directive. Such directive shall not require evacuation of personnel and shutting-in and securing of equipment for a period of time greater than seventy-two (72) hours; however, such period of time may be extended by subsequent directive from the Secretary. Equipment and structures may remain in place on the lease during such time as the directive remains in effect.

STIPULATION No. 4

Pipelines will be required: (1) If pipeline rights-of-way can be determined and obtained; (2) if laying such pipelines is technologically feasible and environmentally preferable, and (3) if, in the opinion of the lessor, pipelines can be laid without net social loss, taking into account any incremental costs of pipelines over alternative methods of transportation and any incremental benefits in the form of increased environmental protection or reduced multiple use conflicts. The lessor specifically reserves the right to require that any pipeline used for transporting production to shore be placed in certain designated management areas. In selecting the means of transportation, consideration will be given to any recommendation of the Intergovernmental Planning Program for Leasing and Management of Transportation of Outer Continental Shelf Oil and Gas with the participation of Federal, State, and local government and the industry. Where feasible, all DOI regulated pipelines, including both flow lines and gathering lines for oil and gas, shall be buried to a depth suitable for adequate protection from water currents, sand waves, storm scouring, fisheries trawling gear, and other uses as detemined on a case-by-case basis.

Following the completion of pipeline installations, no crude oil production will be transported by surface vessel from offshore production sites, except in the case of emergency. Determinations as to emergency conditions and appropriate responses to these conditions will be made by the Supervisor. Where the three criteria set forth in the first sentence of this stipulation are not met and surface transportation must be employed.

All vessels used for carrying hydrocarbons to shore from the leased area will conform with all standards established for such vessels, pursuant to the Ports and Waterways Safety Act of 1972 (46 U.S.C 391a).

STIPULATION No. 5

Lessees shall comply with regulations which affect activities under this lease and which are promulgated under applicable statutes by other Federal agencies, including the Department of Energy, the Department of Transportation, and the Environmental Protection Agency.

STIPULATION No. 6

To be included in any leases resulting from this proposed sale for the sliding scale royalty tracts listed in paragraph 4 of this notice.

(a) The royalty rate on production saved, removed or sold from this lease is subject to consideration for reduction under the same authority that applies to all other oil and gas leases on the Outer Continental Shelf (30 CFR 250.12 (e)). The Director, Geological Survey, may grant a reduction for only 1 year at a time. Reduction of royalty rates will not be approved unless production has been underway for 1 year or more.

(b) Although the royalty rate specified in section 3(b)(1) of this lease or as subsequently modified in accordance with applicable regulations and stipulations is applicable to all production under this lease, not more than 16⅔ percent of the production saved, removed or sold from the lease area may be taken as royalty in amount, except as provided in section 6(c); the royalty on any portion of the production saved, removed or sold from the lease in excess of 16⅔ percent may only be taken in value of the production saved, removed or sold from the lease area.

STIPULATION No. 7

Unless the lessee can demonstrate to the satisfaction of the Supervisor that it would not be in the interests of conservation, all reservoirs underlying this lease which extend into one or more other leases with either a different royalty rate or a royalty rate based on a sliding scale, as indicated by drilling and other information, shall be operated and produced only under a unit agreement including the other lease(s) and approved by the Supervisor. Such a unit agreement shall provide for the fair and equitable allocation of production and costs. The Supervisor shall prescribe the method of allocating production and costs in the event operators are unable to agree on a method acceptable to him.

STIPULATION No. 8

(To be included in any lease resulting from this proposed sale for the following tracts: 65-72 through 65-74, 65-77, 65-78,

65-82 through 65-90, 65-92, 65-93, 65-98 through 65-106, 65-108, 65-112, 65-114 and 65-115.)

Portions of these tracts may contain karst sinkholes. Exploratory drilling operations, emplacement of structures (platforms) or seafloor wellheads for the production of storage of oil or gas will not be allowed on those portions of the tract which contain karst sinkholes until the lessee has demonstrated to the Supervisor's satisfaction that exploratory drilling operations can be safely conducted or structures (platforms), casing, and wellheads can be safely designed and installed at the proposed location.

15. *Information to Lessees.* The Department of the Interior will seek the advice of the States of Mississippi, Louisiana, Alabama, and Florida and other Federal agencies, to identify areas of special concern which might require appropriate protective measures for live bottom areas and areas which might contain cultural resources.

If it is determined that live bottom areas might be adversely impacted by the proposed activities, then the Supervisor, in consultation with the Regional Director, Fish and Wildlife Service (FWS), the Manager, BLM and the States, will require the lessee to undertake any measures deemed economically, environmentally, and technically feasible to protect live bottom areas.

Some of the tracts offered for lease may fall in areas which may be included in fairways, precautionary zones, or traffic separation schemes. Corps of Engineers permits are required for construction of any fixed structures or artificial islands located on the Outer Continental Shelf in accordance with section 4(f) of the Outer Continental Shelf Lands Act of 1953 (67 Stat. 463; 43 U.S.C. 1333(f)).

In applying safety, environmental and conservation laws and regulations, the Supervisor will require the use of the best available and safest technology which is determined to be economically achievable. To the extent practicable, the Supervisor will consult with the relevant Federal agencies and the affected State(s) in the execution of these responsibilities.

Bidders are advised that the Departments of the Interior and Transportation have entered into a memorandum of understanding dated May 6, 1976, concerning the design, installation, operation and maintenance of offshore pipelines. Bidders should consult both Departments for regulations applicable to offshore pipelines.

The U.S. Congress is considering OCS Lands Act Amendments which would institute many new provisions in the leasing and administration of the resources on the OCS. Two of these provisions: (1) The Fishermen's Gear Compensation Fund; and (2) the Oil Spill Liability Fund will, if enacted, establish programs to repay damages and the costs of oil spills resulting from OCS activities. These funds may be supported by assessments levied on lessees and operators. Bidders are hereby notified that these and other provisions of the OCS Lands Act Amendments may apply to leases resulting from sale 65.

The Department's regulations found in 30 CFR and 43 CFR, as amended, are applicable to this lease sale. Recent amendments to these regulations are found in 42 FR 53956, October 4, 1977 (suspension of leases); 43 FR 3880, January 27, 1978 (oil and gas operations and oil and gas information program); and 43 FR 3892, January 27, 1978 (environmental assessment and oil and gas information program).

16. *OCS Orders.* Operations on all leases resulting from this sale will be conducted in accordance with the provisions of all Gulf of Mexico OCS Orders, as of their effective date, and any other applicable OCS Order as it becomes effective.

17. *Suggested Bid Form.* It is suggested that bidders submit their bids to the Manager, New Orleans Outer Continental Shelf Office, in the following form:

Oil and Gas Bid

The following bid is submitted for an oil and gas lease on the tract of the Outer Continental Shelf specified below:

Tract No.	Total Amount Bid	Amount per Acre	Amount of Cash Bonus Submitted with Bid
_____	_____	_____	_____

Proportionate Interest of Company(s) Submitting Bid

Qualification No. _____ _____ _____
Company

Percent Interest _____%

_____
Address

_____
Signature
(Please type signer's name under signature)

18. *Required Joint Bidders Statement.* In the case of joint bids, each joint bidder is required to execute a joint bidder's statement before a notary public and submit it with his bid. A suggested form for this statement is shown below.

Joint Bidder's Statement

I hereby certify that _____ (entity submitting bid) is eligible under 43 CFR 3302 to bid jointly with the other parties submitting this bid.

_____
Signature
(Please type signer's name under signature)

Sworn to and subscribed before me this ____ day of _____ 19__.

_____
NOTARY PUBLIC

State of _____

County of _____

[FR Doc. 78-20717 Filed 7-27-78; 8:45 am]

[4310-84]

[W-64624]

WYOMING

Notice of Application

JULY 20, 1978.

Notice is hereby given that pursuant to section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Northern Utilities, Inc. of Casper, Wyo., filed an application for a right-of-way to construct a dehydrator station site for the purpose of reducing water vapor content of natural gas being transported and will affect the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 39 N., R. 78 W.,
Sec. 19, SW¼SE¼.

The proposed dehydrator station site will consist of 0.086 acres and will be located adjacent to an existing measuring station and 6 inch pipeline, all located in Natrona County, Wyo.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, 951 Union Boulevard, Casper, Wyo. 82601.

WILLIAM S. GILMER,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-20880 Filed 7-27-78; 8:45 am]

[CA 5200]

CALIFORNIA

Proposed Withdrawal and Reservation of Lands

JULY 20, 1978.

The Department of the Army, Corps of Engineers, has filed application number CA 5200 to withdraw from all forms of appropriation under the nondiscretionary public land laws, including mining under the general mining laws, subject to prior valid existing rights, the following described land:

T. 3N., R. 14 E., M.D.M.
Sec. 35, SE¼NE¼SE¼ and N½NE¼SE¼ SE¼.

The area aggregates 15 acres in Tuolumne County, Calif. The withdrawal of the land is necessary to preserve the unique cave ecosystem associated with the New Melones Lake Project.

For a period of 30 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the undersigned officer of the Bureau of Land Management, U.S. Department of the Interior, Room E-2841 Federal Office Building, 2800 Cottage Way, Sacramento, Calif. 95825.

The Department's regulations provide that the authorized officer of the Bureau of Land Management will undertake such investigations as are necessary to determine the existing and potential demands for the lands and their resources. He will also undertake negotiations with the applicant agency with the view of adjusting the application to reduce the area to the minimum essential to meet the applicant's needs, to provide the maximum concurrent utilization of the lands for purposes other than the applicant's, to eliminate lands needed for purposes more essential than the applicant's, and to reach agreement on the concurrent management of the lands and their resources.

The authorized officer will also prepare a report for consideration by the Secretary of the Interior, who will determine whether or not the land will be withdrawn as requested by the applicant agency.

Pursuant to section 204(b) of the Federal Land Policy and Management Act of 1976, notice is hereby given that an opportunity for a public hearing is offered in connection with the proposed withdrawal. All interested persons who desire to be heard on the proposed withdrawal must submit a written request for a hearing to the undersigned. Notice of the public hearing will be published in the FEDERAL REGISTER, giving the time and place of said hearing.

For a period of 2 years from date of publication of this notice in the FEDERAL REGISTER, the land will be segregated from entry as specified above, unless the application is rejected or the withdrawal is approved prior to that date. If the withdrawal is approved by the Secretary, it will be for a 20-year period and the land will remain segregated for the duration of the withdrawal.

All communications in connection with this proposed withdrawal should be addressed to the undersigned.

JOAN B. RUSSELL,
Chief, Lands Section Branch of Lands and Minerals Operations.

[FR Doc. 78-20913 Filed 7-27-78; 8:45 am]

[4310-55]

Fish and Wildlife Service

ENDANGERED SPECIES PERMIT

Notice of Receipt of Application

Applicant: Ila Loetscher, P.O. Box 2049, South Padre Island, Texas 78597.

The applicant requests a permit to salvage endangered and threatened species of sea turtles for rehabilitation at her facilities and release to the wild to enhance the survivial of the species. Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2158. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.

Dated: July 25, 1978.

DONALD G. DONAHOO,
Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 78-20905 Filed 7-27-78; 8:45 am]

[4310-55]

ENDANGERED SPECIES PERMIT

Notice of Receipt of Application

Applicant: Yerkes Regional Primate Research Center, Emory University, Atlanta, Georgia 30322

The applicant wishes to export refrigerated or frozen blood and tissue samples collected from laboratory gorillas (*Gorilla gorilla*) and orangutan (*Pongo pygmaeus*) for biomedical research.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2390. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.

Dated: July 25, 1978.

DONALD G. DONAHOO,
Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 78-20906 Filed 7-27-78; 8:45 am]

[4310-55]

THREATENED SPECIES PERMIT

Notice of Receipt of Application

Applicant: William F. Vokoun, 2605—63rd St., Downers Grove, Illinois 60515.

The applicant wishes to apply for a Captive Self-Sustaining Population permit authorizing the purchase and sale for propagation those species of pheasants listed in 50 CFR 17.11 as [T(C/P)]. Humane shipment and care in transit is assured.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2496. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.

Dated: July 25, 1978.

DONALD G. DONAHOO,
Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 78-20907 Filed 7-27-78; 8:45 am]

[4310-55]

ENDANGERED SPECIES PERMIT

Notice of Receipt of Application

Applicant: Otis Edward Trosper, 8649 Southaven Circle East, Southaven, Miss. 38671.

The applicant requests a permit to purchase in interstate commerce, two pairs of captive-bred masked bobwhite quail (*Colinus virginianus ridgwayi*) from Maresa Co., Inc., Vista, Calif., for enhancement of propagation. Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H. Street, NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2746. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.

Dated: July 25, 1978.

DONALD G. DONAHOO,
Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 78-20908 Filed 7-27-78; 8:45 am]

[4310-55]

ENDANGERED SPECIES PERMIT

Notice of Receipt of Application

Applicant: Dr. Lawrence J. Foerder, 9000 Beachy Ave., Arleta, Calif. 91771.

The applicant requests a permit to import from Canada a pair of captive-born leopards (*Panthera pardus*) for propagation and exhibition. Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2878. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.

Dated: July 25, 1978.

DONALD O. DONAHOO,
Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 78-20910 Filed 7-27-78; 8:45 am]

[4310-56]

ASIAN ELEPHANT

Waiver of 30 Day Public Comment Period Prior To Issuance of an Endangered Species Permit

On July 13, 1978, a letter waiving the 30 day public comment period requird prior to issuance of an endangered species permit was issued to the Central Florida Zoological Society, Sanford, Fla., as well as a permit PRT 2-2900 authorizing interstate commerce in the course of a commercial activity for the sale of one male Asian elephant (*Elephas maximus*) to the International Animal Exchange facilities at Grand Prairie, Tex.

It was determined by the U.S. Fish and Wildlife Service that an emergency did in fact exist and that the elephant might have to be destroyed since it posed a threat to human life in that its housing facility was inadequate for its temperament during breeding cycles. It had in fact recently seriously injured three attendants and should be moved to the facilities of the International Animal Exchange which are thought to be adequate.

This emergency waiver was issued in accordance with the Endangered Species Act of 1973, as amended by Pub. L. 94-359 (90 Stat. 911).

Documents and other information submitted with this application are available to the public during normal business hours in room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This permit has been assigned file No. PRT 2-2900. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address by August 28, 1978. Please refer to file No. PRT 2-2900 when submitting comments.

DONALD G. DONAHOO,
Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 78-20911 Filed 7-27-78; 8:45 am]

SNAIL DARTER

Waiver of 30 Day Public Comment Period Prior To Issuance of an Endangered Species Permit

On July 12, 1978, a notice of receipt of an application (PRT 2-2873) received by the Service July 7, 1978, from the Tennessee Valley Authority for a permit to capture, mark and release snail darters (*Percina tanasi*) in order to make population estimates, appeared in the FEDERAL REGISTER. Comments were invited for submission on or before August 11, 1978.

On July 13, 1978, based on a recommendation resulting from a unanimous vote by the Snail Darter Recovery Team, the applicant requested a waiver of the 30 day comment period and immediate issuance of a permit contending that there was a real and present danger of losing the snail darter population in the Little Tennessee River and that the activities proposed in their application must immediately commence in order to secure information essential to scientifically sound recovery plans.

On July 14, 1978, in accordance with the Endangered Species Act of 1973, as amended by Pub. L. 94-359 (90 Stat. 911), the Service concurred with the applicants contention and issued a letter waiving the 30 day comment period and permit PRT 2-2873 to the applicant authorizing the requested activities.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the director, U.S. Fish and wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2873. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address by August 28, 1978. Please refer to the file number when submitting comments.

DONALD G. DONAHOO,
Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 78-20909 Filed 7-27-78; 8:45 am]

[4510-30]

DEPARTMENT OF LABOR

Employment and Training Administration

EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS UNDER THE RURAL DEVELOPMENT ACT

Notice of Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, 7 U.S.C. 1924(b), 1932, or 1942(b).

The act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility.

The act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.

2. Employment trends in the same industry in the local area.

3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.

4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).

5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within 2 weeks of publication of this notice to:

Deputy Assistant Secretary for Employment and Training, 601 D Street NW., Washington, D.C. 20213.

Signed at Washington, D.C., this 24th day of July 1978.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

APPLICATIONS RECEIVED DURING THE WEEK ENDING JULY 21, 1978

Name of applicant and location of enterprise	Principal product or activity
Marion Rohr Corp. (tenant of city of Hornell), Hornell, N.Y.	Manufacture of ladies' underwear.
The Eastern Isles, Inc., Richlands and Grundy, Va.	Manufacture of women's robes and children's nightwear.
The J. R. Clark Co., Moundsville, W. Va.	Manufacture of stainless steel cookware and barbeque grills.
Braemar Group, Ltd., Hilton Head Island, S.C.	Convention hotel.
Branchwood Home for the Aged, Reidsville, N.C.	Domiciliary care.
Weisz Decalomania Inc., Chapin, S.C.	Processor of pressure sensitive film.
Brackin Investment Corp., Dothan, Ala.	Retail discount furniture store.
Cascade Machine & Engineering Corp., Inc., Sylacauga, Ala.	Manufacture and repair of machinery.
Fenwick Hall, Division of Health Institutes, Inc., Johns Island, S.C.	Alcoholism treatment services.
Michigan Culvert Co., Macon, Mich.	Manufacture of corrugated steel pipe.
TCKS Corp., Gallipolis, Ohio.	Restaurant.
Guaranty Fuels, Inc., Bayport, Minn.	Production wood of fuel pellets.
Innovation Industries, Inc., Roswell, N. Mex.	Engineering development and manufacture of OPTO-electronic controls for passenger and freight elevators.
Bay Equipment Co., Hitchcock, Tex.	Manufacture of structural clay products.
Scheduled Skyways, Inc., Fayetteville, Ark.	Air passenger, air cargo, and flying charter services.
Dan Wallace, Michael Kahn, and Fred Gipson, Seminole, Okla.	Motel.
Central Gulf Ice, Inc., Berwick, La.	Ice plant.
Davis Funeral Home, Henrietta, Tex.	Funeral services.
Christian Retirement Corp., Santa Fe, N. Mex.	Nursing care and retirement residence.
O'Riley Brothers Construction Co., Maryville, Mo.	Motel.
Woodmoor Country Club, Inc., Monument, Colo.	Country club.
The I-25 Partnership Monument, Colo.	Gasoline service station and

[FR Doc. 78-20742 Filed 7-27-78; 8:45 am]

[4510-30]

EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS UNDER THE RURAL DEVELOPMENT ACT

Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, 7 U.S.C. 1924(b), 1932, or 1942(b).

The act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility.

The act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.

2. Employment trends in the same industry in the local area.

3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.

4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).

5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within 2 weeks of publication of this notice to: Deputy Assistant Secretary for Employment and Training, 601 D Street NW., Washington, D.C. 20213.

Signed at Washington, D.C., this 17th day of July 1978.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

APPLICATIONS RECEIVED DURING THE WEEK ENDING JULY 14, 1978

NAME OF APPLICANT, LOCATION OF ENTERPRISE, AND PRINCIPAL PRODUCT OR ACTIVITY

Mirror Lake Inn, Inc., Lake Placid, N.Y., hotel, resort and restaurant.

Heritage Nursing Home, Inc., Athens, Pa., nursing care.
Avtex Fibers-Front Royal Inc., Front Royal, Va., specialty rayon fibers.
Covington Inn, Clarksville, Tenn., motel.
Key Petroleum, Inc., Mango, Fla., distribution and retail sales of petroleum products.
John F. Wolcott, Sr., Bossier City, La., complete hotel services.
Muskogee Aluminum, Inc., Muskogee, Okla., manufacture of aluminum sheet and foil.
Allied Fabricators, Inc., Mexia, Tex., masts and substructures for oil well drilling rig.
Speed-A-Way, Inc., Cushing, Okla., wholesale gasoline.
North Platte Venture, Douglas, Wyo., motel.
Thomas A. Sawyer, Sheridan, Wyo., motel, office building, mini mart, self serve and rural gas.
United Budget Luxury Inns, Inc., Brunswick, Ga., motel, restaurant, gift shop, and gas station.
Sasse Corp. T/A Rivertree Inn, Clarkston, Wash., transient accommodations.
Blalock Lumber Co., Cleveland and Alto, Ga., manufacture of softwood and hardwood lumber, hardwood flooring and by-products.
Southeast Manufacturing Co., Inc., Joplin, Mo., manufacture of farm equipment and fireplace grates and accessories.
Somerset Group, Inc., Youngstown, N.Y., operation of foreign trade zone.
Alternate Growing Environment, Inc., Las Cruces, N. Mex., intermediate nursing care.
Rex Monroe Kennedy, Jacksonville, N.C., sale and repair of automobiles.
Prosser-Agrinetics Charcoal Interests, Doniphan, Mo., manufacture, packaging and sales of wood charcoal briquettes.
Donald E. Stephens, Leadville, Colo., motel.

[FR Doc. 78-20923 Filed 7-27-78; 8:45 am]

[4510-26]

Occupational Safety and Health Administration

ADVISORY COMMITTEE ON CONSTRUCTION SAFETY AND HEALTH

Meeting

Notice is hereby given that the Advisory Committee on Construction Safety and Health, established under section 107(e)(1) of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) and section 7(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 656) will meet on Tuesday, August 15; Wednesday, August 16, and Thursday, August 17, 1978, in Room N5437, Department of Labor Building, Third Street and Constitution Avenue NW., Washington, D.C. 20210. The meeting is open to the public and will begin at 9 a.m.

Pursuant to the decision of the U.S. Court of Appeals for the District of Columbia Circuit (*National Constructors Association* v. *Ray Marshall, Secretary of Labor, et al.*, C.A.D.C. No. 77-1197) regarding OSHA's Ground-Fault Circuit Protection Standard (29 CFR 1910.309(c) for general industry and 29 CFR 1926.400(h)), the Advisory Committe will review said standard, and make such recommendations as appropriate.

To assist the Advisory Committee in its review, the agency has provided each member with copies of the following documents:

1. A copy of the Court decision.
2. An index of the Record on Ground-Fault protection.
3. FEDERAL REGISTER Notice, Vol. 40, No. 67—April 7, 1975—Ground-Fault Circuit Protection—Revocation of Standard.
4. FEDERAL REGISTER Notice, Vol. 40,No. 170—September 2, 1975—Notice of Hearing on Ground-Fault Circuit Protection.
5. The Ground-Fault Protection Standard—Federal Register—December 21, 1976.

These and other related documents may also be obtained by members of the public by contacting OSHA's Technical Data Center, telephone 202-523-7894.

A technical presentation will be made on behalf of the agency by Dr. Jerry Purswell, Director of OSHA Safety Standards Programs, and will include a discussion of both the "assured equipment grounding conductor program" alternative and Ground-Fault Circuit Interrupters. In accordance with the above court decision, the standard will continue to remain full in effect during this period of reconsideration.

In addition, the Advisory Committee will discuss residual matters relating to the identification of 29 CFR Part 1910 standards (general industry) specifically applicable to the construction industry (29 CFR Part 1926).

Written data, views, or arguments may be submitted, preferably with 20 copies to the Division of Consumer Affairs. Any such submissions received prior to the meeting will be provided to the members of the committee and will be included in the record of the meeting.

Anyone wishing to make an oral presentation should notify the Division of Consumer Affairs before the meeting. The request should state the amount of time desired, the capacity in which the person will appear, and a brief outline of the content of the presentation.

Oral presentations will be scheduled at the discretion of the chairman, depending on the extent to which time permits. Communications may be mailed to: Ken Hunt, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Third Street and Constitution Avenue NW., Washington, D.C. 20210, telephone 202-523-8024.

Materials provided to members of the Committee are available for inspection and copying at the above address.

Signed at Washington, D.C., this 25th day of July, 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

[FR Doc. 78-20958 Filed 7-27-78; 8:45 am]

[4510-28]

Office of the Secretary,

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted investigations pursuant to section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than——?

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Officer of Trade Adjustment Assistance, at the address shown below, not later than——?

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Signed at Washington, D.C., this 19th day of July, 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers or former worker of—	Location	Date received	Date of petition	Petition No.	Articles produced
Baran-Abrahman Hat Co., Inc. (United Hatters, Cap & Millinery Workers International Union).	Plainfield, N.J	July 17, 1978	July 10, 1978	TA-W-3,976	Roll up fishing/golf hats.
Crosrol, Inc. (workers)	Greenville, S.C	July 13, 1978	July 3, 1978	TA-W-3,977	Planetary collers used in the carding area of textile manufacturing.
Day Mines, Inc., Tamarack Mine (USWA).	Wallace, Idaho	July 17, 1978	July 7, 1978	TA-W-3,978	Mining of silver, lead, and zinc.
Fairfield Glove Co. (ACTWU)	Fairfield, Iowa	do	July 13, 1978	TA-W-3,979	Work gloves.
Do	Bonaparte, Iowa	do	do	TA-W-3,980	Do.
Guteri Specialty Corp., Simonds Steel Division (USWA).	Lockport, N.Y	July 13, 1978	July 12, 1978	TA-W-3,931	Specialty steel including saw steel.
Lake Center Industries, Parts Division (workers).	Winona, Minn	do	July 10, 1978	TA-W-3,932	Cosmetic mirrors.
Montco Manufacturing Co. (ACTWU)	Amsterdam, N.Y	July 17, 1978	June 28, 1978	TA-W-3,933	Contractor of women's knitted sportswear.
National Standard Co., Tire Textile Division (USWA).	Columbiana, Ala	July 13, 1978	July 12, 1978	TA-W-3,934	Steel tensile wire used for radio towers, bead wire, and side cut wire.
Torsion Balance Co. (workers)	Clifton, N.J	July 17, 1978	do	TA-W-3,935	Balance scales, pharmaceutical and student balances.

[FR Doc. 78-20959 Filed 7-27-78; 8:45 am]

[4510-28]

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted investigations pursuant to section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened

total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under title II, chapter 2, of the Act in accordance with the provisions of subpart B of 29 CFR 90. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 7, 1978.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 7, 1978.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Signed at Washington, D.C., this 13th day of July 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers or former workers of.—	Location	Date received	Date of petition	Petition No.	Articles produced
Allegro Fashions (ILGWU)	Lodi, N.J	July 10, 1978	July 7, 1978	TA-W-3,967	Ladies' garments.
Berkey-Keystone (workers)	Clifton, N.J	do	July 4, 1978	TA-W-3,968	Pocket instamatic cameras.
Interpace Corp., Lock Joint Pipe Division (attorney).	Somerville, N.J	July 7, 1978	July 5, 1978	TA-W-3,969	Steel high pressure sewer pipe.
Jean Fashions (ILGWU)	Paterson, N.J	July 10, 1978	July 6, 1978	TA-W-3,970	Ladies' dresses.
Morris White Fashions (International Leather Goods, Plastic and Novelty Workers' Union).	Scranton, Pa	July 13, 1978	July 10, 1978	TA-W-3,971	Ladies' handbags of vinyl and leather.
Neko Togs (ILGWU)	Paterson, N.J	July 10, 1978	July 6, 1978	TA-W-3,972	Children's dresses.
Poirette Corset Co., Inc. (ILGWU)	New York, N.Y	do	June 29, 1978	TA-W-3,973	Brassieres and girdles.
Titanium Enterprises (workers)	Green Cove Springs, Fla	July 5, 1978	July 2, 1978	TA-W-3,974	Mining of heavy minerals, dry mill to produce zircon, monazite, staurolite, ilmenite, leucoxene, and rutile.
F/V Victory II (workers)	Provincetown, Mass	July 10, 1978	June 30, 1978	TA-W-3,975	Catching and selling of fin fish, ground fish, other varieties.

[FR Doc, 78-20960 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2948]

A & F LEATHERS, INC., BOSTON, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2948: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 25, 1978, in response to a worker petition received on January 9, 1978, which was filed on behalf of workers and former workers producing leather coats and jackets at A & F Leathers, Inc., Boston, Mass.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (43 FR 7068). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of A & F Leathers, Inc., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Employment of production workers at A & F Leathers, Inc., increased 2.5 percent in 1977 compared to 1976 and increased 21.4 percent in the first 2 months of 1978 compared to the same period in 1977. Average weekly hours worked by production workers declined 2.8 percent from 1976 to 1977 and then increased 10.2 percent in the first 2 months of the 1978 compared to the same period in 1977. Section 223 of the Trade Act of 1974 states that a certification shall not apply to any worker last separated from employment more than 1 year before the date of the petition, which in this case is January 6, 1978.

From January 6, 1977, to the present, the only significant separations took place in the last week of 1977, a seasonal layoff which also took place in 1976 and 1975, and in the second week of February 1978 when the plant shut down due to a blizzard that affected Boston.

CONCLUSION

After careful review, I determine that all workers at A & F Leathers, Inc., are denied eligibility to apply for trade adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20964 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3127, TA-W-3407]

ANACONDA CO., WIRE AND CABLE DIVISION, GREAT FALLS, MONT., AND ANACONDA CO., REFINERY, GREAT FALLS, MONT.

Certifications Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3127 and TA-W-3407: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

Investigation TA-W-3127 was initiated on February 15, 1978, in response to a worker petition received on January 25, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers producing copper rod at the Great Falls, Mont., plant of the Wire and Cable Division of the Anaconda Co. On March 27, 1978, the investigation was expanded to include workers and former workers producing refined copper at the Great Falls, Mont., Refinery of the Anaconda Co.

Notices of investigations were published in the FEDERAL REGISTER on February 28, 1978 (43 FR 8209) for TA-W-3127 and on April 11, 1978 (43 FR 15205) for TA-W-3407. No public hearing was requested and none was held.

The information upon which the determinations were made was obtained principally from officials of the Anaconda Co., the U.S. Department of Commerce, the U.S. International Trade Commission, the U.S. Department of Interior, "The American Metal Market, Metals Week," industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of refined copper, including copper rod, increased from 147 thousand short tons in 1975 to 384 thousand short tons in 1976 and then increased to 391 thousand short tons in 1977.

The ratio of imported copper to domestic production increased from 8.6 percent in 1975 to 21.0 percent in 1976 and to 22.2 percent in 1977.

Imports of copper are affected by the differential between the domestic price of copper established by COMEX (Commodity Metal Exchange) and the price established by the LME (London Metal Exchange). When the LME price drops more than the estimated transportation cost of 5-8 cents per pound below the COMEX price, the demand for imported copper increases. During May and June 1977, the LME price was almost 11 cents per pound below the COMEX price and in July and August 1977, the LME price was almost 12 cents per pound below the COMEX price. At the same time, the abundant supply of copper stocks in the foreseeable future provides no reason for domestic consumers of copper to maintain ties with domestic producers for purposes of a guarantee against copper shortages. Consequently, in the third quarter of 1977, when many domestic copper producers curtailed production because of the depressed market price of copper, imports of refined copper increased 9.9 percent compared to the third quarter of 1976.

Price pressure from imported copper has reduced the ability to profitably mine domestic ore and convert it to copper concentrates and precipitates and then to refined copper. Industry sources state that the weighted average production costs of the lowest cost domestic copper mines are 63 cents per pound. The weighted average costs for the highest cost domestic copper mines are $1.05 per pound. Thus, with a domestic market price of 60 cents per pound, domestic producers lose, on the average, 3 to 45 cents on each pound of copper they choose to sell.

Anaconda's decision to layoff workers and reduce its operations was based mainly on an attempt to minimize losses which the company could not avoid were it to run at normal production levels at the current market prices for copper.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with refined copper and copper rod produced by the Great Falls, Mont., plant of the Wire and Cable Division of the Anaconda Co. and the Great Falls, Mont., Refinery of the Anaconda Co. contributed importantly to the decline in sales and production and to the total or partial separation of workers at those plants. In accordance with the provisions of the act, I make the following certifications:

All workers at the Great Falls, Mont., plant of the Wire and Cable Division of the Anaconda Co. who became totally or partially separated from employment on or after July 27, 1977, are eligible to apply for adjustment assistance under title II, Chapter 2 of the Trade Act of 1974; and

All workers at the Great Falls, Mont., Refinery of the Anaconda Co. who became totally or partially separated from employment on or after July 27, 1977, are eligible to apply for adjustment assistance under title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20965 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3160; TA-W-3162; TA-W-3358]

ARROW CLOTHES, INC., NEW YORK, N.Y., ET AL.

Certifications Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3160, 3162, 3358: Investigations regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

Investigations TA-W-3160 and TA-W-3162 were initiated on February 21, 1978, in response to a worker petition received on February 6, 1978, which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers producing men's tailored suits and sport jackets at Arrow Clothes, Inc., and producing men's trousers at Bruce Ramsey, Ltd., New York, N.Y. On March 20, 1978, the investigation was expanded to include workers and former workers producing men's tailored suits, sport jackets, and trousers at Andrew Pallack & Co., Inc., New York, N.Y. (TA-W-3358). All three companies operate in an integrated fashion.

Notices of investigation were published in the FEDERAL REGISTER on March 3, 1978 (43 FR 8864) for TA-W-3160 and TA-W-3162 and on April 7, 1978 (43 FR 14776) for TA-W-3358. No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Andrew Pallack & Co., Inc., Arrow Clothes, Inc., Bruce Ramsey, Ltd., their customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of men's tailored suits increased from 3,106 thousand units in 1975 to 3,562 thousand units in 1976 and to 4,091 thousand units in 1977. Imports of men's suits relative to domestic production increased from 18.3 percent in 1975 to 20.0 percent in 1976.

Imports of men's and boys' tailored dress coats and sportcoats increased from 5,465 thousand units in 1975 to 6,965 thousand units in 1976 and then decreased to 6,269 thousand units in 1977. The ratio of imports to domestic production declined from 28.2 percent in 1975 to 25.3 percent in 1976.

Imports of men's and boys' dress and sport trousers and shorts increased from 55,508 thousand units in 1975 to 73,209 thousand units in 1976 and to 76,419 thousand units in 1977. Imports of trousers and shorts relative to domestic production increased from 34.1 percent in 1975 to 41.9 percent in 1976.

A Department survey of customers of Andrew Pallack & Co., revealed that customers increased purchases of imports while decreasing purchases from Andrew Pallack from 1975 to 1976 and from 1976 to 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the men's suits, sportcoats, and slacks produced at Andrew Pallack & Co., Inc., Arrow Clothes, Inc., and Bruce Ramsey, Ltd., New York, N.Y., contributed importantly to the decline in sales and production and to the total or partial separation of workers at those firms. In accordance with the provisions of the act, I make the following certifications:

All workers at Arrow Clothes, Inc., New York, N.Y. (TA-W-3160) who became totally or partially separated from employment on or after January 12, 1978, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974; and

All workers at Bruce Ramsey, Ltd., New York, N.Y. (TA-W-3162) who became totally or partially separated from employment on or after January 12, 1978, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974; and

All workers at Andrew Pallack & Co., Inc., New York, N.Y. (TA-W-3358) who became totally or partially separated from employment on or after January 12, 1978, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20966 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2512]

BELL & HOWELL COMMUNICATIONS CO. AND COMPOSITE MICROCIRCUITS, INC. BURLINGTON, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2512: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on October 27, 1977, in response to a worker petition received on October 25, 1977, which was filed on behalf of workers and former workers producing communications equipment, surveillance equipment, and decoders at Bell & Howell Communications Co. (BHCC), Burlington Mass.

The investigation was expanded to include Composite Microcircuits, Inc. (CMI), a wholly owned subsidiary of BHCC that is located at the Burlington facilities and supplies BHCC with component parts.

The notice of investigation was published in the FEDERAL REGISTER on November 15, 1977 (42 FR 59132). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Bell & Howell, BHCC, CMI, their customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the total or partial separations, or threat thereof, and to the absolute decline in sales or production.

BHCC produced one-way paging receivers, portable transceivers, alarm systems, and special surveillance equipment. Pagers were sold to commercial customers and represented the majority of sales. Transceivers, alarms, and surveillance equipment were sold to State and local police departments and Federal agencies. CMI supplied BHCC with microcircuit assemblies used in the manufacture of communications equipment.

Microcircuits produced at CMI were used almost entirely in the production of communications equipment at BHCC.

U.S. imports of radio paging equipment increased from 2.0 million dollars in 1975 to 6.8 million dollars in 1976 and to 14.2 million dollars in 1977. The ratio of imports to domestic production increased from 12.8 percent in 1976 to 24.6 percent in 1977.

A sample of customers of BHCC was surveyed regarding their purchases of communications equipment. None of the customers surveyed, who reduced purchases from BHCC, purchased any imports.

CONCLUSION

After careful review, I determined that all workers at Bell & Howell Communications Co., Inc., Burlington, Mass., and Composite Microcircuits, Burlington Mass. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20967 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2649]

BUCYRUS-ERIE CO., GLASSPORT, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2649: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on November 23, 1977, in response to a worker petition received on November 14, 1977, which was filed by the United Steelworkers of America on behalf of all workers producing steel castings at the Glassport, Pa., plant of Bucyrus-Erie Co.

The notice of investigation was published in the FEDERAL REGISTER on December 6, 1977 (42 FR 61695). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Bucyrus-Erie Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment as-

sistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the decline in sales or production.

It is believed that imports of heavy steel castings of the type mostly produced by Bucyrus-Erie are well below 5 percent of domestic production.

The Department conducted a survey of some of the companies which purchased castings from Bucyrus-Erie over the past several years. Most of the customers responding to the survey did not purchase any imported castings. Those companies which did purchase some imported castings indicated that those castings were not available from domestic manufacturers.

CONCLUSION

After careful review, I determine that all workers of the Glassport, Pa., plant of Bucyrus-Erie Co. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20968 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3716]

BUFFALO TANK DIVISION, BETHLEHEM STEEL CORP., HALLENDALE BEACH, FLA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3716: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on May 16, 1978, in response to a worker petition received on May 5, 1978, which was filed by the United Steelworkers of America on behalf of all workers producing standard industrial tanks at the Buffalo Tank Division of Bethlehem Steel Corp., Hallendale Beach, Fla.

The Notice of investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27923). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Bethlehem Steel Corp., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The investigation revealed that U.S. imports of metal tanks and vessels decreased from $14,500,000 in 1976 to $8,600,000 in 1977. The ratio of imports to domestic shipments decreased from 0.67 percent in 1976 to 0.29 percent in 1977. During the 5-year period from 1973 through 1977, market penetration of imports was less than 0.7 percent annually.

The Hallendale Beach, Fla., plant of the Buffalo Tank Division of Bethlehem Steel Corp. produced standard industrial tanks for gasoline and water storage. The plant closed on March 31, 1978, primarily due to the lack of business. There are no prospects for reopening.

CONCLUSION

After careful review I determine that all workers of the Buffalo Tank Division of Bethlehem Steel Corp., Hallendale Beach, Fla., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July, 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20969 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3799]

BUFFALO TANK DIVISION, BETHLEHEM STEEL CORP., DUNELLEN, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3799: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on June 5, 1978, in response to a worker petition received on May 26, 1978, which was filed by the United Steelworkers of America on behalf of all workers producing standard and specialized tanks at the Dunellen, N.J., plant of the Buffalo Tank Division, Bethlehem Steel Corp.

The Notice of investigation was published in the Federal Register on June 20, 1978 (43 FR 26498). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Bethlehem Steel Corp., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The investigation revealed that U.S. imports of metal tanks and vessels decreased from $14,500,000 in 1976 to $8,600,000 in 1977. The ratio of imports to domestic shipments also decreased from 0.67 percent in 1976 to 0.29 percent in 1977. During the 5-year period from period from 1973 through 1977, market penetration of imports was less than 0.7 percent annually.

The Dunellen, N.J., plant of the Buffalo Tank Division of Bethlehem Steel Corp. produces standard and some specialized tanks for storage purposes.

CONCLUSION

After careful review, I determine that all workers of the Buffalo Tank Division of Bethlehem Steel Corp., Dunellen, N.J., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20970 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3728]

FREDERICK H. BURNHAM CO., MICHIGAN CITY, IND.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on May 18, 1978, in response to a worker petition received on that date which was filed by the Amalgamated Clothing & Textile Workers Union on behalf of workers and former workers producing work gloves at the Frederick H. Burnham Co., Michigan City, Ind.

Notice of the investigation was published in the FEDERAL REGISTER on June 13, 1978 (43 FR 25498). No public hearing was requested and none was held.

The petitioner in this case requested withdrawal of the petition on June 12, 1978. The investigation is therefore terminated.

Signed at Washington, D.C. this 17th day of July 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-20971 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3727]

BURNHAM-EDINA MANUFACTURING CO., EDINA, MO.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on May 18, 1978 in response to a worker petition received on that date which was filed by the Amalgamated Clothing & Textile Workers Union on behalf of workers and former workers producing work and dress gloves and mittens at the Burnham-Edina Manufacturing Co., Edina, Mo.

Notice of the investigation was published in the FEDERAL REGISTER on June 13, 1978 (43 FR 25498). No public hearing was requested and none was held.

The petitioner in this case requested withdrawal of the petition on June 12, 1978. The investigation is therefore terminated.

Signed at Washington, D.C., this 17th day of July 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-20972 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3273]

CRESTLANE CLOTHES, INC., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3273: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 1, 1978, in response to a worker petition received on February 21, 1978, which was filed by the Amalgamated Clothing & Textile Workers' Union on behalf of workers and former workers producing men's suits at Crestlane Clothes, Inc., New York, N.Y.

The notice of investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10649). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Crestlane Clothes, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

Imports of men's and boys' tailored suits increased from 3,106 thousand units in 1975 to 3,562 thousand units in 1976 and to 4,091 thousand units in 1977. Imports of men's and boys' tailored suits relative to domestic production increased from 18.3 percent in 1975 to 20.0 percent in 1976.

A survey of customers of Crestlane Clothes, Inc., revealed that customers had decreased purchases of men's suits from Crestlane and increased purchases of imports in 1977 compared to 1976.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with men's suits produced by Crestlane Clothes, Inc., New York, N.Y., contributed importantly to the decline in sales and production and to the total or partial separation of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers at Crestlane Clothes, Inc., of New York, N.Y., who became totally or partially separated from employment on or after March 25, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20973 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3436]

ETHEL MANUFACTURING, LINDENHURST, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3436: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 28, 1978 in response to a worker petition received on March 13, 1978, which was filed on behalf of workers and former workers producing ladies' coats at Ethel Manufacturing, Lindenhurst, N.Y. The investigation revealed that ladies' raincoats are also produced.

The notice of investigation was published in the FEDERAL REGISTER on April 11, 1978 (43 FR 15205). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Ethel Manufacturing, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's, misses' and children's coats and jackets increased from 1,517 thousand dozen in 1975 to 2,252 thousand dozen in 1976 and to 2,723 thousand dozen in 1977. Imports relative to U.S. production increased from 38.9 percent in 1975 to 57.5 percent in 1976.

U.S. imports of women's, misses', and children's raincoats increased from 191 thousand dozen in 1975 to 261 thousand dozen in 1976 and then declined to 242 thousand dozen in 1977. The ratio of imported raincoats to domestic production increased from 36.8 percent in 1975 to 50.4 percent in 1976.

Ethel Manufacturing is a garment contractor that sews ladies' coats and

raincoats for one manufacturer. A survey of the customers of that manufacturer revealed that many customers increased purchases of imported ladies' coats and raincoats while decreasing purchasers from the manufacturer from 1976 to 1977. The manufacturer also began to import ladies raincoats in 1977, decreasing its utilization of Ethel Manufacturing.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the ladies' coats and raincoats produced at Ethel Manufacturing, Lindenhurst, N.Y. contributed importantly to the decline in sales or production and to the total or partial separation of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers at Ethel Manufacturing, Lindenhurst, N.Y. who became totally or partially separated from employment on or after March 11, 1977 are eligible to apply for adjustment assistance under title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20974 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3278]

GENERAL ELECTRIC CO. TUBE PRODUCTS DEPARTMENT OWENSBORO, KY.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In Accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3278: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 1, 1978 in response to a worker petition received on February 21, 1978 which was filed by the Allied Industrial Workers of America on behalf of workers and former workers producing electronic receiving tubes and mounts at the 9th Street and Old Hartford Road, Owensboro, KY plants of the Tube Products Department, General Electric Co.

The Notice of Investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10649). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of General Electric Co., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

On March 31, 1976, the Department of Labor issued a certification of eligibility to apply for adjustment assistance for employees producing electronic receiving tubes and mounts at the Owensboro, KY plants of General Electric Co. (TA-W-272). That certification expired March 31, 1978.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

The Department's investigation revealed that imports of electronic receiving tubes (including finished tubes, unfinished tubes, and mounts) increased in each year from 1975 to 1977. Imports increased from 52 million units in 1976 to 54 million units and increased from 12.6 million units in the first quarter of 1977 to 13.0 million units in the first quarter of 1978. The ratio of imports to domestic production of electronic receiving tubes increased in each year from 1975 to 1977, increasing from 54.2 percent in 1976 to 68.4 percent in 1977, and increasing from 55.8 percent in the first quarter of 1977 to 63.4 percent in the first quarter of 1978.

General Electric Co.'s imports of electronic receiving tube mounts increased from 1975 to 1976, from 1976 to 1977, and in the first quarter of 1978 compared to the same period in 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with electronic receiving tubes and mounts produced at the Owensboro, Ky plants of General Electric Co. contributed importantly to the decline in sales and production and to the separation of workers at those plants. In accordance with the provisions of the act, I make the following certification:

All workers who are engaged in the production of electronic receiving tubes and mounts at the 9th Street and Old Hartford Road, Owensboro, KY plants, Tube Products Department of General Electric Co., who became totally or partially separated from employment on or after March 31, 1978 are certified eligible to apply for trade adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20975 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2974]

GIRLTOWN CORP., BOSTON, MASS.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2974: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 30, 1978, in response to a worker petition received on January 12, 1978, which was filed on behalf of Workers and former workers producing girls' sportswear at Girltown Corp., Boston, Mass.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (43 FR 7069). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Girltown Corp., its customers, the U.S. Department of Commerce, the National Cotton Council of America, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's, misses', and children's slacks, shorts, blouses, and skirts increased absolutely and relative to domestic production in 1976 over 1975 and increased absolutely in 1977 over 1976.

U.S. imports of women's, misses', and children's skirts increased absolutely and relative to domestic production in 1976 over 1975 and decreased absolutely from 1976 to 1977.

Girltown imports of products competitive with those produced at the Girltown facility have increased in 1977 over 1976 and in January 1978 over January 1977. Girltown contracts approximately one third of its work overseas.

Some customers of Girltown who were surveyed indicated they have decreased purchases from Girltown and increased imports of girls' sportswear in 1976 over 1975 and in 1977 over 1976.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with girls' sportswear manufactured at Girltown Corp., Boston, Mass., contributed importantly to the decline in sales or production and to the total or partial separation of the workers of that plant. In accordance with the provision of the act I make the following certification:

All workers of Girltown Corp., Boston, Mass., who became totally or partially separated from employment on or after January 9, 1977, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20976 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3326]

GOLDBERG & SUSSELES, INC., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3326: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 9, 1978, in response to a worker petition received on February 28, 1978, which was filed on behalf of former workers producing men's and boys' belts at Goldberg & Susseles, Inc., New York, N.Y.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Goldberg & Susseles, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. The investigation has revealed that all of the requirements have been met.

Imports of leather belts increased from 8,199 thousand dollars in 1975 to 14,845 thousand dollars in 1976. Imports increased from 10,609 thousand dollars during January-September 1976 to 12,537 thousand dollars during January-September 1977. The ratio of imports to domestic production increased from 10.3 percent in 1975 to 18.2 percent in 1976.

Customers surveyed who decreased purchases from Goldberg & Susseles, Inc., in 1976 and 1977 increased purchases of imported men's and boys' belts during the same period.

CONCLUSION

After careful review, I conclude that increases of imports of articles like or directly competitive with men's and boys' belts produced at Goldberg & Susseles, Inc., New York, N.Y., contributed importantly to declines in sales and production and to the total or partial separation of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers of Goldberg & Susseles, Inc., New York, N.Y., who became totally or partially separated from employment on or after February 23, 1977, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-20977 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3119]

IMPALA TEXTILE, INC., NEW YORK, N.Y.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3119: Investigation regarding certification of eligibility to apply for adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 13, 1978, in response to a worker petition received on January 31, 1978, which was filed on behalf of workers and former workers engaged in textile converting at Impala Textile, New York, N.Y.

The notice of investigation was published in the FEDERAL REGISTER on February 28, 1978 (43 FR 8207). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Impala Textile, Inc., its customers, the U.S. International Trade Commission, U.S. Department of Commerce, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of finished fabric increased from 408 million square yards in 1975 to 464 million square yards in 1976 and then declined to 453 million square yards in 1977. The ratio of imports to domestic production rose from 1.6 percent in 1975 to 1.8 percent in 1976.

None of the customers of Impala Textile who were surveyed had purchased imported finished fabric in 1976 or 1977.

Imports of apparel which incorporate finished fabric of the same origin are not like or directly competitive with finished fabric within the meaning of section 222(3) of the Trade Act of 1974.

CONCLUSION

After careful review of the facts obtained in the investigation, I determine that all workers at Impala Textile, Inc., New York, N.Y., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20978 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2902]

JEANS & GAUVIN PATTERN CO., INC., HAVERHILL, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2902: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 11, 1978, in response to a worker petition received on December 19, 1977, which was filed on behalf of workers and former workers producing

shoe patterns at Jeans & Gauvin Pattern Co., Inc., Haverhill, Mass.

The notice of investigation was published in the FEDERAL REGISTER on January 27, 1978 (43 FR 3776). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jeans & Gauvin Pattern Co., Inc., its customers, the U.S. Department of Commerce, the American Footwear Industries Association, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of shoe patterns are not separately identifiable in the official trade statistics. A Department survey of shoe pattern manufacturers, purchasers, and commodity analysts has shown imports of these products to be negligible.

Imports of finished shoes are not "like or directly competitive" with shoe patterns within the meaning of section 222 of the Trade Act of 1974.

A survey of customers of Jeans & Gauvin Pattern Co., Inc., indicated that none of the customers purchased imported shoe patterns from foreign sources during 1976 or 1977.

CONCLUSION

After careful review, I determine that all workers at Jeans & Gauvin Pattern Co., Inc., Haverhill, Mass., are denied eligibility to apply for trade adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20979 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3205]

JOLIET-WAUKEGAN WORKS, UNITED STATES STEEL CORP., JOLIET, ILL.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3205: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 22, 1978, in response to a worker petition received on January 16, 1978, which was filed by the United Steelworkers of America on behalf of all workers engaged in employment related to the production of carbon steel rods and merchant wire (wire and wire products) at the Joliet, Ill., plant of the Joliet-Waukegan Works of the United States Steel Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on March 3, 1978 (43 FR 8863). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the United States Steel Corp. and its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. With respect to workers engaged in employment related to the production of wire and wire products, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both of such firm or subdivision have decreased absolutely;

Plant sales of wire and wire products increased in quantity in 1977 compared to 1976 and continued to increase in the first 2 months of 1978 compared to the like 1977 period. Plant sales approximate plant production.

With respect to workers engaged in employment related to the production of wire rod, all of the criteria have been met.

A significant percentage of the Joliet plant's 1977 production of wire rod was shipped to the Waukegan, Ill., plant of the United States Steel Corp. where it was used in the production of carbon steel wire. All workers of the Waukegan, Ill., plant of the United States Steel Corp. who became totally or partially separated from employment on or after November 15, 1976, have previously been certified eligible to apply for adjustment assistance benefits. See Department case file TA-W-2836.

CONCLUSION

After careful review, I determined that all workers of the Joliet, Ill., plant of the Joliet-Waukegan Works of the United States Steel Corp. engaged in employment related to the production of wire and wire products are not eligible to apply for adjustment assistance benefits.

I further conclude that increased imports of articles like or directly competitive with the carbon steel wire produced at the Waukegan, Ill., plant of the United States Steel Corp. have contributed importantly to the total or partial separation of workers engaged in the production of wire rod, and to the decline in sales or production of wire rod, at the Joliet, Ill., plant of the Joliet-Waukegan Works of the United States Steel Corp. as required for certification under the Trade Act of 1974. In accordance with the provisions of the act, I make the following certification:

All workers of the Joliet, Ill., plant of the Joliet-Waukegan Works of the United States Steel Corp. engaged in employment related to the production of wire rod who became totally or partially separated from employment on or after January 12, 1977, are eligible to apply for adjustment assistance benefits under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20980 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2833]

JONES & LAUGHLIN STEEL CORP., PITTSBURGH WORKS, PITTSBURGH, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2833: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 3, 1978 in response to a worker petition received on December 8, 1977, which was filed by the United Steelworkers of America on behalf of workers producing cold finished bars, hot rolled bars and shapes, cold rolled

sheet and galvanized sheet at the Pittsburgh Works and Hazelwood Works of Jones & Laughlin Steel Corp., Pittsburgh, Pa. During the course of the investigation it was found that workers at Hazelwood Works, producing hot rolled sheet and plate were certified on August 12, 1977 (TA-W-1479).

The Notice of Investigation was published in the FEDERAL REGISTER on January 17, 1978 (43 FR 2459). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jones & Laughlin Steel Corp., its customers, the U.S. International Trade Commission, the U.S. Department of Commerce, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligiblity requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met.

that sales of production, or both, of the firm or subdivision have decreased absolutely.

On August 12, 1977 the Department issued a certification of eligibility to apply for adjustment assistance applicable to workers engaged in employment related to the production of hot rolled plate and hot rolled sheet at the Pittsburgh Works. Total shipments of the remaining products of the Pittsburgh Works—cold rolled sheets, galvanized sheets, hot rolled bars and shapes, and cold finished bars—and shipments of each of the four products increased in 1976 compared to 1975 and in 1977 compared to 1976. Shipments equal production.

CONCLUSION

After careful review, I determine that workers engaged in employment related to the production of cold rolled sheets, galvanized sheets, hot rolled bars and shapes and cold finished bars at the Pittsburgh Works of Jones & Laughlin Steel Corp., Pittsburgh, Pa. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20981 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3086]

JONES & LAUGHLIN STEEL CORP., McKINLEY MINE, McKINLEY, MINN.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3086: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 7, 1978 in response to a worker petition received on January 26, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers engaged in the production of iron ore at the Minnesota Ore Division of Jones & Laughlin Steel Corp., McKinley, Minn. The McKinley Mine is part of Jones & Laughlin's Northwest Ore Division. Another facility of the Northwest Ore Division, the Hill Annex Mine and Plant, Calumet, Minn. is currently under investigation (TA-W-3087).

The Notice of Investigation was published in the FEDERAL REGISTER on February 24, 1978 (43 FR 7744). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jones & Laughlin Steel Corp., the U.S. International Trade Commission, the U.S. Department of Commerce, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

The McKinley Mine ships iron ore during the period from May through October. Shipments equal production. The McKinley Mine ships iron ore to the basic steelmaking facilities of Jones & Laughlin Steel Corp. and to manufacturing facilities not affiliated with Jones & Laughlin. Total shipments of iron ore pellets by the McKinley Mine increased from 1976 to 1977. Shipments to Jones & Laughlin's steelmaking facilities as well as shipments to the other manufacturing facilities increased from 1976 to 1977.

CONCLUSION

After careful review, I determine that all workers of the Northwest Ore Division of Jones & Laughlin Steel Corp., McKinley Mine and Plant, McKinley, Minn. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20982 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3087]

JONES AND LAUGHLIN STEEL CORP., HILL ANNEX MINE, CALUMET, MINN.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3087: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 7, 1978, in response to a worker petition received on January 26, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers engaged in the production of iron ore at the Hill Annex Mine and Plant of Jones and Laughlin Steel Corp., Calumet, Minn. The Hill Annex Mine and Plant are part of Jones and Laughlin's Northwest Ore Division. Another facility of the Northwest Ore Division, the McKinley Mine and Plant, McKinley, Minn., is currently under investigation (TA-W-3086).

The Notice of Investigation was published in the FEDERAL REGISTER on February 24, 1978 (43 FR 7744). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jones and Laughlin Steel Corp., the U.S. International Trade Commission, the U.S. Department of Commerce, the U.S. Department of the Interior, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that sales or production, or both, of the firm or subdivision have decreased absolutely.

The Hill Annex Mine ships iron ore during the period from May through

October. Shipments equal production. The Hill Annex Mine ships iron ore to the basic steelmaking facilities of Jones and Laughlin Steel Corp. and to manufacturing facilities not affiliated with Jones and Laughlin. Total shipments of iron ore pellets by the Hill Annex Mine increased from 1976 to 1977. Shipment to Jones and Laughlin's steelmaking facilities as well as shipments to the other manufacturing facilities increased from 1976 to 1977.

CONCLUSION

After careful review, I determine that all workers of the Northwest Ore Division of Jones and Laughlin Steel Corp., Hill Annex Mine and Plant, Calumet, Minn., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-20983 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3233]

LAND MANUFACTURING CO., NEWARK, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3233: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 23, 1978 in response to a worker petition received on February 7, 1978, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies coats and raincoats at Land Manufacturing Co., Newark, N.J. During the course of the investigation it was determined that only ladies raincoats were produced at the company.

The notice of investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10650). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Land Manufacturing Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports women's, misses' and children's raincoats have increased in 1975 to 191 thousand dozens, increased in 1976 to 261 thousand dozen, and decreased in 1977 to 242 thousand dozens.

Imports of all-weather coats are included in import figures for women's and misses' coats and jackets. U.S. imports in this category increased from 1,517 thousand in 1975 to 2,252 thousand dozens in 1976 and increased to 2,723 thousand dozens in 1977. The ratio of imports to domestic production increased from 38.9 percent in 1975 to 57.5 percent in 1976.

Lanson Industries, the sole manufacturer for whom Land Manufacturing Co. produced ladies raincoats increased purchases of imported ladies raincoats in 1977 over 1976 while decreasing purchases with Land Manufacturing during the same period.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with ladies' raincoats produced at Land Manufacturing Co., Newark, N.J., contributed importantly to the decline in sales or production and to the total or partial separation of the workers of that plant. In accordance with the provisions of the act, I make the following certification:

All workers of Land Manufacturing Co., New York, N.Y. who became totally or partially separated from employment on or after February 2, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-20984 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3468]

McCLURE STEEL MANUFACTURING, BLAIRSVILLE, GA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3468: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on April 4, 1978, in response to a worker petition received on March 27, 1978, which was filed on behalf of four individuals producing wrought iron items at McClure Steel Manufacturing, Blairsville, Ga.

The notice of investigation was published in the FEDERAL REGISTER on April 28, 1978 (43 FR 18360). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from the partners in McClure Steel Manufacturing and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

That a significant number of proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

The basic question in this case is whether the four individuals are "workers," employed by an employer for wages, within the meaning of the Trade Act of 1974.

The four individuals are partners in McClure Steel Manufacturing and are also the only workers at the firm. The partners pay themselves by making periodic withdrawals from the profits of McClure Steel Manufacturing. Rather than "wages," defined at 29 CFR 91.3 all "all compensation for employment with an employer," the partners' withdrawals from the profits of McClure Steel Manufacturing Co. serve as "remuneration"—defined in section 247 of the act as "wages and net earnings derived from services performed as a self-employed individual."

Section 232(a) of the Trade Act of 1974 draws a clear distinction between "remuneration" for services performed as a self-employed individual, and "wages." An individual whose weekly earnings are derived solely from remuneration as opposed to wages would not be eligible to receive trade readjustment allowances.

Although the Trade Act does not contain a definition of the term "worker" for purposes of section 222(1), it is clear that the intent of the act is to cover individuals earning compensation, in the form of wages, in return for employment with an employer.

After careful review of the issues, I have determined that as self-employed individuals the four partners of McClure Steel Manufacturing Co., Blairsville, Ga., are not workers employed by an employer for wages within the meaning of section 222(1) and section

232(a) of the Trade Act of 1974, and therefore are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20985 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3235]

MICKEY BLUMFIELD INC., COMMACK, N.Y., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3235: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 23, 1978, in response to a worker petition received on February 8, 1978, which was filed on behalf of all workers producing ladies' coats and raincoats at Mickey Blumfield, Inc., Commack, N.Y. The investigation revealed the company produces ladies' cloth, wool, leather, and suede coats. No raincoats are produced.

The notice of investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10650). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Mickey Blumfield Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the group eligibility requirements have been met.

Imports of women's, misses', and children's coats and jackets increased 20.9 percent from 2,252,000 dozen in 1976 to 2,723,000 dozen in 1977.

The value of imports of leather coats and jackets increased from $177.8 million in 1976 to $186.4 million in 1977. Market penetration of imports was 85.3 percent in 1977.

Mickey Blumfield began importing leather and suede coats in 1977. Imports continued to increase in January 1978 compared to January 1977.

The Department conducted a survey of some of the customers buying ladies' cloth, wool, leather, and suede coats from Mickey Blumfield Inc. Several of the customers indicated they reduced purchases from Mickey Blumfield and increased purchases of imports in 1976 and 1977 compared to the previous year. Some of the respondents also indicated that imports have adversely affected the domestic market.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' cloth, wool, leather, and suede coats produced at Mickey Blumfield Inc., Commack, N.Y., and their sales and cutting unit in New York, N.Y., contributed importantly to the declines in sales and production and to the total or partial separation of the workers of those plants. In accordance with the provisions of the Act, I make the following certification:

All workers of Mickey Blumfield Inc., Commack, N.Y., and at 519 Eighth Avenue, New York, N.Y., who became totally or partially separated from employment on or after February 3, 1977, are eligible to apply for adjustment assistance under title II, chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-20986 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3283]

NEW B GARMENT CO., NEW BETHLEHEM, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3283: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 1, 1978, in response to a worker petition received on February 22, 1978, which was filed by the Amalgamated Clothing & Textile Workers' Union on behalf of all workers producing ladies' and boys' knit tops and shirts at the New Bethlehem, Pa., plant of New B Garment Co.

The notice of investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10649). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of New B Garment Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Regardless of whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with the articles produced by such workers' firm or an appropriate subdivision thereof contributed importantly to such total or partial separation, or threat thereof, and to such decline in sales or production.

The Department conducted separate surveys of some of the manufacturers for which New B Garment produces as a contractor and of some of the customers that purchase garments directly from New B Garment. None of the manufacturers who responded to the survey purchased imported ladies' or boys' knit tops or shirts in 1976 or 1977. Most of the respondents purchasing knit tops under the private label reported increased purchases from New B Garment in 1977 compared to 1976.

CONCLUSION

After careful review, I determine that all workers of the New B Garment Co., New Bethlehem, Pa., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-20987 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3239]

PENNSYLVANIA ENGINEERING CORP., NEW CASTLE, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3239: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 23, 1978, in response to a worker petition received on February

7, 1978, which was filed by the United Automobile, Aerospace & Agricultural Implement Workers of America (UAW) on behalf of workers and former workers producing basic oxygen furnaces, ladles, and cylinder railroad cars at the New Castle, Pa., plant of Pennsylvania Engineering Corp.

The Department's investigation revealed that the New Castle plant of Pennsylvania Engineering Corp. also produces fume gas hoods and other equipment used in the steel industry.

The notice of investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10650). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Pennsylvania Engineering Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibilty to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that imports of basic oxygen furnaces, ladles, cylinder railroad cars, and fume gas hoods by customers of Pennsylvania Engineering Corp. were small and declining during the period from 1975 through 1977. None of the customers responding to the Department's survey reported any purchases of imports of these items in 1977.

Similarly, imported steel cannot be considered like or directly competitive with equipment used in the steelmaking process. Imports of such equipment must be considered in determining import injury to workers producing basic oxygen furnaces, ladles, cylinder railroad cars, and fume gas hoods.

CONCLUSION

After careful review, I determine that all workers at the New Castle, Pa., plant of Pennsylvania Engineering Corp. are denied eligibility to apply for adjustment assistance under title II, chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20988 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3200]

PRINTS-N-THINGS, INC., NEW YORK, N.Y.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3200: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 22, 1978, in response to a worker petition received on November 15, 1977, which was filed on behalf of workers formerly producing printed fabric at Prints-N-Things, Inc., New York, N.Y.

The notice of investigation was published in the FEDERAL REGISTER on March 3, 1978 (43 FR 8863). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Prints-N-Things, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of finished fabric increased from 408 million square yards in 1975 to 464 million square years in 1976 before decreasing to 453 million square yards in 1977.

The ratio of imported finished fabric to domestic production was 1.6 percent in 1975 and increased to 1.8 percent in 1976.

The petitioners allege that increased imports of apparel contributed importantly to the declines in sales and production of finished fabric and resulting unemployment at Prints-N-Things. However, apparel is not "like or directly competitive" with finished fabric within the meaning of section 222 of the Trade Act. Imports of fabric must be considered in determining import injury to workers producing finished fabric.

A survey of customers who purchased finished fabric from Prints-N-Things, Inc., indicated that these customers did not purchase imported finished fabric in 1975, 1976, or 1977.

CONCLUSION

After careful review, I determine that all workers at Prints-N-Things, Inc., New York, N.Y., are denied eligibility to apply for trade adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20989 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2518, 2639]

RANI-MERONA CORP., LOWELL AND HAVERHILL, MASS.

Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2518 and 2639: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigations were initiated on October 27, 1977 and November 21, 1977 in response to worker petitions received on October 25, 1977 and November 11, 1977, respectively, which were filed on behalf of workers and former workers stitching uppers for shoes at the Lowell and Haverhill, Mass. plants of Rani-Merona Corp.

The notices of investigation were published in the FEDERAL REGISTER on November 15, 1977 (42 FR 39132) and December 6, 1977 (42 FR 61696). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Rani-Merona Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the

other criteria have been met the following criterion has not been met.

That such increased imports of articles like or directly competitive with articles produced by the firm or appropriate subdivisions have contributed importantly to the separations, or threat thereof, and to the decreases in sales or production.

The Department's investigation revealed that the petitioning group of workers were engaged in the production of shoe uppers at the Lowell and Haverhill, Mass. plants of Rani-Merona Corp. These shoe uppers were sold to one independent shoe manufacturer until September 1977.

Imports of footwear uppers are negligible and did not contribute importantly to any dislocations at the firm. The ratio of imports to domestic production was less than one percent from 1972 through the first half of 1977. Imports of shoes which incorporate uppers are not "like or directly competitive" with uppers within the meaning of section 223(3) of the Trade Act of 1974.

The only customer that purchased shoe uppers from the Lowell and Haverhill, Mass. plants of the Rani-Merona Corp. indicated that it did not purchase imported shoe uppers.

From November 1977 through January 1978, the Lowell and Haverhill plants supplied uppers to the Portsmouth, New Hampshire plant of Rani-Merona which produced finished footwear. The Rani-Merona Corp. terminated all footwear production after 2 months in operation.

CONCLUSION

After careful review I determine that all workers at the Lowell and Haverhill, Mass. plants of Rani-Merona Corp. are denied eligibility to apply for trade adjustment assistance under title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20990 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3135]

RANI-MERONA OF NEW HAMPSHIRE, INC., PORTSMOUTH, N.H.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3135: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on February 15, 1978, in response to a worker petition received on January 2, 1978, which was filed on behalf of workers and former workers producing athletic footwear at Rani-Merona of New Hampshire, Inc., Portsmouth, N.H.

The notice of investigation was published in the FEDERAL REGISTER on February 28, 1978 (43 FR 8209). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Rani-Merona of New Hampshire, Inc., its customer, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that Rani-Merona of New Hampshire, Inc., started producing athletic footwear in November 1977 and ceased production in January 1978. The Rani-Merona Corp. terminated all footwear production after 2 months in operation.

CONCLUSION

After careful review I determine that all workers of Rani-Merona of New Hampshire, Inc., Portsmouth, N.H., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20991 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3298]

RONSON CORP. OF DELAWARE, OGLETOWN, DEL.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3298: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 2, 1978, in response to a worker petition received on February 24, 1978, which was filed by the International Association of Machinists & Aerospace Workers on behalf of workers and former workers producing lighters, hairdryers, electric can openers, electric knives, and blenders at Ronson Corp. of Delaware, Ogletown, Del. The investigation revealed that, primarily, lighters and electric shavers were produced. The Ogletown plant closed in April 1978.

The notice of investigation was published in the FEDERAL REGISTER on March 17, 1978 (43 FR 11276). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Ronson Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

Imports of disposable lighters increased both absolutely and relative to domestic production from 1975 to 1976 and from 1976 to 1977.

Imports of electric shavers increased absolutely from 1976 to 1977.

Ronson Corp. imports disposable and refillable lighters. Sales of Ronson's imported lighters increased both absolutely (in value) and relative to their sales of domestically produced lighters from 1976 to 1977.

Customers who purchased electric shavers from Ronson Corp. were surveyed. The survey revealed that customers had reduced purchases from Ronson and increased purchases of imported electric shavers.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with lighters and electric shavers produced at Ronson Corp. of Delaware, Ogletown, Del., contributed importantly to the total or partial separations of the workers at that plant.

In accordance with the provisions of the act, I make the following certification:

All workers at Ronson Corp. of Delaware, Ogletown, Del., who became totally or partially separated from employment on or after August 1, 1977, are eligible to apply

for adjustment assistance under title II, chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20992 Filed 7-27-78. 8:45 am]

[4510-28]

[TA-W-2754]

SHAWMUT TANNING CO., PEABODY, MASS.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

I accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2754: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on December 8, 1977 in response to a worker petition received on November 29, 1977 which was filed on behalf of workers and former workers tanning sheepskin at the Shawmut Tanning Co., Peabody, Mass.

The Notice of Investigation was published in the FEDERAL REGISTER on December 30, 1977 (42 FR 65307). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Shawmut Tanning Co., New England Sports Wear Co., its customers, the U.S. International Trade Commission, U.S. Department of Commerce, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

Shawmut Tanning and New England Sportswear have common ownership and are located in the same facility. New England Sports Wear, the manufacturer, assembles women's suede coats from skins tanned by Shawmut. All finished coats are sold by New England Sportswear.

Imports of Men's, Boys' Women's, Misses', Junior's, and Children's Leather Coats and Jackets, in absolute terms, increased from 1975 to 1976 and increased 4.8 percent from 1976 to 1977. The ratios of imports to domestic production and consumption decreased from 96.3 percent and 49.0 percent, respectively, in 1976 to 85.3 percent and 46.0 percent, respectively in 1977.

A Department survey of New England Sports Wear's customers revealed that many customers who had decreased their purchases of women's leather and suede coats from New England Sports Wear in 1977 compared to 1976 increased their purchases of imported leather coats and jackets or increased their purchases from domestic sources which utilized foreign manufactures of leather coats.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with women's suede coats assembled from sheepskin tanned at the Shawmut Tanning Co., Peabody, Mass. contributed importantly to the total or partial separation of the workers of that plant. In accordance with the provisions of the act, I make the following certification:

All workers at the Shawmut Tanning Co., Peabody, Mass. who became totally or partially separated from employment on or after November, 18, 1976 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20993 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2658]

UNION CARBIDE CORP., CARBON PRODUCTS DIVISION, CLARKSBURG, W. VA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2658: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on November 23, 1977 in response to a worker petition received on November 15, 1977, which was filed by the Oil, Chemical and Atomic Workers Union on behalf of workers and former workers producing graphite electrodes and anodes at the Clarksburg, W. Va. plant of Union Carbide Corp., Carbon Products Division.

The Notice of Investigation was published in the FEDERAL REGISTER on December 6, 1977 (42 FR 61695). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Union Carbide Corp., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analyst and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the total or partial separation, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of graphite electrodes declined from 29,600 short tons in 1975 to 27,700 short tons in 1976 and then increased to 33,800 short tons in 1977. The ratio of imports to domestic production increased from 13.4 percent in 1976 to 14.7 percent in 1977.

The Clarksburg plant produces primarily graphite electrodes. Some graphite anodes and specialty items such as graphite pipes and flexing tubes are also produced.

Customers of Union Carbide were surveyed regarding their purchases from the Clarksburg plant. Of the responding customers, most of those who reduced purchases from Clarksburg, also reduced purchases of imports or did not purchase imported electrodes at all. In 1977, the ratio of imports of graphite electrodes to domestic consumption, at 17.0 percent, was lower than any year since 1972.

CONCLUSION

After careful review, I determine that all workers at the Clarksburg, W. Va. plant of Union Carbide Corp., Carbon Products Division are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20994 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3357]

UNION CARBIDE CORP., CHEMICALS & PLASTICS DIVISION MARIETTA, OHIO

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3357: Investigation regarding certification of eligibility to apply for

worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 15, 1978, in response to a worker petition received on February 10, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers producing polysulfone and phenolic plastics at the Marietta, Ohio Chemicals & Plastics Division plant of Union Carbide Corp. The investigation revealed that the workers at the plant also produced polystyrene plastics.

The Notice of Investigation was published in the FEDERAL REGISTER on April 7, 1978 (43 FR 14774). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Union Carbide Corp., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met.

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that the Marietta, Ohio Chemicals & Plastics Division Plant of Union Carbide Corp. produced three basic families of plastics; polysulfones, phenolics, and polystyrene. In January 1978, Union Carbide sold its polystyrene business and production center at Marietta. The part of the Marietta plant retained by Union Carbide continues to produce phenolic and polysulfone plastics.

Imports of phenolic resins and styrene plastic materials, which includes polystyrene, amounted to less than one-half of 1 percent (0.05 percent) of domestic production in each year from 1973 through 1977. During each year of this period U.S. exports of phenolic resins and styrene plastic materials greatly exceeded imports. The impact of imported phenolic resins and styrene plastic materials on domestic production of those products can be termed "negligible".

There are no imports of polysulfones. Polysulfones are proprietary to Union Carbide. There are no other producers of these products, domestic or foreign.

CONCLUSION

After careful review I determine that all workers at the Marietta, Ohio Chemicals & Plastics Division plant of Union Carbide Corp. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20995 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3345]

UNIVERSAL SPORTSWEAR, ELIZABETH, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3345: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 9, 1978, in response to a worker petition received on February 28, 1978, which was filed on behalf of workers and former workers producing outerwear at Universal Sportswear. The investigation revealed that men's and boys' outer jackets and coats are produced at Universal Sportswear.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increased imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imports of men's and boys' nontailored outer coats and jackets increased from 15.6 million units in 1975 to 15.7 million units in 1976 and again increased to 19.5 million units in 1977. The ratio of imports to domestic production decreased from 26.3 percent in 1975 to 25.3 percent in 1976 and then increased to 30.8 percent in 1977.

Customers surveyed indicated that they did not purchase imported men's and boys' outer jackets or coats and that they did not have any foreign contracts for the production of these garments. The survey showed that these customers' own sales were increasing.

CONCLUSION

After careful review I determine that all workers of Universal Sportswear are denied eligibility to apply for adjustment assistance under title II, chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20996 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-3346]

WAGNER MANUFACTURING DIVISION, J. R. CLARK CO., SIDNEY, OHIO

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3346: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 9, 1978, in response to a worker petition received on February 24, 1978, which was filed by the International Molders & Allied Workers Union on behalf of all workers producing cast iron cookwear at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of J. R. Clark Co., Wagner Manufacturing Division, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is

concluded that all of the requirements have been met.

Imports of cast iron cookwear increased absolutely in 1977 compared to 1976 and in the first quarter of 1978 compared to the first quarter of 1977.

A survey of some of the customers which purchased cast iron cookwear from Wagner Manufacturing Division in 1976 and 1977 indicated that some customers reduced purchases from Wagner and increased purchases of imported cast iron cookwear.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the cast iron cookwear produced by the Wagner Manufacturing Division of the J. R. Clark Co., Sidney, Ohio, contributed importantly to the sales and production declines and to the total or partial separations of the workers of that plant. In accordance with the provisions of the act, I make the following certification:

All workers at the Wagner Manufacturing Division of the J. R. Clark Co., in Sidney, Ohio, engaged in employment related to the production of cast iron cookwear who became totally or partially separated from employment on or after February 20, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20997 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2550]

WESLEY TEXTILE CO., NEW BEDFORD, MASS.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2550: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on November 1, 1977, in response to a worker petition received on October 27, 1977, which was filed on behalf of workers and former workers producing woven greige goods at Wesley Textile Co., New Bedford, Mass.

The notice of investigation was published in the FEDERAL REGISTER on November 15, 1977 (42 FR 59131). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Wesley Textile Co., its customers, the U.S. Department of Commerce, the American Textile Manufacturers' Institute, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the criteria have been met.

U.S. imports of greige woven cotton fabric increased from 570 million square yards in 1975 to 945 million square yards in 1976 before decreasing from 783 million square yards in January through September 1976 to 479 million square yards in the same period in 1977. The ratio of imports to domestic production increased from 11 percent in 1975 to 17 percent in 1976 and then decreased from 17.7 percent in January through June 1976 to 11.3 percent in the same period in 1977.

U.S. imports of finished fabric increased from 408 million square yards in 1975 to 464 million square yards in 1976 before decreasing to 453 million square yards in 1977. The ratio of imports to domestic production increased from 1.6 percent in 1976 to 1.8 percent in 1977.

Cotton greige goods woven at Wesley Textile were sold to converters through the parent firm, Antea Felt. A survey of customers of Antea Felt revealed that a customer representing a substantial percentage of the subject firm's sales in 1976 decreased its purchases from Antea Felt in the first 9 months of 1977 compared to the same period in 1976, while demonstrating an increased reliance on imported greige goods and finished fabric.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with woven cotton greige goods produced at Wesley Textile Co., New Bedford, Mass., contributed importantly to the decline in sales and production and to the total or partial separations of workers of that firm. In accordance with the provisions of the act, I make the following certification:

All workers of Wesley Textile Co., New Bedford, Mass., who became totally or partially separated from employment on or after March 1, 1977, are eligible to apply for adjustment assistance under title II, chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20998 Filed 7-27-78; 8:45 am]

[7501-01]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (78-35)]

APPLICATIONS STEERING COMMITTEE (ASC) SUPPORTING RESEARCH AND TECHNOLOGY (S.R. & T.) AD HOC ADVISORY SUBCOMMITTEE

Meeting

The Non-Renewable/Renewable Resources Panel of the ASC, S.R. & T. Ad Hoc Advisory Subcommittee will meet at the Goddard Space Flight Center, Greenbelt, Md. 20771, on August 7-11, 1978. The meeting will be held in the auditorium of building 8 from 8:30 a.m. to 5:30 p.m. on each day. The subcommittee will conduct a comprehensive evaluation of the proposals submitted to NASA in response to the applications notice for the supporting research and technology phase of the space and terrestrial applications program. Public discussion of the professional qualifications of the proposers and their potential scientific contributions to the S.R. & T. program would invade the privacy of the proposers and the other individuals involved. Since the subcommittee sessions will be concerned throughout with matters listed in 5 U.S.C. 552b(c)(6), as described above, it has been determined that the sessions should be closed to the public.

Since the evaluation activity is required to allow the applications research and development program for fiscal year 1979 to be determined by September 1, 1978, it is imperative that the meeting be held at this time.

For further information, please contact Ms. Ruth Whitman, NASA Headquarters, Washington, D.C. 20546, area code 202-755-8628.

July 24, 1978.

ARNOLD W. FRUTKIN,
Acting Associate Administrator for External Relations.

[FR Doc. 78-20895 Filed 7-27-78; 8:45 am]

[7510-01]

[Notice (78-33)]

NASA ADVISORY COUNCIL (NAC)

Meeting

The Ad Hoc Informal Subcommittee on Handling of Alternative Aircraft

Fuels of the NASA Advisory Council will meet on August 14, 1978, from 9 a.m. to 3:30 p.m. at NASA Headquarters, Room 5026, Federal Office Building 6, 400 Maryland Avenue SW., Washington, D.C. 20546. The meeting will be open to the public up to the seating capacity of the room (approximately 60 persons, including subcomittee members). Visitors will be requested to sign a visitor's register.

This subcommittee, chaired by Mr. Willis Hawkins, consists of three other members drawn from the membership of the NAC and its standing committees. The subcommittee was established to carry out an evaluation of recent work in this field and of related NASA research activity. This first meeting will be devoted to providing the members with the necessary background information and developing the plan for its follow-on activities. The agenda for the meeting is as follows:

MONDAY, AUGUST 14, 1978

9 a.m.—Introduction.
9:15 a.m.—Background briefing.
10:30 a.m.—Solicited evaluations.
1:30 p.m.—Discussion and plan for follow-on work.
3:30 p.m.—Adjourn.

For further information regarding the meeting, contact Mr. Nathaniel B. Cohen, Executive Secretary of the Subcommittee, NASA Headquarters, Washington, D.C. 20546, telephone 202-755-8383.

ARNOLD W. FRUTKIN,
Acting Associate Administrator for External Relations.

JULY 25, 1978.

[FR Doc. 78-20894 Filed 7-27-78; 8:45 am]

[7510-01]

[Notice (78-34)]

NASA Advisory Council

Meeting

The NASA Advisory Council will meet on August 17, 18, and 19, 1978, at the Scripps Institution of Oceanography, Marine Biology Conference Room, LaJolla, Calif. 92093. Except as noted below, the meeting will be open to the public up to the seating capacity of the room (approximately 50 persons, not including Council members). Visitors will be requested to sign a visitor's register.

The meeting will be closed to the public from 8 a.m. to 9 a.m. on August 19, 1978 for a discussion of the qualifications of candidates for membership on the Council. Such a discussion would invade the privacy of the candidates and other individuals involved. Since this session will be concerned throughout with matters listed in 5 U.S.C. 552b(c)(6), it has been determined that this session should be closed to the public.

The NASA Advisory Council was established as an interdisciplinary group to advise NASA senior management on NASA's aeronautics and space programs. The Council is concerned with providing advice in the substantive areas of aeronautics, life sciences, space and terrestrial applications, space sciences, space systems and technology, and history as they relate to aeronautics and space programs. The Chairman of the Council is Dr. William A. Nierenberg. There are currently 15 members on the Council and additional members on standing committees which report to the Council. The following list sets forth the approved schedule for the meeting. For further information contact the Executive Secretary, Mr. Nathaniel B. Cohen, A/C 202-755-8383, NASA Headquarters, Washington, D.C. 20546.

THURSDAY, AUGUST 17, 1978

8 a.m. Introduction.
8:30 a.m. Task team report, hydrogen study.
9:30 a.m. Fiscal year 1980-84 5-year planning.

FRIDAY, AUGUST 18, 1978

8 a.m. Fiscal year 1980-84 5-year planning (continued).

SATURDAY, AUGUST 19, 1978

8 a.m. Executive session (NAC membership).
9 a.m. Fiscal year 1980-84 5-year planning (concluded).
1 p.m. Planning for future NAC activities.

ARNOLD W. FRUTKIN,
Acting Associate Administrator for External Relations.

JULY 21, 1978.

[FR Doc. 78-20896 Filed 7-27-78; 8:45 am]

[7537-01]

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

MEDIA ARTS ADVISORY PANEL

Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Media Arts Advisory Panel (Aid to Film/Video Exhibition) to the National Council on the Arts will take place August 21, 1978, from 9:30 a.m. to 5:30 p.m., and August 22, 1978, from 9:30 a.m. to 5:30 p.m., in room 1422 of the Columbia Plaza Office Building, 2401 E Street, NW., Washington, D.C. 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the FEDERAL REGISTER of March 17, 1977, these sessions will be closed to the public pursuant to subsection (c) (4), (6), and 9(B) of section 552 of title 5, U.S.C.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634-6070.

Dated: July 30, 1978.

JOHN H. CLARK,
Director, Office of Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 78-20914 Filed 7-27-78; 8:45 am]

[7537-01]

NATIONAL COUNCIL ON THE ARTS

Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that a meeting of the National Council on the Arts will be held on August 11, 1978, from 9 a.m. to 5:30 p.m., and August 12, 1978, from 9 a.m. to 5:30 p.m., in the 14th floor conference rooms of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20506.

A portion of this meeting will be open to the public on Friday, August 11, 1978, from 9 a.m. to 5:30 p.m., and Saturday, August 12, 1978, from 10 a.m. to 12:45 p.m. Topics of discussion will be program policy and guidelines for the challenge, dance, Federal-State partnership, and theater programs; reports of the fashion design task force and from regional representatives; the annual evaluation plan; and other general reports.

The remaining sessions of this meeting on Saturday, August 12, 1978, from 9 a.m. to 10 a.m.; and 1:30 p.m. to 5:30 p.m. are for the purpose of Council review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of informaion given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the FEDERAL REGISTER of March 17, 1977, these sessions may be closed to the public pursuant to sub-

sections (c) (4), (6), and 9(B) of section 552b of title 5, U.S.C.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634-6070.

Dated: July 21, 1978.

JOHN H. CLARK,
Director, Office of Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 78-20915 Filed 7-27-78; 8:45 am]

[7555-01]

NATIONAL SCIENCE FOUNDATION

AD HOC SUBCOMMITTEE FOR THE CEPEX SITE REVIEW

Meeting

In accordance with the Federal Advisory Committee Act, as amended, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Ad Hoc Subcommittee for the Site Review of the Controlled Ecosystem Populations Experiment (CEPEX) of the Advisory Committee for Ocean Sciences.

Date and time: August 13-15, 1978; 10 a.m. to 5:30 p.m. daily.

Place: CEPEX Site, Institute of Ocean Sciences, Sidney, British Columbia, Canada.

Type of meeting: Closed.

Contact person: Dr. Lauriston R. King, Acting Head, International Decade of Ocean Exploration Section, room 605, National Science Foundation, Washington, D.C. 20550, telephone 202-632-7356.

Purpose of subcommittee: To provide advice and recommendations concerning support for research on CEPEX.

Agenda: To review and evaluate the past research and the 1978 field season of the CEPEX project as part of the recommendation process for awards.

Reason for closing: The review process includes information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Acting Director, NSF, on February 18, 1977.

M. REBECCA WINKLER,
Committee Management Coordinator.

JULY 24, 1978.

[FR Doc. 78-20879 Filed 7-27-78; 8:45 am]

[7555-01]

ADVISORY GROUPS

Availability of Reports

The National Science Foundation has filed with the Library of Congress some reports which were prepared by various advisory committees of the National Science Foundation:

Report of the Condensed Matter Sciences Advisory Subcommittee on Oversight Review of the NSF Solid State Chemistry Program
Report of the Ad Hoc Advisory Group for Future Scientific Ocean Drilling
Report of the Science Applications Task Force

The reports were filed in accordance with the Federal Advisory Committee Act, Pub. L. 92-463, and are available for public inspection and use at the Library of Congress, Rare Book Division, Room 256, Washington, D.C. A. copy of each report is also available for public inspection and use at the National Science Foundation, Committee Management Office, Room 248, Washington, D.C.

M. REBECCA WINKLER,
Committee Management Coordinator.

JULY 24, 1978.

[FR Doc. 78-20878 Filed 7-27-78; 8:45 am]

[7590-01]

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-416 and 50-417]

MISSISSIPPI POWER & LIGHT CO. AND MIDDLE SOUTH ENERGY, INC. (GRAND GULF NUCLEAR STATION, UNITS 1 & 2)

Receipt of Application for Facility Operating Licenses; Availability of Applicants' Environmental Report; Consideration of Issuance of Facility Operating Licenses and Opportunity for Hearing

Notice is hereby given that the Nuclear Regulatory Commission (the Commission) has received an application for facility operating licenses from Mississippi Power & Light Co. and Middle South Energy, Inc. (the applicants) to possess, use, and operate Grand Gulf Nuclear Station, Units 1 and 2 (the facilities), located on the applicants' site in Claiborne County, Miss., at a core power level of 3,833 megawatts thermal, with an equivalent net electrical output of approximately 1,250 megawatts.

The applicants have also filed, pursuant to the National Environmental Policy Act of 1969 and the regulations of the Commission in 10 CFR Part 51, an environmental report. The report, which discusses environmental considerations related to the proposed operation of the facilities is being made available at the Southwest Mississippi Planning and Development District, P.O. Box 636, Meadville, Miss. 39653.

After the environmental report has been analyzed by the Commission's staff, a draft environmental statement will be prepared. Upon preparation of the draft environmental statement, the Commission will, among other things, cause to be published in the FEDERAL REGISTER a notice of availability of the draft statement, requesting comments from interested persons on the draft statement. The summary notice will also contain a statement to the effect that any comments of Federal agencies and State and local officials will be made available when received. The draft environmental statement will focus only on any matters which differ from those previously discussed in the final environmental statement prepared in connection with the issuance of the construction permits. Upon consideration of comments submitted with respect to the draft environmental statement, the Commission's staff will prepare a final environmental statement, the availability of which will be published in the FEDERAL REGISTER.

The Commission will consider the issuance of facility operating licenses to Mississippi Power & Light Co. and Middle South Energy, Inc., which would authorize the applicants to possess, use, and operate the Grand Gulf Nuclear Station, Units 1 and 2, in accordance with the provisions of the licenses and the technical specifications appended thereto, upon: (1) The completion of a favorable safety evaluation of the application by the Commission's staff; (2) the completion of the environmental review required by the Commission's regulations in 10 CFR Part 51; (3) the receipt of a report on the applicants' application for facility operating licenses by the Advisory Committee on Reactor Safeguards; and (4) a finding by the Commission that the application for the facility licenses, as amended, complies with the requirements of the Atomic Energy Act of 1954, as amended (the act), and the Commission's regulations in 10 CFR Chapter I. Construction of the facilities was authorized by Construction Permit Nos. CPPR-118 and CPPR-119, issued by the Commission on September 4, 1974.

Prior to issuance of any operating licenses, the Commission will inspect

the facilities to determine whether they have been constructed in accordance with the application, as amended, the the provisions of the construction permits. In addition, the licenses will not be issued until the Commission has made the findings reflecting its review of the application under the act, which will be set forth in the proposed licenses, and has concluded that the issuance of the licenses will not be inimical to the common defense and security or to the health and safety of the public. Upon issuance of the licenses, the applicants will be required to execute an indemnity agreement as required by section 170 of the act and 10 CFR Part 140 of the Commission's regulations.

By August 28, 1978, the applicants may file a request for a hearing with respect to issuance of the facility operating licenses and any person whose interest may be affected by this proceeding may file a petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed within the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary of the Commission, or designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR § 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceedings. The petitioner should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which the petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend his petition, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, the petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, attention: Docketing and Service Section, or may be delivered to the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., by August 28, 1978. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Mr. Robert B. McGehee, Wise, Carter, Child, Steen & Caraway, P.O. Box 651, Jackson, Miss. 39205; and Mr. Troy B. Conner, Jr., Conner, Moore & Corber, 1747 Pennsylvania Avenue NW., Washington, D.C. 20006, attorneys for the applicants. Any questions or requests for additional information regarding the content of this notice should be addressed to the Chief Hearing Counsel, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR § 2.714(a)(1)(i)-(v) and § 2.714(d).

For further details pertinent to the matters under consideration, see the application for the facility operating licenses dated June 30, 1978, and the applicants' environmental report dated June 30, 1978, which are available for public inspection at the commission's Public Document Room, 1717 H Street NW., Washington, D.C. 20555 and at Claiborne County Courthouse, Port Gibson, Miss. As they become available, the following documents may be inspected at the above locations: (1) The safety evaluation report prepared by the Commission's staff; (2) the draft environmental statement; (3) the final environmental statement; (4) the report of the Advisory Committee on Reactor Safeguards on the application for facility operating licenses; (5) the proposed facility operating licenses; and (6) the Technical specifications, which will be attached to the proposed facility operating licenses.

Copies of the proposed operating licenses and the ACRS report, when available, may be obtained by request to the Director, Division of Project Management, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the Commission's staff safety evaluation report and final environmental statement, when available, may be purchased at current rates, from the National technical Information Service, Department of Commerce, 5285 Port Royal Road, Springfield, Va. 22161.

For the Nuclear Regulatory Commission.

Dated at Bethesda, Md., this 28th day of July 1978.

JOHN F. STOLZ,
Chief, Light Water Reactors Branch 1, Division of Project Management.

[FR Doc. 78-20752 Filed 7-27-78; 8:45 am]

[7590-01]

[Docket No. P-657A]

NEW YORK STATE ELECTRIC & GAS CORP. AND LONG ISLAND LIGHTING CO.

Receipt of Attorney General's Advice and Time for Filing of Petitions to Intervene on Antitrust Matters

The Commission has received, pursuant to section 105c of the Atomic Energy Act of 1954, as amended, the following advice from the Attorney General of the United States, dated July 14, 1978 with respect to a construction permit application for Nuclear Power Station/New Haven—Stuyvesant Sites, Units 1 and 2:

You have requested our advice pursuant to section 105 of the Atomic Energy Act, as amended, in regard to the above cited application by New York State Electric & Gas Corp. on behalf of itself and Long Island Lighting Co. (Lilco).

Both of the applicants have been the subject of prior antitrust advice letters written by the Department. On January 7, 1975, we rendered antitrust advice on an application by Lilco to construct the Jamesport Nuclear Power Station, Units 1 and 2. Most recently, on January 26, 1978, we rendered antitrust advice concerning New York State with respect to its application to participate in the Jamesport Nuclear Power Station, Units 1 and 2. We also rendered antitrust advice on December 27, 1974, regarding New York State's application to construct the Somerset Nuclear Station, Units 1 and 2.

In each of the above-referenced letters we advised of our conclusion that the activities under the licenses applied for would not create or maintain a situation inconsistent with the antitrust laws.

Since the last antitrust advice letters were written Lilco has had a change in its operations that merits notation.

In April, 1978, the Greenport New York Municipal Electric System, which until that time had been isolated, interconnected with Lilco. The Greenport system has a peak of about 3 MW. In addition, Greenport, as well as Freeport and Rockville Centre, the only two other comparatively small municipal utilities in Lilco's service area, have obtained commitments from the Power Authority of the State of New York (PASNY0 to supply their bulk power needs. Lilco, as well as other investor-owned utilities in the State of New York, have agreed to transmit that power from the PASNY transmission system to the three municipal systems.

After examination of the current application and review of the relevant data, we have concluded that no intervening circumstances have occurred to warrant a reversal of the advice given with respect to the applicants in the above-cited antitrust letters.

We express no opinion, however, concerning the legality under the antitrust laws of the manner in which, or any arrangements pursuant to which, the plants will be operated, should they differ from or extend beyond those matters specifically disclosed in the application.

Accordingly, from the information available to us at the present time we conclude that no antitrust hearing by the Nuclear Regulatory Commission will be required with respect to this application.

Any person whose interest may be affected by this proceeding may, pursuant to § 2.714 of the Commission's "Rules of Practice", 10 CFR Part 2, file a petition for leave to intervene and request a hearing on the antitrust aspects of the application. Petitions for leave to intervene and requests for hearing shall be filed by August 27, 1978, either (1) by delivery to the NRC Docketing and Service Section at 1717 H Street NW., Washington, D.C. or (2) by mail or telegram addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attn: Docketing and Service Section.

For the Nuclear Regulatory Commission.

JEROME SALTZMAN,
Chief, Antitrust and Indemnity Group Office of Nuclear Reactor Regulation.

[FR Doc. 78-20754 Filed 7-27-78; 8:45 am]

[7590-01]

[Docket No. 70-2623]

DUKE POWER CO.

Opportunity for Public Participation in Proposed NRC Licensing Action for Amendment to Materials License SNM-1773 for Oconee Nuclear Station Spent Fuel Transportation and Storage at McGuire Nuclear Station

The U.S. Nuclear Regulatory Commission (the Commission) is giving public notice that it is considering an application for amendment to Special Nuclear Material License No. SNM-1773 issued pursuant to 10 CFR Part 70 to authorize the receipt and storage of Oconee Nuclear Station spent fuel at the McGuire Nuclear Station.

The proposed amendment would authorize the receipt and storage of Oconee Nuclear Station spent fuel at the McGuire facility in accordance with the licensee's application for amendment dated March 9, 1978. Activities for which additional authorization is sought involve receipt, possession, inspection and storage of spent nuclear fuel from the licensee's Oconee Nuclear Facility in Oconee County, S.C., at the licensee's McGuire facility located in Mecklenburg County, N.C., including transport of the Oconee spent fuel by truck between the two sites. The activities being reviewed also include storage of Oconee irradiated fuel with the spent fuel to be generated by the operation of the McGuire facility. In its license amendment Duke Power Co. also requested certain special arrangements with respect to Price-Anderson Act indemnification. This request is under consideration by the Commission as a separate matter, and it will be the subject of a separate action, including any public notice required. Issuance of an operating license for the McGuire Nuclear facility is presently under consideration in a separate proceeding pursuant to 10 CFR Part 50 in Docket Nos. 50-369 and 50-370.

The NRC will not issue the license amendment for storage of Oconee spent fuel at the McGuire Nuclear Station spent fuel pool (1) until the completion of a safety evaluation on the licensee's request and the completion of environmental evaluations made pursuant to 10 CFR Part 51; and (2) unless favorable findings required by the Atomic Energy Act of 1954, as amended (the act), and the NRC's rules and regulations have been made.

The NRC will complete an environmental evaluation in accordance with 10 CFR Part 51 to determine if the preparation of an environmental impact statement, or negative declaration and environmental appraisal is warranted. This action will be the subject of a separate notice in the FEDERAL REGISTER.

On or before August 28, 1978, the licensee may file a request for a hearing and any member of the public whose interest may be affected by the proceeding may file a request for a public hearing in the form of a petition for leave to intervene with respect to whether the proposed amendment to SNM-1773 should be issued.

Petitions for leave to intervene must set forth the interest of the petitioner in the proceeding, how that interest may be affected by the results of the proceeding, and the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Such petitions must be filed in accordance with the above-referenced FEDERAL REGISTER Notice and must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section, by August 28, 1978. A copy of the petition and/or request for hearing should be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Duke Power Co., c/o W. L. Porter, Esq., Associate General Counsel, Legal Department, 422 South Church Street, Charlotte, N.C. 28242, attorney for the applicant. Any questions or requests for additional information regarding the context of this notice should be addressed to the Chief Hearing Counsel, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

The Carolina Environmental Study Group was previously admitted as an Intervenor *In the Matter of Duke Power Company* (William B. McGuire Nuclear Station, Units 1 and 2) Docket Nos. 50-369, 50-370, a separate operating license application proceeding. On May 23, 1978, the Carolina Environmental Study Group filed a motion ("Motion to Reopen Environmental Hearing to Add Contention (2)") in the McGuire operating license proceeding that seeks to raise a contention relating to the proposed transportation and storage of Oconee spent fuel at the McGuire facility pursuant to the application for amendment of the Special Nuclear Material License SNM-1773. The Carolina Environmental Study Group's motion is being treated as a request for hearing pursuant to 10 CFR § 2.105. This notice is being issued based on the determination that an opportunity for hearing should be afforded pursuant to the Carolina Environmental Study Group's request. Carolina Environmental Study Group's motion of May 23, 1978, is deemed to be filed pursuant to this notice of application for amendment to License No. SNM-1773 as of the first day of publication of this notice in the FEDERAL REGISTER, *provided, however,* that the Carolina Environmental Study Group may file a statement within the thirty- (30) day intervention period indicating that it does not wish to participate in the SNM-1773 license amendment proceedings, or it may elect to file any additional material with respect to the specific aspect or aspects of Duke Power Company's application to amend SNM-1773 on which it wishes to intervene.

Not later than fifteen (15) days prior to any prehearing conference scheduled in the proceeding, the petitioner

shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each. All petitions will be acted upon by the Commission or the Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel. Timely petitions will be considered to determine whether a hearing should be noticed or another appropriate order issued regarding the disposition of the petitions.

In the event that a hearing is held and a person is permitted to intervene, that person becomes a party to the proceeding and has a right to participate fully in the conduct of the hearing. For example, that person may present evidence and cross-examine witnesses.

A copy of the FEDERAL REGISTER Notice is available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., and at the local Public Document Rooms at the Public Library of Charlotte and Mecklenburg County, 310 North Tryon Street, Charlotte, N.C. 28202, between the hours of 9 a.m. and 9 p.m. weekdays, 9 a.m. and 6 p.m. on Saturday and 2 p.m. and 6 p.m. on Sunday, and at the Oconee County Library, 201 South Spring Street, Walhalla, S.C. 29691, between the hours of 10 a.m. and 9 p.m. on Monday, 9 a.m. and 5 p.m. Tuesday through Friday, and 9 a.m. and 12 noon on Saturday. The Commission has arranged for other documents and correspondence relating to the proposed amendment to the Special Nuclear Material License No. SNM-1773 to be kept at the same locations.

Dated at Silver Spring, Md., this 14th day of July, 1978.

For the Nuclear Regulatory Commission.

RICHARD W. STAROSTECKI,
Chief, Fuel Reprocessing and Recycle Branch Division of Fuel Cycle and Material Safety.

[FR Doc. 78-20753 Filed 7-27-78; 8:45 am]

[7590-01]

[Docket No. PRM-31-3]

R. F. NACHREINER

Filing of Petition for Rulemaking

Notice is hereby given that Dr. R. F. Nachreiner by letter dated June 19, 1978, has filed with the Nuclear Regulatory Commission a petition for rulemaking to amend the Commission's regulation "General Domestic Licenses for Byproduct Material," 10 CFR Part 31.

The petitioner requests the Commission to amend section 31.11, general license for use of byproduct material for certain in vitro clinical or laboratory testing, to include veterinarians as general licensees. The petitioner states that:

It has been brought to my attention that licensed veterinarians are not eligible to register on Form AEC-483 for in vitro testing under the terms of the general license provided for in section 31.11 of 10 CFR Part 31. Rather, veterinarians must request a specific byproduct material license on form AEC-313. It is also my understanding that the fee for the specific byproduct license will be $190. Since more veterinarians are receiving postgraduate training in clinical pathology and upgrading their diagnostic facilities considerably, I believe it is a hindrance to progress to require a different license than that extended to physicians. The small quantity used and similarity of use to that of a physician (specifically, RIA use) [Radioimmunoassay] would imply a similar type licensure for veterinarians. Would you please consider having this type of licensure for veterinarians also?

A copy of the petition for rulemaking is available for public inspection in the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. A copy of the petition may be obtained by writing to the Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

All persons who desire to submit written comments or suggestions concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington D.C. 20555, Attention: Docketing and Service Branch, By September 26, 1978.

Dated at Washington, D.C. this 21st day of July, 1978.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc. 78-20898 Filed 7-27-78; 8:45 am]

[7590-01]

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS, SUBCOMMITTEE ON EMERGENCY CORE COOLING SYSTEMS (ECCS)

Meeting

The ACRS Subcommittee on Emergency Core Cooling will hold an open meeting on August 14, 1978 at the Westbank Motel Coffee Shop, 475 River Parkway, Idaho Falls, Idaho 83401, to review the status of research projects related to LOFT, SEMISCALE, thermal-hydraulic aspects of the Power Burst Facility (PBF), and 2-phase flow instrumentation. Notice of this meeting was published at 43 FR 26162 and 30631, June 16 and July 17, 1978, respectively.

In accordance with the procedures outlined in the FEDERAL REGISTER on October 31, 1977 (42 FR 56972), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the designated Federal employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The agenda for subject meeting shall be as follows:

Monday, August 14, 1978; 8:30 a.m. until the conclusion of business.

The subcommittee may meet in executive session, with any of its consultants who may be present, to explore and exchange their preliminary opinions regarding matters which should be considered during the meeting and to formulate a report and recommendations to the full committee.

At the conclusion of the executive session, the subcommittee will hear presentations by and hold discussions with representatives of the NRC Staff, the Idaho National Engineering Laboratory (INEL), and their consultants, pertinent to the above topics. The subcommittee may then caucus to determine whether the matters identified in the initial session have been adequately covered and whether the project is ready for review by the full committee.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefore can be obtained by a prepaid telephone call to the designated Federal employee for this meeting, Dr. Andrew L. Bates, telephone 202-634-3267, between 8:15 a.m. and 5 p.m., e.s.t.

Dated: July 26, 1978.

JOHN C. HOYLE,
Advisory Committee Management Officer.

[FR Doc. 78-21132 Filed 7-27-78; 9:09 am]

[3110-01]

OFFICE OF MANAGEMENT AND BUDGET

CLEARANCE OF REPORTS

List of requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on July 24, 1978 (44 U.S.C. 3509). The purpose of pub-

lishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; an indication of who will be the respondents to the proposed collection; the estimated number of responses; the estimated burden in reporting hours; and the name of the reviewer or reviewing division or office.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Government National Mortgage Association:
Schedule of Pooled Mortgages—Mobile Home; HUD-1725, on occasion, 2,000 mortgage bankers, Caywood, D. P., 395-3443.
Schedule of Pooled Project Mortgages, HUD-1721, on occasion, 90 mortgage bankers, Caywood, D. P., 395-3443.

REVISIONS

DEPARTMENT OF COMMERCE

Bureau of Census, Survey of Local Government Finances (school system) F-33A and 33B, annually, State and local public officials, 6,600 responses, 6,600 hours, Offfice of Federal Statistical Policy and Standard, Laverne V. Collins, 673-7956.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Center for Education Statistics, Salaries, Tenure, and Fringe Benefits of Full-Time Instructional Facility 78-79, NCES 2300-3, annually, colleges and universities, 3,100 responses, 9,300 hours, Office of Federal Statistical Policy and Standard, Laverne V. Collins, 673-7956.

EXTENSIONS

GENERAL SERVICES ADMINISTRATION

Contractor's Statement of Contingent or Other Fees, 119, on occasion, contract pricing, 3,700 responses, 3,700 hours, Office of Federal Statistical Policy and Standard, 673-7956.
Contract Pricing Proposal (research and development), OF-60, on occasion contract pricing, 5,000 responses, 15,000 hours, Office of Federal Statistical Policy and Standard, 673-7956.
Contract Pricing Proposal, OF-59, on occasion, contract pricing, 5,000 responses, 15,000 hours, Office of Federal Statistical Policy and Standard, 673-7956.

PENSION BENFIT GUARANTY CORPORATION

Survey Form for Multiemployer Termination Insurance Program, single time, multiemployer pension plans, 26 responses, 104 hours, Office of Federal Statistical Policy and Standard, Strasser, A., 673-7956.

DEPARTMENT OF COMMERCE

Bureu of Census, November 1976 Voting Supplement, CPS-1 and 260, single time, households respondents 56,000 households in 11/78 CPS samples, Office of Federal Statistical Policy and Standard, 673-7956.

DAVID R. LEUTHOLD,
Budget and Management Officer.

[FR Doc. 78-21029 Filed 7-27-78; 8:45 am]

[3110-01]

CLEARANCE OF REPORTS

List of Requests

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Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

NATIONAL ENDOWMENT FOR THE HUMANITIES

Application Form—Practitioners Seminars, annually, 3,500 seminar programs, Warren Topelius, 395-6132.
Program Development Application Face Sheet, quarterly, 150 interested applicants, Warren Topelius, 395-6132.
Media Application Face Sheet, quarterly, 300 interested applicants, Warren Topelius, 395-6132.
Museums and Historical Organization Application Fact Sheet, quarterly, 800 interested applicants, Budget Review Division, Warren Topelius, 395-4775.
Challenge Grant Application Face Sheet, NEH CG-2, annually, 300 humanities institutions, Budget Review Division, Warren Topelius, 395-4775.
Cultural Institutions Application Form, annually, 30 cultural institutions in 175 large metropolitan areas, Budget Review Division, Warren Topelius, 395-4775.
Public Libraries Application Face Sheet, quarterly, 300 interested applicants, Budget Review Division, Warren Topelius, 395-4775.
Report of Contributions, Exhibit B, annually, 350 humanities institutions, Budget Review Division, Warren Topelius, 395-4775.
Application Face Sheets, NEH Youth Projects, semiannually, 150 nonprofit organizations, Budget Review Division, Warren Topelius, 395-4775.
Instructions for Applicants, on occasion, 25 nonprofit and professional associations, Budget Review Division, Warren Topelius, 395-4775.
Guideline for Publications Programs, on occasion, 1,000 scholarly presses, Warren Topelius, 395-6132.
Application Face Sheet, Summary Sheet, and Postal Cards, on occasion, 100 individuals and any U.S. nonprofit group, Budget Review Division, Warren Topelius, 395-4775.
Standard Budget Form, on occasion, 10,000 potential grantees, Warren Topelius, 395-6132.
Application Form—Professions Program—Law Teacher, seminars, annually, 200 individuals, Warren Topelius, 395-6132.
Application Form—Centers for Advanced Study, annually, 40 research centers, Warren Topelius, 395-6132.

DEPARTMENT OF LABOR

Occupational Safety and Health Administration, designation of competent person and log of inspection and tests by competent person, OSHA-73 and 74, on occasion, 625 shipyards, Strasser, A., 395-6132.

REVISIONS

NATIONAL ENDOWMENT FOR THE HUMANITIES

Application Instructions, NEH-2, on occasion, scholars at all kinds of institutions, 700 responses, 175 hours, Warren Topelius, 395-6132.

DEPARTMENT OF LABOR

Employment Standards Administration:
Medical History and Examination for Coal Mine Workers' Pneumoconiosis, CM-988, on occasion, examining physicians, 8,000 responses, 4,000 hours, Richard Eisinger, 395-3214.
Roentgenographic Interpretation, CM-933, on occasion, hospitals, physicians, 40,000 responses, 20,000 hours, Clearance Office, 395-3772.
Miner's Claim for Benefits and Employment History, CM-911 and 911A, on occasion, current and former coal miners, 40,000 responses, 40,000 hours, Strasser, A., 395-6132.

EXTENSIONS

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service, report of child nutrition operations, FNS-10, monthly, State Education Agencies, 672 responses, 672 hours, Ellett, C. A., 395-6132.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration, report of fish and shellfish caught or purchased from fishermen, NOAA 88-12, monthly, wholesale dealers of fishery products and fishermen dealers, 4,690 responses, 1,170 hours, Clearance Office, 395-3772.

DAVID R. LEUTHOLD,
Budget and Management Officer.

[FR Doc. 78-21089 Filed 7-27-78; 8:45 am]

[8025-01]

SMALL BUSINESS ADMINISTRATION

[Proposal No. 05/05-0130]

FEDERATED CAPITAL CORPORATION

Application for a License as a Small Business Investment Company

Notice is hereby given of the filing of an application with the Small Business Administration (SBA) pursuant to § 107.102 of the SBA regulations (13 CFR 107.102 (1977)) by Federated Capital Corp., 20000 West 12 Mile Road, Southfield, Mich. 48076 for a license to operate as a small business investment company (SBIC) under the provisions of the Small Business Investment Act of 1958 (the act), as amended (15 U.S.C. 661 et seq.).

The proposed officers, directors, and shareholders are:

Name and Address, Title and Relationship

Louis P. Ferris, Jr., president, treasurer, and director, percent of ownership, none, 7031 Warren Road, Ann Arbor, Mich. 48105.
Carl A. Scarborough, senior vice president, percent of ownership, none, 3715 Wells Drive, Parlin, N.J. 08859.
Jerold T. Pogue, vice president, percent of ownership, none, 26030 Lila Lane, Dearborn Heights, Mich. 48127.
Susan M. Troyer, secretary, percent of ownership, none, 570 Lindsay, Plymouth, Mich. 48170.
Federated Financial Reserve Corp., percent of ownership, 100, 20000 West 12 Mile Road, Southfield, Mich. 48076.

Federated Financial Reserve Corp.'s principal business activity is to provide equipment financing and leasing services with credit worthy equipment users by purchasing such equipment upon execution of required agreements. All of the outstanding capital stock of Federated Financial Reserve Corp. is owned by Mr. Louis P. Ferris, Jr.

The applicant proposes to begin operations with a capitalization of at least $300,000 and will be a source of equity capital and long-term loan funds for qualified small business concerns.

Matters nvolved in SPA's consideration of the application include the general business reputation and character of the proposed owners and management, and the probability of successful operations of the new company under their management, including adequate profitability and financial soundness, in accordance with the act and regulations.

Notice is further given that any person may, not later than August 14, 1978, submit written comments on the proposed SBIC to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street NW., Washington, D.C. 20416.

A copy of this notice will be published in a newspaper of general circulation in Southfield, Mich.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies.)

Dated: July 21, 1978.

PETER F. MCNEISH,
Deputy Associate Administrator for Investment.

[FR Doc. 78-20875 Filed 7-27-78; 8:45 am]

[8025-01]

[Declaration of Disaster Loan Area No. 1499]

ILLINOIS

Declaration of Disaster Loan Area

St. Clair County and adjacent counties within the State of Illinois constitute a disaster area as a result of damage caused by flooding which occurred on March 25, 1978, through April 30, 1978. Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on September 18, 1978, and for economic injury until the close of business on April 19, 1979, at:

Small Business Administration, Branch Office, Illinois National Bank Building, One North Old State Capitol Plaza, Springfield, Ill. 62701.
or other locally announced locations.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: July 19, 1978.

PATRICIA M. CLOHERTY,
Acting Administrator.

[FR Doc. 78-20873 Filed 7-27-78; 8:45 am]

[Declaration of Disaster Loan Area No. 1504]

MISSOURI

Declaration of Disaster Loan Area

St. Louis County and adjacent counties within the State of Missouri constitute a disaster area as a result of damage caused by heavy rains and flooding which occurred on July 14 and 15, 1978. Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on September 21, 1978, and for economic injury until the close of business on April 23, 1979, at:

Small Business Administration, District Office, Suite 2500, Mercantile Tower, Mercantile Center, St. Louis, Mo. 63101.

or other locally announced locations.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: July 21, 1978.

A. VERNON WEAVER,
Administrator.

[FR Doc. 78-20874 Filed 7-27-78; 8:45 am]

[4710-07]

DEPARTMENT OF STATE

[CM-8/80]

SHIPPING COORDINATING COMMITTEE

SUBCOMMITTEE ON SAFETY OF LIFE AT SEA

Notice of Meeting

The Working Group on Radiocommunications of the Shipping Coordinating Committee's Subcommittee on Safety of Life at Sea (SOLAS) will conduct an open meeting at 1:30 p.m. on Thursday, August 17, 1978 in room 8442 of the Department of Transportation, 400 Seventh Street SW., Washington, D.C.

The purpose of the meeting is to prepare position documents for the nineteenth session of the Subcommittee on Radiocommunications of the Intergovernmental Maritime Consultative Organization (IMCO), to be held in London September 4-8, 1978. In particular, the SOLAS Working Group will discuss the following topics:

Code of safety requirements for mobile offshore drilling units;

Operational standards for shipboard radio equipment;

Revision of Resolution A.283 (VIII Maritime Distress System).

Requests for further information should be directed to Lt. R. F. Carlson, U.S. Coast Guard (G/OTM/74), Washington, D.C. 20590, telephone 202-426-1345.

The Chairman will entertain comments from the public as time permits.

CARL TAYLOR, JR.
Acting Director, Shipping Coordinating Committee.

[FR Doc. 78-20916 Filed 7-27-78; 8:45 am]

[4710-07]

[CM-8/81]

STUDY GROUP 5 OF THE U.S. ORGANIZATION FOR THE INTERNATIONAL RADIO CONSULTATIVE COMMITTEE (CCIR)

Notice of Meeting

The Department of State announces that Study Group 5 of the U.S. Organization for the International Radio Consultative Committee (CCIR) will meet on August 22, 1978, from 9:30 a.m. until 12 noon in Conference Room 3 of the Automation Industries Inc.-VITRO Labs, 2361 South Jefferson Davis Highway, Arlington, Va.

Study Group 5 deals with propagation of radio waves (including radio noise) at the surface of the Earth, through the nonionized regions of the Earth's atmosphere, and in space where the effect of ionization is negligible. The purpose of the meeting is preparation for the Special Preparatory Meeting for the 1979 World Administrative Radio Conference.

Members of the general public may attend the meeting and join in the discussions subject to instructions of the Chairman.

Requests for further information should be directed to G. Huffcutt, State Department, Washington, D.C. 20520, telephone 202-632-2592.

Dated: July 20, 1978.

RICHARD E. SHRUM,
Acting Director, Office of International Communications Policy.

[FR Doc. 78-20917 Filed 7-27-78; 8:45 am]

[4710-07]

[CM-8/82]

SHIPPING COORDINATING COMMITTEE

SUBCOMMITTEE ON SAFETY AT SEA

Notice of Meeting

The Working Group on Fire Protection of the Shipping Coordinating Committee's Subcommitte on Safety of Life at Sea (SOLAS) will conduct an open meeting at 9:30 a.m. on Wednesday, September 13, 1978, in Room 8236 of the Department of Transportation, 400 Seventh Street SW., Washington, D.C.

The purpose of the meeting is to: Review the outcome of the 21st session (January 23-27, 1978); prepare documents for submittal to the 22d session of IMCO Subcommittee on Fire Protection; review recently submitted documents by other delegations to determine if a response is appropriate or required; discuss Ro/Ro fire safety; discuss future concepts for fire protection of machinery spaces; discuss improvements to Chapter II-2 of SOLAS 1974.

Requests for further information should be directed to Mr. Daniel F. Sheehan, U.S. Coast Guard (B-MMT-4/82), Washington, D.C. 20590, telephone (202) 426-2197.

The chairman will entertain comments from the public as time permits.

CARL TAYLOR, Jr.,
Acting Director,
Shipping Coordinating Committee.

[FR Doc. 78-20918 Filed 7-27-78; 8:45 am]

[4710-07]

[CM-8/83]

ADVISORY COMMITTEE ON TRANSNATIONAL ENTERPRISES

Notice of Meeting

The Department of State will hold a meeting on August 17 of the Working Group on Transborder Data Flows of the Advisory Committee on Transnational Enterprises. The Working Group will meet from 9:30 a.m. until 12:30 p.m. The meeting will be held in Room 1105 of the State Department, 2201 C Street NW., Washington, D.C. The meeting will be open to the public.

The purpose of the meeting will be to discuss ongoing work in international bodies in the area of transborder data flows. In particular, the Working Group will focus its discussion on the work of the Organization for Economic Cooperation and Development in drafting "guidelines" relating to international data flows. The Group will examine the results of the July 10-12 meeting of the OECD drafting group, and consider possible next steps in formulating such guidelines.

Requests for further information on the meeting should be directed to Richard Kauzlarich, Department of State, Office of Investment Affairs, Bureau of Economic and Business Affairs, Washington, D.C. 20520. He may be reached by telephone on (area code 202) 632-2728.

Members of the public wishing to attend the meeting must contact Mr. Kauzlarich's office in order to arrange entrance to the State Department building.

The chairman of the Working Group will, as time permits, entertain oral comments from members of the public attending the meeting.

Dated: July 20, 1978.

RICHARD D. KAUZLARICH,
Executive Secretary.

[FR Doc. 78-20919 Filed 7-27-78; 8:45 am]

[4510-29]
[4830-01]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

DEPARTMENT OF LABOR

Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 78-11]

LEO F. QUINN, P.A. PROFIT SHARING TRUST

Grant of Individual Exemption

AGENCIES: Department of the Treasury/Internal Revenue Service, Department of Labor.

ACTION: Grant of individual exemption.

SUMMARY: This exemption enables the Leo F. Quinn, P.A. Profit Sharing Trust (the Trust) to sell certain trust assets to Drs. Jacob L. Raney, Charles G. Dalbey and Leo F. Quinn, who are officers, directors, 10 percent or more shareholders and highly compensated employees of Leo F. Quinn, P.A. (the Employer).

FOR FURTHER INFORMATION CONTACT:

Timothy Smith of the Prohibited Transactions Staff of the Employee Plans Division, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224 (Attention: E:EP:PT:1) (202-566-6761). This is not a toll free number.

SUPPLEMENTARY INFORMATION: On April 25, 1978, notice was published in the FEDERAL REGISTER (43 FR 17561) of the pendency before the Internal Revenue Service and the Department of Labor (the Agencies) of an exemption from the taxes imposed by section 4975 (a) and (b) of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1)(A), (D) and (E) of the Code and from the provisions of section 406(a)(1)(A) and (D), 406(b)(1) and 406(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act), for a transaction described in an application submitted by the employer and the trustees of the Trust. The notice set forth a summary of the facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Agencies in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Internal Revenue Service (the Service). In addition, the notice stated that any interested person might submit a written request that a hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Service.

GENERAL INFORMATION

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 4975(c)(2) of the Code and section 408(a) of the act does not relieve a fiduciary or party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Code and the act. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interests of the participants and beneficiaries of the plan and in a prudent fashion in accordance with subsection (a)(1)(B) of section 404 of the act, nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 4975(c)(1)(F) of the Code and section 406(b)(3) of the act.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Code and the act, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is in fact a prohibited transaction.

(4) This document does not meet the criteria for significant regulations set forth in paragraph 8 of the proposed Treasury directive appearing in the FEDERAL REGISTER for Wednesday, May 24, 1978 (43 FR 22319).

EXEMPTION

In accordance with section 4975(c)(2) of the Code and section 408(a) of the act and the procedures set forth in Rev. Proc. 75-26, 1975-1 C.B. 722, and ERISA Proc. 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Agencies make the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the plan and of the participants and beneficiaries; and

(c) It is protective of the rights of participants and beneficiaries of the plan.

Accordingly, the following exemption is hereby granted under the authority of section 4975(c)(2) of the Code and section 408(a) of the act and in accordance with the procedures set forth in Rev. Proc. 75-26 and ERISA Proc. 75-1.

The taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1) (A), (D) and (E) of the Code and the restrictions of section 406(a)(1) (A) and (D), 406(b)(1) and 406(b)(2) of the act shall not apply to a transaction involving the sale of approximately 1.18 acres of land located in Boca Raton, Palm Beach County, Fla., by the Trust to Drs. Raney, Dalbey and Quinn for $90,000 cash, provided that this amount is not less than the fair market value of the property.

The availability of this exemption is subject to the express conditions that the material facts and representations contained in the application are true and complete and that the application accurately describes all material terms of the transaction consummated pursuant to the exemption.

Signed at Washington, D.C., this 24th day of July 1978.

IAN D. LANOFF,
Administrator for Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

FRED J. OCHS,
Director, Employee Plans Division, Internal Revenue Service.

[FR Doc. 78-20924 Filed 7-27-78; 8:45 am]

[4810-22]

DEPARTMENT OF THE TREASURY

Customs Service

BICYCLE TIRES AND TUBES FROM THE REPUBLIC OF KOREA

Preliminary Countervailing Duty Determination

AGENCY: U.S. Customs Service, Treasury Department.

ACTION: Preliminary Countervailing Duty Determination.

SUMMARY: This notice is to inform the public that a countervailing duty investigation has resulted in a preliminary determination that the Government of the Republic of Korea has given benefits which are considered to be bounties or grants on the manufacture or exportation of bicycle tires and tubes within the meaning of the Countervailing Duty Law. A final determination will be made by December 29, 1978. Interested parties will have an opportunity to comment on this action.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

William Trujillo, U.S. Customs Service, Office of Operations, Duty Assessment Division, Technical Branch, 1301 Constitution Avenue NW., Washington, D.C. 20229, 202-566-5492.

SUPPLEMENTARY INFORMATION: On February 23, 1978, a notice of "Receipt of Countervailing Duty Petition and Initiation of Investigation" was published in the FEDERAL REGISTER (43 FR 7495). The notice stated that a petition had been received alleging that benefits conferred by the Government of South Korea upon the manufacture, production or exportation of bicycle tires and tubes constitute the payment or bestowal of a bounty or grant within the meaning of section 303, Tariff Act of 1930 as amended (19 U.S.C. 1303).

For purposes of this notice the term "bicycle tires and tubes" means pneumatic bicycle tires, and tubes, of rubber or plastic, whether such tires and tubes are sold together as units or separately. Bicycle tires and tubes are covered under items 772.48 and 772.57, respectively, of the Tariff Schedules of the United States (TSUS).

Based upon the information received thus far, pursuant to an investigation conducted under § 159.47(c) of the Customs Regulations (19 CFR 159.47(c)), there appear to be three programs that are utilized by Korean firms exporting bicycle tires and tubes to the United States which constitute bounties or grants within the meaning of the law. However, only one of the three firms exporting to the United States, Korea Inoue Kasei, receives benefits from these programs that in the aggregate exceed what we have in the past regarded as a de minimis amount. The aggregate benefits received by Inoue were 0.50 percent ad valorem. Whether this is to be treated as de minimis in relation to the size of the regular duty or other criteria will be considered in connection with the final determination. The aggregate benefits received by the other two companies investigated, Dae Yung Tire & Rubber Co., Ltd., and Hung-A Industrial Co., Ltd. were 0.31 and 0.34 percent, respectively, which are de minimis by our existing standards.

The three countervailable programs which are taken advantage of by one or all of the companies are as follows:

1. FOREIGN CAPITAL INDUCEMENT LAW

The Foreign Capital Inducement Law (FCIL), which was promulgated on August 3, 1966, has as its purpose the "inducement and protection of foreign capital conducive to the sound develoment of a self-sustaining national economy and the improvement of the international balance of payments." The program provides benefits to companies which are wholly or

partially foreign-owned, based upon the extent of foreign ownership. These benefits take the form of drawback on imported capital equipment, income tax exemption, property acquisition tax exemption and property tax exemption. Although this program ostensibly is designed to compensate foreign investors for risks either inherent in investing in a country faced by the threat of war from North Korea or created by problems of converting and repatriating Korean currency, and thus could be treated as compensation for dislocation costs, no evidence was submitted to indicate that the benefits were related to dislocation costs. Only one of the three Korean firms exporting to the United States, Inoue, qualified for and took advantage of this program. The benefits received amounted to 0.24 percent ad valorem. Therefore, this program, in the case of Inoue, has the effect of a subsidy on production that is subject to countervailing because the entirety of Inoue's production is exported.

2. ACCELERATED DEPRECIATION

Article 51 of the Enforcement Decree to the Corporation Tax Law permits a firm earning more than 50 percent of its total proceeds from foreign exchange to increase its normal depreciation by 30 percent. Although two firms were eligible for this program, only one, Hung-A, could take advantage of it since the other received similar benefits under the Foreign Capital Inducement Law. The benefits received by Hung-A in this instance were equivalent to 0.06 percent ad valorem on the merchandise imported into the United States.

3. SHORT-TERM PREFERENTIAL FINANCING

Pursuant to the "Regulation for Export Financing" Korean exporters are entitled to short-term loans (up to 180 days) at a rate of interest which is normally 8 percent for the purpose of acquiring imported raw materials used in production for export. However, such short term loans are commercially available only at rates that range from 15 percent to 18 percent. All three firms exporting to the United States took advantage of this program. In no case did the individual company benefit exceed 0.31 percent ad valorem.

There are certain practices of the Korean Government alleged to be bounties in this case, which do not on their face constitute bounties or grants. They are the following:

1. EXEMPTION FOR EXPORT-ORIENTED BUSINESSES FROM BUSINESS TAX

This tax has been viewed in previous investigations as an indirect tax which is directly related to the product and therefore, pursuant to consistent policy, as upheld in the *Zenith* case, not a bounty or grant under the law. (Preliminary Countervailing Duty Determination in Footwear from the Republic of Korea, July 3, 1975 (40 FR 28105).)

2. EXEMPTION FROM COMMODITY TAX AND CUSTOMS DUTIES ON IMPORTED MATERIAL

Just as with the Business Tax, both the Commodity Tax and drawback provisions have been viewed as not constituting bounties or grants. (Preliminary Countervailing Duty Determination in Handbags from the Republic of Korea, December 1, 1976 (41 FR 52737).) Furthermore, both the Business Tax and the Commodity Tax were replaced by a Value Added Tax on July 1, 1977, so that the issue is now moot.

3. WASTAGE ALLOWANCE FOR IMPORTED RAW MATERIALS

This program provides what amounts to a drawback on imported raw materials that are used in the production of exported products but which are, in fact, "waste" because they are not actually incorporated in the product. The concept of "wastage allowance" has been determined in previous cases involving Korea to be in conformance with accepted international principles governing drawbacks. Petitioner has alleged that the wastage allowance is excessive and therefore constitutes a bounty. Although the available information indicates that no excessive wastage allowance was granted to this industry, more information is required before this issue can be resolved definitively. However, in light of past practices this is preliminarily not regarded as a bounty or grant.

There were numerous other programs alleged which conceptually are bounties or grants but which were either not utilized by or not available to manufacturers or exporters of bicycle tires and tubes.

These programs are described briefly below:

1. ACCELERATED DEPRECIATION FOR FIRMS LOCATED IN "INDUSTRIAL DEVELOPMENT DISTRICTS"

There is no such "district" in the Republic of Korea, although there are "rural development districts". However, none of the manufacturers exporting to the United States is located in these districts.

2. MISCELLANEOUS TAX BENEFITS

Publicly-held or government-owned corporations are entitled to certain tax benefits, such as tax-exemption from interest on holdings of stocks and debentures. However, none of the firms exporting to the United States is publicly-held or government-owned. Therefore, none of the companies investigated was eligible to benefit from these miscellaneous tax provisions.

3. INDUSTRIAL ESTATES

The Industrial Estate Management Law, which superseded a similar law December 31, 1977, has as its purpose the encouragement of investment outside of the heavily populated areas of the country. The Government develops the necessary infrastructure on these estates. However, the Korean Government claims that the benefits which flow from being located on these estates, such as low land costs, adequate power and water supplies and good road networks, do not arise from government subsidization but instead from the fact that land values and the cost of basic services in the areas where these industrial estates are located, are lower than in other geographic areas of the country. Only one of the three manufacturers investigated is located on one of these industrial estates and no evidence was received indicating that it received any benefits at non-commercial terms not available to any company locating in that region. Furthermore, the present law, in contrast to the old law, does not require that a company be an exporter to be located on such an estate so that there is no direct export relationship to the provision of infrastructure to companies locaing on these estates.

4. FREE EXPORT ZONES

Only one of the companies is located in a Free Export Zone. However, that company utilizes only the drawback provision on imported raw material. It receives no preferential financing as a result of being located in such a zone, nor any other benefits.

5. GOVERNMENT ASSUMPTION OF QUALITY CONTROL ON EXPORTS

Petitioner alleged that the Government assumes the cost of quality control inspections on exported merchandise. The response to the Customs' questionnaire, however, indicates that the bicycle tire and tube manufacturers are fully responsible for the costs of such quality control measures.

6. RAILWAY FREIGHT AND ELECTRIC POWER DISCOUNTS

No manufacturer exporting to the United States utilized rail transportation and all the companies pay standard utility rates. However, more information is needed to determine if utility rates in general might be subsidized by the Government in such a manner as to confer a bounty or grant on the manufacture of this merchan-

dise. At this time, no evidence of such a subsidy has been received.

7. EXPORT-IMPORT "LINK SYSTEM"

This program, which was abolished December 31, 1977, provided for the duty-free importation of certain dutiable items and their domestic resale, with the profit accruing to the seller. Petitioner alleges that the availability of this program was linked to export performance. None of the bicycle tire and tube manufacturers utilized this program in 1977.

8. MEDIUM AND LONG-TERM PREFERENTIAL FINANCING

None of the three manufacturers investigated utilized any preferential financing for medium and long-term loans.

Accordingly, it is determined preliminarily that bounties or grants, within the meaning of section 303, are being paid or bestowed, directly or indirectly, upon the manufacture, production or exportation of bicycle tires and tubes from the Republic of Korea. A final decision in this case is required on or before December 29, 1978.

Before a final determination is made, consideration will be given to any relevant data, views or arguments submitted in writing with respect to the preliminary determination. In particular, comments are invited concerning Treasury's standard for determining de minimis bounties or grants. Submissions should be addressed to the Commissioner of Customs, 1301 Constitution Avenue, NW., Washington, D.C. 20229, in time to be received by him not later than August 28, 1978.

This preliminary determination is published pursuant to section 303(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)).

Pursuant to Reorganization Plan No. 26 of 1950 and Treasury Department Order 190 Revision 15, March 16, 1978, the provisions of Treasury Department Order No. 165, Revised, November 2, 1954 and § 159.47 of the Customs Regulations (19 CFR 159.47), insofar as they pertain to the issuance of a preliminary countervailing duty determination by the Commissioner of Customs are hereby waived.

July 21, 1978.

HENRY C. STOCKELL, Jr.,
Acting General Counsel of the Treasury.

[FR Doc. 78-20899 Filed 7-27-78; 8:45 am]

[4810-22]

BICYCLE TIRES AND TUBES FROM THE REPUBLIC OF CHINA

Preliminary Countervailing Duty Determination

AGENCY: United States Customs Service, Treasury Department.

ACTION: Preliminary Countervailing Duty Determination.

SUMMARY: This notice is to advise the public that a countervailing duty investigation has resulted in a preliminary determination that the Government of the Republic of China (Taiwan) has given benefits which are considered to be bounties or grants on the manufacture, production or exportation of bicycle tires and tubes within the meaning of the Countervailing Duty Law. A final determination will be made not later than December 29, 1978. Interested parties are invited to comment on this action.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

William T. Trujillo, Operations Officer, U.S. Customs Service, Office of Operation, Duty Assessment Division, Technical Branch, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On February 23, 1978, a "Notice of Receipt of Countervailing Duty Petition and Initiation of Investigation" was published in the FEDERAL REGISTER (43 FR 7494-5). The notice stated that benefits conferred by the Government of Taiwan upon the manufacture, production or exportation of bicycle tires and tubes may constitute the payment or bestowal of a bounty or grant within the meaning of section 303, Tariff Act of 1930, as amended (19 U.S.C. 1303) (herein referred to as "the Act").

For purposes of this notice the term "bicycle tires and tubes" means pneumatic bicycle tires, and tubes, of rubber or plastics, whether such tires and tubes are sold together as units or separately. Bicycle tires and tubes are covered under items 772.48 and 772.57, respectively, of the Tariff Schedules of the United States (TSUS).

On the basis of an investigation conducted pursuant to § 159.47(c), Customs Regulations (19 FR 159.47(c)), it preliminarily has been determined that certain practices of the Government of the Republic of China constitute bounties or grants within the meaning of section 303 of the act. These practices, as described by the Taiwanese Government are:

1. INCOME TAX CEILING

Under the Statute for the Encouragement of Investment, firms whose establishment or expansion was approved before December 31, 1973, qualify for a tax ceiling equivalent to 25 percent of the firm's taxable income. Several of the firms exporting bicycle tires and tubes benefited from this provision. Inasmuch as the great preponderance of production is exported, this program has the effect of a bounty.

2. PREFERENTIAL EXPORT FINANCING

Several firms exporting bicycle tires and tubes received advantageous loan rates, in connection with an export loan program, for the purchase of raw materials. The preferential loan rate is 6.5 percent (per annum) for a term not to exceed 6 months. The regular commercial loan rate varies between 10.5 to 10.75 percent for loans of similar terms.

3. DEFERRED PAYMENT OF DUTIES ON IMPORTED MACHINERY AND EQUIPMENT

The bicycle tire and tube industry qualifies for installment payment of Customs duties on imported machinery and equipment. Because this practice represents the interest-free use of money, it is conceptually a bounty or grant. However, more information is needed in order to determine the extent, if any, of the utilization of this program.

4. GOVERNMENT ASSUMPTION OF QUALITY CONTROL EXPENSES

Petitioner provided information which showed the possibility that the Taiwanese Government assumes all or a part of the cost of production quality control measures. If the Government actually assumes the costs of meeting required quality control standards, then that would be viewed as conferring a bounty or grant. However, if the Government merely sets standards, with the responsibility for meeting those standards left to the companies themselves, then that does not constitute a bounty. More information is needed to make this judgment.

There are certain practices of the Taiwanese Government alleged to be bounties or grants in this case which do not on their face constitute bounties or grants. They are the following:

1. EXEMPTION FROM BUSINESS AND COMMODITY TAXES ON EXPORTS

These taxes have been viewed in previous investigations as indirect taxes which are directly related to the product and, therefore, pursuant to consistent policy, as upheld in the *Zenith* case, not a bounty or grant under the law. (Preliminary Countervailing Duty

Determination in Bicycles from the Republic of China, October 27, 1976 (41 FR 47084).)

2. EXEMPTION FROM COMMODITY TAX AND CUSTOMS DUTIES ON IMPORTED MATERIAL

Consistent with Treasury's long-established practice, drawback of duties on imports incorporated into exports are not regarded as bounties or grants.

3. EXEMPTION OF HARBOR DUES ON IMPORTED RAW MATERIAL

The exemption of harbor dues on imported raw material used in production for export has been determined in prior cases not to be countervailable because the Government's decision to finance harbor facilities by means other than user charges is a legitimate state function that does not confer a bounty to industries which benefit from such facilities. Further, there is no information to show that given sectors of the Taiwanese economy benefit from harbor facilities more than others. This is in contrast to the case of Canadian fish wherein the Government of Canada provided grants for the improvement of wharves and dockside storage facilities which were determined to be utilized almost exclusively by the fishing industry.

There were numerous other programs alleged which conceptually are bounties or grants but which were either not utilized by or not available to manufacturers or exporters of bicycle tires and tubes.

These programs are described briefly below:

1. INCOME TAX HOLIDAYS OR ACCELERATED DEPRECIATION

This provision under the Statute for the Encouragement of Investment provides income tax holidays or accelerated depreciation for approved firms. However, no manufacturer in the bicycle tires and tube industry utilized this provision during the period investigated and none has received any tax concession under this provision since January of 1974.

2. TAX INCENTIVES FOR SALES PROMOTION ABROAD

This provision allows qualified firms to deduct overseas sales promotion expenses in excess of those permitted by the income tax law. The actual expenses incurred by bicycle tire and tube manufacturers on travel abroad did not exceed the limitation specified by law and therefore no benefit was realized.

3. TAX CEILING FOR HIGH TECHNOLOGY FIRMS

A tax ceiling of 22 percent of taxable income is established for "high technology" firms. However, no manufacturer in this industry qualified as a "high technology" firm.

4. DEFERRED PAYMENT OF LAND INCREMENT TAXES

Bicycle tire and tube manufacturers qualified for installment payments on land increment taxes. However, no benefits were received by any of the companies during the period investigated.

5. MISCELLANEOUS TAX BENEFITS FOR PUBLICLY-LISTED ENTERPRISES

Although bicycle tire and tube manufacturers qualified for various tax benefits related to publicly-held companies, none of the manufacturers received benefits under any of these provisions.

6. TAX BENEFITS FOR FIRMS IN INDUSTRIAL DISTRICTS

For firms located in such districts, an exemption from the deed tax or house tax is granted. Although manufacturers in this industry qualified for benefits, none received any.

EXPORT PROCESSING ZONES

No bicycle tire or tube manufacturers are located in Export Processing Zones. Consequently, no benefits were received.

9. RAILWAY FREIGHT RATES

Although there was no reduction in railway freight rates granted to bicycle tires and tubes for export, no definitive decision can be made on this practice until it is known whether the Government assumes operating costs or provides other subsidies for the railroads which would result in a general reduction in railway freight rates.

Accordingly, it is determined preliminarily that bounties or grants, within the meaning of section 303, are being paid or bestowed, directly or indirectly, upon the manufacture, production or exportation of bicycle tires and tubes from the Republic of China. A final decision in this case is required on or before December 29, 1978.

Before a final determination is made, consideration will be given to any relevant data, views or arguments, submitted in writing with respect to the preliminary determination. Submissions should be addressed to the Commissioner of Customs, 1301 Constitution Avenue NW., Washington, D.C. 20229, in time to be received by him no later than August 28, 1978.

This preliminary determination is published pursuant to section 303(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)).

Pursuant to Reorganization Plan No. 26 of 1950 and Treasury Department Order 190 Revision 15, March 16, 1978, the provisions of Treasury Department Order No. 165, Revised, November 2, 1954 and § 159.47 of the Customs Regulations (19 CFR 159.47), insofar as they pertain to the issuance of a preliminary countervailing duty determination by the Commissioner of Customs are hereby waived.

July 21, 1978.

HENRY C. STOCKELL, Jr.,
Acting General Counsel of the Treasury.

[FR Doc. 78-20900 Filed 7-27-78; 8:45 am]

[4810-25]

Office of the Secretary

USA-JAMAICA TAX TREATY ISSUES

Public Meeting

The Treasury Department today announced that it will hold a public meeting on August 21, 1978, to solicit the views of interested persons regarding issues being considered during negotiations to develop a new income tax treaty between the United States and Jamaica.

The public meeting will be held at the Treasury Department, at 2 p.m., in room 4121. Persons interested in attending are requested to give notice in writing, by August 15, 1978, of their intention to attend. Notices should be addressed to H. David Rosenbloom, International Tax Counsel, Department of the Treasury, Washington, D.C. 20220.

Today's announcement of the August public meeting follows the recent conclusion of a further round of negotiations between representatives of the United States and Jamaica to develop a new income tax treaty for the avoidance of double taxation and the prevention of tax evasion. The income tax treaty presently in effect is an extension to Jamaica of the United States-United Kingdom income tax treaty of 1945.

In the course of the recent negotiations, many subjects of mutual concern were identified and discussed. Among the major issues being considered are: Taxation of corporations organized in one country but managed or controlled in the other country; taxation of dividends, interest, and royalties; the rules relating to permanent establishments; and the taxation of various forms of personal service income.

The Treasury seeks the views of interested persons in regard to these issues, as well as other matters that may have relevance in the context of an income tax treaty between the United States and Jamaica. The August 21 public meeting is being held to provide an opportunity for an exchange of views, as well as for the purpose of discussing the United States

position in regard to the issues presented in the negotiations.

Dated: July 25, 1978.

DONALD C. LUBICK,
Assistant Secretary
(Tax Policy).

[FR Doc. 78-20901 Filed 7-27-78; 8:45 am]

[4810-25]

USA-BANGLADESH TAX TREATY ISSUES

Request for Public Comments

The Treasury Department today announced that it is soliciting the views of interested persons regarding issues being considered during negotiations to develop an income tax treaty between the United States and Bangladesh.

Persons interested in commenting may do so in writing or they may request a meeting with Treasury officials. Written comments and meeting requests should be addressed to H. David Rosenbloom, International Tax Counsel, Department of the Treasury, Washington, D.C. 20220, by August 15, 1978.

Today's request for comments follows the conclusion of a further round of negotiations between representatives of the United States and Bangladesh to develop an income tax treaty for the avoidance of double taxation and the prevention of tax evasion. There is currently no tax treaty in force between the United States and Bangladesh.

In the course of the recent negotiations, many subjects of mutual concern were identified and discussed. Among the major issues being considered are: Taxation of dividends, interest, and royalties; taxation of rentals of motion picture films; the rules relating to permanent establishments; the treatment of various forms of personal service income; and the treatment of shipping profits. With respect to the taxation of shipping income, the Treasury announced that it is considering a provision that would have the effect of allowing internal law to apply in both countries. The views of interested parties on this matter are particularly sought.

The Treasury seeks the views of interested persons in regard to these issues, as well as any other matters that may have relevance in the context of an income tax treaty between the United States and Bangladesh.

Dated: July 25, 1978.

DONALD C. LUBICK,
Assistant Secretary
(Tax Policy).

[FR Doc. 78-20902 Filed 7-27-78; 8:45 am]

[4810-22]

STAINLESS STEEL ROUND WIRE FROM JAPAN

Antidumping Proceeding Notice

AGENCY: U.S. Treasury Department.

ACTION: Initiation of antidumping investigation.

SUMMARY: This notice is to advise the public that a petition in proper form has been received and an antidumping investigation is being initiated for the purpose of determining whether imports of stainless steel round wire from Japan are being, or are likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended. However, as there appears to be substantial doubt that imports of the subject merchandise at less than fair value are the cause of present, or likely future injury to an industry in the United States, the case is being referred to the U.S. International Trade Commission pursuant to section 201(c)(2) of the act.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Stephen Nyschot, Operations Officer, U.S. Customs Service, Office of Operations, Duty Assessment Division, Technical Branch, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On July 14, 1978, information was received in proper form pursuant to §§ 153.26 and 153.27, Customs Regulations (19 CFR 153.26, 153.27), from counsel acting on behalf of various American manufacturers, indicating a possibility that stainless steel round wire from Japan is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended (19 U.S.C. 160 et seq.). The petitioners are: Alloy Wire Manufacturing Co., Houston, Tex.; Al Tech Specialty Steel Corp., Dunkirk, N.Y.; ARMCO Steel Corp., Philadelphia, Pa.; Branford Wire Manufacturing Co., North Haven, Conn.; Brookfield Wire Co., Inc., Brookfield, Mass.; Carpenter Technology Corp., Reading, Pa.; Crucible Inc., Specialty Metals Division, Syracuse, N.Y.; Cyclops Corp., Pittsburg, Pa.; Harris Metals Co., Holyoke, Mass.; Industrial Alloys, Inc., city of Industry, Calif.; Madison Wire Co., Buffalo, N.Y.; Mapes Piano String Co., Elizabethton, Tenn.; Maryland Specialty Wire Co., Cockeysville, Md.; National Standard Co., Niles, Mich.; H. K. Porter Co., Inc., Alloy Metals Wire Works, Prospect Park, Pa.; Techalloy Co., Inc., Rahns, Pa.; and Willing B. Wire Corp., Beverly, N.J.

For purposes of this notice, the term "stainless steel round wire" means stainless steel wire, as defined and provided for in item 609.45, Tariff Schedules of the United States.

Price information received from the petitioners tends to indicate that the prices of this merchandise sold for exportation to the United States are less than the prices in the home market. Petitioners' information also tends to indicate that home market sales have been occurring at less than the cost of production under section 205(b) of the act (19 U.S.C. 165(b)).

There is evidence on record concerning injury to, or the likelihood of injury to, or prevention of establishment of an industry in the United States. This evidence also indicates, however, that were alleged less than fair value sales of the subject merchandise eliminated, substantial margins of underselling of the domestic industry would still remain. Moreover, domestic sales of coarse wire have nearly doubled between 1975 and 1977 and sales of fine wire are no lower in 1977 than in 1975. On the basis of such evidence it has been concluded that there is a substantial doubt of injury, or likelihood of injury, to an industry in the United States by virtue of such imports from Japan. Accordingly, the U.S. International Trade Commission is being advised of such doubt pursuant to section 201(c)(2) of the act (19 U.S.C. 160(c)(2)).

Having conducted a summary investigation as required by § 153.29 of the Customs Regulations (19 CFR 153.29) and having determined as a result thereof that there are grounds for so doing, the U.S. Customs Service is instituting an inquiry to verify the information submitted and to obtain the facts necessary to reach a determination as to the fact or likelihood of sales at less than fair value. Should the International Trade Commission, within 30 days of receipt of the information cited in the preceding paragraph, advise the the Secretary that there is no reasonable indication that an industry in the United States is being, or is likely to be, injured, or is prevented from being established by reason of the importation of such merchandise into the United States, the Department will publish promptly in the FEDERAL REGISTER a notice terminating the investigation. Otherwise, the investigation will continue to conclusion.

This notice is published pursuant to § 153.30 of the Customs regulations (19 CFR 153.30).

HENRY C. STOCKELL, Jr.,
Acting General Counsel
of the Treasury.

JULY, 20, 1978.

[FR Doc. 78-20903 Filed 7-27-78; 8:45 am]

[4810-22]

VISCOSE RAYON STAPLE FIBER FROM BELGIUM

Antidumping; Modification of Determination of Sales at Less Than Fair Value

AGENCY: U.S. Treasury Department.

ACTION: Modification of determination of sales at less than fair value.

SUMMARY: This notice is to advise the public that the "Determination of Sales at Less Than Fair Value" under the Antidumping Act, 1921, as amended, on viscose rayon staple fiber from Belgium has been reconsidered. The determination is being modified to reflect the results of this reconsideration.

EFFECTIVE DATE: July 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Mary S. Clapp, Operations Officer, Office of Operations, Duty Assessment Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On May 1, 1978, a "Determination of Sales at Less Than Fair Value" was published in the FEDERAL REGISTER (43 FR 18619-20). That notice states:

"Following publication of the Tentative Determination, an additional claim was made that Fabelta's home market sales had been made at less than the cost of producing the merchandise, invoking section 205(b) of the act (19 U.S.C. 164(b)). This allegation is currently being investigated. Should this investigation establish that some or all home market sales must be disregarded and that another basis (i.e., third country sales prices or constructed value) for determining fair value must be used, the new basis will be published and we will immediately advise the U.S. International Trade Commission of any revised LTFV margins for its consideration."

Information requested from Fabelta with respect to the cost of production of this merchandise and the prices charged by Fabelta in sales to third countries has not been received. It has therefore been concluded that a determination whether such home market sales have occurred at less than the cost of production must be made based upon the best evidence otherwise available to the Treasury Department.

The best available evidence to us of the cost of production of this merchandise in Belgium is primarily drawn from information concerning the cost of production of this merchandise by members of the American rayon staple fiber industry, with adjustments for ascertainable differences in costs of materials and direct production labor, between the United States and Western Europe, as corroborated by information from a number of sources including the Bureau of Labor Statistics and European companies affiliated with domestic producers of this merchandise. Information provided by members of the domestic industry with respect to various cost input factors for labor and raw materials have also been compared to information of the same factors submitted by an Austrian producer of such or similar merchandise during a comparable time frame which was received in a companion case concerning such merchandise from Austria and which has been verified by the Customs Service. This examination indicates that information submitted by members of the domestic industry bearing on the cost of production of this merchandise from Belgium is not unreliable.

However, a claim by petitioner that an imputed cost of invested and internally generated working capital should be included if the cost of production calculation has been rejected. Section 153.5 of the Customs regulations (19 CFR 153.5), contemplates the calculation of the cost of production by reference to costs determined in accordance with generally accepted accounting principles in the country of manufacture (unless these artificially distort the results, in which case U.S. generally accepted accounting principles may be applied). In the absence of any evidence that such imputed costs of capital would be regarded as cost of production under generally accepted accounting principles in the United States, much less in Belgium, no adjustment for these costs has been allowed.

Using the above criteria, it has been found that all of Fabelta's sales of viscose rayon staple fiber sold during the period of investigation were made at prices less than the cost of producing the merchandise. Not having received requested information from Fabelta with respect to sales of this product to third countries, the constructed value of the merchandise, as defined in section 206 of the act (19 U.S.C. 165), has been compared to the purchase price as previously calculated for purposes of making fair value comparisons, in accordance with section 153.5 of the Customs regulations (19 CFR 153.5). Comparisons were made on 100 percent of the subject merchandise to the United States during the period of investigation, and the amended weighted average margin so calculated is 57.6 percent.

Accordingly, the "Notice of Determination of Sales at Less Than Fair Value" referred to above is modified to reflect the revised reasons, bases and results of fair value comparisons set forth above.

The U.S. International Trade Commission is being advised of this determination.

This determination is being published pursuant to section 201(d) of the act (19 U.S.C. 160(d)).

Dated: July 21, 1978.

HENRY C. STOCKELL, Jr.,
Acting General Counsel of the Treasury.

[FR Doc. 78-20904 Filed 7-27-78; 8:45 am]

[4810-25]

Office of the Secretary

[Treasury Department Order No. 246 (Revision 1)]

FOREIGN INTELLIGENCE ACTIVITIES UNDER EXECUTIVE ORDER 12036

Responsibilities for Oversight

By virtue of the authority vested in me as Secretary of the Treasury, including the authority vested in me by Reorganization Plan No. 26 of 1950, and pursuant to Executive Order 12036, it is ordered as follows:

1. The Inspector General established by Treasury Department Order No. 256 shall assume for the Treasury Department the duties and responsibilities under Executive Order 12036 (hereinafter Executive Order) for Inspectors General within the Intelligence Community.

2. The General Counsel shall assume for the Treasury Department the duties and responsibilities established under the Executive Order for General Counsels within the Intelligence Community.

3. The Inspector General shall inform in writing all employees in the Office of the Assistant Secretary for International Affairs (OASIA) and in the Office of Intelligence Support of the restrictions on intelligence activities contained in Section 2 of the Executive Order and obtain a written acknowledgment from each such employee that he has read the materials provided by the Inspector General. Heads of inspection services of Treasury Department Bureaus shall provide a copy of Section 2 of the Executive Order to each employee within their bureau.

4. Treasury Department employees shall report in confidence to the Inspector General, the General Counsel, or the head of the inspection service of their bureau any matters which they feel raise questions of propriety or legality under the Executive Order.

5. The Inspector General shall review at appropriate intervals any foreign intelligence activities of the Treasury Department to determine whether any such activities raise questions of propriety under the Executive

Order. Any questions arising from this review as to the legality of such activities shall be referred by the Inspector General to the General Counsel. In connection with the activities of the OASIA representatives stationed overseas, the Inspector General shall seek to make appropriate arrangements with the State Department to provide for adequate inspection while avoiding duplication of inspection activities by the State and Treasury Department.

6. The inspection service within a bureau shall review at appropriate intervals the activities of the bureau in its relations with U.S. foreign intelligence agencies to determine whether such activities raise questions of legality or propriety. Any questions of legality or propriety arising from this review shall be referred to the Inspector General who shall report to the General Counsel any illegal activities. The procedures established by Treasury Department Order No. 240 (Revision 1), which provides for coordination and review of support arrangements between the Treasury Department and U.S. foreign intelligence agencies, shall remain in full force and effect.

7. Treasury Department employees shall cooperate with the Inspector General, the General Counsel, and the inspection service within their bureau and shall make available all necessary data to allow those officials to perform their duties and responsibilities under this Order.

8. Treasury Department Order No. 246 is rescinded, effective this date.

Dated: July 18, 1978.

W. MICHAEL BLUMENTHAL,
Secretary of the Treasury.

[FR Doc. 78-20876 Filed 7-27-78; 8:45 am]

[4810-25]

[Treasury Department Order No. 256]

ESTABLISHMENT OF THE POSITION OF INSPECTOR GENERAL

Pursuant to the authority vested in me as Secretary of the Treasury by Reorganization Plan No. 26 of 1950, there is hereby established the position of Inspector General reporting directly to the Secretary and Deputy Secretary. The Inspector General is authorized to perform the following duties:

1. Receive and analyze allegations of (i) illegal acts, (ii) violations of the Rules of Conduct of the Treasury Department or Bureaus, (iii) violations of the merit system or (iv) any other misconduct (if the matter is one which is not appropriate for normal grievance or appeal procedure or other routine management action) concerning any official or employee of any Treasury office or Bureau.

2. Receive by referral from head of Treasury offices or Bureaus serious allegations of official or employee misconduct which the Treasury office or Bureau does not want to investigate using its own staff.

3. With regard to senior Treasury and Bureau officials:

a. Initiate, organize, direct, and control investigations of any allegations received pursuant to paragraphs 1 or 2 against such officials which have potential validity and which, within the discretion of the Inspector General, merit such action, and,

b. Review and report the results of investigations of senior officials conducted by the Inspector General or at his or her direction to the Secretary or Deputy Secretary for appropriate action.

4. Refer allegations of mis- conduction by any nonsenior official or employee of a Treasury office or Bureau that does not have an Inspection service to any Inspection service within Treasury for investigation and receive a full report of the results of such investigation.

5. Refer any complaints concerning improper activity of a nonsenior official or employee of a Treasury office or Bureau that has an Inspection service to that service and receive a full report concerning the investigation and action taken concerning any such referral.

6. Conduct in exceptional situations such investigations as may be specifically directed by the Secretary or Deputy Secretary concerning any allegations or misconduct by an official or employee of any Treasury office or Bureau.

7. Review existing policies, procedures and operations for ascertaining, reporting and investigating misconduct of officials and employees of any Treasury office or Bureau and, after consulting with other Treasury officials as may be appropriate, make recommendations, if any, to the Secretary or Deputy Secretary for their change or implementation.

8. Carry out those duties and functions set forth in Treasury Department Order No. 246 (Rev.) which are required of the Department under Executive Order 12036 and relate to the oversight of foreign intelligence activities in Treasury.

9. Obtain, as needed, under prescribed procedures developed pursuant to paragraph 10, investigative and other support personnel from Inspection services within Treasury for conducting investigations under his or her direct supervision, any such detailed personnel to remain on the rolls of the services from which they are detailed but to report exclusively to the Inspector General as to the matter being investigated.

10. Develop detailed procedures and definitions for approval by the Deputy Secretary and Secretary which shall become a part of this Order.

This Order does not change or reduce the authority presently existing in Treasury offices or Bureaus having Inspection services to conduct their own investigations in accordance with their procedures with the exception of investigations being conducted by the Inspector General. Where notice is received by a Treasury office or Bureau from the Inspector General that he or she is conducting an investigation in a particular area, no investigation or similar activity will be initiated or continued in that area by any Treasury office or Bureau except with the approval of the Inspector General.

Dated: July 18, 1978.

W. MICHAEL BLUMENTHAL,
Secretary of the Treasury.

[FR Doc. 78-20877 Filed 7-27-78; 8:45 am]

[7035-01]

INTERSTATE COMMERCE COMMISSION

[Notice No. 687]

Assignment of Hearings

JULY 25, 1978.

Cases assigned for hearing, postponement, cancellation, or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the official docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 103993 (Sub-914), Morgan Drive-Away, Inc., now assigned September 26, 1978, at Little Rock, AR, is canceled and transferred to modified procedure.

MC 94201 (Sub-157), Bowman Transportation, Inc., is now assigned for hearing November 28, 1978 (2 weeks) at New Orleans, LA, at a location to be later designated.

MC-F 13400, Overnite Transportation Co.—purchase—St. Louis-Kansas City Express, Inc., is now assigned for hearing October 16, 1978 (1 week) at St. Louis, MO, at a location to be later designated.

MC 114211 (Sub-334), Warren Transport, Inc., now assigned September 27, 1978, at Little Rock, AR, will be held in room 3412, Federal Office Building, 700 West Capitol Street.

MC 111231 (Sub-221), Jones Truck Lines, Inc., now assigned October 2, 1978, at Little Rock, AR, will be held in room 3412, Federal Office Building, 700 West Capitol Street.

MC 141804 (Sub-100F), Western Express, Division of Interstate Rental, Inc., is now

assigned for hearing September 20, 1978 (1 day) at Los Angeles, CA, at a location to be later designated.

MC 141804 (Sub-97), Western Express, Division of Interstate Rental, Inc., is now assigned for hearing September 21, 1978 (2 days) at Los Angeles, CA, at a location to be later designated.

MC 32492 (Sub-173), Michigan & Nebraska Transit Co., Inc., now assigned September 6, 1978, at Columbus, OH, is canceled and transferred to modified procedure.

MC 115841 (Sub-577), Colonial Refrigerated Transportation, Inc., now assigned September 6, 1978, at Nashville, TN, is canceled; application dismissed.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-20945 Filed 7-27-78; 8:45 am]

[7035-01]

[Rule 19; Ex Parte No. 241; Forty-Seventh Rev. Exemption No. 90]

ABERDEEN AND ROCKFISH RAILROAD CO. ET AL.

Exemption Under Provision of Mandatory Car Service Rules

It appearing, that certain of the railroads named below own numerous 50-ft. plain boxcars; that under present conditions, there are substantial surpluses of these cars on their lines; that return of these cars to the owners would result in their being stored idle; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of these cars, resulting in unnecessary loss of utilization of such cars; and

It further appearing, that there are substantial shortages of 50-ft. plain boxcars throughout the country; that the carriers identified in this exemption by the symbol (%) have 150% or more of their ownership of these cars on their lines; and that such a disproportionate use of the total supply of such cars causes shippers served by other lines to be deprived of their proper share of such cars.

It is ordered, That, pursuant to the authority vested in me by Car Service Rule 19, 50-ft. plain boxcars described in the Official Railway Equipment Register, I.C.C.-R.E.R. No. 407, issued by W. J. Trezise, or successive issues thereof, as having mechanical designation "XM", and bearing reporting marks assigned to the railroads named below, shall be exempt from provisions of Car Service Rules 1, 2(a), and 2(b).

Aberdeen and Rockfish Railroad Co.
Reporting Marks: AR
% The Baltimore & Ohio Railroad Co.
Reporting Marks: BO
% Bessemer & Lake Erie Railroad Co.
Reporting Marks: BLE
Camino, Placerville & Lake Tahoe Railroad Co.
Reporting Marks: CPLT
% The Chesapeake & Ohio Railway Co.
Reporting Marks: CO-PM
% Chicago & Illinois Midland Railway Co.
Reporting Marks: CIM
% Chicago, Rock Island & Pacific Railroad Co.
Reporting Marks: RI-ROCK
City of Prineville
Reporting Marks: COP
The Clarendon & Pittsford Railroad Co.
Reporting Marks: CLP
% Consolidated Rail Corp.
Reporting Marks: CR-DLW-EL-ERIE-LV-NH-NYC P&E-PAE-PC-PCA-PRR-RDG
% Delaware & Hudson Railway Co.
Reporting Marks: DH
Duluth, Missabe & Iron Range Railway Co.
Reporting Marks: DMIR
% Florida East Coast Railway Co.
Reporting Marks: FEC
Genessee & Wyoming Railroad Co.
Reporting Marks: GNWR
% Grand Trunk Western Railroad Co.
Reporting Marks: GTW
Greenville & Northern Railway Co.
Reporting Marks: GRN
*Lenawee County Railroad Co., Inc.
Reporting Marks: LCRC
Louisville & Wadley Railway Co.
Reporting Marks: LW
Louisville, New Albany & Corydon Railroad Co.
Reporting Marks: LNAC
Middletown & New Jersey Railway Co., Inc.
Reporting Marks: MNJ
% Missouri-Kansas-Texas Railroad Co.
Reporting Marks: BKTY-MKT

* * * * * [1]

New Orleans Public Belt Railroad
Reporting Marks: NOPB
% Norfolk & Western Railway Co.
Reporting Marks: ACY-N&W-NKP-WAB
Pearl River Valley Railroad Co.
Reporting Marks: PRV
Providence & Worcester Co.
Reporting Marks: PW
Raritan River Railroad Co.
Reporting Marks: RR
Sacramento Northern Railway
Reporting Marks: SN
St. Lawrence Railroad
Reporting Marks: NSL
Sierra Railroad Co.
Reporting Marks: SERA
Terminal Railway, Alabama State Docks
Reporting Marks: TASD
Tidewater Southern Railway Co.
Reporting Marks: TS
Toledo, Peoria & Western Railroad Co.
Reporting Marks: TPW
*Vermont Railway, Inc.
Reporting Marks: VTR
WCTU Railway Co.
Reporting Marks: WCTR
% Western Maryland Railway Co.
Reporting Marks: WM
% Western Railway of Alabama
Reporting Marks: WA
Youngstown & Southern Railway Co.
Reporting Marks: YS
Yreka Western Railroad Co.
Reporting Marks: YW

Effective July 15, 1978, and continuing in effect until further order of this Commission.

Issued at Washington, D.C., July 13, 1978.

INTERSTATE COMMERCE COMMISSION,
ROBERT S. TURKINGTON,
Agent.

[FR Doc. 78-20948 Filed 7-27-78; 8:45 am]

[7035-01]

[Rule 19; Ex Parte No. 241, Twenty-first Rev. Exemption No. 241]

ATLANTA & SAINT ANDREWS BAY RAILROAD CO., ET AL.

Exemption Under Provision of Mandatory Car Service Rules

It appearing, that the railroads named herein own numerous 40-ft. plain boxcars; that under present conditions, there is virtually no demand for these cars on the lines of the car owners; that return of these cars to the car owners would result in their being stored idle on these lines; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of plain boxcars owned by the railroads listed herein, resulting in unnecessary loss of utilization of such cars.

It is ordered, That, pursuant to the authority vested in me by Car Service Rule 19, plain boxcars described in the Official Railway Equipment Register, I.C.C.-R.E.R. No. 407, issued by W. J. Trezise, or successive issues thereof, as having mechanical designation "XM", with inside length 44-ft. 6-in. or less, regardless of door width and bearing reporting marks assigned to the railroads named below, shall be exempt from the provisions of Car Service Rules 1(a), 2(a), and 2(b).

Atlanta & Saint Andrews Bay Railway Co.
Reporting Marks: ASAB
Chicago, West Pullman & Southern Railroad Co.
Reporting Marks: CWP
Detroit and Mackinac Railway Co.
Reporting Marks: D&M-DM
Illinois Terminal Railroad Co.
Reporting Marks: ITC
Louisville, New Albany & Corydon Railroad Co.
Reporting Marks: LNAC
Richmond, Fredericksburg and Potomac Railroad Co.
Reporting Marks: RFP
Southern Railway Co.[1]
Reporting Marks: CG-NS-SA-SOU

Effective 12:01 a.m. July 15, 1978, and continuing in effect until further order of this Commission.

Issued at Washington, D.C., July 13, 1978.

% Carriers having 150% or more of ownership on lines.

*Addition.

[1]Municipality of East Troy, Wis. deleted.

[1]Addition.

INTERSTATE COMMERCE COMMISSION,
ROBERT S. TURKINGTON,
Agent.

[FR Doc. 78-20949 Filed 7-27-78; 8:45 am]

[7035-01]

[Exception No. 4 to Corrected Second Rev. S.O. No. 1309]

BURLINGTON NORTHERN INC.

Decision

DECIDED JULY 24, 1978.

By ICC Order No. 64 under Revised Service Order No. 1252 CP Rail is authorized to reroute certain traffic it is unable to handle over its line between Fort Steele, British Columbia, and Beaverdell, British Columbia, subject to the concurrence of the receiving line. One such route selected is via the line of the Burlington Northern Inc., between Sand Point, Idaho, and Sweetgrass, Montana, thence via CP Rail beyond those points. Because of limited siding capacity and limited availability of motive power on these lines the BN agreed to accept only specified volumes of rerouted traffic from CP Rail for movement over this route. Through inadvertence CP Rail, on July 18 and 19, 1978, delivered substantially more rerouted traffic to BN for movement between these points than the BN had agreed to accept and was able to move within the time period established by Section (a)(4) of Corrected Second Revised Service Order No. 1309.

It is ordered, Pursuant to the authority vested in the Railroad Service Board by Section (a)(1)(v) of Corrected Second Revised Service Order No. 1309, the Burlington Northern Inc. (BN) is directed to forward traffic rerouted by CP Rail over the BN's lines between Sand Point, Idaho, and Sweetgrass, Montana, within ninety-six (96) hours regardless of the provisions of Section (a)(4) of the order.

By the Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael. Member John R. Michael not participating.

Effective: July 19, 1978.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-20954 Filed 7-27-78; 8:45 am]

[7035-01]

[ICC Order No. 62; Rev. S.O. No. 1252]

CHESAPEAKE AND OHIO RAILWAY CO.

Rerouting or Diversion of Traffic

In the opinion of Robert S. Turkington, Agent, The Cheaspeake and Ohio Railway Company is unable to transport promptly all traffic offered for movement through Bison Yard at Buffalo, New York, because of a strike.

It is ordered,

(a) *Rerouting traffic.* The Cheaspeake and Ohio Railway Company being unable to transport promptly all traffic offered for movement through Bison Yard at Buffalo, New York, because of a strike, that line is authorized to divert or reroute such traffic via any available route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing.

(b) *Concurrence of receiving roads to be obtained.* The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(c) *Notification to shippers.* Each carrier rerouting cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided under this order.

(d) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted by said Agent shall be the rates which were applicable at the time of shipments as originally routed.

(e) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(f) *Effective date.* This order shall become effective at 3 p.m., July 12, 1978.

Expiration date. This order shall expire at 11:59 p.m., July 31, 1978, unless otherwise modified, changed, or suspended.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy of this order shall be filed with the Director, Office of the FEDERAL REGISTER.

Issued at Washington, D.C., July 11, 1978.

INTERSTATE COMMERCE COMMISSION,
ROBERT S. TURKINGTON,
Agent.

[FR Doc. 78-20952 Filed 7-27-78; 8:45 am]

[7035-01]

[ICC Order No. 63; Rev. S.O. No. 1252]

CP RAIL

Rerouting or Diversion of Traffic

In the opinion of Robert S. Turkington, Agent, CP Rail is unable to transport promptly all traffic offered for movement over its lines between Brownville Junction, Maine, and Presque Isle, Maine, because of a washout.

It is ordered,

(a) *Rerouting traffic.* CP Rail being unable to transport promptly all traffic offered for movement over its lines between Brownville Junction, Maine, and Presque Isle, Maine, because of a washout, that line is authorized to divert or reroute such traffic via any available route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing.

(b) *Concurrence of receiving roads to be obtained.* The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(c) *Notification to shippers.* Each carrier rerouting cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided under this order.

(d) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted by said Agent shall be the rates which were applicable at the time of shipment on the shipments as originally routed.

(e) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with

pertinent authority conferred upon it by the Interstate Commerce Act.

(f) *Effective date.* This order shall become effective at 1 p.m., July 13, 1978.

Expiration date. This order shall expire at 11:59 p.m., July 21, 1978, unless otherwise modified, changed, or suspended.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy of this order shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., July 13, 1978.

INTERSTATE COMMERCE COMMISSION,
ROBERT S. TURKINGTON,
Agent.

[FR Doc. 78-20950 Filed 7-27-78; 8:45 am]

[7035-01]

[ICC Order No. 61-A; Rev. S.O. No. 1252]

CP RAIL

Rerouting or Diversion of Traffic

Upon further consideration of ICC Order No. 61 (CP Rail), and good cause appearing therefor:

It is ordered, ICC Order No. 61 is vacated.

This amendment shall become effective at 11:59 p.m., July 11, 1978, and that this order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., July 11, 1978.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

[FR Doc. 78-20951 Filed 7-27-78; 8:45 am]

[7035-01]

[ICC Order No. 64; Rev. S. Order No. 1252]

CP RAIL

Rerouting or Diversion of Traffic

In the opinion of Robert S. Turkington, Agent, CP Rail is unable to transport promptly all traffic offered for movement over its lines originating and terminating at stations between Fort Steele, British Columbia, and Beaverdell, British Columbia, because of track barricaded by outside party at milepost 102 Cranbrook Sub on CP Rail.

It is ordered,

(a) *Rerouting traffic.* CP Rail being unable to transport traffic originating and terminating at stations between Fort Steele, British Columbia, and Beaverdell, British Columbia, because of track barricaded by outside party at milepost 102 Cranbrook Sub on CP Rail, that line is authorized to divert or reroute such traffic via any available route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing.

(b) *Concurrence of receiving roads to be obtained.* The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(c) *Notification to shippers.* Each carrier rerouting cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided under this order.

(d) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted by said Agent shall be the rates which were applicable at the time of shipment on the shipments as originally routed.

(e) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(f) *Effective date.* This order shall become effective at 2 p.m., July 14, 1978.

Expiration date. This order shall expire at 11:59 p.m., August 14, 1978, unless otherwise modified, changed, or suspended.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy of this order shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., July 14, 1978.

INTERSTATE COMMERCE COMMISSION,
ROBERT S. TURKINGTON,
Agent.

[FR Doc. 78-20953 Filed 7-27-78; 8:45 am]

[7035-01]

[Notice No. 91]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act.

Each application (except as otherwise specifically noted) contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application.

Protest against approval of the application, which may include a request for oral hearing, must be filed with the Commission on or before August 28, 1978. Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representative(s), or applicants (if no such representative is named), and the protestant must certify that such service has been made.

Unless otherwise specified, the signed original and six copies of the protest shall be filed with the Commission. All protests must specify with particularity the factual basis, and the section of the act, or the applicable rule governing the proposed transfer which protestant believes would preclude approval of the application. If the protest contains a request for oral hearing, the request shall be supported by an explanation as to why the evidence sought to be presented cannot reasonably be submitted through the use of affidavits.

The operating rights set forth below are in synopses form, but are deemed sufficient to place interested persons on notice of the proposed transfer.

FD-28802, filed July 21, 1978. Transferee: INGRAM MATERIALS, INC., 4304 Harding Road, Nashville, TN 37205. Transferor: Ingram Corp., 4100 One Shell Square, New Orleans, LA 70139. Representative: Donal Macleay, 1625 K Street NW., Washington, D.C. 20006. Authority sought for transfer to transferee of the operating rights of transferor, and for E. B. Ingram affiliated with the Wayerhauser Co. (No.

W-417) to control the said rights through ownership of capital stock. The operating rights, as set forth in Permit No. W-353, issued to Ingram Corp., as latest amended on April 1, 1969, authorizes transferor to perform contract carrier towage service over the Mississippi River below and including Geno, WI, the Ohio River below and including Louisville, KY, and the Gulf Intracoastal Waterway and its tributaries east of and including Houston, TX. In addition, the Permit authorizes transferor to engage, at Nashiville, TN, in the furnishing of towing vessels and barges without crews, owned by it, to persons other than carriers to be used by them in the transportation of their own property. Transferee presently holds no authority from this Commission.

35478 filed, June 21, 1978. Lessee: AG TRUCKING, INC., R.R. 1 Box 206, Milford, IN 46542. Lessor: Hoosier Haulers, Inc., 27800 Company Road 38, Route 3, Goshen, IN 46526. Representative: Gregory A. Hartzler, 130 North Main Street, Goshen, IN 46526. Authority sought for lease by lessee of the operating rights, acquired by lessor pursuant to MC-FC-75147, set forth in certificates MC-13367 (Sub-2), MC-13367 (Sub-4), MC-13367 (Sub-5), MC-13367 (Sub-6), MC-13367 (Sub-7), MC-13367 (Sub-8), MC-13367 (Sub-9), and MC-13367 (Sub-13), issued August 10, 1961, May 11, 1962, October 24, 1962, May 10, 1963, May 1, 1969, March 11, 1964, October 2, 1964, and October 7, 1969, respectively, as follows: *Meat scraps, tankage, and dried blood,* from points in IN and the lower peninsula of MI, to Milwaukee, Wi; *meat scraps, tankage, and dried blood,* not fit for human consumption, from Milwaukee, WI, to points in IL, IN, OH, and the lower peninsula of MI; Grain, over specified regular routes, from Wakarusa, IN, to Chicago, IL, serving intermediate and off-route points within 25 miles of Wakarusa, restricted to pickup only; *fertilizer,* from Calumet City, IL, to points in IN on and north of U.S. Hwy 40; *dry manufactured fertilizer,* in bulk, from the plantsite of Michiana Chemical Co., near Niles, MI, to points in named counties in IN; *feed, including meat scraps and tankage,* from Riverdale and Chicago, IL, to points in IN on and north of U.S. Hwy 40; *oats,* from points in a described area of IL, to points in Elkhart, Lagrange, La Porte, and St. Joseph Counties, IN; *meat scraps, tankage, and dried blood,* from points in IL, and described areas of MO and IA, to Milwaukee, WI; *fertilizer,* from points in the Chicago, IL, Commercial Zone, to Charlotte, MI, and points in Kalamazoo, Branch, Van Buren, Berrien, Calhoun, Cass, and St. Joseph Counties, MI; *fruits and vegetables,* from points Berrien, Van Buren, and Cass Counties, MI, to Chicago, IL; *livestock,* from points in Berrien County, MI to Chicago, IL; *frozen fruits, frozen berries, and frozen vegetables,* from parts of Berrien and Van Buren Counties, MI, within 20 miles of Coloma, MI, to Cleveland, OH, Chicago, IL, and Milwaukee, WI, from Cleveland, OH, to Milwaukee, WI; *dry fertilizer,* in bulk, in vehicles equipped with pneumatic unloading equipment, from the plantsite of Swift & Co. at Calumet City, IL, to points in Allegan, Ottawa, Muskegon, Oceana, Newaygo, and Eaton (except Charlotte, MI) Counties, MI; *fertilizer,* dry, in bulk, from Plymouth, IN, to points in Allegan, Berrien, Branch, Cass, Kalamazoo, St. Joseph, Van Buren, Kalakaska, Mecosta, Missaukee, Muskegon, Newaygo, Osceola, and Ottawa Counties, MI; *fertilizer and fertilizer materials* (except anhydrous ammonia and fertilizer or fertilizer materials derived from petroleum products and except in dump vehicles) from Joilet, IL (except from the plantsite of Blockson Chemical Division of Olin Mathieson Corp.), to points in IN, MI, and OH. Lessee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

MC-FC-77650, filed May 2, 1978. Transferee: MOTORFRATE DISPATCH, INC., 16360 Broadway, Maple Heights, OH 44137. Transferor: Motor Dispatch, Inc., 16360 Broadway, Maple Heights, OH 44137. Representative: A. Charles Tell, Attorney at Law, 100 East Broad Street, Columbus, OH 43215. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in certificates, MC-55778 and, Subs-11, 12, 13, 14, 16, 17, issued August 2, 1954, October 19, 1956, September 22, 1967, December 24, 1969, December 16, 1971, February 29, 1972, and January 16, 1974 respectively as follows: *General commodities* (with exceptions), over specified regular routes from, to, or between specified points in IN, OH, MI, and IL; *telephone directories and telephone directory pages,* from the plantsite of R. R. Donnelley & Sons Co. in Dwight, IL, to points in OH, MI, IN, and St. Louis, MO; *frozen prepared foods,* from the facilities of Banquet Foods at Macon, Marshall, Milan, Moberly, and Carrollton, MO, to points in IL, IN, KY, MI, OH, PA, VA and WV, and Davenport, and Dubuque, IA with restrictions; *frozen foods,* from the facilities fo Kitchens of Sara Lee, Inc. located at or near Deerfield, and Chicago, IL, to points in NY, NJ, DE, MD, RI, CT, PA, MA, WV, VA, OH, and DC with restrictions. Transferee presently holds no authority from this Commission. Application has both been filed for temporary authority under section 210a(b).

MC-FC-77654, filed June 27, 1978. Transferee: COUNTY LINE TRUCKING, INC., 224 North Defiance Street, Defiance, OH. Transferor: KDB Express, Inc., P.O. Box 217, Archbold, OH. Representative: Michael M. Briley, 300 Madison Avenue, P.O. Box 2088, Toledo, OH 43603. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate MC-143887 issued June 2, 1978, as follows: *New furniture,* from Archbold, OH, to points in the United States, except AK and HI; Returned shipments of *new furniture, and equipment, materials, and supplies* used in the manufacture and distribution of furniture, from points in the United States (except AK and HI), to Archbold, OH; *Furniture parts and furniture stock,* from Archbold, OH, to points in the United States except AK and HI; *New furniture, furniture parts, and furniture stock* from Stryker, OH, to points in the United States except AK and HI; Returned shipments of *new furniture, and equipment, materials, and supplies* used in the manufacture and distribution of furniture, except commodities in bulk, from points in the United States, except AK and HI, to Stryker, OH; *Uncrated tubular steel scaffolding and accessories, uncrated boarding ramps, uncrated maintenance stands, and uncrated baggage loading stands,* between Archbold, OH, on the one hand, and, on the other, points in the Unites States, except AK and HI; between points in the Unites States, except AL, AK, FL, GA, HI, IN, LA, MS, NC, SC, and TN; *Agricultural machinery, implements, and parts,* as described in Appendix XII to the report on Descriptions in Motor Carrier Certificates, 61 MCC 209, except those requiring the use of special equipment, between the site of the Yoder & Frey, Inc., auction yard, located near Archbold, OH, on the one hand, and, on the other, points in IL, PA, and WI; between the site of the Yoder & Frey, Inc., auction yard, located approximately 1¼ miles northwest of Archbold, OH, on an unnumbered county road, on the one hand, and, on the other, points in AR, IN, IA, KY, MI, MO, NY, NC, TN, and WV; *Agricultural machinery, implements, and parts,* between the auction yard of Yoder & Frey, Inc., located near Archbold, OH, on the one hand, and, on the other, points in ME, VT, NH, MA, CT, NJ, MD, VA, DE, OH, and DC; from points in CA, ID, KS, LA, MS, MT, NV, NM, OK, OR, SD, and WA, to the auction yard of Yoder & Frey, Inc., located near Archbold, OH; Corrugated sheets, pads, boxes, and related packaging, from the facilities of the Archbold Container Corp. at Archbold, OH, to points in IL, IN, and MI; and *materials and supplies* used in the manu-

facture and distribution of corrugated sheets, pads, boxes, and related packaging, except commodities in bulk, from points in the states listed immediately above to the facilities of the Archbold Container Corp. at Archbold, OH. Transferee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

MC-FC-77659, filed May 12, 1978. Transferee: SUPERIOR TRANSFER, INC., 2669 Merchant Drive, Baltimore, MD 21230. Transferor: Chesapeake Motor Lines, Inc., 6748 Dorsey Road, Baltimore, MD 21227. Representatives: Ronald N. Cobert, Attorney for transferee, 1730 M Street NW., Washington, DC 20036. Edward N. Button, Attorney for transferor, P.O. Box 1417 Hagerstown, MD 21740. Authority sought to transfer to transferee that portion of Certificate MC-52917, issued June 15, 1966, as follows: *General commodities,* with specified exceptions, between Baltimore, MD and Alexandria, VA, over U.S. Hwy 1, serving all intermediate points and off-route points within 10 miles of the route north of an east-west line drawn through Alexandria. Transferee presently holds no authority from this Commission. Application has been made for temporary authority under section 210a(b) of the act.

Republication MC-FC-77669, filed May 17, 1978. Transferee: PAT AND JAKE'S, INC., 5838 Monroe Street, Sylvania, OH 43560. Transferor: Carl & Gene Towing Service, Inc., 1418 Elm Street, Toledo, OH 53603. Representative: Wolfgang Drescher and Arthus R. Cline, 403 Security Building, Toledo, OH 43604. Authority sought for purchase of the operating rights set forth in certificate MC-108804 (Sub-1), issued December 7, 1966, as follows: *Wrecked or disabled motor vehicles,* in truckaway service, between points in Lucas County, OH, on the one hand, and, on the other, points in Steuben County, IN and Monroe, Lenawee, and Wayne Counties, MI; and *wrecked, disabled, and replacement motor vehicles,* by use of wrecker equipment only, between points in Lucas, Fulton, Williams, and Wood Counties, OH, on the one hand, and, on the other, points in IN and specified areas in MI, NY, and PA. Transferee holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b) of the act. The purpose of this republication is to include additional authority in the proposed transfer.

MC-FC-77682, filed May 10, 1978. Transferee: BRELAR, INC., Route 2, Box 22, Greenville, MS 38701. Transferor: Bel's Produce Co., Inc., 11357 Vienna Road, Montrose, MI 48457. Representative: Martin J. Leavitt, Law Offices of Sullivan, Leavitt & Bileti, 22375 Haggerty Road, P.O. Box 400, Northville, MI 48167, Transferor. Ed Glasscock, Brown, Todd & Heyburn, Citizens Plaza, Louisville, KY 40202, Transferee. Authority sought for purchase by transferee of that portion of the operating rights of transferor, as set forth in permit MC-141691, issued March 28, 1978, as follows: *Pickles and pickle products* (except frozen and in bulk), from the facilities of Vlasic Foods, Inc., located at Greenville, MS to points in the United States (except MS, AK, and HI), to be performed under a continuing contract or contracts with Vlasic Foods, Inc. Transferee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

MC-FC-77690, filed June 21, 1978. Transferee: ANTHONY D. FIAMINGO, d.b.a. FIAMINGO MOVING & STORAGE CO., R.D. 3, Box 678, Mansfield, PA 16933. Transferor: Seymour Rail Hauling, Inc., 510 Fifth Avenue, Williamsport, PA 17701. Representative: Thomas F. X. Foley, Colts Neck Professional Plaza, State Highway 34, Colts Neck, NJ 07722. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in certificate MC-40174 issued April 22, 1971, as follows: *Packinghouse products,* from Williamsport, PA, to points within 75 miles of Williamsport. Transferee is presently authorized to operate as a common carrier under certificate MC-126900. Application has not been filed for temporary authority under section 210a(b).

MC-FC-77704, filed June 9, 1978. Transferee: MONUMENT VALLEY STAGE LINES, INC., Park Terrace Road, Box 318, Blanding, UT 84511. Transferor: Barton F. Lyman, d.b.a. Lyman Truck Line, P.O. Box 675, Blanding, UT 84511. Representative: William S. Richards, Attorney at Law, P.O. Box 2465, 48 Post Office Place, Salt Lake City, UT 84110. Authority sought for purchase by transferee of the remaining portion of the operating rights of transferor, as set forth in Certificate MC-120836 (Sub-3), issued February 28, 1974, as follows: *General commodities,* with exceptions between points in a specified portion of San Juan County, UT with restrictions. Transferee is presently authorized to operate as a common carrier under Certificate MC-116104 and subs thereafter. Application has not been filed for temporary authority under section 210a(b).

MC-FC-77706, filed June 9, 1978. Transferee: KENNETH L. STUART, d.b.a. K & S Tankline, P.O. Drawer R, Copperhill, TN 37317. Transferor: Howard Kaylor and Kenneth L. Stuart, d.b.a. K & S Tankline, P.O. Drawer R, Copperhill, TN 37317. Representative: Paul M. Daniell, Attorney at Law, P.O. Box 872, Atlanta, GA 30301. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate MC-119557 and (Sub-7), issued August 31, 1970 and June 10, 1976, as follows: *Sulphur dioxide,* in bulk, in tank vehicles, from Copperhill, TN, to Canton and Sylvia, NC, Bastrop and Bogalusa, LA, and points in GA, AL, SC, MS, FL, and MO (except points in MO in the St. Louis, MO.-East St. Louis, IL, commercial zone, as defined by the Commission). Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under section 210a(b).

MC-FC-77707, filed June 6, 1978. Transferee: CALIFORNIA-PACIFIC FREIGHT, INC., 12212 Afton Lane, Santa Ana, CA 92705. Transferor: S & M Freight Lines, 531 North Francisca Street, Redondo Beach, CA 90277. Representative: R. Y. Schureman, 1545 Wilshire Boulevard, Los Angeles, CA 90017. Authority sought for purchase by transferee of a portion of the operating rights of transferor, as set forth in Certificate of Registration MC-10381 (Sub-3), issued March 18, 1964, as follows: *General commodities,* with specified exceptions, between points in the Los Angeles Basin Area, on the one hand, and, on the other, Indio, CA, via U.S. Hwy 99 and California Hwy 111, serving all intermediate points on said Hwys and all points laterally within 5 miles of said Hwys between the Los Angeles Basin Area and Indio. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under section 210a(b).

MC-FC-77710, filed June 14, 1978. Transferee: B & B GENERAL STORAGE WAREHOUSE, INC., 182-10 Liberty Avenue, Jamaica, NY 11412. Transferor: Noble Van & Storage Co., Inc., 1 Hayes Street, Elmsford, NY 10523. Representative: Jack Schiller, One Lefrak City Plaza, Flushing, NY 11368. Authority sought for purchase by transferee of a portion of the operating rights of transferor, as set forth in Certificate MC-93855 (Sub-2), issued August 2, 1971, as follows: *Household goods* as defined by the Commission, between points in Westchester County, NY, on the one hand, and, on the other, points in OH, and VA. Transferee is presently authorized to operate as a common carrier under Certificate MC-42364. Application has not been filed for temporary authority under section 210a(b).

MC 77712, filed June 15, 1978. Transferee: S & T TRANSPORT,

INC., 31 Frederick Place, Old Bridge, NJ 08857. Transferor: Bivins Freight Service, Inc., South 15th Street, Millville, NJ 08332. Representative: Piken & Piken, Attorneys-at-Law, One Lefrak City Plaza, Flushing, NY 11368. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate MC 73618, issued March 20, 1963, as follows: *General commodities* (with the usual exceptions), over regular routes, between Millville, NJ and Philadelphia, PA, and other specified commodities excepted. *Building material, and brick, feed, grain and meat scraps, seed, fertilizer, fertilizer material, airplane engines, airplane engine parts, and airplane accessories, boat building materials, equipment, and supplies,* over irregular routes, generally between Millville and other specified cities in NJ and specified cities in NY, MD, PA, DE, and DC. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under section 210a(b).

MC-FC-77716, filed June 21, 1978. Transferee: Graham Bell, d.b.a. B & W Trucking, P.O. Box 281, 462 Essex Avenue, Gloucester, MA 01903. Transferor: Roger D. Peterson, d.b.a. Peterson Motor Transportation, 107 Portland Street, Rochester, NH. Representative: George C. O'Brien, Attorney-at-Law, 12 Vernon Street, Norwood, MA 02062. Authority sought for purchase by transferee of a portion of the operating rights set forth in Certificate MC 7953, issued November 18, 1975, as follows: *General commodities* (with usual exceptions), over regular routes, between Boston, and Haverhill, MA, serving all intermediate and specified and off-route points; *radio tubes* and *supplies* and *containers* for such commodities during the season extending from the 15th of May to the 15th of September, between Salem, MA and Corning, NY serving no intermediate points; over irregular routes, *general commodities* (with usual exceptions), between Boston, Quincy, Hingham, Milton, and Weymouth, MA; *supplies, materials, equipment,* and *machinery* used in the manufacture of lumber and lumber products, between Providence, RI and Boston, MA on the one hand, and, on the other, Rochester, NH; *Such merchandise* as is dealt in by wholesale, retail, and chain grocery and food business houses, and in connection therewith, equipment, materials, and supplies used in the conduct of such business, between points in Strafford, Rockingham, and Carroll Counties, NH, on the one hand, and, on the other, points in Androscoggin, Cumberland, Oxford, and York Counties, ME; from points in Dover, Portsmouth, and Rochester, NH to points in a described portion of NH; from Rochester, NH to Wallum Lake, RI; groceries and grocery supplies, fruit, and vegetables, from Boston MA to Rochester, NH and South Berwick, ME; *building materials,* from Walpole and Boston, MA and points within 5 miles of Boston, to Rochester; *box shooks,* from Rollinsord, NH to Gloucester, MA and *rejected shipments of box shooks,* from Gloucester, MA to Rollinsford, NH; *wooden box shooks* and *sawdust,* from Rochester, NH to Willimantic, CT; and *metal screws* used in the manufacture of wooden boxes, from Willimantic, CT to Rochester, NH. Transferee holds no Commission authority and does not seek section 210a(b) temporary authority.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-20946 Filed 7-27-78; 8:45 am]

[7035-01]

[Notice No. 92]

MOTOR CARRIER TRANSFER PROCEEDINGS

JULY 28, 1978.

Application filed for temporary authority under section 210a(b) in connection with transfer application under section 212(b) and transfer rules, 49 C.F.R. Part 1132:

MC-FC 77651. By application filed July 5, 1978, OIL COUNTRY HAULERS, INC., 15714 Old Beaumont Hwy (U.S. 90), Houston, TX 77049, seeks temporary authority to transfer the operating rights of SHELDON TRUCKING CO., 15714 Old Beaumont Hwy (U.S. 90), Houston, TX 77049, under section 210a(b). The transfer to OIL COUNTRY HAULERS, INC., of the operating rights of SHELDON TRUCKING CO., is presently pending.

MC-FC 77756. By application filed July 12, 1978, C & H BUS LINES, INC., Route 1, Harrison, GA 31035, seeks temporary authority to transfer the operating rights of NATIONAL BUS SERVICE, INC., 746 Wheaton Street, Savannah, GA 31401, under section 210a(b). The transfer to C & H BUS LINES, INC., of the operating rights of NATIONAL BUS SERVICE, INC., is presently pending.

MC-FC 77757. By application filed July 18, 1978, McNULTY TANK LINES DIVISION, McNULTY INDUSTRIES, INC., d.b.a. McNULTY TANK LINES, U.S. Hwy 130, Bridgeport, NJ 08014, seeks temporary authority to transfer the operating rights of SKYLINE TRANSPORT, INC., 1910 Russell Street, Baltimore, MD 21230, under section 210a(b). The transfer to McNULTY TANK LINES DIVISION, McNULTY INDUSTRIES, INC., d.b.a. McNULTY TANK LINES, of the operating rights of SKYLINE TRANSPORT, INC., is presently pending.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-20947 Filed 7-27-78; 8:45 am]

sunshine act meetings

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409), 5 U.S.C. 552b(e)(3).

Contents

[6351-01]

1

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 10 a.m., July 28, 1978.

PLACE: 2033 K Street NW., Washington, D.C., 5th floor hearing room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Discussion of an *amicus curiae* memorandum.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-1545-78 Filed 7-26-78; 11:44 am]

[6351-01]

2

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 11 a.m., August 4, 1978.

PLACE: Eighth floor conference room, 2033 K Street NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Market surveillance.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-1546-78 Filed 7-26-78; 11:44 am]

[6714-01]

3

FEDERAL DEPOSIT INSURANCE CORPORATION.

TIME AND DATE: 10 a.m., August 2, 1978.

PLACE: Room 6135, FDIC Building, 550 17th Street NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Applications for Federal deposit insurance:

NBD-Portage Bank, a proposed new bank to be located at 6400 South Westnedge Avenue, Portage, Mich., for Federal deposit insurance.

Banco Union de Puerto Rico, a proposed new bank to be located on Ignacio Arzuaga Street, corner of Bernardo Garcia Street, Carolina, Puerto Rico, for Federal deposit insurance.

Application for Federal deposit insurance and for consent to establish a branch (drive-in facility):

Burbank Citizens Bank, a proposed new bank to be located at 333 North Glenoaks Boulevard, Burbank, Calif., for Federal deposit insurance and for consent to establish a branch (drive-in facility) at 372 East Olive Avenue, Burbank, Calif.

Applications for Federal deposit insurance and for consent to exertise limited trust powers:

First Bank & Trust of Carter Lake, a proposed new bank to be located at 1230 Locust Street, Carter Lake, Iowa, for Federal deposit insurance and for consent to exercise limited trust powers.

Applications for consent to establish branches:

Dixie County State Bank, Crose City, Fla., for consent to establish a branch at the northeast corner of State Road 358, south end of the river bridge approach, Unincorporated Jena Area of Dixie County, Fla.

Umatilla State Bank, Umatilla Fla., for consent to establish a branch on Butler Street (State Road 40) near its intersection with Alco Street, unincorporated Lake County (P.O. Astor), Fla.

The Citizens Bank of Perry, Perry, Fla., for consent to establish a branch in the southwest quadrant of the intersection of Ninth Street East and First Avenue, unincorporated area of Steinhatchee, Taylor County, Fla.

United Mutal Savings Bank, New York, N.Y., for consent to establish a branch at 556 Main Street, Islip (unincorporated area), town of Islip, N.Y.

The Western Saving Fund Society of Philadelphia, Haverford, Pa., for consent to establish a branch at 2601-05 South Broad Street, Philadelphia, Pa.

Application for consent to establish a branch-detached facility:

The Kiowa State Bank, Kiowa, Colo., for consent to establish a branch-detached facility on Highway 86, Elizabeth, Colo.

Applications for consent to merge and to establish branches:

Albany Savings Bank, Albany, N.Y., an insured mutal savings bank, for consent to merge under its charter and title with Onedia Federal Savings & Loan Association, Oneida, N.Y., upon the latter's conversion to a State charter, and for consent to establish the sole office of the latter institution as a branch of Albany Savings Bank.

Brookville Bank & Trust Co., Brookville, Pa., an insured State nonmember bank, for consent to merge under its charter, and with the title of "Unibank," with Brockway Citizens Bank, Brockway, Pa., also an insured State nonmember bank, and for consent to establish the one existing office of Brockway Citizens Bank as a branch of the resultant bank.

Farmers Bank & Trust Co., of Hanover, Hanover, Pa., an insured State nonmember bank, for consent to merge under its charter and title with Abbottstown State Bank, Abbottstown, Pa., also an insured State nonmember bank, and for consent to establish the sole office of Abbottstown State Bank as a branch of the resultant bank.

Application for consent to consolidate, establish branches, redesignate the main office location, and exercise trust powers:

Southwest Mississippi Bank, Magnolia, Miss., an insured State nonmember bank, for consent to consolidate under its charter, and with the title of "First Bank of Southwest Mississippi," with Bank of McComb, McComb, Miss., also an insured State nonmember bank; for consent to establish Bank of McComb's four offices as branches of the resultant bank; for consent to redesignate its main office location to the present site of the main office of Bank of McComb; and for consent to exercise trust powers.

Recommendations regarding liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 43,549-L—Bank of Picayune, Picayune, Miss.

Case No. 43,580-L—Fanklin National Bank, New York, N.Y.

Case No. 43,584-NR—United States National Bank, San Diego, Calif.

Case No. 43,588-L—First State Bank Of Northern California, San Leandro, Calif.

Case No. 43,590-L—American City Bank & Trust Co., National Association, Milwaukee, Wis.

Case No. 43,591-L—The Drovers' National Bank of Chicago, Chicago, Ill.

Case No. 43,592-L—The Drovers' National Bank of Chicago, Chicago, Ill.
Case No. 43,596-SR—Ill.The Peoples Bank of the Virgin Islands, Charlotte Amalie, Virgin Islands.
Case No. 43,595-L—The Drovers' National Bank of Chicago, Chicago, Ill.

Recommendations with respect to the initiation or termination of cease-and-desist proceedings, termination-of-insurance proceedings, or suspension or removal proceedings against certain insured banks or officers or directors thereof:
Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b-(c)(6), (c)(8), and (e)(9)(A)(ii)).

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.
Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(2) and (c)(6)).

Grievance officer's findings and recommendations in connection with the formal grievance of a corporation employee:
Name of employee authorized to be exempt from disclosure pursuant to the provisions of subsection (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6)).

CONTACT PERSON FOR MORE INFORMATION:

Alan R. Miller, Executive Secretary, 202-389-4446.

[S-15550-78 Filed 7-26-78; 3:54 pm]

[6714-01]

4

FEDERAL DEPOSIT INSURANCE CORPORATION.

TIME AND DATE: 10:30 a.m., August 2, 1978.

PLACE: Board room, sixth floor, FDIC Building, 550 17th Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Disposition of minutes of previous meetings.
Application for Federal deposit insurance:
Hickory Point Bank, a proposed new bank to be located in the Hickory Point Mall at the intersection of U.S. Highway 51 and Interstate Highway 72, Forsyth, Ill., for Federal deposit insurance.

Request by the Comptroller of the Currency for a report on the competitive factors involved in the proposed merger of Adams County National Bank, Cumberland Township (P.O. Gettysburg), Pa., and The National Bank of Arendtsville, Arendtsville, Pa.

Recommendations with respect to payment for legal services rendered and expenses incurred in connection with receivership and liquidation activities:
Schall, Boudreau & Gore, San Diego, Calif., in connection with the receivership of United States National Bank, San Diego, Calif.
Trager & Trager, Fairfield, Conn., in connection with the liquidation of the Monroe Bank & Trust Co., Monroe, Conn.
Sullivan & Worcester, Boston, Mass., in connection with the receivership of Surety Bank & Trust Co., Wakefield, Mass.
Kaye, Scholer, Pierman, Hays & Handler, New York., N.Y., in connection with the liquidation of Franklin National Bank, New York, N.Y.
O'Neill & Borges, Raco Rey, Puerto Rico, in connection with the liquidation of Banco Credito y Ahorro Ponceno, Ponce, P.R.

Memorandum and resolution proposing certain delegations of authority from the Board of Directors to the Committee on Liquidations, Loans and Purchases of Assets (Case No. 43,386).

Memorandum and resolution proposing the delegation to the General Counsel and the Director of the Division of Liquidation, or their designees, of authority to initiate litigation to which the Corporation will be a party either in its corporate capacity or as receiver of a closed bank.

Memorandum proposing the procurement of new computer equipment.

Memorandums and resolutions proposing that the liquidators of Banco Economias, San German, Puerto Rico, and Banco Credito y Ahorro Ponceno, Ponce, Puerto Rico, be authorized to convey real property.

Reports of Committees and Officers

Minutes of the actions approved by the Committee on Liquidations, Loans, and Purchases of Assets pursuant to authority delegated by the Board of Directors.
Report of the Executive Secretary regarding his transmittal of "no significant effect" competitive factor reports.
Reports of the directory of the Division of Bank Supervision with respect to applications or requests approved by him and the various Regional Directors pursuant to authority delegated by the Board of Directors.
Final report of the Office of the Controller on the termination of the liquidation of First Citizens Bank & Trust Co. of Utica, Utica, N.Y.
Reports of security transactions authorized by the Chairman.

CONTACT PERSON FOR MORE INFORMATION:

Alan R. Miller, Executive Secretary, 202-389-4446.

[S-1551-78 Filed 7-26-78; 3:54 pm]

[6715-01]

5

FEDERAL ELECTION COMMISSION.

DATE AND TIME: Wednesday, August 2, 1978, at 10 a.m.

PLACE: 1325 K Street NW., Washington, D.C.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Audits, compliance, and personnel.

* * * * *

DATE AND TIME: Thursday, August 3, 1978, at 10 a.m.

MATTERS TO BE CONSIDERED:

Portions open to the public:

Setting of Future Meeting Dates
Correction and Approval of Minutes
Advisory Opinion 1978-42
Advisory Opinion 1978-48
Response to Advisory Opinion Request From National Treasury Employees Union
Policy Regarding Transfers to Registered Entities From Unregistered Organizations
Quarterly Management Report
Pending Legislation
Pending Litigation
Appropriations and Budget
Liaison With Other Federal Agencies
Classification Actions
Routine Administrative Matters

Portions closed to the public (executive session):

Any Matters Not Concluded on August 2, 1978.

PERSON TO CONTACT FOR INFORMATION:

Mr. David Fiske, Press Officer, telephone 202-523-4065.

MARJORIE W. EMMONS,
Secretary to the Commission.

[S-1549-78 Filed 7-26-78; 3:54 pm]

[6740-02]

6

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: (Published July 24, 1978; 43 FR 32025).

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., July 26, 1978.

CHANGE IN THE MEETING: The following items have been added:

Item No., Docket No., and Company

M-4—Memorandum of Understanding between the Secretary of Energy and the Federal Energy Regulatory Commission concerning procedures for review of proposed rules, regulations, and statements of policy.
M-5—RM78-40, Natural Gas Companies' Annual Report of Proved Domestic Gas Reserves: FPC No. 40—extension of 1977 filing deadlines.

C1-4—CI75-45, et al., Tenneco Oil Co., et al.

KENNETH F. PLUMB,
Secretary.

[S-1547-78 Filed 7-26-78; 11:44 am]

[6720-01]

7

FEDERAL HOME LOAN BANK BOARD.

TIME AND DATE: 9:30 a.m., August 2, 1978.

PLACE: 1700 G Street NW., Sixth Floor, Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION:

Franklin O. Bolling, 202-377-6677.

MATTERS TO BE CONSIDERED:

Consideration of Final Regulations Re: FTC Pre-Merger Notification Requirements.
Consideration of Amendments Relating to Servicing of Loans.
Consideration of Waiver of Condition Re: Branch Office Opening—First Federal Savings & Loan Association of Pineville, Pineville, Ky.
Consideration of Proposed Acquisition of Western Savings Association, Pratt, Kans., and Larned Savings & Loan Association, Larned, Kans., by Western Financial Corp., Pratt, Kans.
Applications for Bank Membership and Insurance of Accounts—Evergreen Savings & Loan Association, Redwood City, Calif.
Branch Office Application—First Federal Savings & Loan Association of Brunswick, Brunswick, Ga.

No. 169, July 26, 1978.

[S-1553-78 Filed 7-26-78; 3:54 pm]

[6730-01]

8

FEDERAL MARITIME COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: July 21, 1978, 43 FR 31503.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., July 26, 1978.

CHANGES IN THE MEETING: Addition of the following item to the closed session:

3. Practices of Zim-American Israeli Shipping Co., Inc.

[S-1543-78 Filed 7-26-78; 11:50 am]

[6730-01]

9

FEDERAL MARITIME COMMISSION.

TIME AND DATE: August 2, 1978—10 a.m.

PLACE: Room 12126—1100 L Street NW., Washington, D.C. 20573.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Agreement No. 8660-8: Modification of the Latin America/Pacific Coast Steamship Conference to include intermodal service.
2. Agreement No. 9510-4: Modification of the Household Goods Forwarders Association of America Rate Agreement to permit independent action of the members.
2. Agreement No. 7680-D.R.: Petition of American West African Freight Conference for unlimited extension dual rate contract.
4. Agreement No. 9973-4: Modification of Johnson ScanStar Combined Service Agreement to permit service to the Pacific Coast via minibridge.
5. Petition for Declaratory Order—Dr. Jenaro Collazo, Secretary of Social Services of Puerto Rico (Petitioner).
6. Petition for Reconsideration of Agreements Nos. 2846-28 and 5660-21.
7. Docket No. 76-60: Petition for Declaratory Order of Seatrain International, S.A.—Consideration of record.
8. Docket No. 70-50: Marine Terminal Practices of the Port of Seattle—Possible violation of section 17, Shipping Act, 1916—Consideration of initial decision.

CONTACT PERSON FOR MORE INFORMATION:

Francis C. Hurney, Secretary, 202-523-5725.

[S-1544-78 Filed 7-26-78; 11:44 am]

[6210-01]

10

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM.

TIME AND DATE: 10 a.m., Wednesday, August 2, 1978.

PLACE: 20th Street and Constitution Avenue NW., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED: Summary Agenda: Because of their routine nature, no substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board requests that an item be moved to the discussion agenda:

1. Request for an exemption from the Federal Home Mortgage Disclosure Act and Regulation C for Connecticut chartered depository institutions that are subject to the Connecticut Home Mortgage Disclosure Act and the implementing regulations of the Connecticut Banking Department.
2. Proposed extension and revision of the Commercial Bank Report of Consumer Credit (FR 571).

Discussion Agenda:

1. Proposed statement to be presented to the Senate Committee on Banking, Housing, and Urban Affairs regarding S. 2011, the Regulatory Reduction and Congressional Control Act.
2. Any agenda items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board, 202-452-3204.

Dated: July 25, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[S-1552-78 Filed 7-26-78; 3:54 pm]

[7020-02]

11

[USITC SE-78-36A]

UNITED STATES INTERNATIONAL TRADE COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 43 FR 32220, July 25, 1978.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., Thursday, August 3, 1978.

CHANGES IN THE MEETING: Enlargement of the scope of item No. 5:

5. Copper (Inv. TA-201-32)—Vote on injury (at 2 p.m.) *and briefing on remedy, if necessary.*

CONTACT PERSON FOR MORE INFORMATION:

Kenneth R. Mason, Secretary, 202-523-0161.

[S-1554-78 Filed 7-26-78; 3:54 pm]

[7020-02]

12

[USITC SE-78-37]

UNITED STATES INTERNATIONAL TRADE COMMISSION.

TIME AND DATE: 10 a.m., Thursday, August 10, 1978.

PLACE: Room 117, 701 E Street NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and complaints (if necessary).
5. Copper (Inv. TA-201-32)—Vote on remedy, if necessary.
6. Bicycle tires and tubes (Inv. TA-201-33)—Vote on injury.
7. Appeal of denial of information under the FOIA (if necessary).
8. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION:

Kenneth R. Mason, Secretary, 202-523-0161.

[S-1555-78 Filed 7-26-78; 3:54 pm]

[4110-39]

13

NATIONAL COUNCIL ON EDUCATIONAL RESEARCH.

The National Council on Educational Research hereby gives notice that it has tentatively scheduled meetings to be held in Washington, D.C., on the following dates: September 15, 1978; November 3, 1978; January 11-12, 1979; March 23, 1979; May 11, 1979; July 12-13, 1979.

Agendas for these meetings and any changes in meeting dates or locations will be published in the FEDERAL REGISTER as promptly as possible.

PERSON TO CONTACT FOR INFORMATION:

Ella L. Jones, Administrative Coordinator, telephone 202-254-7900.

PETER H. GERBER,
Chief, Policy and Administrative Coordination, National Council on Educational Research.

[S-1548-78 Filed 7-26-78; 11:44 am]

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BOOK 2 OF 2 BOOKS

FRIDAY, JULY 28, 1978
PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

MEDICAL DEVICES

Classification Procedures

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

SUBCHAPTER H—MEDICAL DEVICES

[Docket No. 77N-0155]

Classification Procedures

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule sets forth criteria and procedures for classifying devices intended for human use into classes of regulatory control sufficient to provide reasonable assurance of safety and effectiveness. The rule also explains the determination of the safety and effectiveness of devices, prescribes the procedures for the submission and review of petitions for reclassification, and defines the circumstances under which information and data associated with the classification or reclassification of devices will be released to the public. These actions are taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: August 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Joseph Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: The proposal upon which this final regulation is based was published in the FEDERAL REGISTER of September 13, 1977 (42 FR 46028). Interested persons were given until November 14, 1977 to comment. Twenty-five comments were received on the proposal, presenting a wide range of issues.

This regulation essentially codifies existing procedures that have been followed in the classification process to date. Manufacturers and other interested persons have already become involved in the various aspects of the classification process described in this regulation. The agency has been urged to promulgate this regulation as quickly as possible to provide industry a more certain basis for production decisions. Although the Commissioner doubts that this procedural regulation will affect manufacturers' production decisions, the Commissioner has decided that it is in the best interest of the public and of all parties concerned that this regulation become effective August 28, 1978.

GENERAL

The Commissioner has made many minor editorial changes in the regulation for clarity.

1. Several comments stated that publication of panel recommendations and proposed regulations for the classification of devices before promulgation of the final regulation establishing classification procedures violates the basic principles of administrative rulemaking. The comments pointed out that an agency must provide public notice and an opportunity for interested parties to participate before implementation of a rule.

Section 513(c)(1) of the act requires the promulgation by regulation of the procedures to be followed by classification panels in making their reviews and recommendations. The section does not require, however, that the final classification procedures regulation precede every other step in the classification process. Moreover, this classification procedures regulation essentially codifies the procedures that the agency has been following in the classification process. Public notice of these procedures was provided in a notice published in the FEDERAL REGISTER on May 19, 1975 (40 FR 21848). Because classification panels are public advisory committees, the general procedures under which the panels operate have already been promulgated by regulation (21 CFR Part 14).

2. One comment, referring to the portion of the preamble to the proposed regulation that discussed the classification criteria (42 FR 46030), argued against consideration of such "practical matters" as the difficulty involved in enforcing general controls and the length of time required to develop performance standards. The comment stated that such considerations should be irrelevant to classification decisions, and that any inconvenience to the agency does not change the fact that adequate information may exist to allow proper classification in accordance with the statutory criteria.

The Commissioner agrees that it is improper to consider the length of time required to develop a performance standard when determining whether to classify a device into class II unless compliance with a standard is essential to provide reasonable assurance of a device's safety and effectiveness. The legislative history reveals both that Congress recognized that considerable time may elapse between classification of a device into class II and the development of a performance standard for the device (Ref. 1, p. 27), and that FDA has ample latitude to classify a device into the premarket approval category in instances in which use of the device poses public health concerns. The Commissioner believes also, however, that the degree of difficulty involved in enforcing general controls with respect to a particular device may well be a relevant consideration in determining whether general controls will provide reasonable assurance of the safety and effectiveness of the device.

3. A few comments expressed concern that the definition of "implant" in proposed § 860.3(d) would include many devices which should not be classified into class III, such as dental fillings. The comments suggested that the proposed definition be worded so as not to include such devices.

The Commissioner acknowledges the broad scope of the proposed definition, but also notes that a device which is termed an implant is not necessarily classified into class III. Sections 513 (c)(2)(C) and (d)(2)(B) of the act clearly states that an implant need not be classified into class III if such classification is not necessary to provide reasonable assurance of safety and effectiveness. The proposed definition, therefore, has been retained without change in the final regulation.

4. Several comments requested revision of the proposed definition of "life-supporting or life-sustaining device" in § 860.3(e). The comment suggested that the proposed wording is redundant and vague. The comments also stated that the proposed definition is too broad because Congress intended that only devices essential to supporting or sustaining life be considered life-supporting or life-sustaining devices for classification purposes. Some comments suggested that the words "or yields information that

is to be used for restoration, maintenance or continuation of such function" be deleted from the definition. Other comments suggested that the definition be reworded to include only devices the discontinuance of which would result in a high probability of death.

The proposed definition has been reworded. The Commissioner believes that the special regulatory treatment afforded life-supporting or life-sustaining devices is necessary for devices which yield information essential to supporting or sustaining life, as well as for devices which are themselves life-supporting or life-sustaining. The Commissioner also rejects the idea that discontinuation of the use of a particular device must result in a high probability of death in order for that device to be properly termed life-supporting or life-sustaining. Congress expressed its intent that the phrase "life-supporting or life-sustaining" be interpreted broadly (ref. 1, p. 35). The Commissioner has reworded the definition to eliminate redundancy and to reflect more accurately the congressional intent (ref. 2, p. 58).

5. A few comments objected to the fact that the classification questionnaire was included in the preamble but not in the proposed regulation. The comments stated that the questionnaire is a substantive part of the classification process and expressed concern that if it were not included in the regulation FDA could revise the questionnaire without notice.

The classification questionnaire is merely a guideline intended to aid the panels in applying the legal requirements to the practical task of device classification. Devices will be classified and reclassified only according to the criteria in section 513 of the act. The entire questionnaire may not be applicable to all present cases. Furthermore, it is foreseeable that technological developments or other circumstances might necessitate future changes in the questionnaire, although such significant changes should be rare and would be announced by appropriate notice published in the FEDERAL REGISTER. Copies of the current classification questionnaire may be obtained from the Classification Coordinator (HFK-401), Bureau of Medical Devices, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, Md. 20910.

6. Some comments suggested that § 860.3(g)(7), requiring the supplemental data sheet to identify any needed restrictions on the use of the device, exceeds classification panel authority and requires a level of experience and competence beyond that possessed by most classification panel members. The comments suggested that because the power to recommend restrictions on the use of a device could be abused, and because of possible conflicts of interest, any identification of necessary restrictions should be accompanied by a statement of reasons and should be supported by objective evidence. Several comments also recommended that the phrase "authorization of a physician" be changed to "authorization of a licensed practitioner," to conform with the wording of section 520(e) of the act.

The general classification recommendations, required to be made by classification panels, necessarily involve identification of any needed restrictions on the use of the device. Moreover, there is no prohibition against FDA's asking its classification panels for advice on needed restrictions on device use or other matters within FDA's authority, even if the act does not require FDA to solicit such advice. The Commissioner rejects the contention that such determinations are beyond the authority or competence of the panels, or that they present the panels with a unique opportunity to abuse their power. These objections have been adequately considered and provided for in the act and in FDA regulations. The restrictions mentioned in § 860.3(g)(7) are merely examples of the possible types of restrictions on the use of a device which may be necessary. The phrase "authorization of a physician" has been changed in the final regulation to "authorization of a licensed practitioner" to reflect the wording in section 520(e) of the act.

7. Several comments on proposed § 860.3(i) questioned the need to introduce the new term "generic type of device." The comments suggested that the statutory terms "within a type" and "substantially equivalent" are accepted and well understood, while the phrase "generic type of device" is vague.

The Commissioner rejects the suggestion that the phrase "generic type of device" is vague and is at variance with the statute. The statutory terms, "within a type" and "substantially equivalent," serve a purpose different from that of FDA's definition of "generic type of device." Application of the two statutory terms determines whether a device is classified in class III under sections 513(f) and 520(l)(1)(D) of the act. The term "generic type of device" describes FDA's grouping, for reasons of administrative convenience, of devices that are to be regulated in the same way because they present similar safety and effectiveness concerns. A generic type of device will include devices that may or may not be "within a type" and "substantially equivalent" to each other.

For example, to reduce unnecessary proliferation of regulations, FDA may treat all pathology stains as a single generic type of device and may issue a single proposed and final classification regulation concerning these stains. If a single regulation is issued, not all of the stains in the generic type, and covered by the regulation, would be "substantially equivalent" to each other. If a manufacturer submitted a premarket notification seeking to market a new stain, FDA would determine whether the new stain was "substantially equivalent" to any stain in the generic type, that is subject to the classification regulation, and thus whether the new stain was itself subject to the regulation. If the new stain was not "substantially equivalent" to any stain covered by the regulation, the new stain would be classified into class III by section 513(f) of the act. If the manufacturer sought reclassification of the new stain, under § 860.120(b) only the new stain and any later "substantially equivalent" devices would be affected by the reclassification.

The Commissioner warns that FDA may find it difficult to describe the generic type of devices subject to a classification regulation so precisely that an interested person will be able to determine whether a new device is subject to the regulation merely by reading it, without FDA's comparing the new device to existing devices already covered by the regulation. This difficulty is recognized and addressed in the premarket notification procedure in section 510(k) of the act and 21 CFR 807.81.

8. One comment pointed out that the requirement of proposed § 860.5(c)(1) that safety and effectiveness data regarding devices classified into class III be regarded as confidential and not be disclosed unless the data have been disclosed previously to the public was impossible to satisfy under the present system of open panel meetings. The comment suggested that some provision be made for closed panel meetings.

The requirements of 21 CFR 14.27, which are applicable to classification panel meetings, provide that portions of a panel meeting may be closed for discussion of certain matters including trade secrets and confidential commercial information.

9. The comments on proposed § 860.5 (d) and (e) questioned the legality of publicly disclosing otherwise confidential information when contain in reclassification petitions. The comments suggested several provisions which would restrict the extent to which such information would be subject to public disclosure. The comments also questioned the apparent inconsistency in proposed § 860.5(d)(2) which allows a petitioner to show that any of the contents of a deficient petition should

be exempt from public disclosure, when the entire contents of the petition are disclosable once the deficiencies have been corrected.

The Commissioner has determined that a petitioner voluntarily surrenders the confidentiality of the contents of a nondeficient reclassification petition. As explained in the preamble to the proposed regulation, the loss of confidentiality is based in part on the necessity that reclassification proceedings be as open as possible. Because all devices within a generic type are reclassified together, one reclassification petition may affect several manufacturers, and each manufacturer affected by the petition should be afforded an opportunity to address the issue.

Because reclassification decisions concern generic types of devices, trade secrets, or other confidential information which relates only to individual devices is irrelevant to reclassification decisions. The Commissioner neither requires nor desires that manufacturers or importers submit such confidential information in reclassification petitions. Furthermore, the Commissioner has determined that the legislative intent precludes the use of such confidential information as the basis for the reclassification of devices into class III (ref. 1, pp. 48 through 50). See section 520(c) of the act (21 U.S.C. 360j(c)). Consequently, petitioners should not include in their petitions any data or information that is unnecessary to a decision on the petition, especially if the petitioner wishes to keep such data or information confidential.

Because the policy of disclosure is not yet widely known by those petitioning for reclassification, all reclassification petitions will be screened for possible confidential information at the same time that they are being reviewed for deficiencies, until 180 days after the final classification regulation becomes effective. All petitioners will be offered an informal opportunity to delete any confidential data from their petition, or to withdraw the entire petition before it becomes available for public disclosure. However, 180 days after the final classification regulation becomes effective, petitioners should have become familiar with the reclassification process, and FDA will cease reviewing nondeficient petitions for confidential information and will make the entire contents of all petitions available for public disclosure once they have been determined to be nondeficient.

Because a deficient petition will not be considered on its merits until the deficiencies have been corrected, submission of a petition is not considered a surrender of the confidentiality of its contents until all deficiencies have been corrected. Following notification of a deficiency in the petition, the petitioner is allowed a period of time in which to submit supplemental material intended to correct the deficiency. To provide adequate time for response to a notification of deficiency, the Commissioner has increased the period of time allowed from 20 days to 30 days. If, during this 30-day period, the petitioner wishes to withdraw the deficient petition rather than have its contents be available to the public, the Commissioner, in his discretion, may allow the withdrawal. This provision has been added to §860.5(d)(2). Once the deficient petition has been corrected, the entire contents of the petition will be available for public disclosure. The Commissioner has added the provision that any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. The Commissioner has also added the provision that a deficient petition which is not corrected within 180 days after notification of a deficiency will be returned to the petitioner, and will not be considered further unless resubmitted.

10. One comment stated that the provisions of §860.7, defining valid scientific evidence and well-controlled investigations should apply only to evidence developed or compiled after the effective date of the final regulation.

The provisions in that section do not depart from traditionally recognized concepts, are flexible, are required by section 513(a)(3) of the act, and closely reflect the legislative intent in this area (ref. 1, pp. 17 and 40). Because the provisions do not require a new approach to the proper substantiation of device safety or effectiveness, there is no valid reason for their being applied only to evidence compiled or developed after the effective date of the final regulation.

The Commissioner has deleted the first sentence of §860.7(a) because it is obvious that no single standard of safety and effectiveness could apply to all devices, and it is not necessary to include that fact in the regulation.

11. Several comments addressed the safety and effectiveness factors listed in proposed §860.7(b). The comments suggested that advertising should not be considered with regard to intended conditions of use, that surgical risks should not be considered when weighing the risks of implants, and that the reliability of a device is not a relevant factor in determining its safetly and effectiveness. Several comments also suggested that classification panels should either include engineers as members or seek technical engineering advice if the reliability of devices must be considered.

The legislative history of section 513 of the act clearly reveals that Congress intended the phrase "conditions of use" to include uses promoted through advertising, but that a device should not be regarded as unsafe merely because of "collateral risks" not inherent in the use of the device (ref. 1, p. 16). The Commissioner believes that FDA must retain some discretion in determining which surgical risks are to be considered inherent in the use of any particular device, including implants. The legislative history also reveals that Congress intended that device reliability be considered in determining device safety and effectiveness (ref. 1, p. 16). Furthermore, engineers are represented on panels in order to facilitate consideration of device reliability. Consequently, §860.7(b) has been retained without change in the final regulation.

12. Several comments argued that proposed §860.7(c), by restricting consideration to valid scientific evidence when determining the safety and effectiveness of a device, does not reflect accurately the legislative intent. Several comments also questioned whether the Commissioner should have the authority, "in his discretion," to determine whether evidence submitted is valid scientific evidence. Several comments also suggested that if nonvalid scientific evidence is irrelevant in establishing the effectiveness of a device, such evidence also should be irrelevant in establishing that a device is not effective. One comment suggested that the panel should investigate and corroborate islolated case reports, random experience, and similar forms of evidence.

The purpose of the act is to assure the safety and effectiveness of medical devices intended for human use. Because such assurance necessarily demands a high standard of proof, section 513(a)(3) of the act requires that device effectiveness be established only by valid scientific evidence. The Commissioner has extended this requirement to the establishment of device safety as well. The requirement that only valid scientific evidence be used to establish device safety and effectiveness, however, does not preclude consideration of other forms of evidence when determining whether a device is safe or effective. Although it is imperative that early and sometimes informal indications of the danger or ineffectiveness of a device be considered fully, every effort will be made to corroborate such evidence before acting on it. The phrase "in his discretion" has been deleted from the second sentence of §860.7(c)(1) in the final regulation because it is superflu-

ous, but the remainder of the section has not been changed.

13. Comments on proposed § 860.7(d) requested a more objective and specific definition of what constitutes reasonable assurance of device safety, and clearer guidelines as to what constitutes "adequate efforts to demonstrate the absence of unreasonable risk of illness or injury."

The wording of the proposed section closely follows the wording of section 513 of the act. The legislative history (ref. 1, pp. 16–17) explains that determination of device safety involves balancing the probable benefits of a device against its probable risks. Consequently, proof of device safety is intended to establish that the risks are not unreasonably disproportionate to the benefits. The proposed section merely expands this concept, emphasizing that only valid scientific evidence may be used to establish device safety. The Commissioner does not believe that any change in the final regulation is necessary.

14. One comment on proposed § 860.7(e) suggested that a determination of device effectiveness should be based upon whether a device meets the claims of its manufacturer.

Section 513 of the act and § 860.7(b)(2) provide that the effect which a device purports or is represented to have is to be considered in determining its effectiveness. Proposed § 860.7(e) is consistent with those provisions and has been retained in the final regulation with minor clarifying word changes.

A question has arisen concerning the number of studies required to establish the effectiveness of a device. The Commissioner advises that section 513(a)(3) of the act and § 860.7 (e) and (f) require at least two well-controlled investigations showing effectiveness, unless the Commissioner, under § 860.7(f), authorizes reliance upon other valid scientific evidence. With respect to the general requirement of two or more effectiveness studies, device law is similar to drug law (sec. 505(d) of the act, 21 U.S.C. 355(d); 21 CFR 312.1, 314.111(a)(5)).

15. Comments suggested that the testing described in proposed § 860.7(f) is oriented too heavily toward drugs and is not appropriate for electronic, mechanical, or similar devices. It was suggested that many of these devices could be adequately tested by purely electronic or similar testing.

Section 860.7(e) provides that other valid scientific evidence may be used to prove device effectiveness in cases where the Commissioner determines that the requirements of § 860.7(f) are not reasonably applicable or essential to the testing of the device in question. Furthermore, the requirements of § 860.7(f) are designed to allow some leeway, including alternative approaches in some areas, and thus should prove compatible with most device testing.

16. Comments objected to proposed § 860.7(g) which requires the manufacturer or importer to show that general controls or performance standards would provide sufficient assurance of the safety and effectiveness of a device. The comments suggested that failure to make such a showing should not result in classification of the device into class III if the device is of the type described in section 513(a)(1)(A)(ii) of the act. Other comments suggested that the section be deleted in its entirety. Several comments also objected to the provision authorizing the Commissioner to require device manufacturers, importers, or distributors to submit reports or other information. The comments objected that, because section 519 of the act contemplated a more specific rulemaking process, such reporting requirements may not be promulgated in this manner.

The legislative history indicates that Congress intentionally placed upon industry the burden of furnishing sufficient evidence to substantiate the safety and effectiveness of a device, and that the absence of such data may be the basis for classification of the device into class III (ref. 1, p. 40). Although section 513(a)(1)(A)(ii) of the act provides that some devices may be classified into class I even if there is insufficient information from which to determine that general controls would provide reasonable assurance of their safety and effectiveness, such classification is permitted only for devices which do not present a potential unreasonable risk of illness or injury. In the absence of safety and effectiveness data, it may be impossible to determine that no such potential risk exists. The Commissioner emphasizes the need for industry to provide collectively sufficient safety and effectiveness data to ensure the proper classification of each generic type of device. The Commissioner believes that § 860.7(g) complies with the requirements of section 519 of the act.

CLASSIFICATION

17. One comment on proposed § 860.84 suggested that a classification of a device by the Commissioner which differs from the classification recommended by the panel should be supported by valid scientific evidence. It was also suggested that panel recommendations be required to identify only unreasonable risks to health, rather than all risks to health, presented by a particular device.

The act clearly provides the basis for determining device safety and effectiveness and prescribes the criteria for device classification. All classification decisions reached by the Commissioner or by the classification panels will be made in accordance with the provisions of the act. The Commissioner may disagree with a panel recommendation if his interpretation of available scientific evidence differs from that of the panel. In addition, the Commissioner intends to evaluate carefully panel recommendations in istances where valid scientific evidence is not available to support a panel recommendation. The requirement that panel recommendations specifically include identification of the risks to health presented by a device is based on section 513(c)(2)(A)(i)(III) of the act.

The Commissioner has redesignated some of the paragraphs in proposed § 860.84 in order to facilitate reference, but the section has been incorporated in the final regulation with no substantive changes.

18. One comment on proposed § 860.95 suggested that, in their recommendations, panels should not be required to state the reasons for recommending that a device be exempt from the requirements of section 510, 519, or 520(f) of the act. Another comment suggested that a regulation or order classifying or reclassifying a device into class I be required to state the reasons for not granting exemptions as well as the reasons for granting exemptions.

Section 513 of the act requires that panel recommendations for classification into class I, and final regulations or orders classifying devices into class I, specify whether the device is exempted from the requirements of sections 510, 519, or 520(f) of the act. The legislative history reveals that Congress considered "general controls," such as those provided for in sections 510, 519, and 520(f), important safeguards for public health (ref. 1, p. 17). Consequently, the act provides for exemption from only certain general controls, and requires that such exemptions be justified. There is no need to justify a requirement that devices that are not exempted comply with general controls. Proposed § 860.95 has been incorporated in the final regulation without change.

RECLASSIFICATION

19. One comment on proposed § 860.120 suggested that reclassification of one device within a generic type of device should not cause reclassification of all other devices within that generic type unless all such devices present the same unreasonable risk. Another comment stated that some clarification was needed as to who may file a reclassification petition. Several comments suggested that manufacturers and importers who

have not petitioned for the reclassification of a device should be provided a reasonable time to comply with new requirements applicable to the device following its reclassification.

By definition, all devices within a generic type present the same or very similar risks to health. The similarity in health risks is fundamental to the concept of classification by generic type of device. If devices thought to be within the same generic type present different risks, it is likely that the devices are not really of the same generic type. Manufacturers and importers of devices within a generic type will be provided an opportunity to participate in all reclassification proceedings regarding the generic type of device. The open nature of the reclassification process is assured by the provisions in the regulation regarding public disclosure of reclassification of petitions and panel recommendations. If compliance with a performance standard is required because of reclassification, the performance standard will be promulgated under the procedures in section 514 of the act which provide manufacturers notice and a grace period for compliance.

The Commissioner has added new § 860.120(c) to clarify who may file a petition for reclassification. FDA previously announced, in 21 CFR 10.25, its general policy that any interested party (whether a manufacturer, consumer, importer, or member of the public) may petition the Commissioner to issue, amend, or revoke a regulation or order promulgated by him. As explained below, reclassification petitions are subject to the special procedures of subpart C of part 860 rather than the citizen petition procedures. However, under the policy of the citizen petition procedure as applied to the classification process, any interested person is afforded an opportunity to file a petition for reclassification under the regulation based on sections 513(e), 514(b), or 515(b) of the act. The reclassification process under section 513(f) or 520(1) of the act is limited to the manufacturer or importer of the specific device involved because of the special procedural safeguards for reclassifying new devices and devices previously regarded as new drugs. The Commissioner has reorganized the remainder of proposed § 860.120 for clarification, but the substance of the section has not been changed in the final regulation.

20. Two comments on proposed § 860.123 questioned why reclassification petitions were not treated as citizen petitions, and why the Commissioner was not required to respond to such petitions within a definite period of time.

Section 10.30 (21 CFR 10.30) defines "citizen petitions" and provides that other sections regarding other types of petitions may include different requirements. The Commissioner has determined that petitions for device reclassification shall conform to the requirements of proposed § 860.123, and has added new § 860.3(j) to define the meaning of the term "petition" as it is used in part 860. The Commissioner agrees that a response time should be provided for reclassification petitions submitted under section 513(e) of the act, and § 860.130 of the final regulation has been revised accordingly. The act provides specific response times for all other reclassification petitions.

21. Several comments on proposed § 860.125 objected that consultation by the Commissioner with less than an entire panel would defeat the effectiveness of the panel and is contrary to the legislative intent in this area. It was also mentioned that informal means of consultation, especially consultation by telephone, might result in an unsatisfactory record. One comment suggested that a petitioner should be able to request that the Commissioner consult with the classification panel at a regular panel meeting.

The Commissioner agrees that every effort should be made to consult with an entire classification panel, and that an adequate record of such consultation is essential. There will be circumstances, however, in which statutory time constraints, the request by the petitioner for a timely response, or the unavailability of panel members will require the Commissioner to consult with less than an entire panel, and by means other than discussion at a regular panel meeting. The Commissioner had preceded the phrase "a majority of current voting panel members," in proposed § 860.125(a) (1) and (2), with the words "at least." Whenever possible, the Commissioner will consult with nonvoting members, and § 860.125(a) (1) and (2) has been changed accordingly.

22. Comments on proposed § 860.130 suggested that the Commissioner be required to secure a panel recommendation for reclassification of a device under section 513(e), that all reclassifications of devices from class III to class II should take effect immediately, that all regulations promulgating reclassifications should identify and revoke specific requirements of the prior classification which are no longer applicable to the device, and that the Commissioner should be required to publish oral panel recommendations made under § 860.125(a) (1) or (3) as well as written recommendations. One comment also noted that no deadline is provided for response to petitions submitted under this section.

Section 513(e) of the act provides that the Commissioner may act on the basis of new information to reclassify a device without seeking a panel recommendation. There will be circumstances in which the Commissioner will need to consult with a panel in order to reach a proper decision regarding such reclassifications. Whenever a panel is consulted, any panel advice will be recorded, whether the advice is written or oral. Oral advice will be written down. A regulation reclassifying a device will identify and revoke all requirements of the previous classification which no longer apply to the device. In the case of devices reclassified from class III to class II, section 513(e) of the act specifically provides that the effective date of a reclassification in class II may be delayed pending the development of a performance standard for the device, and FDA will take this approach when it is appropriate. The Commissioner has added the provision that petitions submitted under § 860.130 will be approved or denied within 180 days after the filing of the petition.

23. One comment on proposed § 860.132 suggested that the title be reworded, and that the text of § 860.132(b) be condensed and reorganized. The proposed title of § 860.132 was "Procedures when the Commissioner initiates a performance standard or premarket approval requirement under section 514(b) or 515(b) of the act." Several comments also objected that the 15-day deadline for filing petitions is inadequate.

The Commissioner believes that the title of proposed § 860.132, when read in the context of the other sections in the reclassification subpart, clearly states the subject of the section. The Commissioner recognizes no need to reorganize the section. Sections 514(b) and 515(b) of the act require the 15-day deadline for the submission of a petition. Proposed § 860.132 has been incorporated in the final regulation with minor editorial changes.

24. Comments on proposed § 860.134 suggested that the 210-day response time was too long, that an order denying a petition should set forth the reasons for the denial, that any decision by the Commissioner which differs form the panel recommendation should be supported by valid scientific evidence, and that any interested person should be able to petition for reclassification under this section.

The 210-day period for final action on reclassification petitions for "new devices" is established by section 513(f) of the act and is not unreasonable in light of the many steps required to process such petitions. Any order denying a petition for reclassification of a new device will set forth the reasons for that decision, as will orders approving such petitions. The Commissioner's decision regarding re-

classification will be based upon the same criteria considered by panels in making their recommendations, and will be in accordance with the provisions of the act. Section 513(f) of the act authorizes only the manufacturer or importer of a "new device" to initiate reclassification proceedings for the device. Other interested persons may seek reclassification of the device under section 513(e) of the act and § 860.130. The Commissioner has made minor changes in the wording of the proposed section in order to follow more closely the wording of section 513(f) of the act.

REFERENCES

Background data and information upon which the Commissioner relies in promulgating this regulation have been placed on file for public review in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. The following is a list of those documents:

1. House Report No. 94-853, Medical Device Amendments, February 29, 1976 (Committee on Interstate and Foreign Commerce).

2. House Report No. 94-1090, Medical Device Amendments, May 6, 1976 (Committee of Conference).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 514, 515, 519, 520, and 701(a), 52 Stat. 1055, 90 Stat. 540-559, 564-574 (21 U.S.C. 360c, 360d, 360e, 360i, 360j, and 371(a))), and under authority delegated to the Commissioner (21 CFR 5.1), 21 CFR Chapter I is amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. Part 16 is amended in § 16.1 by adding new paragraph (b)(31), to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(31) Section 860.136 of this chapter, relating to petitions for reclassification of a medical device currently in class III by operation of section 520(l)(1) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

PART 20—PUBLIC INFORMATION

2. Part 20 is amended in § 20.100 by adding new paragraph (c)(31), to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(31) Data and information submitted to the Commissioner or to classification panels in connection with the classification or reclassification of devices intended for human use, in § 860.5 of this chapter.

3. Part 860 is added to read as follows:

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

Subpart A—General

Sec.
860.1 Scope.
860.3 Definitions.
860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.
860.7 Determination of safety and effectiveness.

Subpart B—Classification

860.84 Classification procedures for "old devices."
860.93 Classification of implants, life-supporting or life-sustaining devices.
860.95 Exemptions from sections 510, 519, and 520(f) of the act.

Subpart C—Reclassification

860.120 General.
860.123 Reclassification petition: content and form.
860.125 Consultation with panels.
860.130 General procedures under section 513(e) of the act.
860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 515(b) of the act.
860.134 Procedures for "new devices" under section 513(f) of the act.
860.136 Procedures for transitional products under section 520(l) of the act.

AUTHORITY: Secs. 513, 514, 515, 519, 520, and 701(a), 52 Stat. 1055, 90 Stat. 540-559, 564-574 (21 U.S.C. 360c, 360d, 360e, 360i, 360j, and 371(a)), unless otherwise noted.

Subpart A—General

§ 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the kind of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to classification panels or to the Commissioner in connection with classification and reclassification proceedings will be available to the public.

§ 860.3 Definitions.

For the purposes of this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Commissioner" means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health, Education, and Welfare, or the Commissioner's designee.

(c) "Class" means one of the three categories of regulatory control for medical devices, defined below:

(1) "Class I" means the class of devices that are subject to only the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the act. A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance, but which is not life-supporting or life-sustaining or for a use which is of substanial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness of injury.

(2) "Class II" means the class of devices that are or eventually will be subject to the requirements of a performance standard promulgated in accordance with section 514 of the act. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish a performance standard to provide such assurance.

(3) "Class III" means the class of devices for which premarket approval is or will be required in accordance with section 515 of the act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or to establish a performance standard to provide such assurance and if, in addition, the device is life-

supporting of life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

(d) "Implant" means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.

"Life-supporting or life-sustaining device" means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

(f) "Classification questionnaire" means a specific series of questions prepared by the Commissioner for use as guidelines by classification panels preparing recommendations to the Commissioner regarding classification and by petitioners submitting petitions for reclassification. The questions relate to the safety and effectiveness characteristics of a device and the answers are designed to help the Commissioner determine the proper classification of the device.

(g) "Supplemental data sheet" means information compiled by a classification panel or submitted in a petition for reclassification, including:

(1) A summary of the reasons for the recommendation (or petition);

(2) A summary of the data upon which the recommendation (or petition) is based;

(3) An identification of the risks to health (if any) presented by the device;

(4) To the extent practicable in the case of a class II or class III device, a recommendation for the assignment of a priority for the application of the requirements of performance standards or premarket approval;

(5) In the case of a class I device, a recommendation whether the device should be exempted from any of the requirements of registration, recordkeeping and reporting, or good manufacturing practice regulations;

(6) In the case of an implant or a life-supporting or life-sustaining device for which classification in class III is not recommended, a statement of the reasons for not recommending that the device be classified in class III;

(7) Identification of any needed restrictions on the use of the device, e.g., whether the device requires special labeling, should be banned, or should be used only upon authorization of a practitioner licensed by law to administer or use such device; and

(8) Any known existing standards applicable to the device, device components, or device materials.

(h) "Classification panel" means one of the several advisory committees established by the Commissioner under section 513 of the act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the classification and reclassification of devices and for other purposes prescribed by the act or by the Commissioner.

(i) "Generic type of device" means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

(j) "Petition" means a submission seeking reclassification of a device in accordance with § 860.123.

§ 860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

(a) This section governs the availability for public disclosure and the use by the Commissioner of data and information submitted to classification panels or to the Commissioner in connection with the classification or reclassification of devices under this part.

(b) In general, data and information submitted to classification panels in connection with the classification of devices under § 860.84 will be available immediately for public disclosure upon request. However, except as provided by the special rules in paragraph (c) of this section, this provision does not apply to data and information exempt from public disclosure in accordance with part 20 of this chapter: Such data and information will be available only in accordance with part 20.

(c)(1) Safety and effectiveness data submitted to classification panels or to the Commissioner in connection with the classification of a device under § 860.84, which have not been disclosed previously to the public, as described in § 20.81 of this chapter, shall be regarded as confidential if the device is classified in to class III. Because the classification of a device under § 860.84 may be ascertained only upon publication of a final regulation, all safety and effectiveness data that have not been disclosed previously are not available for public disclosure unless and until the device is classified into class I or II, in which case the procedure in paragraph (c)(2) of this section applies.

(2) Thirty days after publication of a final regulation under § 860.84 classifying a device into class I or class II, safety and effectiveness data submitted for that device that had been regarded as confidential under paragraph (c)(1) of this section will be available for public disclosure and placed on public display in the office of the Hearing Clerk, Food and Drug Administration unless, within that 30-day period, the person who submitted the data demonstrates that the data still fall within the exemption for trade secrets and confidential commercial information described in § 20.61 of this chapter. Safety and effectiveness data submitted for a device that is classified into class III by regulation in accordance with § 860.84 will remain confidential and unavailable for public disclosure so long as such data have not been disclosed to the public as described in § 20.81 of this chapter.

(3) Because device classification affects generic types of devices, in making determinations under § 860.84 concerning the initial classification of a device, the classification panels and the Commissioner may consider safety and effectiveness data developed for another device in the same generic type, regardless of whether such data are regarded currently as confidential under paragraph (c)(1) of this section.

(d)(1) The fact of its existence and the contents of a petition for reclassification filed in accordance with § 860.130 or § 860.132 are available for public disclosure at the time the petition is received by the Food and Drug Administration.

(2) The fact of the existence of a petition for reclassification filed in accordance with § 860.134 or § 860.136 is available for public disclosure at the time the petition is received by the Food and Drug Administration. The contents of such a petition are not available for public disclosure for the period of time following its receipt (not longer than 30 days) during which the petition is reviewed for any deficiencies preventing the Commissioner from making a decision on it. Once it is determined that the petition contains no deficiencies preventing the Commissioner from making a decision on it, the petition will be filed with the Hearing Clerk and its entire contents will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. If, during this 30-day period of time, the petition is found to contain deficiencies that prevent the Commissioner from making a decision on it, the petitioner will be so notified and afforded an opportunity to correct the deficiencies.

Thirty days after notice to the petitioner of deficiencies in the petition,

the contents of the petition will be available for public disclosure unless, within that 30 days, the petitioner submits supplemental material intended to correct the deficiencies in the petition. The Commissioner, in the Commissioner's discretion, may allow withdrawal of a deficient petition during the 30-day period provided for correcting deficiencies. Any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. Once the petitioner has corrected the deficiencies, the entire contents of the petition will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. Deficient petitions which have not been corrected within 180 days after notification of deficiency will be returned to the petitioner and will not be considered further unless resubmitted.

(e) The Commissioner may not disclose, or use as the basis for reclassification of a device from class III to class II, any information reported to or otherwise obtained by the Commissioner under section 513, 514, 515, 516, 518, 519, 520(f), 520(g), or 704 of the act that falls within the exemption described in §20.61 of this chapter for trade secrets and confidential commercial information. The exemption described in §20.61 does not apply to data or information contained in a petition for reclassification submitted in accordance with §860.130 or §860.132, or in a petition submitted in accordance with §860.134 or §860.136 that has been determined to contain no deficiencies that prevent the Commissioner from making a decision on it. Accordingly, all data and information contained in such petitions may be disclosed by the Commissioner and used as the basis for reclassification of a device from class III to class II.

(f) For purposes of this section, safety and effectiveness data include data and results derived from all studies and tests of a device on animals and humans and from all studies and tests of the device itself intended to establish or determine its safety and effectiveness.

§860.7 Determination of safety and effectiveness.

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of performance standards for class II devices, and premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

(c) (1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.

(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. Such information may be considered, however, in identifying a device the safety and effectiveness of which is questionable.

(d) (1) There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe are investigations using laboratory animals, investigations involving human subjects, and nonclinical investigations including in vitro studies.

(e) (1) There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

(2) The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations, as defined in paragraph (f) of this section, unless the Commissioner authorizes reliance upon other valid scientific evidence which the Commissioner has determined is sufficient evidence from which to determine the effectiveness of a device, even in the absence of well-controlled investigations. The Commissioner may make such a determination where the requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

(f) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation. They provide the basis for the Commissioner's determination whether there is reasonable assurance that a device is effective based upon well-controlled investigations and are also useful in assessing the weight to be given to other valid scientific evidence permitted under this section.

(1) The plan or protocol for the study and the report of the results of a well-controlled investigation shall include the following:

(i) A clear statement of the objectives of the study;

(ii) A method of selection of the subjects that:

(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the act: section 510 (registration, product listing, and premarket notification) section 519 (records and reports) and section 520(f) (good manufacturing practice regulations) in accordance with § 860.95;

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement;

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device, accompanied by references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(e) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed in the Hearing Clerk's office upon receipt and are available to the public upon request.

(f) The Commissioner publishes the panel's recommendation in the FEDERAL REGISTER, together with a proposed regulation classifying the device, and other devices of that generic type, and provides interested persons an opportunity to submit comments on the recommendation and proposed regulation.

(g) The Commissioner reviews the comments and issues a final regulation classifying the device and other devices of that generic type. The regulation will:

(1) If classifying the device into class I, prescribe which, if any, of the requirements of sections 510, 519, and 520(f) of the act will not apply to the device and state the reasons for making the requirements inapplicable, in accordance with § 860.95;

(2) If classifying the device into class II or class III, at the discretion of the Commissioner, establish priorities for the application to the device of a performance standard or a premarket approval requirement;

(3) If classifying an implant, or life-supporting or life-sustaining device, comply with § 860.93(b).

§ 860.93 Classification of implants, life-supporting or life-sustaining devices.

(a) The classification panel will recommend classification into class III of any implant or life-supporting or life-sustaining device unless the panel determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the panel recommends classification or reclassification of such a device into a class other than class III, it shall set forth in its recommendation the reasons for so doing together with references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(b) The Commissioner will classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the Commissioner proposes to classify or reclassify such a device into a class other than class III, the regulation or order effecting such classification or reclassification will be accompanied by a full statement of the reasons for so doing. A statement of the reasons for not classifying or retaining the device in class III may be in the form of concurrence with the reasons for the recommendation of the classification panel, together with supporting documentation and data satisfying the requirements of § 860.7 and an identification of the risks to health, if any, presented by the device.

§ 860.95 Exemptions from sections 510, 519, and 520(f) of the act.

(a) A panel recommendation to the Commissioner that a device be classified or reclassified into class I will include a recommendation as to whether the device should be exempted from some or all of the requirements of one or more of the following sections of the act: section 510 (registration, product listing and premarket notification), section 519 (records and reports), and section 520(f) (good manufacturing practice regulations).

(b) A regulation or an order classifying or reclassifying a device into class I will specify which requirements, if any, of sections 510, 519, and 520(f) of the act the device is to be exempted from, together with the reasons for such exemption.

(c) The Commissioner will grant exemptions under this section only if the Commissioner determines that the requirements from which the device is exempted are not necessary to provide reasonable assurance of the safety and effectiveness of the device.

Subpart C—Reclassification

§ 860.120 General.

(a) Sections 513(e) and (f), 514(b), 515(b), and 520(l) of the act provide for reclassification of a device and prescribe the procedures to be followed to effect reclassification. The purposes of subpart C are to:

(1) Set forth the requirements as to form and content of petitions for reclassification;

(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in § 860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(e), 514(b), or 515(b). A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(l).

§ 860.123 Reclassification petition: content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., "It is requested that — device(s) be reclassified from class III to a class II";

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(a) Provides adequate assurance that the subjects are suitable for the purposes of the study, provides diagnostic criteria of the condition to be treated or diagnosed, provides confirmatory laboratory tests where appropriate and, in the case of a device to prevent a disease or condition, provides evidence of susceptibility and exposure to the condition against which prophylaxis is desired;

(b) Assigns the subjects to test groups, if used, in such a way as to minimize any possible bias;

(c) Assures comparability between test groups and any control groups of pertinent variables such as sex, severity or duration of the disease, and use of therapy other than the test device;

(iii) An explanation of the methods of observation and recording of results utilized, including the variables measured, quantitation, assessment of any subject's response, and steps taken to minimize any possible bias of subjects and observers;

(iv) A comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be specified and an explanation provided of the methods employed to minimize any possible bias of the observers and analysts of the data. Level and methods of "blinding," if appropriate and used, are to be documented. Generally, four types of comparisons are recognized:

(a) *No treatments.*—Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated patients;

(b) *Placebo control.*—Where there may be a placebo effect with the use of a device, comparison of the results of use of the device with an ineffective device used under conditions designed to resemble the conditions of use under investigation as far as possible;

(c) *Active treatment control.*—Where an effective regimen of therapy may be used for comparison, e.g., the condition being treated is such that the use of a placebo or the withholding of treatment would be inappropriate or contrary to the interest of the patient;

(d) *Historical control.*—In certain circumstances, such as those involving diseases with high and predictable mortality or signs and symptoms of predictable duration or severity, or in the case of prophylaxis where morbidity is predictable, the results of use of the device may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable patients or populations who received no treatment or who followed an established effective regimen (therapeutic, diagnostic, prophylactic).

(v) A summary of the methods of analysis and an evaluation of the data derived from the study, including any appropriate statistical methods utilized.

(2) To insure the reliability of the results of an investigation, a well-controlled investigation shall involve the use of a test device that is standardized in its composition or design and performance.

(g) (1) It is the responsibility of each manufacturer and importer of a device to assure that adequate, valid scientific evidence exists, and to furnish such evidence to the Food and Drug Administration to provide reasonable assurance that the device is safe and effective for its intended uses and conditions of use. The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific evidence showing that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone, or by general controls and performance standards, may support a determination that the device be classified into class III.

(2) The Commissioner may require that a manufacturer, importer, or distributor make reports or provide other information bearing on the classification of a device and indicating whether there is reasonable assurance of the safety and effectiveness of the device or whether it is adulterated or misbranded under the act.

(3) A requirement for a report or other information under this paragraph will comply with section 519 of the act. Accordingly, the requirement will state the reason or purpose for such request; will describe the required report or information as clearly as possible; will not be imposed on a manufacturer, importer, or distributor of a classified device that has been exempted from such a requirement in accordance with § 860.95; will prescribe the time for compliance with the requirement; and will prescribe the form and manner in which the report or information is to be provided.

(4) Required information that has been submitted previously to the Bureau of Medical Devices need not be resubmitted, but may be incorporated by reference.

Subpart B—Classification

§ 860.84 Classification procedures for "old devices."

(a) This subpart sets forth the procedures for the original classification of a device that either was in commercial distribution before May 28, 1976, or is substantially equivalent to a device that was in commercial distribution before that date. Such a device will be classified by regulation into either class I (general controls), class II (performance standards), or class III (premarket approval), depending upon the level of regulatory control required to provide reasonable assurance of the safety and effectiveness of the device (§ 860.3(c)). This subpart does not apply to a device that is classified into class III by statute under section 513(f) of the act because the Food and Drug Administration has determined that the device is not "substantially equivalent" to any device subject to this subpart or under section 520(l) (1) through (3) of the act because the device was regarded previously as a new drug. This subpart does apply to a device that was previously regarded as an antibiotic drug and that is subject to section 520(l)(4) of the act. In classifying a device under this section, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

(b) The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513 (b) and (c) of the act and part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7;

(3) Answers the questions in the classification questionnaire applicable to the device being classified;

(4) Completes a supplemental data sheet for the device;

(5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter.

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of each class in § 860.3(c), the panel submits to the Commissioner a recommendation regarding the classification of the device. The recommendation will include:

(1) A summary of the reasons for the recommendation;

(2) A summary of the data upon which the recommendation is based, accompanied by references to the sources containing such data;

(3) An identification of the risks to health (if any) presented by the device;

the contents of the petition will be available for public disclosure unless, within that 30 days, the petitioner submits supplemental material intended to correct the deficiencies in the petition. The Commissioner, in the Commissioner's discretion, may allow withdrawal of a deficient petition during the 30-day period provided for correcting deficiencies. Any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. Once the petitioner has corrected the deficiencies, the entire contents of the petition will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. Deficient petitions which have not been corrected within 180 days after notification of deficiency will be returned to the petitioner and will not be considered further unless resubmitted.

(e) The Commissioner may not disclose, or use as the basis for reclassification of a device from class III to class II, any information reported to or otherwise obtained by the Commissioner under section 513, 514, 515, 516, 518, 519, 520(f), 520(g), or 704 of the act that falls within the exemption described in §20.61 of this chapter for trade secrets and confidential commercial information. The exemption described in §20.61 does not apply to data or information contained in a petition for reclassification submitted in accordance with §860.130 or §860.132, or in a petition submitted in accordance with §860.134 or §860.136 that has been determined to contain no deficiencies that prevent the Commissioner from making a decision on it. Accordingly, all data and information contained in such petitions may be disclosed by the Commissioner and used as the basis for reclassification of a device from class III to class II.

(f) For purposes of this section, safety and effectiveness data include data and results derived from all studies and tests of a device on animals and humans and from all studies and tests of the device itself intended to establish or determine its safety and effectiveness.

§860.7 Determination of safety and effectiveness.

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of performance standards for class II devices, and premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

(c) (1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.

(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. Such information may be considered, however, in identifying a device the safety and effectiveness of which is questionable.

(d) (1) There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe are investigations using laboratory animals, investigations involving human subjects, and nonclinical investigations including in vitro studies.

(e) (1) There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

(2) The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations, as defined in paragraph (f) of this section, unless the Commissioner authorizes reliance upon other valid scientific evidence which the Commissioner has determined is sufficient evidence from which to determine the effectiveness of a device, even in the absence of well-controlled investigations. The Commissioner may make such a determination where the requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

(f) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation. They provide the basis for the Commissioner's determination whether there is reasonable assurance that a device is effective based upon well-controlled investigations and are also useful in assessing the weight to be given to other valid scientific evidence permitted under this section.

(1) The plan or protocol for the study and the report of the results of a well-controlled investigation shall include the following:

(i) A clear statement of the objectives of the study;

(ii) A method of selection of the subjects that:

(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the act: section 510 (registration, product listing, and premarket notification) section 519 (records and reports) and section 520(f) (good manufacturing practice regulations) in accordance with § 860.95;

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement;

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device, accompanied by references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(e) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed in the Hearing Clerk's office upon receipt and are available to the public upon request.

(f) The Commissioner publishes the panel's recommendation in the FEDERAL REGISTER, together with a proposed regulation classifying the device, and other devices of that generic type, and provides interested persons an opportunity to submit comments on the recommendation and proposed regulation.

(g) The Commissioner reviews the comments and issues a final regulation classifying the device and other devices of that generic type. The regulation will:

(1) If classifying the device into class I, prescribe which, if any, of the requirements of sections 510, 519, and 520(f) of the act will not apply to the device and state the reasons for making the requirements inapplicable, in accordance with § 860.95;

(2) If classifying the device into class II or class III, at the discretion of the Commissioner, establish priorities for the application to the device of a performance standard or a premarket approval requirement;

(3) If classifying an implant, or life-supporting or life-sustaining device, comply with § 860.93(b).

§ 860.93 Classification of implants, life-supporting or life-sustaining devices.

(a) The classification panel will recommend classification into class III of any implant or life-supporting or life-sustaining device unless the panel determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the panel recommends classification or reclassification of such a device into a class other than class III, it shall set forth in its recommendation the reasons for so doing together with references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(b) The Commissioner will classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the Commissioner proposes to classify or reclassify such a device into a class other than class III, the regulation or order effecting such classification or reclassification will be accompanied by a full statement of the reasons for so doing. A statement of the reasons for not classifying or retaining the device in class III may be in the form of concurrence with the reasons for the recommendation of the classification panel, together with supporting documentation and data satisfying the requirements of § 860.7 and an identification of the risks to health, if any, presented by the device.

§ 860.95 Exemptions from sections 510, 519, and 520(f) of the act.

(a) A panel recommendation to the Commissioner that a device be classified or reclassified into class I will include a recommendation as to whether the device should be exempted from some or all of the requirements of one or more of the following sections of the act: section 510 (registration, product listing and premarket notification), section 519 (records and reports), and section 520(f) (good manufacturing practice regulations).

(b) A regulation or an order classifying or reclassifying a device into class I will specify which requirements, if any, of sections 510, 519, and 520(f) of the act the device is to be exempted from, together with the reasons for such exemption.

(c) The Commissioner will grant exemptions under this section only if the Commissioner determines that the requirements from which the device is exempted are not necessary to provide reasonable assurance of the safety and effectiveness of the device.

Subpart C—Reclassification

§ 860.120 General.

(a) Sections 513(e) and (f), 514(b), 515(b), and 520(l) of the act provide for reclassification of a device and prescribe the procedures to be followed to effect reclassification. The purposes of subpart C are to:

(1) Set forth the requirements as to form and content of petitions for reclassification;

(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in § 860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(e), 514(b), or 515(b). A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(l).

§ 860.123 Reclassification petition: content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., "It is requested that — device(s) be reclassified from class III to a class II";

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(8) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the act, a summary of the new information;

(9) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition).

(b) Each petition submitted pursuant to this section shall be:

(1) Addressed to the Food and Drug Administration, Bureau of Medical Devices, Document Control Center (HFK-20), 8757 Georgia Avenue, Silver Spring, Md. 20910;

(2) Marked clearly with the section of the act under which the petition is being submitted, i.e., "513(e)," "513(f)," "514(b)," "515(b)," or "520(l) Petition";

(3) Bound in a volume or volumes, where necessary; and

(4) Submitted in quintuplicate.

§ 860.125 Consultation with panels.

(a) When the Commissioner is required to refer a reclassification petition to a classification panel for its recommendation under § 860.134, or is required, or chooses, to consult with a panel concerning a reclassification petition, such as under § 860.130, § 860.132, or § 860.136, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member and will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members;

(2) Consultation by mail with at least a majority of current voting panel members and, when possible, nonvoting panel members; and

(3) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

(c) When a petition is submitted under § 860.134 for a post-enactment, not substantially equivalent device ("new device"), in consulting with the panel the Commissioner will obtain a recommendation that includes the information described in § 860.84(d). In consulting with a panel about a petition submitted under § 860.130, § 860.132, or § 860.136, the Commissioner may or may not obtain a formal recommendation.

§ 860.130 General procedures under section 513(e) of the act.

(a) Section 513(e) of the act applies to reclassification proceedings under the act based upon new information.

(b) A proceeding to reclassify a device under section 513(e) may be initiated:

(1) On the initiative of the Commissioner alone;

(2) On the initiative of the Commissioner in response to a request for change in classification based upon new information, under section 514(b) or 515(b) of the act (see § 860.132); or

(3) In response to the petition of an interested person, based upon new information, filed in accordance with § 860.123.

(c) The rulemaking procedures in § 10.40 of this chapter apply to proceedings to reclassify a device under section 513(e), except that the Commissioner may secure a recommendation with respect to a proposed reclassification from the classification panel to which the device was last referred. The panel will consider a proposed reclassification submitted to it by the Commissioner in accordance with the consultation procedures of § 860.125. Any recommendation submitted to the Commissioner by the panel will be published in the FEDERAL REGISTER when the Commissioner promulgates a regulation under this section.

(d) Within 180 days after the filing of a petition for reclassification under this section, the Commissioner, by order published in the FEDERAL REGISTER, will either deny the petition or give notice of his intent to initiate a change in the classification of the device.

(e) If a device is reclassified under this section, the regulation effecting the reclassification may revoke any performance standard or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.

(f) A regulation under this section changing the classification of a device from class III to class II may provide that such classification will not take effect until the effective date of a performance standard for the device established under section 514 of the act.

§ 860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 515(b) of the act.

(a) Sections 514(b) and 515(b) of the act require the Commissioner to provide, by notice in the FEDERAL REGISTER, an opportunity for interested parties to request a change in the classification of a device based upon new information relevant to its classification when the Commissioner initiates a proceeding either to develop a performance standard for the device if in class II, or to promulgate a regulation requiring premarket approval for the device if in class III. In either case, if the Commissioner agrees that the new information warrants a change in classification, the Commissioner will publish in the FEDERAL REGISTER notice of the Commissioner's intent to initiate a proceeding under section 513(e) of the act and § 860.130 to effect such a change.

(b) The procedures for effecting a change in classification under sections 514(b) and 515(b) of the act are as follows:

(1) Within 15 days after publication of the Commissioner's notice referred to in paragraph (a) of this section, an interested person files a petition for reclassification in accordance with § 860.123.

(2) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(3) Within 60 days after publication of the notice referred to in paragraph (a) of this section, the Commissioner, by order published in the FEDERAL REGISTER, either denies the petition or gives notice of his intent to initiate a change in classification in accordance with § 860.130.

§ 860.134 Procedures for "new devices" under section 513(f) of the act.

(a) Section 513(f)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 513(f)(1) of the act. This category includes any device that is to be first introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, unless:

(1) It is substantially equivalent to another device that was in commercial distribution before that date and had not been regulated before that date as a new drug; or

(2) It is substantially equivalent to another device that was not in commercial distribution before such date but which has been classified into class I or class II; or

(3) The Commissioner has classified the device into class I or class II in response to a petition for reclassification under this section.

The Commissioner determines whether a device is "substantially equivalent" for purposes of the application of this section. If a manufacturer or importer believes that a device is not "substantially equivalent" but that it should not be in class III under the criteria in § 860.3(c), the manufacturer or importer may petition for reclassification under this section. A

manufacturer or importer who believes that a device is "substantially equivalent" and wishes to proceed to market the device shall submit a premarket notification in accordance with part 807 of this chapter. After considering a premarket notification, the Commissioner will determine whether the device is "substantially equivalent" and will notify the manufacturer or importer of such determination in accordance with part 807 of this chapter.

(b) The procedures for effecting reclassification under section 513(f) of the act are as follows:

(1) The manufacturer or importer of the device petitions for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it and allows the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) After determining that the petition contains no deficiencies precluding a decision on it, the Commissioner refers the petition to the appropriate classification panel for its review and recommendation whether to approve or deny the petition.

(4) Within 90 days after the date the petition is referred to the panel, following the review procedures set forth in § 860.84(c) for the original classification of an "old" device, the panel submits to the Commissioner its recommendation containing the information set forth in § 860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed in the hearing clerk's office upon receipt and are available to the public upon request.

(5) The panel recommendation is published in the FEDERAL REGISTER as soon as practicable and interested persons are provided an opportunity to comment on the recommendation.

(6) Within 90 days after the panel's recommendation is received (and no more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with the criteria set forth in § 860.3(c) and subject to the applicable requirements of § 860.93, relating to the classification of implants, life-supporting or life-sustaining devices, and § 860.95, relating to exemptions from certain requirements of the act.

(7) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

§ 860.136 Procedures for transitional products under section 520(l) of the act.

(a) Section 520(l)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(l)(1) of the act. This section applies only to devices that the Food and Drug Administration regarded as "new drugs" before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(l) are as follows:

(1) The manufacturer or importer of the device files a petition for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it, allowing the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) The Commissioner provides the petitioner an opportunity for a regulatory hearing conducted in accordance with part 16 of this chapter.

(4) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(5) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in § 860.3(c).

(6) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

Effective date: This regulation shall be effective August 28, 1978.

(Secs. 513, 514, 515, 519, 520, 701(a), 52 Stat. 1055, 90 Stat. 540-559, 564-574 (21 U.S.C. 360c, 360d, 360e, 360i, 360j, and 371(a)).)

Dated: July 18, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 78-20625 Filed 7-27-78; 8:45 am]

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FRIDAY, JULY 28, 1978
PART III

DEPARTMENT OF LABOR

Employment Standards Administration

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MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

[4510-27]

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, procedure for predetermination of wage rates (37 FR 21138), and of Secretary of Labor's orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision together with any modification issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

MODIFICATIONS AND SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, procedure for predetermination of wage rates (37 FR 21138) and of Secretary of Labor's orders 13-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Special Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original general wage determination decision.

NEW GENERAL WAGE DETERMINATION DECISIONS

Indiana—IN78-2066.

MODIFICATIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the FEDERAL REGISTER are listed with each State.

California:	
CA78-5107	July 7, 1978.
District of Columbia:	
DC78-3008	Mar. 17, 1978.
Florida:	
FL78-1062	July 14, 1978.
Iowa:	
IA77-4223; IA77-4224; IA77-4225; IA77-4226; IA77-4227; IA77-4228; IA77-4229; IA77-4230; IA77-4231; IA77-4232; IA77-4233; IA77-4234; IA77-4235	Sept. 30, 1977.
North Carolina:	
NC78-1061	July 7, 1978.
Oklahoma:	
OK77-4060	Mar. 11, 1977.
Pennsylvania:	
PA77-3122	Sept. 9, 1977.
PA78-3037	Apr. 21, 1978.
Tennessee:	
TN78-1058	July 7, 1978.

SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being superseded and their dates of publication in the FEDERAL REGISTER are listed with each State. Supersedeas decision numbers are in parentheses following the numbers of the decisions being superseded.

Arizona:	
AZ77-5115 (AZ78-5025); AZ77-5026 (AZ78-5116)	June 17, 1977.
Arkansas:	
AR78-4070 (AR78-4074)	June 30, 1978.
Connecticut:	
CT78-3003 (CT78-3055); CT78-3004 (CT78-3056)	Feb. 17, 1978.
Louisiana:	
AR78-4070 (AR78-4074)	June 30, 1978.
Mississippi:	
AR78-4070 (AR78-4074)	Do.
Tennessee:	
AR78-4070 (AR78-4074)	Do.
Vermont:	
VT76-2170 (VT78-2067)	Dec. 10, 1976.

CANCELLATION OF GENERAL WAGE DETERMINATION DECISIONS

None.

Signed at Washington, D.C., this 21st day of July 1978.

XAVIER M. VELA,
Adminstrator,
Wage and Hour Division.

NEW DECISION

STATE: INDIANA
DECISION NO : IN78-2066
COUNTIES: *See below
DATE: Date of Publication
DESCRIPTION OF WORK: Building Construction (Does not include single family homes & garden type apartments up to & including 4 stories)

*Elkhart, Jasper, Kosciusko, LaGrange, Marshall, Newton, Pulaski, & Starke

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr.
ASBESTOS WORKERS:					
Elkhart, Jasper, Kosciusko, Marshall, Pulaski, & Starke Cos	$12 13	65	90		
LaGrange Co	13 15	50	75		
Newton Co	12 11	81	72		.12
BOILERMAKERS	12 55	80	1 00		03
BRICKLAYERS; Stonemasons					
Elkhart, Kosciusko, & LaGrange Cos	11 43		30		02
Jasper, Newton & Starke Cos	11 85	75	55		05
Marshall Co	11 36	1 00	90		06
Pulaski Co	10 10	1 00	40		
CARPENTERS; Millwrights; Piledrivermen; & Soft Floor Layers:					
Elkhart Co					
Carpenters; Soft Floor Layers	10 65	70	55		08
Millwrights; Piledrivermen	10 90	70	55		08
Jasper, Newton, & Starke Cos :					
Carpenters; Soft Floor Layers	12 78	65	67		05
Millwrights	12 88	65	67		05
Kosciusko (Warsaw & Vic) Marshall, & Pulaski Cos.:					
Carpenters; Soft Floor Layers	10 23	80	60		05
Millwrights	10 73	80	60		05
Piledrivermen	10 43	80	60		05
Kosciusko (Remaining Portion) Co.	10 90	60	85		08
LaGrange Co :					
Carpenters; Soft Floor Layers	10 57	6%a			08
Millwrights; Piledrivermen	10 90	6%a			08
CEMENT MASONS:					
Elkhart, Kosciusko, & LaGrange Cos	10 48		30		02
Jasper (Northern 1/3), Pulaski (Northern 2/3), & Starke Cos	10 95	90	1 00		06
Jasper (Remaining Portion), & Newton (Southeastern 2/3) Cos	10 00	60	75		
Newton (Northern 1/3)	11.42	90	60		03
ELECTRICIANS:					
Elkhart, Kosciusko, & Marshall Cos	11 85	4 8%	7%		2%
Jasper, Pulaski, & Starke Cos	12 10	4%	7½%		5%
LaGrange Co	11 60	50	3%+ 30		06
Newton Co	12.60	6 5%	8.3%		7%

DECISION NO IN78-2066

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ELEVATOR CONSTRUCTORS:					
Elkhart, Jasper, Kosciusko (NW Portion), LaGrange (NW of city of LaGrange), Marshall, Pulaski, & Starke Cos					
Elevator Constructors	$11.115	895	69	b&c	035
Helpers	70%JR	895	69	b&c	035
Helpers (Prob)	50%JR				
Kosciusko (SE part), & LaGrange (Remaining Portion) Cos :					
Elevator Constructors	11.195	895	69	b&c	035
Helpers	70%JR	895	.69	b&c	035
Helpers (Prob)	50%JR				
Newton Co :					
Elevator Constructors	12.740	895	69	b&c	035
Helpers	70%JR	895	69	b&c	035
Helpers (Prob)	50%JR				
GLAZIERS:					
Kosciusko (Southern portion), & LaGrange Cos	10 20		25	40d	04
IRONWORKERS:					
Elkhart, Kosciusko (NW portion exclu Warsaw), LaGrange (W ½ exclu city of LaGrange), Marshall, Pulaski, & Starke Cos.	11 45	90	1 33		03
Jasper (N½), & Newton Cos.	12 72	80	1 66		09
Jasper (S½) Co	11 14	90	1 25		02
Kosciusko (SW portion inclu. Warsaw), & LaGrange (E½ of Co inclu city of LaGrange) Cos.	11.80	90	1 45		.02
LATHERS:					
Elkhart, Kosciusko, LaGrange, Marshall & Starke Cos	10 12	43	50		01
Jasper (So of Hwy 14) Co	10 54	55	35		01
MARBLE SETTERS; Terrazzo Workers; & Tile Setters:					
Elkhart, Kosciusko, & LaGrange Cos :					
Terrazzo Workers; & Tile Setters	10 20		30	e	02
Jasper, Newton, & Starke Cos :					
Marble Setters	11.85	.75	55		05
Tile Setters	11 75	.75	55		02
Marshall, & Pulaski Cos.	9.65	1 00	.90	f	01

DECISION NO IN78-2066

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PAINTERS:					
Elkhart, Kosciusko, Marshall, Pulaski, & Starke Cos :					
Brush; Drywall tapers & Finishers	9 59		40		$15 00p/yr
Jasper & Newton Cos :					
Brush	10 50	64	50		05
Paperhanging	10 75	64	50		05
Sandblasting; Spray	11 25	64	50		05
Drywall taping	11 55	64	50		05
LaGrange Co :					
Brush; Paperhangers; Rollers; & Tapers	8 60	42	45		10
Sandblasting; Spray; & Steam cleaning	9 60	42	45		10
PIPEFITTERS; Plumbers; & Steamfitters:					
Elkhart, Kosciusko, & LaGrange Cos	12 15	55	85		07
Jasper (N side of city of Rensselaer, S.), Marshall, Pulaski, & Starke Cos	11 25	48	95		10
Pipefitters; Steamfitters:					
Jasper (Rem of Co), & Newton Cos	12 90	80	1 00		02
Plumbers:					
Jasper (Rem of Co) Co	12 20	.90	1 50		04
Newton Co	12 22	1 00	1 15		04
PLASTERERS:					
Elkhart, Kosciusko, & LaGrange Cos	10 28		30		02
Jasper (NE portion of Co. w to, but not inclu. Wheatfield), Pulaski (N 2/3 of Co), & Starke Cos,	10 87	90	1.00		06
Newton Co (N½ of Co)	10 21	90	60		01
ROOFERS:					
Elkhart, Kosciusko, Marshall, Pulaski, & Starke Cos.:					
Composition, Damp & Waterproof	10 95	50	40		03
Slate, Tile, & Asbestos	11 45	50	40		03
Jasper & Newton Cos	12 21	70	50		
LaGrange Co :					
Roofers	10 90		.10		
Pitch	11 15		10		

DECISION NO IN78-2066

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
SHEET METAL WORKERS:					
Elkhart, Kosciusko, & Marshall Cos	$10 98	65	615		035
Jasper, Newton, Pulaski, & Starke Cos	12 15	75	1 16		12
LaGrange Co	11 98	50	60		12
SPRINKLER FITTERS	12 10	75	1 05		08

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

FOOTNOTES:
a 6% for health and welfare includes pension
b 7 paid holidays: A through F, and Day after Thanksgiving Day
c Employer contributes 8% of regular hourly rate to vacation pay credit for employee who has worked in business more than 5 years; 6% for employee who has worked in business less than 5 years
d 6 paid holidays: A through F provided such employees work the last scheduled day prior to and the next scheduled work day after the holiday unless permission for not working on such days is granted by the employer
e 6 paid holidays: A through F
f 6 paid holidays: A through F

TRUCK DRIVERS Elkhart, Kosciusko, LaGrange, & Marshall Counties	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PICK-UPS	$6 94	$13 50a	$ 22 00a	b	
SINGLE AXLES	7 15	13 50a	22 00a	b	
TANDEMS; Fuels	7 26	13 50a	22 00a	b	
TRI AXLES	7 31	13 50a	22 00a	b	
SEMI-TRAILERS	7 36	13 50a	22 00a	b	

FOOTNOTES:
a Per week per employee
b 1 week's paid vacation for 3 years' service, 2 weeks' paid vacation for 10 years' service & 3 weeks' paid vacation for 15 years' service

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LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Elkhart, Kosciusko, LaGrange, & Marshall Counties					
GROUP I	$8 25	70	50		09
GROUP II	8 45	70	50		.09
GROUP III	8 55	70	50		09
GROUP IV	9 25	70	50		09
Jasper & Newton Counties					
GROUP I	8 70	70	55		09
GROUP II	8 90	70	55		09
GROUP III	9 00	70	55		09
GROUP IV	9 70	70	55		09
Pulaski County					
GROUP I	7.70	.70	.50		.09
GROUP II	7.90	.70	.50		.09
GROUP III	8 00	70	50		.09
GROUP IV	8 70	.70	50		09
Starke County					
GROUP I	8.50	.70	.50		09
GROUP II	8 70	70	50		.09
GROUP III	8.80	.70	.50		.09
GROUP IV	9.50	.70	50		.09

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LABORERS

GROUP I: Building & Construction laborers; Scaffold builders (other than for masons or plasterers); Ironworker helpers; Mechanic tenders; Civil engineer helpers & surveyor helpers; Rodmen & Chainmen; Window washers & cleaners; Waterboy: & Toolhousemen; Roofer's helpers; Railroad workers; Masonry wall washers (interior & exterior); Cement finisher helpers; Carpenter helpers; Helpers of all other crafts not listed; Mason tenders for Areas I, IA, IB, and Counties of Adams, Allen, DeKalb, Steuben, Huntington, Noble, Wabash, Wells, & Whitley; All portable water pumps with discharge up to 3 inches

GROUP II: Waterproofing; Handling of creosote lumber or like treated material (excluding railroad material); Asphalt rakers & tutmen; Kettlemen; Air tool operators, vibrators, chipping hammer operators and all pneumatic tool operators; Earth compactors; Jackmen & sheetmen working ditches deeper than 6 ft in depth; Laborers working ditches 6 ft. in depth or deeper; Assembly of Unierete pump; Chain saw operators; Tile layers (sewer or field) & sewer pipe layers (metallic or non-metallic); Motor driven wheelbarrows & concrete buggies; Hyster operators; Pump crete assemblers; Conveyor assemblers; Core drill operators; Cement, lime or silica Clay handlers (bulk or bag); Handling of toxic materials damaging to clothing; Pneumatic spikers; Deck engine & winch operators; Water main & cable ducking (metallic & non-metallic)

GROUP III: Plasterers' tenders; Mason tenders, except for Areas I, IA, IB, and Counties of Adams, Allen, DeKalb, Steuben, Huntington, Noble, Wabash, Wells, & Whitley; Mortar mixers; Welders (acetylene or electric); Cutting torch or burner; Cement nozzle laborers; Cement gun operators; Scaffold builders when working for plasterers; Scaffold builders when working for masons (except in Areas I, IA, IB, and Counties of Adams, Allen, DeKalb, Steuben, Huntington, Noble, Wabash, Wells, & Whitley)

GROUP IV: Dynamite men

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POWER EQUIPMENT OPERATORS

Elkhart, Kosciusko, LaGrange, & Marshall Counties

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
GROUP I	$10 52	65	85	40	05
GROUP II	9 16	65	85	40	05
GROUP III	8 38	65	85	40	05
GROUP IV	7 70	65	85	40	05

CLASSIFICATIONS

GROUP I: All power cranes; Truck cranes; Locomotive cranes; LeTourneau Tournapulls; Shovels; Draglines; Derricks; Pile drivers; Highlifts; Tractors w/Side boom or "A" Frame; Forklifts 18' 6" in height or over; Motor patrols; Combination backhoe & loader; Mechanic; Conveyor systems; Hoist (3 drum) & over

GROUP II: All bulldozers; Scoops; Push cats; Concrete mixers of more than 21 cu ft. capacity; Locomotives; Rollers; Stone crushers; Fork lifts under 18' 6"; Air compressors - 600 cu ft & over; Combination of Gasoline or Deisel driven welding machine & compressor; Engineers operating throttle valve with boiler and compressor for piledriving; Concrete pumps; Trench machines excluding ditch witches; Cableways; Hoist (2 drum)

GROUP III: Truck winches w/A Frame & Power winches; Tractors-farm type; Drills & conveyors; Small rubber tire end loaders ½ cu yd & under; Bobcat

GROUP IV : Gin poles; Sasgen derricks & similar hoists; Firemen; Oilers; One drum hoist; Single drum tugger hoist; Automatic hoist; Elevators; Compressor over 210 cu ft & under 600 cu ft ; Well points

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POWER EQUIPMENT OPERATORS

Jasper, Newton, Pulaski, & Starke Counties

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pe sions	Vacati	App Tr
Class I	$ 10 30	65	85		05
Class II	9 80	65	85		05
Class III	8 25	65	85		05
Class IV	7.25	.65	85		05

CLASS I Mechanic; asphalt plant; autograde; batch plant; benoto (requires two engineers); boiler & throttle valve; caisson rigs; central redimix plant; combination backhoe, front end loader with backhoe bucket of 1 cu yd & over; combination tugger hoist & air compressor; compressor and throttle; concrete breaker (truck mounted); concrete conveyor; concrete paver over 27E cu. ft ; concrete paver 27E cu. ft and under; concrete tower; cranes, all; cranes, tower; derricks, all; derricks, traveling; fork-lift-lull type; forklift - 10 ton and over; hoists, one, two, and three drum; hoists, two tugger one floor; hydraulic boom truck; locomotive, all; pile drivers and skid rig; pit machines; pre-stress machine; pump cretes and similar types; rock drill (self-propelled); rock drill (truck mounted); slipform paver; straddle buggies; tractor with boom & side boom; trenching machine; winch tractors

CLASS II Asphalt spreader; boiler; bulldozers; combination backhoe, front-end loader with backhoe bucket, less than 1 cu yd ; engineer acting as conductor in charge of crew; grader, elevating; greaser engineer; grouting machines; highlift shovels or front endloader; hoists, automatic; cowboy drilling machines; hoists all elevators; hoists, tugger single drum; motor patrol; post hole digger; rollers, all; scoops - tractor drawn; stone crushers; tournapull; winch trucks

CLASS III Concrete mixer (2 bag & over); conveyor, portable; steam generators; tractors, farm & similar type; air compressor small 150 & under (1 to 5 not to exceed a total of 300 ft); air compressor - large over 150 combination - small equipment operator; forklift trucks; generators; pumps (1 to 3 not to exceed a total of 300 ft); pumps, well points; welding machines (2 through 5); winches ¼ electric drill winches

CLASS IV Heaters, mechanical (1 to 5); oilers & switchmen

DECISION NO 11178-2066

Jasper & Newton Counties	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
TRUCK DRIVERS:					
Pickup trucks	$7 64	$19 00a	$31.00a	b & c	
Helpers; Greasers; Tiremen	7 74	19 00a	31 00a	b & c	
Single axles; Straight trucks; & Warehousemen	7 79	19 00a	31.00a	b & c	
Tandem axle & Dogleg straight trucks	7 89	19 00a	31 00a	b & c	
Bituminous Distributors	7 94	19 00a	31 00a	b & c	
Mechanics; Tri-axles; Semi trucks	8 09	19 00a	31 00a	b & c	

FOOTNOTES:
a Per week per employee
b Six paid holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; & Christmas Day
c One week's paid vacation after one year's employment; Two weeks' paid vacation after three years' employment; Three weeks' paid vacation after ten years' employment

DECISION NO. CA78-5107 - Mod. #1 (43 FR 29444 - July 7, 1978)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Alameda, Alpine, Amador, Butte, Calaveras, Colusa, Contra Costa, Del Norte, Eldorado, Fresno, Glenn, Humboldt, Kings, Lake, Lassen, Madera, Marin, Mariposa, Mendocino, Merced, Modoc, Monterey, Napa, Nevada, Placer, Plumas, Sacramento, San Benito, San Francisco, San Joaquin, San Mateo, Santa Clara, Santa Cruz, Shasta, Sierra, Siskiyou, Solano, Sonoma, Stanislaus, Sutter, Tehama, Trinity, Tulare, Tuolumne, Yolo and Yuba Counties, California					
Add:					
Painters:					
Sacramento, Sierra, Solano Counties (excluding portions of Counties in the Lake Tahoe Area)					
Brush	$12 31	1 10	1 50	80	06
Spray	12 81	1 10	1 50	80	06
Tapers	13 11	1 10	1 50	80	06
Change:					
Decision reference numbers on pages 29461, 29462 and 29463 to Decision No CA78-5107					

DECISION #DC78-3008 - Mod. # 5 (43 FR 11464 - March 17, 1978) District of Columbia; Maryland-Montgomery and Prince Georges; and D C Training School; - Virginia - Independent City of Alexandria & Arlington	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Change:					
WATER & SEWER LINES:					
(District of Columbia and Montgomery County Maryland)					
Power Equipment Operators:					
Backhoes, cable ways, cranes, draglines power shovels, tunnel shovels, tunnel mucking machines, derricks, 1 cu yd and over	$8 49	35	45		05
Backhoes, cableways, cranes derricks, dragline, tunnel shovels, tunnel mucking machines up to 1 cu yd, boom cats, elevating graders, hoists, paving mixers, pile-driving engines, batch plants concrete pumps	8 24	35	45		05
Trenching machines (above 8' 3")	8 04	35	45		05
Backhoes (hydraulic, under ½ c y)	8 12	35	45		05
Trenching machines (up to 8' 3"), boilers skelton, well drilling machines	9 94	35	45		05
Air compressors, tunnel	7 91	35	45		05
Front end loaders (high lift), bulldozers	7 89	35	45		05
Concrete mixers, power wheel scoops and scrapers, motor graders, tunnel motor men, blade graders, tunnel mechanics	7 79	35	45		05
Mechanics	7 77	35	45		05
Bulldozer, hydraulic tampers	7 69	35	45		05
Roller	7 59	35	45		05
Air compressors, pump, welding machine well points	7 515	35	45		05

DECISION #DC78-3008 - Mod # 5, Cont'd	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Add:					
Building Schedule					
Motor Repairman (Removal and reinstalling of electrical motors)	$9 87	.70	3%+ 80	h	

Footnote:

h Employer contributes to employee who have worked six (6) months or more, shall be given two and one-half days vacation or equivalent thereof All men in the employ of the employer for one (1) year or more shall be given one week's vacation with pay or the equivalent thereof All men in the employ of the employer three (3) years or more shall be given two (2) week's vacation with pay or the equivalent thereor All men in the employ of the employer ten (10) years or more shall be given three (3) weeks vacation with pay or the equivalent thereof

Omit:					
Laborers:					
Residential over 4 stories:					
Unskilled	5 09	35			05
Scaffold builders, paving breakers and mortar mixers	5 24	35			05
Work below 6 feet depth	5.34	35			05
DECISION #FL78-1062 - Mod. #1 (43 FR 30456 - July 14, 1978) Pinellas County, Florida					
Change:					
Carpenters	$6 56				
Electricians	6 60				
Sheet metal workers	8 00	.85	.55		06

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Decision #IA77-4223-Mod. #4					
(42 FR-53002-September 30, 1977)					
Black Hawk County, Iowa					
Changes:					
Boilermakers	12 30	85	1 00		02
Carpenters	9 09	45	1 25		
Cement Masons	9 05	45	1 00		
Electricians	12 22	45	3%		3/4%
Cable Splicers	12 59	45	3%		3/4%
Ironworkers	12 18				06
Line Construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%
Millwrights	9 59	45	1 25		
Piledrivermen	9 09	45	1 25		
Truck Driver	7 95	45	75		
Helpers	7 78	45	75		
Decision #IA77-4224-Mod. #5					
(42 FR-53004-September 30, 1977)					
Cerro Gordo County, Iowa					
Changes:					
Boilermakers	12 30	.85	1 00		02
Bricklayers	10 64		75		
Electricians	12 19	45	3%		3/4%
Line Construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	45	7%	a	½%
Group 3	6.78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Decision #IA77-4225-Mod. #3					
(42 FR-53006-September 30, 1977)					
Clinton County, Iowa					
Changes:					
Boilermakers	12 30	85	1 00		02
Carpenters	10 30	45	70		.04
Glaziers	10 59	70	1 00		02
Painters					
Roller, steel	10 27	55	85		18
Spray, structural steel	10 77	55	85		18
Piledrivermen	10 70	45	70		04
Decision #IA77-4228-Mod. #4					
(42 FR-53011-September 30, 1977)					
Johnson County, Iowa					
Changes:					
Boilermakers	12 30	85	1 00		02
Cement Masons	10 78	45			
Glaziers	10 59	70	1 00		02
Ironworkers	12 18				06
Line Construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%
Sheet metal worker	12 20		.55		01
Tile setter	10.71		.55		
Decision #IA77-4233-Mod. # 3					
(42 FR-53020-September 30, 1977)					
Story County, Iowa					
Changes:					
Boilermakers	12 30	85	1 00		02
Carpenters	9 80		75		
Cement Mason	10.56		80		04
Line Construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	.45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%
Millwrights	10.23	.85	.75		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Decision #IA77-4227-Mod. 4 (42 FR-53009-September 30, 1977) Dubuque County, Iowa					
Change:					
Boilermakers	12 30	85	1 00		02
Carpenters	10 18		37		35 00 P/yr
Electricians	11 50	65	3%+ 35		3/4%
Glaziers	10 59	70	1 00		02
Laborers:					
Group 1	8 33	30	30		
Group 2	8 43	30	30		
Group 3	8 58	30	30		
Millwrights	10 68		37		35 00 P/yr
Painters:					
Brush or roller epoxy, paperhanging, tapers	8 95		30		
Spraying, high work & steel	9 50		30		
Piledrivermen	10 58		37		35 00 P/yr
Roofers	9 55		20		
Decision #IA77-4230-Mod. #6 (42 FR-53015-September 30, 1977) Polk County, Iowa					
Change:					
Boilermakers	12 30	85	1 00		02
Carpenters	10 18	60	75		08
Cement Masons	10 56		80		04
Electricians	12 53	40	3%+ 80		3/4%
Line Construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%
Millwrights, Piledrivermen	10 53	60	75		08
Soft Floor Layer	9 93	60	75		08
Tile Marble Terrazzo	11 69				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Decision #IA77-4231-Mod. #4 42 FR-53017-September 30 1977) Pottawattamie County, Iowa					
Change:					
Boilermaker	12 30	85	1 00		02
Carpenters	10 14	50	50	1 00	03
Line Construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%
Millwrights	10 39	50	50	1 00	03
Piledrivermen	10 265	50	50	1 00	03
Decision #IA77-4229-Mod. #5 (42 FR-53013-September 30, 1977) Linn County, Iowa					
Change:					
Boilermakers	12 30	85	1 00		02
Cement Masons	10 78	45			
Glaziers	10 59	70	1 00		02
Ironworkers	12 18				06
Line construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%
Sheet metal workers	12 20		55		01
Tile Setters	10 71		55		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Decision #IA77-4234-Mod. #3					
(42 FR-53022-September 30, 1977)					
Webster County, Iowa					
Change:					
Boilermakers	12 30	85	1 00		02
Bricklayers	10 27		40		
Carpenters	9 60				
Electricians	11 20	40	3%		3/4%
Line Construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	.45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%
Millwrights	9 85				
Decision #IA77-4232-Mod. #3					
(42 FR 53019-September 30, 1978)					
Scott County, Iowa					
Change:					
Boilermakers	12 30	85	1 00		02
Glaziers	10 59	70	1 00		02
Laborers					
Group 1	9 72	.40	1 00		035
Group 2	9 97	40	1 00		035
Group 3	10 22	40	1 00		035
Painters					
Brush, Roller	10 27	55	85		18
spray, structural steel	10 77	55	85		18

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Decision #IA77-4235-Mod. #5					
(42 FR-53024-September 30, 1977)					
Woodbury County, Iowa					
Boilermakers	12 30	85	1 00		02
Electricians:					
With 15 mile radius of Sioux City and all electrical contracts over $300,000	12 01	50	3%+ 60		3/4%
Line construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45	7%	a	½%
Plumbers	11 52	.74	.80		10
Sheetmetal workers	10 79	50	55		04
Decision #IA77-4226-Mod. #4					
(42 FR-53007-September 30, 1977)					
Des Moines County, Iowa					
Change:					
Boilermakers	12 30	85	1 00		02
Carpenters	10 70	75	.90		.04
Electricians	12 45	55	3%		3/4%
Glaziers	10 59	70	1.00		02
Ironworkers	11 50	.55	90		06
Line Construction:					
Group 1	10 12	45	7%	a	½%
Group 2	6 58	45	7%	a	½%
Group 3	6 78	45	7%	a	½%
Group 4	8 10	45	7%	a	½%
Group 5	5 57	45,	7%	a	½%
Millwrights	11.40	75	90		04
Painters					
Group 1	9 70		.25		
Group 2	10 40		.25		
Group 3	9 80		25		
Group 4	10 70		25		
Group 5	10.20		25		
Piledrivermen	11 40	75	.90		04
Roofers	10 12				

Decision No. NC78-1061 - Mod. #1 (43 FR 29463 - July 7, 1978) Statewide, North Carolina Change: Page 2: Decision No NC78-1061	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
DECISION NO. OK77-4060 - Mod. #2 (42 FR 13786 - March 11, 1977) Comanche County, Oklahoma CHANGE: PAINTERS, brush	$6 00		25	70	.05

Decision PA77-3122 - Mod. # 7 (42 FR 45614 - Sept , 9, 1977) Cumberland, Dauphin, Perry, Juniata, New Cumberland Depot in York County, Pennsylvania Change: Piledrivermen Modification # 2, dated March 10, 1978, in 43 FR 10159 to read Modification # 3; Modification # 3, dated May 5, 1978, in 43 FR 19548, to read Modification # 4; Modification # 4, dated May 26, 1978, in 43 FR 22870, to read Modification # 5; Modification # 5, dated July 7, 1978, in 43 FR 29424, to read Modification # 6	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
	$11 12	2 33	1.35	a	12
DECISION #PA78-3037 - Mod. # 1 (43 FR 17239 - April 21, 1978) Blair County, Pennsylvania Add: Elevator Constructors Elevator Constructors Helpers Elevator Constructors Helpers (Prob) Footnotes: a Employers contributes 8% basic hourly rate for 5 years or more of service as vacation pay credit b Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day, plus the Friday after Thanksgiving Day	$10 98 7 69 5 49	745 745	56 56	a+b a+b	025 025

DECISION NO. TN78-1058 - Mod. #1
(43 FR 29464 - July 7, 1978)
Hamilton, Marion, Polk, and Rhea Counties, Tennessee

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CHANGE:					
Bricklayers, Stone masons, Cement masons, & Plasterers: Polk County Only	$ 8 90				
Glaziers	8.81			4%	
Laborers:					
Group A	6 60	25	30		
Group B	6 70	25	30		
Group C	6.80	25	30		
Group D	6.90	25	30		
Group E	6.95	25	30		
Group F	7.25	25	30		
Group G	7 30	25	30		
Free Air Shafts & Tunnels					
Group H	7 00	25	30		
Group I	7 15	.25	.30		
Group J	7 40	25	30		
(Note, see page 2 of Mod. for classifications definitions.)					
Sheet metal workers:					
Hamilton County	10 23	61	77		0¼
All other Counties	10 73	61	77		0¼
ADD:					
Line Construction: Groundmen	7 45	70	9%		½ of 1%

DECISION NO. TN78-1058 - Mod. #1 (Cont'd)

CLASSIFICATIONS DEFINITIONS

Group A - General laborers, concrete laborers, carpenter tenders, window and floor cleaners, and flagman on road and street crossings, form strippers, handling of rope to clam bucket, grout men, laborers working on demolition work, handling, cleaning and pulling of nails from materials

Group B - Powder man helpers, tenders to all trowel trades and terraza work, carrying re-inforced steel, operating motorized wheel barrows, doping and painting of pipe, railroad track laborers, snake men on pipe work

Group C - Sanitary and storm pipe layers or any other pipe outside of foundation, grade checker, yarner, and pot man, steel form setters, mortar mixers, by hand or machine, power saw operators, jackhammer operator, air tool operators, regular air tamp operators, wacker tamp operator, chipping hammer operator, hand operated ditching machine operator, ditching machine operator, concrete grinder, floor sweeping machind operator, concrete buffer and grinder power operator, persons working with concrete pumping machines, vibrator operators, and air spade operators.

Group D - Asphalt raker, wagon drill operator, sand blasting, track drill operators, concrete saw operator, using cutter torch or burner on demolition work, flagging of rigs

Group E - Barco tamp operator and specially designed tamp operator, black top or concrete curbing machine operator, and pavement breaker operator

Group F - Powderman, motorized post hole digger operator and terraza machine grinder

Group G - Pneumatic concrete gun operator and nozzleman

Group H - Tunnel laborer

Group I - Chuck tender, top lander on shaft work

Group J - Tunnel miner, including men required to go down in pier hole drilled machines.

SUPERSEDEAS DECISION

STATES: Arkansas, Louisiana, Mississippi and Tennessee
DECISION NO : AR78-4074 DATE: Date of Publication
Supersedes Decision No AR78-4070, dated June 30, 1978, in 43 FR 28722
DESCRIPTION OF WORK: For construction of all river, harbor and floor control work on the Mississippi River and tributaries (excluding the metropolitan areas of Vicksburg, Greenville and Natchez, Mississippi; Pine Bluff, Little Rock and Ft Smith, Arkansas; Memphis, Tennessee and New Orleans, Baton Rouge, Alexandria, Monroe and Shreveport, Louisiana and any contracts for any phase of construction of a lock or dam)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CARPENTERS	$ 4 50				
LABORERS:					
Unskilled	3 15				
Revetment and dikes	3 15				
Chain saw operator or filer	3 50				
Air tool operator	3 50				
Powderman	4 50				
POWER EQUIPMENT OPERATORS:					
Pile driver operator, mechanic (heavy equipment), cranes, derricks, draglines, welder, power shovels and backhoes, mixer (concrete, 21 cu ft & over), asphalt plant operator, trenching machine (over 18")	6 35				05
Bulldozer (finisher, push cat & on barges), motor patrol finisher, scraper and like equipment, front end loader, backhoe (tractor mounted), asphalt finisher or spreading machine, well point system operator, self-propelled loader (conveyor type)	5 30				05
Fireman (heavy construction), pile driver, leadsman, winchman	4 50				05
Asphalt plant dryer operator, asphalt distributor, asphalt roller, bulldozer (rough, including disc, plow or roller), motor patrol (haul roads), trenching machine (18" and under), self-propelled roller (except asphalt), end dump equipment (off highway), mixer (concrete up to 21 cu ft), bottom dump euclids (and like equipment)	4 40				05
Oiler, pump, mechanic helper, greaser, welder helper, tractor (farm type including disc, plow or roller)	3 95				05
TRUCK DRIVERS:					
1½ tons or less	3 50				
Over 1½ tons	4 00				

SUPERSEDEAS DECISION

STATE: Arizona COUNTY: Pima
DECISION NUMBER: AZ78-5116 DATE : Date of Publication
Supersedes Decision No AZ77-5026 dated June 17, 1977, in 42 FR 31070
DESCRIPTION OF WORK: Residential Construction (consisting of single family homes and garden type apartments up to and including 4 stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ASBESTOS WORKERS	$ 11 94	50	$ 1 20		02
BOILERMAKERS	13 625	1 075	1 00	75	02
BRICKLAYERS; Stonemasons:					
Zone A (0-15 miles from Tucson)	11 22	1 00	90		06
Zone B (15-30 miles from Tucson)	11 59	1.00	90		06
Zone C (30-40 miles from Tucson)	11 96	1.00	90		06
Zone D (40 miles and over from Tucson)	12 72	1 00	90		06
CARPENTERS:					
Carpenters; Drywall Applicator	9 785	845	955		025
Piledrivermen; Floor Layers (finish)	10 07	845	955		025
Millwrights	10 20	845	955		025
CEMENT MASONS	10 22	85	85		05
ELECTRICIANS:					
Zone A (0-16 miles from City Hall in Tucson)	9 39	8 4%	3%		1/2%
Zone B (26-32 miles from City Hall in Tucson)	9 89	8 4%	3%		1/2%
Zone C (32-48 miles from City Hall in Tucson)	10 39	8 4%	3%		1/2%
Zone D (48 miles and over from City Hall in Tucson)	10 89	8 4%	3%		1/2%
ELEVATOR CONSTRUCTORS	11 775	745	56	3%+a	025
ELEVATOR CONSTRUCTORS' HELPERS	70%JR	745	56	3%+a	025
ELEVATOR CONSTRUCTORS' HELPERS (PROB)	50%JR				
GLAZIERS	9 42	70	30		01
IRONWORKERS	11 48	1 24	2 22		08
LATHERS:					
Zone A (0-30 miles from Tucson)	9 28	35	40		
Zone B (30-40 miles from Tucson)	9 78	35	40		
Zone C (40-50 miles from Tucson)	10 03	35	40		
Zone D (Area outside Zone C)	10 78	35	40		
MARBLE SETTERS; Terrazzo Workers; Tile Setters	9 42	70	75		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PAINTERS, Brush:					
Zone A (0-30 miles from Tucson Post Office)	$ 8 78	67	35		04
Zone B (31-40 miles from Tucson Post Office)	9 53	67	35		04
Zone C (41-50 miles from Tucson Post Office)	10 03	67	35		04
Zone D (51 miles and over from Tucson Post Office)	10 78	67	35		04
PAINTERS; Structural Steel, Brush:					
Zone A (0-30 miles from Tucson Post Office)	9 78	67	35		04
Zone B (31-40 miles from Tucson Post Office)	10 53	67	35		04
Zone C (41-50 miles from Tucson Post Office)	11 03	67	35		04
Zone D (51 miles and over from Tucson Post Office)	11 78	67	35		04
PLASTERERS:					
Zone A (0-30 miles from Tucson Post Office)	8 57	.35	60		
Zone B (30-40 miles from Tucson Post Office)	9 07	35	60		
Zone C (40-50 miles from Tucson Post Office)	9 32	35	60		
Zone D (50 miles and over from Tucson Post Office)	10 07	35	60		
PLASTERERS' TENDERS	9 16	85	85		10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
PLUMBERS; Steamfitters:					
FREE ZONE 0-15 miles					
The "Free Zone" (Zone I shall be 15 road miles from the stated base points in Flagstaff, Yuma, Tucson and Douglas The "Free Zone" from Phoenix shall be 15 miles radius from the stated base point In addition, all areas within the City limits of Phoenix, Chandler, Scottsdale, Tempe, Glendale, Mesa, Kingman, Havasu City, Prescott, Winslow and Holbrook will be included as Free Zones) Any work contracted from outside of these zones will be determined from the Phoenix and Tucson basing points	$ 12 24	75	$ 1 35		10
Zone II (15-30 miles)	12 59	75	1 35		10
Zone III (30-40 miles)	13 01	75	1 35		10
Zone IV (40 miles and over)	14 31	75	1 35		10
ROOFERS:					
Zone A (0-44 miles from Tucson)	8 97	845	20		02'
Zone B (over 44 miles from Tucson)	10 72	845	20		.02
SHEET METAL WORKERS:					
Zone A (0-22 miles from Tucson)	9 90	3%+1 04	1 91		04
Zone B (22-45 miles from Tucson)	10 85	3%+1 04	1 91		04
Zone C (Over 45 miles from Tucson)	12.40	3%+1.04	1 91		04
SOFT FLOOR LAYERS	9 25	.38			
SPRINKLER FITTERS	12 29	65	95		08
TERRAZZO WORKERS; TILE SETTERS; MARBLE SETTERS	9 27	90	85		

FOOTNOTE:
a Employer credits 4% basic hourly rate of employee with over 5 years service, 2% basic hourly rate from 6 months' to 5 years' service to Vacation Fund. 6 Paid Holidays: A through F.

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

LABORERS	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr Tr
Group 1:	$ 8 01	85	85		10
Group 2:	8 14	85	85		10
Group 3:	8 28	85	85		10
Group 4:	8 39	85	85		10
Group 5:	8 56	85	85		10
Group 6:	8 935	85	85		10
Group 7:	9 565	85	85		10
POWER EQUIPMENT OPERATORS (Except Piledriving & Steel Erection)					
Group 1:	8 60	95	90		06
Group 2:	8 97	95	90		06
Group 3:	9 43	95	90		06
Group 4:	9 96	95	90		06
Group 5:	10 49	95	90		06
Group 5A:	10 80	95	90		06
Group 6:	11 13	95	90		06
Group 7:	11 73	95	90		06
TRUCK DRIVERS					
Group 1:	8 19	85	85		06
Group 2:	8 32	85	85		06
Group 3:	8 54	85	85		06
Group 4:	8 89	85	85		06
Group 5:	9 05	85	85		06
Group 5A:	9 23	85	85		06
Group 6:	9 37	85	85		06
Group 7:	9 78	85	85		06
Group 8:	10 295	,85	,85		06
Group 8A:	10 96	85	85		06
Group 8B:	10 64	,85	,85		06
Group 8C:	8 75	85	85		06

LABORERS

Group 1: All Helpers not herein separately classified; Cesspool Diggers and installers; Chat Box Man; Checker, tool dispatcher; Concrete dump manbelt, pipe and/or hoseman; Dumpman and/or spotter; Fence builder, guard rail builder highway; Form strippers; Labor, general or construction; Landscape gardener and nurseryman; Packing rod steel and pans; Rip rap stoneman; Astro turf layer; Cleanup, Bull gang; Trackman-railroad

Group 2: Cement finisher tender; Concrete curer (impervious membrane); Cutting torch operator; Fine grader (highway, engineering and sewer work only); Kettleman - Tarman; Power type concrete buggy

Group 3: Bander; Chucktender (except tunnel); Creosote tieman; Guinea chaser; Powderman helper; Rip-rap stone paver; Sandblaster (pot tender); Spiker and wrenchers

Group 4: Cement dumpers (Skip-type mixer or handling bulk cement); Chain saw machines (on clearing and grubbing); Concrete vibrating machines; Cribber and shorer (except tunnel); Floor sanders concrete; Hydraulic jacks, and similar mechanical tools not separately classified herein; Operators and tenders of pneumatic and electric tools; Pipe caulker and/or backup man (pipeline); Pipe wrapper; Pneumatic gopher; Rigger/Signalman (pipeline)

Group 5: Air and water wash-out nozzleman; Asphalt rakers and ironers; Driller; Grade setter (pipeline); Hand guided trencher and similar operated equipment; Jackhammer and/or pavement breakers; Pipelayers (including but not limited to non-metallic, transite and plastic pipe, water pipe, sewer pipe, drain pipe, underground tile and conduit); Rock slinger; Scaler (using Bos'ns chairs or safety belt); Tampers (mechanical - all types); Precast manhole erector

Group 6: Concrete Cutting Torch; Concrete saw (hand guided); Driller, (core, diamond, wagon or air track); Drill doctor and/or air tool repairman; Gunman and mixerman (gunite); Sandblaster (nozzleman)

Group 7: Concrete Road Form Setter; Gunite nozzleman or roadman; Drillers, Joy Mustang, PR 143, 200 Gardner-Denver, Hydrasonic; Powderman; Scaler (drillers); Welders and/or pipelayers installing process piping; Form setter and/or builder

POWER EQUIPMENT OPERATORS
(Except Piledriving and Steel Erection)

Group 1: Air compressor operator; Field equipment servicemen helper; Heavy duty repair helper; Heavy duty welder helper; Oiler; Pump operator

Group 2: Conveyor operator; Generator operator - portable; Power grizzly operator; Self-propelled chip spreading machine - conveyor operator; Watch fireman; Welding machine operator - gasoline and diesel power

Group 3: Concrete mixer operator - skip type; Dinky operator - (under 20 tons wt); Driver-moto paver, Slurry seal machine, and similar type equipment; Motor crane driver; Power sweeper operator - self-propelled; Ross carrier or fork lift operator; Skip loader operator - all types with rated capacity 1-1/2 cu yds or less; Wheel type tractor operator (Ford, Ferguson, or similar type) with attachments such as fresno, push blade, post hole auger, mower, etc , excluding compacting equipment

Group 4: A-Frame boom truck or winch truck operator; Asphalt plant fireman; Elevator hoist operator (including Tuskey hoist or similar type); Grade checker (excluding civil engineer); Multiple power concrete saw operator; Pavement breaker, mechanical compactor operator, power propelled; Roller operator - all types - except as otherwise classified; Screed operator; Self-propelled chip spreading machine operator (including Slurry seal machine operator) Stationary pipewrapping and cleaning machine operator; Tugger operator

Group 5: Aggregate plant operator (including crushing, screening and sand plants, etc); Asphalt plant mixer operator; Belterete machine; Boring machines operator; Concrete mechanical tamping, spreading or finishing machine (including Clary, Johnson or similar types); Concrete pumps operator; Concrete batch plant operator, all types and sizes; Conductor, brakeman, or handler; Drilling machine, including water wells; Elevating grader operator - all types and sizes (except as otherwise classfied); Field equipment serviceman; Highline cableway signalman; Kolman belt loader operator or similar, with belt width 48" or over; Locomotive engineer (including Dinky - 20 tons wt and over); Moto-paver and similar type equipment operator; Operating engineer rigger; Pneumatic-tired scraper operator (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment) up to and including 12 cu yds.; Power jumbo form setter operator; Pressure grout machine operator (as used in heavy engineering construction); Rapid oil mixing machine operator; Roller operator - on all types asphalt pavement; Self-propelled compactor, with blade; Skip loader operator - all types with rated capacity over 1-1/2 but less than 4 cu yds ; Slip form operator (power driven lifting device for concrete forms); Soil cement road mixing machine operator - single pass type, Stationary Central generating plant operator - rated 300 K W or more; Surface heater and planer operator; Traveling pipewrapping machine operator

POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Group 5-A: Heavy duty mechanic and/or welder; Pneumatic tired scraper, all sizes and types over 12 cu yds up to and including 45 cu yds MRC (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment); Tractor operator (Pusher, Bulldozer, Scraper) up to 400 net horsepower rating; Trenching machine operator

Group 6: Auto-Grade machine (CMI and similar equipment); Boring machine operator (including Mole, Badger and similar type); Concrete Mixer operator-paving type, and mobile mixer; Concrete pump operator with boom attachment (truck mounted); Crane operator - crawler and pneumatic type, under 100 ton capacity MRC; Crawler type tractor operator - with boom attachment; Derrick operator; Forklift operator for hoisting personnel; Grade-all operator; Helicopter hoist; Highline cableway operator (less than 20 tons rated capacity); Mass excavator operator (150 Bucyrus Erie and similar types); Mechanical hoist operator (two or more drums); Motor grade operator - any type power blade; Motor grade operator with elevating grader attachment; Mucking machine operator; Overhead crane operator; Piledriver engineer (portable, stationary or skid rig); Pneumatic-tired scraper operator - all sizes and types (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment over 45 cu yds , MRC); Power driven ditch lining or ditch trimming machine operator; Skip loader operator - all types with rated capacity 4 cu yds , but less than 8 cu yds ; Slip form paving machine operator (including Gunnert, Zimmerman and similar types); Specialized power digger operator - attached to wheel-type tractor; Tower crane (or similar type) operator; Tractor operator (Pusher, Bulldozer, Scraper (400 net horsepower and over); Tugger operator (two or more); Universal equipment operator - Shovel, Backhoe, Dragline, Clamshell, etc up to 8 cu yds

Group 7: Crane operator - pneumatic or crawler (100 ton hoisting capacity and over MRC rating); Helicopter pilot - FAA qualified when used in construction work; Highline cableway operator, over 20 ton rated capacity and using traveling head and tail tower; Remote control earth moving equipment operator; Skip loader operator - all types with rated capacity of 8 cu. yds or more; Universal equipment - Shovel, Backhoe, Dragline, Clamshell, etc , 8 cu yds and over

TRUCK DRIVERS

Group 1: Teamsters; Pickups; Station Wagons; Manhaul driver

Group 2: Dump or flatrack (2 or 3 axle); Water truck (under 2500 gallons); Buggymobile (1 cu yd or less); Tireman; Bus drivers, ambulance driver, self-propelled street sweeper; Warehouseman

Group 3: Dump or flatrack (4 axle); Dumptor or dumpster (less than 7 cu yds); Water truck (2500 gallons but less than 4000 gallons)

Group 4: Dumptor or dumpster (7 cu yds but less than 16 cu yds); Dump or flatrack (5 axle); Water truck (4000 gallons and over); Slurry type equipment or leverman; Flaherty spreader or similar type equipment or leverman; Transit mix (8 cu yds or less)

Group 5: Dump or flatrack (6 axle); Transit mix (over 8 cu yds but less than 10 5 cu yds); Rock truck (i e Dart, Euclid and other similar type end dumps, single unit less than 16 cu yds)

Group 5-A: Oil tanker or spreader and/or bootman, retortman or leverman

Group 6: Transit mix (over 10,5 cu yds but less than 14 cu yds); Ross Carrier; Fork lift or lift truck; Hydro lift, Swedish crane Iowa 300 and similar types; Concrete pump (when integral part of transit mix truck); Dump or flat rack (7 axle)

Group 7: Dump or Flatrack (8 axles)

Group 8: Off-highway equipment driver including but not limited to: 2 or 4 wheel power unit, i e , Cat, DW Series, Euclid, International and similar type equipment, transporting material when top loaded or by external means including pulling water tanks, fuel tanks or other applications under Teamster Classifications; Rock trucks (Dart, Euclid, or other similar end dump types) 16 cu yds and over; Eject-alls; Dumptor or dumpster (16 cu. yds and over); Dump or flatrack (9 axles)

Group 8A: Heavy duty mechanic/welder; Body and fender man

Group 8B: Field equipment serviceman or fuel truck driver

Group 8C: Heavy duty mechanic/welder helper

SUPERSEDEAS DECISION

STATE: Arizona COUNTY: Maricopa
DECISION NUMBER: AZ78-5115 DATE: Date of Publication
Supersedes Decision No AZ77-5025 dated June 17, 1977, in 42 FR 31065
DESCRIPTION OF WORK: Residential Construction (consisting of single family homes and garden type apartments up to and including 4 stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ASBESTOS WORKERS	$ 11 94	50	$ 1 20		02
BOILERMAKERS	13 625	1 075	1 00	75	02
BRICKLAYERS; Stonemasons:					
Zone A (0-25 miles from City Hall of Phoenix; Flagstaff and Yuma)	11 77	65	90		09
Zone B (25-40 miles from City Hall of Phoenix; and Williams AFB)	12 71	65	90		09
Zone C (40-70 miles from City Hall of Phoenix)	13 30	65	90		.09
Zone D (70-100 miles from City Hall of Phoenix)	13 89	65	90		09
Zone E (100-200 miles from City Hall of Phoenix)	14 36	65	90		09
Zone F (200 miles and over from City Hall of Phoenix)	15 30	65	90		09
CARPENTERS:					
Carpenters; Drywall Applicator Piledriverman; Floorlayers (finish)	9 785	.845	.955		05
Millwrights	10,07	.845	955		05
CEMENT MASONS:	10 20	845	955		05
Northern portion	10 21	95	1 30		05
Southern portion	10 22	85	85		05
DRYWALL:					
(from Courthouse in Phoenix, Mesa, including Williams AFB and Luke AFB):					
Zone A (0-40 miles)	10 21	59	50		07
Zone B (41-60 miles)	11.21	59	50		07
Zone C (61 miles and over)	12 46	59	50		07
Texture Spraymen:					
Zone A (0-40 miles)	9 81	59	50		07
Zone B (41-60 miles)	10 81	.59	50		07
Zone C (51 miles and over)	12 06	59	50		07

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ELECTRICIANS:					
Zone A (Beginning at the northeast corner; a line extending southward on Bush Highway to McKellips Road; a line extending east on McKellips Road to a point one mile east of the intersection of State Highway 88 and U S 60 and 70 near Apache Junction; southward to Baseline Road; west on Baseline Road to the intersection of Baseline Road and Ellsworth Road; South on Ellsworth Road to Hunt Highway; West on Hunt Highway to Powers Road; a line extending south on Powers Road five miles, then extending straight west to a point five miles west of Interstate 10, then northwest on a line parallel with Interstate 10 to intersect with Pecos Road; West on Pecos to intersect with Cotton Lane North on Cotton Lane to Beloat Road West on Beloat Road to Airport Road North on Airport Road in a straight line to intersect Waddell Road East on Waddell Road to intersect with Cotton Lane North on Cotton Lane to Deer Valley Drive and east on Deer Valley Drive to intersection with Bush Highway and including Luke and Williams Air Force Bases)					
Electricians	$ 12 78	96	3%+ 88		3/4%
Cable Splicers	12.64	.96	3%+ 88		3/4%

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ELECTRICIANS: (Cont'd)					
Zone B (Area outside of Zone A and bounded by a line formed by measuring sixteen (16) road miles from the outer boundaries of an area enclosed by the following boundaries; Power Road on the east from Hunt Highway on the south to one mile south of Pinnacle Peak Road on the north One mile south of Pinnacle Peak Road to Cotton Lane on the west. Cotton Lane to Pecos Road on the south. Pecos Road to Price Road and from Price Road to Hunt Highway on the south Hunt Highway to Powers Road on the east)					
Electricians	$ 15 02	96	3%+ 88		3/4%
Cable Splicers	14 85	96	3%+ 88		3/4%
Zone C (Outside edge of Zone B and extend to the outside limits of the Union's jurisdiction)					
Electricians	16 17	96	3%+ 88		3/4%
Cable Splicers	15 99	96	3%+ 88		3/4%
ELEVATOR CONSTRUCTORS	11 775	745	56	3%+a	025
ELEVATOR CONSTRUCTORS' HELPERS	70%JR	745	56	3%+a	025
ELEVATOR CONSTRUCTORS' HELPERS (PROB)	50%JR				
GLAZIERS	9 42	70	30		01
IRONWORKERS	11 40	1 24	2 22		.08

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PAINTERS:					
Zone A (0-40 miles from Court House in Phoenix, Mesa and including Luke and Williams Air Force Bases):					
Brush; Tapers	$ 9 85	60	40		08
Spray; Paperhangers	10 10	60	40		08
Zone B (41-60 miles from Court House in Phoenix)					
Brush; Tapers	10 85	60	40		.08
Spray; Paperhangers	11 10	60	40		08
Zone C (61 miles and over from Court House in Phoenix)					
Brush; Tapers	12 10	60	40		08
Spray; Paperhangers	12 35	60	40		08
PLASTERERS (Northern 3/4 of County):					
Zone A (0-35 miles from Phoenix)	9 045	60	85		035
Zone B (35-60 miles from Phoenix)	9 795	60	85		035
Zone C (60 miles and over from Phoenix)	10 67	60	85		035
PLASTERERS (Southern 1/4 of County):					
Zone A (0-30 miles from Tucson)	8 57	35	60		
Zone B (30-40 miles from Tucson)	9 07	35	60		
Zone c (40-50 miles from Tucson)	9 32	35	60		
Zone D (50 miles and over from Tucson)	10 07	35	60		
PLASTERERS' TENDERS	9 16	85	85		10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PLUMBERS; Steamfitters: FREE ZONE 0-15 miles The "Free Zone" (Zone I shall be 15 road miles from the stated base points in Flagstaff, Yuma, Tucson and Douglas The "Free Zone" from Phoenix shall be 15 mile radius from the state base point In addition, all areas within the City limits of Phoenix, Chandler, Scottsdale, Tempe, Glendale, Mesa, Kingman, Havasu City, Prescott, Winslow and Holbrook will be included as Free Zones Any work contracted from outside of these zones will be determined from the Phoenix and Tucson basing points:					
Plumbers; Steamfitters	$ 12 24	75	$ 1 35		10
Zone II (15-30 miles)	12 59	75	1 35		10
Zone III (30-40 miles)	13 01	75	1 35		10
Zone IV (40 miles and over)	14 31	75	1 35		10
ROOFERS	9 66	845	20		02
SHEET METAL WORKERS:					
Zone I (0-25 miles excluding Luke and Williams AFB)	10 83	3%+ 80	1 30		10
Zone II (25-50 miles including Luke and Williams AFB)	11 48	3%+ 80	1 30		10
Zone III (50 miles and over)	13 33	3%+ 80	1 30		10
SOFT FLOOR LAYERS:					
Zone A (0-40 miles from Court House in Phoenix and including Luke and Williams AFB)	9 21	59	12		12
Zone B (41-60 miles from Court House in Phoenix)	10 21	59	12		12
Zone C (61 miles and over)	10 71	59	12		12
SPRINKLER FITTERS	12 29	65	95		08

FOOTNOTE:

a Employer contributes 4% of basic hourly rate for 5 years' service and 2% of basic hourly rate for 6 months' to 5 years' service as Vacation Pay Credit Six Paid Holidays: A through F

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Group 1:	$ 8 01	85	85		10
Group 2:	8 14	85	85		10
Group 3:	8 28	85	85		10
Group 4:	8 39	85	85		10
Group 5:	8 56	85	85		10
Group 6:	8 935	85	85		10
Group 7:	9 565	85	85		10
POWER EQUIPMENT OPERATORS (Except Piledriving & Steel Erection)					
Group 1:	8 60	95	90		06
Group 2:	8 97	95	90		06
Group 3:	9 43	95	90		06
Group 4:	9 96	95	90		06
Group 5:	10 49	95	90		06
Group 5A:	10 80	95	90		06
Group 6:	11 13	95	90		06
Group 7:	11 73	95	90		06
TRUCK DRIVERS					
Group 1:	8 19	85	85		06
Group 2:	8 32	.85	85		06
Group 3:	8 54	85	85		06
Group 4:	8 89	85	85		06
Group 5:	9 05	85	85		06
Group 5A:	9 23	85	85		06
Group 6:	9 37	85	85		06
Group 7:	9 70	85	85		.06
Group 8:	10 295	85	85		06
Group 8A:	10.95	85	85		.06
Group 8B:	10 64	85	.85		06
Group 8C:	8 75	.85	.85		.06

LABORERS

Group 1: All Helpers not herein separately classified; Cesspool Diggers and installers; Chat Box Man; Checker, tool dispatcher; Concrete dump manbelt, pipe and/or hoseman; Dumpman and/or spotter; Fence builder, guard rail builder highway; Form strippers; Labor, general or construction; Landscape gardener and nurseryman; Packing rod steel and pans; Rip rap stoneman; Astro turf layer; Cleanup, Bull gang; Trackman-railroad

Group 2: Cement finisher tender; Concrete curer (impervious membrane); Cutting torch operator; Fine grader (highway, engineering and sewer work only); Kettleman - Tarman; Power type concrete buggy

Group 3: Bander; Chucktender (except tunnel); Creosote tieman; Guinea chaser; Powderman helper; Rip-rap stone paver; Sandblaster (pot tender); Spiker and wrenchers

Group 4: Cement dumpers (Skip-type mixer or handling bulk cement); Chain saw machines (on clearing and grubbing); Concrete vibrating machines; Cribber and shorer (except tunnel); Floor sanders concrete; Hydraulic jacks, and similar mechanical tools not separately classified herein; Operators and tenders of pneumatic and electric tools; Pipe caulker and/or backup man (pipeline); Pipe wrapper; Pneumatic gopher; Rigger/Signalman (pipeline)

Group 5: Air and water wash-out nozzleman; Asphalt rakers and ironers; Driller; Grade setter (pipeline); Hand guided trencher and similar operated equipment; Jackhammer and/or pavement breakers; Pipelayers (including but not limited to non-metallic, transite and plastic pipe, water pipe, sewer pipe, drain pipe, underground tile and conduit); Rock slinger; Scaler (using Bos'n chairs or safety belt); Tampers (mechanical - all types); Precast manhole erector

Group 6: Concrete Cutting Torch; Concrete saw (hand guided); Driller, (core, diamond, wagon or air track); Drill doctor and/or air tool repairman; Gunman and mixerman (gunite); Sandblaster (nozzleman)

Group 7: Concrete Road Form Setter; Gunite nozzleman or roadman; Drillers, Joy Muntang, PR 143, 200 Gardner-Denver, Hydraconic; Powderman; Scaler (drillers); Welders and/or pipelayers installing process piping; Form setter and/or builder

POWER EQUIPMENT OPERATORS
(Except Piledriving and Steel Erection)

Group 1: Air compressor operator; Field equipment serviceman helper; Heavy duty repair helper; Heavy duty welder helper; Oiler; Pump operator

Group 2: Conveyor operator; Generator operator - portable; Power grizzly operator; Self-propelled chip spreading machine - conveyor operator; Watch fireman; Welding machine operator - gasoline and diesel power

Group 3: Concrete mixer operator - skip type; Dinky operator - (under 20 tons wt); Driver-moto paver, Slurry seal machine, and similar type equipment; Motor crane driver; Power sweeper operator - self-propelled; Ross carrier or fork lift operator; Skip loader operator - all types with rated capacity 1-1/2 cu yds or less; Wheel type tractor operator (Ford, Ferguson, or similar type) with attachments such as fresno, push blade, post hole auger, mower, etc , excluding compacting equipment

Group 4: A-Frame boom truck or winch truck operator; Asphalt plant firemen; Elevator hoist operator (including Tuskey hoist or similar type); Grade checker (excluding civil engineer); Multiple power concrete saw operator; Pavement breaker, mechanical compactor operator, power propelled; Roller operator - all types - except as otherwise classified; Screed operator; Self-propelled chip spreading machine operator (including Slurry seal machine operator) Stationary pipewrapping and cleaning machine operator; Tugger operator

Group 5: Aggregate plant operator (including crushing, screening and sand plants, etc); Asphalt plant mixer operator; Beltcrete machine; Boring machines operator; Concrete mechanical tamping, spreading or finishing machine (including Clary, Johnson or similar types); Concrete pumps operator; Concrete batch plant operator, all types and sizes; Conductor, brakeman, or handler; Drilling machine, including water wells; Elevating grader operator - all types and sizes (except as otherwise classfied); Field equipment serviceman; Highline cableway signalman; Kolman belt loader operator or similar, with belt width 48" or over; Locomotive engineer (including Dinky - 20 tons wt and over); Moto-paver and similar type equipment operator; Operating engineer rigger; Pneumatic-tired scraper operator (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment) up to and including 12 cu yds ; Power jumbo form setter operator; Pressure grout machine operator (as used in heavy engineering construction); Road oil mixing machine operator; Roller operator - on all types asphalt pavement; Self-propelled compactor, with blade; Skip loader operator - all types with rated capacity over 1-1/2 but less than 4 cu yds ; Slip form operator (power driven lifting device for concrete forms); Soil cement road mixing machine operator - single pass type; Stationary Central generating plant operator - rated 300 K W or more; Surface heater and planer operator; Traveling pipewrapping machine operator

POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Group 5-A: Heavy duty mechanic and/or welder; Pneumatic tired scraper, all sizes and types over 12 cu yds up to and including 45 cu yds MRC (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment); Tractor operator (Pusher, Bulldozer, Scraper) up to 400 net horsepower rating; Trenching machine operator

Group 6: Auto-Grade machine (CMI and similar equipment); Boring machine operator (including Mole, Badger and similar type); Concrete Mixer operator-paving type, and mobile mixer; Concrete pump operator with boom attachment (truck mounted); Crane operator - crawler and pneumatic type, under 100 ton capacity MRC; Crawler type tractor operator - with boom attachment; Derrick operator; Forklift operator for hoisting personnel; Grade-all operator; Helicopter hoist; Highline cableway operator (less than 20 tons rated capacity); Mass excavator operator (150 Bucyrus Erie and similar types); Mechanical hoist operator (two or more drums); Motor grade operator - any type power blade; Motor grade operator with elevating grader attachment; Mucking machine operator; Overhead crane operator; Piledriver engineer (portable, stationary or skid rig); Pneumatic-tired scraper operator - all sizes and types (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment over 45 cu yds , MRC); Power driven ditch lining or ditch trimming machine operator; Skip loader operator - all types with rated capacity 4 cu yds , but less than 8 cu yds ; Slip form paving machine operator (including Gunnert, Zimmerman and similar types); Specialized power digger operator - attached to wheel-type tractor; Tower crane (or similar type) operator; Tractor operator (Pusher, Bulldozer, Scraper (400 net horsepower and over); Tugger operator (two or more); Universal equipment operator - Shovel, Backhoe, Dragline, Clamshell, etc up to 8 cu yds

Group 7: Crane operator - pneumatic or crawler (100 ton hoisting capacity and over MRC rating); Helicopter pilot - FAA qualified when used in construction work; Highline cableway operator, over 20 ton rated capacity and using traveling head and tail tower; Remote control earth moving equipment operator; Skip loader operator - all types with rated capacity of 8 cu yds or more; Universal equipment - Shovel, Backhoe, Dragline, Clamshell, etc , 8 cu yds and over

TRUCK DRIVERS

Group 1: Teamsters; Pickups; Station Wagons; Manhaul driver

Group 2: Dump or flatrack (2 or 3 axle); Water truck (under 2500 gallons); Buggymobile (1 cu yd. or less); Tireman; Bus drivers, ambulance driver, self-propelled street sweeper; Warehouseman

Group 3: Dump or flatrack (4 axle); Dumptor or dumpster (less than 7 cu yds); Water truck (2500 gallons but less than 4000 gallons)

Group 4: Dumptor or dumpster (7 cu yds but less than 16 cu yds); Dump or flatrack (5 axle); Water truck (4000 gallons and over); Slurry type equipment or leverman; Flaherty spreader or similar type equipment or leverman; Transit mix (8 cu yds or less)

Group 5: Dump or flatrack (6 axle); Transit mix (over 8 cu yds but less than 10 5 cu yds); Rock truck (i e Dart, Euclid and other similar type end dumps, single unit less than 16 cu yds)

Group 5-A: Oil tanker or spreader and/or bootman, retortman or leverman

Group 6: Transit mix (over 10 5 cu yds but less than 14 cu yds); Ross Carrier; Fork lift or lift truck; Hydro lift, Swedish crane Iowa 300 and similar types; Concrete pump (when integral part of transit mix truck); Dump or flat rack (7 axle)

Group 7: Dump or Flatrack (8 axles)

Group 8: Off-highway equipment driver including but not limited to: 2 or 4 wheel power unit, i e , Cat, DW Series, Euclid, International and similar type equipment, transporting material when top loaded or by external means including pulling water tanks, fuel tanks or other applications under Teamster Classifications; Rock trucks (Dart, Euclid, or other similar end dump types) 16 cu. yds and over; Ejectalls; Dumptor or dumpster (16 cu yds and over); Dump or flatrack (9 axles)

Group 8A: Heavy duty mechanic/welder; Body and fender man

Group 8B: Field equipment serviceman or fuel truck driver

Group 8C: Heavy duty mechanic/welder helper

SUPERSEDES DECISION

STATE: CONNECTICUT COUNTIES: *SEE BELOW
DECISION NUMBER: CT78-3055 DATE: DATE OF PUBLICATION
Supersedes Decision No : CT78-3003 dated February 17, 1978 in 43 FR 7110
DESCRIPTION OF WORK: Building Construction (including residential), heavy (excluding tunnel construction) and highway construction

*Fairfield, Litchfield and Windham Counties	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ASBESTOS WORKERS:					
Fairfield Co.; Litchfield Co.: Barkhamsted, Bethlehem, Bridgewater, Cornwall, Goshen, Harwinton, Kent, Litchfield, Morris New Hartford, New Milford, Plymouth, Roxbury, Sharon, Torrington, Warren, Washington, Watertown, Winchester, Woodbury, & Thomaston; Windham Co : Ashford, Chaplin, Eastford, Hampton, Scotland & Windham	$11 84	75	1 16		
Litchfield Co.: Canaan, Colbrook Norfolk, N Canaan & Salisbury;	10 65	94	1 25		01
Windham Co.: Woodstock					
Windham Co.: Brooklyn, Canterbury, Killingly, Plainfield, Pomfret, Putnam, Sterling & Thompson	10 28	1 00	1.18		
BOILERMAKERS	10 00	60	108		01
BRICKLAYERS: Cement masons; Pinishers; Marble masons; Plasterers, Stonemasons; Terrazzo Workers; Tile setters (Building Construction):					
Fairfield Co.: Shelton	9 70	.75	75		
Fairfield Co : Bridgeport, Easton, Fairfield, Monroe, Stratford & Trumbull	10 05	75	75		
Fairfield Co.: New Canaan, Norwalk, Ridgefield, Weston, Westport & Wilton	10 20	75	75		
Fairfield Co.: Darien & Stamford	10 62	83	25		
Fairfield Co.: Greenwich	10 45	70	70		.03
Fairfield Co.: Bethel, Brookfield Danbury, New Fairfield, Newtown Redding & Sherman; Litchfield Co.: Bridgewater, Kent, New Milford & Roxbury	10 00	75	75		

DECISION NO CT78-3055	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
BRICKLAYERS (CONT'D):					
Litchfield Co.: Barkhamsted, Bethlehem, Canaan, Colebrook, Cornwall, Goshen, Harwinton, Litchfield, Morris, New Hartford, Norfolk, N Canaan, Salisbury, Sharon, Torrington, Warren, Washington, Winchester	9 80	75	75		
Windham Co.	10 20	75	75		
Litchfield Co.: Plymouth, Thomaston, Watertown, & Woodbury	9 95	75	75		
BRICKLAYERS (Heavy & Highway Construction):					
Except Towns of Darien, Greenwich & Stamford	9 50	75	75	b	
Darien & Stamford	9 83	83	25	b	
Greenwich	9 90	55	55	b	
CARPENTERS; Millwrights; Pile-drivermen & Soft floor layers (Building Construction):					
Fairfield Co.: Greenwich	10 10	85	65		05
Fairfield Co.: Bridgeport, Easton, Fairfield, Monroe, Shelton, Stratford, Trumbull, Weston, & Westport	10 25	90	65	c	a
Fairfield Co.: Bethel, Brookfield, Danbury, Darien, New Canaan, New Fairfield, Newtown, Norwalk, Redding, Ridgefield, Sherman, Stamford & Wilton; Litchfield Co : Barkhamsted, Bethlehem, Bridgewater, Canaan, Colebrook Cornwall, Goshen, Kent, Litchfield, Morris, New Hartford, New Milford, Norfolk, North Canaan, Roxbury, Salisbury, Sharon, Torrington, Warren, Washington, Winchester & Woodbury					
Commercial	10 10	90	65		10
Residential	6 90	90	65		10

DECISION NO CT78-3055	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Litchfield Co.: Harwinton, Plymouth, Thomaston & Watertown	10 10	80	55		05
Windham Co.	10 25	90	65		03
CARPENTERS (Heavy & Highway Construction):					
Fairfield Co.: Bridgeport, Easton, Fairfield, Monroe, Shelton Stratford, Trumbull, Weston & Westport	10 05	90	65	f	e
Fairfield Co.: Bethel, Brookfield, Danbury, Darien, New Canaan, New Fairfield, Newtown, Norwalk, Wilton, Redding, Ridgefield, Sherman, Stamford & Litchfield Co.: Remainder of Co	10 05	90	65	f	10
Fairfield Co.: Greenwich	10 10	90	65	f	02
Litchfield Co.: Harwinton, Plymouth, Thomaston & Watertown	10 05	90	65		05
Windham Co.:	10 05	90	65	f	03
ELECTRICIANS:					
Fairfield Co.: Norwalk (E of Five Mile River), Weston, Westport & Weston Building Construction	10 50	68	3%+ 30	6%	½%
Fairfield Co.: Bethel, Bridgeport, Brookfield, Danbury, Easton, Fairfield, Monroe, New Fairfield, Newton, Redding Ridgefield, Shelton, Sherman, Stratford & Trumbull; Litchfield Co.: Bridgewater & New Milford Building construction	11 05	1 10	3%+ 30		½%
Residential construction	5 65	1 10	3%+ 20		½%
Fairfield Co.: Darien, Greenwich, New Canaan & Stamford	12 00	6%+e	9½%	10%	06
Litchfield Co.: Plymouth Building Construction	10 17	1 00	3%+ 50		½%
Residential construction	5 53	1 00	3%+ 50		½%
Windham Co.: Building construction	11 30	1 50	3%+ 50		½%
Litchfield Co.: Rem of Co.	10 40	1 22	3% 60	g	1/8%

DECISION NO CT78-3055	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
ELEVATOR CONSTRUCTORS	10 35	545	35	4%+h+i	02
ELEVATOR CONSTRUCTORS' HELPERS	7 245	545	35	4%+h+i	02
ELEVATOR CONSTRUCTORS' HELPERS (PROB)	5 175				
GLAZIERS:					
Fairfield Co.: Greenwich	9 10	66	1 66	365	03
Fairfield Co.: Rem of Co ; & Litchfield Co.	9 83	95	47	j	01
Windham Co.	11 41	84	55	k	
IRONWORKERS: Ornamental; Reinforcing; Structural; and Precast concrete erection	12 25	75	1 45	1	08
LATHERS:					
Fairfield Co.: Bridgeport, Easton, Fairfield, Monroe, Redding, Ridgefield, Shelton, Stratford, Trumbull, Weston, Westport & Wilton	10 00	50	40		01
Fairfield Co.: Greenwich, New Canaan, Norwalk & Stamford	8 51	35	20	.75	01
Fairfield Co.: Bethel, Brookfield, Danbury, New Fairfield Newton & Sherman; Litchfield Co.: Bethlehem, Bridgewater, Cornwall, Goshen, Harwinton, Litchfield, Morris, New Milford N Canaan, Plymouth, Roxbury, Thomaston, Torrington Warren, Washington, Watertown & Woodbury	9 65	35	30		01
Litchfield Co.: Barkhamsted, Colebrook, New Hartford, Norfolk & Winchester; Windham Co.: Chaplin, Hampton, Scotland & Windham	9 90	50	30		01
Windham Co.: Danielson	9 25	45	55		.01
LEADBURNERS	9 25	35		m	01
LINE CONSTRUCTION:					
Fairfield Co.: Darien, Greenwich, New Canaan, Stamford & that portion of Norwalk, w. of Five Mile River					

DECISION NO CT78-3055	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
Lineman	9 33	3-3/4%	6%+n+o	10%	½%
Cable splicers	9 33	3-3/4%	6%+n+o	10%	½%
Driver groundmen	9 33	3-3/4%	6%+n+o	10%	½%
Fairfield Co.: Rem of Co ; Litchfield Co.; & Windham Co.					
Lineman	10 92	70	3%+ 50	p	
Equipment operators	10 19	70	3%+ 50	p	
Driver groundmen	7 87	70	3%+ 50	p	
MARBLE SETTERS' HELPERS:					
Fairfield Co.: Darien, Greenwich, Norfolk, Stamford & Westport	7 33	74	.88	q	
MARBLE SETTERS' HELPERS; Terrazzo workers' helpers; & Tile setters' helpers:					
Fairfield Co.: Rem of Co ; Litchfield Co.; & Windham Co.	8 65	50	65		
PAINTERS:					
Bridge:					
Structural steel	12 00				
Spray	15 50				
Sandblasting or power tools	13 00				
Fairfield Co.: Greenwich					
Brush; Structural steel; paperhangers; Tapers	8 40	20	75	30	
Spray	12 60	20	75	30	
Fairfield Co.: Bridgeport, Easton, Fairfield, Southport, Stratford and Trumbull					
Brush	8 65	50	65	r	
Spray	10 65	50	65	r	
Taper	9 04	50	65	r	
Fairfield Co.: Darien, Stamford, New Canaan, Norwalk, Weston, Westport & Wilton					
Brush	8 35	.50	50		.01
Roller, paperhangers, tapers epoxy	8 85	50	50		.01
Fairfield Co.: Bethel, Brookfield, Danbury, New Fairfield, Newton, Redding, Ridgefield, Sandy Hook & Sherman; Litchfield Co.: New Milford					

DECISION NO CT78-3055

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Brush, Roller	10 85	50	50	r	
Steel	11 95	50	50	r	
Paperhangers; Tapers	10 85	50	50	r	
Epoxy	12 35	50	50	r	
Residential	9 10	50	50	r	
Fairfield Co.: Byram					
Brush	8 15	45	45+ 426/7	40	
Spray	9 15	45	45+ 426/7	40	
Steel & Swing stage & boatswain Chair	9 313/7	45	45+ 426/7	40	
Drywall taper	8 95	45	45+ 426/7	40	
Fairfield Co.: Monroe & Shelton					
Brush	10 75	50	80	s	01
Hand roller; Paperhangers	11 25	50	80	s	01
Structural steel, epoxy, polyester	11 75	50	80	s	01
Spray	14 75	50	80	s	01
Windham Co.: Willimantic & Windham					
Brush; Tapers	10 00	80	60		
Paperhangers	10 50	80	60		
Riding steel; steamcleaning; sandblasting; tanks; towers; & Hazardous work	10 58	80	60		
Spray	13 00	80	60		
Litchfield Co.: Bantam, Barkhamsted, Canaan, Colebrook, Cornwall, Goshen, Harwinton, Kent, Litchfield, New Hartford, New field, N Canaan, Plymouth, Salisbury, Sharon, Terryville, Torrington, Warren, Winchester & Winsted					
Brush; Roller; Taping	9 60	80	45		
Spray; High	12 00	80	45		
Epoxy	9 85	80	45		
Paperhanging	10 10	80	45		
Work over 60' & Boatswain chair; Open steel	14 40	80	45		
Swing Stage 40-60	10 60	80	45		

DECISION NO CT78-3055

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Windham Co., except Willimantic & Windham					
Brush	9 90	50	70		.01
Paperhangers	10 20	50	70		01
Sign	10 28	50	70		01
Taping	10 30	50	70		01
Roller	10 40	50	70		.01
Structural Steel	10 70	50	70		01
Spraying oil paint	13 05	50	70		01
Spraying epoxy	15 58	50	70		01
PLUMBERS:					
Windham Co.: Windham	10 10	62	62		20
PLUMBERS; Steamfitters:					
Fairfield Co.: Greenwich	10 00	45	70		02
Fairfield Co.: Bridgeport, Easton, Fairfield, Monroe, Shelton, Stratford & Trumbull	10 49	75	70	42	.01
Fairfield Co.: Georgetown, Norwalk, S Norwalk, Weston, Westport & Wilton	9.50	.75	50	36	.02
Fairfield Co.: Bethel, Brookfield, Danbury, New Fairfield, Newton, Redding, Ridgefield & Sherman; Litchfield Co.: Bridgewater & New Milford	10 70	.75	70	50	02
Fairfield Co.: Darien, New Canaan & Stamford	10 55	75	70	48	02
Litchfield Co.: Bantam, Barkhamsted, Canaan, Colebrook, Cornwall, Falls Village, Goshen, Harwinton, Kent, Lakeville, Litchfield, Morris, New Hartford, Norfolk, N Canaan, Salisbury, Sharon, Torrington, Warren, Winchester & Winstead	9.64	83	70	t	05
Litchfield Co.: Bethlehem, New Preston Plymouth (incl Terryville), Roxbury, Thomaston, Washington, Watertown & Woodsbury	10 00	83	70	t	05
Windham Co., except Windham	11 92	60	70	u	05

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
ROOFERS:					
Fairfield Co., except that portion of Fairfield Co bounded on the e by the eastern boundary of Greenwich; Litchfield Co.: Bethlehem, Bridgewater, Kent New Milford, Roxbury, Washington & Woodbury	10 90	1 05	45		
Litchfield Co.: Bantam, Canaan, Colebrook, Cornwall, Cornwall Bridge, E Canaan, Falls Village, Gaylordsville, Goshen Lakeside, Litchfield, Marbledale, Morris, New Hartford, New Preston, Norfolk, Northfield, Oakville, Prequabuck, Pine Meadow Pleasant Valley, Plymouth, Riverton, Salisbury, Sharon, S Kent, Taconic, Terryville, Thomaston, Torrington, Washington Depot, Watertown, W. Cornwall, W Goshen, Winchester Center & Winsted;					
Windham Co.					
Composition	8 75	525	70	55	
Slate & tile	9 25	525	70	55	
Fairfield Co.: that portion of Fairfield Co bounded on the e by the eastern boundary of Greenwich					
Slate & Tile	9 20	.50	1 40	1 40	
Helpers	7.50	50	1 00	1 00	
SHEET METAL WORKER:					
Fairfield Co.; Litchfield Co.	11 50	1 28	1 04		.02,
Windham Co.	10 55	70	86		.05
SPRINKLER FITTERS	11.75	.75	1 05		.08
STEAMFITTERS:					
Windham Co.: Windham	10 27	1 16	.66		.13
TILE SETTERS' HELPERS:					
Fairfield Co.: Darien, Greenwich, Stamford, Norfolk & Westport	7 58	.50	1.27		

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PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas

FOOTNOTES:

a 7 paid holidays: A, C, D, E, F, Decoration Day & Good Friday.
b 1 paid holiday: Good Friday. Employee must work 3 days during the work week in which the holiday falls, if scheduled, and if scheduled, the working day before and the working day after the holiday
c 4 paid holiday: B, C D, and Good Friday Employee must be employed 14 consecutive days immediately, prior to the holiday
d. 3 paid holidays: C, D and E
e $7 00 per day
f 3 paid holidays: B, C, and D
g. The last 4 regular working hours prior to Christmas shall be paid half day
h 6 paid holidays: A through F
i. Employer contributes 4% of basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as vacation pay credit
j. 9 paid holidays: A through F, Washington's Birthday, Good Friday and Columbus Day
k 9 paid holidays: A through F, Washington's Birthday, Good Friday and Columbus Day
l The last 4 hours on Christmas Eve is a pid half day if employee has worked 5 consecutive days prior to Christmas Eve.
m 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Christmas Eve provided the employee has worked 45 full days for the employer during the 120 days prior to the holiday and is availabel for work the day preceding and following the holiday.
n 1% of the gross electrical labor payroll
o Employer contributes $1 50 per day to a supplemental unemployment fund
p 9 paid holidays: A through F, Washington's Birthday, Good Friday, and a floating holiday per year provided the employee has been employed for a period of 5 working days prior to the holidays and works the scheduled work days immediately preceding and following the holidays.
q 1 paid holiday: St Patrick's Day.
r 2 paid holidays: C and D providing the employee works the day before and the day after the holiday
s. 4 paid holidays: B, C, D and E providing the employee works the day before and the after the holiday
t. 2 paid holidays: B and D and half day paid holiday the Friday after Thanksgiving and the last working day before Christmas and Good Friday paid half day
u 1 paid holiday: D
y. 3% of gross earnings to SASMI

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS (Building Construction)					
Derrick; Hoisting engineer 2 drums and over; Hoisting structural steel; Pile driver & Setting Stone	11 55	.90	85	a	10
Dragline; Forklift - over 4' lift; Front end loader - 7cy; or over; Gradall; Hoisting engineer (all types of equipment where a drum and cable are used to hoist, pull, motive power or operation); Koehring scooper loader and/or hoe; master mechanic; shovel; & tower crane	11.43	90	85	a	10
Maintenance engineer	11.33	.90	85	a	10
Central mix operator; Coleman loader and screeing plant or similar equipment; combination hoe and loader over ½ yd; Conveyors - regardless of motive power; Front end loader 3cy, up to 7 cy.; Joy drill limited to joy heavy weight champion or equivalent; Mucking machine; Post hole digger; pumpcrete machine; rock boring machine; vibratory hammer; welder & well digger	11 07	90	85	a	10
Compressor battery operator	10 26	90	85	a	10
Asphalt spreader	10 85	90	85	a	10
Bulldozer; Carry-all operators; Graders; & Scraper pan	10 79	.90	85	a	10
Combination hoe and loader machine; concrete mixer - 5 bags over; Front end loader under 3 cy.; power-stone spreader	10 74	90	.85	a	10

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Air and steam valve	9 99	90	85	a	10
Compressor; generator; pump and well point; welding machine	9.88	90	85	a	10
Fork lift not over 4'; & Steam Jenny	10 63	90	85	a	10
Mechanical heater	9 71	90	85	a	10
Roller	10 52	90	85	a	10
Dinky machine; power pavement breaker	10 36	90	85	a	10
Fireman (High pressure	9 50	90	85	a	10
Oiler	9 02	90	85	a	.10
Crane with boom, excluding jib, over 150' = $.25 extra					
Crane with boom, excluding jib, over 200' = $.50 extra					
LABORERS (Heavy and Highway Construction)					
Laborers	7 95	50	70		10
Acetylene burners; Asphalt raker; Chain saw operator; Concrete & power buggy operators; Concrete saw operator; fence & guard rail erectors; form setters; hand operated concrete vibrator operators; hand operated vibratory compactor operators; Mason tenders; pipelayers; pneumatic drill operators; pneumatic gas & electric drill operators; powdermen & wagon drill operators	8 20	50	70		10
Air track operators; block paver; curb setters	8 45	50	70		10
Blasters	8 70	50	70		10

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr.
LABORERS (Building Construction)					
Laborer	7 95	50	70		10
Asphalt rakers, concrete & power buggy ops, concrete saw ops, chain saw ops, fence & guard rail erectors, form setters, pipelayers, dry stone wall builders, mason tenders, pneumatic drill ops, pneumatic gas & electric drill ops, powdermen & wagon drill operators	8 20	50	70		10
Air track ops, block pavers; and curb setters	8 45	50	70		10
Blasters	8 70	50	70		10
Open air caisson, cylindrical work and boring crew:					
Top man	7 95	50	70		10
Bottom man	8 45	50	70		10

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS:					
CLASS 1	11 58	90	.85	a	10
CLASS 2	11 42	90	85	a	10
CLASS 3	11 08	90	85	a	10
CLASS 4	10 88	90	85	a	10
CLASS 5	10 73	90	.85	a	10
CLASS 6	10 53	90	85	a	10
CLASS 7	10 32	90	85	a	10
CLASS 8	9 41	90	85	a	.10
CLASS 9	9 52	90	85	a	10
CLASS 10	9 89	90	85	a	10
CLASS 11	10 24	90	85	a	10
CLASS 12	9 05	90	85	a	10
CLASS 13	9 82	90	85	a	10
Crane with 150' boom - $ 25 extra					
Crane with 200' boom - $ 50 extra					

CLASSIFICATIONS: POWER EQUIPMENT OPERATORS

CLASS 1: Erecting and handling structural steel; front end loader (7cy. or over)
CLASS 2: Piledriver; Power shovel and crane; Dragline; Gradall; Trenching machine; lighter derrick; paver (concrete); derrick (stiff leg and guy); steel pile shooting; koehring loader (skooper) master mechanic
CLASS 3: Drill (joy heavy weight champion or equivalent); side boom; loader (euclid); mucking machine; pumpcrete; rock and earth boring machine; Post hole digger; well digger; & hammer (vibratory); central mix; combination hoe & loader (over ½ yd)
CLASS 4: Asphalt spreader
CLASS 5: Front end loader (3yds or over); Grader; power stone spreader; combination hoe and loader
CLASS 6: Asphalt roller; bulldozer; carryall; maintenance engineer; concrete mixer (5 bags and over); Welder
CLASS 7: Front end loader (under 3yds.); roller; power chipper; fork lift; finishing machine; asphalt plant; power pavement breaker; dinky machine
CLASS 8: Compressor; pump
CLASS 9: Fireman (high pressure)
CLASS 10: Well point system
CLASS 11: Compressor battery
CLASS 12: Oiler
CLASS 13: Batch plant; bulk cement plant

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
TRUCK DRIVERS (Building, Heavy and Highway Construction)					
CLASS 1	7 81	74	725	a	
CLASS 2	7 91	74	725	a	
CLASS 3	8 01	74	725	a	
CLASS 4	7 96	74	725	a	
CLASS 5	8 06	74	725	a	
CLASS 6	8 11	74	725	a	

CLASSIFICATIONS: TRUCK DRIVERS

CLASS 1: Two axle trucks; helpers
CLASS 2: Three axle trucks; two axle ready mix
CLASS 3: Four axle trucks; heavy duty trailer-up to 40 tons
CLASS 4: Three axle ready-mix
CLASS 5: Four axle ready-mix; specialized earth moving equipment other than conventional type on-the-road trucks and simi-trailer (including Euclids)
CLASS 6: Heavy duty trailer-40 tons and over

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day & F-Christmas Day

FOOTNOTE:
a 7 paid holidays: A through F and Good Friday

SUPERSEDEAS DECISION

STATE: CONNECTICUT COUNTIES: *SEE BELOW
DECISION NUMBER: CT78-3056 DATE: DATE OF PUBLICATION
Supersedes Decision No CT78-3004 dated February 17, 1978 in 43 FR 7117
DESCRIPTION OF WORK: Building Construction (excluding single family homes and garden type apartments up to and including 4 stories), heavy (excluding tunnel construction) and highway construction:

*Hartford, Middlesex, New Haven *New London, and Tolland Counties	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ASBESTOS WORKERS: Hartford Co.: Avon, Berlin, Bloomfield, Bristol, Burlington, Canton, E Hartford, E Windsor, Farmington, Glastonbury, Hartford, Manchester, Marlborough, New Britain, Newington, Plainville, Rocky Hill, Simsbury, Southington, S. Windsor, W Hartford, Wethersfield & Windsor) Middlesex Co.; New Haven Co.; New London Co.: Bozrah, Colchester, E. Lyme, Franklin, Groton, Lebanon, Lyme, Montville, New London, Norwich, Old Lyme, Salem, Sprague & Waterford; & Tolland Co.: Andover, Bolton, Columbia, Coventry, Ellington, Hebron, Mansfield, Tolland, Vernon & Willington	$11 84	75	1 16		
Hartford Co.: E Granby, Enfield, Granby, Hartland, Suffield & Windsor Locks; Tolland Co.: Somers, Stafford & Union	10.65	.94	1.29		.01
New London Co.: Griswold, Ledyard, Lisbon, N Stonington, Preston, Stonington & Voluntown	10.28	1 00	1.18		
BOILERMAKERS	10 00	.60	10%		.01
BRICKLAYERS; Cement masons; Finishers; Marble masons; Plasterers; Stonemasons; Terrazzo workers & Tile setters (Building Construction): Hartford Co.: Avon, Bloomfield, Burlington, Enfield, E Granby, E. Hartford, Farmington, Glastonbury, Granby, Hartford, Hartland, Manchester, Marlborough, Rocky Hill, Simsbury					

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
BRICKLAYERS (CONT'D): S. Windsor, Suffield, Thompsonville, W Hartford, Wethersfield, Windsor, Windsor Locks; Tolland Co.: Andover, Bolton, Columbia Coventry, Ellington, Hebron, Mansfield, Somers, Stafford, Storrs, Tolland, Union, Vernon & Willington	$ 9 75	90	75		
Hartford Co.: Berlin, New Britain, Newington, & Southington; New Haven Co.: Meriden, Wallingford, Cheshire (North of Route 68)	10 05	75	75		
Hartford Co.: Canton	9 80	75	75		
Middlesex Co.: & New London Co.	10 20	75	75		
New Haven Co.: Bethany, Branford, E Haven, Guilford, Hamden, Madison, New Haven, N Brandford, N Haven, Orange, W. Haven, Woodbridge, Rem of Milford & Cheshire	10 10	75	75		
New Haven Co.: Ansonia, Derby, Oxford, Seymour & Southbury	9 70	75	75		
Hartford Co.: Bristol,& Plainville; New Haven Co.: Beacon Falls, Middlebury, Hixville, Naugatuck, Prospect, Waterbury & Wolcott	9 95	75	75		
New Haven Co.: Milford (West of Indian River to the Orange Town line)	10 05	75	75		
BRICKLAYERS (Heavy & Highway Construction)	9 50	75	75	b	
CARPENTERS: MILLWRIGHTS; PILEDRIVERMEN: RESILIENT FLOOR LAYERS (Building Construction) Hartford Co.: Hartford, West Hartford, Avon, Farmington, Simsbury, Bloomfield, Windsor, East Granby, Granby, Windsor Locks, Suffield, Enfield, East Windsor, South Windsor, East Hartford, Manchester, Glastonbury, Rocky Hill, Wethersfield, Hartland; Tolland Co.: Stafford, Somers, Tolland, Ellington, Bolton Vernon	10 35	90	65		05
Hartford Co.: New Britain, Newington, Berlin, Southington Plainville, Burlington, Canton, Bristol; New Haven Co.: Meriden, Wallingford, New Haven, East Haven, Brandord, Guilford, Madison, North Branford, North Haven, Hamden, West Haven, Orange (east of Orange Center Road and North of Route 1; also north of Route 1 and east of the Oyster River), Cheshire, Waterbury, Wolcott, Middlebury, Southbury, Naugatuck, Prospect, Bethany Beacon Falls, Woodbridge; Middlesex Co.	10 10	80	55		05
New Haven Co.: Milford, Oxford, Derby, Seymour, Ansonia, Orange (that part west of Orange Center Rd and south of Route 1, and that part south of Route 1 and West of the Oyster River	10 25	90	65	c	c
New London Co.: Tolland Co.: Mansfield, Union, Willington, Coventry, Hebron, Columbia, Andover	10 25	90	65		03
CARPENTERS (Heavy & Highway Construction): New Haven Co.: Ansonia, Derby, Milford, Orange (W. of Orange Center Road & S. of Rte #1 & W of the Oyster River), Oxford & Seymour	10 05	90	65	f	c
Hartford Co.; Middlesex Co.; & New Haven Co.: Remainder of Co.; Tolland Co.: Bolton, Ellington, Somers, Stafford, Tolland & Vernon	10 05	90	.65	f	.05

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DECISION NO CT78-3056	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CARPENTERS CONT'D):					
New London Co.; Tolland Co.: Andover, Columbia, Conventry, Hebron, Mansfield, Union & Willington	10 05	90	65	f	03
ELECTRICIANS:					
New Haven Co.: Milford	10 40	1 10	3%+ 30		½%
Hartford Co.: Berlin, Bristol, New Britain, Newington, Plainville & Southington	10 17	1 00	3%+ 30		½%
Hartford Co.: Suffield & Enfield (portion of Thompsonville West of George Washington Road and North of Hazard Ave)	9 85	70	3%+ 30	.43	03
Hartford Co.: Hartland; New Haven Co.: Beacon Falls, Middlebury, Naugatuck, Oxford, Prospect, Seymour, Southbury, Waterbury & Wolcott	10 40	1 22	3%+ 60	h	1/8%
Hartford Co.: Rem of Co.; Middlesex Co.: Cromwell, Middlefield, Middletown & Portland; New London Co.: Bozrah Colchestery, Franklin, Lisbon, Montville, N Stonington, Norwich, Griswold, Lebanon, Ledyard, (except Submarine Base) Preston, Salem, Sprague, Stonington & Voluntown & Tolland Co.	11 30	1 50	3%+ 50		½%
Middlesex Co.: Remainder of County					
New Haven Co.: Reaminder of Co ; ford; New London Co.: E Lyme, New London, Fishers Island Sound Old Lyme, Groton, Waterford & Ledyard (Submarine Base Only	10 36	1 00	3%+ 40		¼ of 1%
ELEVATOR CONSTRUCTORS	10 35	545	35	3%+i+j	02
ELEVATOR CONSTRUCTORS' HELPERS	7 245	545	35	3%+i+j	02
ELEVATOR CONSTRUCTORS' HELPERS (PROB)	5.175				

DECISION No CT78-3056	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
GLAZIERS:					
New Haven Co., except Wallingford	9 83	95	47	k	01
Hartford Co.; Middlesex Co.; New Haven Co.; Wallingford; New London Co.; & Tolland Co.	11 81	84	55	1	
IRONWORKERS:					
Ornamental; Reinforcing; Structural and Precast concrete erection	12 25	75	1 45	m	08
LATHERS:					
Hartford Co.: Bristol, Southington; New Haven Co.: Beacon Falls, Bethany, Cheshire, Meriden, Middlebury, Naugatuck, Oxford, Prospect, Southbury, Waterbury & Wolcott	9 65	35	30		01
Hartford Co.: Avon, Berlin, Bloomfield, Burlington, Canton, E Granby, E Hartford, Farmington, Glastonbury, Granby, Hartford, Manchester, Marlborough, New Britain, Newington, Plainville, Rocky Hill, Simsbury, S Windsor, W Hartford, Windsor & Windsor Locks; Middlesex Co.: Cromwell, E Haddam, E Hampton, Middlefield, Middletown & Portland; New London Co.: Bozrah, Colchester, E Lyme, Franklin, Grofton, Lebanon, Lisbon, Lyme, Salem, Sprague & Waterford; Tolland Co.: Andover, Bolton, Columbia, Coventry, Hebron, Mansfield & Vernon	9 90	50	30		01
Hartford Co.: Broad Brook, Enfield, Hazardville, Melrose, Suffield, Thompsonville & Warehouse Point; Tolland Co.: Crystal Lake, N, Somers, Somers, Straffold, Stafford Springs, Straffordville & Union	9 40	45	25		.01

DECISION NO CT78-3056	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
LATHERS (CONT'D):					
Middlesex Co.: Chester, Clinton, Deep River, Durham, Essex, Haddam, Killingworth, Old Saybrook & Westbrook; New Haven Co.: Ansonia, Branford, Derby, E Haven, Guilford, Hamden, Madison, Milford, New Haven, N Branford, N Haven, Orange, Seymour, Wallingford, W Haven & Woodbridge	9 80	75	45		01
LEADBURNERS	9 25	35		n	01
LINE CONSTRUCTION:					
Linemen	10 92	70	3%+ 50	o	
Equipment operators	10 19	70	3%+ 50	o	
Driver groundmen	7 87	70	3%+ 50	o	
MARBLE SETTERS' HELPERS; Terrazzo workers' Helpers; & Tile setters' helpers	8 75	50	65		
PAINTERS:					
Bridge and Highway	12 45				
Structural steel	12 45				
Sandblasting of power tools	13 45				
Spray	15 95				
New Haven Co.: Milford (up to Gulf Street)					
Brush	8 65	50	65	P	
Taping	9 04	50	65	P	
Spray	10 65	50	65	P	
Hartford Co.: Avon, Bloomfield, Broad Brook, Canton, E Granby, E Hartford, E Windsor, Enfield, Farmington, Glastonbury, Granby, Hartford, Manchester, Marlborough, Rocky Hill, Poquonock, Simsbury, S Windsor, Suffield, S. Manchester, W Hartford, W Simsbury, Wethersfield, Windsor, & Windsor Locks; Tolland Co.: Andover, Ashford, Bolton, Columbia, Conventry, Ellington, Hebron, Mansfield, Rockville, Strafford, Somers, Tolland,					

DECISION NO CT78-3056	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PAINTERS (CONT'D):					
Union, Vernon, & Willington					
Brush; Tapers	10 00	80	60		
Paperhangers	10 50	80	60		
Riding steel; steamcleaning; Sandblasting; Tank; Towers, & Hazardous work	10 58	80	60		
Spray	13 00	80	60		
Hartford Co.: Berlin, Bristol, Burlington, E Berlin, Forestville, Hartland, Kensington, Milldale, New Britain, Newington, Plainville, Plantsville, Southington, & Unionville; New Haven Co.: Cheshire, Guilford Madison, Meriden, & Wallingford;					
Middlesex Co.: Chester, Clinton, Cromwell, Deep River, Durham, E. Haddam, E. Hampton, Essex, Haddam, Higganum, Ivoryton; Killingworth, Middlefield, Middletown, Moodus, Norfolk, Portland, Saybrook, & Westbrook					
Brush; Roller; Taping	9 60	80	45		
Spray	12 00	80	45		
Epoxy	9 85	80	45		
Paperhanging	10 10	80	45		
Work over 60' & Boatswain Chair; Open Steel	14 40	80	45		
Swing Stage 40 - 60'	10 60	80	45		
New Haven Co.: Ansonia, Beacon, Falls, Derby; Oxford, & Seymour Brush	10 75	50	80	q	01
Hand roller; Paperhangers	11 25	50	80	q	01
Structural steel, epoxy polyester	11.75	50	80	q	01
Spray	14 75	50	80	q	01
New Haven Co.: Bethany, Branford, E. Haven Hamden, Milford, (S on Gulf Street & N on North Street, New Haven, N Bradford, N. Haven, Orange, W Haven, Woodbridge, & Woodmont					

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PAINTERS (CONT'D)					
Brush; Sandblasting	9 45	50	60		02
Tapers	9 80	50	60		02
Paperhangers	9 95	50	60		02
Spray	12 10	50	60		02
Structural steel	9 70	50	60		02
New Haven Co.: Middlebury, Naugatuck, Prospect, Roxbury, Southbury, Thomaston, Washington, Waterbury, Watertown, Wolcott, & Woodbury					
Brush	8 80	50	60		
Paperhanger & Tapers	9 05	50	60		
Spray	13 50	50	60		
New London Co.: Norwich					
Brush	9 90	50	70		01
Paperhangers	10 70	50	70		01
Sign	10 28	50	70		01
Taping	10 30	50	70		01
Roller	10 40	50	70		01
Structural steel	10 70	50	70		01
Spraying oil paint	13 05	50	70		01
Spraying epoxy	15 58	50	70		01
PLUMBERS:					
Hartford Co.: Avon, Bloomfield, Burlington, Canton, E Granby, E Hartford, E Windsor, Enfield, Farmington, Glastonbury, Granby, Hartford, Manchester, Marlborough Newington, Rocky Hill, Simsbury, S Windsor, Suffield, W Hartford, Wethersfield, Windsor, Windsor, Locks Middlesex Co.: Chester, Cromwell, Deep River, E Haddam, E Hampton, Haddam, Maromas (Atomic River Project) Middlefield, Middletown & Portland; Tolland Co.: Andover, Bolton, Columbia, Coventry; Ellington, Hebron, Mansfield, Somers, Stafford, Storrs, Tolland, Union, Vernon, &					

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Willington	10 31	1 10	1 39		10
PLUMBERS: Steamfitters:					
New Haven Co.: Milford	10 49	75	70	42	01
Hartford Co.: Southington; Middlesex Co.: Durham; New Haven Co.: Cheshire, Meriden & Wallingford	10 35	75	70	r	03
Hartford Co.: Berlin, Bristol, E Berlin, Kensington, New Britain, & Plainville	10 34	75	70	s	03
Middlesex Co.: Clinton, Killingworth, S Westbrook; New Haven Co.: Branford, Derby, E Haven, Orange, W Haven, & Woodbridge	10 55	75	70	t	02
Middlesex Co.: Essex, Ivoryton,, Old Saybrook, & Saybrook; New London Co.: Bozrah, Colchester, E, Lyme, Montville, New London, N Stonington, Norwich, Old Lyme, Preston, Salem, Sprague, Stonington, Voluntown, & Waterford	11 92	60	70	u	05
New Haven Co.: Ansonia, Beacon Falls, Bethany, Naugatuck, Oxford, Prospect, & Seymour New Haven Co.: Middlebury, Southbury, S Britain, Waterbury & Wolcott					
Hartford Co.: Hartland	10 45	88	70	v	05
ROOFERS:					
New Haven Co.: Ansonia, Beacon Falls, Bethany, Branford, Derby E Haven, Guilford, Hamden, Madison, Milford, Middlebury, Naugatuck, New Haven, N Branford, N Haven, Orange, Oxford, Seymour, Union City, W Haven, & Woodbridge	10 15	1 05	45		
Hartford Co.; Middlesex Co.; New Haven Co.: Cheshire, Meriden, Prospect, Wallingford, & Wolcott; New London Co.; & Tolland Co.					
Composition	8 75	525	70	55	
Slate, Tile	9 25	525	70	55	

DECISION NO CT78-3056

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
SHEET METAL WORKERS	10 55	70	86		05
SPRINKLER FITTERS	11 75	75	1 05		08
STEAMFITTERS:					
Hartford Co.: Avon, Bloomfield, Burlington, Canton, E Granby, E Hartford, E Windsor, Enfield, Farmington, Glastonbury, Granby, Hartford, Manchester, Marlborough, Newington, Rocky Hill, Simsbury, S Windsor, Suffield, W Hartford, Wethersfield, Windsor, & Windsor Locks; Middlesex Co.: Chester, Cromwell, Deep River, E Haddam, E. Hampton, Haddam, Maromas (Atomic River Project), Middlefield, Middletown, & Portland; Tolland Co.: Andover; Bolton, Columbia, Coventry, Ellington, Hebron, Mansfield, Somers, Stafford, Storrs, Tolland, Union, Vernon, & Willington	10 57	1.36	.81		.13

DECISION NO CT78-3056

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

FOOTNOTES:

a 7 paid holidays: A through F, and Good Friday
b 1 paid holiday: Good Friday. Employee must work 3 days during the work week in which the holiday falls, if scheduled, and if scheduled, the working day before and the working day after the holiday
c 4 paid holidays: B, C, D, and Good Friday Employee must be employed 14 consecutive days immediately prior to the holiday
d 3 paid holidays: C, D, and E
e $ 50 per worker per year
f 3 paid holidays: B, C, and D
h The last 4 regular working hours prior to Christmas Day shall be paid half day
i 6 paid holidays: A through F
j Employer contributes 4% of basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as vacation pay credit
k 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Columbus Day
l. 9 paid holidays: A through F, Washington's Birthday, Good Friday and Columbus Day
m. The last 4 hours on Christmas Eve is a paid half day if employee has worked 5 consecutive days prior to Christmas Eve
n 9 paid holidays: A through F, Washington's Birthday, Good Friday and Xmas Eve provided the employee has worked 45 full days for the employer during the 120 days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
o 9 paid holidays: A through F Washington's Birthday, Good Friday and a floating holiday per year provided the employee has been employed for a period of 5 working days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
p 2 paid holidays: C and D providing the employee works the day before and the day after the holiday
q. 4 paid holidays: D, C, D, and E providing the employee works the day before and the dat after the holiday
r. 1 paid holiday: D
s. Paid holidays: D, and the Friday after Thanksgiving is a paid half day, and December 24, provided it falls on a working day, is a paid half day
t. 3½ paid holidays: C, D, E, and the half day Friday after Thanksgiving
u. 1 paid holidays: D
v. 2 paid holidays: D, D & half day paid holiday the Friday after Thanksgiving and the last working day before Christmas, & Good Friday paid half day

DECISION NO CT78-3056	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS: (BUILDING CONSTRUCTION)					
Derrick; Hoisting engineer 2 drums and over; Hoisting structural steel; Pile driver; & Setting stone	11 55	90	85	a	10
Dragline; Fork lift - over 4' lift; Front end loader - 7 cy or over; Gradall; Hoisting engineer (all types of equipment where a drum and cable are used to hoist, pull, or drag material regardless of motive power or operation); Koehring scooper loader and/or hoe; master mechanic; shovel; & tower crane	11 43	90	85	a	10
Maintenance engineer	11 33	90	85	a	10
Central mix operator; Coleman loader and screening plant or similar equipment; combination hoe and loader over ¼ yd ; Conveyors - regardless of motive power; Front end loader - 3 cy up to 7 cy ; High pressure portable boiler; Joy drill - limited to joy heavy weight champion or equivalent; mucking machines; post hoe digger; pumpcrete machine; rock boring machine; vibratory hammer; welder; & Well digger	11 07	90	85	a	10
Compressor battery operator	10 26	90	85	a	10
Asphalt spreader	10 85	90	85	a	10
Bulldozer; Carry-all operators; Grader; & Scraper pan	10 79	90	85	a	10
Combinationhoe and loader machine; concrete mixer - 5 bags or over; front end loader under 3 cy ; powerstone spreader	10 74	90	85	a	10

DECISION NO CT78-3056	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS (CONT'D)					
Air and steam valve	9 99	90	85	a	10
Compressor; generator; pump and well point; welding machine	9 88	90	85	a	10
Fork lidt not over 4'; & Steam Jenny	10 63	90	85	a	10
Mechanical heater	9 71	90	85	a	10
Roller	10 52	90	85	a	10
Dinky machine; Power pavement breaker	10 36	90	85	a	10
Fireman (High pressure)	9 50	90	85	a	10
Oiler	9 02	90	85	a	10
Crane with boom, excluding jib, over 150' - $ 25 extra					
Crane with boom, excluding jib, over 200' - $ 50 extra					
LABORERS(Heavy and Highway Construction):					
Laborers	7 95	50	70		10
Acetylene burners; Asphalt raker; chain saw operator; concrete & power buggy operators; Concrete saw operator; fence & guard rail erectors; Form setters; Hand operated vibratory compactor operators; Mason tenders; pipelayers; pneumatic gas & electric drill operators; powdermen & wagon drill operators	8 20	50	70		10
Air track operator; block pavers; curb setters	8 45	50	70		10
Blasters	8 70	50	70		10

DECISION NO CT78-3056

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
LABORERS (Building Construction)					
Laborers	7 95	50	70		10
Asphalt rakers, concrete & power buggyops, concrete saw ops, chain saw ops, fence & guard rail erectors, form setters, pipelayers, dry stone wall builders, mason tenders, pneumatic gas & electric drill ops powdermen, & wagon drill ops	8.20	50	70		10
Air track ops, block pavers, and curb setters	8 45	50	70		10
Blasters	8 70	50	70		10
Open Air Caisson, Cylindrical Work and Boring Crew:					
Top man	7 95	50	70		10
Bottom man	9 45	50	70		10

DECISION NO CT78-3056

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS: (HEAVY & HIGHWAY CONSTRUCTION)					
Class 1	11 58	90	85	a	10
Class 2	11 42	90	85	a	10
Class 3	11 08	90	.85	a	10
Class 4	10 88	.90	.85	a	10
Class 5	10 73	.90	85	a	10
Class 6	10.53	.90	85	a	.10
Class 7	10.32	.90	.85	a	10
Class 8	9 41	.90	.85	a	10
Class 9	9.52	90	85	a	.10
Class 10	9.89	.90	85	a	.10
Class 11	10.24	.90	85	a	.10
Class 12	9 05	.90	.85	a	10
Class 13	9 82	.90	.85	a	10
Crane with 150' boom - $ 25 extra					
Crane with 200' boom - $ 50 extra					

POWER EQUIPMENT OPERATORS CLASSIFICATIONS

Class 1: Erecting and handling structural steel; front end loader (7 cy. or over)
Class 2: Piledriver; Power shovel and crane; dragline; gradline; gradall; trenching machine; lighter derrick; paver (concrete); derrick (stiff leg and guy); Steel pile sheeting; koehring loader (skooper); master mechanic
Class 3: Drill (Joy heavy weight champion or equivalent); Side boom loader (Euclid); Mucking machine; Pumpcrete; Rock and earth boring machine; post hole digger; well digger; & hammer (vibratory); central mix; combination hole & loader (over ½ yd)
Class 4: Asphalt
Class 5: Front end loader (3 yds or over); grader; power stone spreader; combination hoe and loader
Class 6: Asphalt roller; bulldozer; carryall; maintenance engineer; concrete mixer (5 bags and over); welder
Class 7: Front end loader (under 3 yds); roller; power chipper; fork lift; finishing machine; asphalt plant; power pavement breaker; dinky machine
Class 8: Compressor; pump
Class 9: Fireman (high pressure)
Class 10: Well point system
Class 11: Compressor battery
Class 12: Oiler
Class 13: Batch plant; Bulk cement plant

DECISION NO CT78-3056

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
TRUCK DRIVERS (Building, Heavy & Highway Construction)					
TRUCK DRIVERS:					
Class 1	7 81	74	725	a	
Class 2	7 91	74	725	a	
Class 3	8 01	74	725	a	
Class 4	7 96	74	725	a	
Class 5	8 06	74	725	a	
Class 6	8 11	74	725	a	

TRUCK DRIVERS

Class 1: Two axle trucks; helpers
Class 2: THree axle trucks; two axle ready-mix
Class 3: Four axle trucks; heavy duty trailer-up to 40 tons
Class 4: Three axle ready mix
Class 5: Four axle ready-mix; specialized earth moving equipment other than conventional type on-the-road trucks and semi-trailers (including Euclids)
Class 6: Heavy duty trailer-40 tons and over

SUPERSEDEAS DECISION

STATE: Vermont
COUNTIES: Chittenden, Franklin, Grand Isle, Addison, & Orleans
DECISION NO VT78-2067
Supersedes Decision No VT76-2170 (above counties only) dated December 10, 1976 in 41 FR 54146
DATE: Date of publication
DESCRIPTION OF WORK: Highway Construction

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Chittenden, Franklin, Grand Isle, and Orleans Counties:					
Carpenters	$6 65	35	30		
Cement masons	7 63				
Laborers:					
Laborers	3 85	15	a		
Drillers: Chittenden County	4 40				
Remainder of Counties	4 69				
Truck Drivers:					
2 axle	5 35				
3 axle	5 50				
Power equipment operators:					
Augers	5 50				
Backhoe	8 20	35	50	b	02
Bulldozer	7 75	35	50	b	02
Compactor:					
Orleans	7 20	35	50	b	02
Franklin, Grand Isle, & Chittenden	7 75	35	50	b	02
Crane	8 20	35	50	b	02
Gradall	8 20	35	50	b	02
Mechanic	7 75	35	50	b	02
Paver	7 75	35	50	b	02
Roller	7 75	35	50	b	02
Loader	7 75	35	50	b	02
Spreader (Orleans County only)	7 75	35	50	b	02
Grader:					
Chittenden Co.	4 30				
Remainder of Counties	7 95	35	50	b	02

Footnotes:
a 2 paid holidays: Memorial Day, Independence Day, provided the employee has been employed for at least 7 days or more prior to the holiday and has worked 2 full days in the calendar week in which the holiday falls.

b 9 paid holidays: New Year's Day; Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day, Washington's Birthday, Columbus Day, and Veteran's Day

DECISION NO VT78 2067

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Addison County:					
Carpenters	$6 65	35	30		
Cement masons	6 65	35	30		
Ironworkers:					
Reinforcing	6 46	25			05
Structural	7 40	45	60		
Laborers	3 85	15		a	
Driller	4 48				
Asphalt raker	4 35				
Air tool operators	4 10				
Truck drivers:					
2 axle	5 35				
3 axle	5.50				
Power equipment operators:					
Roller	7 75	35	50	b	05
Grader	7 95	35	50	b	05
Mechanic	7 75	35	50	b	05
Paver	7 75	35	50	b	05
Backhoe	8 20	35	50	b	05
Bulldozer	7 75	35	50	b	05
Crance	8.20	35	50	b	05
Front end loader	7 75	35	50	b	05
Spreader	7 75	35	50	b	05
Compactor roller	7 20	.35	50	b	05

Footnotes:

a 2 paid holidays-- Memorial Day and Independ. Day, provided the worker worked 2 full days in the calendar week in which the holiday falls

b 9 paid holidays-- Ney Years Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas, Washington's Birthday, Columbus Day, Veterans Day

[FR Doc 78-20679 Filed 7-27-78; 8:45 am]

Federal Register

FRIDAY, JULY 28, 1978
PART IV

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

■

RECOMBINANT DNA RESEARCH

Proposed Revised Guidelines

[4110-08]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

RECOMBINANT DNA RESEARCH

Proposed Revised Guidelines

STATEMENT BY JOSEPH A. CALIFANO, Jr., SECRETARY OF HEALTH, EDUCATION, AND WELFARE

The Director of the National Institutes of Health is publishing proposed revisions to the NIH guidelines on research involving recombinant DNA molecules.

The original guidelines are being updated in light of NIH's experience operating under them and in light of our increasing knowledge about the potential risks and benefits of this research technique. As experience accumulates, we should review and evaluate the evidence to assure that the restrictions imposed are appropriate to potential risks—strengthening restrictions where needed, relaxing regulation where justified.

In publishing these proposals for public comment, I recognize the extraordinarily difficult challenge that developing sensitive but effective regulations in this field poses for NIH, for the research community, and for the concerned public.

Necessarily, this task poses difficult questions that we will never be able to answer with complete certainty. I hope that those concerned will analyze the proposed revisions with care and give us their views on the strength of the evidence that supports the proposed revisions, the specific scientific and research containment procedures that the proposed revisions require, and the procedures and the standards they establish for future changes in the guidelines and for the exercise of discretion under them.

We particularly seek comment on the sections in the proposed revisions that establish the mechanisms for administering and revising the guidelines. For example, do the proposed revisions strike the proper balance in establishing:

The procedures for permitting otherwise prohibited experiments and for exempting classes of research from the guidelines;

The standards for the exercise of administrative discretion under the guidelines;

The composition of the Department's Recombinant DNA Advisory Committee and of the institutional biohazard committees.

To review the comments on the proposed revisions, I am establishing a departmental review committee, consisting of Mr. Peter Libassi, the Department's General Counsel (Chairperson); Dr. Donald Fredrickson, the Director of NIH (Vice-Chairperson); Dr. Julius Richmond, Assistant Secretary for Health; and Dr. Henry Aaron, Assistant Secretary for Planning and Evaluation.

I have asked this committee to hold a public hearing to insure full and complete opportunity for comment. In order to hold this hearing and to issue the revised guidelines on a reasonably prompt schedule, no extension of the 60-day period for public comment will be possible.

In preparing these revisions, the National Institutes of Health have already held 19 hours of public hearings and have received continual advice from the scientific community and from the public. I want this open process to continue. I urge those concerned to help us find the proper balance by providing us with their comments on NIH's proposed revisions.

Dated: July 19, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

NATIONAL INSTITUTES OF HEALTH

RECOMBINANT DNA RESEARCH

PROPOSED REVISED GUIDELINES—NIH

This will introduce three related documents that the National Institutes of Health (NIH) is publishing for public comment: (1) a *Decision of the Director, NIH,* to publish revised NIH guidelines for research involving recombinant DNA molecules, (2) the *Proposed Revised Guidelines—NIH,* and (3) an *Environmental Impact Assessment* of the proposed action. The Secretary of Health, Education, and Welfare has approved the release of these documents for public comment.

As stated in the Secretary's preface, we are particularly concerned that public comment be invited on the scientific and procedural aspects of the proposed guidelines. A public hearing on these proposed revisions will be held in late September at the Hubert H. Humphrey Building, Washington, D.C. All comments received on or before September 25, 1978, will be considered, and no extension of the comment period will be granted. Within 45 days after the comment period, final guidelines will be promulgated with a notice in the FEDERAL REGISTER.

The events leading to the proposed revisions are described in the "Introduction and Overview" to the *Decision* and in the "Foreword" to the *Assessment.* This preface will orient the reader to other NIH documents that are directly related to the present publications. One is the current *Recombinant DNA Research Guidelines,* effective since June 23, 1976 (published in the FEDERAL REGISTER, July 7, 1976). Another is the *Environmental Impact Statement* (EIS) on those guidelines, published in 1977. The EIS, which contains a copy of the guidelines, is available from the Government Printing Office (stock No. 017-040-00413-3) and in GPO depository libraries throughout the country. A third related document is *Proposed Revised Guidelines on Recombinant DNA Research,* which the NIH Recombinant DNA Advisory Committee (RAC) recommended to the NIH Director on September 1, 1977. The RAC proposal was published in the FEDERAL REGISTER, September 27, 1977, for public comment.

The RAC-proposed revisions were discussed at a public meeting of the Advisory Committee to the Director (DAC), held at NIH on December 15-16, 1977. The DAC and special consultants heard witnesses from environmental groups, the scientific community, industry, etc. All correspondence from the public in response in the FEDERAL REGISTER publication was available to those present and will be published, with the transcript of the meeting and other documents, as part of a continuing public record of NIH activities concerning recombinant DNA. The Director, NIH, acting in light of the 2-day discussion, all commentaries, and the DAC's recommendations, has arrived at the present proposal—the *Proposed Revised Guidelines* (NIH)—and offers it for public review.

The current (1976) guidelines contain an appendix entitled "Supplementary Information on Physical Containment." This has been omitted from the present proposed guidelines but, in revised and expanded form, will be available on request as "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research." For a copy, write to the Office of Recombinant DNA Activities, Building 31, Room 4A52, National Institutes of Health, Bethesda, Md. 20014.

The *Environmental Impact Assessment* is based on an intensive analysis of the current guidelines, the RAC-proposed alternative, and the present NIH alternative. The conclusion of this analysis is that there would be no adverse impact of the NIH-proposed changes upon the environment.

The guidelines as presently proposed are designed to discharge the continuing obligation of NIH to insure that recombinant DNA research goes forward under standards of safety reflecting the latest scientific knowledge, so that the public and the environment are protected from any hazards while deriving the full benefits of the recombinant DNA technique.

Written comments and inquiries concerning the *Proposed Revised Guidelines* should be addressed to the Director, National Institutes of Health, Bethesda, Md. 20014. All comments received will be available for public inspection at the Director's office on weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

Dated: July 19, 1978.

DONALD S. FREDRICKSON,
Director,
National Institutes of Health.

DECISION OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, TO ISSUE REVISED GUIDELINES FOR RECOMBINANT DNA RESEARCH

JULY 19, 1978.

CONTENTS

INTRODUCTION AND OVERVIEW

Today, with the concurrence of the Secretary of Health, Education, and Welfare, and the Assistant Secretary for Health, I am proposing revisions to the NIH Guidelines for Recombinant DNA Research.(1) These Guidelines were first issued on June 23, 1976. The proposed revisions result from a continuing process of scientific and public exchange similar to that of the 1976 edition. This overview sketches the background for proposed revisions and summarizes the proposed changes. It references accompanying documents and other pertinent sources of information.

The probable risks and benefits of recombinant DNA research—the larger subject of which the NIH Guidelines are a part—have been discussed in numerous forums since first addressed in 1973.(2) Congress has held multiple hearings on related issues, including proposals to convert the Guidelines to Federal regulations(3) and redefine recombinant DNA research to narrow the range of experiments subject to regulations. Early in 1977 the NIH Recombinant DNA Advisory Committee (RAC), the scientific and technical committee responsible for proposing revisions to the Guidelines, began its task of identifying changes needed in the Guidelines and forwarded suggestions to me for consideration. In order that public comments could be heard on the RAC-proposed revisions, published in September 1977,(4) a meeting of the Advisory Committee to the Director, NIH (DAC), the committee responsible for public oversight, was held in December. The extensive record of this hearing bears witness to almost unanimous agreement that the original Guidelines badly need updating, and suggests numerous directions in which revisions might move.(5)

Much of the discussion at the December 1977 meeting of the DAC affirmed the need for continuous reevaluation of the scientific premises underlying the original Guidelines. Since Asilomar,(2) growing evidence has suggested that other experts ought to review the concerns of the molecular biologists who first raised questions about the safety of recombinant DNA research. Scrutiny from experts in infectious diseases, epidemiology, virology, botany, ecology, laboratory safety, and other disciplines has been needed. NIH sponsored a workshop for this purpose at Falmouth, Mass., 6 months before the DAC meeting. Here, old and new information about *E. coli* K-12—the host most used in recombinant DNA experiments—was interpreted carefully. From this came a consensus that the chances of this host being convertible to an epidemic pathogen are negligible.

Those attending the December DAC meeting also heard complaints that containment levels were set too stringently for recombinant DNA work on viruses and plants. This applied both to the original Guidelines and to the revisions proposed in September 1977. A decision was made to address the issues through workshops without delay.

One of these workshops, held at Ascot, England, dealt specifically with viruses.(7) Here, experts from several countries, most of whom had no stake in recombinant DNA experiments, reached an unequivocal opinion that the risks of cloning viral DNA in a bacterium like *E. coli* K-12 are not greater, and are usually much less, than the risks of handling the parent virus alone. They also stressed that defective viruses pose little risk of infection when used as vectors for cloning DNA in eukaryotic cells, since the cells cannot survive outside permissive laboratory conditions and the virus cannot escape in a viable form. A second working group, meeting in Bethesda,(7) then reviewed the conclusions. It agreed that the original Guidelines imposed stricter containment on use of viral DNA or of viruses as vectors than could be justified by any available fact, and recommended changes.

A group of agricultural scientists met in Washington, D.C., in March 1978(8) to consider the containment conditions for incorporation of DNA from plant pathogens into *E. coli* K-12 and for use of viral and other vectors in plants. An important concept discussed at this workshop is the lack of evidence that *E. coli* K-12, or any other strain of this bacterium, is capable of acquiring an ecological niche in plants and thus infecting them.

On April 27-28, 1978, the RAC considered the recommendations concerning viruses and plants and agreed with most of them. With a few changes, they are a part of the proposed revision.

At the December 1977 hearings before the DAC, other aspects of the Guidelines evoked requests for revisions.(5) There was overwhelming sentiment for exempting from the Guidelines experiments involving recombination of DNA within the same strains or from pairs of organisms that transfer genes in nature. Discretion to exempt such experiments is not provided in the original Guidelines; nor does one find there the flexibility to permit other experiments for purposes of risk assessments needed to determine the merits of particular standards, or how these should be revised. Other criticisms of the Guidelines stressed the delays and confusion created by excessive centralization of administrative control, and it is evident that implementing procedures must be changed.

Certain background elements merit comment. Shortly after the NIH Guidelines were published, the British guidelines appeared.(9) Subsequently other national guidelines have been issued, most recently those of the Soviet Union. Many international aspects of DNA research and its regulation have been reviewed elsewhere.(9) The December 1977 DAC meeting directed attention to instances where the NIH Guidelines either exclude experiments that have been conducted abroad or make them far more diffi-

cult to do.(*10*) Moreover, factual bases for the greater stringency of the U.S. (NIH) Guidelines cannot be shown.

Five years have passed since concerns were first raised about the hypothetical hazards of laboratory experiments with recombinant DNA. The thousands of individual applications of such techniques have produced much useful knowledge, but no evidence has come to light of a product created by these techniques that has been harmful to man or the environment. Foreign genes inserted into prokaryotic host-vector systems have been faithfully replicated and produced in quantities valuable to science. On the other hand, prokaryotes generally have not been able to translate eukaryotic genes into biologically active proteins. No new facts or unconsidered older ones have emerged to support the fears of harmful effects, and one prominent early proponent of guidelines has repudiated his support for them.(*11*) At the least, there is growing sentiment that the burden of proof is shifting toward those who would restrict recombinant DNA research.(*12*)

Although clearly the time has come to revise the original NIH Guidelines for Recombinant DNA Research, it is not the time to conclude that they are being altered in preparation for their early abandonment. Understanding of gene regulation and expression is increasing inexorably and at an awesome pace. We may predict that ways will be found to achieve and control the translation of foreign genes by a variety of hosts.(*13*) As the barriers to translation are dropped, some of the larger promise of recombinant technology will be realized. In some proportion to the harvest of positive results, a capability must be maintained for observing any capacity of these experiments to yield harmful products, and for communicating this to all who have an interest in similar experiments.

In preparation for this next phase of recombinant DNA research, several shifts in NIH guidance are necessary. Experiments posing no threat to safety must be exempted from the Guidelines; and provisions must be made to remove others as soon as their harmlessness becomes evident. Any universal rules imposed on this kind of activity derive validity from continual modification dictated by results of the experimentation they govern.

Primary responsibility for comliance with the rules must be located where the work is done. There it must be shared fully by principal investigators, those who work in their laboratories, institutional biosafety committees, and the institutional leaders. The NIH Office of Recombinant DNA Activities (ORDA) should be relieved of its burden of obligatory prior approval of certain experiments, so that it can better carry out, along with the RAC, two central functions. These are the continuing synthesis and interpretation of the Guidelines, and the maintenance of full communication among all who must use them.

To recapitulate, these new proposed Guidelines arose from a proposal made to me by the RAC in September 1977. Numerous amendments have been made on the basis of public comments received at the December 1977 hearing, in extensive correspondence before and after that, and recommendations of special expert workshops whose reports were then assessed by the RAC in April 1978. The proposal and the amendments have been the products of long and intense participation by numerous persons representing many points of view. I now summarize the more important proposed changes. The basis for decision on each element of revision is provided in detail in subsequent sections of this document.

SCOPE AND APPLICABILITY OF THE GUIDELINES

Recombinant DNA containing synthetic sequences is now explicitly part of the definition of what is included under the Guidelines. The standards of the Guidelines now apply to all recombinant DNA experiments conducted in an institution that receives any support from NIH for recombinant DNA research. This includes a registration requirement.

The original Guidelines contain a number of prohibited experiments. There was little sentiment for the removal of all the original prohibitions—although it has been noted that the U.S. (NIH) Guidelines are the only national guidelines to stipulate "prohibited" activities. The original prohibitions, with one modification and a necessary "flexibility" clause,(*14*) are therefore retained in the proposed revision. They immediately precede a new section called "Exemptions"—a juxtaposition chosen to emphasize that the prohibitions still override.

The first exemption from the guidelines covers the handling of DNA outside a host organism or virus. Such "naked DNA" has been handled in laboratories for years and is rapidly inactivated in nature.

The exempted experiments of the second class consist essentially in rearranging, or deleting from, molecules of nonchromosomal or viral DNA. No foreign DNA is involved. An example would be the introduction of a DNA molecule formed from pieces of SV40 virus into eukaryotic cells in tissue culture. Since there is little if any basis for presuming such "rearrangement" or "deletion" experiments to be hazardous, they are now excluded.

A third class of exemptions are experiments called "self-cloning," in which DNA found naturally in a host may be reinserted into that host. These are reproductions in the laboratory of events that occur in nature.

Similarly, provision is made in the proposed guidelines for exemption of a fourth class of experiments that involve donor-host pairs that normally exchange DNA. Such genetic exchange is known to occur widely between various species of bacteria and is generally mediated by certain plasmids or viruses. Experimental recombinations of this type are only an imitation of what nature is able to accomplish handily in the absence of Federal regulation. A list of donor-host pairs to be exempted is begun in this revision and will be expanded periodically as knowledge grows. The initial choice from several possible lists submitted to me by the RAC is a conservative one, restricted to pairs of organisms for which there is documented evidence of natural exchange.

Finally, a fifth exemption is provided for removal of other recombinations when they are shown to be safe. The last two exemptions create some of the discretionary power for modifying the guidelines that was so lacking in the original. Provision will be made for public input to such decisions, either by announcement of proposed exemptions prior to consideration by the RAC or before a decision by the Director becomes effective.

CONTAINMENT

I have made one decision that will not be regarded with equal pleasure by all engaged in recombinant DNA research. P1 containment previously permitted mouth pipetting. In accord with a previous recommendation by the European Molecular Biology Organization (EMBO), its virus Working Group strongly recommended prohibiting this practice; and so did NIH safety advisors. The RAC at its meeting on April 27-28, 1978, recommended that mouth pipetting be prohibited only for those P1 recombinant DNA experiments involving viral DNA. Rather than create two separate classes of P1, and in recognition of the present availability of excellent mechanical devices for pipetting, I am proposing that mouth pipetting no longer be permitted in P1 containment. Since it is already prohibited in P2-P4 containment, this bans the use of mouth pipetting for any experiment covered by the Guidelines.

CONTAINMENT GUIDELINES FOR COVERED EXPERIMENTS

The recommendations of the RAC, arising from the Ascot-Bethesda work-

shops, represent the first realistic appraisal of any hazards that might lie in the use of viral vectors or the cloning of viral DNA. Recombinant techniques offer access to ares of viral biology that are vitally important. Such studies should not be impeded unnecessarily. I have accepted the April 1978 recommendations of the RAC in this area with minor amendments. The revised guidelines emphasize the current dictum that any hazards of working with viruses in recombinant DNA experiments are maximal at the first stage, when the virus itself with its full genomic complement is handled.

The RAC unanimously approved modest changes in containment for plant experiments. I have also approved them provisionally, contingent upon concurrence by the Department of Agriculture.

A new sentence has been added to the guidelines giving much needed flexibility in the setting of containment levels.(15)

ROLES AND RESPONSIBILITIES

Two years' experience with the guidelines has offered valuable tutelage in the limits of external (Federal) control of laboratory experimentation. Scientists and their co-workers have long experimented with pathogenic organisms, poisonous plants and animals, and hazardous chemicals. The laboratory is not among the more notorious occupational settings for accidents or illness, and damage to community or environment by basic laboratory research is almost unknown. Control over the use of radioisotopes in the laboratory, long a Federal preserve, is not comparable to use of recombinant DNA techniques; for the risks of using radioisotopes are calculable and mistakes are easily measured. Thus realistic and durable standards can be set. Without a base for the setting of such standards, conventional regulation is difficult at best, and at worst can be preposterous.

In the case of recombinant DNA technology, we are in the midst of a search for any risks, and thus for applicable standards. The scientists who raised the possibility of risks also realized that the only effective safeguards lay in a maximum enhancement of the collective nature of the scientific process. The usual communications networks of science had to be augmented and the evaluation of results and the reaching of consensus accelerated. These actions, is was reasoned, would help establish a set of initial rules, and there was the added assumption that they could and should be kept up to date. All using the new techniques would sign a "memorandum of understanding" to the effect that, until things became clearer, the basic communality of scientific inquiry would be especially emphasized in any work with recombinant DNA techniques.

The power of the Government to require such discipline of its grantees was an attractive reason for the scientists to request Federal intervention. And the Federal capacity to achieve the essential communication and consensus-building has been one of the most positive results of this experiment in adminstration. But the price of Fedeal intervention includes a heavy tax of formalism. In the instance of these guidelines, diverse pressures have made difficult the appropriate balancing of substance and procedure. I have already alluded to one of the undesirable results—a chilling inflexibility of the original guidelines—and its proposed correction by revision.

Prior NIH clearance is mandatory for new NIH grants and contracts involving recombinant DNA techniques and for all projects in P4 facilities. In the proposed revised guidelines, prior NIH clearance is no longer required for changes at the P1-P3 levels. These changes must be approved by the institutional biosafety committee (IBC), and NIH will then review the IBC actions. This proposal reverses an October 1977 issuance stating that changes in ongoing projects require prior NIH clearance. The requirement resulted in numerous delays in projects which could not be justified on grounds of safety.

The proposed guidelines would strengthen institutional responsibilities and authorities in determining compliance. A full partnership with all investigators and their institutions is intended. The role of the IBC is particularly enhanced through delegation of some discretionary powers that were previously reserved for NIH and the RAC. To better meet these obligations, an institution using P3 or P4 containmen is required under the proposed guidelines to have a qualified biological safety officer.

Experience gained in the past 5 years in explaining recombinant DNA technology has shown how valuable can be a community's activities. At least one member of the IBC is to be a "public member"—i.e., one who has no financial connection with the institution. Further, to ensure opportunity for public particiation at the national level, procedural are set forth, as explained in Part IV of the decision, that provide public notice and solicit comment on the major actions of NIAH.

Another stipulation of the revised guidelines is that failure of compliance can lead to suspension of NIH support for recombinant DNA research.(16)

Provision is now made for the private sector to register voluntarily its recombinant DNA activities with NIH. Also, other consulting services, including certification of host-vector systems, will be provided. The service will be accompanied by protection of proprietary data as mandated by law.

NIH issued a draft environmental impact statement on the guidelines in September 1976. This was revised after public comment and issued in final form in October 1977. It concluded that the activities covered by the guidelines had no predictable impact on the environment, since all the risks discussed were hypothetical. The EIS was examined by a Federal district court in 1978.(17)

In parallel with the process of revising the guidelines, NIH has conducted an environmental impact assessment, including an analysis of how current experiments supported by NIH will be affected by this revision. Again, the activities covered by the revised guidelines deal only with hypothetical risks, and thus the assessment reveals no predictable impact on the environment. Its content is published herewith in a companion document.

ORGANIZATION OF THE REMAINDER OF THIS DOCUMENT AND ABBREVIATIONS USED

The Recombinant DNA Molecule Program Advisory Committee is somnetimes referred to below as the Recombinant DNA Advisory Committee or Recombinant Advisory Committee or RAC.

The meeting of the Advisory Committee to the Director, NIH, which took place in December 1977 is sometimes referred to below as the meeting of the Director's Advisory Committee or of the DAC or the December 1977 public hearing.

The "NIH Guidelines for Research Involving Recombinant DNA Molecules" as issued on June 23, 1976, and publishes in the FEDERAL REGISTER on July 7, 1976, are sometimes referred to below as the original guidelines or the 1976 guidelines or the current guidelines.

The proposed revised guidelines prepared by the RAC and published in the FEDERAL REGISTER on September 27, 1977, are referred to below as the PRG-RAC.

The proposed revised guidelines which are being proposed now by NIH are referred to below as the PRG-NIH.

The remainder of this document is divided into four parts corresponding to the four parts of the guidelines; i.e., I. Scope of the Guidelines; II. Containment; III. Containment Guidelines for Covered Experiments; and IV. Roles and Responsibilities.

Within each of these four parts there are two subsections; i.e., Review of RAC-Proposed Guidelines and Review of Comments and NIH-Proposed Guidelines. The first subsection

describes how the PRG-RAC differs from the 1976 guidelines; the second describes (1) the public comments received both before and after the December 1977 DAC meeting, concerning the PRG-RAC, and (2) the changes which have been made in response to these comments leading to the PRG-NIH.

FOOTNOTES TO INTRODUCTION AND OVERVIEW

(1) In addition to the proposed revised guidelines and this "Decision Document," there is also being released an Environmental Impact Assesemment, including numerous appendices.

(2) The capability to perform DNA recombinations, and the potential hazards, had become apparent to scientists at the Gordon Research Conference on Nucleic Acids in July 1973. At their behest the National Academy of Sciences created a committee that organized an international conference held in February 1975 at Asilomar Conference Center, Pacific Grover, Calif. Approximately 150 scientists, of whom a third were from foreign countries, were present. The committee also called on the National Institutes of Health to establish an advisory committee to draft guidelines for the conduct of this research. Temporary guidelines were issued at Asilomar pending issuance of NIH guidelines.

In response, the NIH Recombinant Advisory Committee (formally "NIH Recombinant DNA Molecule Program Advisory Committee") was established in October 1974 to advise the Secretary of HEW, the Assistant Secretary for Health, and the Director of NIH to accomplish these tasks. The several meetings at which the Recombinant Advisory Committee developed its proposed guidelines in 1975 were announced in the FEDERAL REGISTER and were open to the public. The committee, after preparing several draft versions of guidelines, reached agreement on a recommended revised version, which was referred to the NIH Director for review in December 1975.

A special meeting of the public advisory Committee to the Director, NIH, was convened in February 1976 to review these proposed guidelines. In addition to current members of the committee, a number of former committee members as well as other scientific and public representatives had been invited to participate. There was ample opportunity for comment and an airing of the issues, both by the committee members and the public witnesses. All major points of view were broadly represented.

The proposed guidelines were reviewed by the Director, NIH, in the light of comments and suggestions made at the public hearing as well as extensive written correspondence received after the meeting. When the final guidelines were released in June 1976, an accompanying decision paper described in great detail all relevant public comments and the reason for accepting or rejecting specific recommendations in preparing the final guidelines. The NIH guidelines and the Decision of the Director, NIH, were published in the FEDERAL REGISTER on July 7, 1976. In addition, copies of the guidelines were widely distributed to foreign embassies, medical and scientific journals, NIH grantees and contractors, and professional research societies.

(3) The following committees have held hearings and/or markup sessions on Recombinant DNA legislation:

House—The Subcommittee on Health and the Environment and its parent, the Committee on Interstate and Foreign Commerce; the Subcommittee on Science, Research, and Technology and its parent, the Committee on Science and Technology.

Senate—The Subcommittee on Health and Scientific Research and its parent, the Committee on Human Resources; the Subcommittee on Science, Technology, and Space. Its parent, the Committee on Commerce, Science, and Transportation, has not held any hearings or markup sessions on this topic.

	Bill	Chief sponsor	Date
House:			
H. Res. 131		Richard Ottinger, Democrat of New York.	Jan. 19, 1977.
H.R. 3191	Identical to S. 621	do	Feb. 7, 1977.
H.R. 3591	do	do	Feb. 16, 1977.
H.R. 3592	do	do	Do.
H.R. 4232		Stephen Solarz, Democrat of New York.	Mar. 1, 1977.
H.R. 4759		Paul Rogers, Democrat of FLorida..	Mar. 9, 1977.
H.R. 4849	Identical to H.R. 4759	do	Mar. 10, 1977.
H.R. 5020	Identical to S. 621	Ottinger	Mar. 14, 1977.
H.R. 6158	Administration bill	Rogers	Apr. 6, 1977.
H.R. 7418		do	May 24, 1977
H.R. 7897		do	June 20, 1977.
H.R. 11192		Rogers and Harley Staggers, Democrats of West Virginia.	Feb. 28, 1978.
Senate:			
S. 621		Dale Bumpers, Democrat of Arkansas.	Feb. 4, 1977.
S. 945		Howard Metzenbaum, Democrat of Ohio.	Mar. 8, 1977.
S. 1217	Administration bill	Edward Kennedy, Democrat of Massachusetts.	Apr. 1, 1977
S. 1217	As reported: accompanied by Report 95-359.	do	July 22, 1977.
S. 1217	Amendment 754 in the nature of a substitute.	Gaylord Nelson, Democrat of Wisconsin.	Aug. 2, 1977.
S. 1217	Amendment 1713 in the nature of a substitute.	Kennedy	Mar. 1, 1978

The following bills on recombinant DNA technology have been formally introduced:

(4) The Recombinant Advisory Committee considered its proposed revisions at meetings throughout 1977. The version proposed to the Director, NIH, in September 1977, appeared in the FEDERAL REGISTER on September 27, 1977.

(5) This meeting of the Director's Advisory Committee took place in Bethesda on December 15-16, 1977. A summary of the meeting appeared in the recombinant DNA technical bulletin, and the complete record will shortly be published by NIH in vol. 3 of the series recombinant DNA research.

(6) The NIH-sponsored meeting at Falmouth, Mass., on June 20-22, 1977, was chaired by Dr. Sherwood Gorbach. A complete record of this meeting appears in the "Journal of Infectious Diseases" (May 1978).

(7) The "U.S.-EMBO Workshop to Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insect Viruses" was held on January 26-28, 1978, in Ascot, England. It was attended by experts on viruses from the United States, Britain, and other European countries, a majority of whom were not engaged in recombinant DNA research. The primary purpose of the meeting was to conduct a scientific and technical analysis of possible risks associated with cloning eukaryotic viral DNA segments in *E. coli* K-12 host-vector systems and with the use of eukaryotic viruses as cloning vectors in animal, plant, and insect systems. The report of the workshop was published in the FEDERAL REGISTER on March 31, 1978, and appears as appendix E to the accompanying environmental impact assessment. The results of the Ascot meeting were then reviewed by another group of U.S. virologists who converted them into recommendations for revision of the guidelines. This working group was chaired by Dr. Harold Ginsberg and met on April 6-7, 1978. Its report appears as appendix F to the accompanying environmental impact assessment. The report was considered by the Recombinant Advisory Committee at its April 27-28, 1978, meeting.

(8) The "Workshop on Risk Assessment of Agricultural Pathogens" was held on March 20-21, 1978, in Washington, D.C., under the auspices of the National Science Foundation, the Department of Agriculture, and the National Institutes of Health. A copy of the report of this workshop appears as appendix G to the accompanying environmental impact assessment.

(9) The United Kingdom guidelines, also known as the "Williams report," were issued in August 1976. A fairly comprehensive review of the international aspects of recombinant DNA research, including issuance of national guidelines, is contained in the "Report of the Federal Interagency Committee on Recombinant DNA Research: International Activities," November 1977. This is available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Md. 20014.

(10) Under the NIH guidelines, experiments using prokaryotic hosts other than *E. coli* K-12 are severely limited whereas such experiments are proceeding in Europe, especially with *Bacillus subtilis*. Certain other categories of experiments require, according to the NIH guidelines, either P4+EK2 or P3+EK3 containment. Since no EK3 system

has as yet been certified and since the first P4 facility has only recently been certified, these experiments were effectively forbidden. The same experiments require significantly lower containment under some European guidelines.

(11) Prof. James Watson, in testimony at the December 1977 DAC meeting and in print, has sought repentance for his earlier activities in support of special precautions for recombinant DNA research.

(12) The report, "Science Policy Implications of DNA Recombinant Molecule Research," March 1978, of the Subcommittee on Science, Research, and Technology of the Committee on Science and Technology, U.S. House of Representatives, says, "The burden of proof of safety factors should not be borne exclusively by proponents of recombinant DNA research; opponents must assume a corresponding burden."

(13) Significant differences exist between prokaryotes and eukaryotes in the ways proteins are synthesized under genic direction, and these account for limitations on the apparent success of many recombinant DNA experiments to date. A major thrust of current recombinant DNA research is in the direction of overcoming these differences. There is every reason to believe that this research will succeed. At my invitation, Dr. Malcolm Martin of NIH has drawn up this brief analysis of the state-of-the-art:

The potential use of recombinant DNA techniques to produce biologically useful reagents is predicated on: (a) the faithful replication of a segment of foreign DNA in a new host cell; (b) the synthesis of messenger RNA (mRNA) complementary to the inserted DNA; and (c) the efficient translation of the mRNA into a polypeptide. In nearly all cases that have been examined to date, DNA, from both eukaryotic and prokaryotic sources, has been amplified in prokaryotic host-vector systems. The fidelity of this entire process (a, b, and c) has been verified in several instances in which prokaryotic DNA segments have been cloned in *E. coli* and resulted in the synthesis of new polypeptides. Thus, in such cases, the informational content contained in the inserted prokaryotic DNA is expressed as evidenced by the synthesis of mRNA and novel proteins.

With few exceptions (some yeast inserts) the expression of eukaryotic DNA in the form of biologically active or biochemically detectable polypeptides in prokaryotes has not been demonstrated using chromosomal DNA inserts and unmodified vectors. In nearly all cases where the system has been rigorously examined, it has been shown that eukaryotic DNA has replicated in *E. coli;* in some instances, RNA complementary to the inserted eukaryotic DNA has been identified.

Messenger RNA synthesis and function in E. coli. The synthesis of messenger RNA (mRNA) in a prokaryote, such as *E. coli,* proceeds in a linear fashion along the DNA template of individual gene segments or groups of related genes. In nearly all cases examined, the mRNA molecules are the faithful colinear transcripts of prokaryotic genetic information and can be used in an unmodified form to direct the synthesis of prokaryotic polypeptides. The informational content of mRNA corresponds directly to the nucleotide sequence of DNA in such systems (i.e., *all* nucleotides present in a prokaryotic gene are transcribed into messenger RNA which, in turn, programs the synthesis of a corresponding protein). Control of this phase of gene expression appears to be solely at the level of RNA synthesis.

In prokaryotes (and eukaryotes), nucleotide sequences preceding the sequences corresponding to the actual genes play a major role in determining (a) whether a given DNA sequence will be transcribed into RNA and (b) whether the RNA so synthesized will efficiently bind to ribosomes, a prerequisite for protein synthesis. For example, certain DNA sequences interact with regions of RNA polymerase and thereby participate in the initiation of RNA synthesis; they are not represented in the final RNA product. DNA sequences specifying binding to ribosomes are physically located between those for initiation of RNA synthesis and sequences encoding the amino acids of a particular protein (the gene) and are also contained in the functional mRNA molecules.

Messenger RNA synthesis and metabolism in eukaryotes. Our understanding of gene regulation and expression in eukaryotic cells has increased markedly during the past 10 months. A common feature of all systems that have been carefully evaluated is that the initial, faithful RNA copy of the DNA is extensively modified to produce a functional form of mRNA. The final mRNA contains only a fraction of the sequences present in the original RNA product. That is to say portions of large RNA molecules are removed by mechanisms that are, at present, poorly understood and the remaining segments of the primary RNA transcript are then rejoined to one another. In nearly all cases an RNA segment containing a ribosomal binding site is joined to a segment coding for a polypeptide; in addition, larger gene segments are often joined together. This process was first observed in animal virus systems (1, 2) where it was shown that viral mRNA, containing the information for a product which had been previously mapped to a specific locus on the viral genome, was complementary to regions of the viral DNA which were separated by more than a thousand nucleotides.

Support for the concept of complex modification leading to functional mRNA in eukaryotic cells has recently come from recombinant DNA experiments in which chromosomal DNA has been cloned in *E. coli.* When individual cloned eukaryotic genes are carefully analyzed, intervening DNA sequences which interrupt the actual sequence of the gene in chromosomal DNA have been identified. To date, such intragenic DNA has been detected in ovalbumin (3, 4), β globin (5, 6), immunoglobulin (7), and even tRNA genes (8). In one instance it has been clearly shown that the intervening DNA sequences, present in the primary RNA transcript of β globin DNA, are absent in β globin mRNA (5). These mechanisms presumably function in some regulatory fashion to modulate eukaryotic gene activity.

Implications for Recombinant DNA Research

A. The discovery of the existence of complex processes involved in the maturation of mRNA eukaryotic cells and the demonstration of intragenic DNA in several eukaryotic genes suggests that: (1) cloning of chromosomal DNA in *E. coli* DNA (shotgun or purified) will pose little, if any, risk since the maturation mechanisms have never been observed in prokaryotes; and (2) investigators who wish to develop prokaryotic cloning systems for the purpose of synthesizing useful biological products will utilize cDNA copies of functional mRNAs or synthetic DNA with a nucleotide sequence derived from a known amino acid sequence as DNA inserts.

B. Vectors are currently being "engineered" to ensure efficient transcription and translation of DNA inserts. Using slightly different approaches, groups in San Francisco and at Harvard (9-11) are preparing DNA segments which: (1) contain the sequences necessary for interaction with *E. coli* RNA polymerase linked closely to (2) sequences which encode a bacterial ribosome binding site. Such DNA segments can then be added to a prokaryotic cloning vector next to the site into which a foreign DNA will be inserted. This arrangement will facilitate the transcription of the inserted DNA and enable the mRNA so synthesized to bind to bacterial ribosomes. This embellishment has already been used to maximize the expression of a bacteriophage gene and human somatostatin DNA in a plasmid vector system (10, 11).

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(14) Prohibition (i) in the original guidelines forbids experiments with "oncogenic viruses classified by NCI as moderate risk." The absence of evidence that use of these viruses will lead to formation of agents harmful to man and the potential for obtaining useful new knowledge, relevant to carcinogenesis in particular, and genetics in general, supports the removal of the prohi-

bition. The removal of this prohibition was proposed in the report of the Working Group on Viruses which met on Apr. 6-8, 1978, and endorsed by the RAC at its Apr. 27-28, 1978, meeting. The reasoning behind this is that recombinant DNA experiments with pieces of these viruses cloned in *E. coli* K-12 pose no more risk, and actually appear to pose clearly less risk, than work with the whole infectious virus itself. Since NCI recommends that work with these whole viruses not be prohibited, but rather be performed under containment conditions similar to P3, there is no scientific reason to prohibit recombinant DNA work with these viruses. The "flexibility" clause refers to power of the Director, NIH, to waive prohibitions when the public interest may be served by such action.

(*15*) The Guidelines say at the beginning of Pt. III, "Given below are containment guidelines for permissible experiments. Changes in these levels for specific experiments (or the assignment of levels to experiments not explicitly considered in this section) may be expressly approved by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee." Insertion of such language into the guidelines was recommended by the RAC at its Apr. 27-28, 1978, meeting. It recognizes that the classification of experiments given in Pt. III will necessarily be imperfect, as investigators in the future devise new ways to conduct recombinant DNA experiments not currently foreseen and therefore not explicitly considered in the guidelines. Also, new data may become available showing that certain particular experiments currently assigned a particular containment level are, indeed, clearly more (or less) safe than envisioned at this time.

(*16*) See App. C to the guidelines and Part IV of this "Decision Document."

(*17*) In May 1977, a resident of Frederick, Md., brought suit in the U.S. District Court for the District of Columbia to enjoin a proposed risk-assessment experiment which was about to be undertaken in a maximum containment facility (P4) located at the Frederick Cancer Research Center. (*Mack* v. *Califano*, Civil Action No. 77-0916). On February 23, 1978, the court issued a decision refusing to grant the injuction. In so doing, the court observed that the environmental impact statement on the original guidelines constituted a "hard look" at recombinant DNA research performed in accordance with the guidelines. The court further noted that compliance with the guidelines, it appeared, would insure that no recombinant DNA molecules would escape from the carefully controlled laboratory to the environment, and that the guidelines "represent an effort by many scientists to evaluate the hazards and provide safe methods for their control."

The plaintiff appealed (Appeal No. 78-1156), and on Mar. 8, 1978, the Court of Appeals for the District of Columbia upheld the district court decision.

I. Scope of the Guidelines

Review of RAC-proposed guidelines

It was the determination of the Recombinant Advisory Committee that advances in knowledge pertaining to recombinant DNA activities in past years warranted significant revisions in the "purpose," "definition," and "prohibition" sections of the NIH guidelines. A comparison of the "purpose" language of the two sets of guidelines[1] reveals that the standards in the PRG-RAC were meant to pertain to recombinant DNA molecules in organisms. The analogues language in the 1976 guidelines addresses recombinant DNA molecules whether or not they are contained within a cell or virus. The rationale for this change is that DNA by itself (commonly referred to as "naked" DNA) is extremely unlikely to be hazardous under experimental conditions, as it is rapidly inactivated in nature.

The definition in the PRG-RAC consisted of two parts: (1) an operational definition of recombinant DNA and (2) a qualification that the guidelines would pertain only to "novel" recombinant DNA's. The operational definition does not differ significantly from that in the original guidelines.

The second part, however, called for the creation of a list of organisms that exchange genetic information in nature, commonly referred to as "nonnovel exchangers." Recombinant DNA formed with DNA from such organisms would be exempted from the provisions of the PRG-RAC, with the rationale that there is no justification for requiring containment procedures for the handling of recombinations that occur regularly in nature and are not known to be associated with any special hazards.

The provision of an open-ended listing was recommended rather than issuance or a blanket exemption, because this would allow the RAC and NIH to consider evidence that (1) the putative gene transfers do take place naturally and (2) their exemption from the guidelines is justifiable (see footnote 1 of the PRG-RAC).

Although the PRG-RAC deals with prohibited experiments under Part III, this decision document, for purposes that become apparent below, will consider the definition, exemptions, and prohibitions together under section I.

The "prohibitions" section was called section III-A, "Experiments That Are Not To Be Performed," in both the 1976 guidelines and PRG-RAC. Changes from the 1976 guidelines, proposed in the PRG-RAC, included minor wording changes in items (iii), (iv), and (vi).

The ability to grant exemptions for certain experiments from the "prohibitions" was limited in the 1976 guidelines to only the sixth prohibition (large-scale experiments with recombinant DNA's known to make harmful products). In the PRG-RAC the Director, NIH, is given the authority to grant exceptions from any of the six prohibitions. Such a determination must be based upon the recommendation of the RAC, and weight must be given in the decisionmaking "both to scientific and societal benefits and to potential risks." The rationale for this proposed change was the desire of the RAC not to preclude the possibility of conduction such experiments for some compelling social or scientific reasons—for example, risk-assessment experiments.

The sections of the PRG-RAC dealing with purpose of the guidelines, definition of recombinant DNA, exemptions, and prohibitions evoked a great deal of comment both before and after the December 1977 public hearing. An anylsis of these comments and my decision in response to the issues raised are presented in the following section.

Review of comments and NIH-proposed guidelines

There was considerable discussion at the public hearing over the scope of the guidelines. Some felt that the guidelines were too narrow in their preoccupation with recombinant DNA, as there exist other forms of genetic research capable of producing organisms of unknown potential hazard. It was further suggested that the title of the guidelines be modified to reflect the preoccupation with experiments involving prokaryotes and cells in culture, and that a companion document be released dealing with higher eukaryotes. On the other hand, it was also argued that genetic research has now received attention far beyond its due, and that other matters of experimentation await their turn.

While it is true that other techniques in genetic research, such as cell fusion and chromosome transfer, may result in formation of recombinant molecules, I do not believe at this time that we should mandate or extend the guidelines to these research areas. There are inherent in these techniques a range of natural barriers to the formation of hazardous organisms which apparently afford adequate containment, making unnecessary the issuance of Federal standards. I base this conclusion on the fact that such techniques have been used in the laboratory for decades with no known harmful effects on either the public health or the environment. I should also emphasize that the entire area of laboratory safety is of primary concern to NIH and is the subject of constant review and attention. A description of NIH activities in these areas is presented in the environmental impact assessment.

A commentator suggested that the language be deleted stating that "* * *

[1] The current guidelines as published in the Federal Register, July 7, 1976 (41 FR 27902), and the RAC's proposed revisions (PRG-RAC) as published in the Federal Register, Sept. 27, 1977 (42 FR 49596).

the revised guidelines [have] the intent of erring on the side of caution." While believing that the guidelines are, and should be, deliberately restrictive, I agree with the criticism that scientists should not enter into an activity with the intent of erring. The PRG-NIH now reflects this opinion by deletion of this phrase.

Another commentator suggested that the guidelines should contain language requiring all publications dealing with recombinant DNA activities to include a description of the physical and biological containment procedures used. While the PRG-NIH urges "that all publications dealing with recombinant DNA work include a description of the physical and biological containment procedures employed," NIH is not well advised to dictate to researchers or editors what must be included in a scientific publication.

There were several suggestions that the purpose of the guidelines be more clearly stated and that terms be more precisely defined. I have, therefore, added considerable new material to Part I of the PRG-NIH, renamed "Scope of the Guidelines," and divided it into the following sections, each of which is discussed further below: Purpose; Definition of Recombinant DNA Molecules; General Applicability; Prohibitions; Exemptions; and General Definitions.

Purpose

The introduction to the 1976 guidelines states that "the purpose of these guidelines is to recommend safeguards for research on recombinant DNA molecules." As noted above, to eliminate "naked" recombinant DNA from the guidelines, the PRG-RAC proposed this passage to read that the purpose is to "establish procedures for handling organisms and viruses containing recombinant DNA molecules."

This proposed revision would have had the effect of removing from coverage by the guidelines certain experiments which are prohibited by the 1976 guidelines—for example, deliberate formation of naked recombinant DNA containing genes for the biosynthesis of potent toxins. I have decided to resolve this issue conservatively. The language in the PRG-NIH, therefore, clearly states that the guidelines are intended to pertain to the construction and handling of naked recombinant DNA molecules as well as of organisms and viruses containing such molecules.

General applicability

Many commentators urged that a statement of general applicability of the guidelines be included in an early part. The issues relate to (1) the applicability of the guidelines to non-NIH funded research with recombinant DNA at institutions receiving NIH funds for this purpose, (2) the applicability of the guidelines to NIH-supported recombinant DNA research conducted in foreign countries, and (3) the location of responsibility for insuring compliance with the guidelines. Therefore, a section entitled "General Applicability" now appears after the "Purpose" section in Part I of the PRG-NIH.

The existence of guidelines for recombinant DNA research assumes their general application. Partial adherence within an institution would defeat the purpose of extending maximal protection to the community. Thus, it would be inconsistent for NIH to provide funds for biomedical research activities to an institution that did not meet the standards of the guidelines in all of its recombinant DNA research, regardless of the source of funding. This principle is now stated explicity in the PRG-NIH, and we intend to consider withholding NIH funds as a sanction against violation.

Rules must be established for the conduct of recombinant DNA activities funded by NIH in other countries. Generally, the requirements in force in those countries shall apply. A memorandum of understanding and agreement (MUA) must still be filed with NIH, indicating specifically which guidelines will govern the activities; and NIH reserves the right to withhold funding if the safety practices to be employed are not comparable to the NIH guidelines. An explicit statement about this has been inserted in the PRG-NIH.

Part IV of the PRG-NIH describes the responsibilities of all individuals and organizational entities involved in the conduct and review of a recombinant DNA activity. Two years of experience with administering the NIH guidelines has indicated that the ultimate responsibility for insuring compliance must be borne by the institution where the research is being done. This implies some discretion under well-defined limits for interpretation of common standards, and imposes a requirement for local expertise other than the investigator's. Accordingly, Part I of the PRG-NIH now requires that an individual receiving NIH support for recombinant DNA research be associated with an institution that is willing and able to accept the responsibilities and conditions of local governance, described more fully in Part IV of the PRG-NIH.

Definition of recombinant DNA molecules

It became apparent from the comments received that the PRG-RAC definition was inadequate in that it did not address the handling of recombinant DNA molecules containing segments of chemically synthesized DNA. I have decided that the most effective way to achieve this objective is simply to include "natural or synthetic DNA" in the definition of a recombinant DNA molecule, and this has been inserted in the PRG-NIH definition. A new section, therefore, has also been added to Part III of the PRG-NIH giving containment levels for work with recombinant DNA molecules containing synthetic DNA.

I have also revised what I perceived to be an ambiguity in the PRG-RAC definition by including within the PRG-NIH definition language explicitly stating that DNA molecules which result from the replication of recombinant DNA molecules are subject to the safety provisions of the guidelines.

Finally, no other provision of the PRG-RAC definition evoked as much comment as did the wording to exclude "non-novel" recombinant DNA from the standards. The ambiguity of such phrases as "known to exchange chromosomal DNA" and "by natural physiological processess" was strongly noted, and I agree with the commentators that we must strive for a greater degree of clarity and objectivity. Thus, it has been decided to eliminate in the PRG-NIH the two conditions cited above as criteria for exemption from the guidelines. Staff discussions of the public comments made it clear that inclusion of exemption provisions within the definition itself was not desirable. Several attempts at appropriate language did not bear careful scrutiny.

Given this situation, and also my opinion that certain categories of recombinant DNA experiments are indeed so apparently free of causing harm that they should not come under the guidelines, it was my decision to remove the criterion of "novelty" from the definition and use it as a basis for the development of a new section entitled "Exemptions."

Exemptions

The nature of the public comments on the PRG-RAC exclusion of nonnovel exchangers can be divided into categories—those that pertain to the proposed standards and those to the proposed process.

The standards proposed by the PRG-RAC were that novel recombinant DNA's are those consisting of "segments of any DNA from different species not known to exchange chromosomal DNA by natural physiological processes * * * In general recombinant DNA molecules * * * will not be considered novel when all the components are derived from genomes known to replicate within the organism used to propagate the recombinant DNA." This is qualified, however, by a footnote stating that the "recombinant DNA formed between segments of eu-

karyotic viral DNA and any eukaryotic DNA * * * shall not be excluded * * * until such time as there is more information about the extent of naturally occurring recombinational events between these DNAs."

The public comments on these standards raised the following issues:

● That safety rather than novelty should be the criterion for exclusion; that is, any recombinant DNA molecule that poses a threat to the public health or the environment should be covered by the guidelines regardless of whether the molecule is a novel one.

● Others argued that the proper criterion should not be safety but rather whether the potential hazard of the recombinant DNA molecules differs significantly in degree or in kind from those found in nature or from biohazards that are successfully handled by conventional methods.

○ That there is a question of quantification that goes beyond novelty; that is, a recombinational event that occurs very rarely in nature can be mimicked more frequently in the laboratory.

● That the PRG-RAC was ambiguous in describing the criteria to be used in judging novelty.

● That the list of nohnovel exchangers should not be limited to the exchange of chromosomal DNA, but should also include plasmid DNA exchange.

● That the list should not be drawn broadly at the species level, but should deal with exchange at subspecies levels.

● That footnote 1 of the PRG-RAC unjustly discrimated against natural recombinants involving eukaryotic viral DNA and other eukaryotic DNA. Others urged that this footnote be expanded to ensure that recombinants involving pathogenic bacteria not appear on the list.

○ That experiments classified as P1+EK1 be exempted from the guidelines. Apparently harmless experiments do not warrant the administrative burden that accompanies inclusion within the guidelines.

● That it was unclear whether the PRG-RAC definition woud permit "self-cloning" experiments (such as the cloning of *B. subtilis* genes in *B. subtilis*).

It proved impossible to reconcile these differences of opinion in the definition itself, but in my opinion the "Exemptions" section of the PRG-NIH as drafted does so successfully. This section was drafted by NIH staff in conjunction with a working group of the RAC; it was then modified slightly and endorsed by the full RAC at its meeting on April 27-28, 1978, and subsequently modified slightly for clarity by NIH staff. Before proceeding to a discussion of these exemptions, however, I want to emphasize that no provision in this section may be cited to exempt from the guidelines an activity listed in the "Prohibitions" section.

The first exemption concerns recombinant DNA molecules that are not in organisms or viruses. This is in recognition that "naked" DNA, which is rapidly inactivated in nature, is extremely unlikely to be hazardous under experimental conditions. To guard against the remote possibility, however, that potentially harmful naked recombinant DNA will be incorporated into an organism, the handling of certain naked recombinant DNA molecules described in the "Prohibitions" section remains prohibited. It should also be noted that the concept of extremely low hazard of naked recombinant DNA was included in the PRG-RAC in the section on "Handling Recombinant DNA Molecules" at the end of part III. This language, I believe, is more appropriately presented under the "Exemptions" section.

The second exemption pertains to recombinant DNA molecules consisting entirely of DNA segments from a single nonchromosomal or viral source. This statement clarifies a category of "self-cloning" experiments that are considered safe enough to be excluded from the guidelines. This is a concept which the RAC tried to convey in the PRG-RAC definition by use of the phrase "different genomes," but which some commentators found ambiguous.

The third exemption concerns "self-cloning." It exempts from the guidelines recombinant DNA molecules made entirely from the DNA of a single organism including the plasmids, viruses, mitochondria, or chloroplasts indigenous to (i.e., found in nature in) that organism, when propagated only in that organism (or a closely related strain of the same species). This partially responds to the suggestion made by many commentators that experiments previously classified as P1+EK1 be excluded from the guidelines. It also covers some of the cases the RAC was including in the concepts of "novelty" and "different genomes." This exemption, however, does not include recombinant DNA molecules formed between viral DNA and eukaryotic host DNA. In this regard it is analogous to footnote 1 of the PRG-RAC.

The fourth exemption covers "certain specified recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes." In this case a list is prepared and periodically revised by the Director, NIH, on the recommendation of the RAC, after appropriate notice and opportunity for public comment. This list is analogous to the list of "nonnovel exchangers" proposed in the PRG-RAC.

The initial entries on the list specified under exemption I-E-4 are given in appendix A to the guidelines. Any recombinant DNA molecules composed entirely of DNA segments coming from organisms listed in appendix A, would be exempt from the PRG-NIH under exemption I-E-4. The inclusion of the particular organisms listed in appendix A was recommended by the RAC at its meeting on April 27-28, 1978. (For further discussion of this list see appendix D to the accompanying Environmental Impact Assessment.)

The fifth exemption allows the Director, NIH, on the recommendation of the RAC, after appropriate notice and opportunity for public comment, to exempt other classes of recombinant DNA molecules if he finds that "they do not present a significant risk to health or the environment." The exemption of classes of experiments that do "not present a significant risk to health or the environment" is the language used in proposed legislation (H.R. 11192), recently reported out of the committee on Interstate and Foreign Commmerce and the Committee on Science and Technology of the U.S. House of Representatives.

In addition to comments pertaining to the standards for exemption in the PRG-RAC, the following comments were directed toward the processes whereby exemptions would be made:

● Rather than compile a list of nonnovel exchangers exempt from the guidelines, the burden of proof should be on the Director, NIH, to compile a list of novel exchangers which are subject to the guidelines.

● The procedures and critieria used in the development of the list should be explained thoroughly, and adequate opportunity should be given for public review and comment.

○ Before being placed on the list, all the data pertaining to the application should be available for public review.

In response to these comments, the PRG-NIH specifies, that for exemption I-E-4 and I-E-5—the two exemptions which involve the development of "lists"—these lists will be prepared by the Director, NIH, on the advice of the RAC, *after appropriate notice and opportunity for public comment.* Publication of the PRG-NIH includes appendix A giving an initial proposed list for exemption I-E-4. As part of the public comment which I am soliciting on the entire PRG-NIH, I include appendix A. In the future, no additions will be made to appendix A, nor will any items be listed as exemptions under exemption I-E-5, without ap-

propriate notice and opportunity for public comment.

Prohibitions

Two changes in this section have been initiated to make it more compatible with the new "Definition" and "Exemptions" sections. The first was to transfer this section from part III of the guidelines to part I. This is again to emphasize that the exemptions are not applicable to the six activities listed as being prohibited. The second was to drop all references to novel recombinant DNA's and natural genetic exchange. My other actions were based upon the following comments:

● There was general endorsement of the provision in this section which grants to the Director, NIH, upon the recommendation of the RAC, the authority to waive any of the prohibitions. The widespread support for this authority reflects the realization that many important risk-assessments experiments may not be able to proceed otherwise. NIH is now supporting and will continue to support experiments that will yield knowledge contributing to a better understanding of the nature of potential risks of recombinant DNA. This section has been expended in the PRG-NIH to indicate that if any experiments are excepted from the prohibitions, they will "at that time be assigned appropriate levels of physical and biological containment."

● It was urged that the advice of other Government agencies, such as the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA), should be sought when the Director, NIH, considers invoking this waiver authority. The Federal Interagency Committee on Recombinant DNA Research provides for coordination of policies in this area. EPA and OSHA are represented on the Committee. The advice of relevant research and regulatory agencies will continue to be sought when appropriate.

● It was suggested that the RAC as presently constituted should not be the sole advisory body because societal as well as scientific considerations must enter into the waiver decision. As explained in greater detail in part IV of this document, the membership of the RAC will be broadened modestly as needed for expertise, but provisions for public notice and opportunity to comment, and other appropriate adminstrative practices, can be used to ensure adequate public input when the issues warrant.

● It was suggested that an Environmental Impact Assessment or Statement should accompany each waiver. My waiver decisions will include a careful consideration of the potential environmental impact, and certain decisions may be accompanied by a formal assessment or statement. This must be determined on a case-by-case basis.

● It was suggested that waiver of the prohibition on the large-scale use of culture containing recombinant DNA's be issued on the basis of industry's experience in dealing with such cultures. While such experience will surely be weighed in the decisionmaking, I believe that it should not be the sole criterion for granting such a waiver.

● Agricultural scientists noted the importance to their research community of being allowed eventually to release organisms containing recombinant DNA into the environment. When the original guidelines were presented to me in draft form in 1976, the release of organisms containing recombinant DNA molecules into the environment was to be allowed if a series of controlled tests had been done to leave no reasonable doubt of safety. At that time I rejected this waiver provision because of the limited scientific evidence available that any of the potential benefits from such a release were near realization.

The prohibition of deliberate release into the environment of recombinant DNA-containing organisms can be waived if all of the requirements for a waiver are met (and if the requirements of the National Environmental Policy Act are considered). Given the limited experience of NIH in agricultural research, the U.S. Department of Agriculture would be deeply involved in this process. I have given written notice of this opinion to the appropriate officials of the USDA.

● The Standing Advisory Committee on Recombinant DNA Research of the European Molecular Biology Organization (EMBO) has noted that the list of pathogenic organisms under prohibition I-D-1, especially those in class 5, may not be appropriate for all European countries, and that "the decision as to which pathogenic orgamisms should be classified as too dangerous to use must be the responsibility of national or regional authorities." In response to this a footnote could be added to the guidelines stating that prohibition I-D-1 relates only to research in the United States. I have decided, however, not to include such a footnote, because these guidelines are directed to NIH grantees and contractors, almost all within this country. In other countries, different criteria may govern.

● A final change in the PRG-NIH relates to prohibition I-D-1. As discussed below in this document in part III, considerable changes have been made in the sections dealing with the use of viral DNA in recombinant DNA experiments. The history leading to these changes, including the report of the "Ascot" workshop (appearing as appendix E to the accompanying Environmental Impact Assessment) and the report of the working group held on April 6-7, 1978 (appearing as appendix F to the accompanying Environmental Impact Assessment), are discussed in detail in part III of this document under the heading "Recombinant DNA Experiments Involving Viral DNA."

One of the Working Group's recommendations, arising out of the "Ascot" report and endorsed by the RAC at its April 27-28, 1978, meeting and endorsed by me, is that the previous prohibition on the use in recombinant DNA experiments of Vesicular Stomatitis Virus (VSV) and of oncogenic viruses classified by the National Cancer Institute (NCI) as "moderate risk" should be lifted; instead, use of these viruses should be permitted under containment conditions to be specified in part III of the guidelines. The reasoning behind this is that recombinant DNA experiments with pieces of these viruses cloned in *E. coli* K-12 pose no more risk, and actually appear to pose clearly less risk, than work with the whole infectious virus itself. Since the Center for Disease Control (CDC) and NCI recommend that work with these whole viruses not be prohibited, but rather be performed under containment conditions similar to P3, there is no scientific reason to prohibit recombinant DNA work with these viruses.

Therefore, prohibition I-D-1 in the PRG-NIH no longer prohibits the use of VSV or oncogenic viruses classified by NCI as moderate risk; containment conditions for their use are specified in part III of the guidelines.

General Definitions

In response to commentators' suggestions that terms be more precisely defined, I have added a new section to the PRG-NIH with such definitions. Many of these terms are further discussed in part IV of PRG-NIH.

In summary, part I of the PRG-NIH has been extensively modified from that proposed in the PRG-RAC. In an effort to be responsive to the suggestions of commentators and to make the guidelines more comprehensible, the definition of recombinant DNA molecules has been simplified and clarified, the "Prohibitions" section has been transferred from part III to part I, and new sections have been added to part I including "Exemptions." part I, now entitled "Scope of the Guidelines." is composed of the following sections:

● Purpose

● Definition of Recombinant DNA Molecules

- General Applicability
- Prohibitions
- Exemptions
- General Definitions

It should be noted that the Prohibitions appear before the Exemptions. This will again emphasize the fact that the latter provisions cannot be used to claim relief from the former.

II. Containment

The object of these revised guidelines is to insure that experimental DNA recombination will have no ill effects on the researchers, on the general public, or on the environment. The essence of their construction, as in the case of the 1976 Guidelines, is subdivision of potential experiments by class, and assignment to these of certain procedures for containment.

Containment is both physical and biological. *Physical* containment involves the isolation of the research by procedures that have evolved over many years of experience in laboratories studying infectious micro-organisms. P1 containment—the first physical containment level—is that used in most routine bacteriology laboratories. P2 and P3 afford increasing isolation of the research from the environment. P4 represents the most extreme measures used for containing virulent pathogens, and permits no escape of contaminated air, wastes, or untreated materials. *Biological* containment is the use of biological agents that are crippled by mutation so as to be incapable of surviving under natural conditions.

Physical Containment

Review of RAC-Proposed Guidelines

Two major changes were proposed in the physical containment section of the PRG-RAC. One deals with the organization of the section; the other incorporates into the PRG-RAC the philosophy and guidance of the report of the NIH European Molecular Biology Organization (EMBO) Workshop on parameters of physical containment.[2]

Physical containment requirements for each P level have been organized under the topic headings *Laboratory Practices, Containment Equipment,* and *Special Laboratory Design.* This was done to emphasize the importance of laboratory practices and containment equipment in achieving the desired safety objective.

Other revisions contained in the "Physical Containment" section reflect a conscious effort to encourage international uniformity with respect to recombinant DNA guidelines. This has been achieved by revising the containment descriptions so that they are consistent with the guidance provided in the NIH/EMBO report. In addition, some statements have been rewritten and others added in order to clarify the basic requirements for each level of containment. The most significant clarifications were made in the areas on containment equipment and special facility design. The revisions, however, have not resulted in changing the purpose or intent of the physical containment descriptions in the 1976 Guidelines.

Two specific additions to the Guidelines that originated from the NIH/EMBO report are particularly notable. The first is that Tables I and II have been added to the P3 and P4 sections, respectively. These tables show combinations of safeguards that provide similar protection. The combinations are dependent on the level of biological containment. This approach allows flexibility in selecting containment equipment for a particular study without compromising safety.

The second specific addition is the inclusion of laboratory design criteria for an area in which personnel wear positive-pressure suits ventilated by life-support systems. This added approach provides a level of physical containment equivalent to that afforded by the glove-box cabinet requirement at the P4 level.

Other important changes are summarized below:

- Certain specific microbiological practices are mandated at the P1 level in the PRG-RAC (whereas in the 1976 Guidelines they were merely encouraged);
- At the P2 level, prohibitions against eating, drinking, smoking, and storage of foods have been extended from the work area to the entire laboratory;
- The universal biohazard sign is now required at the P2 level. Use of these signs has been extended to equipment such as freezers and refrigerators in which organisms containing recombinant DNA molecules are stored;
- Access procedures in controlled areas adjacent to P3 laboratories have been specified;
- Installation of foot-, elbow-, or automatically-operated facilities for washing hands is now required in P3-level laboratories;
- Specific guidance on containment equipment appropriate for laboratory animals has been added to the P3 and P4 sections;
- The labeling requirements for shipment of etiologic agents now apply to all organisms containing recombinant DNA molecules. Thus, the Center for Disease Control, U.S. Public Health Service, must be notified in the event of any accidental breakage during shipment. Also, agents requiring P4 containment must be packaged according to strict Federal standards and be shipped by registered mail or an equivalent system that provides for notifying the shipper upon delivery.

I have carefully reviewed the recommendations of the PRG-RAC relating to physical containment and propose to adopt them with certain modifications. The modifications, based on issues raised by the Director's Advisory Committee and public commentators, are discussed below.

Review of comments and NIH-proposed guidelines

As reported in the "Decision Document" which accompanied the release of the 1976 guidelines, comments on the containment provisions of the original Guidelines were directed to the definitions of both physical and biological containment and to the safety and effectiveness of the prescribed levels. Several commentators at that time found the concept of physical containment imprecise and subject to human error. Others questioned the concept of biological containment in terms of its safety and purported effectiveness in averting potential hazards. The commentators were divided on which method of containment would provide the most effective and safe system.

Several suggested that each of the physical levels be explained more fully. The physical containment section of the 1976 guidelines—and now of the PRG-NIH—is directly responsive to many of these commentators. In addition, the PRG-NIH takes into account the more recent comments related to standards for physical and biological containment. Commentators on the PRG-RAC have expressed particular concern over (1) the flexibility which allows various combinations of containment safeguards, (2) the design of containment systems, and (3) the adequacy of training in laboratory safety practices. The Standing Advisory Committee on Recombinant DNA Research of the European Molecular Biology Organization (EMBO) made a number of recommendations that NIH has considered, and public commentators have proffered additional suggestions relating to specific levels of physical containment and to shipment of recombinant DNA materials. These are examined below.

Concept of "Flexibility." Some commentators have expressed concern over the flexibility provided in Tables I and II that allows various combinations of containment safeguards. For

[2] The "Report of the NIH/EMBO Workshop (Parameters of Physical Containment)" may be obtained from the Office of Research Safety, National Cancer Institute, Room 3E47, Building 13, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014.

example, some feel that work in a P3 facility conveys a desirable sense of hazard, whereas a reduction to the P2 level will promote an undesirable relaxation of vigilance. it has also been suggested that an increase in the options increases the difficulty of control and implementation of the guidelines. Some commentators object to specific options provided at the P3 and P4 levels. NIH has been urged to include a better explanation of the rationale for this flexibility.

Indeed, the calculus of switching physical and biological containment levels has been questioned. Does an increase in biological containment from EK1 to EK2 truly compensate a reduction in physical containment from P3 to P2?

The scale of either form of containment from least to greatest is not necessarily linear, and substitutions are only roughly approximate. Nevertheless, there are some numerical bases for comparison.

For example, a class III biological safety cabinet is required at the P4 level (if a positive pressure suit is not used); whereas at P3, one can work in an open-front biological safety cabinet. The class III cabinet is virtually an absolute containment system. It is certified gas-tight when tested under positive pressure. It is operated under negative pressure to gain optimum safety. It provides at least a 10,000- to 100,000-fold increase in safety over that provided by a Class I or II cabinet, which is required at the P3 level.

The relative safety of these two containment cabinets is based on the efficiency of their exhaust-air treatment systems. The exhaust-air treatment for the class III cabinet is provided by two HEPA filters installed in series. This arrangement gives a containment efficiency of at least 99.99 percent. The exhaust-air treatment for class I and II cabinets, with only one HEPA filter, provides a containment efficiency of 99.99 percent. The potential for escape of microorganisms across the open front of the class I and II cabinets is similar to that for escape through the exhaust-air treatment system under operating conditions. These cabinets must meet a performance criterion which permits fewer than 20 microorganisms to escape through the open front when 1×10^8 (100,000,000) to 8×10^8 (800,000,000) microorganisms are experimentally released within the cabinet. The degree of protection provided by the class I or II cabinets is equivalent to the increase in safety at the P3 level over that provided at the P1 level which allows open-bench operations.

The symbol HV (Host-Vector) is used in the PRG-NIH to designate biological containment systems encompassing the present EK systems. HV2 is defined in terms of a probability of escape of recombinant DNA of less than 1 in 10^8 (1 in 100,000,000). In considering "equivalency" between P and EK levels, it is recognized that the two systems are conceptually different. Biological safety cabinets are designed primarily for the protection of the laboratory worker, and all physical containment protection stops at the walls of the laboratory. Biological containment continues to operate even were an organism to escape from the laboratory.

The flexibility allowed in alternate P and HV levels is carefully explained in the text of the PRG-NIH, and the investigator must follow the explicit requirements set forth in Part III of the proposed guidelines and Tables I and II.

Redundancy. A question has been raised concerning redundancy in the safety systems to insure that alternate systems will come into play in case of an emergency—for example, power failures or major accidents. The concept of redundancy is inherent in the design of the containment systems used in recombinant DNA research. Redundancy, however, is provided by standby systems, but rather by design features and operational requirements of the safety systems used. For example, primary containment at the P4 level is provided by the gas-tight class III cabinet system. These cabinets are also maintained under negative air pressure, which would provide protection against the release of microrganisms in the event that a glove were to rupture or a leak to develop. Similarly, the physical isolation of the class III cabinet would not be compromised in the event of a power failure. However, since the redundant protection provided by the negative pressure would be compromised, personnel would be instructed to stop work immediately during the power interruption. Another example is the requirement that the exhaust and supply fans for P4 facilities be interlocked. This assures that in the event of failure of the exhaust fan, the supply fan will automatically shut down, preventing the pressurization of the laboratory environment. As with the class III cabinet example, personnel would stop their work because of the loss of secondary protection provided by the ventilation systems. Operational procedures, therefore, become an important element in assuring safety in the event of any system failure.

Institutions are required to devise emergency plans to handle possible problems. In response to recommendations of the Environmental Protection Agency Study Group on Recombinant DNA and to concerns raised by commentators, NIH has stipulated more clearly (in the supplement to the PRG-NIH entitled, "Laboratory Safety Monograph") certain elements in these emergency plans. Moreover, NIH staff have recently met with representatives of the center for Disease Control (CDC) to establish a mechanism for providing advice, consultation, or assistance, if necessary, in case of an emergency, such as an accident in the laboratory.

Laboratory safety. A number of commentators felt that the PRG-RAC was vague in regard to the training in safety of researchers, students, and janitors. It was urged that specific curricula be developed and that a requirement for certification of training be stipulated in the guidelines (a recommendation also made by the EPA Study Group on Recombinant DNA). It has been suggested, further, that NIH develop curricula for training.

At the present time, NIH has a contract with the American Society for Microbiology (ASM) to develop minimum standards for training participants in recombinant DNA research. The ASM Working Panel will consider what standards of training in microbiologic techniques are appropriate for the conduct of experiment requiring P1 through P3 containment conditions. The Panel will solicit views from the scientific community to develop minimum requirements for training. The Panel's report will be made available to the IBC's and investigators to set standards for all who participate in this research. In view of these developments, formal certification requirements by NIH are considered premature.

Other commentators stressed the need for more stringent measures in regard to safe practices. In particular, these commentators urged regular monitoring of laboratory facilities, preferably at all P levels. This would include monitoring of microbiological practices, serological monitoring, and CDC review of incidence of infections. It was also suggested that regular inspections be performed by individuals not associated with the institution (to preclude conflict of interest); that the guidelines require a member of the work force to be represented on the institutional biosafety committee; and that penalties (other than cutoff of funds) be imposed on violators as a deterrent. I have accepted many of these proposals; the specific NIH actions in regard to them are discussed in Part IV of this document.

Appendix D, "Supplementary Information on Physical Containment," was added to the 1976 guidelines in response to numerous requests for greater specificity in describing containment requirements. Commentators noted the absence of this document from the PRG-RAC and urged that it be retained and further expanded. Ac-

cordingly, a special committee of safety and health experts was convened by W. Emmett Barkley, Ph. D., Director of the Office of Research Safety, National Cancer Institute, to review and revise this supplementary information. Several sections have been extensively rewritten, and new sections have been added on evaluation methods for P3 facilities, certification procedures for P4 facilities, certification of biological safety cabinets, emergency control procedures, medical surveillance programs, and other topics. This document is separately available as "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research."

Other comments. A number of additional comments have been received from public commentators relating to proposed actions at specific levels of physical containment.

It has been suggested that certain requirements at the P1 level remain "permissive" rather than be changed to "mandatory"; i.e., that the language in the PRG-NIH read "should" rather than "shall." NIH considers this inconsistent with the stated principle of specifying requirements, and has therefore mandated adherence to these good microbiological practices.

The EMBO Standing Advisory Committee on Recombinant DNA Research has recommended that simple air exhaust cabinets be used at the P1 level when there is likelihood of producing large amounts of aerosols. In the view of NIH such cabinets are unnecessary, as the agents used at this level would not create aerosols hazardous to laboratory workers.

A recommendation has been received from the EMBO Standing Advisory Committee on Recombinant DNA Research to reclassify P2 with a class III cabinet as equivalent to P3 specifications. While this option was permitted in the 1976 guidelines, it is no longer considered practical. The cost of fabricating and installing class III cabinets would far exceed the cost of installing a new exhaust-air system for the laboratory. It is considered more cost-effective and desirable to convert P2 laboratories into P3 laboratories. The elimination of the 1976 option should be viewed as an encouragement to upgrade laboratories.

It has been observed that many class II safety cabinets do not meet accepted standards. A recommendation has been made that the local IBC be authorized to certify these cabinets, and that such a requirement be included in the guidelines. It should be noted that the guidelines already authorize IBC's to certify safety practices and procedures; however, to respond more directly to the above suggestion, a special section on certification of biological safety cabinets has been included in the supplement to the PRG-NIH entitled "Laboratory Safety Monograph."

The EMBO Standing Advisory Committee on Recombinant DNA Research observes that in the case of a P3 facility, the proposed revisions do not speak to precautions against the contamination of the main water supplies by laboratory water systems. It is noted that building codes and laboratory design standards require that precautionary measures be taken to separate potable water systems from laboratory process water. Additional precautions have been required at the P4 level. Standard design practice is felt to be appropriate at the P3 level.

Some commentators have pointed out that the PRG-RAC did not require an autoclave in the P3 laboratory itself, but only within the building. The 1976 guidelines require that for P3 laboratories an autoclave be available "within the building and preferably within the controlled laboratory area." Some believe an autoclave in the P3 laboratory should be required. One commentator felt that the autoclave should be "as close as possible" to the controlled area of the P3 laboratory, not merely available in the same building. He pointed out that from an operational point of view, the closer the autoclave can be to the solid waste, the better. This is especially true in the larger medical research complexes, where transport of wastes from the laboratory to the autoclave might involve passage "via some rather sensitive patient areas of the institution." He prefers that the autoclave be located either in the controlled area or as close to it as possible, with such explicit language in the guidelines. The language in the 1976 guidelines stating that in a P3 laboratory "an autoclave shall be available within the building and preferably within the controlled laboratory area" has been reinserted in the PRG-NIH. However, an absolute requirement that the autoclave must be within the controlled area is not considered appropriate, since contaminated materials can be safely transported. Such a requirement would exclude the use of autoclaves in waste staging areas that have been conveniently sited to support an entire facility.

The PRG-RAC states that P4 work can be done in either (1) a class III cabinet system or (2) a class I or class II cabinet system in a special area where all personnel wear one-piece, positive-pressure suits. Some investigators apparently prefer use of pressure suits over work in the class III cabinets. NIH believes that the suits are especially useful in working with experimental animals in a P4 facility or with large amounts of material. At present, however, most recombinant DNA studies are handled more practically in a class III without need for a suit.

In 1976, several commentators advocated that NIH arrange for sharing of P4 facilities, both by investigators from the NIH intramural program and from institutions supported through NIH awards. In response to these suggestions and those of recent commentators, we have arranged to make our recently established P4 facilities at the Frederick Cancer Research Center (Fort Detrick) available to outside scientists.

Shipment. Some commentators have urged that stricter controls be required on shipping recombinant DNA molecules in or out of the country. It has been recommended, for example, that shipping procedures differentiate between types of substances being transported. We wish to emphasize that requirements for shipping organisms that contain recombinant DNA molecules are consistent with relevant Public Health Service, Department of Transportation, and Civil Aeronautics Board regulations, and are also in compliance with the World Health Organization recommendations on the international shipment of biologic agents. It should be noted that organisms containing recombinant DNA molecules all require the same containment conditions as for the most hazardous known agents.

The EMBO Standing Advisory Committee on Recombinant DNA Research recommends that before a shipment is made, the recipients of organisms containing recombinant DNA molecules should affirm to the donors that they are following the safety standards and practices of their country. NIH considers this a sound recommendation and requires the following (as stated in the NIH Guide for grants and contracts):

All memoranda of understanding and agreement (MUA's) submitted with competing and noncompeting applications involving recombinant DNA research must indicate that the principal investigator (program director, fellow, or candidate) agrees to comply with the NIH Guidelines and other specific NIH instructions pertaining to the proposed project. Included in the provisions are the following pertaining to shipment or transfer or recombinant DNA materials:

A. Prior to shipment or transfer of recombinant DNA materials to other Federally funded investigators within the United States, the sending laboratory shall obtain a letter from the requesting laboratory stating that:

1. Research involving recombinant DNA molecules shall be conducted in compliance with the NIH Guidelines and other NIH instructions, and that the requesting laboratory shall not transfer the recombinant DNA materials to other laboratories;

2. The requesting laboratory has been reviewed by its Institutional Biosafety Com-

mittee which has certified that facilities, procedures, and the training and expertise of the personnel involved are adequate;

3. An approve MUA with a certification is on file with the funding agency of the requesting laboratory;

4. A copy of this letter is on file with the requesting laboratory's Institutional Biohazards Committee.

B. Prior to shipment or transfer of recombinant DNA materials to non-Federally funded investigators or institutions within the United States, the sending laboratory shall obtain a letter from the requesting laboratory stating items 1, 2, and 4 under A above.

C. Prior to international shipment of recombinant DNA materials, the sending laboratory shall obtain a statement from the requesting laboratory stating that research involving recombinant DNA molecules shall be conducted in accordance with the containment levels specified by the NIH Guidelines, or applicable national guidelines if such have been adopted by the country in which the research is to be conducted, and that the requesting laboratory shall not transfer the recombinant DNA material to other laboratories.

D. The sending laboratory shall maintain a record of all shipments of recombinant DNA materials and shall provide NIH with a complete list of such shipments in the annual progess report for NIH grants and contracts.

Mouth-pipetting at the P1 level. Both the 1976 guidelines and the PRG-RAC prohibit mouth-pipetting at the P2, P3, and P4 levels. For the P1 level, however, they state, "Although pipetting by mouth is permitted, it is preferable that mechanical pipetting devices be used. When pipetting by mouth, cotton-plugged pipettes shall be employed." A number of commentators have urged that mouth-pipetting be prohibited at the P1 level of physical containment. This is strongly endorsed by NIH safety experts, who point out that this is an important safety feature, and that efficient new mechanical pipetting aids should not greatly hamper researchers. Also, the EMBO Standing Advisory Committee on Recombinant DNA Research "believes that mouth pipetting should be prohibited in the P1 laboratory, as it is prohibited in P2-P4 laboratories." In addition, the Working Group of American virologists which met on April 6-7, 1978, to review the report of the U.S.-EMBO Workshop to Assess Risks for Recombinant Experiments Involving the Genomes of Animal, Plant, and Insect Viruses[1] wrote the following in their report:

> In its deliberations, the Working Group was impressed with the safeguards afforded by a ban on mouth pipetting for recombinant DNA experiments involving *E. coli* K-12 host-vectors. The group felt that the only plausible way *E. coli* K-12 could gain entry into laboratory workers was by oral ingestion. The analysis contained in the U.S.-EMBO Report was predicated on the remote possibility that *E. coli* K-12, containing eukaryotic viral DNA, would be swallowed and the viral DNA insert would be delivered to a tissue in the body which ordinarily would be inaccessible to the virus. A prohibition of mouth pipetting would clearly prevent this sequence of events from even beginning. The Working Group therefore recommended that no mouth pipetting be allowed at *any* level of physical containment (including P1) when working with *E. coli* K-12.

On the other hand, when I requested that the RAC, at their April 27-28, 1978, meeting reconsider whether mouth pipetting should not be banned at the P1 level, it was their consensus that many experiments classified as P1 need not include a ban on mouth-pipetting, and that therefore P1 in general should not be redefined. Instead, they recommended that only certain classes of P1 experiments be designated as requiring no mouth-pipetting.

In resolving this issue, I have decided to adopt the conservative position and ban mouth-pipetting. Accordingly, language has been inserted in the PRG-NIH saying that at the P1 level, "Mechanical pipetting devices shall be used; pipetting by mouth is prohibited." Since mouth-pipetting had already been banned at the P2-P4 levels, this means that it is now banned for all experiments covered by these guidelines.

BIOLOGICAL CONTAINMENT

Review of RAC-proposed guidelines

Experiments on recombinant DNA's by their very nature lend themselves to applications of highly specific biological barriers as a means of containment. In fact, there are natural barriers that limit either the infectivity of a vector or vehicle (plasmid or virus) to specific hosts, or its dissemination and survival in the environment. Both the vectors whereby DNA is transferred to the recipient host and the host cells wherein it replicates can be designed genetically to decrease by many orders of magnitude the probability of dissemination of recombinant DNA outside the laboratory.

The proposed revised guidelines describe the categories of hosts and vectors to be used in minimizing the spread of organisms containing recombinant DNA. The PRG-RAC differs in some respects from the 1976 guidelines as a result of certain changes in definitions of HV systems and in the requirements at specific HV levels (notably HV3). A new section has been added on certification of host-vector systems.

Definitions of host-vector systems. A new nomenclature—HV1, HV2, and HV3—has been developed to incorporate a variety of hosts and vectors into the framework initially established for *E. coli* K-12. In particular, the PRG-RAC provides criteria for HV1 systems other than *E. coli* K-12. In the 1976 guidelines, cloning systems other than *E. coli* K-12 were to be considered only if superior to *E. coli* K-12 in containment properties; but it is now recognized that many useful experiments can only be conducted using HV systems other than those based on *E. coli* K-12, and that such experiments should be permitted so long as the proposed HV system provides equivalent biological containment. The new HV1 criteria provide a structure for approval of systems that meet these requirements.[3]

HV2 systems. AT the HV2 level of containment, there are no substantive changes comparing the 1976 guidelines with the PRG-RAC. However, the RAC, on June 23, 1977—the same day it approved the PRG-RAC—also adopted unanimously "Instructions to Investigators Concerning Data To Be Submitted on Host-Plasmid Systems Proposed for EK2 Certification." Although not officially part of the PRG-RAC, these instructions set forth criteria that any putative EK2 host-vector systems must meet before recommendation by the RAC for certification. The RAC applied these criteria in reviewing new systems (pBR322 and pBR313 in x1776) at the June 23, 1977, meeting, and will do so for all future submissions. It was made clear at the meeting that these criteria are definitely more stringent than previous ones, and this greater stringency means that EK2 host-vector systems approved now and to be approved in the future are even safer than those approved previously.

Requirements for HV3 systems. These have been made more stringent in the PRG-RAC than the corresponding requirements for EK3 in the 1976 guidelines. The PRG-RAC requires that the vector be dependent on its propagation host or be highly defective in mobilizability. "Reversion to host-independence must be less than $1/10^8$ per vector genome per generation." Also, the vector may carry no resistance to antibiotics used clinically or in agriculture. The provision that antibiotic resistance markers of medical or agricultural importance are not to be used in the vector should prevent any inadvertent advantage for recombinant DNA-bearing vectors that encounter antibiotics in the environment.

[1] The history of the U.S.-EMBO Workshop and the April 6-07, 1978, working group is discussed in detail in Pt. III of this document under the heading "Recombinant DNA Experiments Involving Viral DNA" and the report of the working group appears as App. E to the accompanying environmental impact assessment.

[3] Under the proposed revisions, HV1s other than *E. coli* K-12 need not offer a distinct advantage over *E. coli* K-12 host-vectors, need not be capable of modification to HV2 and HV3, and need not be class I etiologic agents.

Certification of host-vector systems. A new section has been added detailing the responsibility for certification of HV1, HV2, and HV3 systems, the types of data to be submitted, and the mechanisms for distributing strains once certified. The section delineates procedures used by the RAC for the past 2 years and therefore represents no change from practices under the 1976 guidelines.

Review of comments and NIH-proposed guidelines

I have reviewed the biological containment section of the PRG-RAC in the light of comments and suggestions made by participants of the Director's Advisory Committee (DAC) as well as written comments received before and afterward, and have adopted the recommendations of the PRG-RAC with some revisions. An analysis of the specific issues raised by commentators and the basis for my decision follow.

Development of Alternative Host-Vector Systems. Many commentators from the scientific community believe that the PRG-RAC discriminates against alternate host-vector systems other than *E. coli* K-12. They urge development of other systems, maintaining that new systems will be needed increasingly, both in pure research and in industry, and should be certified as soon as possible. It is unlikely, according to one commentator, that agriculture will best be served through the use of *E. coli* K-12 (or *B. subtilis*), and that alternate host-vector systems are therefore essential if the potential of recombinant DNA technology for agriculture is to be realized. In view of the support evident at the 1976 DAC meeting for NIH to encourage development of alternate host-vector systems, one commentator expressed disappointment that there was not now a large NIH contract program in this area.

Others view the introduction of alternate HV systems with some misgivings. It was pointed out, for example, that if uncertainty continues to surround research with so well-studied an organism as *E. coli* K-12, our ignorance must be that much greater with regard to any other organism—its ecological involvement, the organisms with which it can exchange DNA, etc. Moreover, the guidelines, which have been developed around the use of *E. coli* K-12, are primarily focused on dangers to man, and the introduction of new systems may affect other life forms with which we should be equally concerned. In the view of commentators who urge restraint, the larger the number of systems certified, the greater the problem of monitoring the work.

Clearly, however, research addressed to the development of other host-vector systems must proceed. This is particularly evident in the agricultural sector, where the potential for immediate benefits to man is great. At present, a number of alternate systems, including those using *B. subtilis* and *Saccharomyces cerevisiae*, are being developed by NIH grantees. The interest shown by numerous investigators in developing new host-vector systems means that NIH need not develop a special program to promote research in this area.

I appreciate and understand the concern of those who urge deliberate caution. I would stress that the same considerations of safety and risk associated with the use of *E. coli* K-12 will also apply to any new host-vector systems to be certified in the future.

Risk Assessment. Many commentators advocate more studies in risk assessment. It has been maintained that assumptions about biological containment may not be valid and that all components should be tested. Concern has been expressed that the biological containment safety systems may fail altogether.

Some risk assessment studies are prohibited by the 1976 guidelines. Under the PRG-RAC, however, the Director, NIH, on recommendation of the RAC, would have discretion to permit such risk assessment experiments by granting a waiver from a specific prohibition. There was virtually unanimous support for this discretion at the DAC hearing in December 1977. Of course, its exercise must be consistent with standards of due process for the scientific community and the public.

Risk assessment studies are proceeding both within and outside the United States. For example, the "polyoma" experiment,[4] which was delayed in this country because of litigation and the renovations necessary to meet the extremely stringent P4 requirements, has now begun here, and a similar experiment is proceeding in Europe. The work of Robin Holliday in assessing statistical probabilities of biological accidents is also noteworthy (see appendix P of the October 1977 Environmental Impact Statement).

NIH is committed to the conduct and support of risk analysis studies to determine the extent to which certain potentially harmful effects from recombinant DNA molecules may occur. It is intended that the NIH P4 facilities both in Bethesda, Md., and at the Frederick Cancer Research Center will serve as a focal point for many such studies. Provision has already been made to share these facilities with non-governmental scientists.

It should be stressed that prior to certification as EK2, each candidate EK2 host-vector system is analyzed in great detail by the RAC and NIH. Much data must be submitted, a good deal of which is risk assessment data.

Safety of E. Coli K-12. In 1976, there was considerable comment regarding the use of *E. coli* K-12 as a host, including recommendations that its use be prohibited. Some recent commentators have also questioned the safety of *E. coli* K-12, noting that the Falmouth Workshop proceedings had not been published for public review. On the other hand, one commentator urged that, base on the safety of *E. coli* K-12, essentially all experiments employing *E. coli* K-12, be exempted from the Guidelines. An extensive discussion of *E. coli* K-12 together with new scientific information on its safety are presented in part III of this document and in a special section of the Environmental Impact Assessment.

The proceedings of the Falmouth Workshop have now been published in the May 1978 issue of Journal of Infectious Diseases. Reprints are available from the Office of Recombinant DNA Activities, NIH, Bethesda, Md. 20014. As noted in a letter of July 14, 1977, from Dr. Sherwood Gorbach, moderator of the Falmouth Workshop and Chief of Infectious Disease and Professor of Medicine at Tufts University School of Medicine, "The participants arrived at unanimous agreement that *E. coli* K-12 cannot be converted into an epidemic pathogen by laboratory manipulations with DNA inserts."

Comments on Specific Containment Levels. One commentator sought clarification of section II-D-1-a of the PRG-RAC, which defines HV1. According to the second sentence, "The host should have a low potential for survival in its natural environment." As the commentator noted, "'natural environment' could be ambiguous, in practice. Presumably many of the host cells that people may wish to use have no natural environment other than the laboratory." I referred this comment to the RAC at its April 27-28, 1978, meeting. The RAC agreed that this sentence is ambiguous and recommended that it be deleted. I have done so in the PRG-NIH.

A question was raised on whether HV1 hosts could be wild type organisms or if they are always "meant to harbor containment mutations." If wild type organisms can qualify as HV1, then the definition of HV1 should be reworded to state this explicitly. The answer to the question is that if wild type organisms meet the criteria for HV1, they may be certified

[4] Two NIH virologists, Drs. Wallace Rowe and Malcolm Martin, are linking viral DNA from the mouse polyoma virus with the DNA of bacterial plasmids and bacteriophages and inserting this recombined DNA into a weakened strain of *E. coli*. The bacteria will then be injected into or fed to mice to determine the effects, if any, of the viral DNA.

as HV1. However, I see no need to modify the definition to state this explicitly.

One commentator thought the standards for HV1 should be significantly relaxed and that NIH approval should not be necessary. He proposed that the Guidelines state that "wild type isolets of any bacterial species not known to be pathogenic to humans, to domestic animals, or to agriculturally important plants may be used as an HV1 host-vector system, provided that all components of recombinant DNA molecules introduced into such a host-vector system, are derived from other prokaryotic organisms within Etiologic Agent Class 1." I have rejected this suggestion since I believe it prudent, at least for the present, to have higher standards and to require NIH approval before a system may be called HV1. Some commentators have urged that the requirement for independent confirmation of relevant phenotypic and genotypic traits before certification at the HV3 level should also be applied at the HV2 level. There are two objects of such testing: (1) To determine whether a system already approved has changed its characteristics before a new sample of it is distributed (for example, whether the amber mutations for phage systems are still present), and (2) to repeat independently all the safety tests required before each new system would be certified. The first could be done easily and is sufficient to confirm the safety characteristics; the second is cumbersome and difficult. It should be pointed out that the RAC and its working groups that review the data on proposed HV2 systems are, in effect, conducting an independent check and know this area of research well. Further, the Committee may request that additional experimental data be submitted as part of its review. NIH believes these controls to be sufficient. Consequently, the requirement for an independent check at the HV2 level is deemed unnecessary.

For the HV3 level of containment, some objections have been raised to the requirement banning antibiotic-resistance markers. Antibiotic resistance can serve as a valuable marker in experiments with organisms bearing recombinant DNA. The ban at the HV3 level, however, is prudent inasmuch as organisms rendered antibiotic resistant would be less amenable to control should they escape from the laboratory. This requirement also allows only a certain class of certified HV2 systems to qualify for HV3. Therefore, attempts to develop systems that meet these HV3 criteria should simultaneously upgrade the HV2 systems in use, since it is to the experimenter's advantage to use those HV2 systems with the greatest likelihood of meeting HV3 criteria.

Certification. A number of commentators have urged more precise criteria for biological containment systems. They feel that criteria should be as objective as possible and should be framed in terms of performance, as in the case of physical containment (for example, safety cabinets). It should be stressed that specific objective criteria do exist for EK2 host-vector systems. These, however, do not appear in the Guidelines themselves, but rather as information in the Environmental Impact Statement, Appendix H, entitled "Certification of EK2 Host-Vector Systems." To insure that detailed material on certification of host-vector systems is readily accessible, NIH will publish specific criteria in a standarized format in the *Recombinant DNA Technical Bulletin.* Specific instructions concerning the type of data to be submitted to NIH for proposed EK2 systems involving either plasmids or bacteriophage lambda in *E. coli* K-12 are available from the NIH Office of Recombinant DNA Activities, and a statement to this effect is included in the PRG-NIH.

Many problems persist for setting general criteria that could be applied to all organisms for possible certification as HV2 and HV3. For example, with *B. subtilis*, which forms spores, safety would depend on nonsporulating derivatives. Some commentators urged that all new systems be certified with deliberate caution, and that criteria and evidence should be a matter of public record before decisions are made. The *B. subtilis* system was cited as a case in point; extensive public analysis and debate should precede certification.

I agree that prior notification to the public in the FEDERAL REGISTER should be given when the RAC considers applications for certification. (It should be noted that all meetings of the RAC are announced in the FEDERAL REGISTER.) I also agree with the suggestion that the RAC should have a more fixed schedule of meetings throughout the year so that the public and scientific communities may know the schedule of events clearly.

The entire section (II-D-2-a) on responsibility for certification of host-vector systems has been rewritten in the PRG-NIH to clarify this process.

Distribution of Certified Host-Vectors. Some commentators have suggested that NIH distribute HV1 systems as well as HV2 and HV3 systems. Language has been placed in the PRG-NIH indicating that, where appropriate, HV1 systems other than *E. coli* K-12 may be sent by NIH to investigators.

Concern has been expressed about culture contamination and how this problem would be addressed. The PRG-NIH provides that if NIH propagates any of the host strains or phages, it will not distribute the culture before sending a sample to the investigator who developed the system or to an appropriate contractor for verification that "the material is free from contamination and unchanged in phenotypic properties." The PRG-NIH also assigns to the investigator the responsibility for "insuring the integrity of physical containment (e.g., biological safety cabinets) and biological containment (e.g., genotypic and phenotypic characteristics, purity, etc.)."

Distribution of certified host-vector systems has raised comment relating to the protection of proprietary information and patent rights, for this section of the Guidelines seems to mandate distribution and might conflict with patent protection. NIH has carefully considered such protection. Language has been included in the PRG-NIH (in section IV-C) allowing RAC review for certification at the request of the private sector. The language notes, however, that interested individuals should consider filing for patent protection before submitting information to DHEW. To be consistent with the institutional patent agreement policies of the Department of Health, Education, and Welfare, support is accorded the concept of protection of proprietary and patent rights within the bounds of due process for public review.

III. CONTAINMENT GUIDELINES FOR COVERED EXPERIMENTS

REVIEW OF RAC-PROPOSED GUIDELINES

A major concern of all individuals who have participated in establishing guidelines for recombinant DNA research is that any guidelines that are drafted and adopted be reassessed periodically and changes made when warranted by new information and/or experimental data. In keeping with this responsibility, the RAC compiled additional information pertaining to risk assessment in recombinant DNA research. This information is in the following forms:

1. Consultations with scientists with expertise in the areas of evolution, plant biology, bacteriology, virology, and human and animal infectious diseases;

2. Reports from scientific meetings dealing with the potential biohazards of recombinant DNA research (for example, the *Tenth Miles International Symposium on Recombinant Molecules—Impact on Science and Society,* Cambridge, Mass., June 1976; the *National Academy of Sciences Forum on Recombinant DNA Research,* Washington, D.C., March 1977; *Genetic Engineering for Nitrogen Fixation,* Brook-

haven, N.Y., March 1977; and the *Workshop on Studies for Assessment of Potential Risk Associated with Recombinant DNA Experimentation,* Falmouth, Mass., June 1977);

3. Results from experiments specifically designed to test (a) the survivability and colonizing ability of *E. coli* K-12 and EK2 host-vector systems, (b) the transmissibility of plasmids and phage vectors, (c) the potential of *E. coli* K-12 for pathogenicity, and (d) the potential of genetic exchange between diverse bacteria and between eukaryotic and prokaryotic organisms.

Each category of experiments in part III of the original guidelines was then extensively examined, applying the following criteria to the new information:

⊕ The degree to which the DNA segment has been purified away from other genes and shown to be free of harmful characteristics;

◑ The potential biohazard associated with the DNA of the cell or microorganism that serves as the DNA source (e.g., genes for toxin production);

⊕ The potential biohazard associated with the vector that serves to transmit the source DNA to a recipient host cell;

◑ The ability of the vector to survive in natural environments or habitats;

⊕ The kinds and number of different organisms that are susceptible to infection by the vector or recipient;

⊕ The potential biohazard of the recipient host cell that serves to replicate the recombinant DNA molecule;

⊕ The ability of the recipient cell to survive in natural environments of habitats;

⊙ The ability of the recipient cell to transmit the recombinant DNA molecule to other cells capable of surviving in natural environments or habitats;

⊙ The potential of the recipient cell to obtain the source DNA by natural means; and

○ The evolutionary relatedness of the DNA source to humans. The potential dangers are considered to increase as the organism providing the source DNA approaches humans phylogenetically. Thus, source DNA from primate cells is considered to have greater potential danger than source DNA from prokaryotes.

To present more clearly the changes in containment levels proposed by the PRG-RAC, a table was prepared for use at the December 1977 meeting of the Advisory Committee to the Director, which compared the containment levels in the PRG-RAC with those of the 1976 guidelines. This table has now been expanded with a third column to show the containment levels of the proposed revised guidelines which are now being proposed by NIH (called PRG-NIH). The table appears as appendix A to the accompanying Environmental Impact Assessment.

The remainder of this section summarizes a number of the proposed changes comparing the 1976 guidelines with the PRG-RAC. (Not all the changes are discussed here; certain items in which the PRG-NIH differs significantly from the PRG-RAC are considered below in the section entitled "Review of Comments and NIH Proposed Guidelines.") The numbers in parentheses indicated the line numbers on the table to which the proposed revision applies.

The principal changes reflected in the table are as follows:

● Several categories of experiments (primarily those involving prokaryotes that are exchangers of genetic information with *E. coli* in nature) are no longer subject to the provisions of the PRG-RAC due to the changes in the definition. (See lines 20, 21, 27, 46, and 47.)

● Shotgun experiments involving birds and mammals other than primates were the subject of lowering of containment from P3+EK2 to P2+EK2. This action reflects the increased confidence of the RAC in the EK2 host-vector systems. (See lines 4 and 5.)

● Another category which the RAC decided was in need of revision was that pertaining to the cloning of DNA from organisms producing a toxic product. This was clarified in the PRG-RAC by specifying whether or not polypeptide toxins are produced, and setting containment levels accordingly. Polypeptide toxins are specified, since they might be encoded by a single gene or cluster of genes. Toxins of other chemical structure would not result from a single gene or cluster of genes. (See lines 8, 9, 10, 11, 12, 16, 17, and 19.)

◑ For several categories of experiments, it is proposed that the investigator have the option of working at P2+EK1 or P1+EK2 rather than the P2+EK1 levels previously specified. This again reflects confidence in the EK2 systems. (See lines 7, 14, and 15.)

● The lowering of containment for experiments with rigorously characterized clones free of harmful genes was revised to provide more fexibility. Under the PRG-RAC, institutional biosafety committees (IBC's) would be able to lower containment by a single level. The IBC should consider the purity, extent of characterization, and harmlessness of the clone before allowing such lowering. Reduction of containment by more than one level would require approval by NIH. Under the 1976 guidelines, NIH had the option of lowering containment down to certain specified levels or not lowering it at all. The PRG-RAC would allow NIH to consider all available data for the clone and to lower containment accordingly.

In addition, the section now applies to rigorously characterized clones from any permissible experiment in *E. coli* K-12. Under the original guidelines, containment for *E. coli* K-12 clones containing characterized and harmless portion of viruses and plasmids could not be lowered.

The rationale for these proposed changes is explained in further detail in the Environmental Impact Assessment.

REVIEW OF COMMENTS AND NIH PROPOSED GUIDELINES (GENERAL)

Rationale

Part III of the guidelines received the most extensive comment of any section during the development of the original guidelines in early 1976. While there was also much discussion of this part in the PRG-RAC, the issues raised did not primarily address the proposed changes in the containment levels but more general topics such as the need for a rationale for each of the changes.

A number of commentators asked that the rationale for the classification of pemissible experiments be clearly spelled out. It was pointed out that (1) the part on permissible experiments is especially difficult for a lay person to understand, (2) the whole categorization is dependent upon investigatorial confidence rather than documented fact, and (3) the quantification of containment levels, the means by which the levels were decided, and the rationale for raising and lowering these levels are not clear.

In general, the classification may appear somewhat arbitrary, because it depends in large part on the scientific judgment of the RAC rather than on demonstrable risk, since there is actually no scientific evidence of hazard in any recombinant DNA experiment.

The rationale for classifying different recombinant DNA experiments at different containment levels was explained in the "Decision of the Director, National Institutes of Health, To Release Guidelines for Research on Recombinant DNA Molecules," which was published along with the current guidelines in the FEDERAL REGISTER on July 7, 1976, as follows:

> The guidelines assign different levels of containment for experiments in which DNA from different sources is to be introduced into an *E. coli* K-12 host-vector system. The variation is based on both facts and assumptions. There are some prokaryotes (bacteria) which constantly exchange DNA with *E. coli.* Here it is assumed that experimental conditions beyond those obtained in careful, routine microbiology laboratories are super-

fluous, because an exchange experiments have undoubtedly been performed already in nature.

In every instance of artificial recombination, consideration must be given to the possibility that foreign DNA may be translated into protein (expressed), and also to the possibility that normally repressed genes of the host may be expressed and thus change, undesirably, the characteristics of the cell. It is assumed that the more similar the DNAs of donor and host, the greater the probability of expression of foreign DNA, or of possible derepression of host genes. In those cases where the donor exchanges DNA with *E. coli* in nature, it is unlikely that recombination experiments will create new genetic combinations. When prokaryote donors not known to exchange DNA with *E. coli* in nature are used, however, there is a greater potential for new genetic combinations to be formed and be expressed. Therefore, it is required that experiments involving prokaryotic DNA from a donor that is not known to exchange DNA with *E. coli* in nature be carried out at a higher level of containment. Recombination using prokaryotic DNA from an organism known to be highly pathogenic is prohibited.

There are only limited data available concerning the expression of DNA from higher forms of life (eukaryotes) in *E. coli* (or any other prokaryote). Therefore, the containment prescriptions for experiments inserting eukaryotic DNA into prokaryotes are based on risks having quite uncertain probabilities.

On the assumption that a prokaryote host might translate eukaryotic DNA, it is further presumed that the product of that foreign gene would be most harmful to man if it were an enzyme, hormone, or other protein that was similar (homologous) to proteins already produced by or active in man. An example is a bacterium that could produce insulin. Such a "rogue" bacterium could be of benefit if contained, a nuisance or possibly dangerous if capable of surviving in nature. This is one reason that the higher the phylogenetic order of the eukaryote, the higher the recommended containment, at least until the efficiency of expression of DNA from higher eukaryotes in prokaryotes can be determined.

There is a second, more concrete reason for scaling containment upward as the eukaryote host becomes similar to man. This is the concern that viruses capable of propagating in human tissue, and possibly causing diseases, can contaminate DNA, replicate in prokaryote hosts and infect the experimentalist. Such risks are greatest when total DNA from donor tissue is used in "shotgun" recombinant experiments; it diminishes to much lower levels when pure cloned DNA is used.

The structure of the classification for permissible experiments is based, therefore, on assumptions governing potential risk. It should be emphasized again that although recombinant DNA experiments have now been performed for over five years in hundreds of laboratories throughout the world with hundreds of thousands of different recombinant DNA molecules produced, no case of hazard has been demonstrated.

Part III of the guidelines assigns to each specified class of experiments a level of physical containment and a level of biological containment at which the experiment shall be performed. As noted before, there is 10,000- to 100,000-fold protection in going from a class I or II biological safety cabinet to a class III biological safety cabinet (i.e., from P3 to P4). Similarly, in going from P1 to P3 there may be a 10,000- to 100,000-fold increase in safety. For biological containment, there is the criterion for HV2 systems that "escape of the recombinant DNA either via survival of the organisms or via transmission of recombinant DNA to other organisms should be less than $1/10^8$ under specified conditions." However, that criterion is not relative to the HV1 host-vector systems but absolute; thus, this might be a characteristic found for some host-vectors in the HV1 system, but it is mandated for all HV2 systems. This level was chosen, it was pointed out, because it represents a practical limit which one can measure experimentally.

Use of E. coli *K-12*

A number of comments were made concerning the use of *E. coli* host-vector systems. It was observed that because *E. coli* K-12 is currently a "poor" pathogen doesn't mean that it might not be converted to a "good" pathogen with the addition of one or two genes; the enfeebled nature of *E. coli* K-12 "is presumably the consequence of mutation(s) introduced during its laboratory passage," but that perhaps different strains of K-12 with different histories may not all be similarly enfeebled.

Further, it was claimed that the failure to convert K-12 to a pathogen by the use of certain plasmids or *Salmonella* genes is not definitive; to be definitive, we must have the detailed nature of the mutations in K-12 "which prevent the expression of pathogenicity." Also, it was noted that there is no way to assess the absolute risk associated with these experiments, and that it is important to assess the potential harm not only to man but to plants, animals, and the enviroment.

Another commentator urged that this section be supplemented with the evidence from the Falmouth Conference to show that the potential risk is minimal. A commentator cited the potential risk on the basis that "virtually any highly conserved physiologically active eukaryotic protein * * * or fragment thereof could be highly toxic when introduced out of context by a bacterium which received the appropriate gene in a recombination experiment." This criticism of the *E. coli* K-12 system does not detract from the scientific knowledge over the past two years of the great safety of this system. This evidence is presented in detail in the Environmental Impact Assessment. I agree that different strains of K-12 with different histories may not all be similarly enfeebled and that failure to convert K-12 to a pathogen to date does not prove it can never happen. However, the safety of *E. coli* K-12 has been clearly shown and there is no need to limit or specify particular strains for EK1. After 30 years of work with many different strains, there is still no known pathogenic *E. coli* K-12 strain. Thus, there is presumptive evidence that all K-12 strains are safe. They are well suited for laboratory experiments because they take up DNA easily, but their cell wall makes them unsuited to compete in nature with wild-type *E. coli*.

On the basis of the Falmouth Conference (which is discussed further in the Environmental Impact Assessment), the conclusion can be drawn that it is essentially impossible for *E. coli* K-12 to be transformed by recombinant DNA into a wild-type, pathogenic *E. coli*. An *E. coli* K-12 containing toxic genes through recombination could theoretically present a risk to a laboratory worker who accidentally ingested it; but it would only be to that laboratory worker. There is evidence to show that harmful genes will have a very low probability of being transferred from *E. coli* to another organism. The plasmids used at the HV2 level are engineered so that they neither self-transfer nor transfer when another plasmid induces conjugation. Thus, the high degree of safety of this system is clear and explains why it is preferable to any other host-vector system at present.

General Classification

Disagreement was expressed over whether the PRG-RAC was too stringent or too lax. Those arguing the former position maintain that the guidelines should be relaxed even further because all the experimental evidence gathered and analyzed in the past 2 years indicates that the initial fears concerning the potential hazards were extremely exaggerated; moreover, the benefits to be derived from the research are great. Also, it is pointed out that recombinant DNA experiments not allowed under the current NIH guidelines are proceeding with the approval of responsible national committees in a number of European countries. Those opposing this view argue that there is a lack of experimental data for a sound evaluation of the potential risks, and the fact that a recombinant DNA experiment is permitted in Europe is irrelevant to the establishment of standards in the United States.

Recombinant DNA Experiments Involving Viral DNA

Many of the commentators agreed that both the original guidelines and the PRG-RAC were overly stringent with regard to virus experiments. In commenting on the PRG-RAC, the EMBO Standing Committee on Recombinant DNA Research wrote:

> The EMBO Committee believes that the containment categorization of experiments with animal virus DNA's which is proposed by the NIH Advisory Committee is too indiscriminate and excessively stringent considering the proposed classification of experiments with other classes of DNA and the longstanding, accepted safety precautions for handling intact virus particles and viral nucleic acids * * *. The EMBO Committee proposes that it would be more reasonable either to consider experiments with viral DNA on a case-by-case basis or to produce a detailed set of recommended categories for experiments with specific viral DNA's. The EMBO Committee hopes in the near future to establish an ad hoc international group of virologists to draw up such proposals.

In response to this suggestion (i.e., for an international group of virologists to consider this issue), a joint U.S.-EMBO Workshop To Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insect Viruses was held in Ascot, England, on January 26-28, 1978. The workshop was attended by 27 distinguished scientists from the United States, the United Kingdom, West Germany, Finland, France, Sweden, and Switzerland. The report of the "Ascot" Workshop was published in the FEDERAL REGISTER on March 31, 1978, and appears as appendix E to the accompanying Environmental Impact Assessment. The workshop concluded:

> The probability that K-12 organisms carrying viral DNA inserts could represent a significant hazard to the community was so small as to be of no practical consequence * * * viral genomes or fragments thereof, cloned in *E. coli* K-12 using approved plasmid or phage vectors, pose no more risk than work with the infectious virus or its nucleic acid and in most, if not all cases, clearly present less risk. In fact, the workshop participants agreed that cloning of viral DNA in *E. coli* K-12 may provide a unique opportunity to study with greatly reduced risks the biology of extremely pathogenic and virulent viruses.

On April 6-7, 1978 (as announced on March 17 in the FEDERAL REGISTER), a working group sponsored by the RAC, composed of distinguished American microbiologists, met to review the report of the "Ascot" Workshop. The report of this working group appears as appendix F to the accompanying Environmental Impact Assessment. The working group unanimously endorsed the "Ascot" report with certain minor amendments. Their report included recommended new language to be inserted in the PRG-NIH in place of the sections dealing with viruses in the PRG-RAC. This report was presented to the RAC at its April 27-28, 1978, meeting, and was unanimously endorsed by the RAC with certain minor amendments. I have accepted these recommendations of the RAC, with certain additional minor amendments, and these now constitute the sections dealing with viruses in part III of the PRG-NIH.

Recombinant DNA Experiments Involving DNA from Plants and Plant Pathogens

One of the comments made at the December 1977 meeting of the Advisory Committee to the Director, NIH was that "the NIH guidelines do not adequately deal with the use of recombinant DNA in plants * * *" Other commentators have expressed similar sentiments, and the suggestion has been made that "a subcommittee be formed to deal with plants and plant pathogens and make specific recommendations for revision of the guidelines." In response, a Workshop on Risk Assessment of Agricultural Pathogens, composed of distinguished American plant pathologists, was held on March 20-21, 1978 (as announced on March 6 in the FEDERAL REGISTER). Sponsored by the U.S. Department of Agriculture, the National Science Foundation, and the NIH, the report of this workshop appears as appendix G to the accompanying Environmental Impact Assessment. The report was presented to the RAC at its April 27-28, 1978, meeting and was unanimously endorsed by the RAC with certain minor amendments. I have accepted these recommendations of the RAC with certain additional minor amendments; these involve changes in the PRG-NIH in sections dealing with the use of plants and plant pathogens in recombinant DNA research.

Using the 10 criteria previously discussed in light of what is known today, I believe the revisions in containment standards proposed by the PRG-NIH are sound. The changes in containment standards in the PRG-NIH are discussed below in greater detail for each of the subsections of part III.

SPECIFIC CONSIDERATIONS

Section III—Opening Paragraphs

As discussed above in part I of this document, the section of the guidelines numbered III-A in both the 1976 guidelines and the PRG-RAC and entitled "Experiments That Are Not To Be Performed" has been moved in the PRG-NIH to become section I-D entitled "Prohibitions." This leads to a renumbering of the remaining subsections of part III of the PRG-NIH as compared to the PRC-RAC.

Two new paragraphs have been inserted at the beginning of part III of the PRG-NIH. The first reminds the reader to consult part I "where listings are given of prohibited and exempt experiments."

The second inserted paragraph is a "general flexibility clause." Insertion of such a "clause" was recommended by the RAC at its April 27-28, 1978, meeting. It recognizes that the classification of experiments given in part III will necessarily be imperfect, as investigators in the future devise new ways to conduct recombinant DNA experiments not currently foreseen and therefore not explicitly considered in the guidelines. Also, new data may become available showing that certain particular experiments currently assigned a particular containment level are, indeed, clearly more (or less) safe than envisioned at this time. Therefore, this "clause" states that "changes in these levels for specific experiments (or the assignment of levels to experiments not explicitly considered here) may be expressly approved by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee (RAC)."

Section III-A-1-a. Shotgun Experiments into E. coli *K-12 with Inserted Eukaryotic DNA*

At a number of places in this subsection the principal investigator is allowed to choose between two combinations of containment procedures. For example, in several instances one is permitted to use P2+EK1 or P1+EK2. This was endorsed by some commentators but questioned by others. This concept of flexibility was addressed in part II of this document. I also wish to point out that the concept is not a new one—it was allowed under the original guidelines. Based upon events of the past 2 years, the RAC merely proposed that this principle be extended to certain specified additional cases where they believe it appropriate. I agree with their proposals and have therefore included in the PRG-NIH all such specific cases of flexibility recommended in the PRG-RAC.

On the other hand, in certain other specific cases (e.g., DNA from birds) the PRG-RAC recommended the containment level be P2+EK2, without the option of P3+EK1. Certain commentators urged that in all cases where the containment level of P2+EK2 is given, the option of P3+EK1 be allowed. However, the RAC felt that in view of their increased confidence in the biological containment offered by the EK2 system, P2+EK2 offers more containment than P3+EK1, and that P2+EK2 without the option of P3+EK1 should be the containment level for certain specified classes of experiments. I accept the view of the RAC and have therefore specified in the PRG-NIH the containment levels of P2+EK2 without the option of

P3+EK1 in every case where it appeared in the PRG-RAC.

The section of this document on "Recombinant DNA Experiments Involving Viral DNA" discussed the "Ascot" workshop report, and the April 6-7, 1978, working group report which endorsed the "Ascot" report. The RAC at its April 27-28, 1978, meeting unanimously endorsed the working group report recommending lower containment levels for deliberate cloning of viral DNA into *E. coli* K-12 (see below for discussion of section III-A-2). One of the reasons given originally for the higher containment level for shotgun experiments involving primate DNA into *E. coli* K-12 was the possible *inadvertent* cloning of viral DNA. In view of their recommendation of lower containment for *deliberate* cloning of viral DNA into *E. coli* K-12, the RAC on April 27-28, 1978, reconsidered primate shotgun levels, and voted unanimously for new language as follows: *"Primates.* P2 physical containment + an EK2 host-vector. Any lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee but requires NIH approval." I have accepted this new language and inserted it in the PRG-NIH, as well as a similar lowering of containment for shotgun cloning of cold-blooded vertebrate DNA into *E. coli* K-12.

One commentator noted that section III-B-1-a-(1)-(g) of the PRG-RAC entitled "Cloning of Viral Genomes From Eukaryotic Cell DNA" * * * "focuses on cloning integrated retrovirus nucleotide sequences from mammalian cell DNA but says nothing about nucleotide sequences of integrated DNA viruses." This entire section has been eliminated from the PRG-NIH and instead a new subsection III-A-2-a-(3) entitled "Intracellular Viral DNA" has been added to the PRG-NIH which covers both integrated retroviruses and DNA virus sequences; it says, "Physical and biological contaminant specified for shotgun experiments with eukaryotic cellular DNA (See section III-A-1a) shall be used for DNA recombinants produced with integrated viral DNA or viral genomes present in infected cells."

Section III-A-1-b. Shotgun Experiments Into E. Coli *K-12 With Inserted Prokaryotic DNA*

In the 1976 guidelines, the section (III-B-2-(a)-(ii)) dealing with shotgun experiments into *E. coli* K-12 with inserted prokaryotic DNA was subdivided into two sections, i.e., "Prokaryotes That Exchange Genetic Information With *E. coli*" and "Prokaryotes That Do Not Exchange Genetic Information With *E. coli.*" In the PRG-RAC it was assumed that all prokaryotes that exchange genetic information with *E. coli* would be exempt from the guidelines by appearing on the "list of nonnovel exchangers." Therefore, in the PRG-RAC the section (III-B-1-a-(2)) dealing with shotgun experiments into *E. coli* K-12 with inserted prokaryotic DNA actually considered only prokaryotes that did not exchange genetic information with *E. coli.* The problem with this approach was discussed by commentators, focusing especially on the case of *Agrobacterium tumefaciens.* It meant that a prokaryote which exchanges genetic information with *E. coli,* and was therefore properly assigned a low containment level under the 1976 Guidelines, would under the PRG-RAC either appear on the "list" and therefore be exempt from the guidelines, or if for some reason it did not appear on the list, the containment level would actually in some cases be raised. This was not the intent of the RAC. Therefore, I proposed to the RAC, and they accepted at their April 27-28, 1978, meeting, that language be reinserted in the the PRG-NIH covering prokaryotes that exchange genetic information with *E. coli* but which do not appear on the list. This section in the PRG-NIH (III-A-1-b-(1)) reads:

Prokaryotes That Exchange Genetic Information [35] *with* E. coli. It is expected that many of the prokaryotes that exchange genetic information with *E. coli* by known physiological processes will be exempted from these guidelines by appearing on the "list of exchangers" (see sec. I E-4).

For those not on the list, the containment levels are P1 physical containment + an EK1 host-vector. In fact, experiments in this category can be performed with *E. coli* K-12 vectors exhibiting a lesser containment (e.g., conjugative plasmids) than EK1 vectors. However, for prokaryotes that are classified [1] as Class 2 the containment levels are P2+EK1.

For prokaryotes that do not exchange genetic information with *E. coli,* the PRG-RAC proposed that P1+EK2 or P2+EK1 conditions apply only in cases of extensive characterization and RAC approval. "Experiments with DNA's from bacteria that are not extensively characterized require P2 physical containment + an EK2 host-vector or P3+EK1. Experiments with DNA's from pathogenic species (class 2 and plant pathogens, see App. B) must use P3+EK2." A number of commentators objected to two different aspects of this subsection of the PRG-RAC: (1) Many felt that experiments involving nonpathogenic prokaryotes should be conducted at P1+EK2 or P2+EK1 without extensive characterization or RAC approval; (2) It was argued that plant pathogens should not be included with CDC class 2 agents as requiring P3+EK2 containment. Both of these comments were referred to the RAC at their April 27-28, 1978, meeting and they agreed with the commentators. Therefore, this Section of the PRG-NIH (III-A-1-b-(2)) reads:

(2) Prokaryotes that Do Not Exchange Genetic Information with E. coli. P2 physical containment + an EK1 host-vector, or P1+EK2, except for DNA from class 2 agents, [1] which require P3+EK2.

The EMBO Standing Advisory Committee on Recombinant DNA Research recommends that the containment level for all novel non pathogenic prokaryotic DNA into *E. coli* K-12 be P1+EK1. It is my opinion that it is prudent to retain the levels of P2+EK1 or P1+EK2 for nonpathogenic prokaryotes that do not exchange gentic information with *E. coli.*

The PRG RAC received substantial criticisms for identifying all agents classified as class 2 in the CDC's publication "Classification of Etiologic Agents on the Basis of Hazard" (Fourth edition, July 1974) as being pathogenic for the purpose of assigning containment levels. Many commentators stated that many of the organisms so classified were harmless and others were of such low pathogenicity that severe safety precautions were unwarranted. It was also pointed out that the pathogenicity of an intact micro-organism and the conjectural hazard of a piece of DNA from such an organism within *E. coli* K-12 were quite different matters. It should be noted that the difficulties in application of the CDC classification for the purposes of these guidelines was recognized in the original guidelines. For example, all species of *Salmonella* are classified as class 2 organisms by CDC. The original guidelines, however, distinguish between the pathogenicity of *S. typhimurium* and *S. typhi* for the assignment of containment levels. I have therefore accepted the suggestion of these commentators and have added footnote 1 to the PRG-NIH. This gives NIH the authority, upon the recommendation of the RAC, to designate certain agents which are listed as class 2 by CDC as class 1 agents for the purpose of these guidelines.

Section III-A-2-a. DNA from viruses of eukaryotes into E. coli K-12

Discussed earlier within part III of this document under the heading "Recombinant DNA Experiments Involving Viral DNA" was the history of the "Ascot" workshop report (App. E to the accompanying environmental impact assessment) and the report of the working group which met on April 6-7 1978 (App. F to the accompanying environmental impact assessment). Section III-A-2 of the PRG-NIH adopts the recommendations of the working group with minor modifica-

tion. It is based on a reassessment made by these experts in the field of virology of the potential hazards of inserting pieces of viral DNA into *E. coli*. I believe the argument presented in the "Ascot" report and the working group report are well founded, specifically that "the probability that K-12 organisms carrying viral DNA inserts could represent a significant hazard to the community was so small as to be of no practical consequence * * * viral genomes or fragments thereof, cloned in *E. coli* K-12 using approved plasmid or phage vectors pose no more risk than work with the infectious virus or its nucleic acid and in most, if not all, cases clearly present less risk." Accordingly, section III-A-2-a of the PRG-NIH has been completely rewritten.

Section III-A-2-b. Eukaryotic Organelle DNA into E. coli K-12

To be consistent with the one step lowering of physical containment described earlier for shotgun experiments with primate DNA, the levels for mitochondrial DNA from primates has been similarly lowered by one step in physical containment in the PRG-NIH as compared to the PRG-RAC.

Section III-A-3. Lowering of containment for characterized or purified DNA preparations and clones

Concern was expressed by several commentators regarding the revisions in the PRG-RAC which would allow the local IBC (with notification to be sent to NIH) to reduce either the biological or physical containment level by one step if (1) the DNA is 99-percent purified and shown to be free of harmful genes prior to its insertion into a recombinant molecule, or (2) if subsequent to insertion the clone is rigorously characterized and shown to be free of harmful genes. In the original guidelines lowering in case (2) could only be done with NIH prior approval.

There was support from several commentators for the changes in this subsection. The rationale is explained in new language inserted into this section of the PRG-RAC, which is retained in the PRG-NIH; i.e.:

> Many of the risks which might conceivably arise from some types of recombinant DNA experiments, particularly shotgun experiments, would result from the inadvertent cloning of a harmful sequence. Therefore, in cases where the risk or inadvertently cloning the 'wrong' DNA is reduced by prior enrichment for the desire piece, or in which a clone, made from a random assortment of DNAs, has been purified and the absence of harmful sequences established, the containment conditions for further work may be reduced.

Some commentators noted the ambiguity and difficulty attendant in the phrase "free of harmful genes." The EMBO Standing Advisory Committee on Recombinant DNA Research reports that "several national guidelines for recombinant DNA research state that containment measures may be relaxed once a cloned DNA fragment has been biochemically characterized and shown to be free of harmful genes (NIH guidelines) or devoid of any known pathogenic characteristic (French guidelines). The EMBO committee believes the latter to be a more feasible requirement, but neither can readily be met, and the committee finds it difficult to suggest what sorts of experimental tests might be devised to meet these requirements."

I agree that "the terms 'characterized' and 'free of harmful genes' are unavoidably vague." However, footnote 3 of the PRG-NIH goes on to list five types of data which should be considered in making this determination.

Some commentators were also concerned that this grant of additional authority to the local IBC's for single step lowering in containment levels might introduce variability in the application of the guidelines. I have considered this possiblity and have decided that the principle of promoting local involvement in the implementation of the guidelines outweighs the difficulties which may be eoncountered in this process. In an attempt to minimize these problems, I have (1) attempted to make all parts of the guidelines as clear, specific, and unambiguous as possible, and (2) expanded the "Roles and Responsibilities" secton to outline functions and responsibilities in greater detail. Also, the guidelines require that the Office of Recombinant DNA Activities at the NIH be notified in writing of such an action. A mechanism is therefore in place to ensure that such actions proceed with an acceptable degree of uniformity.

The question was raised whether a clone, the containment level of which was lowered by the IBC at Institution X, may after shipment to Institution Y still be used at the lower level without review by the IBC at Institution Y. It clearly has been, and remains, the intention of both the RAC and myself that the IBC at the receiving institution must approve the reducton in containment for the handling of the clone in such a situation. The investigator at the receiving institution must handle the clone at the higher level until such permission is granted.

One commentator urged that prior cloning be accepted as a technique for the purification of DNA molecules prior to their reinsertion in a new recombinant DNA molecule. The PRG-RAC specified that purification must be achieved "by physical or chemical techniques." The criterion for the single step reduction in containment levels in this situation is that the DNA preparation be 99 percent pure; I see no reason to so restrict the means by which such purification is attained. I have accepted this suggestion as a means of better serving the needs of the investigator without reducing the margin of safety to the public and the environment, and therefore have stricken from the PRG-NIH the words "by physical and chemical techniques" following the worked "purified."

One commentator noted that the PRG-NIH might be nterpreted as allowing a single step reduction in containment levels for purification of the DNA prior to its insertion into a recombinant DNA molecule, and then a subsequent further single step reduction in containment level once the same molecule was cloned. This was not intended. Therefore, clarifying language has been added in the PRG-NIH stating that an IBC "may give approval for a single step reduction in physical or biological containment on receipt of evidence of characterization of a clone derived from a shotgun experiment and its * * *."

Finally, as noted above in this document under "Section III-A1-a—Shotgun Experiments into *E. coli* K-12 With Inserted Eukaryotic DNA," the RAC recommended at its April 27-28, 1978, meeting (and I have accepted the recommendation and inserted it in the PRG-NIH), that the containment levels for shotgun of primate DNA into *E. coli* K-12 be lowered to P2+EK2. However, on the recommendation of the RAC, a stipulation added in section III-A-1-a of the PRG-NIH is that for primate shotgun "any lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee but requires NIH approval." Language stating this limitation in authority of the IBC with regard to primate DNA has been inserted into subsection III-A-3 of the PRG-NIH, as has language indicating that any lowering of containment under this section to levels below P1+EK1 requires prior NIH approval.

Section III-B. Experiments with Other Prokaryotic Host-Vectors

Some commentators felt that the PRG-RAC unnecessarily emphasized the use of *E. coli* K-12 and would not allow important recombinant DNA experiments to be done in other prokaryotic hosts. Section III-B describes the use of prokaryotic host-vector systems other than *E. coli* K-12 which have been approved as HVI hosts. It should be remembered that "self-cloning experiments with prokaryotic hosts are exempt from the guidelines under exemptions I-E-2 and I-E-3 and that other experiments involving DNA segments from species that exchange

DNA by known physiological processes are exempt from the Guidelines under exemption I-E-4.

The RAC at its April 27-28, 1978, meeting pointed out that there are certain scientifically important experiments which are very safe but which neither fit the criteria to be exempt from the guidelines, nor the criteria for HVI certification. A new section III-B-2 has been added to the PRG-NIH to cover these cases and assign appropriate containment levels. In these experiments DNA from a prokaryotic host (Host X) is cloned into *E. coli* K-12 (this situation is already covered in sec. III-A-1-b(2) of the guidelines); in the second part of the experiment the recombinant DNA (consisting of DNA sequences from Host X linked to an *E. coli* plasmid or bacteriophage) is returned to Host X and propagated there.

Section III-C. Experiments with eukaryotic host-vectors

A number of commentators felt that the stringent containment conditions required both in the original guidelines and in the PRG-RAC for introduction of recombinant DNA into tissue culture cells, using viruses as vectors, were unwarranted. The EMBO Standing Advisory Committee on Recombinant DNA Research wrote:

> In experiments involving the introduction of foreign DNA into cultured cells of animals using DNA viruses as vectors, biological containment is assured by the very restricted permissive conditions for the host cells; the only routes by which the recombinant molecule might escape are by chance infection of a contaminating microorganism or within a viral capsid and the size of the recombinant molecule may well preclude its encapsidation * * *. For example, cloning of mouse DNA using polyoma virus as a vector and mouse cells as host should not require precautions more stringent than those routinely used for many years in laboratories studying polyoma virus infection of mouse cells and mice. The EMBO Committee finds the proposals for this class of experiments in the revised NIH Guidelines not sufficiently discriminating because they would impose unnecessarily high levels of physical containment for experiments with many eukaryotic DNA's.

Discussed earlier within Part III of this document under the heading "Recombinant DNA Experiments Involving Viral DNA" was the history of the "Ascot" workshop report (See App. E to the accompanying environmental impact assessment, and the report of the working group which met on April 6-7, 1978 (App. F to the accompanying environmental impact assessment). I have accepted the recommendations of the work group and incorporated their suggested revision of this section which now becomes section III-C of the PRG-NIH. The result of this change is that section III-B-3 of the PRG-RAC "Experiments with Eukaryotic Host-Vectors," subparts (a) "Vertebrate Host-Vector Systems," and (b) "Invertebrate Host-Vector Systems," are eliminated; substituted for it in the PRG-NIH is new language derived from the working group report which become section III-C "Experiments With Eukaryotic Host-Vectors," subparts (1) Vertebrate Host-Vector System"; (2) "Invertebrate Host-Vector Systems in which Insect Viruses Are Used To Propagate Other DNA Segments", and (3) "Plant Viral Host-Vector Systems."

Section III-C-4. Plant Host-Vector Systems Other Than Viruses

Discussed earlier within Part III of this document under the heading "Recombinant DNA Experiments Involving DNA From Plants and Plant Pathogens" was the Workshop on Risk Assessment of Agricultural Pathogens, held on March 20-21, 1978, sponsored by USDA, NSF, and NIH. Based on the Workshop report (See Appendix G to the accompaying Environmental Impact Assessment), section III-D of the PRG—NIH has been rewritten.

Section III-C-5. Fungal or Similar Lower Eukaryotic Host-Vector Systems

Both the 1976 Guidelines and the PRG-RAC used the same short paragraph for this section, giving little detail, because they noted "the development of these host-vector is presently in the speculative stage." Since that time a specific host-vector system of this class has been developed, i.e., *Saccharomyces cerevisiae* (baker's yeast), and other similar systems may also soon be proposed. Accordingly, this section (III-C-5) of the PRG-NIH has been expanded to give more specific instructions on appropriate containment levels.

Section III-D. Complementary DNAs

Since specific containment levels for the use of purified cDNA of viral mRNA are now given in section III-A-2-a of the PRG-NIH, a sentence has been added noting this at the beginning of section III-D of the PRG-NIH. Otherwise, the rest of this evoked no comments and remains identical in the PRG-NIH to the PRG-RAC.

Section III-E. Synthetic DNA

Because synthetic DNA is now explicitly included in the PRG-NIH (as discussed in section I of this document), it was necessary to add language to Part III of the PRG-NIH detailing the appropriate containment levels for these experiments. The RAC at its meeting on April 27-28, 1978, approved such language, and it has been inserted in the PRG-NIH as section III—E.

IV. Roles and Responibilities

Review of RAC Proposed Guidelines

This section, as in the 1976 Guidelines, provides an administrative framework for implementation. Modifications to the various roles and responsibilities proposed by the RAC are listed below.

Institutional Responsibilities

Institution. Several changes were proposed in the PRG-RAC as compared to the 1976 Guidelines in the responsibilities of the institution. Responsibilities that were added or further detailed included: (1) a requirement for insuring the training of research personnel and the use of good microbiological technique, and (2) a requirement to determine the need for medical procedures, with recommendations of possible specific practices.

Institutional Biosafety Committees. Membership of the committees was clarified by a recommendation to include other than scientific members. In thePRG-RAC (section III), institutional biosafety committees (IBCs) are given the discretion to approve single-step reductions in containment levels for experiments with characterized clones and purified DNA. The IBC's would be required to notify the NIH Office of Recombinant DNA Activities (ORDA) of these approvals.

Biological Safety Officer. Institutions at which P3 and P4 level recombinant DNA work is conducted would be required to have a biological safety officer, whose specific roles and responsibilities are outlined.

Principal Investigator. The role and responsibilities of the principal investigator would remain basically the same except for the important addition of a requirement for training in microbiological techniques. Responsibility for the determination of the practices necessary for medical surveillance would be relocated to the institution.

NIH Responsibilities

Office of the Director. The responsibilities of the Director would remain unchanged. A sentence was added which clarified the Director's authority to implement the Guidelines and to be the final arbiter in the interpretation of the Guidelines.

Recombinant Advisory Committee. There were no changes in the current responsibilities of the RAC; however, there were clarifications of the scope of some duties, for example, the certification process. The language of the 1976 Guidelines caused confusion among some concerning the certification of EK2 (HV2) and EK3 (HV3) host-vector systems. In practice, the certification process involved a two-step procedure: (1) the RAC's recommendation to the Director, NIH, that

a particular host-vestor system be certified; and (2) certification of the system by the Director, NIH. The PRG-RAC clarifies the fact that a two-step procedure is followed. The rationale for the two-step procedure is that it allows the Director, NIH, to solicit the opinions of additional experts prior to making a final decision on certification.

The RAC's authority to recommend exceptions from the proibitions was also clarified. The 1976 version of the Guidelines envisioned the possibility of the RAC's recommending an exception to the 10-liter limit on culture volume for recombinant DNA's known to make harmful products. The proposed revision would extend the possibility of an exception to the five other classes of currently prohibited experiments. The general rationale for this addition is the RAC's inability to foresee all possible future circumstances and the RAC's desire to specify, within the limits of strict safeguards, the possibility of an exception for compelling social or scientific reasons. A more immediate and specific justification for the paragraph on exceptions from the prohibitions is that the risk-assessment studies necessary for a clearer understanding of the potential biohazards of recombinant DNA research may not be able to be carried out without technical violations of the current Guidelines, unless there is a mechanism for approving exceptions.

REVIEW OF COMMENTS AND NIH PROPOSED GUIDEINES

As in the public hearing on the originally proposed Guidelines in 1976, many public commentators urged openness, candor, and public participation in the revision process, emphasizing shared responsibility and accountability from the local to the national level. We have heeded these suggestions. In addition to holding all RAC meetings in the open and holding a public hearing on the PRG-RAC in December 1977, we have published both the PRG-RAC and now the PRG-NIH in the FEDERAL REGISTER for public comment.

It remains clear, as stated in my 1976 decision, that much of the success of the guidelines will depend on the wisdom with which they are implemented. The recommendations of the PRG-RAC have been carefully weighed along with other public and scientific comments received on the "roles and responsibilities" section. In general, I have adopted the RAC proposals with certain additional modifications based on issues raised by the Director's Advisory Committee and other commentators. The issues I have considered, and a discussion of them follows:

Responsibilities of the institution (general)

Again, as in 1976, this section of the guidelines drew considerable comment directed to the roles and responsibilities of the institution and its several constituents. Generally, commentators requested more information and greater clarification of the structure and operation of the IBC, the function of the biological safety officer, and the duties of the institution. Because of the importance of this section with regard to successful implementation of the guidelines, and therefore safe conduct of this research, these suggestions and comments have been carefully considered. NIH acknowledges its special responsibility in assuming leadership in developing and promoting safety programs relevant to recombinant DNA research. Therefore, as in 1976, another committee chaired by Dr. W. Emmett Barkley, Director, Office of Research Safety, NCI, was convened to address concerns raised. As a result, and in response to a number of commentators' requests, appendix D of the original guidelines has been restored and enhanced to give additional advice on safety matters (see "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research"). The revised guidelines also retain requirements for emergency plans to cover accidents as well as strengthening the requirement for training of all recombinant DNA researchers in safe laboratory procedures.

The intent of this section, as before, is to integrate safety practice into the conduct of recombinant DNA research and to assign responsibilities for this to the principal investigator institution, IBC, and biological safety officer. Therefore, it is important that these responsibilities be stated in an unambiguous manner. For this reason, and in response to many commentators, Part IV has been restructured, to distinguish in greater detail and more clearly align some of these functions. The appendices contain additional complementary information on roles and responsibilities, including information for IBC's and biological safety officers.

In response to several comments, the scope of review of research has been broadened to cover all recombinant DNA research at an institution receiving funds from NIH for recombinant DNA research, whether or not the specific recombinant DNA project is being funded by NIH. While this increases the responsibility of the institution and the IBC's, it is believed that this revision will enhance the overall safety of the conduct of this research. Furthermore, at the suggestion of one commentator, I have decided to change the name of the biohazards committees to biosafety committees to reflect the spirit of the guidelines more closely.

Several generic comments deserve to be highlighted as they represent significantly increased authority to be delegated to the institution. In 1976, the RAC did not accept commentators' suggestions for requiring local committees to make an independent evaluation of the containment levels required by the guidelines for individual research projects. I therefore stated in the 1976 decision that NIH would not require local institutions to have their committees perform this function, although they would not be prohibited from doing so. Commentators have now noted that in order for an IBC to accomplish its mandated responsibilities under the 1976 guidelines, including reviewing and approving recombinant DNA research projects, it has been necessary for the committee implicitly to determine containment conditions. Therefore, in order to better clarify its role, the assessment of appropriate containment levels is now made an explicit responsibility of the IBC.

In addition, institutions through their IBC's will be given increased responsibility for primary oversight of this research as they have now been delegated the authority from NIH to approve or disapprove proposed recombinant DNA projects. NIH through ORDA will conduct a review of institutional actions, upon registration of the projects, to ensure compliance with the NIH guidelines, thereby maintaining a national standard for the research. This action has been in response to several comments calling for increased local responsibility and a more simplified administrative process with regard to gaining approval for this research to proceed. In view of the impossibility of Federal surveillance to enforce these standards externally, I feel it is essential to increase the authority and responsibility of the local institution. It was also requested that IBC's have a role if legislation in this area is adopted, and this concept is endorsed in the bill report of March 24, 1978, on the Recombinant DNA Act, by the House Committee on Interstate and Foreign Commerce, which says, "It is the view of the committee that the appropriate portions of the administrative requirements of section IV of the NIH guidelines are a reasonable model upon which the Secretary could base administrative regulations. In particular, the current practice in the NIH guidelines of delegating to local biohazards committees most of the responsibility for the inspection of facilities and the approval of the specific safety requirements appropriate to each project or activity is an effec-

tive and relatively inexpensive administrative mechanism."

As in the 1976 decision, a number of recommendations were received regarding the membership of IBC's. In 1976, suggestions were made for broadening IBC representation to include members not only from various disciplines related to recombinant DNA molecule technology, biological safety, and engineering but also to include those knowledgeable in applicable laws, regulations, standards of practice, community attitudes, and health and environmental considerations. Consequently, at that time I recommended in my decision that these diverse points of view be included or made available to the committees. The language in the PRG-RAC requires a diversity of membership, but does not mandate noninstitutional members. In response to several requests, and in view of increased responsibility at the local level, I am now going beyond the RAC proposal and adding a provision that "no IBC may consist entirely of persons who are officers, employees, or agents of, or are otherwise associated with the institution, apart from their membership on the IBC." Other specific categories for membership are not mandated although the PRG-NIH now states that "membership should include individuals from disciplines relevant to recombinant DNA technology, biological safety, and engineering"; that it is recommended that "at least one member be a nondoctoral individual from a laboratory technical staff"; and that the IBC "include members knowledgeable about such matters as applicable law, standards of professional conduct and practice, community attitudes, and the environment."

The possibility of conflict between IBC's and local community oversight committees was raised. With noninstitutional membership on IBC's I believe there is no need to have additional community committees.

A number of other recommendations were received from public commentators relating to more specific issues; they are considered below under the appropriate headings.

Responsibilities of the institution (specific)

Institution. A number of points were raised by commentators concerning health monitoring by institutions. NIH was requested to develop a model for institutional medical surveillance for recombinant DNA research workers. The issue of medical monitoring is one of considerable interest to the NIH. This is a general problem not unique to recombinant DNA research. As one commentator noted, instituting a routine health monitoring and reporting program for personnel engaged in areas of research besides recombinant DNA, such as tumor viruses and pathogenic organisms, is important. However, the state-of-the-art is primitive in terms of what can be done to monitor workers' health generally, but particularly in the area of recombinant DNA research where there is no known hazard. At my request, an NIH committee reviewed this area and has made recommendations as to what such a program may include. This recommendation, which calls for monitoring illnesses, collecting serum samples, and keeping a register of agents handled, is responsive to several suggestions received on this issue, and it has, therefore, been adopted in the PRG-NIH. Additionally, appendix D will include more detailed information on medical surveillance.

Grievance procedures for workers under the guidelines were requested but this is not considered necessary as the Occupational Safety and Health Act (OSHA) rules and regulations already provide such a mechanism. In the 1976 decision it was also noted that OSHA standards and procedures apply to most institutions, so it was not considered necessary then, or now, to require in the guidelines that IBC's insure OSHA compliance. Further, the Federal Interagency Committee on Recombinant DNA Research, which I chair, includes representatives from the Occupational Safety and Health Administration (Department of Labor), assuring cooperation at the Federal level.

One commentator spoke to the need for a biosafety control manager which would be similar to the head of a campus environmental health and safety office. While such a program and manager may be desirable, it is felt that this is an institutional administrative matter and should not be addressed in the guidelines.

Institutional Biosafety Committee (IBC). Several commentators requested more detail on IBC duties and this has been accomplished in the supplement to the PRG-NIH entitled, "Laboratory Safety Monograph." For example, information is included here on facility certification, periodic inspections and monitoring, and a model for IBC operation.

There was concern about the establishment of area biosafety committees and possible jurisdictional disputes between them and institutional biosafety committees. This has been further clarified in the definitions in Part I.

It was suggested that biosafety committee meetings be open to the public. The guidelines currently require only that the minutes be available to the public. In view of possible discussion of proprietary and patentable information, IBC meetings cannot always be open. I do urge, however, that local committees, when possible, have open meetings and suggest that all meetings be announced.

The question was raised concerning possible conflict of interest of local committee members. This is an important point, and I have added a provision prohibiting an individual engaged in, or expecting to be engaged in, or having a direct financial interest in, a recombinant DNA project from being involved in the review or approval of that project.

Concern was expressed about the cost of IBC operations, and suggestions were made that the Government underwrite this expense. Because NIH already pays, through indirect costs, the operations of such committees, I have decided that there is no need at this time to separate them out from other indirect costs of the institutions.

Biological Safety Officer. Because increased authority and responsibility have been given the IBC's, it is appropriate that institutions conducting P3 or P4 level research have someone designated to handle biological safety questions generally.

I have accepted the suggestion that the biological safety officer shall be a member of the IBC because his or her responsibilities are so closely allied to the function of the committee.

Another commentator noted that too much emphasis was placed in the PRG-RAC on the regulatory role of the biosafety officer rather than on his or her role as a technical consultant; therefore, language indicating this latter role has been inserted in the PRG-NIH.

In response to questions on the qualifications of biological safety officers, I note that the officer need not be an M.D. Further, it is not necessary that he or she be engaged in research. Since the passage of the Occupational Safety and Health Act, most institutions have established occupational safety and health departments or programs with institutional safety officers. There are no standard certification procedures for such individuals, although their qualifications, in many cases, could be commensurate with those of a biological safety officer. The supplement to the PRG-NIH entitled, "Laboratory Safety Monograph," provides in greater detail the kinds of qualifications that biosafety officers should have. NIH is developing a training course for campus safety officers, including biological safety officers, and requests for information should be directed to Dr. Emmett Barkley, Director, Office of Research Safety, National Cancer Institute, Bethesda, Md. 20014.

Principal Investigator. In response to several commentators, the steps the investigator needs to take in order to have proposed research approved at

the local and national levels have been delineated in Appendix C to the guidelines which contains documentation of NIH administrative procedures for recombinant DNA research projects.

Considerable attention has been given to the issue of training. Several commentators urged that training standards be set by the NIH, preferably in the guidelines. Other commentators wanted the guidelines to direct the institution or IBC to set standards for training; however, some opposed this view. Still others wanted investigator competency evaluated or certified after training had been undertaken. It should be noted that the PRG-RAC represented a strengthening of training requirements, compared to those in the 1976 guidelines. Commentators remain concerned regarding the quality and uniformity of such training. The NIH is responding to this by placing as a high priority the development of training standards and courses. Currently, NIH is supporting a Working Panel of the American Society for Microbiology (ASM) which is considering standards of training in microbiological techniques for recombinant DNA research. When a report is submitted to NIH, it will be shared with institutions, IBC's, and principal investigators for their use. At this time, however, national certification should not be attempted until the ASM/NIH criteria for training have been formulated and subsequently evaluated. It should be noted that, aside from Nuclear Regulatory Commission standards for training for radioisotope work, there are apparently no other formal training criteria presently required for biomedical research. Thus, the work of the ASM Panel will be establishing a precedent. It is for these reasons that I feel NIH should proceed carefully and in stages, at the same time promoting safety training for researchers. Accordingly, NIH will develop courses based on these standards of training and make them widely available.

Responsibilities of the NIH (General)

Due Process Considerations. A focus of public comment at the December hearing was on "procedural due process," to insure public participation in the development of NIH recombinant DNA policies. Much of the public testimony and comment in letters thereafter focused on public representation on committees. Also stressed was the need for public notice of all meetings, and for procedures to insure public participation in the exercise of responsibilities by the RAC, the Office of the Director, NIH, and the Advisory Committee to the Director, NIH.

Several commentators specifically urged that the guidelines spell out the procedures to be used for the following:

- To develop and amend the list of "non-novel experiments";
- To permit the Director, on the advice of the RAC, to grant exceptions from prohibited experiments, such as for risk-assessment experiments;
- To certify host-vector systems;
- To modify guidelines in the future.

There were also suggestions that guidance be given on how to deal with infractions of the guidelines. Specifically, one commentator suggested that procedures outline in detail:

- How charges of non-compliance could be brought;
- How charges of non-compliance would be evaluated;
- What opportunities would be provided for the principal investigator and his institution to defend themselves against charges; and
- What appeals procedures would be available before the termination of funding or the invoking of other penalties.

Because of the key role of the RAC in the development and monitoring on NIH recombinant DNA policies, a number of comments were directed to its composition and functions. Many commentators focused on the RAC's membership, urging that the guidelines define procedures for nomination and selection of members. Suggestions for potential membership on the RAC included more representation for certain scientific disciplines, such as virology and microbiology; greater representation of individuals skilled in occupational and environmental health and safety; and more public representation, including perhaps a "dissenter" from current NIH policies.

A number of comments concerned Committee operations. The RAC was urged to formalize schedules so that all would know when it would meet over the next 2 to 3 years. Further, it was urged that notices and complete agendas be placed in the FEDERAL REGISTER for each meeting; that all documents for Committee consideration be made available to the public; and that the NIH pay for public witnesses to attend meetings of the RAC.

In response to these comments, Part IV of the guidelines has been reorganized extensively. The responsibilities from the local to national level have been stated and defined more clearly. Further, for NIH responsibilities, procedures suggested by commentators have been specified to afford opportunity for public comment. A special appendix to the guidelines includes relevant implementation documents from ORDA that explain the administration of the NIH guidelines at the local and national levels.

From the beginning, the NIH has gone to great lengths to insure procedural due process for the public and scientific communities. The RAC conducts all meetings in the open, and files notice of each meeting in the FEDERAL REGISTER. All the documents listed on the agenda of the RAC meetings have been available to the public. Additionally, the Advisory Committee to the Director, NIH, has provided a public forum on the 1976 guidelines and now on the proposed revisions. The public hearing in February 1976 on the originally proposed guidelines resulted in extensive revision of that proposal. The PRG-RAC was published in the FEDERAL REGISTER on September 27, 1977, for public comment, and the meeting of the Director's Advisory Committee held in December 1977 was announced in the FEDERAL REGISTER. In addition to a general invitation for public testimony, the NIH provided funds for witnesses from the public, private, and scientific sectors to attend and present their views.

The proposed reorganization of Part IV has more clearly defined a structure for responsibilities at the local and national level, with opportunity for public and scientific participation. It makes more formal a process that has been occurring informally. Flexibility, however, remains essential to avoid unnecessary and protracted delays in decisionmaking. Clearly a full panoply of review, including a public hearing, is not essential for most of the functions under the guidelines. For many functions, the need for public review can be met through publication in the FEDERAL REGISTER. For certain responsibilities comment may be solicited. Because procedures by which policies will be developed at the national and local levels are of key importance, notice for major policy initiatives is required. I believe the reorganization of Part IV achieves that goal.

Application to the Private Sector. Several commentators spoke on the application of the NIH guidelines to the private sector. Specifically, the NIH was urged to provide, voluntarily, to the private sector, the following:

- Advice on interpretation of the guidelines;
- Registration of projects;
- Certification of host-vector systems;
- Advice on the operation of institutional biosafety committees; and
- Protection for patent and proprietary information.

Prior to the release of the guidelines in June 1976, representatives of private industry were invited to NIH to be briefed on the guidelines. Since the release of the guidelines, several other meetings with representatives from the private sector have been held. Commerce Department representatives on the Interagency Committee

played a lead role in working with private industry leading to the agreement of relevant industries to abide by the safety standards of the NIH guidelines.

Many of the services provided by the NIH to its grantees and contractors had not been extended to the private sector. After carefully considering the comments at the public hearing and in correspondence received, I now believe the NIH should extend certain services to the private sector in several of the areas suggested by the commentators. A new section has been added to Part IV that provides the opportunity for private industry participation in a voluntary fashion. If legislation is enacted, the NIH Guidelines will serve as the basis for regulation that will encompass the private sector.

Occupational and Environmental Safety. A key concern of all commentators was the need for programs in occupational and environmental safety, that would include health surveillance for laboratory personnel and the community. As I stated in my Decision in 1976, the NIH has a special responsibility for national leadership in programs for laboratory safety. This responsibility is a critical one and we must accept it. Recombinant DNA research policies have stimulated a broad NIH commitment and interest in laboratory safety. The PRG-NIH reflects that commitment. As previously described, there are several training programs that the NIH has undertaken and supported. Several NIH committees are involved in development of policies in this area. The newly updated and expanded supplement to the PRG-NIH entitled, "Laboratory Safety Monograph," reflects the growing experience in this area.

A collaborative effort has been initiated between NIH and the Center for Disease Control (CDC) to establish a mechanism for providing advice, consultation, and if necessary, assistance regarding major accidents in laboratories involved in recombinant DNA research. It was not considered necessary to have a standing "strike force" as suggested by one commentator; however, in the event of an emergency, a team of experts from NIH and CDC could be formed to respond, depending on the nature of the problem.

Several commentators suggested that the NIH examine laboratory work involving genetic techniques other than recombinant DNA research. Indeed, it was recommended that another advisory committee akin to the RAC be established to propose standards for work involving biosafety, generally. I appreciate and understand this concern. The NIH over the past year and a half has created several internal committees that are critically examining different areas where laboratory work is conducted with potential biohazards. These committees are considering possible recommendations for safety standards.

Another commentator also urged the NIH to consider a forum for dealing with social issues related to "genetic engineering." The NIH responsibility to date has been in addressing policy questions involving safety of recombinant DNA research in single cells in the laboratory. I recognize the importance of the potential future application of this and other genetic research to the altering of the genetic character of higher forms of life including man. However, the application of this research to the "genetic engineering" of man is clearly far from imminent. In light of public concern, a study is warranted of the ethical, legal, and social implications of these techniques. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral research considered, but was unable to initiate, a study because of its pressing workload. Such a study, however, should be a key priority for the Commission currently being considered by Congress as part of the legislation to regulate recombinant DNA research.

It has also been suggested that the NIH work closely with other relevant research and regulatory agencies, particularly the Environmental Protection Agency and the Occupational Safety and Health Administration. Indeed, the NIH, from the inception of the Guidelines, has worked to foster cooperation among the Federal agencies. Prior to the release of the Guidelines, representatives from several agencies met at the NIH for a briefing on the Guidelines. After the release of the Guidelines, the question of their extension to the rest of the Federal Government and the private sector prompted the creation of an Interagency Committee. This Federal Interagency Committee on Recombinant DNA Research on which I have served as Chairman, was created by the Secretary of HEW at the request of the President in October 1976. It is composed of all relevant Federal research and regulatory agencies and has provided for coordination of Federal policies concerning recombinant DNA research. In March 1977, the committee developed recommendations for legislation.

It was suggested by a commentator that the NIH address the international implications of control of recombinant DNA research. Indeed, the Federal Interagency Committee issued in November 1977 a thorough and comprehensive review of all guidelines for such research internationally with recommendations for continued cooperation. This report is available from the Office of Recombinant DNA Activities, NIH, Bethesda, Md. 20014.

Responsibilities of NIH (Specific)

Office of the Director. As suggested by the commentators, for purposes of clarity, the responsibilities of the NIH Director have been grouped under a specific heading in the PRG-NIH entitled "Office of the Director, NIH." These responsibilities (many of which are mentioned in Parts I, II, and III of the PRG-NIH, and are repeated again in Part IV) include: final interpretation of the Guidelines; revision and amendment of the Guidelines; certification of new host-vector systems; promulgating and amending a list of classes of recombinant DNA molecules to be exempt from the Guidelines; permitting specific exceptions to the Prohibitions in the Guidelines; approving changes in containment levels for specific experiments; designating certain agents which are listed as Class 2 agents, as Class 1 agents for the purposes of the Guidelines; and overseeing the implementation of the Guidelines. For many of the responsibilities, appropriate notice and opportunity for public comment will be provided.

Recombinant Advisory Committee. At the hearing in 1976, many commentators made suggestions concerning the structure, function, and scope of responsibility of the RAC. Comments on possible structural mechanisms for decision-making included suggestions that there be a scientific and technical committee and a general advisory public policy committee. It was also suggested that the scientific committee include scientists who are to actively engaged in recombinant DNA research, and that the public policy committee have a broad scientific and public representation. In response to those suggestions in 1976, the roles of the RAC and the NIH Advisory Committee to the Director (DAC) were spelled out. The RAC responsibility has been primarily a scientific and technical one with recommendations for revisions of the Guidelines reviewed by the DAC, the public advisory group. In the main, that process has worked well over the past 1½ years and its structure is maintained in the PRG-NIH.

I am acutely aware of the need for broad scientific representation on the RAC, and I have carefully considered these needs in the selection of new members. The emphasis has been to ensure relevant scientific representation. It is absolutely essential that this committee have the technical expertise necessary to develop, modify, and interpret the Guidelines based on scientific evidence. Additonal representatives have been added from scientific disciplines, such as botany, to ensure a broad scientific overview. As a bridge

between the scientific and the public policy implications, public members now serve on the RAC and additional public members may be added. Current public members are Dr. Emmette S. Redford, Ashbel Smith Professor of Governement and Public Affairs, Lyndon B. Johnson School of Public Affairs, University of Texas at Austin; and Dr. LeRoy Walters, Director, Center for Bioethics, Kennedy Institute, Georgetown University. Both have served the public interest well and have done a superb job as have all members of the committee. The task for all RAC members has been enormous and their work and spirit of cooperation have been exemplary.

In order to ensure fairness, and sensitivity to the public commentators, solicitation of nominations for openings on the RAC will be in accord with the recommendations of the NIH Grants Peer Review Study Team concerning announcements of vacancies on committees. Thus, NIH will publish, periodically, an announcement of upcoming vacanices on the RAC with instructions on how to submit nominations. By this means I will be able to consider carefully a wide spectrum of nominations and assure appropriate representation suited to the needs of this committee.

One commentator suggested that representatives from Federal agencies serve on the RAC. Several agencies, including the National Science Foundation, the Department of Energy, and the Department of Agriculture, have liaison representatives who come regularly to the RAC meetings and, of course, the Federal Interagency Committee is kept fully informed of the activities of this committee.

It was also recommended by a commentator that the NIH finance the cost of attendance at RAC meetings by interest members of the public. For the present I do not believe such a policy is necessary, especially in light of the responsibilities of the DAC for public oversight where public witnesses may be invited and their expenses paid (as they were at the December 1977 hearing). All RAC meetings are announced in the FEDERAL REGISTER and are open to the public.

In sum, the operations of the RAC have been more clearly detailed in the PRG-NIH. The procedures for the selection of members and the operations of the committee have been, or are in the process of being, formalized for the benefit of the scientific community and the public.

NIH Components. A new section now describes all other functions of the NIH including the responsibilities of the Office of Recombinant DNA Activities (ORDA). Several commentators at the public hearing in 1976 urged that the NIH create an office to coordinate recombinant DNA activities. On the basis of these suggestions, ORDA was created and Dr. William Gartland was named Director. Since its creation, ORDA has done a splendid job in fulfilling very difficult tasks in the implementation of the NIH Guidelines. Dr. Garland, who also serves as Executive Secretary to the RAC, has provided a focus for coordination of activities within the NIH and with institutional biosafety committees.

It is important to note that the responsibility of the NIH peer review groups (e.g., study sections) for an independent assessment of the recombinant DNA research protocols has been eliminated. This responsibility will now solely be that of ORDA in conjunction with the institutional biosafety committee. In the 1½ years of our experience, such review by NIH peer review groups has been found to be unnecessary and an additional burden on these groups.

Several commentators urged new responsibilities for ORDA and additional personnel to fulfill them. Several urged that ORDA be responsible for inspecting and certifying laboratories at the P3 level. At the present time P4 facilities are operating at the Frederick Cancer Research Center in Frederick, Md, and at the NIH in Bethesda, Md; no other P4 facilities for recombinant DNA research are in operation nationally. The NIH has the responsibility under the Guidelines to certify P4 facilities because of their special nature. However, a P3 facility does not require special expertise at a national level; and there is no need for national certification of P3 facilities. As specified, the local institution has responsibility for monitoring and certifying facilities from the P1 to the P3 level and that, indeed, should be a local responsibility.

Several commentators urged greater dissemination of information to the public and scientific community alike. ORDA has a key responsibility for the dissemination of information through the "Recombinant DNA Technical Bulletin." The Bulletin is a new publication that attempts to link investigators involved in recombinant DNA research, both in the United States and abroad, with the advisory groups and organizations active in this area. In light of comments received, the Bulletin will include more information for institutional biosafety committees, as well as for the advisory groups at the national and local levels. It was suggested that ORDA provide advice to state and local governments, and to the most practical extent, ORDA will be available to state and local governments for technical advice. In large part, ORDA serves as a clearinghouse for information related to recombinant DNA activities internationally, nationally, and locally.

Registration and Compliance (General)

Over the past 2 years in the administration of the NIH Guidelines, it has been clear to me that a new section should be added on the general requirements for registration of activities with the NIH, not only for NIH grantees or contractors, but also, on a voluntary basis, for the private sector. Further, in light of the review of HEW policies on the patenting of recombinant DNA research inventions, a section on disclosure of information was also necessary. And finally, as suggested, a section on compliance with the Guidelines was needed. Thus, new sections C and D have been added under "Roles and Responsibilities" covering Registration (including disclosure of information) and Compliance. Many comments on the Guidelines over the past 1½ years and at the public hearing in December 1977 urged that these provisions be added, and in my view, they are necessary in the absence of legislation. Further, if legislation were to pass, these provisions could serve as a model for the regulations to be promulgated on the basis of the legislation. As in 1976, I believe the Guidelines should not become regulations without new legislation specifically mandating this.

Registration and Compliance (Specific)

Section IV-C has been added providing the elements for registration. Other requirements may need to be added; notice will be given of any change in the requirements. All projects subject to the Guidelines must be registered with ORDA. A mechanism for voluntary registration by the private sector has been provided in response to suggestions by private sector representatives. A requirement for registration is that the registrant must agree to abide by the standards of the Guidelines.

Many comments were directed to the protection of proprietary information. A new section outlining the elements for protection of proprietary data has been included in response to these suggestions.

One commentator urged that no patents be granted for recombinant DNA research inventions. Shortly after the release of the Guidelines in 1976, NIH received a letter requesting a review of HEW policies relating to the patenting of recombinant DNA research inventions. The letter prompted NIH to review current patent regulations governing existing institutional patent agreements and to consider how recombinant DNA research inventions should be handled under the terms of those agreements. On the basis of ex-

tensive Department and Interagency Committee review, it was agreed that, at least for the present, recombinant DNA research inventions developed under HEW/NIH support should continue to be administered within current HEW patent agreements. Each agreement, however, would require that licenses could be granted only if the licensee provides assurance of compliance with the physical and biological containment standards set forth in the Guidelines. My decision and analysis on this were released in March 1978. A copy is available from the Office of Recombinant DNA Activities, NIH, Bethesda, Md. 20014. Thus, I do not believe that a restriction of patents in this research area is warranted.

A commentator urged that a system of fines be spelled out. NIH has no authority to impose fines in the absence of new legislation. However, NIH will suspend, limit, or terminate a grant or contract for noncompliance with the Guidelines. A commentator urged that penalty procedures be specified. Should it be necessary to suspend, limit, or terminate a grant, appropriate HEW procedures will be followed.

In sum, Part IV of the Guidelines on Roles and Responsibilities has been substantially revised in response to the suggestions from many commentators. The Guidelines now provide even more opportunity for advice from the local to the national level. The spirit of cooperation and effective oversight will be enhanced by the revised Guidelines both at the local level between the research community and the public and at the national level with Federal agencies, the scientific community, and private sectors.

DONALD S. FREDRICKSON,
Director,
National Institutes of Health.

RECOMBINANT DNA RESEARCH—REVISED GUIDELINES PROPOSED BY THE DIRECTOR, NIH

JULY 1978.

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I. SCOPE OF THE GUIDELINES

I-A. *Purpose.* The purpose of these guidelines is to specify practices for constructing and handling (i) recombinant DNA molecules and (ii) organisms and viruses containing recombinant DNA molecules.

I-B. *Definition of Recombinant DNA Molecules.* In the context of these guidelines, recombinant DNA molecules are defined as either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above.

I-C. *General Applicability.* The guidelines are applicable to all recombinant DNA research within the United States or its territories conducted at or sponsored by an institution that receives any support for recombinant DNA research from NIH. This includes research performed directly by NIH.

Any individual receiving support must be associated with or sponsored by an institution which can and does assume responsibilities described in these guidelines.

Once approved at the local level, research may proceed but shall be modified in accordance with the recommendations of the NIH if found not to

comport with requirements of the NIH guidelines.

The guidelines are also applicable to projects done abroad if they are supported by NIH funds. If the host country has established rules for the conduct of recombinant DNA projects, then a certificate of compliance with the host country rules may be submitted to NIH in lieu of compliance with the guidelines. NIH reserves the right to withhold funding if the safety practices to be employed are not reasonably consistent with the NIH guidelines. In any case, a memorandum of understanding and agreement (MUA) shall be submitted to NIH for purposes of registration.

I-D. *Prohibitions.* The following experiments are not to be initiated at the present time:

I-D-1. Formation of recombinant DNA's derived from the pathogenic organisms classified(*1*) as class 3, 4, or 5(*2*) or from cells known to be infected with such agents, regardless of the host-vector system used.

I-D-2. Deliberate formation of recombinant DNA's containing genes for the biosynthesis of potent toxins (e.g., botulinum or diphtheria toxins; venoms from insects, snakes, etc.).

I-D-3. Deliberate creation by the use of recombinant DNA of a plant pathogen with increased virulence and host range beyond that which occurs by natural genetic exchange.

I-D-4. Deliberate release into the environment of any organism containing recombinant DNA.

I-D-5. Deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire it naturally, if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture.

I-D-6. Large-scale experiments (e.g., more than 10 liters of culture) with organisms containing recombinant DNA's, unless the recombinant DNA's are rigorously characterized and are shown to be free of harmful genes.(*3*)

We differentiate between small- and large-scale experiments with organisms containing recombinant DNA's because the probability of escape from containment barriers normally increases with increasing scale.

Experiments in these categories may be excepted(*4*) from the prohibitions (and will at that time be assigned appropriate levels of physical and biological containment) provided that these experiments are expressly approved by the Director, NIH, on recommendation of the Recombinant DNA Advisory Committee after appropriate notice and opportunity for public comment. In making such exceptions, weight will be given both to scientific and societal benefits and to potential risks.

I-E. *Exemptions.* It must be emphasized that the following exemptions(*4*) are not meant to apply to experiments described in the section I-D as being prohibited.

The following recombinant DNA molecules are exempt from these guidelines, and no registration with NIH is necessary:

I-E-1. Those that are not in organisms or viruses.(*5*)

I-E-2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA sources, though one or more of the segments may be a synthetic equivalent.

I-E-3. Those that consist entirely of DNA from a prokaryotic host, including its indigenous plasmids or virsuses, when propagated only in that host (or closely related strain of the same species); also those that consist entirely of DNA from a eukaryotic host, including its chloroplasts, mitochondria, or plasmids (but excluding viruses), when propagated only in that host (or a closely related strain of the same species).

I-E-4. Certain specified recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee, after appropriate notice and opportunity for public comment. Certain classes are exempt as of publication of these revised guidelines. The list in appendix A. An updated list may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Md. 20014.

I-E-5. Other classes of recombinant DNA molecules if the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee, after appropriate notice and opportunity for public comment, finds that they do not present a significant risk to health or the environment.

I-F. *General Definitions.* The following terms, which are used throughout these guidelines, are defined as follows:

I-F-1. "DNA" means deoxyribo- nucleic acid.

I-F-2. "Recombinant DNA molecule" means either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules which result from the replication of a molecule described in (i) above.

I-F-3. "Director" means the Director of the National Institutes of Health (NIH) and any other officer or employee of NIH to whom authority has been delegated.

I-F-4. "Institution" means any public or private entity (including Federal, State, and local government agencies).

I-F-5. "Memorandum of Understanding and Agreement" or "MUA" means an institution's certification to NIH that the project will comply with the guidelines. See appendix C regarding the form and contents of an MUA.

I-F-6. "Institutional Biosafety Committee" or "IBC" is discussed in detail in section IV-A-2.

I-F-7. "Area Biosafety Committee" or "ABC" means that in special circumstances, in consultation with the NIH Office of Recombinant DNA Activities, an Area Biosafety Committee may be formed, composed of members from the institution and other organizations beyond its own staff, as an alternative to an IBC when additional expertise outside the institution is needed for the indicated reviews.

I-F-8. "Recombinant DNA Advisory Committee" or "RAC" means the public advisory committee that shall advise the Secretary, Assistant Secretary for Health, and the Director of the National Institutes of Health, concerning recombinant DNA research. The RAC shall consist of members who shall be selected from persons knowledgeable in the fields of recombinant DNA technology, biological safety, and community interests. Nominations for the RAC may be submitted to ORDA and will be considered in accordance with established nomination procedures for NIH peer review groups.

I-F-9. "NIH Office of Recombinant DNA Activities" or "ORDA" means the office within NIH with responsibility to (i) review and coordinate all activities of NIH related to the guidelines; (ii) foster the interrelationships between NIH and other Government agencies, private foundations, professional societies and industry, in order to assure coordination of activities; (iii) promote international cooperation; (iv) review the composition of Institutional Biosafety Committees; (v) review MUA's; (vi) develop registries of activities related to recombinant DNA research (laboratories, projects, new containment facilities, etc.); and (vii) prepare regular reports.

II. Containment

Effective biological safety programs have been operative in a variety of laboratories for many years. Considerable information therefore already exists for the design of physical containment facilities and the selection of laboratory procedures applicable to organisms carrying recombinant DNA's. (*6-19*) The existing programs rely upon mechanisms that, for convenience, can

be divided into two categories: (i) a set of standard practices that are generally used in microbiological laboratories, and (ii) special procedures, equipment, and laboratory installations that provide physical barriers which are applied in varying degrees according to the estimated biohazard.

Experiments on recombinant DNA's, by their very nature, lend themselves to a third containment mechanism—namely, the application of highly specific biological barriers. In fact, natural barriers do exist which limit either (i) the infectivity of a *vector*, or *vehicle*, (plasmid, bacteriophage, or virus) to specific *hosts* or (ii) its dissemination and survival in the environment. The vectors that provide the means for replication of the recombinant DNA's and/or the host cells in which they replicate can be genetically designed to decrease by many orders of magnitude the probability of dissemination of recombinant DNA's outside the laboratory.

As these three means of containment are complimentary, different levels of containment appropriate for experiments with different recombinants can be established by applying various combinations of the physical and biological barriers along with a constant use of the standard practices. We consider these categories of containment separately here in order that such combinations can be conveniently expressed in the guidelines.

In constructing these guidelines, it was necessary to define boundary conditions for the different levels of physical and biological containment and for the classes of experiments to which they apply. We recognize that these definitions do not take into account all existing and anticipated information on special procedures that will allow particular experiments to be carried out under different conditions than indicated here without affecting risk. Indeed, we urge that individual investigators devise simple and more effective containment procedures and that investigators and institutional biosafety committees recommend changes in the guidelines to permit their use.

II-A. *Standard Practices and Training.* The first principle of containment is a strict adherence to good microbiological practices. (*6–15*) Consequently, all personnel directly or indirectly involved in experiments on recombinant DNA's must receive adequate instruction. This should as a minimum include instruction in aseptic techniques and in the biology of the organisms used in the experiments, so that the potential biohazards can be understood and appreciated.

Any research group working with agents with a known or potential biohazard should have an emergency plan which describes the procedures to be followed if an accident contaminates personnel or the environment. The principal investigator must insure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan. If a research group is working with a known pathogen for which an effective vaccine is available, all workers should be immunized. Serological monitoring, where appropriate, should be provided.

II-B. *Physical Containment Levels.* The objective of physical containment is to confine organisms containing novel recombinant DNA molecules, and thus to reduce the potential for exposure of the laboratory worker, persons outside of the laboratory, and the environment to organisms containing novel recombinant DNA molecules. Physical containment is achieved through the use of laboratory practices, containment equipment, and special laboratory design. Emphasis is placed on primary means of physical containment which are provided by laboratory practices and containment equipment. Special laboratory design provides a secondary means of protection against the accidental release of organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities in which experiments of moderate to high potential hazard are performed.

Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment. Four levels of physical containment, which are designated as P1, P2, P3, and P4, are described. It should be emphasized that the descriptions and assignments of physical containment detailed below are based on existing appproaches, to containment of pathogenic organisms. For example, the "Classification of Etiologic Agents on the Basis of Hazard," (*7*) prepared by the Center for Disease Control, describes four general levels which roughly correspond to our descriptions for P1, P2, P3, and P4; and the National Cancer Institute describes three levels for research on oncogenic viruses which roughly correspond to our P2, P3, and P4 levels.(*8*)

It is recognized that several different combinations of laboratory practices, containment equipment, and special laboratory design may be appropriate for containment of specific research activities. The guidelines, therefore, allow alternative selections of primary containment equipment within facilities that have been designed to provide P3 and P4 levels of physical containment. The selection of alternative methods of primary containment is dependent, however, on the level of biological containment provided by the host-vector system used in the experiment. Consideration will also be given by the Recombinant DNA Advisory Committee to other combinations which achieve an equivalent level of containment. Additional material on physical containment for plant host-vector systems is found in sections III-C-3 and III-C-4.

II-B-1. *P1 Level.*

II-B-1-a. *Laboratory Practices.*

II-B-1-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-1-a-(2). Work surfaces shall be decontaminated daily, and immediately following spills of organisms containing recombinant DNA molecules.

II-B-1-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials such as glassware, animal cages, and laboratory equipment shall be decontaminated before washing, reuse, or disposal.

II-B-1-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-1-a-(5). Eating, drinking, smoking, and storage of foods are not permitted in the working area.

II-B-1-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-1-a-(7). Care shall be taken in the conduct of all procedures to minimize the creation of aerosols.

II-B-1-a-(8). Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container which is closed before removal from the laboratory.

II-B-1-a-(9). An insect and rodent control program shall be instituted.

II-B-1-a-(10). The use of laboratory gowns, coats, or uniforms is discretionary with the laboratory supervisor.

II-B-1-a-(11). Use of the hypodermic needle and syringe shall be avoided when alternative methods are available.

II-B-1-b. *Containment Equipment.* Special containment equipment is not required at the P1 level.

II-B-1-c. *Special Laboratory Design.* Special laboratory design is not required at the P1 level.

II-B-2. *P2 Level.*

II-B-2-a. *Laboratory Practices.*

II-B-2-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-2-a-(2). Work surfaces shall be decontaminated daily, and immediately following spills of organisms containing recombinant DNA molecules.

II-B-2-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials such as glassware, animal cages, and labora-

tory equipment shall be decontaminated before washing, reuse, or disposal.

II-B-2-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-2-a-(5). Eating, drinking, smoking, and storage of food are not permitted in the laboratory area.

II-B-2-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-2-a-(7). *Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that it splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-2-a-(8). Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container which is closed before removal from the laboratory.

II-B-2-a-(9). *Only persons who have been advised of the nature of the research being conducted shall enter the laboratory.

II-B-2-a-(10). *Children under 12 years of age shall not enter the laboratory.

II-B-2-a-(11). *The universal biohazard sign shall be posted on all laboratory access doors when experiments requiring P2 containment are in progress. Freezers and refrigerators used to store organisms containing recombinant DNA molecules shall also be posted with the universal biohazard sign.

II-B-2-a-(12). An insect and rodent control program shall be instituted.

II-B-2-a-(13). *The use of laboratory gowns, coats, or uniforms is required. Laboratory clothing shall not be worn to the lunch room or outside of the building in which the laboratory is located.

II-B-2-a-(14). *Animals not related to the experiment shall not be permitted in the laboratory.

II-B-2-a-(15). Use of the hypodermic needle and syringe shall be avoided when alternative methods are available.

II-B-2-a-(16). *The laboratory shall be kept neat and clean.

II-B-2-a-(17). *Experiments of lesser biohazard potential can be carried out concurrently in carefully demarcated areas of the same laboratory.

II-B-2-b. *Containment Equipment.* *Biological safety cabinets (*20*) shall be used to contain aerosol-producing equipment such as blenders, lyophilizers, sonicators, and centrifuges when used to process organisms containing recombinant DNA molecules, except where equipment design provides for containment of the potential aerosol. For example, a centrifuge may be operated in the open if a sealed head or safety centrifuge cups are used.

II-B-2-c. *Special Laboratory Design.* *An autoclave for sterilization of wastes and contaminated materials shall be available in the same building in which organisms containing recombinant DNA molecules are used.

II-B-3. *P3 Level.*

II-B-3-a. *Laboratory Practices.*

II-B-3-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-3-a-(2). *Work surfaces shall be decontaminated following the completion of the experimental activity, and immediately folowing spills of organisms containing recombinant DNA molecules.

II-B-3-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials such as glassware, animal cages, and laboratory equipment shall be decontaminated before washing, reuse, or disposal.

II-B-3-a-(4). Mechanical pipetting devices shall be used; pipetting by month is prohibited.

II-B-3-a-(5). Eating, drinking, smoking, and storage of food are not permitted in the laboratory area.

II-B-3-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-3-a-(7). Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that it splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-3-a-(8). Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container which is closed before removal from the laboratory.

II-B-3-a-(9). *Entry into the laboratory shall be through a controlled access area. Only persons who have been advised of the nature of the research being conducted shall enter the controlled access area. Only persons required on the basis of program or support needs shall be authorized to enter the laboratory. Such persons shall be advised of the nature of the research being conducted before entry, and shall comply with all required entry and exit procedures.

II-B-3-a-(10). Children under 12 years of age shall not enter the laboratory.

II-B-3-a-(11). *The universal biohazard sign shall be posted on the controlled access area door and on all laboratory doors when experiments requiring P3-level containment are in progress. Freezers and refrigerators used to store organisms containing recombinant DNA molecules shall also be posted with the universal biohazard sign.

II-B-3-a-(12). An insect and rodent control program shall be instituted.

II-B-3-a-(13). *Laboratory clothing that protects street clothing (i.e., long-sleeve solid-front or wrap-around gowns, no-button or slipover jackets, etc.) shall be worn in the laboratory. Front-button laboratory coats are unsuitable. Laboratory clothing shall not be worn outside the laboratory and shall be decontaminated before it is sent to the laundry.

II-B-3-a-(14). *Raincoats, overcoats, topcoats, coats, hats, caps, and such street outer-wear shall not be kept in the laboratory.

II-B-3-a-(15). *Gloves shall be worn when handling materials requiring P3 containment. They shall be removed aseptically immediately after the handling procedure and decontaminated.

II-B-3-a-(16). *Animals and plants not related to the experiment shall not ber permitted in the laboratory.

II-B-3-a-(17). *Vacuum outlets shall be protected by filter and liquid disinfectant traps.

II-B-3-a-(18). Use of hypodermic needle and syringe shall be avoided when alternative methods are available.

II-B-3-a-(19). The laboratory shall be kept neat and clean.

II-B-3-a-(20). *If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring P3-level physical containment, they shall be conducted in accordance with all P3-level laboratory practices.

II-B-3-b. *Containment Equipment.*

II-B-3-b-(1). *Biological safety cabinets *20* shall be used for all equipment and manipulations that produce aerosols—e.g., pipetting, dilutions, transfer operations, plating, flaming, grinding, blending, drying, sonicating, shaking, centrifuging—where these procedures involve organisms containing recombinant DNA molecules, except where equipment design provides for containment of the potential aerosol.

II-B-3-b-(2). *Laboratory animals held in a P3 area shall be housed in partial containment caging systems such as Horsfall units, open cages placed in ventilated enclosures, solid-wall-and-bottom cages covered by filter bonnets, or solid-wall and

*Denotes laboratory practices, containment equipment, or special laboratory design which were not required at the next lower level of containment.

bottom-cages placed on holding racks equipped with ultraviolet radiation lamps and reflectors. (NOTE: Conventional caging systems may be used, provided that all personnel wear appropriate personal protective devices. These shall include at a minimum wraparound gowns, head covers, gloves, shoe covers, and respirators. All personnel shall shower on exit from areas where these devices are required.)

II-B-3-b-(3). *Alternative Selection of Containment Equipment.* Experimental procedures involving a host-vector system which provides a one-step higher level of biological containment than that specified in Part III can be conducted in the P3 laboratory using containment equipment specified for the P2 level of physical containment. Experimental procedures involving a host-vector system which provides a one-step lower level of biological containment than that specified in Part III can be conducted in the P3 laboratory using containment equipment specified for the P4 level of physical containment. Alternative combinations of containment safeguards are shown in table I.

Table I

COMBINATIONS OF CONTAINMENT SAFEGUARDS

Classification of experiment according to Guidelines		Alternate combinations of physical and biological containment			
		Physical Containment			
Physical containment	Biological* containment	Laboratory design specified for:	Laboratory practices specified for:	Containment equipment specified for:	Biological containment
P3	HV3	P3	P3	P3	HV3
P3	HV3	P3	P3	P4	HV2
P3	HV2	P3	P3	P3	HV2
P3	HV2	P3	P3	P2	HV3
P3	HV2	P3	P3	P4	HV1
P3	HV1	P3	P3	P3	HV1
P3	HV1	P3	P3	P2	HV2

*See Section II-D for description of biological containment.

II-B-3-c. *Special Laboratory Design.*

II-B-3-c-(1). *The laboratory shall be separated from areas which are open to unrestricted traffic flow by a controlled access area. A controlled access area is an anteroom, a change room, an air lock or any other double-door arrangement which separates the laboratory from areas which are open to unrestricted traffic flow.

II-B-3-c-(2). *The surfaces of walls, floors, and ceilings shall be readily cleanable. Penetrations through these surfaces shall be sealed or capable of being sealed to facilitate space decontamination.

II-B-3-c-(3). *A foot, elbow, or automatically operated handwashing facility shall be provided near each primary laboratory exit area.

II-B-3-c-(4). *Windows in the laboratory shall be sealed.

II-B-3-c-(5). *Laboratory doors shall be self-closing.

II-B-3-c-(6). *An autoclave for sterilization of wastes and contaminated materials shall be available in the same building (and preferably within the controlled laboratory area) in which organisms containing recombinant DNA molecules are used.

II-B-3-c-(7). *An exhaust air ventilation system shall be provided. This system shall be balanced so that the direction of airflow is from the controlled access area into the laboratory environment. The exhaust air shall not be recirculated to any other areas of the building. Recirculation of air within the laboratory room, however, may be provided. The exhaust air from the laboratory shall be discharged to the outdoors so that it is dispersed clear of occupied buildings and air intakes. the exhaust air from the laboratory can be discharged to the outdoors without filtration or other treatment.

II-B-3-c-(8). *The treated exhaust air from class I and class II biological safety cabinets (*20*) may be discharged either directly to the laboratory or to the outdoors. The treated exhaust air from a class III cabinet shall be discharged directly to the outdoors. If the treated exhaust air from these cabinets is to be discharged to the outdoors through a building exhaust air system, it shall be connected to this system so as to avoid any interference with the air balance of the cabinet or building exhaust air system.

II-B-4. *P4 Level.*

II-B-4-a. *Laboratory Practices.*

II-B-4-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-4-a-(2). Work surfaces shall be decontaminated following the completion of the experimental activity and immediately following spills of organisms containing recombinant DNA molecules.

II-B-4-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials such as glassware, animal cages, and laboratory equipment shall be decontaminated before washing, reuse, or disposal.

II-B-4-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-4-a-(5). *Eating, drinking, smoking, and storage of food are not permitted in the P4 facility.

II-B-4-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-4-a-(7). Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that is splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-4-a-(8). *Biological materials to be removed from the P4 facility in a viable or intact state, shall be transferred to a nonbreakable sealed container which is then removed from the P4 facility through a passthrough disinfectant dunk tank or fumigation chamber.

II-B-4-a-(9). *No materials, except for biological materials that are to remain in a viable or intact state, shall be removed from the P4 facility unless they have been sterilized or decontaminated as they pass out of the P4 facility. All wastes and other materials as well as equipment not damaged by high temperature or steam shall be sterilized in the double-door autoclave of the P4 facility. Other materials which may be damaged by temperature or steam shall be removed from the P4 facility through a passthrough fumigation chamber.

II-B-4-a-(10). *Materials within the class III cabinets shall be removed from the cabinet system only after being sterilized in an attached double-door autoclave or after being contained in a nonbreakable sealed container which is then passed through a disinfectant dunk tank or a fumigation chamber.

II-B-4-a-(11). *Only persons whose entry into the P4 facility is required to meet program or support needs shall be authorized to enter. Before entering, such persons shall be advised of the nature of the research being conducted and shall be instructed as to the appropriate safeguards to insure their safety. They shall comply with instructions and all other required procedures.

II-B-4-a-(12). *Persons under 18 years of age shall not enter the P4 facility.

II-B-4-a-(13). *Personnel shall enter into and exit from the P4 facility only through the clothing change and shower rooms. Personnel shall shower at each egress from the P4 facility. Air locks shall not be used for personnel entry or exit except for emergencies.

II-B-4-a-(14). *Street clothing shall be removed in the outer side of the P4 facility clothing change area and kept there. Complete laboratory clothing including undergarments, head cover, shoes, and either pants and shirts or jumpsuits shall be provided and used by all persons who enter the P4 facility. Upon exit, personnel shall store this clothing in lockers provided for this purpose or discard it into collection hampers before entering the shower area.

II-B-4-a-(15). *The universal biohazard sign is required on the P4 facility access doors and all interior doors to individual laboratory rooms where experiments are conducted.

II-B-4-a-(16). An insect and rodent control program shall be instituted.

II-B-4-a-(17). Animals and plants not related to the experiment shall not be permitted in the laboratory in which the experiment is being conducted.

II-B-4-a-(18). Use of the hypodermic needle and syringe shall be avoided when alternate methods are available.

II-B-4-a-(19). The laboratory shall be kept neat and clean.

II-B-4-a-(20). *If experiments involving other organisms which require lower levels of containment are to be conducted in the P4 facility concurrently with experiments requiring P4-level containment, they shall be conducted in accordance with all P4-level laboratory practices specified in this section.

II-B-4-b. *Containment Equipment.*

II-B-4-b-(1). *Experimental procedures involving organisms which require P4-level physical containment shall be conducted either in (i) a class III cabinet system or in (ii) class I or class II cabinets that are located in a specially designed area in which all personnel are required to wear one-piece positive-pressure isolation suits.

II-B-4-b-(2). *Laboratory animals involved in experiments requiring P4-level physical containment shall be housed either in cages contained in class III cabinets or in partial containment caging systems (such as Horsfall units, open cages placed in ventilated enclosures, or solid wall and bottom cages covered by filter bonnets, or solid wall and bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors) that are located in a specially designed area in which all personnel are required to wear one-piece positive-pressure suits.

II-B-4-b-(3). **Alternative Selection of Containment Equipment.* Experimental procedures involving a host-vector system which provides a one-step higher level of biological containment than that specified in Part III can be conducted in the P4 facility using containment equipment requirements specified for the P3 level of physical containment. Alternative combinations of containment safeguards are shown in table II.

Table II

COMBINATIONS OF CONTAINMENT SAFEGUARDS

Classification of experiment according to Guidelines		Alternate combinations of physical and biological containment			
		Physical containment			
Physical containment	Biological* containment	Laboratory design specified for:	Laboratory practices specified for:	Containment equipment specified for:	Biological containment
P4	HV1	P4	P4	P4	HV1
P4	HV1	P4	P4	P3	HV2

* See Section II-D for description of biological containment.

II-B-4-c. *Special Laboratory Design.*

II-B-4-c-(1). *The laboratory shall be located in a restricted access facility which is either a separate building or a clearly demarcated and isolated zone within a building. Clothing change areas and shower rooms shall be provided for personnel entry and egress. These rooms shall be arranged so that personnel egress is through the shower area to the change room. A double-door ventilated vestibule or ultraviolet air lock shall be provided for passage of materials, supplies, and equipment which are not brought into the P4 facility through the change room area.

II-B-4-c-(2). *Walls, floors, and ceilings of the P4 facility are constructed to form an internal shell which readily allows vapor-phase decontamination and is animal- and insect-proof. All penetrations through these structures and surfaces are sealed. (The integrity of the walls, floors, ceilings, and penetration seals should insure adequate containment of a vapor-phase decontaminant under static pressure conditions. This requirement does not imply that these surfaces must be airtight.)

II-B-4-c-(3). *A foot-, elbow-, or automatically-operated hand washing facility shall be provided near the door within each laboratory in which experiments involving recombinant DNA are conducted in open-face biological safety cabinets.

II-B-4-c-(4). *Where a central vacuum system is provided, it shall not serve areas outside the P4 facility. The vacuum system shall include in-line HEPA filters as near as practicable to each use point or service cock. The filters shall be installed so as to permit in-place decontamination and replacement. Water supply and liquid and gaseous services provided to the P4 facility shall be protected by devices that prevent backflow.

II-B-4-c-(5). *Foot-operated water fountains are permitted in the corridors of the P4 facility. The water service provided to the fountain shall be protected from the water services to the laboratory areas of the P4 facility.

II-B-4-c-(6). Laboratory doors shall be self-closing.

II-B-4-c-(7). *A double-door autoclave shall be provided for sterilization of material passing out of the P4 facility. The autoclave doors shall be interlocked so that both doors will not be open at the same time.

II-B-4-c-(8). *A passthrough dunk tank or fumigation chamber shall be provided for removal of material and equipment that cannot be heat-sterilized from the P4 facility.

II-B-4-c-(9). *All liquid effluents from the P4 facility shall be collected and decontaminated before disposal. Liquid effluents from biological safety cabinets and laboratory sinks shall be

sterilized by heat. Liquid effluents from the shower and hand washing facilities may be inactivated by chemical treatment. HEPA filters shall be installed in all effluent drain vent lines.

II-B-4-c-(10). *An individual supply and exhaust-air ventilation system shall be provided for the P4 facility. The system shall maintain pressure differentials and directional airflow as required to assure inflow from areas outside the P4 facility toward areas of highest potential risk within the facility. The system shall be designed to prevent the reversal of airflow. The system shall sound an alarm in the event of system malfunction.

II-B-4-c-(11). *Recirculation of air within individual laboratories of the P4 facility is permissible if this air is filtered by a HEPA filter.

II-B-4-c-(12). *The exhaust air from the P4 facility shall be filtered and discharged to the outdoors so that it is dispersed clear of occupied buildings and air intakes. The filter chambers shall be designed to allow in situ decontamination before removal and to facilitate certification testing after replacement.

II-B-4-c-(13). The treated exhaust air from Class I and Class II biological safety cabinets(*20*) may be discharged directly to the laboratory room environment or to the outdoors. The treated exhaust air from Class III cabinets shall be discharged to the outdoors. If the treated exhaust air from these cabinets is to be discharged to the outdoors through the P4 facility exhaust air system, it shall be connected to this system so as to avoid any interference with the air balance of the cabinets or the facility exhaust air system.

II-B-4-c-(14). *A specially designed suit area may be provided in the facility. Personnel who enter this area shall wear a one-piece positive-pressure suit that is ventilated by a life-support system. The life-support system shall be provided with alarms and emergency backup air. Entry to this area is through an air-lock fitted with airtight doors. A chemical shower area shall be provided to decontaminate the surfaces of the suit before removal. The exhaust air from the suit area shall be filtered by two sets of HEPA filters installed in series, and a duplicate filtration unit and exhaust fan shall be provided. The air pressure within the suit area shall be less than that in any adjacent area. An emergency lighting system, communication systems, and power source shall be provided.

The internal shell of the suit area shall be airtight. A doubledoor autoclave shall be provided for sterilization of all waste materials to be removed from the suit area.

II-C. *Shipment.* Recombinant DNA when contained in an organism or virus shall be shipped in compliance with the requirements issued by the U.S. Public Health Service (section 72.25 of Part 72, Title 42, Code of Federal Regulations), Department of Transportation (section 173.387(b) of Part 173, Title 49, Code of Federal Regulations), and the Civil Aeronautics Board (C.A.B. No. 82, Official Air Transport Restricted Articles Tariff No. 6-D) for shipment of etiologic agents.

The packaging and shipment of organism and viruses containing recombinant DNA molecules shall be in compliance with all requirements specified in subparagraphs (1)-(5) of paragraph (c), "Transportation; etiologic agents subject to additional requirements," of section 72.25 of Part 72, Title 42, Code of Federal Regulations. Subparagraph (6) of paragraph (c) of section 72.25 of Part 72, Title 42, Code of Federal Regulations shall apply to the shipment of all viable host and vector organisms which require P4 physical containment.

Additional information on packaging and shipment is given in "Labortory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research."

II-D. *Biological containment.*

II-D-1. *Levels of biological containment.* In consideration of biological containment, the vector (plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory will be considered together. Any combination of vector and host which are to provide biological containment must be constructed so that the following types of "escape" are minimized: (i) Survival of the vector in its host outside the laboratory, and (ii) transmission of the vector from the propagation host to other nonlaboratory hosts.

The following levels of biological containment (HV, or *Host-Vector*, systems) for prokaryotes will be established; specific criteria will depend on the organisms to be used. Eukaryotic host-vector systems are considered in Part III.

II-D-1-a. *HV1.* A host-vector system which provides a moderate level of containment. *Specific systems:*

II-D-1-a-(1). *EK1.* The host is always *E. coli* K-12 or a derivative thereof, and the vectors include nonconjugative plasmids (e.g., pSC101, ColE1, or derivatives thereof (*21-27*) and variants of bacteriophage, such as 0(*28-33*). The *E. coli* K-12 hosts should not contain conjugation-proficient plasmids, whether autonomous or integrated, or generalized transducing phages.

II-D-1-a-(2). *Other Prokaryotes.* Hosts and vectors should be, at a minimum, comparable in containment to *E. coli* K-12 with a nonconjugative plasmid or bacteriophage vector. The data to be considered and a mechanism for approval of such HV1 systems are described below (section II-D-2).

II-D-1-b. *HV2.* These are host-vector systems shown to provide a high level of biological containment as demonstrated by data from suitable tests performed in the laboratory. Escape of the recombinant DNA either via survival of the organisms or via transmission of recombinant DNA to other organisms should be less than $1/10^8$ under specified conditions. *Specific systems:*

II-D-1-b-(1). For EK2 host-vector systems in which the vector is a plasmid, no more than one in 10^8 host cells should be able to perpetuate a cloned DNA fragment under the specified nonpermissive laboratory conditions designed to represent the natural environment, either by survival of the original host or as a consequence of transmission of the cloned DNA fragment.

II-D-1-b-(2). For EK2 host-vector systems in which the vector is a phage, no more than one in 10^8 phage particles should be able to perpetuate a cloned DNA fragment under the specified nonpermissive laboratory conditions designed to represent the natural environment either (i) as a prophage or plasmid in the laboratory host used for phage propagation or (ii) by surviving in natural environments and transferring a cloned DNA fragment to other hosts (or their resident prophages).

II-D-1-c. *HV3.* These are host-vector systems in which:

II-D-1-c-(1). All HV2 criteria are met.

II-D-1-c-(2). The vector is dependent on its propagation host or is highly defective in mobilizability. Reversion to host-independence must be less than $1/10^8$ per vector genome per generation.

II-D-1-c-(3). No markers conferring resistance to antibiotics commonly used clinically or in agriculture are carried by the vector, unless expression of such markers is dependent on the propagating host or on unique laboratory controlled conditions or is blocked by the inserted DNA.

II-D-1-c-(4). The specified containment shown by laboratory tests has been independently confirmed by specified tests in animals, including primates, and in other relevant environments.

II-D-1-c-(5). The relevant genotypic and phenotypic traits have been independently confirmed.

II-D-2. *Certification of host-vector systems.*

II-D-2-a. *Responsibility.* HV1 systems other than *E. coli* K-12, and HV2 and HV3 host-vector systems may not

be used unless they have been certified by the NIH. Application for certification of a host-vector system is made by written application to the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, Md. 20014.

When appropriate, the proposed host-vector system will be reviewed by the NIH Recombinant DNA Advisory Committee (RAC). This may first involve review of the data on construction, properties, and testing of the proposed host-vector system by a subcommittee composed of one or more members of the RAC and other individuals chosen because of their expertise in evaluating such data. The committee will then evaluate the report of the subcommittee and any other available information at a regular meeting.

When new host-vector systems are certified, notice of the certification will be sent to the applicant and to all IBCs and will be published in the "recombinant DNA Technical Bulletin." Copies of a list of all currently certified host-vector systems may be obtained from ORDA at any time.

NIH may at any time rescind the certification of any host-vector system. If certification of a host-vector system is rescinded, investigators may be asked to transfer cloned DNA into a different system.

Certification of a given system does not extend to modifications of either the host or vector component of that system. Such modified systems must be independently certified by NIH. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. More substantial modifications of a certified system may necessitate submission of complete testing data.

II-D-2-b. *Data to be Submitted for Certification*

II-D2-b-(1). *HV1 Systems Other than E. Coli K-12.* The following types of data should be submitted, modified as appropriate for the particular system under consideration: (i) A description of the organism and vector; the strain's natural habitat and growth requirements; the range of organisms with which this organism normally exchanges genetic information and what sort of information is exchanged; any relevant information on its pathogenicity or toxicity. (ii) A description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information. (iii) A general description of the range of experiments contemplated, with emphasis on the need for developing such an HV1 system.

I-D-2-b-(2). *HV2 Systems.* Investigators planning to request HV2 certification for host-vector systems can obtain instructions from ORDA concerning data to be submitted. In general, the following types of data are required: (i) Description of construction steps, with indication of source, properties, and manner of introduction of genetic traits. (ii) Quantitative data on the stability of genetic traits that contribute to the containment of the system. (iii) Data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment. (iv) Data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and non-permissive conditions. (v) Data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation. (vi) In some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals (e.g., rodents). Such *in vivo* data may be required to confirm the validity of predicting *in vivo* survival on the basis of *in vitro* experiments.

Data must be submitted in writing to ORDA. Ten to twelve weeks are normally required for review and circulation of the data prior to the meeting at which such data can be considered by the NIH Recombinant DNA Advisory Committee (RAC). Investigators are encouraged to publish their data on the construction, properties, and testing of proposed HV2 systems prior to consideration of the system by the RAC and its subcommittee. More specific instructions concerning the type of data to be submitted to NIH for proposed EK2 systems involving either plasmids or bacteriophage 0 in *E. coli* K-12 are available from ORDA

II-D-2-b-(3). *HV3 Systems.* Putative HV3 systems must, as the first step in certification, be certified as HV2 systems. Systems which meet the criteria given above under II-D-1-(c)-1, II-D-1-(c)-2, and II-D-1-(c)-3 will then be recommended for HV3 testing. Tests to evaluate various HV2 host-vector systems for HV3 certification will be performed by contractors selected by NIH. These contractors will repeat tests performed by individuals proposing the HV2 system and, in addition, will conduct more extensive tests on conditions likely to be encountered in nature. The genotypic and phenotypic traits of HV2 systems will be evaluated. Tests on survival and transmissibility in and on animals, including primates, will be performed, as well as tests on survival in certain specified natural environmnets.

II-D-3. *Distribution of Certified Host-Vectors.* Certified HV2 and HV3 host-vector systems (plus appropriate control strains) must be obtained from the NIH or its designees, one of whom will be the investigator who developed the system. NIH shall announce the availability of the system by publication of notices in appropriate journals.

Plasmid vectors will be provided in a suitable host strain, and phage vectors will be distributed as small-volume lysates. If NIH propagates any of the host strains or phage, a sample will be sent to the investigator who developed the system or to an appropriate contractor, prior to distribution, for verification that the material is free from contamination and unchanged in phenotypic properties.

In distributing the certified HV2 and HV3 host-vector systems, NIH or its designee will (i) send out a complete description of the system; (ii) enumerate and describe the tests to be performed by the user in order to verify important phenotypic traits; (iii) remind the user that any modification of the system necessitates independent approval of the system by the NIH on recommendation of the RAC; and (iv) remind the user of responsibility for notifying ORDA of any discrepancies with the reported properties or any problems in the safe use of the system.

NIH may also distribute certified HV1 host-vector systems.

III. Containment Guidelines for Covered Experiments

Part III discusses experiments covered by the guidelines. The reader must first consult part I, where listings are given of prohibited and exempt experiments.

Containment guidelines for permissible experiments are given in part III. Changes in these levels for specific experiments (or the assignment of levels to experiments not explicitly considered here) may be expressly approved by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee (RAC).

III-A. *Classification of Experiments Using the E. coli K-12 Host-Vector Systems.* Most recombinant DNA experiments currently being done employ *E. coli* K-12 host-vector systems. These are the systems for which we have the most experience and knowledge (i) regarding the effectiveness of biological containment provided by existing hosts and vectors, and (ii) necessary for the construction of more effective biological barriers. We therefore consider DNA recombinants in *E. coli* K-12 before proceeding to other host-vector systems. The levels of biological containment for *E. coli* K-12 systems

are designated EK1, EK2, and EK3 in ascending order.

It has been necessary, throughout this section, to use words and phrases such as "purified" or "rigorously characterized." In the text such terms are marked with footnote reference numbers. These footnotes (part V) define more fully what these terms denote.

In the following classification of containment criteria for different kinds of recombinant DNA's, the stated levels of physical and biological containment are minimal for the experiments designated. The use of higher levels of biological containment (EK3 > EK2 > EK1) is encouraged if they are available and equally appropriate for the purposes of the experiment.

III-A-1. *Shotgun Experiments.* These experiments involve the production of recombinant DNA's between the vector and portions of the specified cellular source, preferably a partially purified fraction. Care should be taken either to preclude or eliminate contaminating microogranisms before isolating the DNA.

III-A-1-a. *Eukaryotic DNA Recombinants.*

III-A-a-(1). *Primates.* P2 physical containment + and EK2 host-vector. Any lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee but requires NIH approval.

III-A-1-a-(2). *Other Mammals.* P2 physical containment + an EK2 host-vector.

III-A-1-a-(3). *Birds.* P2 physical containment + an EK2 host-vector.

III-A-1-a-(4). *Cold-Blooded Vertebrates.* P2 physical containment + an EK1 host-vector or P1 + EK2. If the eukaryote is known to produce a potent polypeptide toxin,[34] the containment shall be increased to P3 + EK2.

III-A-1-a-(5). *Other Cold-Blooded Animals and Lower Eukaryotes.* This large class of eukaryotes is divided into two groups:

III-A-1-a-(5)-(a). Species that are known to produce a potent polypeptide toxin(*34*) that acts in vertebrates, or are known pathogens listed in Class 2,(*1*) or are known to carry such pathogens must use P3 physical containment + an EK2 host-vector. When the potent toxin is not a polypeptide and is likely not to be the product of closely linked eukaryote genes, containment may be reduced to P3 + EK1 or P2 + EK2. Species that produce potent toxins that affect invertebrates of plants but not vertebrates require P2 + EK2 or P3 + EK1. Any species that has a demonstrated capacity for carrying particular pathogenic microorganisms is included in this group, unless the organisms used as the source of DNA have been shown not to contain those agents, in which case they may be placed in the following group.

III-A-1-a-(5)-(b). The remainder of the species in this class including plant pathogenic or symbiotic fungi that do not produce potent toxins: P2 + EK1 or P1 + EK2. However, any insect in this group must be either (i) grown under laboratory conditions for at least 10 generations prior to its use as a source of DNA, or (ii) if caught in the wild, must be shown to be free of dissease-causing microorganisms or must belog to a species that does not carry microorganisms causing disease in vertebrates or plants. If these conditions cannot be met, experiments must be done under P3 + EK1 or P2 + EK2 containment.

III-A-1-a-(6). *Plants.* P2 physical containment + an EK1 host-vector or P1 + EK2. If the plant source makes a potent polypeptide toxin,(*34*) the containment must be raised to P3 physical containment + an EK2 host-vector. When the potent toxin is not a polypeptide and is likely not to be the product of closely linked plant genes, containment may be reduced to P3 + EK1 or P2 + EK2.

III-A-1-b. *Prokaryotic DNA Recombinants.*

III-A-1-b-(1). *Prokaryotes That Exchange Genetic Information(35) with E. Coli.* It is expected that many of the prokaryotes that exchange genetic information with *E. coli* by known physiological processes will be exempted from these Guidelines by appearing on the 'list of exchangers' (see Section I-E-4).

For those not on the list, the containment levels are P1 physical containment + an EK1 host-vector. In fact, experiments in this category may be performed with any *E. coli* K-12 vector (e.g., conjugtive plasmids). However, for prokaryotes that are classified(*1*) as Class 2 the containment levels are P2 + EK1.

III-A-1-b-(2). *Prokaryotes That Do Not Exchange Genetic Information With E. Coli.* P2 physical containment + an EK1 host-vector, or P1 + EK2, except for DNA from Class 2 agents,(*1*) which require P3 + EK2.

III-A-2. *Plasmids, Bacteriophages, and Other Viruses.* Recombinants formed between a vector and some other plasmid or virus DNA have in common the potential for acting as double vectors because of the replication functions in these DNA's. The containment conditions given below apply only to propagation of the DNA recombinants in *E. coli* K-12 hosts. They do not apply to other hosts in which the recombinants may be able to replicate as a result of functions provided by the DNA inserted into the EK vectors. These are considered under other host-vector systems.

III-A—2—a. *Viruses of Eukaryotes.* (summary given in Table III).

III-A-2-a-(1). *DNA Viruses.*

III-A-2-a-(1)-(a). *Nontransforming viruses.*

III-A-2-a-(1)-(a)-(*1*). *Adeno-Associated Viruses, Minute Virus of Mice, Mouse Adenovirus (strain FL), and Plant Viruses.* P1 physical containment + and EK1 host-vector shall be used for DNA recombinants produced with (i) the whole viral genome, (ii) subgenomic DNA segments, or (iii) purified cDNA copies of viral mRNA.(*37*).

III-A-2-a-(1)-(a)-(*2*). *Hepatitis B.*

III-A-2-a-(1)-(a)-(*2*)-(*a*). P1 physical containment + an EK1 host-vector shall be used for purified subgenomic DNA segments.

III-A-2-a-(1)-(a)-(*2*)-(*b*). P2 physical containment + an EK2 host-vector or P3 + EK1 shall be used for DNA for recombinants produced with the whole viral genome.

III-A-2-a-(1)-(a)-(*2*)-(*c*). P2 physical containment + an EK1, shall be used for DNA recombinants derived from purified cDNA copies of viral mRNA.

III-A-2-a-(1)-(a)-(*3*). *Other Non transforming Members of Presently Classified Viral Families.*(*36*)

III-A-2-a-(1)-(a)-(*3*)-(*a*). P1 physical containment + an EK1 host-vector shall be used for (i) DNA recombinants produces with purified subgenomic DNA segments or (ii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(1)-(a)-(*3*)-(*b*). P1 physical containment + an EK1 host and a vector certified for use in an EK2 system shall be used for DNA recombinants produced with the whole viral genome.

III-A-2-a-(1)-(b). *Transforming Viruses.*

III-A-2-a-(1)-(b)-(*1*). *Herpes Saimiri, Herpes Ateles, and Epstein Barr Virus.*(*39*)

III-A-2-a-(1)-(b)-(*1*)-(*a*). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified nontransforming subgenamic DNA segments.(*38*)

III-A-2-a-(1)-(b)-(*1*)-(*b*). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system or P3 + EK1 shall be used for (i) DNA recombinants produced with purified subgenamic DNA segments containing an entire transforming gene or (ii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(1)-(b)-(*1*)-(c). P3 physical containment + an EK1 host-vector or P2 + EK2 shall be used for DNA recombinants produced with the whole viral genome.

III-A-2-a-(1)-(B)-(*2*). *Other Transforming Members of Presently Classified Viral Families.*(*36*)

III-A-2-a-(1)-(b)-(*2*)-(*a*). P1 physical containment + an EK1 host-vector

shall be used for DNA recombinants produced with purified nontransforming subgenamic DNA segments.(*38*)

III-A-2-a-(1)-(b)-(*2*)-(*b*). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system or P3 + EK1 shall be used for (i) DNA recombinants produced with the whole viral genome, (ii) purified subgenamic DNA segments containing an entire transforming gene, or (iii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(2). *DNA Transcripts of RNA Viruses.*

III-A-2-a-(2)-(a). *Retroviruses.*

III-A-2-a-(2)-(a)-(*1*). *Gibbon Ape, Woolly Monkey, Feline Leukemia and Feline Sarcoma Viruses.*(*39*)

III-A-2-a-(2)-a-(*1*)-(*a*). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified nontransforming subgenamic DNA segments.(*38*)

III-A-2-a-(2)-(*1*)-(*b*). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system, or P3 + EK1, shall be used for DNA recombinants produced with purified subgenamic DNA segments(*38*) containing an entire transforming gene.

III-A-2-a-(2)-(*1*)-(*c*). P2 physical containment + an EK2 host-vector or P3 + EK1 shall be used for DNA recombinants produced with (i) the whole viral genome or (ii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(2)-(a)-(*2*). *Other Members of the Family Retroviridiae.*(*36*)

III-A-2-a-(2)-(a)-(2)-(*a*). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified nontransforming subgenamic DNA segments.(*38*)

III-A-2-a-(2)-(a)-(*2*)-(*b*). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system or P3 + EK1 shall be used for DNA recombinants produced with (i) purified subgenamic DNA segments containing an entire transforming gene, (ii) the whole viral genome, or (iii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(2)-(b). *Negative Strand RNA Viruses.* P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with (i) cDNA copies of the whole genome, (ii) subgenomic cDNA segments, or (iii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(2)-(c). *Plus-Strand RNA Viruses.*

III-A-2-a-(2)-(c)-(*1*). *Types 1 and 2 Sabin Poliovirus Vaccine Strains and Strain 17D (Theiler) of Yellow Fever Virus.* P1 physical containment + and EK1 host-vector shall be used for DNA recombinants produced with (i) cDNA copies of the whole viral genome, (ii) subgenomic cDNA segments, or (iii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(2)-(c)-(*2*). *Other Plus-Strand RNA Viruses Belonging to Presently Classified Viral Families.*(*36*)

Table III

Recommended Containment for Cloning of Viral DNA or cDNA in E. coli K-12 Host-Vector Systems
(See text for full details)

Virus class	Type of viral DNA segment to be cloned				
	Subgenomic[38]		Genomic		cDNA from viral mRNA[37]
	Nontransforming segment	Segment containing an entire transforming gene	Non-segmented genome	Segmented genome	
DNA					
Nontransforming viruses					
AAV, MVM, Mouse Adeno (Strain FL)	P1 + EK1		P1 + EK1		P1 + EK1
Plant Viruses	P1 + EK1		P1 + EK1		P1 + EK1
Hepatitis B	P1 + EK1		P2 + EK2 or P3 + EK1		P2 + EK1CV[40] or P3 + EK1
Other	P1 + EK1		P1 + EK1CV[40]		P1 + EK1
Transforming Viruses					
Herpes Saimiri, H. Ateles and EBV[39]	P1 + EK1	P2 + EK1CV[40] or P3 + EK1	P2 + EK2 or P3 + EK1		P2 + EK1CV[40] or P3 + EK1
Other	P1 + EK1	P2 + EK1CV[40] or P3 + EK1	P2 + EK1CV[40] or P3 + EK1		P2 + EK1CV[40] or P3 + EK1
RNA					
Retroviruses					
Gibbon Ape, Woolly Monkey FeLV and FeSV[39]	P1 + EK1	P2 + EK1CV[40] or P3 + EK1	P2 + EK2 or P3 + EK1		P2 + EK2 or P3 + EK1
Other	P1 + EK1	P2 + EK1CV[40] or P3 + EK1	P2 + EK1CV[40] or P3 + EK1		P2 + EK1CV[40] or P3 + EK1

Table III

Recommended Containment for Cloning of Viral DNA or cDNA in E. coli K-12 Host-Vector Systems
(See text for full details)

Virus class	Type of viral DNA segment to be cloned				
	Subgenomic[38]		Genomic		cDNA from viral mRNA[37]
	Nontransforming segment	Segment containing an entire transforming gene	Nonsegmented genome	Segmented genome	
Negative Strand RNA	P1 + EK1		P1 + EK1	P1 + EK1	P1 + EK1
Plus Strand RNA					
Types 1 and 2 Sabin Polio, 17D Yellow Fever Vaccine Strains	P1 + EK1		P1 + EK1		P1 + EK1
Other	P1 + EK1		P2 + EK1CV[40] or P3 + EK1		P2 + EK1CV[40] or P3 + EK1
Double Stranded RNA	P1 + EK1			P1 + EK1	P1 + EK1
Plant Viruses + Viroids	P1 + EK1		P1 + EK1	P1 + EK1	P1 + EK1
Intracellular Viral DNA	See text	See text	See text		

III-A-2-a-(2)-(c)-(*2*)-(*a*). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified subgenomic cDNA segments.(*38*)

III-A-2-a-(2)-(c)-(*2*)-(*b*). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system of P3+EK1 shall be used for DNA recombinants produced with (i) cDNA copies of the whole genome, or (ii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(2)-(d). *Double-Stranded Segmented RNA Viruses.* P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with (i) mixtures of subgenomic cDNA segments, (ii) a specific subgenomic cDNA segment, or (iii) purified cDNA copies of viral mRNA. (*37*)

III-A-2-a-(2)-(e). *RNA Plant Viruses and Plant Viroids.* P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with (i) cDNA copies of the whole viral genome, (ii) subgenomic cDNA segments, or (iii) purified cDNA copies of viral mRNA.(*37*)

III-A-2-a-(3). *Intracellular Viral DNA.* Physical and biological containment specified for shotgun experiments with eukaryotic cellular DNA [see section III-A-(1)-(a)] shall be used for DNA recombinants produced with integrated viral DNA or viral genomes present in infected cells.

III—A-2-b. *Eukaryotic Organelle DNA's.* P2 physical containment + an EK1 host-vector, or P1+EK2, for mitochondrial or chloroplast DNA from eukaryotes when the organelle DNA has been obtained from isolated organelles. Otherwise, the conditions given for shotgun experiments apply.

III-A-2-c. *Prokaryotic Plasmid and Phage DNA's.* The containment levels required for shotgun experiments with DNA from prokaryotes apply to their plasmids or phages.

III-A-3. *Lowering of Containment Levels for Characterized or Purified DNA Preparations and Clones.* Many of the risks which might conceivably arise from some types of recombinant DNA experiments, particularly shotgun experiments, would result from the inadvertent cloning of a harmful sequence. Therefore, in cases where the risk of inadvertently cloning the "wrong" DNA is reduced by prior enrichment for the desired piece, or in which a clone, made from a random assortment of DNA's, has been purified and the absence of harmful sequences established, the containment conditions for further work may be reduced. The following section outlines the mechanisms for such reductions.

III-A-3-a. *Purified DNA Other than Plasmids, Bacteriophages, and Other Viruses.* The formation of DNA recombinants from cellular DNA's that have been purified (*41*) and which are free of harmful genes(*3*) can be carried out under lower containment conditions than used for the corresponding shotgun experiment. (*42*) The containment may be decreased one step in physical containment (P4 → P3 → P2 → P1) while maintaining the biological containment specified for the shotgun experiment or one step in biological containment (EK3 → EK2 → EK1) while maintaining the specified physical containment. The institutional biosafety committee (IBC) must review and may approve such a reduction. The IBC must notify the NIH Office of Recombinant DNA Activities (ORDA) in writing of all such actions. IBC approval is sufficient for such a reduction except for (i) primate DNA which also requires prior NIH approval [see section III-A-1-a-(1)] or (ii) any lowering of containment under section III-A-3-a to levels below P1+EK1, which also requires prior NIH approval.

III-A-3-b. *Characterized Clones of DNA Recombinants.* When a cloned DNA recombinant has been rigorously characterized and there is sufficient evidence that it is free of harmful genes, (*3*) experiments involving this recombinant DNA may be carried out under lower containment conditions, as described below.

III-A-3-b-(1). Institutional biosafety committees (IBC's) may give approval for a single-step reduction in physical or biological containment on receipt of evidence of characterization of a clone derived from a shotgun experiment and its probable freedom from harmful genes. The IBC must notify ORDA in writing of all such actions. IBC approval is sufficient for such a reduction except for (i) primate DNA, which requires prior NIH approval [see section III-A-1-a-(1)], or (ii) any lowering of containment under section III-A-3-b to levels below P1+EK1, which also requires prior NIH approval.

III-A-3-b-(2). Reduction of containment levels by more than one step or cases involving primate DNA, or cases involving lowering of containment under section III-A-3-b to levels below P1+EK1, will require prior approval by NIH.

III-B. *Experiments with Other Prokaryotic Host-Vectors.*

III-B-1. *HV1 systems.* Host-vector systems which have been approved as HV1 systems may be used under P2 containment conditions for shotgun experiments with phages, plasmids, and DNA from nonpathogenic prokaryotes which do not produce polypeptide toxins.(*34*)

Other classes of recombinant DNA experiments with these HV1 systems will require prior approval and classification by NIH. Experiments with DNA's from eukaryotes (and their plasmids or viruses) will generally follow the criteria for the corresponding experiments with *E. coli* K-12 host-vectors if the major habitats of the given host-vector overlap those of *E. coli.* The habitats of other host-vector systems should also be considered in relation to containment.

III-B-2. *Return of DNA Segments to Non-HV1 Host of Origin.* Many of the prokaryotes that exchange genetic information with *E. coli* by known physiological processes are expected to be exempt from these Guidelines by appearing on the "list of exchangers" (see Section I-E-4). For a prokaryote which can exchange genetic information (*35*) with *E. coli* under laboratory conditions but which is not on the list (Host A), the following type of experiment may be carried out under P1 conditions without Host A having been approved as an HV1 host: DNA from Host A may be inserted into a vector and propagated in *E. coli* K-12 under P1 conditions. Subsequently, this recombinant DNA may be returned to Host A by mobilization, transformation, or transduction and may then be propagated in Host A in any desired vector under P1 conditions.

For a prokaryote which does not exchange genetic information with *E. coli* (Host B), the following type of experiment may be carried out without Host B having been approved as an HV1 host: DNA from Host B may be inserted into a vector from a certified EK2 host-vector system and propagated in *E. coli* K-12 under the appropriate containment conditions [see section III-A-1-b-(2)]. Subsequently, this recombinant DNA may be returned to Host B and propagated in Host B under P1 conditions.(*43*)

III-C. *Experiments with Eukaryotic Host-Vectors.*

III-C-1. *Vertebrate Host-Vector Systems.* (*44*) (Summary Given in Table IV).

III-C-1-a. *Polyoma Virus.*

III-C-1-a-(1). *Productive Virus-Cell Interactions.*

III-C-1-a-(1)-(a). Defective or intact polyoma virus genomes, with appropriate helper, if necessary, can be used in P2 conditions to propagate DNA sequences:

III-C-1-a-(1)-(a)-(*1*). From bacteria of class 1 or class 2[1] or their phages or plasmids, except for those that produce potent polypeptide toxins; (*34*)

III-C-1-a-(1)-(a)-(*2*). From mice;

III-C-1-a-(1)-(a)-(*3*). From eukaryotic organisms that do not produce potent polypeptide toxins, (*34*) provided the DNA segment is > 99 percent pure.

III-C-1-a-(1)-(b). Defective polyoma genomes, with appropriate helper, if necessary, can be used in P2 conditions for shotgun experiments to propagate DNA sequences from eukaryotic or-

ganisms that do not produce potent polypeptide toxins.(*34*)

III-C-1-a-(1)-(c). Intact virus genomes with appropriate helper, if necessary, can be used in P3 conditions for shotgun experiments to propagate DNA sequences from eukaryotic organisms that do not produce potent polypeptide toxins.(*34*)

III-C-1-a-(1)-(d). Experiments involving the use of defective polyoma virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis (*45*) and will be conducted under the recommended physical containment conditions.

III-C-1-a-(2). *Nonproductive Virus-Cell Interactions.* Defective or intact polyoma virus genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture, provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis.(*45*)

III-C-1-b. *Simian Virus 40.*

III-C-1-b-(1). *Productive Viruses-Cell Interactions.*

III-C-1-b-(1)-(a). SV40 DNA, rendered unconditionally defective by a deletion in an essential gene, with appropriate helper, can be used in P2 conditions to propagate DNA sequences from:

III-C-1-b-(1)-(a)-(*1*). Bacteria of Class 1 or Class 2[1], or their phages or plasmids, except for those that produce potent polypeptide toxins;(*34*)

III-C-1-b-(1)-(a)-(*2*). Uninfected African green monkey kidney cell cultures.

III-C-1-b-(1)-(b). SV40 DNA, rendered unconditionally defective by a deletion in an essential gene, with an appropriate helper, can be used in P3 conditions to propagate DNA sequences from eukaryotic organisms that do not produce potent polypeptide toxins(*34*) (shotgun experiments or purified DNA).

III-C-1-b-(1)-(c). Experiments involving the use of defective SV40 genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by the NIH on a case-by-case basis (*45*) and will be conducted under the recommended physical containment conditions.

III-C-1-b-(2). *Nonproductive Virus-Cell Interactions.* Defective or intact SV40 genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture, provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis.(*45*)

III-C-1-c. *Human Adeno- viruses 2 and 5.*

III-C-1-c-(1). *Productive Virus-Cell Interactions.*

III-C-1-c-(1)-(a). Human adenoviruses 2 and 5, rendered unconditionally defective by deletion of at least two capsid genes, with appropriate helper, can be used in P3 conditions to propagate DNA sequences from:

III-C-1-c-(1)-(a)-(*1*). Bacteria of Class 1 or Class 2[1] or their phages or plasmids except for those that produce potent polypeptide toxins; (*34*)

III-C-1-c-(1)-(a)-(2). Eukaryotic organisms that do not produce potent polypeptide toxins(*34*) (shotgun experiments or purified DNA).

III-C-1-c-(1)-(b). Experiments involving the use of unconditionally defective human adenovirus 2 and 5 genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis(*45*) and will be conducted under the recommended physical containment conditions.

III-C-1-c-(2). *Non-productive virus-cell interactions.* Defective or intact human adenovirus 2 and 5 genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture, provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis.(*45*)

III-C-1-d. *Murine Adenovirus Strain FL.*

III-C-1-d-(1). *Productive Virus-Cell Interactions.*

III-C-1-d-(1)-(a). Unconditionally defective murine adenovirus strain FL genomes, with appropriate helper, can be used in P2 conditions to propagate DNA sequences from:

III-C-1-d-(1)-(a)-(*1*). Bacteria of Class 1 or Class 2 [1] or their phages or plasmids except for those that produce potent polypeptide toxins;(*34*)

III-C-1-d-(1)-(a)-(*2*). Eukaryotic organisms that do not produce potent polypeptide toxins(*34*) (shotgun experiments or purified DNA).

III-C-1-d-(1)-(b). Experiments involving the use of intact murine adenovirus strain FL genomes to propagate DNA sequences from prokaryotic or eukaryotic organisms will be evaluated by NIH on a case-by-case basis(*45*) and will be conducted under the recommended physical containment conditions.

III-C-1-d-(1)-(c). Experiments involving the use of unconditionally defective murine adenovirus strain FL genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis(*45*) and will be conducted under the recommended physical containment conditions.

III-C-1-d-(2). *Non-Productive Virus-Cell Interactions.* Defective or intact murine adenovirus strain FL genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture, provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis(*45*).

III-C-1-e. *All Other Potential Viral Vectors.*

III-C-1-e-(1). Experiments involving recombinant DNA molecules containing viral DNA segments consisting of 25 percent or less of the virus genome can be done:

III-C-1-e(1)-(a). In P2 conditions when the recombinant DNA is to be integrated into the cell genome or is known to replicate as a plasmid in cells in culture, provided the additional DNA sequences are not derived from a eukaryotic virus. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis;(*45*).

III-C-1-e—(1)-(b). Under physical containment conditions to be determined by NIH(*45*) when a viral helper will be used to propagate DNA sequences from prokaryotic or eukaryotic organisms.

III-C-1-e-(2). Experiments involving the use of other intact or defective virus genomes to propagate DNA sequences from prokaryotic or eukaryotic organisms (and viruses), or as vectors to transform nonpermissive cells, will be evaluated by NIH on a case-by-case basis(*45*) and will be conducted under the recommended physical containment conditions.

NIH will also review all experiments involving the use of virus vectors in animals and the physical containment conditions appropriate for such studies.

III-C-2. *Invertebrate Host-Vector Systems in Which Insect Viruses Are Used To Propagate Other DNA Segments.* As soon as information becomes available on the host range restrictions and on the infectivity, persistance, and integration of the viral DNA in vertebrate and invertebrate cells, experiments involving the use of insect viruses to propagate DNA sequences will be evaluated by NIH on a case-by-case basis(*45*) and will be conducted under the recommended physical containment conditions. Experiments should be done in established invertebrate cell lines and should follow, where appropriate, criteria recommended for vertebrate viral DNA vectors (see Section III-C-1).

III-C-3. *Plant Viral Host-Vector Systems.* The DNA plan viruses which could currently serve as vectors for cloning genes in plants and plant cell protoplasts are Cauliflower Mosaic Virus (CaMV) and its close relatives, which have relaxed circular double-stranded DNA genomes with a molecular weight of 4.5×10^6, and Bean Golden Mosaic Virus (BGMV) and re-

lated viruses with small ($<10^6$ daltons) single-stranded DNA genomes. These viruses are not known to integrate into host chromosomes or to incorporate cellular genes into their genomes. CaMV is spread in nature by aphids, in which it survives for a few hours. Spontaneous mutants of CaMV which lack a factor essential for aphid transmission arise frequently. BGMV is spread in nature by whiteflies, and certain other single-stranded DNA plant viruses are transmitted by leafhoppers. These single-stranded plant viruses persist for days or weeks in their insect vectors, but are thought not to replicate there.

The DNA plant viruses have narrow host ranges and are relatively difficult to transmit mechanically to plants. For this reason, they are most unlikely to be accidentally transmitted from spillage of purified virus preparations.

When these viruses are used as vectors in intact plants, or propagative plant parts, the plants should be grown under P1 conditions—that is, in either a limited access greenhouse or plant growth cabinet which is insect-proof, preferably with positive air pressure, and in which an insect fumigation regime is maintained. Soil, plant pots, and unwanted infected plant materials should be removed from the greenhouse or cabinet in sealed insect-proof containers and sterilized. It is not necessary to sterilize run-off water from the infected plants, as this is not a plausible route for secondary infection. When the viruses are used as vectors in tissue cultures or in small plants in axenic cultures, no special containment is recommended. Infected plant materials which have to be removed from the greenhouse or cabinet for further research, should be maintained under insect-proof conditions. These measures provide an entirely adequate degree of containment. They are similar to those required in many countries for licensed handling of "exotic" plant viruses.

The CaMV strain used as a cloning vector should be a mutant that lacks the aphid transmission factor.

The viruses or their DNA may also be useful as vectors to introduce genes into plant protoplasts. The fragility of plant protoplasts combined with the properties of the viruses mentioned above provide adequate safety. Since no risk to the environment from the use of the DNA plant virus/protoplast system is envisaged, no special containment is recommended, except as described in the following paragraph.

Experiments involving the use of plant virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated on a case-by-case basis(*45*) and will be conducted under the recommended containment conditions.

Table IV

Recommended Containment for Recombinant DNA Research Using Eukaryotic Viral Vectors
(See text for full details)

Vector DNA	Productive virus-cell interactions						Nonproductive virus-cell interactions[46]
	Type of DNA insert						
	Prokaryotic		Eukaryotic			Eukaryotic viral	
	Shotgun	Purified	Shotgun		Purified[47]		
			Natural host	Other			
1. Polyoma							
Intact Genome	P2	P2	P2	P3	P2	CBC*	P2
Deleted Genome	P2	P2	P2	P2	P2	CBC*	P2
2. SV40							
Intact Genome	—	—	—	—	—	—	P2
Deleted Genome	P2	P2	P2	P3	P3	CBC*	P2
3. Human Ad2+Ad5							
Deleted Genome	P3	P3	P3	P3	P3	CBC*	P2
4. Mouse Adenovirus (Strain FL)							
Intact Genome	CBC*	CBC*	CBC*	CBC*	CBC*	CBC*	P2
Deleted Genome	P2	P2	P2	P2	P2	CBC*	P2
5. Insect Viruses	CBC*	CBC*	CBC*	CBC*	CBC*	CBC*	—
6. Plant Viruses (CaMV and BGMV)	**	**	**	**	**	CBC*	—
7. All other potential Viral Vectors	CBC*	CBC*	CBC*	CBC*	CBC*	CBC*	CBC*

*CBC = Case-by-case[45]
**See text

III-C-4. *Plant Host-Vector Systems Other than Viruses.* Organelle, plasmid, and chromosomal DNA's may be used as vectors. DNA recombinants formed between such vectors and host DNA, when propagated only in that host (or a closely related strain of the same species), are exempt from these Guidelines (see section I-E). DNA recombinants formed between such vectors and DNA from cells other than the host species require P2 physical containment. The development and use of host-vector systems that exhibit a high level of biological containment, such as those using protoplasts or undifferentiated cells in culture, permit a decrease in the physical containment to P1.

Intact plants or propagative plant parts which because of their large size cannot be grown in a standard P2 laboratory may be grown under the P1 conditions described above in section III-C-3 except that (i) sterilization of run-off water is required where this is a plausible route for secondary infection and (ii) the standard P2 practices are adopted for microbiological work.

III-C-5. *Fungal or Similar Lower Eukaryotic Host-Vector Systems.* The containment criteria for DNA recombinant experiments using these host-vectors most closely resemble those for prokaryotes, rather than those for the preceding eukaryotes, since the host cells usually exhibit a capacity for dissemination outside the laboratory that is similar to that for bacteria. Therefore, the procedures established for certification of HV systems other than *E. coli* K-12 (sec. II-D-2) will also apply to these fungal or similar lower eukaryotic host-vector systems.

Once an HV1 system is approved by NIH, it may be used under P2 containment for shotgun experiments with phages, plasmids, and DNA from Class 1 prokaryotes(*1*) and lower eukaryotes that do not produce polypeptide toxins.(*34*) Other classes of recombinant DNA experiments with these HV1 systems will require prior approval and classification by NIH. Should HV2 or HV3 systems of this type be developed and approved by NIH, guidelines for their use in other types of recombinant DNA experiments will also be established.

In addition to the experiments described above, the following experiments maybe carried out without the eukaryotic host (Host C) having been approved as an HV1 host: DNA from Host C may be inserted into a vector from a certified EK2 host-vector system and propagated in *E. coli* K-12 under the appropriate containment conditions [see Section III-A-1-(a)-(5)]. Subsequently, this recombinant DNA may be returned to Host C and propagated there under P1 conditions. (*43*)

III-D. *Complementary DNA's.* Specific containment levels are given in Section III-A-2-a (see also last column of Table III) for complementary DNA (cDNA) of viral mRNA. For the other Sections of the Guidelines, where applicable, cDNA's synthesized *in vitro* are included within each of the above classifications. For example, cDNA's formed from cellular RNA's that are not purified and characterized are included under III-A-1, shotgun experiments; cDNA's formed from purified and characterized RNA's are included under III-A-3; etc.

Due to the possibility of nucleic acid contamination of enzyme preparations used in the preparation of cDNA's, the investigator must employ purified enzyme preparations that are free of viral nucleic acid.

III-E *Synthetic DNA's.* If the synthetic DNA segment could yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent), the containment conditions must be as stringent as would be used for propagating the natural DNA counterpart.

If the synthetic DNA sequence codes for a harmless product, it may be propagated at the same containment level as its purified natural DNA counterpart. For example, a synthetic DNA segment, to be propagated in *E. coli* K-12, which corresponds to a nonharmful gene of birds, would require P2 physical containment plus an EK1 host-vector, or P1 + EK2.

If the synthetic DNA segment is not expressed *in vivo* as a polynucleotide or polypeptide product, the organisms containing the recombinant DNA molecules are exempt(*4*) from the Guidelines.

IV. Roles and Responsibilities

Safety involving recombinant DNA molecules depends primarily on the individuals conducting the research activities. The guidelines cannot anticipate every possible situation. Motivation and good judgment are the keys to protection of health and the environment.

The guidelines are designed to help the principal investigator determine the safeguards that should be implemented. They will never be complete and final, since all conceivable experiments involving recombinant DNA cannot be foreseen. Therefore, it is the principal investigator's responsibility to insure that the purpose of the guidelines is fulfilled.

The institution, and the Institutional Biosafety Committee (IBC) acting on its behalf, are given responsibility for seeing that recombinant DNA activities comply with the guidelines. This delegation of authority will serve the scientific process and at the same time properly focus accountability for safe conduct of the research.

The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant DNA molecules. Detailed administrative procedures designed to implement this framework are provided in Appendix C. Further clarifications and interpretations of roles and responsibilities will be issued by NIH as necessary.

IV-A. *Responsibilities of the Institution*

IV-A-1. *Institution.* The institution bears primary responsibility for establishing and implementing policies for the safe conduct of research involving recombinant DNA molecules. These shall be policies that assure compliance with the NIH Guidelines. In carrying out its responsibilities, the institution shall:

IV-A-1-a. establish an Institutional Biosafety Committee (IBC) and insure that it is fulfilling its responsibilities;

IV-A-1-b. report to the NIH Office of Recombinant DNA Activities (ORDA) the names of members of its IBC and relevant information on them;

IV-A-1-c. submit to NIH for registration a Memorandum of Understanding and Agreement (MUA) or equivalent information (in the case of non/NIH supported recombinant DNA projects), approved by the IBC, for all recombinant DNA research at an institution receiving any NIH funds for recombinant DNA research (see section IV-C and Appendix C for NIH policies on MUAs and other required documentation);

IV-A-1-d. Assume responsibility for insuring compliance of recombinant DNA projects with the procedures and standards of the NIH Guidelines. If, upon registration and review, NIH (ORDA) finds that IBC approved protocols do not conform with standards set forth in the NIH Guidelines, the institution will be notified by NIH and shall take appropriate action to bring the protocols into compliance (see Appendix C for additional information). Further, the institution shall insure that all principal investigators, irrespective of source of funding, have agreed to carry out their responsibilities under the Guidelines;

IV-A-1-e. Determine, in connection with each project, the necessity for medical surveillance of recombinant DNA research personnel before, during, and after their involvment in this research. Where possible, each institution should cooperate with the local public health department. An institution's medical surveillance program might include, for example, records of agents handled, active investi-

gation of relevant illnesses acquired by recombinant DNA research personnel, and the maintenance of serial serum samples (see "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research" for additional information on medical surveillance);

IV-A-1-f. Establish rules as necessary to implement the Guidelines.

IV-A-2. *Institutional Biosafety Committee.* The principal functions of the IBC are to review and oversee all recombinant DNA projects and to advise the institution and ORDA whether the proposals and the research comply with the NIH Guidelines.

The IBC shall be a committee of not less than five members so selected that the committee has the experience and expertise to assess the safety of proposed recombinant DNA research projects and any potential risks to public health or the environment. Its membership should include individuals from disciplines relevant to recombinant DNA technology, biological safety, and engineering. It is recommended that the IBC also include members knowledgeable about such matters as applicable law, standards of professional conduct and practice, community attitudes, and the environment. It is recommended that at least one member be a nondoctoral person from a laboratory technical staff. No member of an IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he or she has been, or excepts to be engaged, or has a direct finanical interest. At least one member shall not be affiliated with the institution, i.e., no IBC may consist entirely of persons who are officers, employees, or agents of the institution, or are otherwise associated with it apart from their membership on the IBC.

On behalf of the institution, the IBC shall:

IV-A-2-a. Review and, if in compliance with the NIH Guidelines, approved the initiation of all proposed recombinant DNA research conducted at or sponsored by the institution receiving NIH funds for any recombinant DNA research. (All P4 research must recieve prior approval by NIH before its initiation.) This review shall include (i) an independent assessment of the containment levels required by these guidelines for the proposed research, and (ii) review and approval of facilities, procedures, practices, and the training and expertise of recombinant DNA personnel;

IV-A-2-b. Consider requests for approval of single-step reductions in containment levels for experiments with purified DNA and characterized clones and report to ORDA those actions in which approval is given (see section III-A-3);

IV-A-2-c. Review periodically recombinant DNA research being conducted at the institutions;

IV-A-2-d. Review and approve emergency plans covering accidential spills and personnel contamination resulting from this research;

IV-A-2-e. Report promptly to ORDA any problems with the Guidelines of violations;

IV-A-2-f. Keep minutes of meetings and, upon request, make them available to the public;

IV-A-2-g. Otherwise advise the institution and ORDA on policy matters relating to recombinant DNA research.

Appendix C and "Laboratory Safety Monagraph—A Supplement to the NIH Guidelines for Recombinant DNA Research" contain additional information and suggestions regarding the function and operation of IBCs.

IV-A-3. *Biological Safety Officer.* A biological safety officer shall be designated by each institution engaged in recombinant DNA research at the P3 or P4 containment level. The officer shall be a member of the IBC. His or her duties shall include, but need not be limited to:

IV-A-3-a. Insuring through periodic inspections that laboratory safety standards are rigorously followed;

IV-A-3-b. Developing emergency plans for dealing with accidental spills and personnel contamination, and investigating recombinant DNA research laboratory accidents;

IV-A-3-c. Providing advice on laboratory security;

IV-A-3-d. Providing technical advice to the principal investigator and IBC on research safety procedures.

See "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research" for additional information on the duties of the Biological Safety Officer.

IV-A-4. *Principal Investigator.* The principal investigator is responsible for conducting his or her recombinant DNA research in compliance with the NIH Guidelines. On behalf of the institution, the principal investigators responsible for:

IV-A-4-a. Complying fully with the guidelines in carrying out the research;

IV-A-4-b. Making the initial determination of the required levels of physical and biological containment in accordance with the guidelines;

IV-A-4-c. Selecting appropriate microbiological practices and laboratory techniques to be used in the research;

IV-A-4-d. Being adequately trained in good microbiological techniques;

IV-A-4-e. Submitting the proposed research (including subsequent changes in the protocol—e.g., changes in the source of DNA or host-vector system to be used) to the IBC for review and approval or disapproval, and remaining in communication with the IBC throughout the conduct of the project;

IV-A-4-f. Initiating no recombinant DNA research subject to the guidelines until it has been approved by the IBC and has met all other requirements of the guidelines, and agreeing to make changes to conform if ORDA's review so requires;

IV-A-4-g. Petitioning NIH, after notifying the IBC, for exceptions or exemptions (4) to these guidelines—e.g., for an exception to a prohibition (see section I-D) or an exemption from the guidelines (see section I-E-4 and I-E-5). Each request for such an exception or exemption must be accompanied by adequate documentation (see appendix C for additional information on procedures);

IV-A-4-h. Reporting promptly to the IBC and NIH (ORDA) any problems with or violations of the guidelines;

IV-A-4-i. Submitting information on proposed new host-vector systems to ORDA in order to have them certified;

IV-A-4-j. Reporting to the IBC and ORDA new information bearing on the guidelines;

IV-A-4-k. Adhering to IBC-approved emergency plans for dealing with accidental spills and personnel contamination;

IV-A-4-l. Complying with shipping requirements for recombinant DNA molecules (see section II-C, appendix C, and "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research" for instructions on shipping and distributing organisms and viruses containing recombinant DNA);

IV-A-4-m. After receiving IBC approval and before initiating the research, the principal investigator is responsible for:

IV-A-4-m-(1). Making available to the laboratory staff copies of the approved protocols that describe the potential biohazards and the precautions to be taken;

IV-A-4-m-(2). Instructing and training the staff in the practices and techniques required to insure safety and in the procedures for dealing with accidents;

IV-A-4-m-(3). Informing the staff of the reasons and provisions for any advised or requested precautionary medical practices, such as vaccinations or serum collection.

IV-A-4-n. During the conduct of the research, the principal investigator is responsible for:

IV-A-4-n-(1). Supervising the safety performance of the staff to insure

that the required safety practices and techniques are employed;

IV-A-4-n-(2). Investigating and reporting in writing to ORDA and the IBC any serious or extended illnesses of a worker or any accident that results in (i) inoculation of recombinant DNA materials through cutaneous penetration, (ii) ingestion of recombinant DNA materials, (iii) probable inhalation of recombinant DNA materials following gross aerosolization, or (iv) any incident causing serious exposure to personnel or danger of environmental contamination;

IV-A-4-n-(3). Investigating and reporting in writing to ORDA, the biological safety officer (where applicable), and the IBC any significant problems pertaining to operation and implementation of biological and physical containment practices and procedures;

IV-A-4-n-(4). Correcting work errors and conditions that may result in the release of recombinant DNA materials;

IV-A-4-n-(5). Insuring the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., genotypic and phenotypic characteristics, purity, etc.).

See "Laboratory Safety Monograph—A Supplement to NIH Guidelines for Recombinant DNA Research" for additional information on training and laboratory and accident procedures.

IV-A-4-o. While not a requirement, it is urged that all publications dealing with recombinant DNA research include a description of the physical and biological containment procedures employed, to aid others who might consider repeating the work.

IV-B. *Responsibilities of NIH.*

IV-B-1. *Office of the Director, NIH.* The Office of the Director shall be responsible for:

IV-B-1-a. Final interpretation of the guidelines;

IV-B-1-b. Revision and amendment of the guidelines after appropriate notice and opportunity for public comment;

IV-B-1-c. Certification of new host-vector systems and decertification of existing host-vector systems after appropriate notice and opportunity for public comment (see Section II-D-2-a);

IV-B-1d. Promulgating and amending a list of classes of recombinant DNA molecules to be exempt(*4*) from these guidelines after appropriate notice and opportunity for public comment, if it is found that they consist entirely of DNA segments from different species that exchange DNA by known physiological processes or otherwise do not present a significant risk to health or environment (see section I-E-4 and I-E-5);

IV-B-1-e. Permitting, after appropriate notice and opportunity for public comment, exceptions(*4*) to the Prohibitions in the guidelines for experiments—e.g., risk-assessment studies. In making such decisions on exceptions, weight will be given both to scientific and societal benefits and to potential risks (see section I-D). Also, approving changes in containment levels for specific experiments, or the assignment of levels to experiments not explicitly considered in the guidelines (see part III). Also, designating as class 1 for purposes of these guidelines certain agents which are listed as class 2 (see footnote 1);

IV-B-1-f. Overseeing the implementation of the guidelines;

IV-B-1-g. Requesting, when appropriate, the advice of the Advisory Committee to the Director, NIH, on matters relevant to recombinant DNA policy issues;

IV-B-1-h. Promulgating rules as necessary to implement the guidelines.

IV-B-2. *NIH Recombinant DNA Advisory Committee.* The duties of the Recombinant DNA Advisory Committee (RAC) shall include:

IV-B-2-a. Recommending to the Director, NIH, revisions of these guidelines periodically and any amendments to the guidelines as necessary;

IV-B-2-b. Advising the Director, NIH, and ORDA on questions of interpretation of the guidelines;

IV-B-2-c. Recommending to the Director, NIH whether host-vector systems qualify for certification (see section II-D-2-a);

IV-B-2-d. Recommending to the Director, NIH, whether currently certified host-vector systems should be decertified;

IV-B-2-e. Recommending to the Director, NIH, a list (and amendments to the list) of other classes of experiments to be exempt(*4*) from these guidelines (see section I-E-4 and I-E-5);

IV-B-2-f. Recommending to the Director, NIH, whether experiments should be granted an exception (*4*) from the prohibitions in the guidelines—for example, in order to allow risk-assessment studies—and at the same time recommending appropriate levels of physical and biological containment for these experiments. In making such recommendations, weight shall be given both to scientific and societal benefits and to potential risks (see section I-D);

IV-B-2-g. Recommending to the Director, NIH, changes in containment levels for specific experiments, or the assignment of levels to experiments not explicitly considered in the guidelines (see part III);

IV-B-2-h. Recommending to the Director, NIH, designation as class 1 for purposes of these guidelines certain agents that are listed as class 2 (see footnote 1);

IV-B-2-i. Recommending to NIH whether a cloned recombinant DNA segment has been rigorously characterized and whether there is sufficient evidence that it is free of harmful genes, so that experiments involving it may be conducted under lower containment conditions;

IV-B-2-j. Carrying out other functions as assigned under the RAC's charter or by the Secretary, the Assistant Secretary for Health, or the Director, NIH.

IV-B-3. *NIH Components.* Various NIH components shall perform the following:

IV-B-3-a. *ORDA.* ORDA shall serve as a focal point for information on recombinant DNA activities and provide advice to all within and outside NIH, including institutions, biosafety committees, principal investigators, and State and local governments. In addition, ORDA shall:

IV-B-3-a-(1). Make an independent evaluation of the containment levels required for the research covered by these guidelines;

IV-B-3-a-(2). Determine whether the physical and biological containment levels approved by the IBC are in accord with the requirements of the guidelines;

IV-B-3-a-(3). Make interpertations of the guidelines and approve reduction of containment levels of more than one step for characterized clones, or for cases involving primate DNA, or to levels below P1+EK1 (see section III-A-3). In most cases this will involve prior review by the RAC;

IV-B-3-a-(4). Provide timely notice to local institutions when protocols, including modifications to ongoing projects, do not conform to the standards in the NIH guidelines;

IV-B-3-a-(5). Maintain a register of recombinant DNA projects;

IV-B-3-a-(6). Serve as executive secretariat for the RAC;

IV-B-3-a-(7). Publish the *Recombinant DNA Technical Bulletin;*

IV-B-3-a-(8). Review membership of IBC's.

IV-B-3-b. *Other NIH Components.* Other NIH components shall be responsible for:

IV-B-3-b-(1). Awarding no grants or contracts unless properly executed MUAs have been received;

IV-B-3-b-(2). Certifying P4 facilities, inspecting them periodically, and inspecting other recombinant DNA facilities as deemed necessary;

IV-B-3-b-(3). Announcing and distributing certified HV2 and HV3 host-vector systems (see section II-D-3).

See Appendix C for additional information on the administrative procedures of ORDA and other NIH components.

IV-C. *Registration.*

IV-C-1. *Required Registration.* All institutions receiving NIH funds for recombinant DNA projects shall inform NIH of all recombinant DNA projects at the institution. A non-NIH project shall be registered with NIH after it has been approved by the IBC and initiated. Applications for NIH projects must be accompanied by an MUA.

For information on MUA's or equivalent documents, which must be submitted for registration of recombinant DNA projects, see section IV of appendix C.

IV-C-2. *Voluntary Registration and Certification.* Any institution which is not required to comply with the guidelines may nevertheless register recombinant DNA research projects with NIH by submitting the appropriate information to ORDA. NIH will accept requests for certification of host-vector systems proposed by the institution. The submitter must agree to abide by the physical and biological containment standards of the NIH guidelines.

IV-C-3. *Disclosure of Information*

IV-C-3-a. DHEW or the institution, in carrying out their responsibilities under the guidelines, shall not release confidential or proprietary information submitted pursuant to the guidelines, except to the extent:

IV-C-3-a-(1). Required by law;

IV-C-3-a-(2). Necessary to certify host-Vector systems;

IV-C-3-a-(3). Necessary to determine whether or not to allow exemptions from the guidelines;

IV-C-3-a-(4). Necessary, in the judgment of the Secretary or his designee, the protect the public or the environment against an unreasonable risk of injury to health or the environment.

IV-C-4. *Patentable Material.* Institutions are reminded that whenever they regard information as potentially proprietary, they should consider applying for a patent before submitting information to DHEW.

IV-D. *Compliance.* As a condition for NIH funding of recombinant DNA research, institutions must insure that recombinant DNA research conducted at or sponsored by that institution shall comply with the guidelines irrespective of the source of funding.

IV-D-1. *Policy on Noncompliance*

IV-D-1-a. All NIH-funded projects involving recombinant DNA technology must comply with the NIH guidelines. Noncompliance may result in suspension, limitation, or termination of financial assistance for such projects, and for other recombinant DNA research at the institution.

IV-D-1-b. All non-NIH funded projects involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving recombinant DNA techniques must comply with the NIH guidelines. Noncompliance may result in suspension, limitation, or termination of NIH funds for recombinant DNA research.

IV-D-1-c. Information concerning noncompliance with the guidelines may be brought forward by any person. It should be delivered to both ORDA and the relevant institution. The institution, generally through the IBC, shall take such action as appropriate. It shall forward a complete report of the incident to ORDA and, if appropriate, shall include recommendations for further action.

IV-D-1-d. In cases where NIH proposes to suspend, limit, or terminate financial assistance because of a noncompliance with the guidelines, applicable HEW and PHS procedures shall govern. Volume 42, parts 50 and 52, and volume 45, parts 16 and 74, of the Code of Federal Regulations are sources of information about these procedures for grants.

V. Footnotes And References

1. The reference to organisms as class 1, 2, 3, 4, or 5 refers to the classification in the publication *Classification of Etiologic Agents on the Basis of Hazard*, 4th edition, July 1974; U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, Office of Biosafety, Atlanta, Ga. 30333. The list of organisms in each class, as given in this publication, is reprinted in appendix B to these guidelines.

However, the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee, may designate certain of the agents which are listed as class 2 in the *Classification of Etiologic Agents on the Basis of Hazard*, 4th edition, July 1974, as class 1 agents for the purposes of these guidelines. An updated list of such agents may be obtained from the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, Md. 20014.

The entire *Classification of Etiologic Agents on the Basis of Hazard* is in the process of revision.

2. One exception to the prohibition of formation of recombinant DNA's derived from class 3, 4, or 5 agents is that the formation of recombinant DNA's derived from Vesicular Stomatitis Virus (VSV) is not prohibited. The reason for this is explained in the accompanying "Decision Document." However, as noted in appendix B, a permit form the U.S. Department of Agriculture is required for the import or interstate transport of VSV. This can be obtained from USDA-APHIS, Veterinary Service, Federal Building, Hyattsville, Md. 20782.

3. The following types of data should be considered in determining whether DNA recombinants are "characterized" and "free of harmful genes": (a) the absence of potentially harmful genes (e.g., sequences contained in indigenous tumor viruses or sequences that code for toxins, invasins, virulence factors, etc., that might potentiate the pathogenicity or communicability of the vector and/or host or be detrimental to humans, animals, or plants); (b) the types(s) of genetic information on the cloned segment and the nature of transcriptional and translation gene products specified; (c) the relationship between the recovered and desired segment (e.g., hybridization and restriction endonuclease fragmentation analysis where applicable); (d) the genetic stability of the cloned fragment; and (e), any alterations in the biological properties of the vector and host.

4. In section I-E, " exemptions" from the guidelines are discussed. Such experiments are not covered by the guidelines and need not be registered with NIH. In section I-D on "prohibitions," the possibility of "exceptions" is discussed. An "exception" means that an experiment may be expressly released from a prohibition. At that time it will be assigned appropriate levels of physical and biological containment.

5. See "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research" for information on inactivating DNA.

6. *Laboratory Safety at the Center for Disease Control* (Sept. 1974). U.S. Department of Health Education and Welfare Publication No. CDC 75-8118.

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8. *National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses* (Oct. 1974). U.S. Department of Health, Education and Welfare Publication No. (NIH 75-790.

9. *National Institutes of Health Biohazards Safety Guide* (1974). U.S. Department of Health, Education, and Welfare, Public Health Service, National Institutes of Health. U.S. Government Printing Office, Stock No. 1740-00333.

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19. Chatigny, M. A., and D. I. Clinger (1969). *Containmination Control in Aerobiology.* In R. L. Dimmick and A. B. Akers' (eds.) An Introduction to Experimental Aerobiology. John Wiley & Sons, New York pp. 194-263.

20. Biological safety cabinets referred to in this section are classified as *class I, class II,* or *class III* cabinets. A *class I* is a ventilated cabinet for personnel protection having an inward flow of air away from the operator. The exhaust air from this cabinet is filtered through a high-efficiency particulate air (HEPA) filter. This cabinet is used in three operational modes: (1) with a full-width open front, (2) with an installed front closure panel (having four 8-inch diameter openings) without gloves, and (3) with an installed front closure panel equipped with arm-length rubber gloves. The face velocity of the inward flow of air through the full-width open front is 75 feet per minute or greater. A *class II* cabinet is a ventilated cabinet for personnel and product protection having an open front with inward air flow for personnel protection, and HEPA filtered mass recirculated air flow for product protection. The cabinet exhaust air is filtered through a HEPA filter. The face velocity of the inward flow of air through the full-width open front is 75 feet per minute or greater. Design and performance specifications for *class II* cabinets have been adopted by the National Sanitation Foundation, Ann Arbor, Mich. A *class III* cabinet is a closed-front ventilated cabinet of gas-tight construction which provides the highest level of personnel protection of all biohazard safety cabinets. The interior of the cabinet is protected from contaminants exterior to the cabinet. The cabinet is fitted with arm-length rubber gloves and is operated under a negative pressure of at least 0.5 inch water gauge. All supply air is filtered through HEPA filters. Exhaust air is filtered through two HEPA filters or one HEPA filter and incinerator before being discharged to the outside environment.

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31. Blattner, F. R., B. G. Williams, A. E. Bleche, K. Denniston-Thompson, H. E. Faber, L. A. Furlong, D. J. Gunwald, D. O. Kiefer, D. D. Moore, J. W. Shumm, E. L. Sheldon, and O. Smithies (1977). *Charon Phages: Safer Derivatives of Bacteriophage Lambda for DNA Cloning.* Science *196,* 163-169.

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33. Leder, P., D. Tiemeier and L. Enquist (1977). *EK2 Derivatives of Bacteriophage Lambda Useful in the Cloning of DNA from Higher Organisms: The gt WES System.* Science *196,*175-177.

34. We are specifically concerned with potent toxins which could be produced by acquiring a single gene or cluster of genes.

35. Defined as observable under optimal laboratory conditions by transformation, transduction, phage infection, and/or conjugation with transfer of phage, plasmid, and/or chromosomal genetic information. Note that this definition of exchange may be less stringent than that applied to exempt organisms under section I-E-4.

36. As classified in the Second Report of the International Committee on Taxonomy of Viruses: Classification and Nomenclature of Viruses, Frank Fenner, Ed. Intervirology 7 (19-115) 1976. (As noted in the Prohibition Section, the use of viruses classified[1] as class 3, 4, or 5, other than VSV, is prohibited.)

37. The cDNA copy of the viral mRNA must be >99 percent pure; otherwise as for shotgun experiments with eukaryotic cellular DNA.

38. >99 percent pure (i.e., less than 1 percent of the DNA consists of intact viral genames); otherwise as for whole genames.

39. The viruses have been classified by NCI as "moderate risk oncogenic viruses." See "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research" for recomendations on handling the viruses themselves.

40. EKICV means the use of an EK1 host and a vector certified for use in an EK2 system.

41. The DNA preparation is defined as "purified" if the desired DNA represents at least 99 percent (w/w) of the total DNA in the preparation, provided that it was verified by more than one procedure.

42. The lowering of the containment level when this degree of purification has been obtained is based on the fact that the total number of clones that must be examined to obtain the desired clone is markedly reduced. Thus, the probability of cloning a harmful gene could, for example, be reduced by more than 10^3-fold when a nonrepetitive gene from mammals was being sought. Furthermore, the level of purity specified here makes it easier to establish that the desired DNA does not contain harmful genes.

43. This is not permitted, of course, if it falls under any of the Prohibitions of section I-D. Of particular concern here is prohibition (v), i.e., "Transfer of a drug resistance trait to microorganisms that are not known to acquire it naturally if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture."

44. Because this work will be done almost exclusively in tissue culture cells, which have no capacity for propagation outside the laboratory, the primary focus for containment is the vector. It should be pointed out that risk of laboratory-acquired infection as a consequence of tissue culture manipulation is very low. Given good microbiological practices, the most likely mode of escape of recombinant DNA's from a physically contained laboratory is carriage by an infected human. Thus the vector with an inserted DNA segment should have little or no ability to replicate or spread in humans.

For use as a vector in a vertebrate host cell system, an animal viral DNA molecule should display the following properties:

(i) It should not consist of the whole genome of any agent that is infectious for humans or that replicates to a significant extent in human cells in tissue culture. If the recombinant molecule is used to transform nonpermissive cells (i.e., cells which do not produce infectious virus particles), this is not a requirement.

(ii) It should be derived from a virus whose epidemiological behavior and host range are well understood.

(iii) In permissive cells, it should be defective when carrying an inserted DNA segment (i.e., propagation of the recombinant DNA as a virus must be dependent upon the presence of a complementing helper genome). In almost all cases this condition would be achieved automatically by the manipulations used to construct and propagate the recombinants. In addition, the amount of DNA encapsidated in the particles of most animal viruses is defined within fairly close limits. The insertion of sizable foreign DNA sequences, therefore, generally demands a compensatory deletion of viral sequences. It may be possible to introduce very short insertions (50-100 base pairs) without rendering the viral vector defective. In such a situation, the requirement that the viral vector be defective is not necessary, except in those cases in which the inserted DNA encodes a bilogically active polypeptide.

It is desired but not required that the functional anatomy of the vector be known—that is, there should be a clear idea of the location within the molecule of:

(i) the sited at which DNA synthesis originates and terminates,

(ii) the sites that are cleaved by restriction endonucleases,

(iii) the template regions for the major gene product.

If possible the helper virus genome should:

(i) be integrated into the genome of a stable line of host cells (a situation that would effectively limit the growth of the vector recombinant to such cell lines) or

(ii) consist of a defective genome, or an appropriate conditional lethal mutant virus, making vector and helper dependent upon each other for propagation.

However, neither of these stipulations is a requirement.

45. Review by NIH on a case-by-case basis means prior review and the setting or appropriate containment conditions by NIH. NIH actions in such case-by-case reviews will be published in the *Recombinant DNA Technical Bulletin*.

46. Provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated on a case-by-case basis.

47. ≥ 99% pure; otherwise as for shotgun experiments.

APPENDIX A

Section I-E-4 states that exempt from these Guidelines are "certain specified recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchanges will be prepared and periodically revised by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee, after appropriate notice and opportunity for public comment. Certain classes are exempt as of publication of these Revised Guidelines. The list is in Appendix A."

Under exemption I-E-4, as of the publication of these Revised Guidelines, are any recombinant DNA molecules that are (1) composed entirely of DNA segments from one or more of the organisms listed below and (2) to be propagated in any of the organisms listed below.

Escherichia species
Edwardsiella species
Citrobacter species (including *Levinea*)
Salmonella species (including *Arizona*)
Shigella species
Klebsiella species
Enterobacter species
Hafnia species
Serratia species
Erwinia species (including *Pectobacterium*)
Pseudomonas species
Rhizobium species
Acinetobacter calcoaceticus
Agrobacterium tumefaciens
Rhodopseudomonas sphaeroides

APPENDIX B

CLASSIFICATION OF MICROORGANISMS ON THE BASIS OF HAZARD*

I. Classification of Etiologic Agents on the Basis of Hazard (1)

A. CLASS 1 AGENTS

All bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents not included in higher classes.

B. CLASS 2 AGENTS

1. Bacterial agents:
Actinobacillus—all species except *A. mallei*, which is in Class 3
Arizona hinshawii—all serotypes
Bacillus anthracis
Bordetella—all species
Borrelia recurrentis, B. vincenti
Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani
Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale
Diplococcus (Streptococcus) pneumoniae
Erysipelothrix insidiosa
Escherichia coli—all enteropathogenic serotypes
Haemophilus ducreyi, H. influenzae
Herellea vaginicola
Klebsiella—all species and all serotypes
Leptospira interrogans—all serotypes
Listeria—all species
Mima polymorpha
Moraxella—all species
Mycobacteria—all species except those listed in Class 3
Mycoplasma—all species except *Mycoplasma mycoides* and *Mycoplasma agalactiae*, which are in Class 5
Neisseria gonorrhoeae, N. meningitidis
Pasteurella—all species except those listed in Class 3
Salmonella—all species and all serotypes
Shigella—all species and all serotypes
Sphaerophorus necrophorus
Staphylococcus aureus
Streptobacilus moniliformis
Streptococcus pyogenes
Treponema carateum, T. pallidum, and *T. pertenue*
Bibrio fetus, V. comma, including biotype El Tor, and *V. parahemolyticus*
2. Fungal agents:
Actinomycetes (including *Nocardia* species and *Actinomyces* species and *Arachnia propionica*)
Blastomyces dermatitidis
Cryptococcus neoformans
Paracoccidioides brasiliensis
3. Parasitic agents:
Endamoeba histolytica
Leishmania sp.
Naegleria gruberi
Toxoplasma gondii
Toxocara canis
Trichinella spiralis
Trypanosoma cruzi
4. Viral, Rickettsial, and Chlamydial agents:
Adenoviruses—human—all types
Cache Valley virus
Coxsackie A and *B viruses*
Cytomegaloviruses
Echoviruses—all types
Encephalomyocarditis virus (EMC)
Flanders virus
Hart Park virus
Hepatitis-associated antigen material
Herpes viruses—except *Herpesvirus simiae* (Monkey B virus) which is in Class 4
Corona virus
Influenza viruses—all types except A/PR8/34, which is in Class 1
Langet virus
Lymphogranuloma venereum agent
Measles virus
Mumps virus
Parainfluenza virus—all types except Parainfluenza virus 3, SF4 strain, which is in Class 1
Polioviruses—all types, wild and attenuated
Poxviruses—all types except *Alastrim, Smallpox, Monkey pox*, and *Whitepox*, which, depending on experiments, are in Class 3 or Class 4
Rabies virus—all strains except *Rabies street virus*, which should be classified in Class 3 when inoculated into carnivores
Reoviruses—all types
Respiratory syncytial virus
Rhinoviruses—all types
Rubella virus
Simian viruses—all types except *Herpesvirus simiae (Monkey B virus)* and *Marburg virus*, which are in Class 4
Sindbis virus
Tensaw virus
Turlock virus
Vaccinia virus
Varicella virus
Vole rickettsia
Yellow fever virus, 17D vaccine strain

C. CLASS 3 AGENTS

1. Bacterial agents:
*Actinobacillus mallei**
Bartonella—all species
Burcella—all species
Francisella tularensis
Mycobacterium avium, M. bovis, M. tuberculosis
Pasteurella multocide type B ("buffalo" and other foreign virulent strains*)
*Pseudomonas pseudomallei**
Yersenia pestis
2. Fungal agents:
Coccidioides immitis
Histoplasma capsulatum
Histoplasma capsulatum var. *duboisii*
3. Parasitic agents:
Schistosoma mansoni
4. Viral, Rickettsial, and Chlamydial agents:
Alastrim, Smallpox, Monkey pox, and *Whitepox*, when used *in vitro*
Arboviruses—all strains except those in Class 2 and 4 (Arboviruses indig-

*See Part V, Footnotes and References, ref. 7.

*USDA permit also required for import or interstate transport.

enous to the United States are in Class 3, except those listed in Class 2. *West Nile* and *Semliki Forest* viruses may be classified up or down, depending on the conditions of use and geographical location of the laboratory.)
Dengue virus, when used for transmission or animal inoculation experiments
Lymphocytic chorimeningitis virus (LCM)
Psittacosis-Ornithosis-Trachoma group of agents
Rabies street virus, when used in inoculation of carnivores (See Class 2)
Rickettsia—all species except *Vole rickettsia* when used for transmission or animal inoculation experiments
*Vesicular stomatitis virus**
Yellow fever virus—wild, when used *in vitro*

D. CLASS 4 AGENTS

1. Bacterial agerits: None.
2. Fungal agents: None.
3. Parasitic Agents: None.
4. Viral, rickettsial, and Chlamydial Agents:
Alastrim, Smallpox, Monkey pox, and *Whitepox,* when used for transmission or animal inoculation experiments
Hemorrhagic fever agents, including *Crimean hemorrhagic fever (Congo), Junin,* and *Machupo* viruses, and others as yet undefined
Herpesvirus simiae (Monkey B virus)
Lassa virus
Marburg virus
Tick-borne encephalitis virus complex, including *Russian spring-summer encephalitis, kyasanur forest disease, Omsk hemorrhagic fever,* and *Central European encephalitis viruses*
Venezuelan equine encephalitis virus, epidemic strains, when used for transmission or animal inoculation experiments
Yellow fever virus—wild, when used for transmission or animal inoculation experiments

II. Classification of Oncogenic Viruses on the Basis of Potential Hazard (2)

A. LOW-RISK ONCOGENIC VIRUSES

Rous Sarcoma
SV-40
CELO
Ad7-SV40
Polyoma
Bovine papoilloma
Rat mammary tumor
Avian Leukosis
Murine Leukemia
Murine Sarcoma
Mouse mammary tumor
Rat Leukemia
Hamster Leukemia
Bovine Leukemia
Dog Sarcoma
Mason-Pfizer Monkey Virus
Marek's
Guinea Pig Herpes
Lucke (Frog)
Adenovirus
Shope Fibroma
Shope Papilloma

B. MODERATE RISK ONCOGENIC VIRUSES

Ad2-SV40
FeLV
HV Saimiri
EBV
SSV-1
GaLV
HV ateles
Yaba
FeSV

III. Animal Pathogens (3)

A. ANIMAL DISEASE ORGANISMS WHICH ARE FORBIDDEN ENTRY INTO THE UNITED STATES BY LAW (CDC CLASS 5 AGENT)

1. Foot and mouth disease virus

B. ANIMAL DISEASE ORGANISMS AND VECTORS WHICH ARE FORBIDDEN ENTRY INTO THE UNITED STATES BY USDA POLICY (CDC CLASS 5 AGENTS)

African horse sickness virus
African swine fever virus
Besnoitia besnoiti
Borna disease virus
Bovine infectious petechial fever
Camel pox virus
Ephemeral fever virus
Fowl plague virus
Goat pox virus
Hog cholera virus
Louping ill virus
Lumpy skin disease virus
Nairobi sheep disease virus
Newcastle disease virus (Asiatic strains)
Mycoplasma mycoides (contagious bovine pleuropneumonia)
Mycoplasma agalactiae (contagious agalactia of sheep)
Rickettsia ruminatium (heart water)
Rift valley fever virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Teschen disease virus
Trypanosoma vivax (Nagana)
Trypanosoma evansi
Theileria parva (East Coast fever)
Theileria annulata
Theileria lawrencei
Theileria bovis
Theileria hirci
Vesicular exanthema virus
Wesselshron disease virus
Zyonema farciminosum (pseudofarcy)

REFERENCES

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2. "National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses" (October 1974). U.S. Department of Health, Education, and Welfare Publication No. (NIH) 75-790.
3. U.S. Department of Agriculture, Animal and Plant Health Inspection Service.

APPENDIX C—TABLE OF CONTENTS

APPENDIX C—NIH POLICES AND ADMINISTRATIVE PROCEDURES FOR EXPERIMENTS SUBJECT TO THE NIH GUIDELINES

The policies and procedures in this appendix apply only to recombinant DNA research subject to the NIH guidelines (see Pt. I of the guidelines).

These policies and procedures are mandatory for all recombinant DNA research conducted at institutions receiving any funds for recombinant DNA research from NIH. This appendix supersedes previous announcements published in the October 17, 1977, and February 15, 1978, issues of the NIH Guide for Grants and Contracts and previous notices placed in application kits for Public Health Service research and training grants.

This appendix contains NIH policies and procedures in effect as of the date of publication of the final revised guidelines. These policies and procedures can be superseded by subsequent issuances. For current NIH policies, contact the NIH Office of Recombinant DNA Activities (ORDA).

I. *General Requirements.*

A. *Institutional Biosafety Committee (IBC).* Each institution at which recombinant DNA research subject to the guidelines is being conducted must have a standing biosafety committee. Suggestions for the composition of such a committee are discussed under Part IV of the guidelines, which also discusses the roles and responsibilities of principal investigators and institutions. A roster of the members of the Institutional Biosafety Committee (IBC) must be submitted to NIH.

The minimum information must include the names, addresses, occupations, qualifications, and curricula vitae of the chairperson and members of the committee. This information must be submitted to: Office of Recombinant DNA Activities, National Institutes of Health, Room 4A52, Building 31, Bethesda, Md. 20014.

The membership of IBC's is subject to review by ORDA for compliance with recommendations stated in the guidelines. It is the responsibility of each institution to update this information at least annually. As stipulated in the guidelines, ORDA will assist in the formation of an Area Biosafety Committee (ABC) when appropriate. Such a committee will be necessary when additional expertise from outside a given institution is necessary for the IBC to fulfill its functions.

B. *Approval and Registration of Projects.* Central to the implementation of the guidelines is the review of proposed projects by the IBC. When the IBC has approved the project, the experiments may be initiated (except for experiments requiring P4 physical containment, which require prior NIH approval; special procedures cover NIH awards, see sec. II-D below). The institution is responsible for registering approved projects with NIH. ORDA will review approved projects and notify investigators and institutions of the results of such review. (See sec. II-B for requirements for competing and noncompeting NIH applications. See sec. II-E for changes in ongoing projects, and Pt. IV for information on registration.)

II. *Requirements and Procedures for NIH-Supported Projects.* This section describes policies and procedures for projects supported by NIH.

A. *Memorandum of Understanding and Agreement (MUA).* Each application to the National Institutes of Health for a project which involves experiments subject to the NIH guidelines for recombinant DNA research (see sec. I-E of the guidelines) must be accompanied by an MUA prepared in the format shown in the attached illustration. Applicants are urged to follow the sequence and format of the illustration as closely as possible.

An application submitted to NIH without an attached MUA is incomplete and will not be reviewed until a properly executed MUA is provided.

1. *Contents of an MUA.* An MUA must contain the following sections:

a. *Description.* A description of each proposed project, and the name of the individual investigator responsible for the research if other than the principal investigator.

Descriptions must include information on:

(1) source(s) of DNA,

(2) nature of inserted DNA sequences, and

(3) hosts and vectors to be used.

The descriptions must be sufficient to provide information about the experiments without need for reference to other documents. Each performance site must be identified with the name(s) of the organization, city, and State. Ordinarily, no more than two pages of description for each series of experiments are necessary.

b. *Assessment of Containment Levels.* An assessment of the physical and biological containment levels required by the current NIH guidelines for each series of experiments.

c. *Statement by Principal Investigator.* A specific brief statement by the principal investigator agreeing to abide by the provisions of the NIH guidelines and the requirements contained in this appendix concerning shipment and transfer of recombinant DNA materials (see sec. II-F of this appendix).

The principal investigator must also attest to the accuracy of the information in the MUA (see illustration in this appendix).

d. *Information concerning IBC review:*

(1) When facilities are in existence, a certification is required indicating that the IBC has reviewed the facilities and the proposed project(s) and found them to be in compliance with the NIH Guidelines, this Appendix, and other specific NIH instructions. The date of the IBC review must be specified.

(2) When facilities are proposed or are under construction or renovation at the time of the application, an assurance in lieu of a certification must be provided. The assurance indicates that the IBC has reviewed the proposed project and the plans for the facilities proposed or under construction or renovation. The assurance must include a statement that recombinant DNA experimentation will not occur until the completed facility has been reviewed by the IBC and an amendment to the MUA (i.e., the certification described in subparagraph (1)), has been submitted to NIH.

NOTE: Some MUA's may have to incorporate a certification as well as an assurance if there are both certified facilities and facilities under construction or renovation.

e. *Statement Regarding Continuing Compliance.* A statement by the appropriate institutional official that the IBC will insure compliance with the Guidelines throughout the duration of the project.

f. *Signatures.* The signatures of the principal investigator, the IBC chairperson, and the institutional official(s) are required.

g. *Date of MUA.* The date of the MUA for future reference will be the date of the institutional official's signature.

2. *MUA's for Recombinant DNA Research at Multiple Sites.* When research at multiple sites is proposed, the MUA must specify where each part of the project will be carried out. When research is proposed at sites governed by other than the applicant institution, signatures of the appropriate officials at both the applicant institution and the institution(s) where the recombinant DNA research is to be conducted are required. The signatures shall indicate that the IBC's of each of the institution(s) where the research is to be performed have given the certification and/or assurance required in item d of the MUA.

3. *MUA's Associated with Individual Fellowship Applications, Research Career Development Award Candidates (RCDA), Research Career Awardees (RCA), and Institutional National Research Service Fellowship Applications.* When projects involving recombinant DNA technology subject to the Guidelines are involved, fellowship applicants, RCDA candidates, RCA's, or Program Directors for Institutional National Research Service Fellowship Applications should attach to the application either a copy of MUA(s) already submitted to the NIH, or submit a new MUA(s) as indicated below. If a copy is submitted, the fellowship applicant, RCDA candidate, RCA, or Program Director (if other than the principal investigator) must sign the MUA copy under the signature of the principal investigator.

If any recombinant DNA work is proposed other than that indicated in an existing MUA(s), a new or amended MUA must be submitted to NIH in accordance with procedures in II-B and II-E of this Appendix. These procedures also apply to experiments using recombinant DNA technology in courses supported by an institutional fellowship.

B. *Submission of Memorandum of Understanding and Agreement (MUA).*

1. *Competing Applications.* For competing applications involving recombinant DNA research subject to the Guidelines, an MUA must be submitted to the Division of Research Grants, NIH, with the application.

2. *Noncompeting Applications.* Each noncompeting continuation application involving recombinant DNA research subject to the Guidelines must be accompanied by an updated MUA that indicates that the IBC has reviewed the project prior to submission of the application, and has found it still in compliance with NIH Guidelines.

IMPORTANT NOTE: If an investigator wishes immediately to initiate a project after IBC approval, after submitting a new competing application to NIH, the procedures for registration of non-NIH projects, described in section IV of this Appendix, must also be followed. If an investigator wishes immediately to initiate new experiments in an ongoing project, an MUA must be filed with NIH within 30 days of IBC approval, even if the proposed experiments are described in an MUA submitted with a noncompeting or a competing renewal application. In the latter cases, see procedures in section II-E of this Appendix, dealing with changes in ongoing projects, which must also be followed.

C. *Notation on Applications for Research and Training Grants.* NIH application forms will be revised to include a block to be checked indicating whether recombinant DNA research subject to the Guidelines is involved. Until such time as revised forms are available, applicants should specify in capital letters at the bottom of the first page of the application the following statement:

APPLICATION INVOLVES EXPERIMENTS SUBJECT TO GUIDELINES FOR RECOMBINANT DNA RESEARCH

D. *Award Procedures.* Prior to award, MUA's will be reviewed by ORDA for compliance with the requirements of the Guidelines. Notification of the status of NIH review of the MUA will be accomplished by one of the following 3 footnotes on the Notice of Grant Award:

Footnote 1. "Protocols in MUA dated —/—/— conform to standards of NIH Guidelines."

Footnote 2. "Protocols in MUA dated —/—/—, as modified, conform to standards of NIH Guidelines."

Footnote 3. "Protocols in MUA dated —/—/— do not conform to standards of NIH Guidelines."

Footnote 1 will be used to indicate that the MUA has been reviewed by ORDA, and the protocols have been found to conform to the standards set forth in the Guidelines.

Footnote 2 will be used to indicate that the MUA has been reviewed by ORDA and that certain aspects of the MUA do not conform to standards set forth in the Guidelines. Use of this footnote indicates that NIH has notified the institution that appropriate action must be taken to bring the protocols in question into compliance with NIH standards, or that the protocols in question must not be carried out.

Footnote 3 will be used to indicate that the MUA has been reviewed by ORDA and the protocols have been found not to conform to standards set forth in the Guidelines. This footnote indicates that the proposed experiments are not to be carried out until they have been brought into compliance with NIH standards, and a revised MUA has been submitted to the NIH.

E. *Changes in Ongoing Projects.* Changes in a project subject to the Guidelines must be reported to the IBC by the principal investigator.

1. *Protocols for Which Containment Levels are Explicitly Specified by Guidelines.* The procedures described in this section apply only to research projects for which containment levels are explicitly stated in the Guidelines or in announcements from ORDA, except for projects requiring P4 physical containment, which require NIH approval prior to initiation of the research.

Depending upon the judgment of the IBC as to whether the proposed changes are major or minor, the procedures described in a and b below are to be followed.

a. *Major Changes.* A new or revised MUA is required for introduction of recombinant DNA research subject to the guidelines into an ongoing project, or for significant changes in the recombinant DNA aspects of an ongoing project. Examples of changes in an ongoing recombinant DNA project which would require the filing of a new or amended MUA would include (i) significant changes in hosts or vectors. (ii) significant changes in the donor species or the nature of the DNA segment being selected, (iii) major changes in the physical location of the experiments, or (iv) a change of the investigator responsible for the conduct of the experiments.

For such changes in an ongoing project, a new or revised MUA must be submitted to the IBC. Once IBC approval has been obtained for other than projects requiring P4 containment, the experiments may be initiated. The institution must then forward the MUA directly to the program administrator of the awarding NIH Bureau, Institute, or Division within 30 days of approval by the IBC. The MUA must identify the project by grant number. The principal investigator will be notified by letter regarding the NIH review of the new or revised MUA. If review by ORDA finds that an MUA, or certain aspects of an MUA, do not conform to standards set forth in the guidelines, the principal investigator and the IBC will be notified. In such cases, immediate action must be undertaken to bring the protocols into compliance with NIH standards or the experiments in question must be suspended.

b. *Minor Changes.* Principal investigators should submit information on

minor changes in research protocols to the IBC. Minor changes need not be reported to NIH until an updated MUA is required (see section II-B of this appendix).

2. *Protocols for Which Containment Levels are Not Explicitly Specified by the NIH Guidelines.* Investigators who wish to initiate recombinant DNA experiments for which containment levels are not explicitly stated in the guidelines or in announcements from ORDA must obtain approval from the NIH prior to initiating the proposed experiments.

Because it is anticipated that the setting of containment levels for this class of experiments will require review by the Recombinant DNA Advisory Committee, investigators are strongly urged to provide to ORDA in writing full information on the proposed experiments prior to submission of a formal MUA.

F. *Shipping Requirements.*

NOTE.—Requirements regarding shipment and transfer of recombinant DNA materials may be incorporated by reference into the MUA (see illustration in this appendix).

All MUA's must indicate that the principal investigator (program director, fellow, or candidate) agrees to comply with the following provisions pertaining to shipment or transfer of recombinant DNA materials:

1. Prior to shipment or transfer of recombinant DNA materials within the United States, the sending laboratory shall obtain a written statement from the requesting laboratory that:

a. Research involving recombinant DNA molecules shall be conducted in compliance with NIH guidelines, this appendix, and other NIH instructions, and

b. The project proposed by the requesting laboratory has been reviewed and approved by the IBC of the requesting laboratory.

2. Prior to shipment of recombinant DNA materials to a country other than the United States, the sending laboratory shall obtain a statement from the requesting laboratory stating that research involving recombinant DNA molecules shall be conducted in accordance with the containment levels specified by the NIH guidelines, or applicable national guidelines if such have been adopted by the country in which the research is to be conducted.

3. The sending investigator shall maintain a record of all shipments of recombinant DNA materials.

NOTE.—See section II-D-3 of the guidelines for restrictions on distribution of certified host-vector systems.

III. *Policy and Procedures for Recombinant DNA Research Supported by NIH and Conducted in Foreign Countries.*

A. *Policy.* Many countries in which NIH-supported recombinant DNA research may be conducted have adopted guidelines for the conduct of this research which are either comparable to or based on principles similar to those of the NIH guidelines for recombinant DNA research. Also, many countries have existing organizations and procedures to review and register recombinant DNA research, and require documentation similar to that of NIH. If such guidelines and procedures exist and are comparable to the NIH guidelines, review and approval by the appropriate national body in the country in which the research is to be conducted, in general, will be accepted as assurance that the research will be conducted in a responsible manner and in accord with national guidelines. However, NIH reserves the right to withhold funding if the safety practices to be employed are not reasonably consistent with the NIH guidelines.

B. *Requirements and Procedures for NIH-Supported Research in Countries with Guidelines.* The following procedures apply both to NIH awards in foreign countries and to U,S. investigators intending to conduct recombinant DNA research with NIH support in foreign countries which have adopted guidelines. For applications for NIH awards in foreign countries, the required documentation (see below) may be included with the application, or may be submitted at a later date, but must be submitted prior to the time of award. For U.S. investigators intending to conduct recombinant DNA research abroad, the documentation should be submitted prior to initiation of the project.

For all NIH-supported research abroad using recombinant DNA technology, a document providing the following information must be submitted to NIH:

1. A description of each proposed project and the individual investigator responsible for the research, if other than the principal investigator. Descriptions should indicate the sources of DNA, nature of inserted DNA sequences, hosts and vectors to be used, and must be of sufficient detail to provide information about the research without need for reference to other documentation. Ordinarily, no more than two pages of description for each series of experiments are necessary.

2. An assessment of the level(s) of physical and biological containment required by the guidelines of the country in which the research is to be conducted.

3. Documentation that the research project is in compliance with the applicable national guidelines and, where required, has been registered with the appropriate national body in the country in which the research is to be conducted. If approval of the national body is required prior to initiation of the research, the documentation must indicate that such approval has been received.

4. The signatures of both a responsible official and the principal investigator.

5. The date of signature of the responsible official. This will become the date of the document for future reference.

C. *Requirements Regarding Countries Which Have Not Adopted Guidelines.* NIH funds may not be used for the conduct of recombinant DNA research in a country which has not adopted national guidelines, unless the research is in full compliance with NIH Guidelines and the procedures required for U.S. grant applications have been fulfilled—i.e., establishment of an institutional biosafety committee, filing of an MUA, etc.

IV. *Registration of Recombinant DNA Projects.*

A. *NIH-Supported Projects.* An NIH-approved MUA will constitute registration of projects awarded by NIH. For immediate initiation of projects pending with NIH see "Important Note" under section II-B of this appendix.

B. *Required Registration of Non-NIH Projects.* The guidelines require that institutions receiving NIH funds for recombinant DNA research shall inform NIH of all initiated recombinant DNA projects subject to the guidelines (see section IV-C-1 of the guidelines). For these projects, the required information must be submitted within 30 days of the IBC's approval.

C. *Voluntary Registration of Non-NIH Projects.* The guidelines stipulate that any institution which is not required to comply with the guidelines may nevertheless register with the NIH ongoing projects involving recombinant DNA research subject to the guidelines (see section IV-C-2 of the guidelines).

D. *Procedures for Registration.* The procedures in this section apply to registration of projects in B and C above. Because non-NIH projects filed with the NIH will immediately be added to the register of ongoing recombinant DNA research, institutions may register only those projects which are ongoing or about to be initiated. Institutions should not submit pending projects to this register.

Institutions must register these projects directly with ORDA. It is the responsibility of the institution to insure that this information is accurate and up-to-date by submitting any necessary revised information on a timely basis. Institutions are responsible for notifying ORDA when a project is completed or terminated so that it may be removed from the register.

For registration of projects described in B and C above, the following information must be submitted:

1. A short title for the project.
2. Registry number of project.
3. Start and end dates of the project.
4. The name of the principal investigator and the name and address of the institution, including the department in which the research is being conducted and the location of the project.
5. The source of support for the project.
6. A description of each project and the name of the investigator responsible for the research. Descriptions should indicate information on the sources of DNA, nature of inserted DNA sequences, and the host-vector systems being used. Ordinarily, no more than two pages of description for each series of experiments are necessary.
7. An assessment of the level(s) of physical and biological containment required by the Guidelines for each series of experiments.
8. A statement that an Institutional Biosafety Committee has reviewed the project and found it to be in compliance with the NIH Guidelines.
9. The signatures of the principal investigator, the chairperson of the IBC, and the institutional official.
10. The date of signature by the institutional official. This date will be used for reference purposes.

E. *Review.* Institutions will be notified in writing of ORDA's review of the information submitted for registration of recombinant DNA projects not supported by NIH. If review by ORDA finds that the protocols do not conform to standards set forth in the Guidelines, the institution is expected to take appropriate action to bring the protocols into compliance with NIH standards.

V. *Lowering of Containment Levels for Purified DNA and Characterized Clones.*

A. *Purified DNA Other Than Plasmids, Bacteriophages, and Other Viruses.*

The Guidelines stipulate that the formation of DNA recombinants from cellular DNA's that have been purified and which are free of harmful genes can be carried out under lower containment conditions than those required for the corresponding shotgun experiment. IBC approval is sufficient for such a reduction of containment level, except for (i) primate DNA, which also requires prior NIH approval, or (ii) any lowering of containment to levels below P1+EK1, which also requires prior NIH approval (see sec. III-A-3-a of the Guidelines).

The IBC must notify ORDA in writing of all such actions. Many of these actions will be in the context of submission of a new or revised MUA.

B. *Characterized Clones of DNA Recombinants.* The Guidelines permit IBC's to give approval for a single-step reduction in physical or biological containment on receipt of evidence of characterization of a clone derived from a shotgun experiment and its probable freedom from harmful genes (see sec. III-A-3-b of the Guidelines). IBC approval is sufficient for such a reduction except for (i) primate DNA which requires prior NIH approval, or (ii) any lowering of containment to levels below P1+EK1, which also requires prior NIH approval. The IBC must notify ORDA in writing of all such actions. Such notification must clearly indicate the name of the principal investigator and the project supporting the work.

Reduction of containment levels by more than one step, use of primate DNA, or cases involving lowering of containment to levels below P1+EK1 require prior approval by NIH. In the latter cases, complete information must be submitted to ORDA. Many of these cases are expected to require review by the RAC at its next scheduled meeting.

VI. *Exceptions and Exemptions to the Guidelines.*

A. *Exceptions.* Exceptions to prohibited experiments require express approval by the Director, NIH, on recommendation of the RAC after appropriate notice and opportunity for public comment (see sec. I-D of the Guidelines).

B. *Exemptions.* Classes of exempt experiments, which are not covered by the Guidelines, are cited in section I-E of the Guidelines. It is anticipated that additional exemptions for specific experiments which fall into the categories cited in sections I-E-4 and I-E-5 of the Guidelines may be granted by the Director, NIH, on the recommendation of the RAC and after appropriate notice and opportunity for public comment.

C. *Requests for Exceptions and Exemptions.* Requests for an exception to a prohibition or an exemption from the Guidelines must be submitted to ORDA accompanied by adequate documentation. Because the handling of requests for exceptions and exemptions will probably be a time-consuming process, investigators are strongly urged to discuss the proposed request with the staff of ORDA by telephone in advance of submission of a formal request. Decisions or requests for exceptions or exemptions will be published in the *Recombinant DNA Technical Bulletin.*

Illustration

NAME OF INSTITUTION

MEMORANDUM OF UNDERSTANDING AND AGREEMENT

Application/Grant Number (if applicable) _____

Investigator's Telephone Number _____

Description

(To be supplied)

Assessment of Levels of Physical and Biological Containment

(To be supplied)

The information above is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH Guidelines and other specific NIH instructions pertaining to the proposed project. I agree to comply with the requirements specified in Appendix C pertaining to shipment and transfer of recombinant DNA materials.

_____
Principal Investigator Date

I certify that the Institutional Biosafety Committee (IBC) has reviewed on (date) the proposed project for recombinant DNA experiments, and has found it to be in compliance with NIH Guidelines and other specific NIH instructions pertaining to the proposed project.

AND/OR

I assure that the IBC has reviewed on (date) the proposed project and the plans for facilities proposed or under construction or renovation. Recombinant DNA experimentation will not occur until the completed facilities have been reviewed by the IBC and an MUA with certification has been submitted to the NIH.

I agree that the IBC shall monitor throughout the duration of the project the facilities, procedures, and training and expertise of the personnel who are working on the project and for the facilities.

_____
IBC Chairperson Date

_____
Applicant Institutional Official Date

_____
Institutional Official Date
(Additional Performance Sites, if applicable)

NATIONAL INSTITUTES OF HEALTH, ENVIRONMENTAL IMPACT ASSESSMENT OF A PROPOSAL TO RELEASE REVISED NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

PREPARED BY THE OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH—JULY 1978

SUMMARY

Nature of Document: Environmental Impact Assessment.

Agency: National Institutes of Health, Public Health Service, U.S. Department of Health, Education, and Welfare.

Type of Action: (X) Administrative. ( ) Legislative.

Description of Action: Publication for public comment of proposed revised guidelines for research involving recombinant DNA molecules.

Organization of Material: Background information is presented on the recombinant DNA process and on the presumed risks and demonstrable benefits of this basic research technique. Next the proposed revised guidelines are analyzed according to their four main parts: scope, principles of containment of possibly hazardous agents, proposed changes in the containment for experiments to be covered by the revised guidelines, and roles and responsibilities of investigators and institutions.

Analysis of Alternatives: For each of these four main parts, the assessment is presented under four sections: analysis of the current Guidelines (in effect since June 23, 1976); alternatives (revisions) proposed by the NIH Recombinant DNA Advisory Committee (RAC) [FEDERAL REGISTER, September 27, 1977]; alternatives proposed by the Director, NIH, after full consideration of scientific evidence, public comments, and the testimony taken in a 2-day meeting of the Director's Advisory Committee (DAC) at which scientists of various disciplines, representatives of environmental groups, and other witnesses discussed the RAC proposals; and finally, the projected environmental impact of research to be conducted under the NIH Director's proposed guidelines. Appendix A will aid in comparing the containment levels under the current guidelines with those under the two alternatives. Appendix B shows how those alternatives would have affected all NIH-funded recombinant DNA experiments active in December 1977.

Environmental Impact of the Proposed Action: As can best be determined from all evidence compiled to date and analyzed in numerous scientific and public forums, there will be no adverse environmental impact from recombinant DNA research conducted under the Director's proposed revisions. The *Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules,* issued in October 1977, predicted that the environmental impact of research conducted under the 1976 NIH Guidelines would be the continued protection of the laboratory worker, the general public, and the environment from conjectural hazards. So far, this prediction has been confirmed: We know of no scientists conducting recombinant DNA research in the United States or other countries who are not following the NIH or comparable guidelines, and no untoward effect of the research has been reported. Meanwhile, new scientific evidence as well as extensive experience in operating under the NIH Guidelines indicate that revisions are in order. The predictable effect of continued use of recombinant DNA techniques under the Director's proposed revisions would be a greater realization of the benefits of this valuable tool without compromise of safety.

CONTENTS

FOREWORD

In June 1976 the National Institutes of Health, with the concurrence of the Secretary of Health, Education, and Welfare and the Assistant Secretary for Health, issued guidelines to govern the conduct of NIH-supported research involving recombinant DNA molecules. These guidelines stated that they would be "subjected to periodic review (at least annually) and modified to reflect improvements in our knowledge of the potential biohazards and of the available safeguards." Since that time, a number of scientific, administrative, and legislative events have occurred that should be summarized at the outset, for they are reflected in the revisions of the NIH guidelines as proposed, first by the Recombinant Advisory Committee and currently by the Director, NIH.

Recombinant DNA experiments have proceeded in hundreds of laboratories throughout the world. The subject has been discussed and debated in countless meetings, and the public has been consulted as well as the scientific community. NIH has taken into account public comments in preparing the original guidelines, an environmental impact statement (EIS), and the proposed Director's revision.

One of the most important recent developments has been the careful scrutiny, from a very broad point of view, of the premises upon which the original guidelines were based. Thus, the molecular biologists, who first raised questions about the safety of recombinant research, have now had greater opportunity to consider their concerns in the company of many experts on infectious disease, epidemiology, viruses, plants, laboratory safety practices, ecology, and other relevant disciplines.

From all of these activities have emerged certain important facts. For one, no evidence has come to light that any of the thousands of individual recombinant DNA clones construct-

ed over the last 5 years have yielded a product harmful to man or the environment. On the other hand, many examples of useful knowledge obtained through such techniques continue to accumulate rapidly.

Scientific developments

No scientific evidence not considered in the promulgation of the guidelines has emerged to support the fears that the use of these techniques will create a harmful product. On the contrary, scientific information has been developed over the past 2 years that lessens concern over the possible environmental hazard. Dr. Roy Curtiss, professor of microbiology at the University of Alabama School of Medicine in Birmingham, and others have demonstrated that biological containment measures—methods developed to weaken bacteria used in the experiments—do prevent these bacteria from surviving in a natural environment, and would do so if they escaped from the laboratory.

While the probability of doing harm with laboratory recombination of genes has not been, and never will be, reduced to zero, we have reached a point where the burden of proof is shifting toward those who would restrict such activities. The careful interpretation of evidence obtained before and after June 1976 has reduced to inconsequential levels the probabilities that *E. coli* K-12, the host most used in recombinant DNA experiments, can be converted to an epidemic pathogen. Much of the relevant data and their discussion by experts are now available in the published proceedings of an NIH-sponsored meeting in Falmouth, Mass., on June 20-21, 1977 (Journal of Infectious Diseases, May 1978).

The Falmouth conference brought out evidence that the risk of transforming *E. coli* K-12 into a pathogen is minimal, either for laboratory personnel or the public at large. Dr. Sherwood Gorbach, chairman of the conference, has reported that there was scientific consensus on this matter among all in attendance, including microbiologists who work with disease-producing bacteria.

Much of the concern expressed about recombinant DNA experiments relates to the creation of novel organisms in the laboratory. Additional evidence, however, suggests that the recombinations of DNA produced in the laboratory may be very similar to many that occur in nature. If further work confirms and extends this evidence, then the concern about creating novel forms of life will be put into a new perspective.

Administrative developments

Implementation of the NIH guidelines

The current NIH guidelines provide not only explicit instructions about the conduct of experiments, but also an administrative framework for their implementation. They set out the respective responsibilities of the principal investigator, the institution where the work is conducted (including the institutional biohazard committee), the NIH Recombinant DNA Advisory Committee (or simply "Recombinant Advisory Committee" or "RAC," the technical body responsible for proposing the guidelines), and the NIH staff.

The NIH Office of Recombinant DNA Activities (ORDA) was established to coordinate the administration of NIH policies and procedures for safe utilization of recombinant DNA technology in research. Dr. William Gartland is Director of ORDA. Over the 2 years the implementation of the guidelines by participants in this research has proceeded well. Approximately 130 institutions where NIH-supported research is taking place have established institutional biohazard committees, and approximately 350 projects are involved.

Over the past 2 years administrative practices have evolved to deal with requirements of the guidelines. One of the requirements is a means for interpretation. The standards in the guidelines are very explicit about the conduct of permissible experiments. Still, questions of interpretation continue to arise and must be dealt with. Our determination to assure that the experiments comport with the standards of the guidelines has necessitated a number of administrative delays in acting on research protocols.

Another area of difficult administration has been certification of new host-vector systems. These represent microorganisms weakened by various methods to prevent their survival were they to escape from their specially contained environment in the laboratory. Under the current guidelines, the Recombinant Advisory Committee must review all applications for new host-vector systems and recommend for certification those that meet the relevant criteria.

Undoubtedly the presence of the guidelines and their implementation have caused some experiments to be postponed and some scientific work to be delayed. At the same time, NIH, having embarked upon this conservative course, believes it must guarantee the integrity of the administrative safeguards and see that due process is observed in implementation.

Policy issues

Three key policy issues concerning recombinant DNA research have dominated NIH attention during the administration of the NIH Guidelines. They are the determination of the environmental impact, if any, of the NIH Guidelines and the research conducted thereunder; the patenting of recombinant DNA research inventions developed under Federal support; and the extension of the NIH Guidelines nationally through existing regulation or new legislation. Discussions of these policy issues follow:

National Environmental Policy Act (NEPA). In accordance with the National Environmental Policy Act of 1969 (NEPA), NIH undertook an environmental impact assessment of environmental effects, if any, of the original NIH Guidelines. A draft environmental impact statement was published in the FEDERAL REGISTER in September 1976 for public review and comments. On the basis of the comments received, NIH published a final EIS in October 1977.

During the development of the EIS, two suits under NEPA were brought against the Department. One suit, in the Federal District Court in New York, alleged that NIH failed to comply with NEPA by not completing an EIS before supporting recombinant DNA research and before releasing the original guidelines. The Government has answered the allegations, and the case is pending in New York.

The second suit filed in the Federal District Court in Washington, D.C., by a resident of Frederick, Md., sought an injunction to prevent NIH from conducting a risk-assessment experiment at the Frederick Cancer Research Center without first filing an environmental impact statement. On February 23, 1978, a decision was rendered by the U.S. District Court against the issuance of an injunction, and this decision was affirmed by the U.S. Court of Appeals on March 8, 1978. It was the decision of the court that recombinant DNA research was beneficial, that the experiment under question was important, and that it posed no substantial risk. The court went on to state that "the Recombinant DNA Research Guidelines represent an effort by many scientists to evaluate the hazards and provide safe methods for their control. The record reflects that NIH has carefully considered the potential risks of this experiment under the guidelines and has taken the necessary precautions * * *. The EIS does represent a 'hard look' by NIH at recombinant DNA research performed in accordance with its guidelines. It appears that compliance with the NIH guidelines will insure that no recombinant DNA molecules will escape from the carefully controlled laboratory to the environment."

Patent Policy. Shortly before release of the NIH Guidelines in June 1976, NIH received a letter from Stanford University noting that both Stanford and the University of California were

applying for patent protection for recombinant DNA inventions developed by their NIH-supported investigators, and asking NIH to review relevant DHEW policies. In view of the intense public interest in this research generally, the two universities felt the need for a formal advisory opinion on the patenting of such inventions developed under NIH grants or contracts. A number of other universities indicated similar interest in obtaining the official NIH view.

Prior to making an official pronouncement of DHEW-NIH policy with respect to patenting of recombinant DNA research inventions, NIH decided to solicit comments from a broad range of individuals and institutions. An analysis of the comments received was completed in December 1976 and was referred to the Federal Interagency Committee on Re- combinant DNA Research.

When the guidelines were released in June 1976, a key public issue was their extension to the rest of the public and private sectors. Commentators whose views were solicited agreed that there must be standards to govern recombinant DNA research and that the NIH Guidelines could provide the standards for such research nationally. They were divided, however, on whether to approach that goal through the use of patent agreements. They noted that the implementation of the NIH Guidelines through licenses granted under patents would be awkward at best and only a partial solution.

The Interagency Committee members reviewed the matter in April and May of 1977. Most members voiced strong support for DHEW policies governing Institutional Patent Agreements (IPA's), and all except representatives of the Department of Justice believed that recombinant DNA inventions should be considered within the existing terms of the IPA. The Justice Department opinions rested heavily on a draft bill originally proposed by Senator Kennedy for the regulation of recombinant DNA research activities. Specifically, Justice referred to the patent sections of this bill that were based on the concept of Government ownership of recombinant DNA research inventions. In subsequent versions of this bill, however, all references to patents were eliminated.

On the basis of the review by the Interagency Committee and by the Assistant Secretary for Health and the General Counsel for DHEW, it was decided that, at least for the present, recombinant DNA research inventions developed under DHEW-NIH support should continue to be administered within current DHEW patent agreements with universities. Each agreement, however, will be amended to permit the institution to grant a license under patents secured on any such invention only if the licensee provides assurance of compliance with the physical and biological containment standards set forth in the guidelines. Thus, the requirements set for NIH grantees and contractors will thus be honored by licensees as well.

Legislative Developments. The Federal Interagency Committee on Recombinant DNA Research recommended in March 1977 that legislation be passed to extend the standards of the NIH Guidelines to all recombinant DNA activities in the public and private sectors. On the basis of the recommendations, legislation was developed under HEW Secretary Joseph A. Califano, Jr., and an Administration bill was introduced in the Congress. The bill was considered in Congressional hearings; other bills on the subject were introduced. After several redrafts by the relevant subcommittees during 1977, a Senate bill was reported to the Floor and a House bill was reported to the full Committee.

The two bills reported out contained many elements of the original Administration bill. A number of differences emerged, however, that would necessarily involve a greater administrative burden and some further delays and duplication in handling the highly technical matters involved in standard-setting and monitoring.

Pending legislation introduced in 1978 provides the most promising solution yet available for establishing national standards for the use of recombinant DNA techniques. The bill H.R. 11192 was reported by the Committee on Interstate and Foreign Commerce on March 24, 1978. It is an interim 2-year measure that provides for sensible regulation and public oversight. It was referred to the Committee on Science and Technology, was considered by its Subcommittee on Science, Research and Technology for a period of 21 days, and was reported from the Committee for House action on April 21. H.R. 11192 reflects new scientific information and administrative developments since the release of the NIH Guidelines in June 1976. The general administrative structure of the guidelines and the standards for biological and physical containment are endorsed for purposes of regulation. Thus, flexible regulation with national standards is the intent of the bill.

International activities

During the legislative hearings on recombinant DNA research, a number of questions were raised concerning international activities in this field. In light of this interest, the Federal Interagency Committee, at the request of representatives from the State Department, undertook a review of activities in other countries. This review was the basis for a Committee report issued in November 1977 on recombinant DNA activities throughout the world, with recommendations for fostering common safety standards. Scientists abroad, as in the United States, have played a major role in bringing potential hazards of recombinant DNA research to the attention of scientists, governments, and international organizations.

The issue of recombinant DNA research has been studied by national and international bodies. In many cases some form of control has been adopted, but nowhere has the research been totally banned. The United Kingdom, Canada, France, the Federal Republic of Germany, and the Soviet Union have issued guidelines that differ in detail but are similar conceptually to the NIH Guidelines. Other countries are generally following the NIH or U.K. Guidelines, including Denmark, the Netherlands, Israel, Sweden, and Switzerland. The European Science Foundation (ESF) has endorsed the U.K. Guidelines; the European Molecular Biology Organization (EMBO) has endorsed use of either the U.K. or the NIH Guidelines; and the International Council of Scientific Unions (ICSU) and the World Health Organization (WHO) have urged nations to adopt the principles that these two sets of guidelines embody.

As of the summer of 1977, there were an estimated 150 research projects using recombinant DNA techniques under way in Europe, 300 in the United States, and perhaps 20-25 altogether in Australia, Japan, and the Soviet Union. All appear to be conducted under some form of safety practices and procedures.

A number of national and international activities foster the monitoring of recombinant DNA research for purposes of safety and health. In the United Kingdom, the government's health and safety executive will be responsible after October 1978 for insuring that the standards of the United Kingdom Genetic Manipulation Advisory Group (GMAG) are followed in matters relating to safety of employees and the general public. The GMAG, consisting of representatives from the scientific, public, and private sectors, reviews recombinant DNA research projects for conformance to appropriate safety standards and practices. Similar advisory groups have also been established in other European countries, and efforts are underway to identify appropriate governmental bodies to insure compliance with GMAG standards.

Proposed Revised Guidelines

The RAC-proposed revisions

In December 1975 the Recombinant Advisory Committee recommended proposed guidelines for review and decision by the Director, NIH. To assist in the review, a special meeting of the Advisory Committee to the Director, NIH, was convened in February 1976. Members of the committee represented not only science but such other disciplines as law, ethics, and consumer affairs. Comments received from committee members and a number of public witnesses represented a wide range of views. A number of issues were referred back to the Recombinant Advisory Committee for their comments in April 1976. On the basis of all the comments received and the responses of the RAC, the NIH guidelines were finalized by the Director, NIH, and released in June 1976 along with an extensive "Decision document."

In 1977 the Recombinant Advisory Committee, in accordance with its mandate in the original guidelines, began the process of proposing revisions to them. A subcommittee of the RAC held open meetings in March and April. Following this, the proposed revisions were considered and revised by the full committee at open meetings in May and June. On September 1, 1977, the RAC's proposed revised guidelines were referred to the Director, NIH, for consideration and decision.

These proposed guidelines were published in September for comment in the NIH Recombinant DNA Technical Bulletin. The bulletin is a new NIH publication that links recombinant DNA investigators in the United States and abroad with the advisory groups and organizations active in this field. To provide further opportunity for public comment, the proposed revised guidelines were published in the FEDERAL REGISTER on September 27, 1977 (42 FR 49596). The revisions proposed by the RAC are described in detail in the following assessment, but the key changes can be summarized as follows:

Definition. A new definition was proposed to cover only "novel recombinant DNA"—namely, DNA segments from species not known to exchange chromosomal DNA by natural physiological processes. Accordingly, a class of recombinant DNA, to be exempt from the guidelines, would have to appear on a list of "non-novel exchangers."

Physical Containment. revisions here incorporated the philosophy and guidance of the report by NIH and the European Molecular Biology Organization (EMBO) on the requirement of physical containment. A number of revisions were also made in the organization of this section.

Biological Containment. This section was expanded from the 1976 guidelines to include (1) a new nomenclature—HV1, HV2, and HV3—incorporating a variety of host-vector systems into the framework initially established for *E. coli* K-12; (2) a more restrictive set of requirements for HV3 host-vector systems; and (3) a new section describing mechanisms for certification of host-vector systems.

Prohibited Experiments. A major recommendation would allow the Director, NIH, to exercise discretion in permitting exceptions to the prohibited experiments, as in studies of risk assessment.

Permissible Experiments. On the basis of the scientific evidence on the safety of *E. coli* K-12, some categories of experiments were classified at lower containment levels. Several other categories, however, remained the same as in the current guidelines. For certain categories, discretion was permitted by the investigator, and some categories of experiments were exempted.

Implementation. Several changes were recommended in the responsibilities for the local institution. The recommendations included requirements for training of research personnel, criteria for determining the need for medical procedures, clarification of membership on institutional bio- hazards committees, and the requirements for a biological safety officer where work is being done at the P3 and P4 levels.

The NIH-proposed revisions

The proposed revisions by the Recombinant Advisory Committee were published in the FEDERAL REGISTER for comment on September 27, 1977 (42 FR 49596), and notice of a public hearing was published in the FEDERAL REGISTER on November 22, 1977 (42 FR 59918). In December the RAC-proposed revisions were considered by the Advisory Committee to the Director, NIH (DAC) at a hearing attended by scientific experts and public witnesses. As at the 1976 hearing of the DAC, the membership was augmented to assure that the committee's perspectives included sufficient expertise and opinion on relative scientific, environmental, occupational, and public policy issues. In addition, special arrangements for the meeting included inviting 12 witnesses to represent industrial research, academic research, labor, and environmental groups. A number of others requested the opportunity to contribute their views and testified at the hearing.

Members of the Recombinant Advisory Committee attended to explain the proposed revisions, and members were present from the Federal Interagency committee on Recombinant DNA Research which represents all Federal departments and agencies that support or conduct such research or have regulatory authority in this area.

Since September 1977, when the proposed revisions were published in the FEDERAL REGISTER, they have been reviewed in light of the many comments received from the public and the scientific community. The public hearing provided a forum for all points of view, especially from the environmental perspective. On the basis of the analysis of the hearing and the correspondence, the following general points emerged:

- The recommendations by the Recombinant Advisory Committee were generally supported. There was universal sentiment for giving the Director, NIH, discretion to exempt certain experiments from the provisions of the guidelines, especially when this would permit knowledge to be gained bearing on the provisions themselves. There was overwhelming sentiment for exempting from the guidelines experiments involving most "self-cloning" systems, as well as pairs of harmless organisms that transfer genes in nature. That is, many of the experiments currently classified at the P1 + EK1 level should be exempted from the guidelines. And witnesses from the scientific community strongly advocated further consideration of revisions involving work with viruses and plant pathogens.
- On the basis of these suggestions, a "Joint United States-EMBO Workshop to Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insect Viruses" was convened on January 26-28, 1978, in Ascot, England. The report of the workshop (see appendix E) was reviewed by a working group sponsored by NIH on April 6-7, and the recommendations from that group (see appendix F) were referred to the Recombinant Advisory Committee. The committee, in turn, lent their endorsement in recommendations at a meeting held at NIH on April 27-29. The analysis of existing knowledge of viruses by the groups of experts indicate that the risks of cloning viral DNA in a bacterium like *E. coli* is not greater, and is usually much less, than the risk of handling the parent virus itself.
- Further, a meeting of agricultural scientists was convened on March 20-21, 1978, under the joint sponsorship of the Department of Agriculture, the National Science Foundation, and the National Institutes of Health. Their recommendations were also reviewed by the Recombinant Advisory Committee at their April meeting. It was the conclusion of the agricultural scientists that containment conditions for incorporation of DNA from plant pathogens into *E. coli* K-12 were unjustifiably high.

● International scientific representatives present at the hearing reported on guidelines prevailing in the United Kingdom and Western Europe and on their interpretation by Genetic Manipulation Advisory Groups. It was pointed out that some experiments are permitted in Europe which are not permitted in America. More importantly, it was noted that there is no factual basis upon which to defend the greater stringency of the U.S. (NIH) guidelines.

● There was special emphasis by public commentators on the need for procedures at the local and national level to insure public participation and oversight. The public and scientific commentators were especially concerned that there should be a commitment at the local and national levels to the training of all laboratory personnel, and to health surveillance, when feasible, to insure occupational health and safety. Concern was also expressed for local community participation to insure that practices in the laboratory meet public and environmental safety requirements.

● Several representatives from the private sector urged that NIH consider introducing mechanisms into the proposed revisions to allow private-sector participation through the guidelines. They urged that NIH provide for their voluntary registration, certification of their host-vector systems, and provision for the protection of proprietary information and patent rights.

● Strong support came from both the scientific community and the public for clear enunciation of the benefits and potential risks of this research. In addition, several of the public commentators urged that the rationale for the classification of permissible experiments be stated more clearly.

● Finally, a number of commentators in the scientific community and representatives from institutional biohazards committees advocated more flexible implementation of the NIH guidelines. Specifically, the locus of responsibility for the use of the guidelines must shift further toward the institutions conducting the research. Present requirements for NIH approval before an experiment may proceed have caused delays unjustified by proof that safety has been enhanced.

All of the issues raised by the commentators were carefully analyzed. A number of possible revisions were developed and referred to the Recombinant Advisory Committee for review. The following items were among those on the agenda of the Recombinant Advisory Committee at its April 1978 meeting:

● To redefine the scope of the guidelines, including construction of a first list of "exempted exchangers";

● To review selected issues on the guidelines raised by the public commentators;

● To review the containment levels for experiments with viral DNA or viral vectors and with plant pathogens or viruses.

On the basis of the issues raised and the response of the Recombinant Advisory Committee, a decision and environmental impact assessment on proposed revisions is offered for public comment. The assessment that follows explains the present guidelines, the RAC's alternatives, the alternatives posed by the public and scientific commentators at the public hearing and in correspondence, the RAC's views on the issues raised at the April 1978 meeting, and the assessment of the revisions as proposed by the Director, NIH.

The Recombinant DNA Experimental Process

All living things, from subcellular particles to higher organisms, contain the specific information needed for their reproduction and functions. The basic source of this information is deoxyribonucleic acid (DNA), which is the principal substance of the genes—the units of heredity. Genes determine the characteristics of the species as well as individual traits such as size and eye color.

Each cell of an organism is composed of various organized structures, several of which contain DNA. Figure 1 illustrates a typical eukaryotic, or nucleated, cell. Bacterial cells (prokaryotic) are much less complex, showing fewer organelles and no organized nucleus.

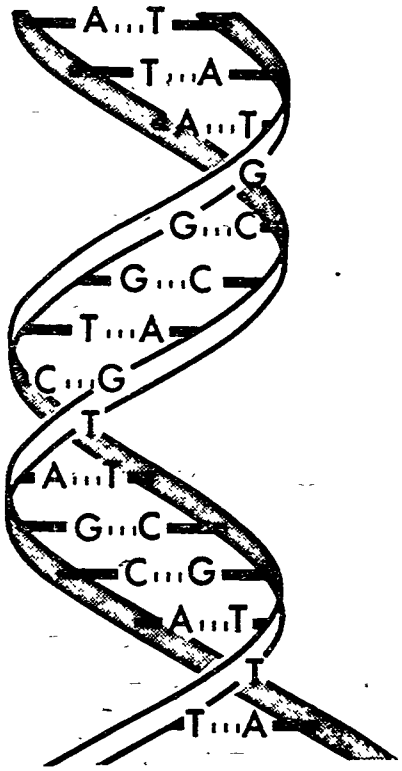
Figure 1

DNA plays to two roles: (1) provides information for the reproduction, growth, and functions of the cell, and (2) preserves and directs replication of this information and transfers it to the offspring. These two roles of DNA are common to animals, plants, single-cell organisms, and many viruses. The DNA of cells is mainly found in organized structures called "chromosomes."

Intracellular DNA also occurs outside of the chromosomes as separately replicating molecules. Such DNA molecules include the plasmids, found in bacteria; the DNA of chloroplasts, common to green plants; and the DNA of mitochondria, the energy-producing units of the cells of complex organisms. These DNA's, while not strictly part of the inherent genetic make-up of a cell, help define the cell's functional capability. Another type of DNA commonly found in cells is the DNA of infecting viruses.

During the past 30 years the structure of DNA molecules has been studied intensively, and it can now be described in much detail. The molecule may be compared to a long-twisted stepladder with thousands to millions of rungs. A short piece of DNA is represented in Figure 2.

Figure 2



The sides of the ladder are formed of sugar molecules (dexoyribose) attached end to end through phosphate groups. At right angles to each sugar molecule is one of four possible bases—adenine, guanine, thymine, and cytosine. The precise sequence of these bases, the rungs of the ladder, codes the information content. The "reading" of the code contained in the sequence of bases results in the formation of proteins, which in turn carry out most of the essential functions of the cell.

A gene is a portion of the DNA molecule which codes for the manufacture of a protein. In higher organisms, much of the DNA may not serve as genes in this sense, but may regulate the activity of nearby genes. It is possible to break open cells and isolate DNA, free of other cellular constituents.

The formation of "recombinant DNA" in the laboratory was made possible by a series of discoveries. W. Arber and D. Dussoix, in 1962, showed that bacteria contain substances called restriction enzymes. Serving to defend the bacteria against viruses, these enzymes can split foreign DNA molecules into specific fragments. R. Yoshimori, in H. Boyer's laboratory, isolated a restriction enzyme that was later found to split DNA into fragments whose ends stick together when they touch. In 1973 S. Cohen and others succeeded in combining genes of different species and introducing them into bacteria. Then they grew the bacteria in cultures, multiplying the combined characteristics.

The capabilities sketched here—to split DNA selectively, to recombine it by virtue of "sticky" ends, to reintroduce it into cells, and to cultivate the cells—constitute the recombinant DNA technique.

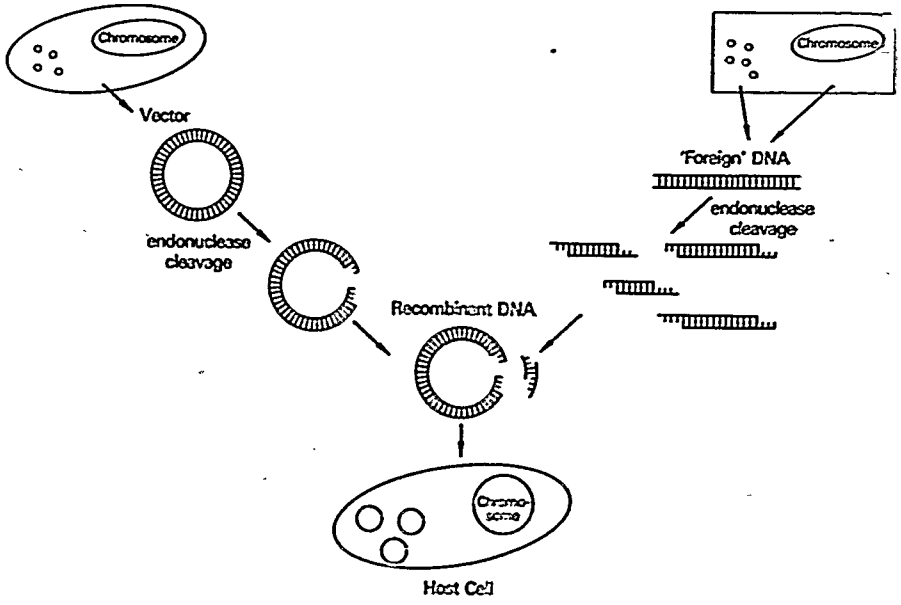
In the recombinant DNA experiments that are the subject of the NIH guidelines, the DNA can be derived from widely divergent sources. DNA from one of the sources may serve as a carrier, or "vector," for the insertion of the recombined DNA into a cell, or "host." The vector may be a plasmid, usually derived from the same species as the host, or it may be a virus. The DNA to be inserted is called the "foreign" DNA. When a large mixture of DNA fragments from the foreign source is used in the joining, the experiment is referred to as a "shotgun" experiment. In other instances, a particular DNA fragment of interest will be purified and then incorporated in the vector.

From a growth culture of the host cells, one containing the interesting DNA fragment is selected and allowed to multiply. The resulting population of identical cells is called a "clone." In some experiments the DNA will be extracted from the cells for study; in others, the properties of the cells themselves will be investigated.

In the experiments discussed in the guidelines, the host cells are generally single-cell microorganisms such as bacteria, or animal or plant cells that were originally obtained from living tissue but are grown as single cells under special laboratory conditions.

The process of producing recombinant DNA molecules and introducing them into cells is illustrated in figure 3.

Figure 3



The cell represented at the upper left contains chromosomal DNA and several separately replicating DNA molecules. The nonchromosomal DNA molecules can be isolated from the cell and manipulated to serve as vectors (carriers) for DNA from a foreign cell. Most DNA molecules used as vectors are circular. They can be cleaved, as shown, by enzymes (restriction endonucleases) to yield linear molecules with rejoinable ends.

At the upper right is another cell, represented here as a rectangle. It serves as the source of the foreign DNA to be inserted into the vector. This DNA can also be cleaved by enzymes. The rectangular cell could be

derived from any living species, and the foreign DNA might contain chromosomal or nonchromosomal DNA, or both.

In the next steps, the foreign DNA fragment is mixed and combined with the vector DNA, and the recombinant DNA is reinserted into a host cell. In most experiments this host cell will be of the same species as the source of the vector. The recipient cells are then placed under conditions where they grow and multiply by division. Each new cell will contain recombinant DNA.

Recombinant DNA technology represents a method that is applicable to many areas of biological research. Essentially, it represents a new tool. Investigations supported by many NIH Institutes and programs utilize this technique, much as a new instrument is applied in studying many different things. Areas of biological research to which recombinant DNA experiments are underway include the study of bacterial enzymes and metabolism, the synthesis of hormones, the reproduction of viruses, the organization of chromosomes, and the structure and regulation of genes. Except for studies to improve the technology, NIH sponsors no program on recombinant DNA as such; but recombinant DNA technology is used, where applicable, as an additional tool for increasing understanding of normal and abnormal biological processes.

Risks and Benefits of Recombinant DNA Research

Research, by definition, is investigation of the unknown. The results of research, whether beneficial, neutral, detrimental, or some combination of these, cannot be fully predicted ahead of time. The following discussions are assessments based on present knowledge and collective technical judgments. Unexpected benefits and unexpected hazards are possible.

Possible Hazardous Situations

The insertion of DNA derived from a different species into a cell or virus (and thus the progeny thereof) may change certain properties of the host. The changes may affect adversely or beneficially (a) the survival of the recipient species, (b) other forms of life that come in contact with the recipient, and (c) aspects of the nonliving environment. Current knowledge does not permit accurate assessment of such effects in contemplation of every recombinant DNA experiment. At present it is only possible to speculate on ways in which the presence of recombinant DNA in a cell or virus could bring about these effects.

It should be noted that there is no known instance in which a hazardous agent has been created by recombinant DNA technology. The following discussion is speculative and considers ways in which hazardous agents might be produced. In principle, the analysis is applicable to animals, including humans, and to plants, when potential effects on complex organisms are described.

The effect of foreign DNA on the survival of recipient species (host cell, plasmids, or viruses)

The effect of foreign DNA on the survival of receipent species is important to the discussion of possible hazards of recombinant DNA experiments. A recipient species may acquire a potential for harmful effects as a result of the foreign DNA, but the possibility of the occurrence of the harmful effects will depend on the survival of the recipient and its ability to multiply. If acquisition of foreign DNA increases the probability of survival and multiplication, the possibility of harmful effects will increase. Similarly, if acquisition of foreign DNA decreases the probability of survival or multiplication, the possibility of harmful effects will decrease. It is important to recognize, in evaluating the potential for harmful effects, that significant infections of animals and plants by bacteria or viruses may require contact with a critical number of the infectious agents, quantities that may be large or small depending on the agent and the recipient.

There are various indications that both host bacteria and plasmid or virus vectors containing inserted foreign DNA are less likely to survive and multiply than are the original organisms, except for the very unusual instances where the foreign DNA supplies some function, such as antibiotic resistance, that favors the organism in a particular, non-natural environment. (*1*) Natural selection results in the survival of only well-balanced and efficient organisms; unneeded genetic material tends to be lost. Essential functions are carefully controlled and are switched on and off as needed.

The activity of a particular gene product depends upon, and in turn influences, many other functions of a cell. Such uncontrolled, non-essential properties as might be introduced by foreign genes would probably not result in any advantage to the survival and multiplication of an otherwise well-balanced organism. Rather, the new properties might be expected to confer some relative disability. It is unlikely that elimination of a gene product by insertion of a foreign DNA sequence would be advantageous. More likely than not, any new properties derived from insertion of foreign DNA would confer some relative disability on the recipient organism. Therefore, it is probable that bacterial cells, plasmids, or viruses containing inserted foreign DNA would multiply more slowly in nature than the same cells or vectors without foreign DNA; and in a natural competitive environment, those organisms containing recombinant DNA would generally be expected to disappear. For bacterial hosts, the rate of disappearance would depend on the relative rate of growth compared to other, competing bacteria. The following calculation demonstrates this point.

Assume that a new organism constitutes 90 percent of a population, but grows 10 percent less rapidly than its natural counterpart. The new organism will drop from a concentration of 90 percent to a concentration of 0.0001 percent (1 part in 1,000,000) in 207 generations. If the generation time of the natural organism is 1 hour, this amounts to about 8½ days.

Although unlikely, there is a chance that a bacterial host of recombinant DNA will grow more rapidly than if it were lacking the foreign DNA, especially if the cells encounter new environments. (The calculation given above can be applied here also.) A relevant example of such a situation can be found in the rapid and widespread increase in the resistance of bacteria to clinically important antibiotics during the last 20 years. It is well known that such resistance is genetically determined, and genes specifying resistance have been described. (*2*)

The ability of recipient bacterial host cells to survive and multiply might also be enhanced by acquisition and expression of a foreign gene conferring the ability to metabolize particular nutrients. In an environmental niche containing the nutrient, such a recombinant might compete successfully against organisms native to the niche. Thus an important nutrient there might be destroyed. Also, if the native organisms were performing beneficial functions, those functions could be lost upon the successful establishment of the recombinant in the niche.

These examples serve to illustrate some of the complexities involved in determining whether the insertion of a given fragment of foreign DNA will be advantageous or disadvantageous to the recipient organism: The nature of the inserted genes, the nature of the environment, and the relation between the two must be considered. However, this analysis is necessarily simplistic. In the absence of the highly specific relationships that are, for example, apparent in the case of antibiotic resistance, very little is understood about how the totality of the genetic makeup of a given organism or species contributes to its competitive advantage even in a defined ecological niche. Modern evolutionary theory does not provide useful frameworks for analy-

sis. There are in fact current major controversies concerning the role of natural mutations in evolution, and the same questions are relevant to the issues raised by recombinant DNA research.

Because potentially useful vectors such as plasmids and viruses may be transferred from the initial recipient host cell to other cells, independent of the growth and survival of the host, it is also necessary to consider survival of the vectors. Plasmids and viruses occur widely in nature. Any particular plasmid or virus will normally multiply only within a limited number of species. Thus, for example, viruses that infect particular bacteria neither multiply nor cause disease in the cells of other bacterial species or complex organisms. In many instances, they do not even enter the cells of any organism other than the particular natural host.

Only limited information concerning the effect of foreign DNA insertions on the survival or transferability of plasmid and viral vectors is available. In the case of plasmids, the factors contributing to their maintenance or loss from cells in natural environments, even without insertion of a foreign DNA, are not clearly understood. (2) One exception is the selective advantage for maintenance provided by an antibiotic-resistance gene on the plasmid.

Also, some plasmids are known to confer on host cells the ability to manufacture substances poisonous to closely related cells, thus giving the poison-producers special advantage in a competitive situation. Insertion of a foreign DNA fragment into the DNA sequence coding for the poison has been shown to eliminate production of the poison, (3) decreasing the likelihood that the cells and their resident recombinant DNA will survive in nature.

Experiments carried out during the last few years have yielded only minimal information on the stability of plasmids containing foreign DNA in host cells, or on the stability of the foreign fragment itself. For experimental purposes, cells containing recombined plasmids are generally grown under conditions especially designed to increase the stability of the plasmid (called "selective" conditions.) For consideration of the loss of the plasmids in natural environments—the important point for matters of safety—the stability of the plasmid or recombined DNA under ordinary, or nonselective, conditions needs to be known. A review of a limited number of unpublished observations indicates that generalizations as to the rate of loss of the recombined plasmid relative to the original are impossible.

The ability of a plasmid to be transferred from the original laboratory host to another cell and thereby perpetuate itself is also important. In short, certain plasmids are incapable of being transferred except under particular and inferquent conditions. Others transfer more readily. Since the ability to be transferred depends on multiple factors, (2) it is not likely to be increased by insertions of a single foreign DNA fragment. Other than this, no generalization concerning the effect of a foreign DNA fragment on transferability can be made.

The effect of bacteria and veruses containing recombined DNA on other forms of life

The analysis leading to the guidelines centered on the possibility of deleterious effects, since the concern was the health and safety of living organisms, including humans, and the environment. Agents constructed by recombinant DNA technology could prove hazardous to other forms of life by becoming pathogenic (disease-producing) or toxigenic (toxin-producing), or by becoming more pathogenic or toxigenic than the original agent.

There are two basic mechanisms by which a recipient micro-organism might be altered with regard to its pathogenicity or toxicity as a result of a resident recombinant:

(1) *The recombinant DNA may result in formation of a protein that has undesirable effects.* The case in which bacterial cells are used as carriers of foreign DNA is discussed first. A foreign protein, specified by the foreign DNA, might act after being liberated from the micro-organism, or it could function within the micro-organism and alter, secondarily, normal microbial cell function in such a way that the cell is rendered harmful to other living things. Either means depends on the expression of the foreign genes; that is, the information in the foreign genes must be used by the recipient bacterium to produce a foreign protein. Examples of proteins that might prove harmful to other organisms are hormones, enzymes, and toxins.

Present evidence suggests that foreign DNA from bacteria of one species, when inserted into bacteria of another species, may be expressed in the recipient, depending on the similarities of the protein synthesis mechanisms in the two organisms. (4) For example, if the donor of the foreign DNA produces a toxic substance, than the recipient cell may produce such a substance, provided the gene for the toxic substance is present in the recombinant. The recipient may or may not be more hazardous than the original donor organism, depending on the relative ability of the two organisms to grow and infect an animal or plant species at risk.

Expression of foreign genes from complex organisms (yeast, fruit flies) in cloned bacteria has recently been demonstrated experimentally. (5) In other experiments, insertion of a synthetic gene into *E. coli* led to the production of somatostatin, a hormone found in the mammalian brain. (6)

Analogous issues must be considered for the case in which animal viruses are the carriers of foreign DNA. Inadvertent dispersal of such viruses outside the laboratory might result in entry of the recombinant DNA into cells of living organisms. The foreign genes might be expressed, resulting in the uncontrolled synthesis of a normal protein or the formation of a protein foreign to the infected cell. Currently, few relevent experimental data are available. (3)

(2) *The recombined DNA may itself cause pathogenic or toxic effects.* As discussed above, foreign DNA inserted in a bacterial gene might so alter the microbial cell's properties that it becomes harmful to other organisms. It is also necessary to consider situations in which DNA molecules themselves may escape from the laboratory or from the experimental host cell an enter cells of living organisms with which they come in contact. Free DNA molecules are themselves relatively fragile, and the probability that they would survive, in a significant form or for a significant time, in air, water, or any medium, is considered remote. DNA that is protected in any of a variety of ways within cells and viruses might be released either into, or close to, a living cell.

When a cell or virus dies, or comes close to or invades the tissue of another living organism, the recombinant DNA may effectively enter a new cell. A hazardous situation similar to that described above might ensue if foreign proteins were manufactured in this "secondary" recipient. The recombinant DNA might survive as an independent cellular component, or it could recombine by natural process with the DNA of the secondary recipient. Various possible deleterious consequences of such a recombination may be considered.

If the secondary recipient is another micro-organism, the considerations described earlier apply. If the secondary recipient is one of the cells of an animal or plant, the possible effects are different. They include alterations of normal cellular control mechanisms, synthesis of a foreign protein (such as a hormone), and insertion of genes involved in cancer production (if, for example, the foreign DNA were derived from a cancer-producing virus).

It should be pointed out that the likelihood of such a mechanism causing inheritable changes in the offspring of complex organisms is extremely low because of the protection afforded germ-line cells (eggs and sperm) by their location. Thus, it is highly improbable or perhaps impossible for recombined foreign DNA to reach germline cells at a time in their life when secondary recombination can occur. With one-celled organisms, plants, or simple multicellular organisms, the probability of heritable change resulting from secondary recombination is higher.

What is the probability of secondary recombination between prokaryotes and eukaryotes in nature? It is generally held that the recombination in nature is more likely if similar or identical sequences of bases (rungs in the DNA ladder) occur in the two recombining DNA's.(*7*) The greater the degree of similar sequences, the more likely is recombination. In general, the more closely two species are related, the more likely it is that similar sequences will be found in their DNA's. Thus, DNA from primates has more DNA sequences in common with human DNA than does DNA from mice, or fish, or plants. Recombination may also occur between DNA's not sharing sequences, but at lower frequencies.

It is possible that the capacity for interspecies recombination between distantly related species exists in nature. For example, bacteria in animal intestines are constantly exposed to fragments of animal DNA released from dead intestinal cells. Significant recombination, however, would require the uptake of intact segments of animal DNA and their subsequent incorporation into the bacterial DNA. Such uptake and incorporation has been demonstrated experimentally. The frequency of such events in nature is unknown.

Similarly, there are very few data permitting assessment of the reverse process; namely, the incorporation of bacterial DNA into the cells, or DNA, of more complex organisms. Although there are reports of experiments in which bacterial DNA was inserted into animal and plant species and production of the bacterial protein followed, the process is very inefficient and many investigators have been unable to repeat these experiments.(*8–10*)

There are certain well-documented instances in which the DNA's of different living things become more or less permanently recombined in nature. These instances involve recombination between the DNA's of nonchromosomal genes, such as those of viruses or plasmids, or between the DNA's of viruses or plasmids and chromosomal genes. The former instance, for example, is the mechanism behind the rapid spread of resistance to antibiotics among different bacterial species.(*2, 11*) This spread accompanied the prevalent use of antibiotics in medicine and agriculture. Another example is the insertion of DNA from the bacterium *Agrobacterium tumefaciens* into plant cells.(*13*)

Expected Benefits of Recombinant DNA Research

Benefits may be divided into two broad categories: an increased understanding of basic biological processes, and practical applications for medicine, agriculture, and industry.

At this time, most of the practical applications are speculative. It is important to stress that the most significant results of this work, as with any truly innovative endeavor, are likely to arise in unexpected ways and will almost certainly not follow a predictable path.

Increased understanding of basic biological processes

There are many important fundamental biomedical questions that can be answered or approached by DNA recombinant research. In order to advance against inheritable diseases, we need to understand the structure of genes and how they work. The DNA recombinant methodology provides a simple and inexpensive way to prepare large quantities of specific genetic information in pure form. This should permit elucidation of the organization and function of the genetic information in higher organisms. For example, current estimates of the fraction of this information that codes for proteins are simply educated guesses. There are almost no clues about the function of the portions of DNA that do not code for proteins, although these DNA sequences are suspected of being involved in the regulation of gene expression.

The existing state of ignorance is largely attributable to our previous inability to isolate discrete segments of the DNA in a form that permits detailed molecular analysis. Recombinant DNA methodology removes this barrier. Furthermore, ancillary techniques have been developed whereby pure DNA segments that contain particular sequences of interest can be identified and selected. Of particular interest is the isolation of pure DNA segments that contain the genes for the variable and constant portions of the immunoglobin proteins. The analyses of such segments obtained from both germ-line and somatic cells should be of inestimable value in determining the mechanism of immunologic diversity.

A major problem in understanding the mechanism by which certain viruses cause cancer is how and where the infecting or endogenous viral genomes are integrated into the cell's chromosome.(*12*) This bears on the question of how the integrated viral genes affect cellular regulation, thus leading to the abnormal growth characteristics of cancer cells. With the recombinant DNA techniques for isolation and purification of specific genes, this research problem is reduced to manageable proportions. It is possible to isolate the desired DNA segment in pure form. Large quantities can be obtained for detailed study by simply extracting a culture of the bacteria carrying the viral DNA segment in a plasmid.

Important recent achievements in recombinant DNA research

It was anticipated (see EIS of October 1977) that the ability to excise, isolate, and amplify specific segments of DNA from higher organisms would provide an unprecedented opportunity to study the structure of eukaryotic genomes and to correlate the results with concepts of how they evolved and are regulated. Recent work has yielded much more. Indeed, some of the genomic structures discovered through use of recombinant DNA techniques have occasioned a substantial reassessment of several major paradigms of molecular biology.

Many of the initial studies using recombinant DNA techniques focused on DNA sequences that are repeated in the genomes of eukaryotes. In some instances, these repeated sequences specify an RNA product, such as ribosomal RNA, or fulfill a function as yet unknown—for example, the sequences called "satellite" DNA. The organization of such sequences is being examined extensively with recombinant DNA techniques(*14–20*).

The genes that specify ribosomal RNA are repeated in the eukaryotic genome several hundredfold. It has been known for some years that in a variety of species, such as the frog *Xenopus laevis*, these genes are arranged as a series of tandem repeats. Each set of ribosomal genes is separated from its neighbors by regions of DNA, of varying length, that are not transcribed. Cloning of several of these nontranscribed, or "spacer," regions has allowed analysis of the manner in which they are related to one another(*21, 22*) and proposals of evolutionary mechanisms by which they may have arisen.

Moreover, the availability of these cloned DNA sequences has made it possible(*23*) to localize the DNA site at which the transcription of the ribosomal genes is initiated. The exact DNA sequence at this site is being determined. Such information will further the understanding of the mechanisms

that regulate gene expression and the construction of new host/vector cloning systems.

Many of the basic concepts of molecular biology have had to be based upon work on prokaryotes. These concepts have influenced the interpretation of data on the structure and possible mode of functioning of the eukaryotic genome. Recombinant DNA technology, however, has allowed the structure of the genomes of higher organisms to be examined in a manner previously restricted to studies on bacteria. Some of the results have upset earlier assumptions. For example, the cloning of eukaryotic DNA sequences that specify the proteins β globin,(*24, 25, 30, 34*) ovalbumin,(*26, 27, 28, 32, 33*) and immunoglobulin(*29, 31*) has demonstrated that certain basic facts of DNA organization in prokaryotes are not applicable to eukaryotes. The major new finding of "intervening" sequences in these higher forms (discussed in footnote 13 to the "Introduction and Overview" of the accompanying decision document) may provide an explanation for the cause of the hereditary disorder, β^+ thalassemia. It also demands a reconsideration of the basic mechanisms of differentiation and evolution.

The work on immunoglobulin(*29, 31*) has shown that the DNA sequences that encode two different regions of an immunoglobulin polypeptide are widely separated in germ-line cells. During differentiation, these DNA sequences move closer together but do not become contiguous. Detailed examination of DNA fragments has resolved one of the fundamental and longstanding puzzles of immunology. Very recent data indicate that the intervening sequences found in the gene for ovalbumin differ from individual to individual(*32, 33*), indicating that genetic variability may occur within a species to an extent not previously imagined.

Practical implications

The possibility that recombinant DNA techniques could be used to alter the properties of recipient organisms, or to produce desired substances, such as peptide hormones, rests largely upon two factors: (1) the fidelity of the cloning procedures and (2) the ability to obtain expression of the cloned DNA sequence. It has been demonstrated that cloning does provide faithful copies of the original sequence.(*34*) More recently, experiments in which cloned fragments of yeast DNA were introduced into *E. coli* have provided further evidence that fidelity is maintained and that expression of cloned sequences can be achieved. All the bacterial strains used contained genetic lesions that rendered them incapable of synthesizing a particular amino acid. However, the yeast DNA sequences were capable of correcting these deficiencies(*35*) and were shown to specify the synthesis of a yeast protein that substituted successfully for its defective bacterial counterpart.

There have been several accomplishments during the last year and a half that may be expected to yield both economic and medical benefits in the near future. Work has begun on the cloning of the nitrogen fixation genes of the bacterium *Klebsiella pneumoniae*.(*36*) The introduction of these genes into appropriate plant or bacterial hosts may drastically reduce the requirement for nitrogenous fertilizers. Such fertilizers, currently consumed at the rate of 40 million tons per year, are synthesized by processes involving large energy costs.

An area that has proved to be extremely productive has been the cloning of DNA sequences specifying peptide hormones. During 1977 there were succeses in the cloning of genes for the following hormones:

Insulin.(*37*)

Somatostatin,(*6*) a hormone that inhibits the secretion of glucagon, insulin, and growth hormone; potentially useful in the treatment of acromegaly, acute pancreatitis, and insulin-dependent diabetes.

Growth hormone,(*38*) used in the treatment of dwarfism; in short supply throughout the world.

Somatomammotropin,(*39*) a hormone secreted by the placenta; appears to act on maternal metabolism to insure that the fetus obtains nutrients required for normal growth.

The cloning of the somatostatin gene is particularly noteworthy, since the gene was synthesized chemically, thus avoiding any risk of inadvertant cloning of contaiminating sequences, and was then inserted into a specially constructed plasmid vector. The inserted DNA sequence was expressed and an inactive precursor of somatostatin was synthesized and isolated. From this, active somatostatin was subsequently liberated. Because the polypeptide precursor synthesized within the *E. coli* K-12 host is inactive, the procedure also decreases markedly and likelihood that the host cell itself could be hazardous. This same strategy may be used in the cloning of any of the small peptide hormones.

Long-range implications

The experimental situations treated in the guidelines are those that appear feasible either currently or in the near future. The experiments primarily involve insertion of recombined DNA into bacteria or into single cells derived from more complex organisms and maintained under special laboratory conditions. It is only in the case of plants that the guidelines cover experiments involving insertion of DNA into cells capable of developing into complex, multicellular organisms. The guidelines and the discussions leading to their development have focused on problems of safety.

It is possible that techniques similar to or derived from current recombinant DNA methodology may, in the future, be applicable to the deliberate modification of complex animals, including humans. Such modification might serve to correct an inherited defect in an individual, or to alter heritable characteristics in the offspring of individuals or a given species. The latter type of alteration has been successfully achieved in agriculture for centuries by classical breeding techniques. It may be that recombinant DNA methods, should they develop in appropriate ways, will offer new opportunities for specificity and accuracy in animal breeding. It should be noted, however, that the techniques covered by the NIH guidelines involve the recombining of DNA fragments in the test tube, and the guidelines prohibit the deliberate release into the environment of any organism containing recombinant DNA molecules.

Should the deliberate application of such methods for the correction of individuals genetic defects or the alteration of heritable characteristics in man ever become possible, it will raise complex and difficult problems. In addition to philosophical, moral, and ethical questions of concern to individuals, serious societal issues will be involved. Broad discussion of these problems in a variety of forums will then be required to inform both private and public decisionmaking.

Possible Deliberate Misuse

In the event that recombinant DNA technology can yield hazardous agents, such agents might be considered for deliberate perpetration of harm to animals (including humans), plants or the environment. The possibilities include biological warfare or sabotage. Because it is not known whether recombinant DNA technology can yield such agents, discussion of these problems, such as theft by saboteurs, is hypothetical and difficult. With regard to biological warfare, the use of recombinant DNA for such purposes is prohibited by the Biological Weapons Convention. In a statement to the Conference of the Committee of Disarmament, on August 17, 1976, Ambassador Joseph Martin, Jr., made the following remarks on the subject:

When advances in science and technology are made, it is natural to ask about their possible use for hostile purposes and whether or not such uses are prohibited or restricted by existing international agreements. In the case of potential use of recombinant DNA molecules for weapons pur

poses, it is our view that such use clearly falls within the scope of the Convention's prohibition.

This interpretation is based upon the negotiating history as well as the explicit language of the Convention, and we believe that it is shared by the other signatories. I do not believe it is possible to read the Biological Weapons Convention and come to any other conclusion. According to the Preamble, the States Parties are "determined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons." The intent of Article I, which begins, "Each State Party to this Convention undertakes never in any circumstances * * *," is equally forceful and clear. To take a more restricted view would rob the Convention of much of its value and could even lead to States to call into question its scope and continued viability. These were the views of the United States when the Convention was negotiated and ratified. They are still its views today. This is a matter of great importance to my Government and one on which doubt cannot be permitted to exist.

It is noteworthy that, prior to his statement, Dr. David Baltimore had requested an opinion from James L. Malone, General Counsel of the United States Arms Control and Disarmament Agency, on whether the Biological Weapons Convention prohibits production of recombinant DNA molecules for purposes of constructing biological weapons. On July 3, 1975, Mr. Malone replied: "In our opinion the answer is in the affirmative. The use of recombinant DNA molecules for such purposes clearly falls within the scope of the Convention's provisions."

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I. Scope of the Guidelines

Analysis of Current Guidelines [1]

For the purposes of the current Guidelines, recombinant DNA experiments are defined as those involving molecules that consist of segments of DNA from different sources which have been joined together in cell-free systems, and which have the capacity to replicate in some host cell, either autonomously or as an integrated part of the host's genome. The host cells in these experiments are generally single living cells. They may be microorganisms such as bacteria, or animal or plant cells grown in tissue culture.

General principles

The Guidelines start with a statement of general principles, which are consistent with the conclusions in the report of the International Conference on Recombinant DNA Molecules held at Asilomar, Calif. in February 1975. The first principle is that certain experiments may be judged, in the light of currently available information, to present such serious potential hazards that they should not be attempted at this time. Second, a large group of feasible experiments appear to pose less or no potential hazard, and can therefore be performed under appropriate safeguards if the information or benefits sought cannot be obtained by conventional methods. Third, the more serious the nature of any presumed consequence, the more stringent should be the safeguards against escape of the potentially hazardous agents.

Experiments to be deferred

The first class of experiments described in the Guidelines are those that are not to be carried out at the present time. While it may be argued that a combination of maximal physical and biological safeguards could essentially contain these recombinants, the magnitude of the possible dangers if containment were to fail dictates that these experiments be deferred. This class of experiments includes the following:

- Those in which any of the recombinant DNA derives from pathogenic organisms listed under classes 3, 4, and 5 of the document *Classification of Etiologic Agents on the Basis of Hazard,* published by the Center for Disease Control (CDC) of the U.S. Public Health Service, or from oncogenic (cancer-causing) viruses classified by the National Cancer Institute as "moderate risk." The CDC document categorizes naturally occurring organisms and viruses known to be pathogenic to man and agriculturally important species, on a scale of increasing hazard from 1 to 5.
- Those characterized by deliberate formation of recombinants containing the genes for potent toxins. Examples are botulinus or diphtheria toxins, and venoms from insects and snakes.
- Those involving deliberate creation from plant pathogens of recombinant DNA's that are likely to increase the virulence of the pathogenic material or the range of susceptible species.
- Those involving transfer of a drug-resistance trait to microorganisms that are not known to acquire it naturally if this could compromise the use of a drug to control disease in humans, animals, or plants.

Other restrictions concern the volume of recombinant DNA to be produced and the deliberate release of organisms into the environment:

- Experiments with recombinant DNA's known to make harmful products must be limited in scale to quantities of fluid less than 10 liters. The RAC may make exceptions for particular experiments deemed to be of direct societal benefit, if appropriate equipment is used.
- The creation of organisms with ability to carry out useful environmental functions has been contemplated. Release of such organisms into the environment may be required to test their efficacy, and certainly to make use of them. The Guidelines, however, prohibit at present the release of any organism containing a recombinant DNA molecule.

Alternatives: RAC-Proposed Revisions

It was the determination of the Recombinant Advisory Committee that advances in knowledge pertaining to recombinant activities in past years warranted significant revisions in the purpose, definition, and prohibition sections of the NIH Guidelines. A comparison of the "purpose" language of the current Guidelines with that of the proposed revised guidelines of the RAC (hereafter called "PRG-RAC") reveals that the standards in the latter set are meant to pertain to recombinant DNA molecules *in organisms.* The analogous language in the current Guidelines addresses recombinant DNA molecules whether or not they are contained within a cell or virus. The rationale for this change is that DNA by itself (commonly referred to as "naked" DNA) is extremely unlikely to be hazardous under experimental conditions, as it is rapidly inactivated in nature.

The definition in the PRG-RAC consists of two parts: (1) an operational definition of recombinant DNA and (2) a qualification that the Guidelines would pertain only to "novel" recombinant DNA's. The operational definition does not differ significantly from that in the original Guidelines.

The second part, however, calls for the creation of a list of organisms that exchange genetic information in nature, commonly referred to as "non-novel exchangers." Recombinant DNA formed with DNA from such organisms would be exempted from the provisions of the Guidelines, with the rationale that there is no justification for requiring stringent containment procedures for the handling of recombinations that occur regularly in nature and are not known to be associated with any special hazards.

The provision of an open-ended listing was recommended rather than issuance of a blanket exemption, because this would allow the RAC and NIH to consider evidence that (1) the putative gene transfers do take place naturally and (2) that their exemption from the Guidelines is justifiable.

Although the PRG-RAC deal with prohibited experiments under part III, this assessment, for purposes that become apparent below, will consider the definition, exemptions, and prohibitions together under part I.

A major proposed revision would give the Director, NIH, authority to grant exceptions to any of the six prohibitions. Such a determination must be based upon the recommendation of the RAC, and weight must be given in the decision-making "both to scientific and societal benefits and to potential risks." The rationale for this proposed change was the desire of the RAC not to bar automatically the conduct of experiments desirable for some compelling social or scientific reasons—for example, risk assessment.

Alternatives: Public Commentators

There was considerable discussion at the public hearings over the scope of

[1] As published in the Federal Register, July 7, 1976 (41 FR 27902).

the Guidelines. Some mentioned that the Guidelines were too narrow in their preocuppation with recombinant DNA, as there are other forms of genetic research capable of producing cells and organisms of unknown potential hazard. It was further suggested that the title of the Guidelines be modified to reflect their concern with experiments involving prokaryotes and cells in culture and that a companion document be released dealing with higher eukaryotes. On the other hand, it was also argued that genetic research has not received attention far beyond its due and that other matters of experimentation await their turn.

It is true that other techniques in genetic research, such as cell fusion and chromosome transfer, may result in formation of recombinant molecules. However, there are inherent in these techniques a range of natural barriers to the formation of hazardous organisms which apparently afford adequate containment, making unnecessary the issuance of Federal standards. Such techniques have been used in the laboratory for decades with no known harmful effects on either the public health or the environmnent. The entire area of laboratory safety is of primary concern to NIH and is the subject of constant review and attention.

There were several suggestions that the purpose of the Guidelines be more clearly stated and that terms be more precisely identified. Therefore, the sections "Purpose," "General Applicability," and "General Definitions" have been added to part I of the guidelines now being proposed by NIH—hereafter called "PRG-NIH."

Purpose of the guidelines

The Introduction to the 1976 Guidelines states that "the purpose of these Guidelines is to recommend safeguards for research on *recombinant DNA molecules.*" As noted above, to eliminate the handling of naked DNA from the Guidelines, the PRG-RAC proposed this passage to read that the purpose is to "establish procedures for handling *organisms and viruses containing recombinant DNA molecules.*"

This proposed revision would have had the effect of removing from coverage by the guidelines certain experiments that are now prohibited by the 1976 Guidelines—for example, deliberate formation of "naked" recombinant DNA-containing genes for the biosynthesis of potent toxins. The Director, NIH, proposes to resolve this issue conservatively. The language in the PRG-NIH, therefore, clearly states that the Guidelines are intended to pertain to the construction and handling of naked recombinant DNA molecules as well as organisms and viruses containing such molecules.

General applicability

Many commentators urged that a statement of general applicability of the Guidelines be included in an early part. The issues relate to (1) the applicability of the Guidelines to non-NIH-funded research with recombinant DNA at institutions receiving NIH funds for this purpose, (2) the applicability of the Guidelines to NIH-supported recombinant DNA research conducted in foreign countries, and (3) the location of responsibility for ensuring compliance with the Guidelines. Therefore, a section entitled "General Applicability" now appears after the "Purpose" section in Part I of the PRG-NIH.

The existence of guidelines for recombinant DNA research assumes their general application. Partial adherence within an institution would defeat the purpose of extending maximal protection to the community. Thus, it would be inconsistent for NIH to provide funds for biomedical research activities to an institution that did not meet the standards of the Guidelines in all of its recombinant DNA research, regardless of the source of funding. This principle is now stated explicitly in the Guidelines, and we intend to consider withholding NIH funds as a sanction against violation.

Rules must be established for the conduct of recombinant DNA activities funded by NIH in other countries. Generally, the requirements in force in those countries shall apply. A Memorandum of Understanding and Agreement (MUA) must still be filed with NIH, indicating specifically which guidelines will govern the activities; and NIH reserves the right to withhold funding if the safety practices to be employed are not reasonably consistent with the NIH Guidelines. An explicit statement about this has been inserted in the PRG-NIH.

Part IV of the PRG-NIH defines the responsibilities of all individuals and organizational entities involved in the conduct and review of a recombinant DNA activity. Two years of experience with administering the NIH Guidelines have demonstrated that the ultimate responsibility for ensuring compliance must be borne by the institution where the research is being done. This implies some discretion under well-defined limits for interpretation of common standards, and imposes a requirement for local expertise other than the investigator's. Accordingly, part I of the PRG-NIH now requires that an individual receiving NIH support for recombinant DNA research be associated with an institution that is willing and able to accept the responsibilities and conditions of local governance, described more explicitly in Part IV of the PRG-NIH.

Definition of recombinant DNA molecules

It became apparent from the comments received that the PRG-RAC definition was inadequate in not addressing the handling of recombinant DNA molecules containing segments of chemically synthesized DNA. It was decided that the most effective way to achieve this objective is simply to include "natural or synthetic DNA" in the definition of a recombinant DNA molecule, and this has been inserted in the PRG-NIH definition. A new section, therefore, has also been aded to part III of the PRG-NIH giving containment levels for work with recombinant DNA molecules containing synthetic DNA.

A perceived ambiguity in the PRG-RAC definition has been corrected by the inclusion of language within the PRG-NIH definition which explicitly states that DNA molecules resulting from the replication of recombinant DNA molecules are subject to the safety provisions of the Guidelines.

Finally, no other provisions of the PRG-RAC definition evoked as much comment as did the wording to exclude "non-novel" recombinant DNA from the standards. The ambiguity of such phrases as "known to exchange chromosomal DNA" and "by natural physiological processes" was strongly noted. A greater degree of clarity and objectivity is needed. Thus, it has been decided to eliminate in the PRG-NIH the two conditions cited above as criteria for exemption from the Guidelines. Staff discussions of the public comments made it clear that inclusion of exemption provisions within the definition itself was not desirable; several attempts at appropriate language did not bear careful scrutiny.

Given this situation, and also the realization that certain categories of recombinant DNA experiments are indeed so apparently free of causing harm that they should not come under the Guidelines, the criterion of "novelty" was removed from the definition and used as a basis for the development of a new section entitled "Exemptions."

Exemptions

The nature of the public comments on the PRG-RAC exclusion of non-novel exchangers can be divided into two categories—those that pertain to the proposed standards and those to the proposed process.

The standards proposed by the PRG-RAC were that novel recombinant DNA's consist of "segments of any DNA from different species not known to exchange chromosomal DNA by natural physiological processes * * *. In general, recombinant DNA molecules * * * will not be considered novel when all the components are derived

from genomes known to replicate within the organism used to propagate the recombinant DNA." This is qualified, however, by a footnote stating that "recombinant DNA formed between segments of eukaryotic viral DNA and any eukaryotic DNA * * * shall not be excluded * * * until such time as there is more information about the extent of naturally occurring recombinational events between these DNA's."

The public comments on these standards raised a number of issues. For example, some said that safety rather than novelty should be the criterion for exclusion. That is, any recombinant molecule that poses a threat to the public health or the environment should be covered by the Guidelines regardless of whether the molecule is a novel one. Others held that the proper criterion should not be safety, but rather whether the potential hazard of the recombinant DNA molecule differs significantly in degree or in kind from those found in nature or from biohazards that are successfully handled by conventional methods. It proved impossible to reconcile these differences of opinion in the deinition itself and so an "Exemptions" section was drafted by NIH staff in conjunction with an RAC working group. It should be noted that no provision in that section may be cited to exempt from the Guidelines an activity listed in the "Prohibitions" section.

The first exemption concerns recombinant DNA molecules that are not in organisms or viruses. This is in recognition that "naked" DNA, which is rapidly inactivated in nature, is extremely unlikely to be hazardous under experimental conditions. To guard, however, against the remote possibility that potentially harmful naked recombinant DNA will be incorporated into an organism, the handling of certain naked recombinant DNA molecules described in the "Prohibitions" section remains prohibited. It should also be noted that the concept of extremely low hazard of naked recombinant DNA was included in the PRG-RAC in the section on "Handling Recombinant DNA Molecules" at the end of Part III. This language is more appropriately presented under the "Exemptions" section.

The section exemption pertains to recombinant DNA molecules consisting entirely of DNA segments from a single non-chromosomal or viral source. This statement clarifies a category of "self-cloning" experiments that are considered safe enough to be excluded from the Guidelines. This is a concept which the RAC tried to convey in the PRG-RAC definition by use of the phrase "different genomes" but which some commentators found ambiguous.

The third exemption concerns "self-cloning." It exempts from the Guidelines recombinant DNA molecules made entirely from the DNA of a single organism, including the indigenous plasmids, viruses, mitochondria, or chloroplasts, when propagated only in that oranism (or a closely related strain of the same species). This partially responds to the suggestion made by many commentators that experiments previously classified as P1+EK1 be excluded from the Guidelines. It also covers some of the cases the RAC was including in the concept of "novelty" and "different genomes." This exemption, however, does not include recombinant DNA molecules formed between viral DNA and eukaryotic host DNA. In this regard it is analogous to footnote 1 of the PRG-RAC.

The fourth exemption covers "certain specified recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes." In this case a list is prepared and periodically revised by the Director, NIH, on the recommendation of the RAC, after appropriate notice and opportunity for public comment. This list is analogous to the list of "non-novel exchangers" proposed in the PRG-RAC. Appendix A to the PRG-NIH gives a proposed list for this exemption. This list is discussed in Appendix D to the present document.

The fifth exemption allows the Director, NIH, on the recommendation of the RAC and after appropriate notice and opportunity for public comment, to exempt other classes or recombinant DNA molecules if he finds that "they do not present a significant risk to health or the environment." This language for exempting classes of experiments is used in proposed legislation (H.R. 11192) recently reported out of the Committee on Interstate and Foreign Commerce and the Committee on Science and Technology of the U.S. House of Representatives.

In addition to these comments pertaining to the standards for exemption in the PRG-RAC, the following were directed toward the processes whereby exemption would be made:

- Rather than compile a list of non-novel exchangers exempt from the Guidelines, the burden of proof should be on the Director to compile a list of novel exchangers that are subject to the Guidelines.
- The procedures and criteria used in the development of the list should be thoroughly explained, and adequate opportunity should be given for public review and comment.
- Before an organism is placed on the list, all the data pertaining to the application should be available for public review.

In response to these comments, the PRG-NIH specifies that for exemptions I-E-4 and I-E-5—the two that involve the development of "lists"—the Director, NIH, on the advice of the RAC, will develop lists after appropriate notice and opportunity for public comment. The initial list proposed in Appendix A to the PRG-NIH is submitted for public comment along with the entire revision of the Guidelines. In the future, appropriate notice and opportunity for public comment will precede any additions to Appendix A or exemption I-E-5.

Prohibitions

Two changes in this section have been initiated to make it more compatible with the new "Definition" and "Exemptions" sections. The first was to transfer this section from Part III of the Guidelines to Part I, reemphasizing that the exemptions are not applicable to the six activities listed as prohibited. The second was to drop all references to novel recombinant DNA's and natural genetic exchange. Other alternatives suggested by commenters:

- There was a general endorsement for the provision in this section which grants to the Director, NIH, upon the recommendation of the RAC, the authority to waive any of the prohibitions. The widespread support for this authority reflects the realization that many important risk-assessment experiments would not be able to proceed otherwise. NIH is now supporting and will continue to support experiments that will yield knowledge contributing to a better understanding of the nature of potential risks of recombinant DNA.
- It was urged that the advice of other Government agencies, such as the Environmental Protection Agency and the Occupational Safety and Health Administration, should be sought when the Director, NIH, considers invoking this waiver authority. The Federal Interagency Committee on Recombinant DNA Research provides for coordination of policies in this area. EPA and OSHA are represented on the Committee. The advice of relevant research and regulatory agencies will continue to be sought when appropriate.

It was suggested that the RAC as presently constituted should not be the sole advisory body because societal as well as scientific considerations must enter into the waiver decision. As explained in greater detail in Part IV of this document, the membership of the RAC will be broadened modestly

as needed for expertise, but provision for public notice and opportunity to comment, and other appropriate administrative practices, can be used to insure adequate public input when the issues warrant.

● It was suggested that an Environmental Impact Assessment or Statement should accompany each waiver. Waiver decisions will include a careful consideration of the potential environmental impact, and certain decisions may be accompanied by a formal assessment or statement. This must be determined on a case-by-case basis.

● It was suggested that waiver of the prohibition on the large-scale use of cultures containing recombinant DNA's be issued on the basis of industry's experience in dealing with such cultures. While experience will surely be weighed in the decisionmaking, it whould not be the sole criterion for granting such a waiver.

● Agricultural scientists noted the importance to their research community of being allowed eventually to release organisms containing recombinant DNA into the environment. When the original Guidelines were proposed to the NIH Director in draft form in 1976, the release of organisms containing recombinant DNA molecules into the environment was to be allowed if a series of controlled tests had been done to leave no reasonable doubt of safety. This waiver provision was rejected at that time because of the limited scientific evidence available that any of the potential benefits from such a release were near realization. As now proposed, the prohibition of deliberate release into the environment of recombinant-DNA-containing organisms can be waived if all the requirements for a waiver (and those of the National Environmental Policy Act) are met. Given the limited experience of NIH in agricultural research, the U.S. Department of Agriculture would have to be deeply involved in this process, and written notice of this suggestion has been given to the appropriate officials at USDA.

● The Standing Advisory Committee on Recombinant DNA Research of the European Molecular Biology Organization (EMBO) has noted that the list of pathogenic organisms under prohibition I-D-1, especially those in Class 5, may not be appropriate for all European countries. The decision as to which pathogenic organisms should be classified as too dangerous to work with must be the responsibility of national or regional authorities. EMBO has recommended that a footnote be added to the Guidelines stating that the prohibition of etiologic agents relates to research in the United States. Such a footnote, however, is unnecessary because those Guidelines are directed to NIH grantees and contractors, almost all within this country.

● A final change in the PRG-NIH relates to prohibition I-D-1. As discussed in detail in the "Decision" accompanying the PRG-NIH, the prohibition against using in recombinant DNA experiments vesicular stomatitis virus and oncogenic viruses classified by the National Cancer Institute as "moderate risk" has been lifted.

Proposed Action: Environmental Impact Assessment

Part I of the PRG-NIH as discussed in this Assessment rests on the past 2 years of scientific developments relating to the safety of recombinant DNA research. The proposed alternatives to the current Guidelines reflect that evidence.

The suggested definition in the PRG-RAC spoke to the conclusion that recombinant DNA molecules only pose a potential hazard when placed in an organism, and that events in the laboratory which mimic those in nature pose no special hazard to workers or the environment. The committee also recommended, and there was strong public support for, a mechanism to allow exceptions to the "Prohibitions," as for the conduct of risk-assessment research.

The PRG-NIH also incorporate a number of the alternatives to the 1976 Guidelines suggested by the public commentators. All of the changes reflected in the PRG-NIH permit research to go forward which would not have a significant effect on the environment. Indeed, additions have been made to insure that the safety standards are extended under certain circumstances to meet environmental and occupation concerns.

The scope of the Guidelines continues to be limited to recombinant DNA research. Other techniques in genetic research, such as cell fusion and chromosomes transfer, may result in the formation of recombinant molecules; but inherent in these techniques is a range of natural barriers to the formation of hazardous organisms, and thus the issuance of Federal standards is unnecessary. It should also be noted that such techniques have been used in the laboratory for decades with no harmful effects on either health or the environment.

The definition in the PRG-NIH clearly states that the Guidelines are intended to pertain to the construction and handling of naked recombinant DNA molecules as well as organisms and viruses containing such molecules. This is to insure that the prohibitions on the use of naked DNA remain in effect. And the definition now explicitly includes synthetic molecules under the standards of the Guidelines, thereby increasing the margin of safety.

In response to the recommendations of public commentators, the PRG-NIH now require that all recombinant DNA research at NIH-funded institutions comply with the safety standards of the Guidelines and be under the purview of local institutional biohazard committees. Again, this will minimize the environmental impact, if any, of this research.

The list of exemptions, as previously explained, provides that certain recombinant DNA research need not be subject to the control of the NIH Guidelines on the basis of safety to the laboratory personnel, to the greater community, and to the environment. The proposed exemptions in large part are responsive to the great number of comments received. The "Prohibitions" section, in the 1976 Guidelines under Part III, has been transposed to Part I in the PRG-NIH to insure that none of the "Exemptions" apply to the "Prohibitions." Thus, once again, care has been taken to minimize the possibility of environmental impact.

Under the first exemption, experiments with recombinant DNA molecules that are not in an organism need not be subject to the Guidelines. This is based on the safety of these experiments. The second exemption permits certain "self-cloning" experiments to be done outside the jursidiction of the Guidelines. Again the basis is occupational and environmental safety. The third exemption also concerns "self-cloning" and permits certain experiments previously classified as P1+EK1 to be excluded from the Guidelines. This was strongly endorsed by several public commentators on the basis of no hazard.

The fourth exemption deals with experiments that mimic exchanges already occurring in nature. It allows certain of the experiments previously classified at P1+EK1 to be excluded from the Guidelines, again with the strong endorsement of several public commentators on the basis of no hazard. The final provision allows exemptions when it is found that experiments do not present significant risk to health or the environment. This standard was expressly recommended as the basis for exemption by several public commentators, especially from environmental groups, and is directly responsive to the concerns that there be an explicit reference to health or the environment for the basis of exemption. Further, in the exercise of this and the previous exemption, several procedural requirements have been introduced that will afford significant opportunity for public comment to insure appropriate attention

to occupational and environmental concerns.

A waiver provision in the section on "Prohibitions" will permit NIH support and conduct of risk-assessment experiments of crucial importance to the determination of the safety of this work. Recommendations from the scientific community, the public, and relevant Federal agencies will be sought for their advice on specific projects. Waiver decisions will include a careful consideration of potential environmental impact.

In summary, a number of safety standards and procedural requirements have been included in the PRG-NIH to insure minimal environmental impact. All experiments exempted from the Guidelines are of minimal speculative risk and present no significant hazard to health or the environment.

II. Containment

Analysis of Current Guidelines

Two approaches to the problem of containing potentially hazardous organisms form the basis of the safeguards recommended by the guidelines. Each may be viewed as setting up barriers between the laboratory worker and the organisms and between the laboratory and the greater environment. The first of these approaches involves the limitation of the actual physical escape of organisms and is referred to as "physical containment." The second approach is the use of biological barriers, to be described later as "biological containment."

(The October 1977 EIS on the current guidelines, in response to comments received on the draft EIS, documents in considerable detail the adequacy of the containment requirements and shows the bases on which judgments in this regard have been made.)

Physical containment

A major aspect of physical containment is the set of standard microbiological practices that have been developed over many years and are widely used for handling pathogenic organisms. In the hands of well-trained personnel, these procedures have proved to be effective both in laboratory and clinical settings. A second major aspect of physical containment involves the use of special kinds of equipment and facilities (1) for limiting the spread of aerosols, (2) for decontamination and containing laboratory air and wastes, and (3) for restricting access to laboratories. As with standard microbiological techniques, the type of equipment and facilities are not new but have been developed and used previously for containment of known pathogens.

The guidelines go into some detail concerning the practices and facilities required for physical containment. Four levels are specified: P1, P2, P3, and P4, in the order of increasing safeguards. P1 consists in the use of the standard microbiological practices mentioned above. P2 and the next higher level, P3, require special procedures and facilities designed to limit to increasing extents any possible accidental escape of potentially hazardous organisms. Finally, P4, the maximum level of containment, requires sophisticated and isolated facilities designed for maximum containment.

Each of the levels from P2 through P4 assumes that the standard microbiological practices demanded by P1 will also be followed. Furthermore, for each level, relevant training of personnel is mandatory. The training is to include the nature of the potential hazards, the technical manipulations, and instruction in the biology of the relevant organisms and systems. Specific emergency plans, to be used in case of accident, are required; and serological monitoring is to be provided where appropriate.

Biological containment

Biological containment is defined as the use of host cells and vectors with limited ability to survive outside of very special and fastidious laboratory conditions that are unlikely to be encountered by escaped organisms in natural environments. This is an integral part of the experimental design, since the host and vector will need to be chosen, in any given experiment, with a view to the purpose of the experiment as well as to containment.

The guidelines stress that physical and biological containment procedures are complementary, each serving to control any possible failure in the order. The use of both in a given experiment affords much higher levels of containment than either alone. Therefore, the guidelines always recommend both a particular level of physical containment and a level of biological containment for any given experiment. The guidelines explicitly recognize that better physical containment capabilities are likely to evolve as research proceeds and may reduce the needs for the standard physical containment procedures. Such innovations are to be considered as part of the on-going review of the guidelines for appropriate revision.

The Use of Bacterial Hosts and Vectors. In recognition of the relation between the host-vector system required by the experiment and the design of suitable biological containment, experments using the same host-vector system are grouped together. At present, the system of choice for many experiments is the common laboratory bacterium *E. coli*, strain K-12, and independent genetic elements (plasmids and bacteriophage) known to reside or replicate in this strain.

There are several factors contributing to this (discussed more fully in part III). Strain K-12 has been studied extensively and can be readily manipulated for recombinant DNA experiments. This extensive experience and ease of manipulation permit modification of *E. coli* K-12 and vectors used with it by classical genetic techniques for the purpose of establishing biological containment.

The guidelines discuss arguments against as well as for the use of *E. coli* K-12. The main argument against it is the intimate association of various other strains of *E. coli* with humans. By reason of the prevalence of *E. coli* strains (but not K-12) in mammals, the guidelines recommend the cautious use of *E. coli* K-12 host-vector systems and urge that efforts be made to develop alternate hosts and vectors.

E. coli K-12 appears to be harmless: It does not usually establish itself in the normal bowel or multiply significantly in the alimentary tract. These facts suggest that accidental ingestion of a small number of bacteria by a laboratory worker would not result in their extensive spread outside the laboratory. This property of the organism may be altered, however, when the infected person is taking antibiotics or has certain abnormal digestive conditions, and it is recommended that such persons not work for the duration of the abnormal circumstances.

While *E. coli* K-12 does not establish itself as a growing strain in the normal bowel, it does remain alive during its passage through the intestinal tract. Therefore, transfer of plasmid or bacteriophage vectors containing foreign DNA from the original *E. coli* K-12 host to bacteria resident in the intestines or encountered after excretion must be considered. The guidelines take into account the transferability of certain vectors in recombinant research. In brief, host-vector systems derived from *E. coli* K-12 and certain plasmids or bacteriophage appear to have extremely limited ability to spread recombinant DNA molecules.

Considering, then, the properties of *E. coli* K-12 and the known plasmid and bacteriophage vectors, the guidelines conclude that recombinant DNA's manipulated through such host-vector systems are unlikely to be spread by the ingestion or dissemination of the few hundred or thousand bacteria that might be involved in a laboratory accident, given standard microbiological practice. Therefore, these existing systems, and analogous combinations of *E. coli* K-12 with other vectors and bacteriophage, are judged to offer a moderate level of bio-

logical containment and are defined as EK1.

As with physical containment levels, increasing numbers specify increasing levels of biological containment for *E. coli* systems. For the next level, called EK2, host-vector combinations must be demonstrated to provide a high level of biological containment by suitable laboratory tests. Such combinations are obtained by genetic modification of either *E. coli* K-12 host cells or the relevant plasmids and bacteriophage or both. Various examples of the types of necessary modifications are suggested in the guidelines.

One additional level of contained *E. coli* host-vector systems, defined in the guidelines, is called EK3. EK3 systems are EK2 systems for which the specified containment properties have been demonstrated, not only by microbiological and genetic analysis but by appropriate tests in animals, including humans or primates and other relevant environments.

EK2 and EK3 host-vector systems must be certified as such by the Director, NIH, after evaluation and recommendation by the Recombinant Advisory Committee.

Alternatives: RAC-Proposed Revisions

Physical containment

Two major changes were proposed in the physical containment section of the PRG-RAC. One deals with the organization of the section; the other incorporates into the PRG-RAC the philosophy and guidance of the report of the NIH/European Molecular Biology Organization (EMBO) workshop on parameters of physical containment.

Physical containment requirements for each P-level have been organized under the topic headings "Laboratory Practices," "Containment Equipment," and "Special Laboratory Design." This was done to emphasize the importance of laboratory practices and containment equipment in achieving the desired safety objective.

Other proposed revisions contained in the physical containment section reflect a conscious effort to encourage international uniformity with respect to recombinant DNA guidelines. This has been achieved by revising the containment descriptions so that they are consistent with the guidance provided in the NIH/EMBO report. In addition, some statements have been rewritten and others added in order to clarify the basic requirements for each level of containment. The most significant clarifications have been made in the areas on containment equipment and special facility design. The revisions, however, have not resulted in changing the purpose or intent of the physical containment descriptions in the 1976 guidelines.

One specific addition to the PRG-RAC that has originated from the NIH/EMBO report is the inclusion of design criteria for an area of the laboratory in which personnel wear positive-pressure suits ventilated by life-support systems. This added approach provides a level of physical containment equivalent to that afforded by glove-box cabinets at the P4 level.

Other important recommended changes include—

- Certain good microbiological practices are mandatory at the P1 level in the PRG-RAC (the 1976 guidelines encourage but do not require such practices);
- At the P2 level, prohibitions against eating, drinking, smoking, and storage of foods have been extended from the work area to the entire laboratory;
- The universal biohazard sign is now required at the P2 level, and its use has been extended to equipment such as freezers and refrigerators in which organisms containing recombinant DNA molecules are stored;
- Access procedures have been specified for controlled areas adjacent to P3 laboratories;
- Installation of foot-, elbow-, or automatically-operated facilities for washing hands is now required for all laboratories in which P3-level work is done;
- Specific guidance on containment equipment appropriate for laboratory animals has been added to the P3 and P4 sections; and
- The labeling requirements for shipment of etiologic agents now apply to all organisms containing recombinant DNA molecules. Thus, the Center for Disease Control, U.S. Public Health Service, must be notified in the event of any accidental breakage during shipment. Also, agents requiring P4 containment must be packaged according to strict Federal standards and shipped by registered mail or an equivalent system that provides for sending notifications to the shipper upon delivery.

The PRG-NIH adopt these suggestions in large part. Thus, they strengthen the safety standards and procedures for physical containment and move toward international agreement.

Biological containment

The PRG-RAC describe the categories of hosts and vectors to be used in minimizing the spread of organisms containing recombinant DNA. The PRG-RAC differ from the 1976 guidelines in that they were expanded to include (1) further definitions of host-vector systems, (2) a more restrictive set of requirements for HV3 systems (see below), and (3) a new section describing mechanisms for certification.

Definitions of Host-Vector Systems. A new nomenclature—HV1, HV2, and HV3—was developed to incorporate a variety of hosts and vectors into the framework initially established for *E. coli* K-12. In particular, the PRG-RAC provide criteria for HV1 systems other than *E. coli* K-12. In the 1976 Guidelines, cloning systems other *E. coli* K-12 were to be considered only if superior to K-12 in containment properties; but it is now recognized that many useful experiments can only be conducted using host-vector systems other than those based on *E. coli* K-12, and that such experiments should be permitted so long as the proposed system provides equivalent biological containment. The new HV1 criteria provide a structure for approval of systems that meet these requirements.[2]

Requirements for HV3 Systems. These have been made more stringent than the corresponding requirements for EK3 in the 1976 guidelines. The PRG-RAC require that the vector be dependent on its propagation host or be highly defective in mobilizability. Also, it may carry no markers conferring resistance to antibiotics used clinically or in agriculture. This provision should preclude any inadvertent advantage for recombinant-DNA-bearing vectors that encounter antibiotics in the environment.

Certification of Host-Vector Systems. A new section has been added detailing the responsibility for certification of HV1, HV2, and HV3 systems, the types of data to be submitted, and the mechanisms for distributing strains once certified. The section delineates procedures used by the RAC for the past 2 years and therefore represents no change from practices under the 1976 guidelines.

These recommendations, reflected in the proposed revisions, set improved procedures and standards to meet environmental and occupational concerns.

Physical and biological interaction

Another specific addition to the guidelines that has originated from the NIH/EMBO report is particularly notable—the addition of tables I and II to the P3 and P4 sections, respectively. These tables show combinations of physical and biological safeguards that provide similar protection. This approach allows flexibility in selecting comtainment equipment for a particular study without compromising safety.

Alternatives: Public Commentators

Commentators have expressed particular concern over (1) the flexibility

[2]Under the proposed revisions, new HV1's need not offer a distinct advantage over *E. coli* K-12 host-vectors, need not be capable of modification to HV2 and HV3, and need not be class 1 etiologic agents.

that allows various combinations of containment safeguards, (2) the adequacy of risk-assessment studies in relation to physical containment, (3) the adequacy of training in laboratory safety practices, (4) plans for dealing with emergencies, and (5) various aspects of the biological safety concepts. NIH has considered a number of recommendations by EMBO. Public commentators have made additional suggestions relating to actions at specific levels of physical containment and to shipment of recombinant DNA materials.

Concept of "flexibility"

Some commentators have expressed concern over the flexibility provided in tables I and II which allows various combinations of containment safeguards. Some feel, for example, that work in a P3 facility conveys a desirable sense of hazard, whereas a reduction to the P2 level will promote an undesirable relaxation of vigilance. It has also been suggested that an increase in the options augments the difficulty of control and implementation. Some commentators object to specific options provided at the P3 and P4 levels.

NIH has been urged to include a better explanation of the rationale for flexibility. Indeed, the calculus of switching physical and biological containment levels has been questioned. Is reducing a physical containment level from P3 to P2 truly compensated by increasing biological containment from EK1 to EK2?

The scale of either form of containment from least to greatest is not necessarily linear, and substitutions are only roughly approximate. Nevertheless, there are some numerical bases for comparison. At the P4 level, for example, a Class III biological safety cabinet is required (if a positive-pressure suit is not used); whereas one can work in an open-front biological safety cabinet at the P3 level. Studies using molecular counts of gases have shown that there is a 4–5 log protection in going from a Class I or II biological safety cabinet to a Class III cabinet—that is, from P3 to P4. Similarly, in going from P1 to P3 there may be a 4–5 log increase in safety.

The measure of safety provided by open-front biological safety cabinets, used in work at the P2 and P3 levels, consists in design and performance criteria that permit fewer than 20 microorganisms to escape through the open front when 1×10^8 to 8×10^8 (100,000,000 to 800,000,000) microorganisms are experimentally released within the cabinet. (See pp. 92-93 of the 1977 EIS for a more detailed discussion of safeguards associated with use of biological safety cabinets.)

HV2 is defined in terms of a probability of escape of recombinant DNA of less than 10^{-8} (1 in 100,000,000). In considering "equivalency" between P and EK levels, it is recognized that the two systems are conceptually different. Biological safety cabinets are designed primarily for the protection of the laboratory worker, and all physical containment protection stops at the walls of the laboratory. Biological containment continues to operate even if an organism should escape from the laboratory.

The flexibility allowed in alternate P and HV levels are carefully explained in the text of the PRG-NIH, and the investigator must follow the explicit requirements set forth in Part III of the PRG-NIH and in Tables I and II.

Risk assessment

Many commentators have urged more studies in risk assessment. It has been maintained that assumptions about biological containment may not be valid and that all components should be tested. Concern has been expressed that the biological containment safety systems may fail altogether.

Some risk-assessment studies are prohibited by the 1976 Guidelines. Under the PRG-RAC, however, the Director, NIH, on recommendation of the RAC, would have discretion to permit such risk-assessment experiments by granting a waiver from a specific prohibition. There was virtually unamimous support for this discretion at the public hearing in December 1977. Of course, its exercise must be consistent with standards of due process for the scientific community and the public.

Risk-assessment studies are proceeding both within and outside the United States. NIH is committed to the conduct and support of such studies to determine the extent to which certain potentially harmful effects from recombinant DNA molecules may occur. It is intended that the NIH P4 facilities at the Frederick Cancer Research Center will serve as a focal point for such experiments. Provisions have already been made to share these facilities with non-Federal scientists.

Training

A number of commentators urge that specific curricula be developed for training of researchers and that the Guidelines stipulate requirements for certification in safety practices. NIH has a contract with the American Society for Microbiology to develop minimum standards for training participants in recombinant DNA research. The work panel's report is to be used by the IBCs and investigators to set appropriate standards.

Emergency plans

In response to the concerns of commentators, the elements of emergency plans to handle possible safety problems are described more clearly in "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research." Further, NIH staff have recently met with representatives of CDC to establish a mechanism for providing advice, consultation, or assistance if necessary in case of an emergency, such as a laboratory accident involving recombinant DNA.

Biological containment considerations

Considerations of biological containment related mainly to the development of alternative host-vector systems. Many commentators from the scientific community believe that the PRG-RAC discriminate against host-vector systems alternate to *E. coli* K-12. They urge development of other systems, maintaining that they will be needed increasingly both in pure research and in industry and should be certified as soon as possible. It is unlikely, according to one commentator, that agriculture will best be served through the use of *E. coli* K-12 (or *B. subtilis*) and that alternate host-vector systems are essential if the potential of recombinant DNA technology for agriculture is to be realized. In view of the support evident at the 1976 public meeting for NIH to encourage development of alternate host-vector systems, one commentator expressed disappointment that there was not a large NIH contract program in this area.

Others view the introduction of alternate HV systems with some misgivings. It was pointed out, for example, that if uncertainty continues to surround research with so well-studied an organism as *E. coli* K-12, our ignorance must be that much greater with regard to any other organism—its ecological involvement, the organisms with which it can exchange DNA, etc. Moreover, the Guidelines, which have been developed around the use of *E. coli* K-12, are primarily focused on dangers to man, and the introduction of new systems may affect other life forms with which we should be equally concerned. In the view of commentators who urge restraint, the larger the number of systems certified, the greater the problem of monitoring the work.

Clearly, however, research address to the development of other host-vector systems must proceed. This is particularly evident in the agricultural sector, where the potential for immediate benefits to man is great. At present, a number of alternate systems are being developed by NIH grantees. In the use of such systems, the same con-

siderations of safety and risk associated with the use of *E. coli* K-12 will, of course, apply.

Mouth pipetting at the P1 level

Both the 1976 guidelines and the PRG-RAC prohibit mouth pipetting at the P2, P3, and P4 levels. For the P1 level, however, they state, "Although pipetting by mouth is permitted, it is preferable that mechanical pipetting devices be used." A number of commentators have urged that mouth pipetting be prohibited at the P1 level of physical containment. The decision accompanying the PRG-NIH discusses in detail the arguments of various groups on both sides of the issue. In resolving this, the Director, NIH, has decided to adopt the conservative position and ban mouth pipetting. Accordingly, language has been inserted in the PRG-NIH saying that at the P1 level "mechanical pipetting devices shall be used; pipetting by mouth is prohibited." Since mouth pipetting had already been banned at the P2-P4 levels, this means that mouth pipetting would now be banned for all experiments covered by these guidelines.

Proposed Action: Environmental Impact Assessment

Physical containment

The PRG-NIH include the following specific changes at each P level, aimed at clarifying and strengthening physical containment requirements and thereby reducing the probability of recombinant DNA molecules being accidentally released into the environment.

P1 Level. The 1976 guidelines establish as a principle of containment the adherence to good microbiological practices. At the P1 level, however, certain practices are not required but merely encouraged. The PRG-NIH now make adherence to certain of these practices mandatory at all four physical containment levels.

A major change in the PRG-NIH is the banning of mouth pipetting at the P1 level, meaning that mouth pipetting is now banned for all experiments covered by the guidelines. Since the only plausible way *E. coli* K-12 could gain entry into laboratory workers is by oral ingestion, this ban greatly reduces the possibility that any organisms containing recombinant DNA will escape and thus minimizes the risk of environmental impact.

P2 Level. The PRG-NIH have extended the prohibitions against eating, drinking, smoking, and storage of foods from just the work area to the entire P2 laboratory. This change was made to achieve consistency with recommended practices in laboratories where research with low-risk human pathogens is conducted.

The PRG-NIH call for posting of the universal biohazard sign on storage freezers and refrigerators. This additional requirement was specified to facilitate safe storage of organisms containing recombinant DNA molecules when research with them is not in progress.

P3 Level. In the PRG-NIH, a controlled access area is defined as one that separates the P3 laboratory from areas open to unrestricted traffic flow. Access procedures for this area are specified, clarifying the juxtaposition of the P3 laboratory and uncontrolled areas.

The PRG-NIH require the installation of foot, elbow, or automatically operated facilities for washing hands in laboratories in which P3-level work is conducted. This additional requirement was made to eliminate the possibility of contaminating faucets through contact. The requirement is consistent with practices common to infectious disease laboratories.

The PRG-NIH would permit recirculation of untreated air within individual rooms of the P3 laboratory. Such recirculation can conserve energy without compromising safety. Reference to recirculation of treated air to other areas of the building has been eliminated, because this approach to energy conservation is generally not practical.

Some commentators pointed out that the PRG-RAC did not require an autoclave in the P3 laboratory itself but only within the building. It has been suggested that the autoclave should be as close as possible to the controlled area of the P3 laboratory. The language of the 1976 guidelines, stating a preference for the autoclave to be within the controlled laboratory area, is therefore retained in the PRG-NIH. A requirement, however, that the autoclave be within the controlled area would increase costs, and in the view of NIH would not add measurably to safety.

P4 Level. In the PRG-NIH the minimal age for entry into a P4 laboratory has been raised to 18 years, the commonly accepted legal age.

The PRG-NIH specify containment equipment appropriate for the isolation of experimental animals. This was added because the lack of guidance in the current guidelines has led to confusion in their application to animal experimentation.

The PGR-NIH provide flexibility in selecting combinations of physical and biological containment to be used for a given experiment. All possible combinations available for selection achieve P4-level safety objectives. This approach was patterned after the guidance provided in the NIH/EMBO report.

The PRG-NIH specify design criteria for a suit area where personnel wear positive-pressure suits that are ventilated by life-support systems. This provides an option to the class III cabinet-system requirement at the P4 level of physical containment. This option has been used successfuly in research with extremely hazardous human pathogens. Without compromising safety, it provides an opportunity to conduct research procedures that cannot be confined to conventional class III cabinet systems.

Shipment. In the PRG-NIH, the labeling requirements for the shipment of etiologic agents apply to all organisms containing recombinant DNA molecules, rather than to just those containing molecules derived from an etiologic agent listed in 42 CFR 77.25. This change was made in order to insure that the Center for Disease Control, U.S. Public Health Service, would be notified in the event of accidental breakage during shipment. The PRG-NIH also specify that agents requiring P4 physical containment must be shipped by registered mail or an equivalent system that provides for sending notifications to the shipper immediately upon delivery. This change would impose on the shipment of organisms requiring P4 containment the same standards used for shipment of high-risk human pathogens.

Biological containment

A number of alternate systems for biological containment are being developed by NIH grantees, including ones using *Bacillus subtilis* and *Saccharomyces cerevisiae.* To assure adequate safety control, a new section of certification of host-vector systems has been added to the guidelines. HV1 systems other than *E. coli* K-12 are reviewed by an expert working group, then by the RAC, which makes appropriate recommendatons to the Director, NIH. Descriptions of the organism, its biology, and the characteristics of the particular strains to be used are considered. The same standards of safety and risk associated with the use of *E. coli* K-12 will apply to any new host-vector systems to be certified in the future.

HV2 Level. For the HV2 level of containment, the RAC, on June 23, 1977, unanimously approved a document entitled "Instructions to Investigators Concerning Data To Be Submitted on Host-Plasmid Systems Proposed for EK2 Certification." Although not officially part of the PRG-RAC, this document sets forth criteria that any putative EK2 host-vector systems must meet before recommendation by the RAC for certification (see appendix H of the October 1977 EIS). The committee applied these criteria in reviewing new systems (pBR322 and pBR313 in

x1776) at the June 23 meeting, and will do so for all future submissions. These criteria are clearly more stringent than previous ones, and this means that EK2 host-vector systems approved now and in the future will be even safer than those approved previously.

HV3 Level. Requirements for HV3 systems have been made more stringent that those in the 1976 guidelines. The additional requirements mean that only some HV2 systems are eligible for consideration as HV3 systems. This should significantly increase the containment of HV3 systems and therefore increase the safety of experimentation. In addition, attempts to develop HV3 systems that meet these criteria should simultaneously upgrade the HV2 systems in use, since it is to the experimenter's advantage to use the HV2 systems that have the greatest likelihood of meetihg HV3 criteria.

Certification of HV Systems. A new section has been added to clarify responsibility for certification of all host-vector systems, the types of data to be submitted, and the mechanisms for distributing strains once certified. The section delineates procedures used by the RAC for the past year and thus represents no change from practices under the 1976 guidelines.

Under the PRG-NIH, HV1 systems other than *E. coli* K-12 and HV2 and HV3 systems are considered by an expert working group and then by the RAC, which makes appropriate recommendations to the Director, NIH. Modifications of HV2 and HV3 systems must be independently certified by NIH. Data to be submitted are detailed. All HV2 and HV3 systems are to be obtained from NIH or its designee, and recipients are to report to NIH any discrepancies from the expected properties. If the strains are propagated by NIH, a sample will be tested for relevant properties prior to distribution. The requirements assure adequate controls in the certification and distribution of host-vector systems and provide sufficient protection against potential hazards to the environment.

Containment Properties of Hosts and Vectors. In regard to containment properties of individual organisms used in recombinant DNA research, recent experimental evidence supports the view that biological containment works well. This is particularly borne out by results from experiments specifically designed to test the survivability and colonizing ability of *E. coli* K-12 and EK2 host-vector systems and the transmissibility of plasmids and phage vectors.

At the time of the release of the current guidelines in 1976, EK2 systems were defined but none existed. An extramural contract program was initiated to develop safer host-vector systems and to verify their genotypic constitution and phenotypic traits. The program is administered by the National Institute of Allergy and Infectious Diseases. The ability of these systems to survive in laboratory and natural environments was determined. As a result of this contract program and of work by other investigators, a series of EK2 host-vector systems was developed. The RAC subjected these to great scrutiny and finally recommended them for certification. A list of certified EK2 host-vector systems appears in appendix H of the October 1977 EIS.

III. Containment Guidelines for Covered Experiments

Analysis of Current Guidelines

E. Coli *K-12 Host-Vector Systems*

The several levels of physical and biological containment are defined in part II, and specific recommendations are given for experiments using the *E. coli* K-12 host-vector systems. Each type of experiment is assigned both a physical containment level (that is, a P level) and a biological containment level (an EK level). The particular combination of the two reflects the severity of the estimated potential hazard.[3]

The guidelines are organized, for the *E. Coli* systems, according to the source and nature of the foreign DNA. A sample of DNA containing essentially all the genetic information of an organism can be isolated and fragmented. If the experiment involves such a mixture of DNA fragments, it is referred to as a "shotgun" and will call for a certain level of containment. Experiments involving such mixtures of DNA fragments are assumed to be of higher potential hazard than those done with a single, purified fragment, because of the greater likelihood of dangerous and unknown genes being introduced into a recipient cell. Purified fragments containing mainly genes whose properties are known and are not harmful offer less potential hazard than a shotgun experiment.

In some instances, the foreign DNA will be derived from extra chromosomal genetic elements. Such elements include the DNA of animal viruses, plant viruses, other eukaryote organelles such as mitochondria and chloroplasts, as well as prokaryote plasmids or bacteriophages of the same type used as vectors. Each of these cases is treated separately in the guidelines. The prokaryote sources are treated differently, depending on whether the "foreign" DNA is from an organism that does or does not exchange genetic information with *E. Coli* in nature.

The physical and biological containment is listed for various possible DNA sources: both must be used, as they complement each other. For example, DNA from primates requires the most stringent containment, since the estimated potential hazard, either from genes that might function in humans with untoward effects or from pathogenic viral DNA's residing in primate tissue, is judged to be most serious. The experiments now require either P3 + EK3 or P4 + EK2; and it should be noted that only the latter combination is feasible at present, and then only at the limited number of P4 facilities.

In two instances—primates and cold-blooded vertebrates—containment requirements are lower if the DNA is isolated from embryonic tissue, or germ-line material, since such material is less likely to be contaminated by pathogenic viruses than is adult tissue. Thus, if the foreign DNA is from cold-blooded vertebrates, P2 and EK2 are required, but P2 and EK1 can be used if the DNA is from embroyonic or germ-line tissues. If the cold-blooded vertebrate is known to produce a potent toxin, P3 and EK2 must be used. In some instances—lower eukaryotes, for example—the guidelines require more or less stringent conditions, depending on whether or not the source of foreign DNA is known to be pathogenic or toxigenic, or might be infected with a pathogen, or is known to make a harmful product.

The guidelines for shotgun experiments, when the source of the DNA is a prokaryotic organism, may be summarized. First those prokaryotes that are known to exchange genetic information with *E. Coli* in nature are considered. The containment requirements are low for this group, since it is unlikely that the experiments will create new genetic combinations. Requirements vary with the pathogenicity of the source of foreign DNA. When the source is a prokaryote that does not naturally exchange genetic material with *E. Coli*, the containment recommendations are high, for there is a greater potential for new genetic combinations to be formed and expressed. Further, it is assumed that the more similar the DNA's of donor and host, the greater the probability of expression of foreign DNA or of derepression of host genes.

Characterized clones obtained from shotgun experiments may not be as potentially hazardous as the original mixture of cells. Cloning of the recipient host cell containing the DNA fragment of interest will be one of the normal aims of any recombinant DNA experiment. The guidelines state that

[3] In the PRG-NIH the EK systems are included in the broader HV (host-vector) categories created to accommodate potential systems ranging beyond *E. Coli* K-12.

experiments involving a clone derived from a shotgun experiment can be done under P1 + EK1 conditions if the clone has been rigorously characterized and is free of harmful genes and if the foreign DNA was from a species that exchanges genes with *E. Coli* in nature. If the foreign DNA was from a species that does not do so, then P2 + EK1 is required.

Similarly, when the initial recombination involves a purified segment of the foreign chromosomal DNA, rather than a mixture, the potential for growth of a hazardous organism will be less, since the number of clones that must be examined to obtain the desired clone is markedly reduced. If certain criteria for purity are met, the investigator may lower the containment conditions from those recommended for shotgun experiments with DNA of the same source by one step either in physical containment or biological containment. Thus, for example, shotgun experiments with DNA from birds require P3 + EK2. A DNA fragment from birds that is free from harmful genes, and 99-percent purer before being joined to a vector, would require either P2 + EK2 or P3 + EK1.

The final group of *E. Coli* experiments considered are those in which the foreign DNA is itself from an extrachromosomal element. It is assumed that such DNA is purified away from chromosomal DNA before recombination. For example, DNA from all or part of the genome of an animal virus requires P4 physical containment and an EK2 host-vector system, or P3 + EK3. If the recombinants have been purified by cloning and shown to be free of harmful regions of the viral genome, then experiments can be at P3 + EK2.

When complementary DNA's, synthesized *in vitro* from RNA preparations, are used in recombinant DNA experiments, the containment requirements are as described for isolated DNA preparations.

Animal host-vector systems

Many recombinant DNA experiments will involve the use of systems in which the host cells are eukaryotes grown as single cells in tissue culture. Useful vectors may include extrachromosomal DNA elements, such as the DNA of organelles or viruses. The cells themselves are fragile and fastidious, and there is little or not chance that a living cell could escape from a laboratory in the way than an *E. coli* cell might. Therefore, containment considerations focus on the vectors.

Animal viruses can escape the laboratory in a viable form, especially if laboratory workers become infected. There are now two animal viruses whose DNA's are useful as vectors: polyoma and simian virus 40 (SV40). Both viruses are oncogenic—that is, they cause tumors in small newborn laboratory mammals. Polyoma virus, however, does not infect human cells grown in the laboratory or, judged by the lack of antibody formation, infect whole human beings. SV40 does colonize humans. Indeed, the virus contaminated the early Salk polio vaccine, and millions of people were inadvertently inoculated with in in the 1950's. To date, there is no indication that the recipients suffered any related disease. But under the Guidelines, more stringent physical containment is required for SV40 than for polyoma.

The Guidelines require that the viral DNA used for recombination with a foreign DNA must itself be defective—that is, its propagation as a virus must be dependent on the presence of helper virus that supplies the genes for the missing functions. This helper can be nondefective under certain conditions. In some experiments, no production of viral particles is required and no helper may be needed. Biological containment is inherently greater in the absence of virus particles, since cells themselves are relatively easy to contain. In experiments using a virus as vector, the particular levels of physical containment depend on the source of the foreign DNA, on whether polyoma or SV40 is the chosen vector, and whether virus particles are produced.

Plant host-vector systems

The Guidelines also cover experiments in which plant cells will serve as hosts for recombinant DNA. The cells might be single plant cells grown under laboratory conditions, or seedlings, plant parts, or small whole plants. This is the only instance where the Guidelines address the question of recombinant DNA experiments with whole organisms. Directions are given for modification of the specifications for P1, P2, and P3 containment in order to provide conditions appropriate for work with plants.

Vectors for use in experiments with plants include plant organelle DNA such as that of chloroplasts, and DNA of viruses of low pathogenicity and restricted host range. These vectors offer moderate levels of biological containment. The requirements are organized according to the source of the foreign DNA and to whether it is a species in which the vector DNA is known to replicate. P2 conditions are required if the source is not dangerous and is one in which replication of the vector occurs. If the foreign DNA is derived from a species in which the vector is not known to replicate, then requirements range up to P4 depending on whether the DNA is purified and whether it contains harmful genes.

Other host-vector systems

Theoretically, there are a variety of organisms, both prokaryotes and lower eukaryotes such as fungi and yeast, which will be useful hosts for experiments with recombinant DNA's. Some may offer the special advantage of not infecting humans, animals, or other important ecological niches. The growth characteristics of such hosts indicate that containment problems will be like those for *E. coli* K-12. The Guidelines urge development of these systems and point out that the detailed recommendations made for *E. coli* K-12 systems can serve as a guide in determining physical and biological containment requirements when necessary.

Alternatives: RAC-Proposed Revisions

A major concern for all individuals who have participated in establishing guidelines for recombinant DNA research is that any guidelines that are drafted and adopted be reassessed periodically and changed when warranted by new information. In keeping with this responsibility, the RAC has compiled additional information pertaining to risk assessment in recombinant DNA-research. The information is from the following sources:

- Consultations with scientists expert in the areas of evolution, plant biology, bacteriology, virology, and human and animal infectious diseases;
- Reports from scientific meetings dealing with the potential biohazards of recombinant DNA research (for example, Tenth Miles International Symposium on Recombinant Molecules—Impact on Science and Society, Cambridge, Mass., June 1976; National Academy of Sciences Forum on Recombinant DNA Research, Washington, D.C., March 1977; Genetic Engineering for Nitrogen fixation, Brookhaven, N.Y., March 1977; and the Workshop on Studies for Assessment of Potential Risks Associated with Recombinant DNA Experimentation, Falmouth, Mass., June 1977);
- Results from experiments specifically designed to test (1) the survivability and colonizing ability of *E. coli* K-12 and EK2 host-vector systems, (2) the transmissibility of plasmids and phage vectors, (3) the potential of *E. coli* K-12 for pathogenicity, and (4) the potential for genetic exchange between diverse bacteria and between prokaryotic and eukaryotic organisms.

Each category of experiments in Part III of the 1976 Guidelines was then extensively examined, and the following criteria were applied to the new information:

- The degree to which the DNA segment has been purified away from other genes and shown to be free of harmful characteristics,

- The potential biohazard associated with the DNA of the cell or microorganism that serves as the DNA source (e.g., genes for toxin production),
- The potential biohazard associated with the vector that serves to transmit the source DNA to a recipient host cell,
- The ability of the vector to survive in natural environments or habitats,
- The kinds and number of organisms that are susceptible to infection by the vector or recipient,
- The potential biohazard of the recipient host cell that serves to replicate the recombinant DNA molecules,
- The ability of the host cell to survive in natural environments or habitats,
- The ability of the host cell to transmit the recombinant DNA molecule to other cells capable of surviving in natural environments or habitats,
- The potential of the host cell to obtain the source DNA by natural means, and
- The evolutionary relatedness of the DNA source to humans. The potential dangers are considered to increase as the organism providing the source DNA approaches humans phylogenetically. For example, source DNA from primate cells is considered to be more potentially dangerous than that from prokaryotes.

In an effort to present more clearly the changes in containment levels proposed by the PRG-RAC, a table was prepared for use at the December 1977 DAC meeting which compared the containment levels in the original (current) Guidelines and the PRG-RAC. This table has now been expanded with a third column to show the containment levels of the PRG-NIH (Appendix A). The remainder of this section summarizes a number of the proposed changes, comparing the current Guidelines with the PRG-RAC. (Not all the changes are discussed here; certain items in which the PRG-NIH differs significantly from the PRG-RAC are discussed below under "Alternatives: Public Commentators." The numbers in parentheses indicate the line numbers on the table to which the proposed revision applies.

- Several categories of experiments (primarily those involving prokaryotes that are exchangers of genetic information with *E. coli* in nature) would no longer be subject to the Guidelines because of the changes in the definition. (See lines 20, 21, 27, 46, and 47.)
- Shotgun experiments involving birds and mammals other than primates were the subject of lowering of containment from P3+EK2 to P2+EK2. This action reflects the increased confidence of the RAC in the EK2 host-vector systems. (See lines 4 and 5.)
- Another category which the RAC decided was in need of revision was that pertaining to the cloning of DNA from organisms producing a toxic product. This was clarified in the PRG-RAC by setting containment levels according to whether polypeptide toxins are produced. Polypeptide toxins are specified, since they might be encoded by a single gene or cluster of genes, whereas toxins of other chemical structure would not. (See lines 8, 9, 10, 11, 12, 16, 17, and 19.)
- For several categories of experiments, it is proposed that the investigator have the option of working at P2+EK1 or P1+EK2 rather than the P2+EK1 levels previously specified. This again reflects confidence in the EK2 systems. (See lines 7, 14, and 15.)
- The lowering of containment for experiments with rigorously characterized clones free of harmful genes has been revised to provide more flexibility. Under the PRG-RAC, Institutional Biosafety Committees (IBC's) would be able to lower containment by a single level. The IBC should consider the purity, extent of characterization, and harmlessness of the clone before allowing such lowering. Reduction of containment by more than one level would require approval by NIH. Under the 1976 Guidelines, NIH had the option of lowering containment down to certain specified levels or not lowering it at all. The PRG-RAC would allow NIH to consider all available data for the clone and to lower containment accordingly.

Alternatives: Public Commentators

During the development of the original Guidelines in early 1976, Part III was the section most commented upon. There was also much comment on this section in the PRG-RAC. Many of the issues raised, however, did not address the specific proposals to alter the containment levels but more general topics, such as the need for a rationale for each of the changes.

Rationale

A number of commentators asked that the rationale for the classification of permissible experiments be elucidated. Concern was expressed that:

- It was difficult for a layman to understand the entire section on permissible experiments because the rationale is not detailed in either the current Guidelines or the PRG-RAC;
- The whole categorization is dependent upon investigatorial confidence rather than documented fact; and
- The quantification of containment levels, the means whereby they were decided, and the rationale for raising and lowering them is not clear.

In general, the classification is somewhat arbitrary. It depends in large part on the scientific judgment of the RAC rather than on demonstrable risk, because there is in fact no actual scientific evidence that there is a hazard in any recombinant DNA experiment. The rationale for classifying recombinant DNA experiments at several containment levels was explained in the "Decision of the Director, National Institutes of Health, To Release Guidelines for Research on Re- combinant DNA Molecules," which was published along with the current Guidelines in the FEDERAL REGISTER on July 7, 1976 (page 27908), as follows:

> The guidelines assign different levels of containment for experiments in which DNA from different sources is to be introduced into an *E. coli* K-12 host-vector system. The variation is based on both facts and assumptions. There are some prokaryotes (bacteria) that constantly exchange DNA with *E. coli*. Here it is assumed that experimental conditions beyond those obtained in careful, routined microbiology laboratories are superfluous, because any exchange experiments have undoubtedly been performed already in nature.
>
> In every instance of artificial re- combination, consideration must be given to the possibility that foreign DNA may be translated into protein (expressed), and also to the possibility that normally repressed genes of the host may be expressed and thus change, undesirably, the characteristics of the cell. It is assumed that the more similar the DNAs of donor and host, the greater the probability of expression of foreign DNA, or of possible derepression of host genes. In those cases where the donor exchanges DNA with *E. coli* in nature, it is unlikely that recombination experiments will create new genetic combinations. When prokaryote donors not known to exchange DNA with *E. coli* in nature are used, however, there is a greater potential for new genetic combinations to be formed and be expressed. Therefore it is required that experiments involving prokaryotic DNA from a donor that is not known to exchange DNA with *E. coli* in nature be carried out at a higher level of containment. Recombination using prokaryotic DNA from an organism known to be highly pathogenic is prohibited.
>
> There are only limited data available concerning the expression of DNA from higher forms of life (eukaryotes) in *E. coli* (or any other prokaryote). Therefore, the containment prescriptions for experiments inserting eukaryotic DNA into prokaryotes are based on risks having quite uncertain probabilities.
>
> On the assumption that a prokaryotic host might translate eukaryotic DNA, it is further presumed that the product of that foreign gene would be most harmful to man if it were an enzyme, hormone, or other protein that was similar (homologous) to proteins already produced by or active in man. An example is a bacterium that could produce insulin. Such a "rogue" bacterium could be of benefit if contained, a nuisance or possibly dangerous if capable of surviving in nature. This is one reason that the higher the phylogenetic order of the eukar-

yote, the higher the recommended containment, at least until the efficiency of expression of DNA from higher eukaryotes in prokaryotes can be determined.

The structure of the classification for permissible experiments is based, therefore, on the scientific assumptions governing potential risk. It should be emphasized that although a wide variety of recombinant DNA experiments have now been performed for over 5 years, in hundreds of laboratories throughout the world, no case of hazard has been demonstrated.

Part III of the Guidelines assigns to each specified class of experiments a level of physical containment and a level of biological containment at which the experiments shall be performed. As noted before, there is a 4-5 log protection in going from P1 to P3 or from P3 to P4. For biological containment, there is the criterion for the HV2 system that the chances of the recombinant DNA escaping, either via survival of the organisms or via transmission of recombinant DNA to other organisms, should be less than 10^{-8} (1 in 100,000,000) under specified conditions.

Commentators said that the revisions did not bring the Guidelines any closer to establishing absolute levels of hazard. It was brought out, however, that in the use of *E. coli* K-12, a level of no risk is neared. Data presented at the Falmouth Conference indicate that it is essentially impossible for *E. coli* K-12 to be transformed into a wild-type pathogen. An *E. coli* K-12 containing toxic genes through recombination could present a risk, for example, to the laboratory worker who ingested it. But it would only be a risk to that person.

Harmful genes will have a very low probability of being transfered from *E. coli* to another organism. For example, the plasmids at the HV2 level are engineered so that they neither self-transfer, nor transfer when another plasmid induces conjugation. Current work is designed to determine the probability of *E. coli* K-12 as a host taking up plasmids from the environment that can then receive the recombinant DNA molecules from the engineered plasmid. Recent data indicate that the probability is extremely low. Thus, it is clear that this host-vector system offers a high degree of safety and at present is preferable to any other.

Comments on use of E. coli *K-12*

A number of comments were made concerning the use of *E. coli* host-vector systems. One commentator stressed that because *E. coli* K-12 is currently a "poor" pathogen does not mean that one or two genes might not convert it to a "good" pathogen. The enfeebled nature of *E. coli* K-12 "is presumably the consequence of mutation(s) introduced during its laboratory passage," but different strains of K-12 with different histories may not all be similarly enfeebled.

Further, it was claimed that the failure to convert K-12 to a pathogen by the use of certain plasmids or *Salmonella* genes is not definitive. To be definitive, we must have the detailed nature of the mutations in K-12 that "prevent the expression of pathogenicity." Also, it was noted that there is no way to assess the absolute risk associated with these experiments, and that it is important to assess the potential harm not only to man but to plants, animals, and the environment.

Another commentator urged that this section of the Guidelines be supplemented with evidence from the Falmouth conference to show that the potential risk is minimal. A commentator cited the potential risk on the basis that "virtually any highly conserved physiologically active eukaryotic protein * * * or fragment thereof could be highly toxic when introduced out of context by a bacterium which received the appropriate gene in a recombination experiment." This criticism of *E. coli* K-12 does not detract from the scientific knowledge over the past two years of the great safety of this system. The evidence is presented in detail in the following section, "Environmental Impact of the Proposed Action."

Different strains of K-12 with different histories may not all be similarly enfeebled, and failure so far to convert K-12 to a pathogen does not prove it can never happen. However, the safety of *E. coli* K-12 has been clearly shown, and there is no need to limit or specify particular strains for EK1. After 30 years of work with many different strains, there is still no known pathogenic *E. coli* K-12 strain. Thus, there is presumptive evidence that all K-12 strains are safe. They are well suited for laboratory experiments because they take up DNA easily, but their cell wall makes them unsuited to compete in nature with wild-type *E. coli*.

Still, it is impossible to refute the criticism that absolute conclusions as to risk have not been reached. There is always one more experiment to be performed that would help in analyzing the safety aspects of any potentially hazardous research activity. Two years ago the Director, NIH, in releasing the Guidelines, stated that NIH would proceed with recombinant DNA work in a deliberately cautious manner while simultaneously evaluating all the evidence pertaining to the potential risks. That statement is reaffirmed.

General classification

There was disagreement expressed over whether the PRG-RAC were too stringent or too lax. Those arguing the former position maintain that the RAC did not relax the Guidelines enough, because all the experimental evidence gathered and analyzed in the past 2 years indicates that the initial fears concerning the potential hazards were severely exaggerated. It was also pointed out that recombinant DNA experiments not allowed under the current NIH Guidelines are proceeding with the approval of responsible national committees in a number of European countries.

Those concerned that the PRG-RAC were too lax point to the inadequacy of experimental data for a sound evaluation of the potential risks. And they argue that a recombinant DNA experiment permitted under less stringent safety conditions in Europe is irrelevant to the establishment of standards in the United States.

One of the comments at the December 1977 DAC meeting was that "the NIH Guidelines do not adequately deal with the use of recombinant DNA in plants * * *." Other commentators expressed similar sentiments, including the suggestion that "a subcommittee be formed to deal with plants and plant pathogens and make specific recommendations for revision of the Guidelines." In response to this, a Workshop on Risk Assessment of Agricultural Pathogens, composed of distinguished American plant pathologists, was held on March 20-21, 1978 (as announced on March 6 in the FEDERAL REGISTER). Sponsored by the U.S. Department of Agriculture, the National Science Foundation, and the National Institutes of Health, the report of the Workshop is Appendix G to this document. The report was presented to the RAC at its meeting of April 27-28, 1978, and was unanimously endorsed with certain minor amendments. These recommendations, with certain additional minor amendments, have been incorporated into the PRG-NIH.

Two new paragraphs have been inserted at the beginning of Part III of the PRG-NIH. The first reminds the reader to consult Part I, "where a listing is given of prohibited experiments and experiments exempt from these Guidelines." The second is a "general flexibility clause."

Insertion of the latter passage was recommended by the RAC at its April 27-28 meeting. It recognizes that the classification of experiments given in Part III will necessarily be imperfect as investigators in the future devise ways to conduct recombinant DNA research which are not currently foreseen and therefore not explicitly considered in the Guidelines. Also, new data may become available showing that certain experiments are clearly

more (or less) safe than seen at this time and that the currently assigned containment level should be changed. Therefore the inserted passage states that "changes in these levels for specific experiments (or the assignment of levels to experiments not explicitly considered in this section) may be expressly approved by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee."

Permissible experiments using E. Coli *K-12 host-vector systems*

Eukaryotic DNA Sources. There was disagreement over those provisions in the Guidelines that allow the principal investigator to choose between two combinations of containment procedures. In several instances, for example, one is permitted to use P2+EK1 or P1+EK2.

This flexibility provision was endorsed by some commentators but questioned by others. It was discussed above in Part II. This concept of investigator flexibility is not a new one; it was allowed under the original Guidelines. Based upon events of the past two years, the RAC merely proposed that the principle be extended to certain specified additional cases where they believe it appropriate. Included in the PRG-NIH are all such specific cases of flexibility recommended in the PRG-RAC.

On the other hand, in certain other specific cases (e.g., DNA from birds), the PRG-RAC recommended that the containment level be P2+EK2, without the option of P3+EK1. Certain commentators urged that in all cases where the containment level of P2+EK2 is given, the option of P3+EK1 be allowed. However, the RAC felt that in view of their increased confidence in the biological containment offered by the EK2 system, P2+EK2 offers more containment than P3+EK1, and that P2+EK2 without the option of P3+EK1 should be the containment level for certain specified classes of experiments. Therefore, there is specified in the PRG-NIH the containment levels of P2+EK2 without the option of P3+EK1 in every case where it appeared in the PRG-RAC.

Discussed below and in the accompanying "Decision" document is the reassessment which was made of the cloning of viral DNA into *E. coli* K-12 at the Ascot Workshop and the April 6-7, 1978, Working Group meeting that endorsed the Ascot report. The RAC at its April 27-28 meeting unanimously endorsed the Working Group report recommending lower containment levels for deliberate cloning of viral DNA into *E. coli* K-12. One of the reasons given originally for the higher containment level for shotgun experiments involving primate DNA into *E. coli* K-12 was the possible *inadvertant* cloning of viral DNA. In view of their recommendation of lower containment for *deliberate* cloning of viral DNA into *E. coli* K-12, the RAC on April 27-28, 1978, reconsidered primate shotgun levels and voted unanimously for new language as follows: *"Primates.* P2 physical containment + an EK2 host-vector. Any lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee but requires NIH approval." This new language is inserted in the PRG-NIH, as well as a similar lowering of containment for shotgun cloning of cold-blooded vertebrate DNA into *E. coli* K-12.

Prokaryotic DNA Sources. In the 1976 guidelines the section dealing with shotgun experiments in which prokaryotic DNA is inserted into *E. coli* K-12 was subdivided into two parts—"Prokaryotes That Exchange Genetic Information with *E. coli*" and "Prokaryotes That Do Not Exchange Genetic Information with *E. coli.*" In the PRG-RAC it was assumed that all prokaryotes that exchange genetic information with *E. coli* would be exempt from the guidelines by appearing on the "list of non-novel exchangers." Therefore, the PRG-RAC the section dealing with these experiments actually considered only prokaryotes that did not exchange genetic information with *E. coli.* The problem with this approach was discussed by commentators, focusing especially on the case of *Agrobacterium tumefaciens.* It meant that a prokaryote which exchanges genetic information with *E. coli,* and was therefore properly assigned a low containment level under the 1976 guidelines, would under the PRG-RAC either appear on the list and be exempt from the guidelines or, if not appearing on the list for some reason, would require in some cases a higher containment. This was not the intent of the RAC. Therefore, the RAC agreed at their April 27-28 meeting that language should be reinserted into the PRG-NIH covering prokaryotes that exchange genetic information with *E. coli* but do not appear on the list, and this has now been done.

For prokaryotes that do not exchange genetic information with *E. coli* the PRG-RAC proposed that P1+EK2 or P2+EK1 conditions apply only in cases of extensive characterization and RAC approval. A number of commentators objected. Some felt that experiments involving nonpathogenic prokaryotes should be conducted at these lower levels without extensive characterization or RAC approval, and others argued that plant pathogens should not be included with CDC class 2 agents as requiring P3+EK2 containment. The RAC at their April meeting agreed with the commentators. Accordingly, this section of the PRG-NIH has been rewritten.

The EMBO Standing Advisory Committee on Recombinant DNA Research recommends that the containment level for all experiments involving the insertion of novel nonpathogenic prokaryotic DNA into *E. coli* K-12 be P1+EK1. Acting conservatively, the Director has retained in the PRG-NIH the levels of P2+EK1 or EK2 for nonpathogenic prokaryotes that do not exchange genetic information with *E. coli.*

The PRG-RAC received substantial criticisms for identifying all agents classified as class 2 in the CDC's publication "Classification of Etiologic Agents on the Basis of Hazard" (fourth edition, July 1974) as being pathogenic for the purpose of assigning containment levels. Several commentators stated that many of the organisms so classified were harmless and that others were of such low pathogenicity that severe safety precautions were unwarranted. It was also pointed out that the pathogenicity of an intact microorganism and the conjectural hazard of a piece of DNA from such an organism with *E. coli* K-12 were quite different matters. The suggestion of these commentators has been accepted, and thus footnote 1 has been added to the PRG-NIH. This gives NIH the authority, upon the recommendation of the RAC, to consider certain class 2 agents as class 1 for the purpose of these guidelines.

Plasmid, Phage, and Virus DNA Sources. Many of the commentators agreed that both the original guidelines and the PRG-RAC were overly stringent with regard to virus experiments. In commenting on the PRG-RAC, the EMBO Standing Advisory Committee on Recombinant DNA Research wrote, "The EMBO Committee believes that the containment categorization of experiments with animal virus DNA's which is proposed by the NIH Advisory Committee is too indiscriminate and excessively stringent considering the proposed classification of experiments with other classes of DNA and the longstanding, accepted safety precautions for handling intact virus particles and viral nucleic acids * * *." The EMBO Committee proposed (1) that experiments with viral DNA be considered on a case-by-case basis or (2) that a detailed set of recommended categories for such experiments be produced.

A joint United States-EMBO Workship To Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insert Viruses was held in Ascot, England, on January 26-28, 1978. The workship

was attended by 27 distinguished virologists and other scientists from the United States, the United Kingdom, West Germany, Finland, France, Sweden, and Switzerland. A report was published in the FEDERAL REGISTER on March 31, 1978 (43 FR 13748) and constitutes appendix E to the present document. The "Ascot Workshop" concluded:

> The probability that K12 organisms carrying viral DNA inserts could represent a significant hazard to the community is so small as to be of no practical consequence * * *. Viral genomes or fragments thereof, cloned in *E. coli* K12 using approved plasmid or phage vectors pose no more risk than work with the infectious virus or its nucleic acid and in most, if not all cases, clearly present less risk. In fact, the workshop participants agreed that cloning of viral DNA in *E. coli* K12 may provide a unique opportunity to study with greatly reduced risks the biology of extremely pathogenic and virulent viruses.

On April 6-7, 1978 (as announced in the Mar. 17 FEDERAL REGISTER), an RAC-sponsored working group composed of distinguished American microbiologists met to review the report of the Ascot Workshop. The report of this working group is appendix F. The group unanimously endorsed the Ascot report with certain minor amendments. Their report was presented to the RAC, was unanimously accepted, and has been substantially adopted in part III of the PRG-NIH.

Characterized and Purified Clones. Concern was expressed by several commentators about the revisions in the PRG-RAC which would allow the local IBC (with notification to be sent to NIH) to reduce either the biological or physical containment level by one step if (1) the DNA is 99-percent purified and shown to be free of harmful genes before its insertion into a recombinant molecules or (2) the clone replicating the DNA is rigorously characterized and free of harmful genes. In the original guidelines, the reduction in case (2) could only be done with prior NIH approval.

There was support from several commentators for the changes in this subsection. The rationale is explained in the PRG-RAC and the PRG-NIH:

> Many of the risks which might conceivably arise from some types of recombinant DNA experiments, particularly shotgun experiments, would result from the inadvertent cloning of a harmful sequence. Therefore, in cases where the risk of inadvertently cloning the "wrong" DNA is reduced by prior enrichment for the desired piece, or in which a clone, made from a random assortment of DNA's, has been purified and the absence of harmful sequences established, the containment conditions for further work may be reduced.

Some commentators noted the ambiguity and difficulty attendant in the phrase "free of harmful genes." The aforementioned EMBO Committee reports that "several national guidelines for recombinant DNA research state that containment measures may be relaxed once a cloned DNA fragment has been biochemically characterized and shown to be free of harmful genes (NIH guidelines) or devoid of any known pathogenic characteristic (French guidelines). The EMBO Committee believes the latter to be a more feasible requirement, but neither can readily be met, and the committee finds it difficult to suggest what sorts of experimental tests might be devised to meet these requirements."

The terms "characterized" and "free of harmful genes" are unavoidably vague. However, footnote 3 of the PRG-NIH goes on to list five types of data which should be considered in making this determination.

Some commentators were also concerned that this granting of additional authority to the local IBCs for single-step lowering in containment levels might introduce variability in the application of the guidelines. NIH, having considered that possibility, has decided that the principle of promoting local involvement in the implementation of the guidelines outweighs the difficulties that may be encountered in this process. In an effort to minimize these problems, NIH has (1) attempted to make all parts of the guidelines as clear, specific, and unambiguous as possible and (2) expanded the "roles and responsibilities" section to outline functions and responsibilities in greater detail.

Also, the guidelines require that the Office of Recombinant DNA Activities at the NIH be notified in writing of such an action. A mechanism is therefore in place to insure that such actions proceed with an acceptable degree of uniformity.

The question was raised whether a clone of which the containment level was lowered by the IBC at Institution X may, after shipment to Institution Y, be used at the lower level without review by Y's IBC. It has clearly been the intention of both the RAC and NIH that the IBC at the receiving institution must approve the reduction in containment for the handling of the clone in such a situation. The investigator at the receiving institution, however, must handle the clone at the higher level until such permission is granted.

One commentator urged that prior cloning be accepted as a technique for the purification of DNA molecules before their reinsertion into a recombinant molecule. The PRG-RAC specified that purification must be achieved "by physical or chemical techniques." The criterion for the single-step reduction in containment levels in this situation is that the DNA preparation be 99-percent pure. There is no reason, the commentator held, to restrict the means by which such purification is attained. This suggestion has been accepted. The words "by physical and chemical techniques" following the work "purified" have been stricken from the PRG-NIH, better serving the needs of the investigator without reducing the margin of safety to the public and the environment.

One commentator noted that the PRG-RAC might be interpreted as allowing a single-step reduction in containment levels for purification of the DNA before its insertion into a recombinant molecule, and a further single-step reduction in containment once the same molecule has been cloned. This was not intended. Therefore, clarifying language has been added in the PRG-NIH stating that an IBC "may give approval for a single-step reduction in physical or biological containment on receipt of evidence of characterization of a clone *derived from a shotgun experiment* * * *."

Permissable Experiments With Eukaryotic Host-Vectors

Viral Vectors. A number of commentators felt that the stringent containment conditions required, both in the original guidelines and in the PRG-RAC, for introduction of recombinant DNA into tissue culture cells, using viruses as vectors, were unwarranted. The EMBO Standing Advisory Committee on Recombinant DNA Research wrote:

> In experiments involving the introduction of foreign DNA into cultured cells of animals using DNA viruses as vectors, biological containment is assured by the very restricted permissive conditions for the host cells; the only routes by which the recombinant molecule might escape are by chance infection of a contaminating microorganism or within a viral capsid and the size of the recombinant molecule may well preclude its encapsidation * * *. For example, cloning of mouse DNA using polyoma virus as a vector and mouse cells as host should not require precautions more stringent than those routinely used for many years in laboratories studying polyoma virus infection of mouse cells and mice. The EMBO Committee finds the proposals for this class of experiments in the revised NIH Guidelines not sufficiently discriminating because they would impose unnecessarily high levels of physical containment for experiments with many eukaryotic DNA's.

Discussed earlier within the present document was the ascot Workshop report (appendix E) and the report of the Working Group that met on April 6-7, 1978 (Appendix F). The recommendations of the Working Group have been accepted and incorporated into the PRG-NIH.

Plant Host-Vector Systems. Discussed earlier was the Workshop on Risk Assessment of Agricultural Pathogens, held on March 20-21, 1978, under the sponsorship of USDA, NSF,

and NIH. This section of the PRG-NIH has been rewritten on the basis of the Workshop report (see Appendix G of the present document).

Fungal or Similar Lower Eukaryotic Host-Vector Systems. Both the 1976 Guidelines and the PRG-RAC used the same short paragraph for this section, giving little detail, because they noted "the development of these host-vectors is presently in the speculative stage." Since that time a specific host-vector system of this class has been developed—namely, *Saccharomyces cerevisiae* (baker's yeast)—and other similar systems may soon be proposed. Accordingly, this section of the PRG-NIH has been expanded to give more specific instructions on appropriate containment levels.

Synthetic DNA

Because synthetic DNA is now explicitly included in the PRG-NIH (as discussed in Part I of this document), it was necessary to add language to Part III of the PRG-NIH detailing the appropriate containment levels for these experiments. The RAC at its meeting on April 27-28, 1978, approved such language, and it has been inserted in the PRG-NIH.

Proposed Action: Environmental Impact Assessment

Discussed in the Director's "Decision" accompanying the original Guidelines and in the Environmental Impact Statement on their release are—

- Tthe containment safeguards, physical and biological, that protect the laboratory worker, the general public, and the environment;
- The criteria for assessing the possible dangers from experiments involving recombinant DNA molecules; and
- The criteria for matching the assessed possible dangers of individual experiments with the appropriate safeguards.

It was these criteria for the selection of safeguards that guided the deliberations of the Recombinant Advisory Committee in proposing physical and biological containment levels for certain classes of experiments. These criteria were also the basis for recommendations by the scientific work groups on plants and viruses upon which the RAC made further recommendations in April 1978. The basic structure of classification for permissible experiments is maintained throughout the PRG-NIH.

That structure is based on the host-vector system and the source of the DNA. The *E. coli* K-12 host-vector system is considered first, then other prokaryotic host-vector systems, then eukaryotic host-vector systems. To assist the reader in comprehending the structure of the guidelines for permissible experiements, a table is provided outlining the containment levels given in the current guidelines, the PRG-RAC, and the PRG-NIH (see App. A). To assist further in the consideration of experiments under the guidelines, NIH reviewed all experiments supported by NIH as of December 15, 1977, and characterized them in a comparable table (see App. B). This shows the containment levels required for these experiments under the current guidelines, the PRG-RAC, and the PRG-NIH.

The major areas where changes have occurred in the PRG-NIH include the five categories of exempt experiments and those other classes of experiments for which containment levels are lowered. Many of the experiments under the current guidelines would be exempt under the "Exemptions" section of the PRG-NIH, including those in which recombinant DNA molecules are not in organisms or viruses, are from a single nonchromosomal or viral source, or are from species that exchange DNA by known physiological processes. These exemptions are proposed because evidence has led to the conclusion that the experiments pose no significant risk to health or the environment.

Permissible experiments involving *E. coli* K-12 as a host-vector system in the PRG-NIH may generally be done at lower levels of physical and biological containment. A basis for this is the abundant scientific evidence that *E. coli* K-12 cannot be transformed into a pathogen. (See Pt. III of this document for a summary of the scientific information on the safety of this host-vector system.)

Another reason for reducing containment levels when eukaryotic DNA is inserted "shotgun" into *E. coli* K-12 is new knowledge obtained only recently concerning the significant difference between prokaryotes and eukaryotes in the way proteins are synthesized. This newly discovered phenomenon of "intervening," or "spacer," sequences in eukaryotic DNA (1) is discussed in footnote 13 to the "Introduction and Overview" of the accompanying decision document. It makes the expression of eukaryotic DNA inserted "shotgun" into *E. coli* K-12 using "nonengineered" plasmids less likely than had been postulated 2 years ago before the phenomenon of "intervening" sequences in eukaryotes was discovered.

In the PRG-NIH, containment levels have been significantly reduced for the use of viruses as vectors and as a source of DNA for insertion into *E. coli* K-12. The basis for this was the strong support at the public hearing in December 1977 for a scientific analysis on the use of viruses in these experiments. As a result, a meeting sponsored by NIH and the European Molecular Biology Organization, held in Ascot, England, January 1978, provided a rationale for reconsidering containment levels for recombinant DNA experiments involving viral DNA. On the basis of the NIH/EMBO report and a workshop supported by the NIH, the RAC at its April 1978 meeting recommended a complete revision of the sections of the guidelines dealing with viral DNA that is largely reflected in the PRG-NIH. The bases for these revisions are explained in detail in the reports of the Ascot conference and the NIH working group which appear in Appendices E and F. The Ascot conclusions relating to the insignificance of the hazard associated with viral DNA inserts in *E. coli* K-12 are quoted on page 108.

Few recombinant DNA experiments have been conducted with viral DNA, since the overly stringent containment levels of the current guidelines greatly inhibited their use. Under the PRG-NIH, such work would be carefully monitored to insure that any new information on safety or risk were quickly reviewed and any appropriate amendments to the guidelines were made.

Another major area where containment levels have been reduced involves experiments with plant DNA. At the December public hearing of the Advisory Committee to the Director, NIH, scientists from the agricultural community strongly recommended that the guidelines pertaining to experiments with plants be reviewed. In February, NIH, USDA, and NSF convened a meeting of plant scientists, who made a number of recommendations to the RAC. The RAC's recommendations from its April 1978 meeting are reflected in the PRG-NIH. Few NIH experiments are in this area, and developments will need to be closely monitored by the NSF and USDA to determine what work is being done. Again the recommendations comport with safety requirements to assure no significant risk to health or the environment.

In effect, all of the recommendations for permissible experiments and for those exempt from the guidelines are based on new scientific findings or on reassessment of previous information. Evidence indicates that work should proceed because many recombinant DNA molecules produced in laboratories mimic those already present in nature. The PRG-NIH focus on areas of experimentation that need special attention for the possibility of potential hazard. Work in progress that is expected to yield valuable new information will need to be monitored—for example, experiments in which "engineered" systems should permit intentional expression of ge-

netic functions. the current revisions intend to remove as a focus of attention the type of project that does no more than mimic nature and to permit serious attention to new developments that would further the expression of new genetic functions.

All the accumulated evidence on experiments permitted under the guidelines indicates that the proposed revisions would have no significant environmental impact.

The categorization of experiments is based on several premises, as explained in the 1977 environmental impact statement. Shotgun experiments with DNA from primate sources require containment because they involve genes that might function in humans with untoward effects. Containment levels, however, have been lowered here because the concern about a hazard from pathogenic viral DNA's residing in primate tissue has been largely laid to rest in the viral reports. Alternatives in the use of physical and biological containment are provided in a number of cases on the premise that the greater the containment afforded by the host-vector system, the lower the physical containment needed. Requirements continue to be more stringent when the source of foreign DNA is known to be pathogenic or toxigenic, or might be infected with a pathogen, or is known to make harmful products.

For shotgun experiments when the source of DNA is prokaryotic organism, the guidelines specify containment levels according to whether the organism is known to recombine genetic information with *E. coli* in nature. Many of the experiments involving exchangers are now exempt under Exemptions I-E-4 in the PRG-NIH. The lowering of containment recommendations for those experiments in which the source is a prokaryote that does not naturally exchange genetic material with *E. coli* reflects the safety in the use of *E. coli* K-12. Scientific information over the past 2 years shows that recombinant DNA experiments are most unlikely to create new genetic combinations never tested by nature and that the possibility of transforming *E. coli* K-12 into an epidemic pathogen is virtually nil.

In the case of a clone that has been rigorously characterized and is free from harmful genes, the safety is such as to permit provision for actions by the local biohazard committee rather than NIH. Purification greatly reduces the potential for growth of a hazardous organism, and the containment requirements should be correspondingly lower.

The changes in the eukaryotic host-vector systems reflect in large part the recommendations concerning work with viruses and plants. As noted in the original EIS, recombinant DNA experiments here involve the use of systems in which the host cells have little or no chance of escaping from the laboratory as an *E. coli* cell might.

New scientific information indicates that a variety of organisms, such as the lower eukaryotes fungi and yeast, may be useful hosts for experiments with recombinant DNA's; and useful vectors are now becoming available for these systems. Hence, this section of the guidelines has been expanded to detail safe use of these systems. In addition, because of the ability to use synthetic DNA in recombinant DNA experiments, a new section has been added to the PRG-NIH to specify safe containment levels for this research.

NIH has been mindful of the concerns of those who requested that the EIS on the original guidelines contain further information on individual experiments. We have tried to meet that need by the analysis provided in this section and in Appendix B.

At the public hearing on the PRG-RAC in December 1977, some critical comments were directed at NIH's EIS on the original guidelines. Most of the comments centered on NIH policies vis-a-vis permissible experiments. An analysis of those comments appears as Appendix C.

Because of the critical importance of *E. coli* K-12 in recombinant DNA research, an assessment of the use of this organism in recombinant DNA experiments follows.

Background on the use of E. coli K-12 in recombinant DNA experiments

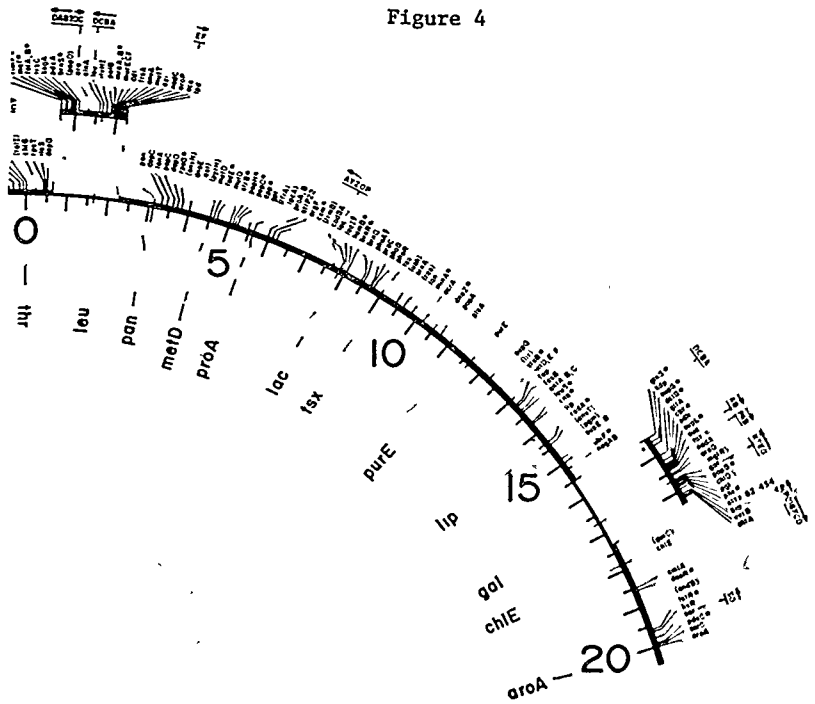
Escherichia coli designates a range of bacterial strains. Each is adapted to live in a certain habitat. Its habitats are found primarily in the vertebrate gut, and it cannot long survive elsewhere—for example, in sewage.(*2*) Some strains are pathogenic, causing disease in the gastrointestinal tract of man or other animals. (*3,4*) One strain of *E. coli,* called "K-12," has been used in laboratory experiments for over 50 years. (*2*) It is not known to have ever caused disease.(*3*)

K-12 became the favorite organism for genetic research because it reproduces rapidly and thrives under controlled laboratory conditions. No living creature is known more thoroughly. Its single chromosome can be easily manipulated by genetic means, permitting its gene structure to be mapped. This work has greatly advanced understanding of how genes express and regulate inherited characteristics.

The chromosome of K-12 is a circular molecule of DNA with about 4 million subunits. These compose 3,000 or 4,000 genes, of which about 650 have been identified and assigned locations. (*5*) An arc of the genetic map of *E. coli* K-12 is shown below.(*5*)

The NIH guidelines limit the vast majority of recombinant DNA experiments to the use of *E. coli* K-12 as host for the foreign genes. This is because the unaltered organism is nonpathogenic and well known in its natural properties—both factors lending confidence that it can be handled safely.

Figure 4



There are those, however, who view the ubiquity of *E. coli* in vertebrates as an argument against the use of even the K-12 strain as a host for foreign DNA. Concern has been expressed, for instance, that the bowels of persons on anitbiotics, ill persons, human infants, or members of other species may be susceptible to colonization.(*7*) Moreover, if *E. coli* K-12 can survive in a person or animal, it might confer genetic characteristics to hardier bacterial inhabitants.

Scientists engaged or interested in recombinant DNA research have addressed these concerns in three ways—first, through guidelines specifying practices and conditions of containment for experiments classified according to the presumed hazard; second, through attempts to develop safer hosts and vectors; and third, through risk-assessment studies. The results of a workshop held in June 1977 at Falmouth, Mass., to evaluate the potential risk of recombinant DNA experimentation with *E. coli* K-12 will be discussed below.

The Evidence That E. Coli *K-12 Is Nonpathogenic.* The laboratory varients of K-12 permitted in recombinant DNA experiments have never been reported to cause disease, even in laboratory workers. K-12 has been grown in large quantities—up to hundreds of liters containing as many as a trillion bacteria. These cultures have been produced in countless laboratories the world over, and under containment conditions lower than the minimal ones in the NIH guidelines. K-12 has none of the properties generally associated with pathogenic bacteria.(*8-15*) It does not—

- survive and multiply readily in natural environments.
- spread from animal to animal or plant to plant,
- multiply readily on body surfaces or intestines and lungs,
- penetrate animal cells or spread through animal bodies,
- produce a toxin or otherwise alter other living things to cause disease, or
- resist normal body defense mechanisms.

Even after as many as 10 billion K-12 organisms have been ingested, their multiplication in normal humans is only transient, and after a time none can be recovered.(*10, 11, 12, 14*) Thus, K-12 does not establish itself as a permanent resident of human beings. On the other hand, K-12 can reside under abnormal conditions, as during antibiotic therapy.(*16*)

A micro-organism, in order to cause disease, must have the genetic capability to do so, as well as the ability to establish itself in the body. It is difficult to conceive how K-12, itself nonpathogenic, could become pathogenic as a result of genetic manipulation. Highly attenuated, it is known only to inhabitat the biological laboratory.

Even when genetic determinants of pathogenicity in other *E. coli* strains were introduced into K-12, no instance of capacity to induce diarrheal disease or urinary tract infection could be detected.(*14, 15*) The workers conclude that the inadvertent transformation of K-12 into a highly pathogenic form by the introduction of a single fragment of foreign DNA is highly unlikely.(*15*) Indeed, the number of characteristics that a microbe must have in order to cause disease is believed to be great, not to mention additional characteristics needed to produce an epidemic.(*17*)

Transfer of Foreign DNA from E. coli *K-12.* While it would appear impossible to render *E. coli* K-12 pathogenic by the introduction of foreign DNA, there is still to be considered whether the inserted fragment could be transmitted to another bacterium with which the K-12 comes in contact, including other strains of *E. coli.* Such a transmission might convert the recipient into a pathogen or render a pathogen more viable. The case of plasmid vectors is considered first.

Plasmids are intracellular particles composed of DNA and not dependent on chromosomes for their replication. Hence, they can be used as vectors, or vehicles, for transporting foreign DNA into the bacterial host, where they multiply and propagate the genes they bear. Certain plasmids (called "conjugative") are inherently able to migrate from one bacterial cell to another. These are prohibited for nearly all recombinant DNA experiments. Only plasmids not capable or barely capable of spontaneous intercellular migration ("nonconjugative") may be used.

The nonconjugative plasmid's ability to migrate is augmented if the cell harboring it is invaded by a conjugative plasmid, which may confer this property. Then even the non- conjugative plasmid may become a potential DNA-bearing invader. It has been calculated, however, that the chance of this occurring with certain K-12 plasmid systems is less than 1 in 10^{15} (10 quadrillion) K-12's surviving per day in the intestine of warm-blooded animals.(*13, 14*) The probability is even lower in sewers, sewage treatment plants, and waterways. It should be noted that since most of the estimates of probability are based on data obtained under laboratory conditions, animal and human feeding studies are needed to verify the predictions.(*18*)

Consideration must also be given to the question of transfer of foreign DNA from the initial K-12 host to other bacteria by means of bacteriophage vectors. Bacteriophages are viruses that infect only bacteria. They could escape the laboratory either as mature infectious particles or in bacterial hosts in which the phage DNA is carried as a plasmid or within the DNA of the cell.

The survival of phage DNA when released as infectious particles depends on their stability in nature, their infectivity, and the probability of effective encounters with naturally occurring *E. coli.* The bacteriophage used in recombinant DNA experiments is known as *lambda.* It is considered very unlikely to survive and to infect resident *E. coli* in animals and humans, being highly sensitive to stomach acid, reluctant to infect smooth *E. coli* cells (the type normally found in the gut), and susceptible to drying, as would occur if it escaped into the air. Moreover, *E. coli* vulnerable to lambda is uncommon in nature. Infective lambda ingested in large amounts (10^{11}, or 100 billion, particles) could not be detected in human feces.(*19*)

Establishement of lambda as a resident of the *E. coli* host cell's DNA is a well-known example of natural recombination, In certain cases, it is a frequent event, as likely to occur as not. Hence, this mode of escape would be the preponderant laboratory hazard. However, most variants of lambda used (or under consideration for use) in recombinant DNA experiments have a much reduced ability to become so incorporated.(*20-22*) Here the probability drops to 10^{-5} or 10^{-6}—1 in 100,000 or 1,000,000.(*23-25*)

The estimates for containment in the use of bacteriophage host-vectors, while not exact, are sufficient to assure that the probability of transferring a foreign DNA fragment from the original K-12 host to other bacteria is remote.

Ability of E. Coli *K-12 To Survive and Spread in Nature.* Thus far, the suitability of K-12 for recombinant DNA experiments has been considered in relation to its ability to do harm

either directly or through transfer of a foreign DNA fragment to another bacterial cell. These properties will depend on the ability of the K-12 to survive, multiply, and infect other living organisms. As already described, K-12 is poorly equipped to survive in natural environments; but if it should survive and multiply, it is still unlikely to infect living things. *E. coli* are seldom spread by aerosols; they are primarily spread by ingestion of contaminated food and water. Between 10^6 and 10^9 (1 million to 1 billion) cells of pathogenic *E. coli* are required to cause disease (*12,25*). In other words, at least a million bacteria would be required to cause disease in a single person if some K-12 did become pathogenic.

The guidelines emphasize protection of laboratory workers because they are the persons most at risk. They are also the most likely means by which recombinant DNA might be spread. Should a worker carry such agents out of the laboratory, however, the probability that others would be affected is still very low, and the risk of a resulting epidemic is virtually nonexistent. There is abundant evidence for this assertion. It has long been known that the separation of sewage from food and water supplies prevents epidemcis of enteric bacteria such as *E. coli*.

The following excerpt from a letter by Roy Curtiss III to Donald S., Fredrickson discusses the K-12 strain of *E. coli* in relation to infectivity.(*13*)

In terms of communicability of *E. coli* K-12, we know that enteric diseases caused by enteropathogenic *E. coli* and various strains of Shigella, Salmonella and Vibrio are transmitted by contaminated food and water and that manifestation of disease symptoms requires consumption of approximately 1 million bacteria. Such enteric diseases are seldom spread by aerosols. Indeed, it is well known, for example, that cages of mice infected with Samonella can be housed in the same room with uninfected mice which remain uninfected. The finding that *E. coli* cells can be recovered from the nasopharynx of approximately 5 percent of those humans tested might suggest that aerosol spread could occur. Such *E. coli* cells, however, are only intermittently present in the nasopharynx and are usually found at concentrations too low to initiate an infection even if they were representative of a pathogenic strain. They most likely get into the nasopharynx due to poor personal hygiene. After learning of these observations quite some years ago, I monitored my nostrils and skin for the presence of those *E. coli* K-12 strains I was working with. I was successful in detecting these strains about 10 percent of the time when the monitoring was done at the end of the work day, but never obtained positive results when the monitoring was done the next morning. I should hasten to add that my research with *E. coli* K-12 at that time involved mouth pipetting and other aerosol-generating procedures on an open lab bench: procedures and conditions which are not permitted by the NIH Guidelines. These results, preliminary as they are, nevertheless suggest that *E. coli* K-12 does not colonize the nasopharynx. Based on these observations, the fact that *E. coli's* normal ecological niche is the colon and the fact that transmission of enteric diseases is by ingestion of contaminated water and food, I doubt that *E. coli* K-12 could be converted to an air-borne "infectious" agent by introduction of recombinant DNA. In terms of the more usual means for spread of enteric pathogens, it is evident tha enteric diseases are bery well controlled in the United States by sanitary engineering, even though there have been reports of poor water quality in some parts of the country and higher-than-desired levels of pollution of rivers, streams, etc. There is however, a concerted effort to improve biological waste water treatment and thus lessen pollution and improve water quality. Even if there were a natural catastrophe such as caused by an earthquake, tornado, hurricane, etc., it is unlikely that *E. coli* K-12 containing recombinant DNA could initiate or sustain an epidemic in view of K-12's inability to colonize and overcome host defense mechanisms.

Seeking a consensus on the matter of risk assessment in recombinant DNA research, with particular reference to the use of *E. coli*, the National Institutes of Health sponsored a workshop in Falmouth, Mass., on June 20–21, 1977. In attendance were approximately 50 invited participants and observers, from the United States and abroad, including experts on all aspects of infectious disease. The following excerpt from a letter by the workshop chariman, Sherwood L. Gorbach, to Donald S. Fredrickson summarizes the principal conclusion:

CONSENSUS AGREEMENT

An important consensus was arrived at by the assembled group which I felt was of sufficient interest to be brought directly to your attention. The participants arrived at unanimous agreement that *E. coli* K-12 cannot be converted into an epidemic pathogen by laboratory manipulations with DNA inserts. On the basis of extensive studies already completed, it appears that *E. coli* K-12 does not implant in the intestinal tract of man. There is no evidence that non-transmissible plasmids can be spread from *E. coli* K-12 to other host bacteria within the gut. Finally, extensive studies in the laboratory to induce virulence in *E. coli* K-12 by insertion of known plasmids and chromosomal segments coding for virulence factors, using standard bacterial genetic techniques, have proven unsuccessful in producing a fully pathogenic strain. As a result of these discussions, it was believed that the proposed hazards concerning *E. coli* K-12 as an epidemic pathogen have been overstated. Such concerns are not compatible with the extensive scientific evidence that has already been accumulated, all of which provides assurance that *E. coli* K-12 is inherently enfeebled and not capable of pathogenic transformation by DNA insertions.

The entire letter from Gorbach is quoted in the NIH environmental impact statement, part II, appendix M.(*27*) The proceedings of the Falmouth workshop on risk-assessment have been published in the May 1978 Journal of Infectious Diseases.

There remains the question whether the insertion of a foreign DNA fragment into K-12 will significantly alter the properties of the latter with regard to survival and multiplication, or the ability of the plasmid and bacteriophage vectors to be spread. The improbability of converting K-12 to a pathogen has already been discussed. Changes in ability to survive and multiply would be expected to involve not only the changes in the K-12 itself, or the plasmid or bacteriophage, but also the nature of the environment in which it finds itself. The subject is discussed in the section of this document entitled "Risk and Benefits of Recombinant DNA Research."

Attenuated K-12 Systems. Theoretically, the most desirable bacterial recipient of recombinant DNA would be a species uniquely adapted to carefully controlled laboratory conditions and unable to survive or transmit DNA to other organisms in any natural environment. This means that it should be unable to establish itself as a long-lived and multiplying resident in or on living things, or in soil or water. In addition, these properties should not be significantly altered by recombination of the bacterium's DNA. The organism should also, of course, lend itself to manipulation for successful execution of experiments.

No bacterium meeting all these requirements is known. It is possible that no such creature exists in nature. Available bacterial systems must be evaluated for relative safety and utility, depending on the extent to which they approach the ideal. The foregoing summary of knowledge concerning K-12 and its known plasmids and bacteriophages indicates that these systems measure up well with the ideal criteria, and can therefore be recommended for use in recombinant DNA research.

The K-12 systems, extant and projected, are known as EK1, EK2, and EK3, referring to increasing degrees of attenuation. The guidelines permit the use of EK1 for those experiments whose potential for hazard is regarded as nil, low, or minimal. For experiments judged to have a somewhat higher (though still conjectural) potential for hazard, the guidelines require the further attenuated system EK2. Here, properties of the K-12 and the vectors must be so modified as to minimize the chance of the vector surviving in its host outside the laboratory and migrating to other hosts. EK3 systems are even stricter, requiring, for example, the use of vectors that cannot propagate outside the host. So far, no EK3 systems have been certified. [In the proposed revised Guidelines (PRG-NIH), the EK

systems are retained within the broader host-vector systems (HV) classification, providing more specificity.]

Implications of the use of EK2 containment are elucidated in the following passage from a paper presented by Bernard D. Davis at a forum on recombinant DNA held by the National Academy of Sciences, March 7-9, 1977.(2)

A very large safety factor is added by the provision in the present guidelines for biological containment. All work with mammalian DNA must be carried out in EK2 strains, which have a drastically impaired ability to multiply, or to transfer their plasmid, except under very special conditions provided in the laboratory. The presently certified EK2 strain has several stable mutational defects (i.e., deletions) that prevent it from multiplying under the nutritional conditions of the gut. But the protection goes much further, and reaches a degree that is unprecedented in the annals of man's exploration of potentially hazardous new materials: this material has been coded for self-destruction. For example, these mutant cells require diaminopimelate, a constituent of cell wall; and without it they can continue to grow and expand but cannot form more wall, and so they quickly burst. Accordingly, under conditions similar to those in the gut such an EK2 strain not only fails to multiply, but less than 1 in 10^8 cells survives after 24 hours—and it would be an extraordinarily sloppy laboratory accident that would result in ingestion of as many as 10^8 cells. In addition, while the cells are dying off in the absence of diaminopimelate they are severely impaired in their ability to transfer plasmids to other, well-adapted cells—and this is the important point for the danger of spreading harmful genes. Finally, not only the cells but also the plasmids being used to carry recombinant genes are also weakened mutant derivaties, selected for severe impairment of their ability to be transmitted from the host cell to another cell.

We thus see that, even with a strain known to carry the gene for a potent toxin, the production of disease in a laboratory worker would require the compounding of two low probabilities: that the strain will initiate an infection and that it will survive long enough to cause harm despite its several disadvantages—that of being a laboratory-adapted strain, that of carrying the burden of foreign DNA, and that of carrying the very large burden of being a suicidal EK2 strain.

The criteria for NIH certification of an EK2 system have been defined and enlarged during the past year. Extensive data are required and very demanding standards have been set. Such organisms are being designed and constructed by NIH contractors and other interested investigators. Their use in recombinant DNA experiments is not allowed until they have been certified by the Director, NIH, upon recommendation by the Recombinant Advisory Committee. The NIH environmental impact statement describes the criteria for certification and lists the certified EK2 systems as of July 1977.(28) It should be noted that the same depth of experience with K-12 that recommends its utility as a host for recombinant DNA experiments is central to the ability to manipulate it for the purpose of improving its safety.

An important recent paper was published by two British workers, Petrochellou and Richmond on the absence of plasmid or *E. coli* K-12 infection among laboratory personnel.(29) In testimony before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science, and Transportation, on November 10, 1977, Dr. Oliver Smithies, professor of medical genetics and genetics at the University of Wisconsin, interpreted the Petrochellou and Richmond results as follows:

Twice weekly for over 2 years these workers tested the feces of five laboratory persons who had been using without special precautions the laboratory strain of *E. coli* called K-12, together with a transmissible plasmid. Neither the *E. coli* K-12 nor the transmissible plasmid was ever found in the feces during these tests. (Transmissible plasmids are naturally occurring circular pieces of DNA that can replicate inside bacteria and which, in nature, transfer genes between them.) So, with *E. Coli* K-12 and a transmissible plasmid, the risk of the plasmid or its host K-12 getting into the feces and surviving to any appreciable extent is less than one per laboratory worker per 10 years of lab work, even when no special precautions are taken.

Now, under the NIH guidelines, none of the even conceivably hazardous experiments are performed in this type of *E. coli*, K-12. Such experiments require a specially weakened strain, Chi 1776, which introduces a safety factor for survival of greater than 100 million. Chi 1776 has been proven by tests to survive 100-million times less well than K-12.

In addition, such experiments require the use of a nontransmissible plasmid which introduces a safety factor for transfer of the plasmid to other bacteria of about 100 million.

Let me emphasize again that this type of work requires a nontransmissible plasmid; that is, a plasmid derived from a transmissible plasmid by elimnating the mechanisms for transfer of the plasmid between bacteria.

So the risk of Chi 1776 strain of *E. coli* K-12 surviving in the feces or of the recombinant DNA plasmid being transferred to some other bacteria becomes less than one chance per 100,000 laboratory workers working for 10,000 years without special physical precautions.

This is what is meant by a "negligible risk."

When we consider that the guidelines require also very special physical precautions, you can see why I think the risk is no longer worth considering.

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IV. Roles and Responsibilities

Analysis of Current Guidelines

The Guidelines contain a large section, Part IV, defining the roles and responsibilities of individuals and institutions in assuring compliance with required containment levels. The procedures described are primarily directed at grantees of the National Institutes of Health. Similar procedures are in force for work within NIH laboratories and for work sponsored by NIH under contracts.

The principal investigator is required to assess any potential biohazards, to institute appropriate safeguards and procedures, to minimize effects of possible accidents by planning, to train and inform all personnel, and to report any accident or any serious or extended illness of a worker. All of these must be carried out on a continuing basis. Thus, the primary responsibility for conducting experiments according to the Guidelines is in the investigator's hands.

Further, in applying for grants to carry out experiments with recombinant DNA, the investigator must include an estimate of the potential biohazards and a statement of the containment procedures to be used. The application must include certification of the existence and availability of appropriate facilities, procedures, and training. The Guidelines indicate that institutions in which recombinant DNA experiments are carried out must establish biohazards committees that examine equipment and facilities and certify their compliance with the requirements. Such committees will also serve as a source of advice and reference on physical containment facilities, on properties of biological containment, and on training of personnel.

According to the Guidelines, the certification and the investigator's assessment of the hazard and containment would be considered by NIH study sections during the normal scientific review of the application. The Guidelines leave flexible the question of resolving any differences between the investigator's evaluation and that of the study section. The Guidelines do state, however, that if differences cannot be resolved, the matter should be referred to the Recombinant Advisory Committee or the NIH Office of Recombinant DNA Activities.

Application of the guidelines to work not supported by NIH

Several agencies of the U.S. Government other than the National Institutes of Health provide support for biological and medical research. Some of these currently sponsor recombinant DNA experiments, and others may do so in the future. Activities of the research agencies represented by the Federal Interagency Committee on Recombinant DNA Research were reviewed by the Committee in the fall of 1976. All member research agencies adopted the NIH Guidelines and standards, including the National Science Foundation, the Department of Agriculture, the Energy Research and Development Administration, the Department of Defense, the National Aeronautics and Space Administration, and the Veterans Administration.

Several conferences have been held at NIH and at other relevant Government agencies with representatives of private industry in the United States. As best detemined by the Federal agencies, recombinant DNA research conducted in the private sector complies with the physical and biological standards of the NIH Guidelines. Relevant industries have agreed to follow the Guidelines on a voluntary basis.

The issue of recombinant DNA research has been studied by national and international bodies in many countries. In most cases some form of control has been recommended, but nowhere has a total ban on the research been advocated. Canada, the Federal Republic of Germany, France, the Soviet Union, and the United Kingdom have issued guidelines that differ in detail but are similar conceptually to the NIH Guidelines. Other countries are generally following the NIH or U.K. Guidelines, including Denmark, Israel, the Netherlands, Sweden, and Switzerland. The International Council of Scientific Unions and the World Health Organization have urged nations to adopt the principles embodied in these two sets of guidelines. The U.K. Guidelines have been endorsed by the European Science Foundation and the European Molecular Biology Organization.

Scientific and governmental activities comparable to those in the United States have been under way in the United Kingdom since January 1975. A working party established at that time recommended that recombinant DNA research in the United Kingdom be permitted to continue under appropriate controls. In August 1976 a followup working group chaired by Sir Robert Williams issued a report establishing guidelines.

In Canada, in March 1976, a special committee of the Canadian Medical Research Council recommended guidelines to govern the handling of recombinant DNA molecules in Council-supported research. The Council adopted these guidelines in February 1977.

Many other nations have reviewed recombinant DNA activities to determine what measures were necessary for safety. With the urging of regional and international bodies, most have adopted the NIH or U.K. Guidelines as a basic framework for safety practices and procedures.

Alternatives: RAC-Proposed Revisions

Part IV (Roles and Responsibilities) of the PRG-RAC is described below. As in the current (1976) Guidelines,

this part of the PRG-RAC was designed to provide an administrative framework for implementation.

Institution

In the PRG-RAC as compared with the current Guidelines, several changes were proposed in the responsibilities of the institution. Responsibilities that were added or further detailed included: (1) a requirement for insuring the training of research personnel and the use of good microbiological technique, and (2) a requirement to determine the need for medical procedures, with recommendations of possible specific practices.

Institutional biosafety committees

Membership of the IBC's was clarified by a recommendation to include other than scientific members. In the PRG-RAC, institutional biosafety committees (called "biohazards committees" in the current Guidelines) are given the discretion to approve single-step reductions in containment levels for experiments with characterized clones and purified DNA. The IBC's would be required to notify the NIH Office of Recombinant DNA Activities (ORDA) of these approvals.

Biological safety officer

Institutions at which P3 and P4 level recombinant DNA work is conducted would be required to have a biological safety officer, whose specific roles and responsibilities are outlined.

Principal Investigator. The role and responsibilities of the principal investigator would remain basically the same, except for the important addition of a requirement for training in microbiological techniques. Responsibility for the determination of the practices necessary for medical surveillance would be relocated to the institution.

NIH responsibilities

Office of the Director. The responsibilities of the Director remain unchanged. A sentence has been added that clarifies the Director's authority to implement the Guidelines and to be the final arbiter in their interpretation.

Recombinant advisory committee

There were no changes in the current responsibilities of the RAC. There were, however, clarifications of the scope of some duties—for example, the certification process. The language of the 1976 Guidelines caused some confusion about the certification of EK2 (HV2) and EK3 (HV3) host-vector systems. In practice, the certification process, clarified in the PRG-RAC, involves a two-step procedure: (1) The RAC's recommendation to the Director, NIH, that a particular host-vector system be certified; and (2) certification of the system by the Director. The rationale for the procedure is that it allows the Director to solicit the opinions of additional experts before making a financial decision on certification.

The RAC's authority to recommend exceptions from the prohibitions was also clarified. The 1976 version of the Guidelines envisioned the possibility of the RAC's recommending an exception to the 10-liter limit on culture volume for recombinant DNA's known to make harmful products. The proposed revision would extend the possibility of an exception to the five other classes of currently prohibited experiments.

The general rationale for this addition is twofold: the RAC's inability to foresee all possible future circumstances and its desire to specify, within the limits of strict safeguards, the possibility of an exception for compelling social or scientific reasons. A more immediate and specific justification for the paragraph on exceptions from the prohibitions is that the risk-assessment studies necessary for a clearer understanding of the potential biohazards of recombinant DNA research may be technically prohibited by the current Guidelines, unless there is a mechanism for approving exceptions.

Alternatives: Public Commentators

Institutional responsibilities

This section of the Guidelines drew considerable comment directed to the roles and responsibility of the local institution and its several constituents. Generally, commentators requested more information and greater clarification of the structure and operation of the IBC, the function of the biological safety officer, and the duties of the institution. The suggestions and comments were carefully considered, in view of the importance of this section to successful implementation of the Guidelines and therefore safe conduct of the research.

NIH has a special responsibility for leadership in developing and promoting safety programs relevant to recombinant DNA experiments. Accordingly, as in 1976, another committee chaired by Dr. W. Emmett Barkley, Director of the National Cancer Institute's Office of Research Safety, was convened to address concerns raised. As a result, and in response to a number of commentators' requests, the substance of Appendix D has been revised and republished as a supplement to the Guidelines. The revised Guidelines also retain requirements for emergency plans to cover accidents and strengthen the requirement for training of all recombinant DNA researchers in safe laboratory procedures.

The intent of this section, as before, is to integrate safety practice into the conduct of recombinant DNA research and to assign responsibilities for this to the principal investigator, institution, IBC, and biological safety officer. It is important that these responsibilities be stated in an unambiguous manner. In response to many commentators. Part IV has been restructured to present some of these functions in greater detail and clarity. The appendices contain additional complementary information on roles and responsibilities, including material for IBC's and biological safety officers.

Expanded Responsibilities. In response to several comments, the review of research has been broadened in the PRG-NIH to cover all recombinant DNA research at an institution receiving NIH funds for this purpose, whether or not the specific recombinant DNA project is funded by NIH. While this increases the responsibility of the institution and the IBC, it is believed that the overall safety of recombinant DNA research will be enhanced. To reflect more closely the spirit of the Guidelines, the name "institutional biohazards committee" is proposed to be changed to "institutional *biosafety* committee."

Several generic comments deserve to be highlighted, as they represent significantly increased authority to be delegated to the institution. In 1976 the RAC did not accept commentators' suggestions to require local committees to make an independent evaluation of the containment levels required by the Guidelines for individual research projects. It was therefore stated in the 1976 Decision that NIH would not require local institutions to have their committees perform this function, although they would not be prohibited from doing so. Commentators have now noted that an IBC, in order to to accomplish its mandated responsibilities under the 1976 Guidelines, including the review and approval of recombinant DNA research projects, must implicitly determine containment conditions. In order to clarify the committee's role, the assessment of appropriate containment levels is now made an explicit responsibility of the IBC.

In addition, institutions through their biosafety committees would be given increased responsibility for primary overview of this research, as they have been delegated the authority to approve or disapprove proposed recombinant DNA projects. NIH, through ORDA, will conduct a review of institutions' actions, upon registration of the projects, to ensure compliance with the NIH Guidelines, thereby maintaining a national standard. This action has been in response to several comments calling for increased local responsibility and a simpler adminis-

trative process in regard to gaining approval for research to proceed.

In view of the unreliability of Federal surveillance to enforce these standards, it is essential to increase the authority and responsibility of the local institution. It was requested that the IBC's have a role if legislation in this area is adopted. This concept is endorsed by the House Committee on Interstate and Foreign Commerce in its Bill Report of March 24, 1978, on the Recombinant DNA Act:

> It is the view of the committee that the appropriate portions of the administrative requirements of section IV of the NIH Guidelines are a reasonable model upon which the Secretary could base administrative regulations. In particular, the current practice in the NIH Guidelines of delegating to local biohazards committees most of the responsibility for the inspection of facilities and the approval of the specific safety requirements appropriate to each project or activity is an effective and relatively inexpensive administrative mechanism.

A number of recommendations were received regarding the membership of IBCs. In 1976, suggestions were made for broadening IBC representation to cover not only various disciplines related to recombinant DNA technology, safety, and engineering, but also to include members knowledgeable in applicable laws and regulations, standards of practice, community attitudes, and health and environmental considerations. These diverse points of view were either to be included or made available to the committees. The language in the PRG-RAC calls for a diversity of membership, but would not mandate public members. In response to several requests, and in view of increased responsibility at the local level, a provision is included in the PRG-NIH that "no IBC may consist entirely of persons who are officers, employees, or agents of, or are otherwise associated with the institution, apart from their membership on the IBC."

A number of other recommendations were received from public commentators relating to more specific issues concerning the various responsibilities of the institution and its constituents. These recommendations and the PRG-NIH decision are considered below under the appropriate headings.

Institution. A number of points were raised by commentators concerning health monitoring by institutions. NIH was requested to develop a model for institutional medical surveillance for recombinant DNA research workers. An NIH committee is reviewing this area and has made recommendations as to what such a program might include. This proposal, which calls for monitoring illnesses, collecting serum samples, and keeping a register of agents handled, is responsive to several suggestions received on this issue, and has therefore been adopted in the PRG-NIH. Additionally, Appendix D will include more detailed information on medical surveillance.

A collaborative effort has been initiated between NIH and the Center for Disease Control (CDC) to establish a mechanism for providing advice, consultation and, if necessary, assistance regarding major accidents in laboratories conducting recombinant DNA research. It was not considered necessary to have a standing "strike force" as suggested by one commentator; but in the event of an emergency, a team of experts from NIH and CDC could be formed to respond.

The issue of medical monitoring is one of considerable interest to NIH. This is a general problem not unique to DNA research. As one commentator noted, a routine health monitoring and reporting program might well be instituted for personnel engaged in areas of research besides recombinant DNA, such as tumor viruses and pathogenic organisms. The state-of-the-art, however, is primitive in terms of what can be done to monitor workers' health, and particularly in the area of recombinant DNA research, where there is no known hazard.

Grievance procedures for workers under the Guidelines were requested, but this is not considered necessary, as the rules and regulations of the Occupational Safety and Health Act (OSHA) already provide such a mechanism. OSHA standards and procedures apply to most institutions, so it is not considered necessary to require in the Guidelines that IBCs ensure OSHA compliance. Further, the Federal Interagency Committee on Recombinant DNA Research includes the Occupational Safety and Health Administration (Department of Labor), assuring cooperation at the Federal level.

Institutional Biosafety Committee. Several commentators requested more detail on IBC duties. This has been accomplished in "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research." For example, information is included there on facility certification, periodic inspections, and monitoring.

It was suggested that biosafety committee meetings be open to the public. The Guidelines currently require only that the minutes by publicly available. In view of possible discussion of proprietary information and patent rights, meetings cannot always be open. Local committees, however, should consider having open meetings when possible.

The question was raised concerning conflict of interest of local committee members. Addressing this important point, a provision in the PRG-NIH prohibits an individual from being involved in the review of a recombinant DNA project in which he or she was engaged or had a direct financial interest.

Biological Safety Officer. Since the passage of OSHA, most institutions have established occupational safety and health departments with safety officers. There are no standard certification procedures for such individuals, although their qualifications, in many cases, could be commensurate with those of a biological safety officer. The Laboratory Safety Monograph provides in detail the kinds of qualifications biosafety officers should have. NIH is developing a training course for biological safety officers and other campus safety personnel. Requests for information should be directed to Dr. Emmett Barkley, Office of Research Safety, National Cancer Institute, NIH.

Princial Investigator. Commentators remain concerned about the quality and uniformity of safety training. NIH is responding to this by placing as a high priority the development of training standards and courses. Currently, NIH is supporting a Working Panel of the American Society for Microbiology (ASM) that is considering standards of training in micro- biological techniques for recombi- nant DNA research. When a report is submitted to NIH, it will be shared with institutions, IBC's, and principal investigators for their use. National certification, however, should not be attempted until the ASM-NIH criteria for training have been adopted and evaluated.

It should be noted that, aside from the Nuclear Regulatory Commission's standards for training in radioisotope work, there seem to be no other training criteria at present in biomedical research. Thus, the work of the ASM Panel will establish a precedent. For these reasons NIH should proceed carefully and in stages while promoting safety training for researchers. NIH will develop training courses based on these standards and will make them widely available.

NIH responsibilities

As in the public hearing on the Guidelines as proposed in 1976, many commentators again urge openness, candor, and public participation in the revision process, emphasizing shared responsibility and accountability from the local to the national level.

Due-Process Considerations. A focus of public comment at the December 1977 hearing was on "procedural due process" to ensure public participation in the development of NIH recombinant DNA policies. Much of the public testimony and comment in letters focused on public representation on

committees. Also stressed was the need for public notice of all meetings, and for procedures to ensure public participation in the exercise of responsibilities by the NIH Re- combinant Advisory Committee (RAC), the Office of the NIH Director, and the Advisory Committee to the Director (DAC).

Several commentators specifically urged that the Guidelines spell out procedures—

- To develop and promulgate the list of "non-novel experiments" and to amend the list;
- To certify host-vector systems;
- To permit the Director, on the advice of the RAC, to grant exceptions from prohibited experiments (as for risk-assessment studies), and
- To modify the Guidelines in the future.

There were also suggestions that guidance be given on how to deal with infractions of the guidelines. Specifically, one commentator suggested that procedures should outline in detail—

- How charges of noncompliance could be brought,
- How charges of noncompliance would be evaluated,
- What opportunities would be provided for the principal investigator and his institution to defend themselves against charges, and
- What procedures would be available before the termination of funding or other penalties are invoked.

Because of the RAC's key role in the development and monitoring of NIH recombinant DNA policies, a number of comments were directed to the committee's nature and functions. Many commentators focused on its membership, urging that the guidelines define procedures for the nomination and selection of members. Suggestions for potential membership included more representation for certain scientific disciplines, such as virology and microbiology; greater representation from the occupational and environmental health and safety community; and more public representation, including perhaps a "dissenter" from current NIH policies.

A number of comments concerned RAC operations. The committee was urged to formalize schedules so that all concerned would know when meetings would be held over the next 2 to 3 years. Further, it was urged that notices and complete agendas be placed in the FEDERAL REGISTER for each meeting, that all documents for committee consideration be made available to the public, and that the NIH pay for public witnesses to attend RAC meetings.

In response to these comments, part IV of the PRG-NIH has been reorganized extensively. The responsibilities from the local to the national level are more clearly stated and defined. For NIH responsibilities, procedures suggested by commentators have been specified to afford opportunity for public comment. A special appendix to the PRG-NIH includes relevant implementation documents from ORDA that explain the administration of the NIH guidelines at the local and national levels.

Part IV of the PRG-NIH has more clearly defined a structure for responsibilities at those levels, with opportunity for public and scientific participation. It formalizes a process that has been occurring informally. Flexibility, however, remains essential to avoid unnecesary and protracted delays in decisionmaking. Clearly, a full panoply of clearance procedures, including a public hearing, is not essential for most of the functions under the guidelines. For many functions, the need for public review can be met through publication in the FEDERAL REGISTER. For certain responsibilities, comment may be solicited. Because procedures by which policies will be developed at the national and local levels are of key importance, notice is required for major policy initiatives.

Application to the Private Sector. Several commentators spoke on the application of the NIH guidelines to the private sector. Specifically, NIH was urged to provide voluntarily to private industry--

- Advice on interpretation of the guidelines,
- Registration of projects,
- Certification of host-vector systems,
- Advice on the operation of institutional biosafety committees, and
- Protection for patent and proprietary information.

In June 1976 representatives of private industry were invited to NIH to be briefed on the guidelines about to be released. Since their release, NIH has held several other meetings with representatives from the private sector. Commerce Department representatives on the interagency committee played a leading role in working with private industry on adoption of the safety standards of the NIH guidelines. All relevant industries have agreed to abide by those standards. However, many of the services provided to NIH grantees and contractors have not been extended to the private sector. In large part, efforts to do so have been held in abeyance because of possible Federal legislation.

After carefully considering the comments at the public hearing and in letters received, NIH will extend certain added services to the private sector in several of the areas suggested by the commentators. It is still important, despite proposed legislation, that the NIH provide for mechanisms to allow private-sector participation. Further, if legislation is enacted, the NIH guidelines will serve as the basis for regulation that will encompass private industry. Thus, a new section has been added to part IV that provides the opportunity for industry's participation in a voluntary fashion.

Office of the Director. As suggested by the commentators, the responsibilities of the Director have been grouped, for purposes of clarity, under specific heading "Office of the Director, NIH" in the PRG-NIH. For many of the responsibilities cited—including revision of the guidelines, certification of host vector systems, and authority for exemptions and exceptions—appropriate notice and opportunity for public comment is specified. This opportunity for comment will provide structure for the exercise of discretion by the Director.

The PRG- RAC clarified the relevant responsibilities of the NIH Director and RAC with regard to the certification of host-vector systems. Those concepts are adopted in the PRG—NIH.

Recombinant Advisory Committee. Many commentators have made suggestions concerning the structure, function, and scope of responsibility of the RAC. The emphasis in RAC membership has been on ensuring relevant scientific representation. It is essential that the committee have the technical expertise necessary to develop, modify, and interpret the guidelines in light of scientific evidence. Representative have been added from scientific disciplines, such as botany, to ensure a broad scientific overview. As a bridge between the implications for science and public policy, public members now serve on the committee, and additional public members may be added. Current public members are Dr. Emmette S. Redford, Ashbel Smith, professor of government and public affairs at the Lyndon B. Johnson School of Public Affairs, University of Texas, at Austin, and Dr. LeRoy Walters, director for the Center of Bioethics, Kennedy Institute, Georgetown University.

In order to insure fairness and sensitivity to the public commentators, procedures for nomination to the RAC will be in accord with the report by the NIH Grants Peer Review Study Committee. Thus, NIH will publish an announcement of upcoming vacancies periodically, with instructions on how to submit nominations. By this means, a wide spectrum of nominations will be considered to assure appropriate representation suited to the RAC's needs.

In brief, the operations of the RAC have been more clearly detailed in the PRG-NIH. The procedures for the selection of members and the operations

of the committee are in the process of being formalized for the benefit of the scientific community and the public.

NIH Components. A new section in the PRG-NIH now describes all other functions of NIH, including the responsibilities of the Office of Recombinant DNA Activities (ORDA). It should be noted that the responsibility of the peer review groups (study sections) for an independent assessment of the recombinant DNA research protocols has been eliminated. This responsibility would be solely ORDA's in conjunction with the local institutional biosafety committee.

Several commentators urged new responsibilities for ORDA and additional personnel to fulfill them. Some recommended that the Office be responsible for inspecting and certifying laboratories at the P3 level. Currently NIH has the responsibility for certifying only P4 facilities. At present NIH operates, at the Frederick Cancer Research Center in Frederick, Md., and at NIH in Bethesda the only P4 facilities in this country. Responsibilities for certification falls to NIH because of the special nature of P4 facilities. P3 facilities, on the other hand, do not require special expertise at the national level, and there is no need for them to be nationally certified. As specified, the local institution has and should have responsibility for monitoring and certifying P1, P2, and P3 facilities.

Several commentators urged an increased flow of information to the public and scientific community alike. ORDA is playing a key role in disseminating information through the Recombinant DNA Technical Bulletin. This is a new publication that attempts to link investigators involved in recombinant DNA research, both in the United States and abroad, with the active advisory groups and organizations. In light of comments received, the bulletin will include in the future far more information for institutional biosafety committees and for the several advisory groups at the national and social levels.

In response to another suggestion, ORDA will be as available as possible to State and local governments for technical advice. Currently ORDA serves as a clearinghouse for information related to recombinant DNA activities internationally, nationally, and locally.

Registration and compliance

It has become clear over the 2 years of administration of the guidelines that a new section must be added on general requirements for registration with NIH. This should apply not only to NIH grantees and contractors, but also to the private sector on a voluntary basis. Further, in light of the review of DHEW policies on the patenting of recombinant DNA research inventions, a section on disclosure of information is also necessary. Finally, as suggested, a section on compliance with the guidelines is needed. Thus new sections C and D on registration (including disclosure of information) and compliance have been added to the roles and responsibilities section of the PRG-NIH. These provisions, recommended in many comments on the guidelines and at the December public hearing, are necessary in the absence of legislation.

Registration. A number of commentators asked that the guidelines specify the requirements for registration. Accordingly, a new subsection has been added delineating the elements. If other requirements need be added, notice will be given of any change. All projects subject to the guidelines must be registered with ORDA. Voluntary registration for the private sector is provided in the revision, in response to suggestions by private-sector representatives.

Disclosure. Many comments, as previously noted, were directed to the protection of proprietary information. A new subsection outlining the elements for protection of proprietary data is included in response to these suggestions.

One commentator urged that no patents be granted for recombinant DNA research.

Shortly after the release of the Guidelines in 1976, NIH received a letter requesting a review of DHEW policies relating to the patenting of recombinant DNA research inventions. The letter prompted NIH to review current patent regulations governing institutional patent agreements and to consider how recombinant DNA research inventions should be handled under those terms. On the basis of extensive Department and Interagency Committee review, it was agreed that, at least for the present, recombinant DNA research inventions developed under DHEW/NIH support should continue to be administered within current HEW patent agreements. Each agreement, however, would require assurance of compliance with the physical and biological containment standards set forth in the Guidelines as a condition for the granting of a license.

Policy on Noncompliance. A commentator urged that a system of fines be spelled out. Monetary fines, more appropriate for regulations under legislation, will not be specified or assessed under the Guidelines; NIH has no current authority to impose fines. It will, however, suspend, limit, or terminate a grant or contract for noncompliance. A commentator recommended that penalty procedures be specified. Should it be necessary to suspend, limit, or terminate a grant, appropriate HEW procedures will be followed.

In summary, Part IV of the Guidelines on Roles and Responsibilities has been substantially revised in response to suggestions from many commentators. The PRG-NIH now provides even more opportunity for advice from the local to the national level. The spirit of cooperation and effective overview will be enhanced by the PRG-NIH at the local level between the research community and the public and at the national level among Federal agencies, the scientific community, and the private sectors.

Proposed Action: Environmental Impact Assessment

The recommendations of the Recombinant Advisory Committee have been carefully weighed, along with other public and scientific comments received on the Roles and Responsibilities section. In general, the PRG-RAC proposals have been adopted in the PRG-NIH, with certain modifications based on issues raised by the Director's Advisory Committee and other commentators. The issues considered by the Director and a discussion of them follow.

The Draft EIS on the original Guidelines published in 1976 elicited a number of recommendations that greater detail be provided on NIH implementation of the Guidelines for NIH grantees and contractors. They also recommended extending the Guideline standards to all public and private sectors where such research is being conducted. More specifically, commentators expressed the following concerns.

- That the membership of institutional biohazards committees (IBCs) should include specialists in population dynamics, ecology, and other disciplines;
- That the Draft EIS did not emphasize relevant safety training for laboratory personnel;
- That the NIH Guidelines had a far too limited scope, not reaching research in the non-Federal sectors;
- That the termination of NIH funds for violation of the Guidelines may not be the best sanction;
- That the inspection, certification, and surveillance processes might not insure compliance;
- That more attention should be given to medical surveillance and epidemiologic measures in the event of possible infection of the laboratory worker or contamination of the environment; and
- That local and State authorities be involved in the review and containment processes at the local level.

These comments were specifically addressed in the Final EIS. It was

noted that the Guidelines established an administrative framework for assigning responsibility to insure safety in NIH-supported recombinant DNA research—a responsibility shared among principal investigators, their institutions, and NIH. The institutions were required to establish biohazards committees to carry out institutional responsibilities.

As discussed in the Final EIS, there were several factors contributing to the expectation that NIH grantees, contractors, and intramural scientists would comply with the Guidelines. They included the fact that noncompliance could result in the termination of funding; that investigators and their institutions share responsibilities for compliance; and that peer pressure on investigators for compliance would be accomplished through responsible institutional officers, local biohazards committees, and NIH review.

The Final EIS also discussed, in response to commentators, general Federal regulations of all such research to insure that work beyond the aegis of NIH would be done under the safety standards of the Guidelines. A Federal Interagency Committee, chartered by the Secretary of HEW with the approval of the President, was convened under the chairmanship of Dr. Donald S. Fredrickson, Director, NIH. In March 1977 that committee with representatives of all relevant research and regulatory agencies recommended to the Secretary of HEW that legislation be enacted to regulate all recombinant DNA research. HEW Secretary Califano had legislation developed in light of the committee's recommendations. An administration bill drafted by the Department was introduced in the Senate by Senator Edward M. Kennedy, Chairman of the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, and in the House by Representatives Paul G. Rogers, Chairman of the Subcommittee on Health and the Environment of the Interstate and Foreign Commerce Committee. Congressional hearings were held, and respective committee bills were drafted, but not acted upon by Congress in its first session. New committee bills are pending congressional action.

The PRG-NIH, Parts I through III, reflect in large measure the safety of many of the experiments that would be exempt from the Guidelines or allowed at lower containment conditions. These changes are now proposed following an assessment that there would be no significant impact on the environment from the proposed revisions. The changes in Part IV largely reflect the concerns of the environmental commentators for greater emphasis on training in occupational and environmental safety and on explicit penalties for noncompliance. In addition, measures are provided that would allow private-sector engagement with the NIH, including registration of recombinant DNA activities.

To address occupational and environmental health and safety concerns, several changes are proposed in the implementation, review, and monitoring of recombinant DNA activities at the local and national levels, to insure appropriate safety practices and procedures that would minimize any significant environmental impact. These modifications primarily focus on a restructuring and amplification of Part IV, "Roles and Responsibilities," and an important and significantly expanded delegation of authority to local institutions.

These major changes from the 1976 Guidelines, which extend beyond the PRG-RAC, have resulted from a careful consideration of many comments received. The foremost concern during this process was to insure occupational and environmental safety, while at the same time refining the interdependent roles necessary to achieve this goal. Also, it was desirable to try to simplify and clarify administration of the Guidelines, as suggested by several commentators, thereby promoting a more successful application of their safety features. The revisions that have been proposed for Part IV represent a further step toward insuring the safe conduct of this research and minimizing the possibility of any untoward environmental effects.

In response to several requests for expanding the applicability of the guidelines, institutions receiving NIH funds for recombinant DNA projects and their "biosafety committees" (the proposed new designation for biohazards committees) are given responsibility for reviewing all recombinant DNA work conducted at the institution regardless of source of funds. This increase in the scope of review will better insure the safe conduct of recombinant DNA research.

Further, biosafety committees (IBCs) have been given broader responsibilities. The PRG-RAC proposed to allow the IBC's to approve single-step reductions in containment levels in experiments with purified DNA or characterized clones. This is retained in the PRG-NIH. In response to other comments, however, it is deemed necessary to specify IBC responsibilities for determining containment levels required by the guidelines. The PRG-NIH requires the IBC's to make independent evaluations of these containment levels. This should strengthen safety considerations locally.

It was also suggested that NIH delegate to biosafety committees the responsibility for approving or disapproving, on behalf of the institution, proposed recombinant DNA research, based on their independent assessment of the safety standards applied, and that IBC approval be sufficient for the research to proceed. NIH, through ORDA, would review all local committee actions to insure compliance with the guidelines, thereby maintaining national standards. This proposal has a number of advantages. It would simplify previous approval procedures and minimize delays due to NIH administration. Accountability for safe conduct of the research would reside at the local level, with appropriate Federal overview.

It is believed that incorporation of these recommendations for increased local authority would enhance implementation of the guidelines, since important responsibilities are clarified and more suitably located.

As mentioned earlier, another major change includes the restructuring and amplification of Part IV of the guidelines. Publication of the Director's decision on the 1976 guidelines, the draft EIS, and the PRG-RAC elicited numerous comments calling for more discussion and information on implementation, particularly for further clarification of responsibilities and roles at the local level. Accordingly, the contents of Part IV are presented in a format different from the current guidelines and the PRG-RAC, with the intent of more clearly alining the various duties.

At the request of several commentators, Appendix D, dropped from the PRG-RAC, has been revised and updated as "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research." It provides a compendium of useful safety information, including instructions on emergency procedures, laboratory techniques for biohazard control, and decontamination and disposal methods. Expanded to include complementary information on roles and responsibilities, it provides directions for the operation of a biosafety committee, suggestions to increase the biological safety officer's efficiency, and more detail on the elements of a medical surveillance program. Criteria for certifying biological safety cabinets illustrate the level of detail. It is believed that the PRG-NIH, strengthened by these additions, provide a higher measure of protection for researchers, the public, and the environment.

Considerable attention has been focused on the institutional biosafety committees. Commentators have raised questions concerning the committees' role, membership, and operation. Consideration of various sugges-

tions has resulted in changes in the IBC membership requirements.

Noninstitutional representation is now proposed on biosafety committees, going beyond the PRG-RAC.

The role and responsibilities of the local biosafety committees have been restated and refined in response to numerous comments. They are also strengthened by the required membership of the biosafety officer. The PRG-RAC proposed the designation of a biological safety officer for each institution where P3- and P4-level recombinant DNA research was conducted, reflecting the practice of a growing number of American institutions and the recommendations of the British "Williams Committee Report." The requirement is intended to insure that a clearly designated individual will have the primary administrative responsibility for the implementation of institutional policies and biosafety committee decisions.

A related issue which drew several comments and recommendations concerned medical surveillance, or health monitoring. Responsibility for determining medical surveillance procedures for research personnel was transferred from the principal investigator to the institution, because the RAC felt that institutions would have access to a broader range of expertise.

Specific information on medical conditions was moved to the laboratory safety monograph, which includes additinal recommendations on health monitoring and program content. General language describing the elements of a medical surveillance program was retained in Part IV as part of the institution's responsibility.

The addition of information and the further emphasis on health monitoring should enhance occupational health and safety at the local level. It should be noted that a collaborative effort is underway between NIH and the Center for Disease Control to establish a mechanism for providing emergency teams of experts to respond to major laboratory accidents.

Probably no other issue generated as much comment as that of training. According to one commentator, training "probably represents the key to safety." He goes on to say that any break in technique could destroy physical containment procedures. Indeed, training in good microbiological practices could be considered the first line of defense, as it serves to protect the worker as well as prevent contamination of the environment inside and outside the laboratory. The PRG-RAC proposed the addition of a requirement for the training of research personnel in the use of good microbiological technique. In the PRG-NIH, the principal investigator must be trained, and must insure the training of laboratory personnel, before undertaking recombinant DNA experiments. The laboratory safety monograph includes a section on "Laboratory Techniques for Biohazard Control" which describes good practices regarding pipetting, centrifuging, and the use of syringes and needles. Altogether, training requirement s have been further emphasized and strengthened in the PRG-NIH.

Several commentators wanted training standards to be set in the Guidelines or by NIH, the institution, or the biosafety committees. Others opposed setting standards. Still others recommended mandatory, formal evaluation and certification of investigators to test for competency in microbiological techniques. NIH is currently funding a Working Panel of the American Society of Microbiology (ASM) which is considering standards of training in microbiological techniques for recombinant DNA research. Plans call for the dissemination of a report for the use of institutions, IBC's, and principal investigators, once NIH receives the recommendation of the ASM Panel.

NIH considers it premature to require national certification, as suggested by some. There are so few models for formal training standards in biomedical research that NIH has decided to proceed cautiously, while continuing to promote safety training. As yet, there is no consensus, no one best way to accomplish this training, and therefore the desired results may best be achieved by allowing institutions, biosafety committees, and investigators some flexibility. Meanwhile, NIH plans to develop courses to be based on the NIH/ASM standards and to offer them widely. The Laboratory Safety Monograph also contains a summary of safety training aids, materials, and courses offered by the NIH and others.

From the discussion of these issues, it should be evident that measures have been undertaken in the revision of Part IV of the Guidelines to emphasize occupational health and safety. The principal measures would be the strengthening of training requirements and activities, the designation of someone in the institution as a member of the biosafety committee to handle biological safety questions generally, the delegation of more authority to the institution, and better definition of responsibilities at the local level. The impact of these actions will be the promotion of safer conduct of this research, thus affording a greater measure of protection to the environment.

In summary, a key focus of public comment was on "procedural due process" to insure public participation in the development of NIH recombinant DNA policies. In response to those suggestions in several instances, opportunity for public comment is afforded through activities of the Director, NIH, and the RAC. In addition, public representation on the RAC will be considered further, with a nomination process to insure a wide range of individuals for selection. New general compliance and registration sections have been included in the PRG-NIH that do not appear in the current Guidelines. These sections are directly responsive to stated concerns that the importance of these safety standards and procedures be emphasized.

NIH will continue to work closely with other relevant research and regulatory agencies, particularly the Environmental Protection Agency and the Occupational Safety and Health Administration. Both of these agencies are represented on the Federal Interagency Committee on Recombinant DNA Research.

NIH has created over the past 2 years several internal committees that are critically examining areas where work with potential biohazards is involved in the laboratory.

Finally, a key concern of all commentators was the need for programs in occupational and environmental safety which would include health surveillance for laboratory personnel and the community. Recombinant DNA research policies have stimulated a broad NIH commitment and interest in laboratory safety. NIH has a mandate for national leadership in laboratory safety programs, and the proposed revisions reflect full acceptance of that responsibility.

APPENDIX A-1

Table: Comparison of Containment Levels

The following table compares the containment levels for all permissible types of recombinant DNA experiments. It designates the levels under the Guidelines now in effect (since June 1976), under those proposed by the RAC (September 1977), and under the present NIH-proposed revisions.

A dash (—) indicates that the category is not classified in the edition of the Guidelines under which the dash appears.

It should be stressed that the table is not definitive, since the containment levels of the Guidelines have been redefined and other requirements modified.

Appendix A

COMPARISON OF THE CONTAINMENT LEVELS OF THE 1976 GUIDELINES AND THE PROPOSED REVISED GUIDELINES

INSERTED DNA	CONTAINMENT LEVELS					
	JUNE 1976 GUIDELINES		RAC PROPOSED REVISED GUIDELINES		NIH DIRECTOR'S REVISED GUIDELINES	
	PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL
Shotgun Experiments						
1. Primate	P4 or P3	EK2 EK3	P4 or P3	EK1 EK3	P2 —	EK2[1] —
2. Primate DNA from uninfected cells	—	—	P3	EK2	—	—
3. Embryonic primate	P3	EK2	—	—	—	—
4. Mammals (other than primates)	P3	EK2	P2	EK2	P2	EK2
5. Birds	P3	EK2	P2	EK2	P2	EK2
6. Cold blooded vertebrates	P2	EK2	P3 or P2	EK1 EK2	P2 or P1	EK1 EK2
7. embryonic and germ line	P2	EK1	P2 or P1	EK1 EK2	—	—
8. producing potent toxins	P3	EK2	—	—	—	—
9. producing potent polypetide toxins	—	—	P3	EK2	P3	EK2
Lower eukaryotes						
10. producing toxins, or are pathogens	P3	EK2	—	—	—	—
Shotgun Experiments (Cont.)						
11. producing potent polypeptide toxins, or are pathogens	—	—	P3	EK2	P3	EK2
12. producing non-polypeptide toxins	—	—	P3 or P2	EK1 EK2	P3 or P2	EK1 EK2
13. producing toxins affecting invertebrates or plants.	—	—	P3 or P2	EK1 EK2	P3 or P2	EK1 EK2
14. remainder of species	P2	EK1	P2 or P1	EK1 EK2	P2 or P1	EK1[2] EK2
15. Plants	P2	EK1	P2 or P1	EK1 EK2	P2 or P1	EK1 EK2
16. carrying pathogens or making dangerous products	P3	EK2	—	—	—	—
17. carrying pathogens or making polypeptide toxins	—	—	P3	EK2	—	—
18. making potent polypeptide toxins	—	—	—	—	P3	EK2
19. making non-polypeptide toxins	—	—	P3 or P2	EK1 EK2	P3 or P2	EK1 EK2

COMPARISON OF THE CONTAINMENT LEVELS OF THE 1976 GUIDELINES AND THE PROPOSED REVISED GUIDELINES

INSERTED DNA	CONTAINMENT LEVELS					
	JUNE 1976 GUIDELINES		RAC PROPOSED REVISED GUIDELINES		NIH DIRECTOR'S REVISED GUIDELINES	
	PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL
Prokaryotes exchanging genetic information with E. coli						
20. Class 1 CDC agents	P1	EK1	— [1]	—	P1	EK1[3]
21. Class 2 CDC agents	P2 or P2	EK1 EK2	—	—	P2	EK1[3]
22. Prokaryotes not exchanging genetic information with E. coli	P3 or P2	EK1 EK2	See Prokaryotic DNA recombinants (Categories 24-26)		P2 or P1	EK1 EK2
23. If pathogenic species	P3	EK2			P3	EK2
Prokaryotic DNA recombinants						
24. source of DNA is extensively characterized	—	—	P2 or P1	EK1 EK2	—	—
25 source of DNA is not extensively characterized	—	—	P2 or P3	EK2 EK1	—	—
26. source of DNA is pathogenic species	—	—	P3	EK2	—	—
Characterized clones						
27 Species that exchange information with E. coli	P1	EK1	—	—	See Characterized clones (Category 50)	
28. Species that do not exchange with E. coli	P2	EK1	See Characterized clones (Category 50)		See Characterized clones (Category 50)	
29. Purified DNA other than Plasmids, Bacteriophages, and Other Viruses:	One step reduction in physical or biological containment from that used in corresponding shotgun experiments		Same		Same, except for primate DNA (See Footnote #1)	
Plasmids, Bacteriophages and Other Viruses						
30. Animal viruses	P4 or P3	EK2 EK3	See Categories 32-41		*	
31. when clones shown to be free of harmful regions	P3	EK2	See Categories 32-41		*	
Viruses of Warm-Blooded Vertebrates						
32. DNA viruses + transcripts of retrovirus genomes	—	—	P4 or P3	EK1 EK3	*	

COMPARISON OF THE CONTAINMENT LEVELS OF THE 1976 GUIDELINES AND THE PROPOSED REVISED GUIDELINES

	INSERTED DNA	CONTAINMENT LEVELS					
		JUNE 1976 GUIDELINES		RAC PROPOSED REVISED GUIDELINES		NIH DIRECTOR'S REVISED GUIDELINES	
		PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL
33.	for purified subgenomic segments or less than complete genome	—	—	P3	EK2	*	
	DNA transcripts of other RNA viruses						
34.	non-segmented genome	—	—	See Categories 32-41		*	
35.	segmented genome	—	—	P3	EK2	*	
	Viruses of Cold-Blooded Vertebrates						
36.	DNA viruses + transcripts of retrovirus genomes	—	—	P4 or P3	EK1 EK2	*	
37.	for purified subgenomic segments or less than complete genome	—	—	P2	EK2	*	
	DNA transcripts of other RNA viruses						
38.	non-segmented genome	—	—	See Categories 36-37		*	
39.	segmented genome	—	—	P2	EK2	*	
	Viruses of Invertebrates and Protozoa						
40.	Baculoviruses, EPA registered	—	—	P1 or P2	EK2 EK1	*	
41.	Other viruses	—	—	Same as for viruses of cold-blooded vertebrates		*	
42.	Plant viruses	P3 or P2	EK1 EK2	P3 or P2	EK1 EK2	*	
43.	Primate mitochondria	P3 or P2	EK1 EK2	P3 or P2	EK1 EK2	—	—
44.	Other eukaryotic mitochondrial or chloroplast DNA	P2	EK1	P2	EK1	—	—
45.	Eukaryotic mitochondrial or chloroplast DNA	—	—	—	—	P2	EK1
46.	Prokaryotic plasmid or phage which exchange with E. coli	Same as shotgun conditions for host		—	—	Same as shotgun conditions for host	
47.	when known not to contain harmful genes, or purified segments	P1	EK1	—	—	(See Footnote #3)	

COMPARISON OF THE CONTAINMENT LEVELS OF THE 1976 GUIDELINES AND THE PROPOSED REVISED GUIDELINES

	INSERTED DNA	CONTAINMENT LEVELS					
		JUNE 1976 GUIDELINES		RAC PROPOSED REVISED GUIDELINES		NIH DIRECTOR'S REVISED GUIDELINES	
		PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL
48.	Prokaryotic plasmid and phage which do not exchange information with E. coli	Same as shotgun conditions for host		Same as shotgun conditions for host		Same as shotgun conditions for host	
49.	minimum containment	P3 or P2	EK1 EK2	—	—	—	—
50.	Characterized Clones	See Characterized clones (Category 27-28)		IBC may approve single-step reduction in physical or biological containment		IBC may approve single-step reduction in physical or biological containment, except for primate DNA	
				Reduction of more than one step requires NIH approval		Reduction of more than one step, or reduction of primate DNA requires NIH approval.	
	Animal Host-Vector Systems						
	Defective polyoma virus						
51.	Containing DNA of non-pathogenic organism	P3	cultured cells	See Categories 58-60		**	
52.	Containing class 2 animal virus sequences	P4	cultured cells	See Categories 58-60		**	
53.	when clone shown to contain only harmless regions	P3	cultured cells	See Categories 58-60		**	
	Defective SV40 virus						
54.	DNA from any non-pathogenic organism or Class 1 virus	P4	established cell lines	See Categories 61-65		**	
55.	if inserted segment is purified prokaryotic DNA or previously cloned eukaryotic DNA whose function is known	P3	established cell lines	See Categories 61-65		**	
56.	if defective SV40 lacks late region, there is no helper virus, and no infectious virus is being produced	P3	established cell lines	See Categories 61-65		**	
57.	if non-permissive cells transformed	P3	established non-permissive cell lines	See Categories 61-65		**	
	Defective or intact polyoma virus						
58.	Containing DNA of Class 1 or Class 2 bacteria, except for species producing potent polypeptide toxins	—	—	P3	cultured cells	**	

COMPARISON OF THE CONTAINMENT LEVELS OF THE 1976 GUIDELINES AND THE PROPOSED REVISED GUIDELINES

	INSERTED DNA	CONTAINMENT LEVELS					
		JUNE 1976 GUIDELINES		RAC PROPOSED REVISED GUIDELINES		NIH DIRECTOR'S REVISED GUIDELINES	
		PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL	PHYSICAL	BIOLOGICAL
59.	Containing DNA of eukaryote not producing potent polypeptide toxin	—	—	P3	cultured cells	**	
	Unconditionally defective polyoma virus						
60.	Subgenomic segments of Class 1 or Class 2 viruses which do not replicate in mouse cells	—	—	P3	cultured cells	**	
	SV40 and Adenovirus Types 2 and 5						
	Unconditionally defective by deletion in essential gene region						
61.	if inserted DNA is from Class 1 or 2 bacteria (except for species producing potent polypeptide toxins) or from eukaryote not producing potent polypeptide toxin	—	—	P4	cultured cells	**	
62.	if inserted DNA is purified prokaryotic segment, or identified segment of eukaryotic DNA previously cloned in prokaryotic host-vector system	—	—	P3	cultured cells	**	
63.	Unconditionally defective by deletion in capsid genes						
	containing DNA from Class 1 agents	—	—	P4	established cell line	**	
64.	if vector is known to be free of complete viral genome	—	—	P3	established cell line	**	
65.	SV40 or Ad. 2 and 5 DNA plus subgenomic sequences from eukaryotic organisms or Class 1 or 2 agents; recombinant molecule defective and no virus being produced	—	—	P3	non-permissive cells	**	

APPENDIX A

FOOTNOTES

1. Lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee, but requires NIH approval.

2. Plant pathogenic or synbiotic fungi that do not produce potent toxins are specifically included among the remainder of species in this class of lower eukaryotes.

3. It is expected that many of the prokaryotes that exchange genetic information with *E. coli* by known physiological processes will be exempted from these Guidelines by appearing on the "list of exchangers" (See Guidelines, Section I-E-4.)

*See table III of Guidelines, Section III-A-2-a-(2)-(e).

**See table IV of Guidelines, Section III-C-3.

APPENDIX B-1

Table: Classification of NIH-Funded Experiments as of December 1976

The following table lists all P2 and P3 recombinant DNA research projects supported by NIH as of December 1977. The P1 projects are roughly a 50-percent sample. The table designates the containment labels under the Guidelines now in effect (since June 1976), under those proposed by the RAC (September 1977), and under the present NIH-proposed revisions.

Appendix B--2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	B. subtilis	K-12, C600*	pBR313	?Exempt	P1 + EK1
P2 + EK1 or EK2	S. typhimurium	K-12	K-12	?Exempt	Exempt
P2 + EK1	Sea Urchin	K-12	pSC101, pSP2	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Slime Mold	K-12	λ, pSC101 pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Maize Chloroplast	K-12, HB101*	various plasmids	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Neurospora	K-12	pMB9, pML21	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Embryonic Xenopus	K-12	pMB9, pSC101	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
	Characterized Xenopus	"	"	P2 + EK1	P1 + EK1
P2 + EK1	B. subtilis	K-12	pMB9, pSC101	?Exempt	P1 + EK1
P2 + EK2	Embryonic Xenopus	χ1776	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
	Characterized Xenopus	"	"	P2 + EK1	P1 + EK1

Appendix B--3

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK2	S. typhimurium	K-12	λ, Col E1	?Exempt	Exempt
P2 + EK2	Characterized Xenopus	K-12	λ	P2 + EK1	P1 + EK1
P2 + EK1	Mouse Mitochondria	C600*	pSC101, pMB9	P2 + EK1	P2 + EK1
P2 + EK1	Drosophila	K-12	various plasmids	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Paramecium	K-12, HB101*	pMB9, λ	P2 + EK1	P2 + EK1
P2 + EK1	Sea Urchin	K-12	λ	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK2 or P3 + EK1	Actinomycetes	K-12,	6λ, Col E1	P2 + EK2 or P3 + EK1	P3 + EK2
P2 + EK2 or P3 + EK1	Streptomyces	K-12, χ1776	pSC101	P2 + EK2 or P3 + EK1	P2 + EK1 or P1 + EK2

Appendix B—4

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Drosophila	K-12	pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Sea Urchin	K-12	pMB9, pBR322, pSF2124, pBGP120	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK2	Triturus cristatus	C600*	pMB9, pSC101, pCR1	P2 + EK2 or P3 + EK1	P2 + EK2 or P3 + EK1
P2 + EK1	Notophthalmus viridesceus		"	P2 + EK1 (RAC decision)	P2 + EK1
P2 + EK1	Silkmoth	HB101*	pML21	P2 + EK1 (RAC decision)	P2 + EK1
P2 + EK1	B. subtilis	C600*	pBR313	?Exempt	P1 + EK1
P2 + EK1	Drosophila	K-12	Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
	Embryonic Xenopus	K-12	pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B—5

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Neurospora	K-12	pMB9, pBR322, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	C600*	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12	pMB9, pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	B. subtilis	C600*	pMB9, pSC101, pBR322	?Exempt	P1 + EK1
P2 + EK1	Drosophila	K-12	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12	λ	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12, C600*	Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--6

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Drosophila	HB101*	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12	pMB9, pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EL2
P2 + EK1	Drosophila	K-12, HB101*, SF8	pMB9, pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Neurospora	K-12	pMB9, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Neurospora	C600*	λ, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12	pBR322, RSF2124	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Caulobacter crescentus	K-12	λ, RSF2124	?Exempt	~~Exempt~~ P1 + EK1

Appendix B--7

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Yeast	C600*, RR1*	λ, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Tetrahymena	HB101*, SF8*	pBR313, RSF2124, pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
	Yeast				
	Drosophila	"	"	"	"
	Embryonic Anhystoma (Amphibian)	"	"	"	"
	Characterized Xenopus	"	"	P2 + EK1	P1 + EK1
	Characterizal rabbit (pBG1)	"	"	P2 + EK1 (RAC decision)	P2 + EK1
	Triturus	"	"	"	"
P2 + EK1	Slime Mold	K-12	λ, pMB9, pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12	λ, pMB9, pBR322, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	S. typhimurius	K-12	λ, pMB9, pBR322, Col E1	?Exempt	Exempt

Appendix B--8

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Mouse Mitochondria	C600*	pSC101, Col E1	P2 + EK1	P2 + EK1
P2 + EK1	Slime Mold	C600*, HB101*, SF8*	λ, pMB9, pBR313, pBR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12	Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12	pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Soybean	HB101*, RR1*	pBR322, pBR313, pSC101, pAC184	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12	RSF2124, pBR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--9

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Characterized Xenopus	C600*, χ1776	pSC101, Col E1	P2 + EK1	P1 + EK1
	Sea Urchin			P2 + EK1 or P2 + EK2	P2 + EK1 or P1 + EK2
	Mouse Mitochondrial			P2 + EK1	P2 + EK1
	Drosophila			P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
	Characterized staphylococcus			P2 + EK1	P2 + EK1
P2 + EK1	Yeast	K-12	pCR1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	DC51*	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Sea Urchin	K-12	pSC105	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Leishmania (protozoan)	K-12	pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--10

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Sea Urchin Paramechinus milaris	K-12	λ, pSC101, pSP2, pSP17	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P1 + EK1	E. coli (enteropathogenic)	K-12, C600*, HB101*	pSC101, ISP 2124, pBR313, pBR322, pBR333	?Exempt	Exempt
P2 + EK1	B. subtilis	K-12	Col E1	?Exempt	P1 + EK1
P2 + EK1	Bean	K-12	λ, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P1 + EK1	E. coli (enteropathogenic)	K-12	Col E1	?Exempt	Exempt
P2 + EK1	B. subtilis	K-12	K-12 plasmids	?Exempt	P1 + EK1
P2 + EK1	S. typhimurium	K-12	λ, pMB9, pSC101	?Exempt	Exempt
P2 + EK1	Yeast	C600*	λ, pSC101, pMB9, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--11

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Drosophila Sea Urchin	K-12	pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
	Characterized Xenopus	K-12	pSC101, Col E1	P2 + EK1	P1 + EK1
P2 + EK1	Drosophila Sea Urchin	K-12	pSC101, pMB9, pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Frog Mitochondria	HB101*	pMB9	P2 + EK1	P2 + EK1
P2 + EK1	Embryonic Frog	HB101*	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Amoeba	HB101*	pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12	pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--12

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Yeast Drosophila	SF8*, HB101*	pMB9, pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	B. subtilis	SF8*	pMB9	?Exempt	P1 + EK1
	B. megaterium			?Exempt	P1 + EK1
	Aerobacter cloacae			?Exempt	P1 + EK1
	Aeromonas formicas			?Exempt	P1 + EK1
	Strep. lactis			?Exempt	P1 + EK1
	Yeast			P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	HB101*	p2124	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	HB101*	pMB9, pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--13

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Embryonic Tibal	HB101*	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Corn	K-12	λ	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Sea Urchin Yeast	K-12	λ, pSC101	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12, HB101*	pSC101, 105, pMB9, pML2, pCR1, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12 C600*	pMB8, pMB9, pBR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	HB101*	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Neurospora	K-12	pBR313, pBR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Corn	K-12	pBR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12	pMB9, pBR322, pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Sea Urchin	C600*	pSC101, Col E1, pCR16, pML21	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila Sea Urchin	K-12	pSC101, pOCP120	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12	λ, pMB9, pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Protozoan Yeast Drosophila Sea Urchin	K-12	pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	S. typhimurium	RR1*	pBR313, 322	?Exempt	Exempt
P2 + EK1	Rabbit	K-12	pCR1	P2 + EK1 (RAC decision)	P2 + EK1
P2 + EK1	Neurospora	K-12	pMB9, Col E1, pSC101	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Embryonic Salmon	K-12	pMB9, Col E1, pSC101	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Sea Urchin	C600*	pSC101, Col E1, pCR16, pML21	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	HB101*, χ1776	pMB9, pCR1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	B. subtilis	χ1776	pSC101	?Exempt	P1 + EK1

Appendix B--16

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Yeast	K-12	pMB9, pML21, λ, pRB313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	S. typhimurium	K-12	pMB9, pML21, λ, pRB313	?Exempt	Exempt
P2 + EK1 (NIH approved)	B. subtilis	B. subtilis, RC138	pIM13	?Exempt	Exempt
P2 + EK1	Caulobacter crescentus	K-12	pMB9, pSC101	?Exempt	~~Exempt~~ P1 + EK1
P2 + EK1	B. subtilis	C600*	pMB9	?Exempt	~~Exempt~~ P1 + EK1
P2 + EK1	Drosophila	HB101*	pMB9, pBR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Protozoan	HB101*	pBR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	C600*, χ1776,	pSC101, pSC105, pMB9, pML2, pCR1, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--17

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Corn	K-12	λ	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	B. subtilis	K-12	pBR313, pMB9, pIM2	?Exempt	P1 + EK1
P2 + EK1	Drosophila	K-12, χ1776	pSC101, pMB9, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	K-12	pMB9, pSC101, pBR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Characterized Yeast	K-12	pSC101, 105, RSF2124	P2 + EK1	P1 + EK1
P2 + EK1	Protozoan	HB101*	pBR313, pBR322, pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Neurospora	K-12	pBR313, pBR322, pMB9, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--18

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Yeast.	K-12	pMB9, pSC101, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Drosophila	C600*	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Klebsiella pneumoniae	K-12	pSC101, Col E1	?Exempt	Exempt
P2 + EK1	Yeast	K-12, x1776	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	S. typhimurium	K-12, C600*	Col E1	?Exempt	Exempt
P2 + EK2	Toad	K-12	pMB9, pSC101	P2 + EK2 or P3 + EK1	P2 + EK2 or P3 + EK1
P2 + EK1	Sea Urchin	K-12	λ	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	C600*	λ, pSC101, pMB9, Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--19

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Drosophila	C600*	pSC101	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Gnat	K-12	pUR313	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Protozoan	K-12	pMB9, pUR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	K-12	Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	S. typhimurium	K-12	pUR322, pUR317	?Exempt	Exempt
P2 + EK1	Yeast	K-12	pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Appendix B--20

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Sea Urchin	K-12	pSP2, pSP17	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Mouse Mitochondria	K-12	pSC101	P2 + EK1	P2 + EK1
P2 + EK1	Embryonic Xenopus	C600*	pCR1, pSC101, Charon 4A	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Yeast	E. coli	λ, pBR322	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Sea Urchin	K-12	2124	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1	Chloroplast	K-12	pSC101, Col E1	P2 + EK1	P2 + EK1
P2 + EK1	Chloroplast	K-12	2124	P2 + EK1	P2 + EK1

Appendix B--21

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P2 + EK1	Yeast	C600* HB101*	λ, pMB9	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1 (RAC approved)	Chicken	K-12	λ	P1 + EK1 (RAC approved)	P1 + EK1 (RAC approved)
P2 + EK1	Yeast	K-12, HB101*, SF8*	λ	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1 (RAC approved)	Rabbit Globin	χ1776, K-12	pMB9	P2 + EK2	P2 + EK2
P2 + EK1 (RAC approved)	Chicken	HB101*	pHB1001, pHB1003	P2 + EK1 (RAC approved)	P2 + EK1 (RAC approved)
P2 + EK1	Yeast	K-12	Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2
P2 + EK1 (RAC approved)	Human Globin	HB101*, C600*	JW102	P2 + EK1 (RAC approved)	P2 + EK1 (RAC approved)
P2 + EK1	Yeast	K-12	Col E1	P2 + EK1 or P1 + EK2	P2 + EK1 or P1 + EK2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P3 + EK2	Mouse	[illegible]	[illegible] EK2	P2 + EK2	P2 + EK2
P3 + EK2	Mouse	χ1776	pBR322	P2 + EK2	P2 + EK2
P3 + EK2	Chicken	χ1776	pBR322	P2 + EK2	P2 + EK2
P3 + EK2	Hamster	χ1776	pCR1, pGC101	P2 + EK2	P2 + EK2
P3	Rabbit Globin DNA	Cultured Monkey Cells	Defective SV40	P3	P3
P3		Non-Permissive Mouse Cells	Defective SV40	P3	P2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P3 + EK2	Mouse	χ1776	pCR1	P2 + EK2	P2 + EK2
P3 + EK2	Rat	χ1776	pMB9, pBR322, pBR313	P2 + EK2	P2 + EK2
P3 + EK2	Human Embryo	"	"	P2 + EK2	P2 + EK2
P3 + EK2	Chicken	"	"	P2 + EK2	P2 + EK2
P3 + EK2	Human Embryo	χ1776 DM50/sup?	pMB9, λgtWES.λB	P3 + EK2	P2 + EK2
P3 + EK2	Chicken	χ1776	pMB9	P2 + EK2	P2 + EK2
P3 + EK2	Mouse	χ1776	pCR1, pGC101	P2 + EK2	P2 + EK2
P3	Yeast Drosophila Mouse	Cultured Mouse and Hamster Cells	Defective SV40 and Polyoma	P3	P2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P3 + EK2	Chicken	χ 1776	pMB9, pCR1, Col E1	P2 + EK2	P2 + EK2
P3 + EK2	Bird	χ 1776	pSC101	P2 + EK2	P2 + EK2
P3 + EK2	Mouse Sarcoma cDNA	χ 1776	pSC101, pMB9, pBR313, pBR322	P2 + EK2	P2 + EK2
P3 + EK2	Hamster	χ 1776	pSC101	P2 + EK2	P2 + EK2
P3 + EK2	Chicken	DP50/supF	Charon 4A Charon 16A	P2 + EK2	P2 + EK2
P3 + EK2	Bird	χ 1776	pCR1	P2 + EK2	P2 + EK2
P3 + EK1 P2 + EK1	Rabbit Globin pHG1	K-12	pMB9, pBR322	P2 + EK1 (RAC decision)	P2 + EK1
P3 + EK2	Mouse Embryo	DP50	Charon 16A	P2 + EK2	P2 + EK1

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P3 + EK1	Hela Mitochondria	C600[R]	pSP2124	P2 + EK2 or P3 + EK1	P2 + EK1
P3 + EK2	Mouse cDNA	χ1776 or DP50	pCR1 or Charon 16A	P2 + EK2	P2 + EK2
P3 + EK2	Chicken Rat	χ1776	pSC101, pCR1	P2 + EK2	P2 + EK2
P3 + EK2	Mouse	χ1776	pMB9, pBR322, pBR313	P2 + EK2	P2 + EK2
P3	E. coli	Mammalian Cells	Defective SV40	P3	P2
P3	E. coli	Cultured Monkey Cells	Defective SV40	P3	P2
P3 + EK2	Mouse	χ1776	pCR1	P2 + EK2	P2 + EK2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P3 + EK2	Goat	EK2	EK2	P2 + EK2	P2 + EK2
P3 + EK2	Rat	x 1776	pMB9, pBR322	P2 + EK2	P2 + EK2
P3 + EK2	Rabbit	HB101*	pMB9	P2 + EK2	P2 + EK2
P3 + EK2	Rat	x 1776 or LE392	pMB1 or Charon 16A	P2 + EK2	P2 + EK2
P3 + EK2	Mouse	EK2	EK2	P2 + EK2	P2 + EK2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P3 + EK2	Rat	x 1776	pBR322	P2 + EK2	P2 + EK2
P3 + EK2	Mouse Cow	x 1776	pSC101, pCR1	P2 + EK2	P2 + EK2
P3 + EK2	Human Embryo	x 1776	pSC101, pCR1	P3 + EK2	P2 + EK2
P3 + EK2	Rat, Dog, Mouse, Chicken, Pig, Human Embryo, Dog, Pig, House, Rat, Chicken, Human Fetal	x 1776	pBR322, pMB9	P3 + EK2	P2 + EK2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P3 + EK2	Mouse	K 12	EK2	P2 + EK2	P2 + EK2
P3 + EK2	Chicken	EK2	EK2	P2 + EK2	P2 + EK2
P3 + EK2	Rabbit, Mouse, Sheep	χ1776	ϕHB9	P2 + EK2	P2 + EK2
P3	λ	Trans-formed Rat Cells	Defective SV40	P3	P2
P3 + EK1 (RAC approved)	Chicken	DP50/supF	Charon 4A, λgtWES.λB	P2 + EK2 or P3 + EK1 (RAC approved)	P2 + EK2 or P3 + EK1
		χ1776	ϕBR322		
P3 + EK2	Chicken, Mouse, Rat	χ1776	ϕBR322, ϕBR313	P2 + EK2	P2 + EK2
P3 + EK2	Human Sperm and Placenta	DP50/supF, χ1776	λgtWES.λB, ϕHB9, ϕCR1, ϕBR322	P3 + EK2	P2 + EK2
P3	Rabbit, Mouse	Permissive Mouse Cells	Defective Polyoma Virus	P3	P2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P3	Mouse, Rabbit	Mouse cells	Defective SV40	P3	P2
P3 + EK2	Chicken	DP50/supF	λgtWES.λB	P2 + EK2	P2 + EK2
		χ1776	ϕHB9, ϕCR1	P2 + EK2	P2 + EK2
P3 + EK2	Purified Monkey	χ1776	ϕBR313, ϕBR322	P2 + EK2 or P3 + EK1	P1 + EK2 or P2 + EK1
P3 + EK2	Dog, Rat, Murine Cells	χ1776, DP50/supF	EK2	P2 + EK2	P2 + EK2

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P1 + EK1	K-12	K-12, C600*	λ, P1	Exempt	Exempt
P1 + EK1	E. coli, λ, P1	K-12	λ	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1, λ	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1	Exempt	Exempt
P1 + EK1	E. coli	K-12	φ80, λ, Col E1	Exempt	Exempt
P1 + EK1	E. coli	K-12	pMC201	Exempt	Exempt
P1 + EK1	E. coli, φ80	RC411*	pMC101	Exempt	Exempt
P1 + EK1	E. coli, λ	K-12	2124, Col E1	Exempt	Exempt
P1 + EK1	λ	K-12	pMB9, pMB322	Exempt	Exempt
P1 + EK1	K-12, λ	K-12, MM1*	λ	Exempt	Exempt
P1 + EK1	λ, Col E1	K-12	λ, pMC201	Exempt	Exempt
P1 + EK1	K-12	K-12	pMC101, pMB322	Exempt	Exempt

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P1 + EK1	E. coli	K-12	Col E1	Exempt	Exempt
P1 + EK1	E. coli	K-12	λ	Exempt	Exempt
P1 + EK1	E. coli	K-12	λ	Exempt	Exempt
P1 + EK1	E. coli	K-12	λ, Col E1, pMC101, P1	Exempt	Exempt
P1 + EK1	λ	K-12	Col E1	Exempt	Exempt
P1 + EK1	E. coli, λ	K-12	λ, pMB9, pMB322, pMB313	Exempt	Exempt
P1 + EK1	λ, E. coli	K-12	pMC16, Col E1, pMC101, pMB322	Exempt	Exempt

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Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P1 + EK1	E. coli	K-12	E. coli	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1	Exempt	Exempt
P1 + EK1	E. coli, K-12	K-12	Col E1, pDGp120	Exempt	Exempt
P1 + EK1	E. coli	K-12	λgt, Col E1	Exempt	Exempt
P1 + EK1	E. coli, K-12	K-12	λ, Col E1, RSF 1010	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1, λ	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1, λ	Exempt	Exempt
P1 + EK1	T4	K-12 (HR28)	pBR322	Exempt	Exempt
P1 + EK1	E. coli, K-12	K-12	λ	Exempt	Exempt
P1	B. subtilis	B. subtilis	B. subtilis	Exempt	Exempt
P1 + EK1	E. coli, Mu, 21, λ	K-12	λ	Exempt	Exempt
P1 + EK1	E. coli,λ	K-12	E. coli,λ	Exempt	Exempt
P1 + EK1	lac transducing phage	K-12	Col E1	Exempt	Exempt
P1 + EK1	E. coli, pCSR604	K-12	pMB9	Exempt	Exempt

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Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P1 + EK1	E. coli plasmids	K-12	pSC101, pMB103, pMB9, pBR313	Exempt	Exempt
P1 + EK1	Col E1	K-12	pSC201, pMB9	Exempt	Exempt
P1 + EK1	Col E1	K-12	Col E1	Exempt	Exempt
P1 + EK1	K-12	K-12	Col E1	Exempt	Exempt
P1 + EK1	T2, T4, T6	K-12	Col E1	Exempt	Exempt
P1 + EK1	E. coli	E. coli	Col E1	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1	Exempt	Exempt
P1 + EK1	K-12	SF8*	λ	Exempt	Exempt
P1 + EK1	K-12	C600*	λ, Col E1	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1	Exempt	Exempt
P1 + EK1	Serratia marcesceno	K-12	Col E1, pSC101	?Exempt	Exempt
P1 + EK1	T4	K-12	λ	Exempt	Exempt
P1 + EK1	T4	E. coli	λ, Col E1	Exempt	Exempt
P1 + EK1	λ	E. coli	pMB9	Exempt	Exempt
P1 + EK1	E. coli	E. coli	λ	Exempt	Exempt

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P1 + EK1	λ	K-12	Col E1	Exempt	Exempt
P1 + EK1	P4	K-12	Col E, pCR1	Exempt	Exempt
P1 + EK1	P plasmid	K-12	Col E1, pSC101	Exempt	Exempt
P1 + EK1	E. coli	K-12	pMB9, pBR314, pBR317, Col E1	Exempt	Exempt
P1 + EK1	pSH-1	K-12	Col E1	Exempt	Exempt
P1 + EK1	K-12	K-12	λ, CK 11, pSC101, Col E1, pML2, pMB9, pBR313, pBR322	Exempt	Exempt
P1 + EK1	λ, Mu	K-12	λ, Mu	Exempt	Exempt
P1 + EK1	TN5	K-12	Col E1	Exempt	Exempt
P1 + EK1	K-12	K-12	λ	Exempt	Exempt
P1 + EK1	K-12	K-12	Col E1, pSC101, pMB9, pBR322, x174, T7	Exempt	Exempt

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P1 + EK1	x174	K-12	pMB9	Exempt	Exempt
P1 + EK1	B. subtilis	B. subtilis	B. subtilis, or S. aureus plasmids	Exempt	Exempt
P1 + EK1	E. coli	K-12	Col E1	Exempt	Exempt
P1 + EK1	P plasmid	K-12	Col E1	Exempt	Exempt
P1 + EK1	Caulobacter crescentus	K-12	pMB9, pBR322	Exempt	~~Exempt~~ P1 + EK1
P1 + EK1	E. coli	K-12	E. coli plasmids	Exempt	Exempt
P1 + EK1	T7	HB101[a]	pMB9	Exempt	Exempt
P1 + EK1	E. coli, K-12	K-12	Col E1	Exempt	Exempt

Current Containment Levels (P and EK)	Source of DNA	Host	Vector	RAC Revised Containment Level	NIH Revised Containment Level
P1 + EK1	Promoter-containing Bacteriophage E. coli, EcoRI	K-12	Col E1	Exempt	Exempt
P1 (NIH approved)	B. subtilis B. pumilus B. lichenformis	B. subtilis	pUB110, pC194, pPL10, pPL576	?Exempt	Exempt
P1 + EK1	Enterobacter aerogenes	K-12	pBR322, pBR317	?Exempt	Exempt

*Derivatives of E. coli K-12.

APPENDIX C

RESPONSES TO SOME COMMENTS ON THE NIH ENVIRONMENTAL IMPACT STATEMENT, BY PUBLIC WITNESSES AT THE DAC MEETING, DECEMBER 15-16, 1977

At the public meeting of the Advisory Committee to the Director, NIH, held at the National Institutes of Health in December 1977, witnesses representing environmental groups commented on the "Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules," published by NIH in October 1977. Some of the comments and responses by the Office of the Director, NIH, are summarized below.

Comment 1. "The environmental impact statement does not respond to the arguments that any gene, if expressed out of its normal context, has the potential for being 'harmful.' Appendix K59-62" (of the EIS).

Response. Page 23 of the EIS (section IV-C-1) states that the "stable insertion of DNA derived from a different species into a cell or virus (and thus the progeny thereof) may change certain properties of the host. The changes may be advantageous, detrimental, or neutral with regard to (*a*) the survival of the recipient species, (*b*) other forms of life that come in contact with the recipient, and (*c*) aspects of the nonliving environment. Current knowledge does not permit accurate assessment of whether such changes will be advantageous, detrimental, or neutral, and to what degree, when considering a particular recombinant DNA experiment." This statement and subsequent elaboration acknowledges the commentator's point—that any gene, if expressed out of its normal context, has a potential for doing harm. The EIS does not qualify here—does not limit itself to the effects of "harmful" genes, such as those coding for synthesis of a toxin. Section IV-C proceedes to discuss ways in which hazardous agents might be produced. Factors such as survival of the host cell, survival of vectors, and effects of hosts or vectors on other forms of life are considered. Moreover, the guidelines classify all DNA that might be manipulated, so that some measure of containment is required for any recombination. Thus "any gene" is covered.

Comment 2. "The EIS does not respond to the argument that while *E. coli* K-12 does not normally colonize the human colon, it is incorrect to infer that this property renders it harmless to humans. Appendix K62-64."

Response. The letter cited (Zimmerman, Environmental Defense Fund) argues that *E. coli* K-12's survival *per se* is not the issue—that genetic exchange is. The point is covered in section IV-C-1-b-(2) on page 29 of the EIS: "When a cell or virus dies, or comes close to or invades the tissue of another living organism, the re- combinant DNA may effectively enter a new cell. A hazardous situation * * * might ensue if foreign proteins were manufactured in this 'secondary' recipient" (et seq.). Further treatment of the issue is presented in section VI-C, page 76, under the heading "Transfer of Foreign DNA from *E. coli* K-12." The EIS does not infer that the demonstrated reluctance of *E. coli* K-12 to colonize the human intestine renders it entirely harmless. If that were so, there would be no guidelines as we know them, where experiments using this attenuated organism are classified over the whole range of containment possibilities.

Comment 3. "The possibility that an organism containing chimeric DNA could possess properties exhibited by neither the host nor the organism is not considered. No response to this in the EIS. Appendix K65."

Response. Section IV-C-1 of the EIS, pages 23-31, describes the ways in which recombinant DNA experiments might be hazardous. Under the subtitle "The effect of bacteria and viruses containing recombined DNA on other forms of life, "there are sections explaining basic mechanisms whereby a recipient microorganism might be altered with regard to its pathogenicity or toxicity as a result of a resident recombinant. "Foreign DNA inserted into a bacterial gene," it is stated, "might so alter the microbial cell's properties that it becomes harmful to other organisms. This might happen, for example, through a change in the growth rate and competitive advantage of the recipient microbial cell, resulting in increased virulence of a mildly pathogenic bacteria." (EIS, p. 29) The statement and those following it are broad enough to include the possibility that "an organism containing chimeric DNA could possess properties exhibited by neither the host nor the organism" (which probably means "neither the foreign donor nor the host organism"). In other words, the EIS has nowhere denied this possibility and, indeed, addressed it in a general way by considering the various mechanisms through which hazards might arise.

Comment 4. "There is no adequate response to the criticism that the publication of the EIS after the release of the guidelines negated the purpose of the National Environmental Policy Act, i.e., to secure broad public comments on the guidelines and the policy of expansion they assume. Appendix K31."

Response. The EIS on page 2 responds to the above criticism as follows: "Although NEPA assumes that such Federal actions will not be taken until the NEPA procedures are completed, the Director of NIH concluded that the public interest required immediate issuance of the guidelines, rather than deferral for the months that would be required for completion of the NEPA process. This was because experiments utilizing recombinant DNA technology were proceeding in various laboratories throughout the country with only general and purely voluntary restrictions." The statement is still valid, and it is difficult to see how the NIH might better have acted in the public interest. NIH has pointed out elsewhere that the release of guidelines was a positive act in the interest of public safety, not an act that could in any way be construed as negative or hazardous.

Comment 5. "No response or correction of the lack of 'classification system for pests and pathogens of plants and animals on the basis of their hazards to agriculture such as exists for etiologic agents of disease on the basis of their hazard to humans.'" Correspondence between Drs. John W. Littlefield and Peter Day, April 14, 1977.

Response. The EIS addresses the guidelines' treatment of plant and animal sources of DNA on page 120, first paragraph. It explains that the analysis of potential hazards in the EIS is given in a general way that is equally applicable to persons, animals, and plants. The section of the guidelines on plants has been expanded in the proposed revision. Specifications for plant host-vector systems provide safeguards in greenhouses, growth chambers, etc., that meet the standards for experiments involving other life forms. As to a classification system, a workshop on risk assessment of agricultural pathogens, comprising distinguished American plant pathologists, was held on March 20-21, 1978 (as announced on March 6 in the FEDERAL REGISTER) under the sponsorship of the U.S. Department of Agriculture, the National Science Foundation, and the National Institutes of Health. The report of this workshop constitutes appendix G. It was presented to the Recombinant Advisory Committee at its meeting on April 27-28, 1978, and was unanimously endorsed with certain minor amendments. The recommendations of the RAC have been adopted in the NIH Director's proposed revised guidelines (PRG-NIH) with additional minor amendments to sections dealing with the use of plants and plant pathogens in recombinant DNA research.

Comment 6. "No response to Dr. Peter Albersheim's concern over the use of the organism *Agrobacterium tumefaciens* in nitrogen-fixation work. Correspondence with Dr. Fredrickson,

July 10, 1977. *Comments* (peach-colored book) p.1."

Response. The letter to Dr. Fredrickson, July 10 (actually to Dr. Gartland, July 5, and received July 10) comments on the guidelines rather than the EIS. All letters received in response to the draft EIS are included in appendix K of the final EIS and are responded to on page 113-137 of the final EIS. Our response to Comment 5 above is also applicable to this comment—i.e., the EIS discusses plants on pages 23 and 120, and further discussion of this issue was held at the recent workshop on risk assessment of agricultural pathogens, which has led to changes in the PRG-NIH.

APPENDIX D

DISCUSSION OF THE "LIST OF EXCHANGERS" CONSTITUTING APPENDIX A TO THE GUIDELINES

Section I-E-4 of the Guidelines states that certain recombinant DNA molecules are exempt from the Guidelines. These are molecules that "consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such will be prepared and periodically revised by the Director, NIH, on the recommendation of the Re- combinant DNA Advisory Committee, after appropriate notice and opportunity for public comment. Certain classes are exempt as of publication of these Revised Guidelines. The list is in Appendix A."

The natural transfer of genes between bacteria occurs by transduction (bacterial virus-mediated), transformation (uptake of isolated DNA by a bacterial cell), or conjugation (plasmid-mediated transfer of genes between bacteria, requiring cell-to-cell contact). A reasonable generalization is that virtually all closely related species of bacteria can exchange genes by transduction and transformation, the former limited by the relatively narrow host-range of transducing bacteriophage and the latter by the requirement, in the case of chromosomal DNA, for homology of DNA in most recombination events. Conjugal mating with exchange of DNA can occur between virtually all Gram-negative bacteria, including naturally occurring soil and intestinal species, when mediated by a plasmid of broad host-range (for example, the Inc P-1 group plasmids). Recently, conjugal mating has also been shown to occur between strains of certain species of *Streptococcus*, a Gram-positive organism (for example, *Streptococcus faecalis*). To date, however, conjugal mating has not been demonstrated between Gram-negative and Gram-positive bacteria.

The relatedness of different microbial species can be estimated by determining the extent of DNA homology between them or by studying the properties of different microorganisms in genetic crosses. As a general rule, organisms that show considerable homology of their nucleotide sequences under a standard set of experimental conditions have the capacity to mutually integrate chromosomal genes. For example, in the case of the *Enterobacteriaceae* family of bacteria (includes *Escherichia coli* K-12), there is both extensive DNA-DNA homology (*1*) and chromosomal gene exchange, (*2*) with a reasonable correlation between the degree of DNA-DNA homology and the capacity to mutually integrate chromosomal genes.

Genetic relatedness, as indicated by a high level of DNA-DNA homology between different microorganisms, is not, however, an absolute requirement for the exchange of chromosomal genes between bacteria. In fact, chromosomal gene transfer among diverse members of the Gram-negative group of bacteria has been demonstrated where the microorganisms involved show little or no DNA-DNA homology. In these cases the exchange of chromosomal genes is promoted by a broad-host-range plasmid of the Inc P-1 incompatibility type. These plasmids mobilize the chromosomes of a wide variety of Gram-negative bacteria, incorporate segments of these chromosomes, and are capable of establishing themselves along with covalently-linked chromosomal genes in a wide range of Gram-negative bacteria. (*3*)

Appendix A to the Guidelines contains a list of documented cases of chromosomal gene exchange between a variety of bacteria and *E. coli* K-12 where the gene exchange is promoted by Inc P-1 or other plasmids. The first ten entries in this table are members of the *Enterobacteriaceae* family of bacteria. The bacterial species in this family not only show chromosomal gene exchange but, as indicated above, exhibit extensive DNA-DNA homology. References listed at the end of this Appendix (*4*) provide documentation for the entries in Appendix A to the Guidelines. All entries in Appendix A exhibit R-prime transfer (R plasmid carrying chromosomal genes) to *E. coli* K-12 mediated by the Inc P-1 or other plasmids.

The Recombinant DNA Advisory Committee at its April 27-28, 1978, meeting proposed three possible alternative lists for consideration by the Director, NIH, to become Appendix A to the Guidelines.

The first list with its criteria and entries was as follows:

The following organisms of the *Enterobacteriaecae* family exhibit chro- mosomal DNA relatedness (20 percent or more homology of DNA of various pairs tested) and genetic recombination or R-prime (R plasmid carrying chromosomal genes) transfer to *E. coli* K-12 mediated by the Inc P-1 plasmids.

All species of the following genera:

1. *Escherichia* (including *E. coli* K-12)
2. *Shigellae*
3. *Salmonella*
4. *Enterobacter*
5. *Arizona*
6. *Citrobacter*
7. *Klebsiellae*

In addition, the following species:

1. *Erwinia amylovora*
2. *Erwinia dissolvens*
3. *Erwinia minipressuralis*
4. *Serratia marcescens*
5. *Levinea malonatica*
6. *Levinea amalonatica*

The second list proposed by the RAC included all the members of the first list but added additional members. The criteria used are that all the members of the list exhibit R-prime transfer (R plasmid carrying chromosomal genes) to *E. coli* K-12 mediated by the IncP-1 or other plasmids. This is the list which (which certain deletions) was selected by the Director, NIH to become Appendix A to PRG-NIH. The references supporting the entries to this list are give (*4*) at the end of this Appendix.

The third list included all the members of the second list but adds additional members. This list, with its criteria and entries, was as follows:

The following genera and/or species possess R plasmids (including R plasmids of the IncP-1 group) transferable to *E. coli* K-12.

1. All members of the *Enterobacteriaceae* family
2. *Vibrio* species (except *Vibrio para- hemolyticus*)
3. *Pseudomonas* species
4. *Rhizobium* species
5. *Acinetobacter calcoaceticus*
6. *Agrobacterium tumefaciens*
7. *Rhodopseudomonas sphaeroides*
8. *Caulobacter crescentus*
9. *Proteus* species
10. *Achromobacter* species
11. *Aeromonas salmonicida*
12. *Alcaligenes faecalis*
13. *Bordetella bronchiseptica*
14. *Myxococcus xanthus*
15. *Neisseria gonorrhoeae*
16. *Pasteurella hemolytica*
17. *Pasteurella multocida*
18. *Yersinia* species (excludes *Y pestis*, since it is a Class 3 agent)
19. *Xanthomonas* species

In addition, recombinant DNA experiments between *H. influenzae* and *H. parainfluenzae* are exempt on the basis of extensive DNA homology.

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APPENDIX E

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
NATIONAL INSTITUTES OF HEALTH,
Bethesda, Md. March 16, 1978.

Dr. DONALD S. FREDRICKSON,
Director, National Institutes of Health, 9000 Rockville Pike, Bethesda, Md.

DEAR Dr. FREDRICKSON: On January 26-28, 1978, a joint U.S.-EMBO Workshop to Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insect Viruses was held in Ascot, England. The workshop was sponsored by the NIH at your request, in response to discussions concerning viruses at the Director's Advisory Committee meeting of December 1977. The workshop was attended by 27 scientists from the United States, the United Kingdom, West Germany, Finland, France, Sweden, and Switzerland. The participants were invited because of their scientific expertise and not as representatives of any government or of any policymaking group.

The primary purpose of the meeting was to conduct a scientific and technical analysis of possible risks associated with cloning eukaryotic viral DNA segments in *E. coli* K-12 host-vector systems and with the use of eukaryotic viruses as cloning vectors in animal, plant, and insect systems. In addition, there were general discussions of the possible importance of recombinant DNA technology for the solution of problems in basic and applied virology and of the classification of viruses with respect to the hazard that laboratory research with them might pose to the laboratory worker or to the community.

A report of the discussions and conclusions of the workshop is transmitted to you along with this letter. A draft of this report was sent to the members for comment and revision, and this final version is based on the replies of all the participants. In view of the favorable responses, we feel that this report will receive the support of virologists in general. We hope that it will be useful to you and the various national committees that are considering containment levels for this type of recombinant DNA research.

Since this is the report of an international group, we generally avoided reference to any particular set of containment conditions. Rather, we anticipate that the various national committees will use this report as the scientific basis for setting the containment conditions they feel appropriate.

Sincerely,

MALCOLM A. MARTIN,
Laboratory of Biology of Viruses, NIAID.
WALLACE P. ROWE,
Laboratory of Viral Diseases, NIAID.
JOHN TOOZE,
Executive Secretary, European Molecular Biology Organization, Heidelberg.
Co-Chairmen.

REPORT OF U.S.-EMBO WORKSHOP TO ASSESS RISKS FOR RECOMBINANT DNA EXPERIMENTS INVOLVING THE GENOMES OF ANIMAL, PLANT, AND INSECT VIRUSES

This is the report of a joint U.S.-EMBO workshop held in Ascot, England, January 27-29, 1978, which was convened to discuss the possible risks of recombinant DNA experiments involving the DNAs of animal, plant, and insect viruses. The 27 scientists in attendance (see attached roster) had expertise in clinical infectious disease; public health, medical and diagnostic virology; the biology of virus infection; biochemical virology; and plant, insect, and veterinary viruses. Five of the participants are actively engaged in recombinant DNA experimentation. A consensus statement of the discussions in the areas of pathogenesis and epidemiology of viral diseases, potential benefits of recombinant DNA experiments involving eukaryotic viral DNA, viral hazard classifications, and cloning in prokaryotic and eukaryotic systems is presented below. The group's conclusions, with respect to possible risks of recombinant DNA experiments involving viruses are based on the best available scientific data derived from publications, knowledge of current activities in the field of virology, and first-hand experience in the virology laboratory.

Introduction

Viral disease is a complex process that involves a series of critical steps; these include entry of the virus particle into the host, infection of specific cells at the portal of entry, replication of the virus in the infected cells, and usually, the spread of the progeny virus particles within the infected host to other susceptible cells. Depending upon the nature of the particular viral agent, the deleterious effects for the host, if any, may result from cytolytic activity, cellular transformation, chronic cellular dysfunction, or the provocation of an injurious immunological response. Viruses contain 5 to 150 or more genes and their coordinated functioning is required for viral growth and, consequently, for survival of the virus in nature. Even though we do not generally understand the precise role of each viral gene product, it seems clear that viral infection and disease production requires proper functioning of most, if not all, viral genes and, in general, is not a consequence of any single viral gene product. In the case of oncogenic papovaviruses, transforming retro- viruses and possibly adenoviruses, individual viral genes are thought to be responsible for the transforming properties of the virus.

Recombinant DNA experiments have already yielded new information about the structure and control of expression of genes in higher organisms that could not have been obtained by conventional techniques. DNA cloning provides unparalleled opportunities to explore the basic biology of animal and plant viruses. Virologists will be able to probe more deeply into the control of viral gene expression and

discover phenomena of general cell biological significance; techniques will be more readily available to elucidate the sequence of viral nucleic acids, to shed light on the role of viral gene products in pathogenicity, and eventually, to understand the molecular biology of animal and plant viruses to the extent that some bacteriophages are now understood. It seems apparent that this new information will lead to a deeper understanding of viral diseases and to new ways of combating them. In the immediate future the ability to obtain useful amounts of pure viral genomes and subgenomic fragments that cannot be obtained by other means will provide scientists and physicians with invaluable and inexpensive diagnostic protein and nucleic acid reagents. In the more distant future it should be possible to use gene cloning techniques to obtain large amounts of viral proteins; one practical benefit from such developments might well be effective and safe vaccines for control of diseases caused by hepatitis viruses, herpesviruses and influenza viruses and many other viruses, both known and, as yet, unknown.

In addition to being able to clone viral genes in bacteria we are now able to envisage using certain animal viruses as vectors for the propagation of foreign genes in animal cells; a similar system for exploiting a plant virus, cauliflower mosaic virus, to clone foreign genes in plant cells may shortly become available. The chief importance of animal and plant virus vectors is that they can be used to carry genes into cells in which they may be fully expressed as well as propagated. By using specifically designed viral vectors it may eventually prove possible to deliver a specific gene to specific target cells; such techniques have obvious medical, economic, and agricultural applications but their realization will depend upon a great deal of basic research.

VIRAL CLASSIFICATION SYSTEMS AND RECOMBINANT DNA EXPERIMENTATION

The group extensively discussed the current safety procedures for holding and handling in the laboratory certain animal viruses, in particular those likely to be used in cloning experiments in the foreseeable future, either as vectors or as the sources of the nucleic acids to be cloned. Inevitably the recommended safety measures for using animal (and plant) viruses in research vary from country to country. In the context of recombinant DNA research, which involves a novel set of circumstances, none of the available classifications of viruses according to the risks they pose is entirely satisfactory. A list of animal viruses was therefore prepared and the viruses were ranked according to their known hazard on the basis of: (a) The severity of human disease that they can cause, particularly in persons exposed in the laboratory; (b) their potential for infecting laboratory workers; (c) the risk that a laboratory infection might result in spread to the community; and (d) the impact such spread might have on the community or environment (table 1). In this list four bacteria and one rickettsial agent with different pathogenic potentials have also been included as a frame of reference for the 22 viruses identified. Because of time constraints, many animal viruses, particularly those of agricultural and veterinary importance, were not included in the table. Although not comprehensive, the list contains most of those animal viruses that have been previously mentioned in the context of recombinant DNA experiments.

This list can also serve the very useful function of a reference scale, familiar to both microbiologists and clinicians, for expressing the degree of concern that a given conjectural hazard may engender, by comparison to a known biohazard.

CLONING VIRAL DNA'S IN E. COLI K-12

The cloning of viral DNA's and cDNA's in *E. coli* K-12 using EK1 and EK2 plasmid and lambda phage vectors was discussed in light of the conclusions of the Falmouth meeting that *E. coli* K-12 is not pathogenic and does not efficiently colonize the vertebrate digestive tract (Gorbach, 1978). Not for want of trying, the participants were unable to envisage a sequence of events which could occur with significant probability that would allow *E. coli* carrying either whole DNA genomes of certain viruses or subgenomic fragments of virtually any virus to lead to disease. The question was also raised as to whether or not, in the extremely remote possibility that all of the biological and physical containment barriers broke down, intestinal bacteria carrying cloned whole viral genomes might bypass the natural barriers to infection by the virus particle. As summarized in the following section, the group concluded that the probability that K-12 organisms carrying viral DNA inserts could represent a significant hazard to the community was so small as to be of no practical consequence.

Risk assessment analysis for cloning viral DNA in E. coli K-12.[1] The following is a summary of the workshop discussions dealing with possible mechanisms of risk resulting from the cloning of genetic material of eukaryotic viruses (i.e., viruses of animals, plants, or lower eukaryotes) in *E. coli* vector systems.

We started with the extremely unlikely "worst case" assumption that a recombinant molecule containing eukaryotic viral genome sequences has in some way become established in wild type *E. coli* and has thereby become disseminated throughout the bowel flora of vertebrates. Given this hypothetical set of conditions, what consequences could be envisaged? For the purposes of analysis the discussions focused on two issues.

First: The mechanisms by which the viral nucleic acid might gain access to cells of the host; and

Second: The nature of the inserted viral sequences.

Access of the viral genome to cells of the vertebrate host might conceivably result from virus particles formed within the bacterium or from release of viral nucleic acid into the proximity of, or into, host cells; this could occur either in the intestine or at the site of extraintestinal *E. coli* infection.

Production of infectious virus particles by bacteria carrying the recombinant DNA molecules was considered to be virtually impossible, regardless of the completeness of the viral genome or the nature of the eukaryotic virus from which it was derived. The basis for this high degree of assurance is in large part our great understanding of the molecular biology of virus replication. The nature of regulation of gene expression in prokaryotes is clearly different from that in eukaryotes as particularly exemplified by the absence in prokaryotes of RNA splicing mechanisms (Berget el al., 1977; Aloni et al., 1977; Lavi and Groner, 1977; Mellon and Duesberg, 1977; Chow et al., 1977; Klessig, 1977; Dunn and Hassell, 1977), RNA capping (Moore, 1966; Stavis and August, 1970; Blattner and Dahlberg, 1972; Maizels, 1973; Wei and Moss, 1975; Furuichi et al., 1975a; Keith and Fraenkel-Conrat, 1975; Abraham et al., 1975; Furuichi et al., 1975b; Dubin and Taylor, 1975; Perry and Scherrer, 1975; Moss and Koczot, 1976) and differences in messenger RNA biogenesis, polyadenylation (Kates and Beeson, 1970; Darnell et al., 1971; Mendecki et al., 1972; Philipson et al., 1971; Weinberg et al., 1972; Ehrenfeld and Summers, 1972; Pridgen and Kingsbury, 1972), and ribosomal binding sites (Shine and Dalgarno, 1974; Steitz and Jakes, 1975; Hagenbuchle et al., 1978). The expression of animal viral mRNA in *E. coli* translation systems is not accurate; in one well studied system, poliovirus, internal initiation signals are read which result in premature chain termination (Rekosh et al., 1970). Thus neither the synthesis of proper mRNA nor its translation into viral protein is likely to occur in *E. coli*.

[1] This portion of the report was prepared subsequent to the U.S.-EMBO workshop by Drs. Martin and Rowe.

Virus replication requires the regulated and coordinated function of multiple enzyme systems derived from both the host and the viral genomes; it seems most unlikely that any prokaryote contains the complement of enzymes required for the synthesis of an infectious animal virus. Animal viruses have evolved to be adapted to replication in eukaryotic cells; except for the instances where they have coevolved to replicate in insect vectors, animal and plant viruses show a high degree of specificity for cells of a particular class or species of host cell or even a particular differentiated cell type. Further, there is no verified example of the replication of a virus of eukaryotes in bacteria, or conversely, the replication of a bacterial virus in any eukaryote. Consequently, since it was not considered possible for recombinant DNA containing a viral chromosome to produce intact virus particles in *E. coli*, the group felt secure in focusing on models involving host cell exposure to viral nucleic acid rather than viral particles.

In a model in which recombinant DNA-containing organisms are confined to the lumen of the intestine, the possibility of viral RNA or DNA gaining access to mucosal cells is extremely remote. First: The large amounts of nucleases in the intestinal contents would rapidly destroy the recombinant molecules (Maturin and Curtiss, 1977). Second: The efficiency of infection of cells by viral nucleic acid molecules, even in the presence of chemical potentiators, is extremely low, both in vitro and in vivo (Ellem and Colter, 1961; Amstey and Parkman, 1966; McCutchan and Pagano, 1968; Graham and van der Eb, 1973; Israel et al., 1978a). Third: Since animal experiments indicate that polyoma viral DNA cannot initiate infection when administered by the oral or nasal routes (Israel et al., 1978a), it is likely that nucleic acids cannot infect across mucous membranes.

Consequently, the only model to which serious attention must be directed is one in which the hypothetical bacterium carrying the viral recombinant DNA gains access to the body tissues. Two cases can be considered. With minor transgressions of the intestinal mucosa that allow brief penetration of organisms into the intestinal wall, lymphatics, or the protal circulation, the bacteria would be ingested by phagocytes. In phagocytes, bacteria are lysed and their nucleic acid is released in the nuclease-rich lysosomes; the effectiveness of the lysosomal enzymes virtuall guarantees that no nucleic acid could survive to cause infection (Bensch et al., 1964; Carrara and Bernardi [1968]; Arsenis et al., 1970).

The second case, extraintestinal infection such as urinary tract or surgical wound infection, deserves serious consideration, but it must be pointed our that this would occur in only a fraction of individuals. In this context the consequences of the infection would be a function of the nature of the viral DNA inserted in the recombinant DNA molecule. We considered the following classes of DNA inserts: (1) Subgenomic segments of nononcogenic viruses; (2) transforming segments of oncogenic viruses; (3) cDNA prepared from the genome of segmented RNA viruses; (4) cDNA copies containing the complete viral genome of nonsegmented RNA viruses and (5) complete DNA viral genomes. The workshop participants reached the conclusion that viral inserts should be thought in terms of three classes of risk: Those for which there was no risk of a harmful outcome, and those for which a possibility of harm, however remote, could be envisioned. The latter were then divided into those scenarios which may well in reality be impossible, and those which are felt to be possible.

Those inserts for which the group could not construct any realistic harmful scenario were: (1) Subgenomic segments of nontransforming RNA or DNA viruses; (2) cDNA copies from RNA viruses with segmented viral genomes and (3) cDNA's of the complete genome of negative strand RNA viruses.

(1) Subgenomic segments (meaning small portions of the viral genome lacking genes needed for replication of the virus) of nontransforming viruses are considered to be harmless because of the absence of any known example of an individual viral encoded protein which can act exogenously on cells. With the exception of some glycoproteins when added to cell cultures in high concentrations (Scheid and Choppin, 1974; McSharry and Choppin, 1978), viral proteins do not induce cell damage from without.

(2) Reverse transcripts of RNA viruses with segmented genomes cannot be envisaged as carrying any risk of producing infectious virus even when the cDNA is made from unfractionated nucleic acid preparations. It would be virtually impossible to ligate together a complete DNA copy, and if this ever did occur, we cannot envisage any way that the proper length RNA genome segments could be transcribed therefrom.

(3) Cloning of reverse transcripts of negative strand RNA viruses is viewed as being free of risk. With these viruses, the process of viral mRNA and genomic RNA synthesis is complex, and the Workshop participants could not envisage a set of circumstances in which RNA segments, transcribed from a DNA template, could eventuate in the synthesis of progeny virus. This is based on the fact that the nucleic acid of negative strand RNA viruses (either the plus or minus strand) has never been shown to be infectious for cells (Kingsbury, 1966; Baltimore et al., 1970; Wagner, 1975) presumably because of their unique molecular biology. Infection by negative strand viruses requires the activity of the virion associated transcriptase (Baltimore et al., 1970; Cormack et al., 1971; Szilagyi and Pringle, 1972); this enzyme catalyzes the synthesis of multiple (segmented) functional plus strand mRNA molecules from the input minus strand (Bratt and Robinson, 1967; Huang et al., 1970; Mudd and Summers, 1970; East and Kingsbury, 1971; Weiss and Bratt, 1976; Freeman et al., 1977). A polypeptide specified by one of these mRNAs then modifies the virion transcriptase to function as a replicase mediating the synthesis of a complete unsegmented plus strand of RNA, the template for synthesis of progeny minus stand RNA molecules. The minus strand has no messenger function (Huang et al., 1970; Grubman and Summers, 1973; Kingsbury, 1973; Morrison et al., 1974). Thus, to initiate the infectious process both a full length RNA transcript (to serve as template) and the segmented plus strand transcripts, capped for function as mRNA, would be required. This would necessitate either the transcription of both DNA strands by cellular RNA polymerase or the synthesis of a full length transcript as well as properly terminated, segmented transcripts from the minus strand DNA. These are obviously extremely unlikely events.

There were two classes in which it was considered that a risk scenario might be constructed but which might indeed be impossible; these involve the cloning of the transforming segments of DNA viruses or of transforming retroviruses, and the cloning of complete reverse transcripts of plus-strand RNA viruses. The model involving subgenomic, transforming segments postulates release of recombinant DNA molecules by lysis of *E. coli* in the tissues, and integration of the transforming gene segment into the DNA of host cells. While this eventuality cannot be ruled out, it was considered to have a very low probability in view of the inefficiency of transforming cells with viral nucleic acid (Aaronson and Martin, 1970; Graham et al., 1974; Abrahams et al., 1975) and the fact that integration of transforming DNA would occur in only a few cells in any one individual and, in the presence of competent immuno- surveillance, would be most unlikely to result in a tumor (Habel, 1961; Sjogren, 1964; Sjogren et al., 1967; Costa et al., 1977). Transplanta-

tion studies with primary tumors and transformed tissue culture cells indicate that large numbers of cells are required to initiate tumor growth; in general, only after adaptation effected by long passage in animals do small numbers of cells produce tumors (Sjogren, 1964; Klein, 1975). In this regard, it should be noted that there is overwhelming evidence that humans are highly effective in averting tumorigenesis by DNA viruses. Man, and many other vertebrates as well, are infected repeatedly with DNA viruses (e.g., papovaviruses and adenoviruses) that contain the transforming regions discussed above (Huebner et al., 1954; Hilleman, 1957; Shah et al., 1973; Padgett and Walker, 1973; Brown et al., 1975; Shah and Nathanson, 1976). Some of these viruses are even known to induce tumors in laboratory rodents, yet, despite intensive search, none of these has been reproducibly associated with the etiology of any malignancy in humans (Mackey et al., 1976; Fiori and DiMayorca, 1976; Wold et al., 1978; Israel et al., 1978b).

The risk scenario whereby a cDNA transcript of a positive strand RNA virus leads to infection of the host was considered to have a finite but low probability. In this model, extraintestinal infection by the bacterium carrying the recombinant DNA results in the recombinant DNA molecule, or plus strand RNA transcripts thereof, entering into host cells with resultant productive viral infection. Neither carries a risk if the cDNA insert is not a complete copy of the RNA genome. Unless a deliberate attempt is made to select full-length cDNA molecules for ligation to prokaryotic DNA vectors, the vast majority of recombinant DNA molecules will contain only a segment of viral specific DNA and, as a consequence, the likelihood of cloning the whole genome will be low.

The major block to synthesis of infectious RNA from the recombinant DNA molecule either in the prokaryotic or eukaryotic cell would be the inaccurate initiation of transcription. There is no reason to believe that the 5' terminus of the viral genome would generate a binding site for either prokaryotic or eukaryotic RNA polymerases following reverse transcription into DNA. Rather, RNA synthesis would be initiated either:

(1) Internally, by a random initiation process which would yield noninfectious molecules;

(2) Upstream, either at a prokaryotic promoter or at a random initiation site, in the eukaryotic cell which would generate a leader sequence lacking the appropriate recognition signals for binding to eukaryotic ribosomes (Shine and Dalgarno, 1974; Steitz and Jakes, 1975; Hagenbuchle et al., 1978). To produce infectious RNA from such a primary transcript, a site-specific cleavage would have to occur;

(3) At the 5' terminus by random initiation, but this undoubtedly would be an extremely rare event.

Any full-length plus strand transcripts synthesized in *E. coli* would have to escape degradation by extracellular ribonucleases following their release from bacteria and then initiate an infection in a sensitive cell, which, under the best conditions in the laboratory, is an extremely inefficient process (Ellem and Colter, 1961).

Further studies of this type of viral DNA insert would clearly be desirable.

The cloning of the complete genome of DNA viruses (including proviral forms of retroviruses) provides a scenario felt to carry a finite probability of risk, but this too is considered extremely low. Since viral DNA molecules are generally infectious, any situation in which the complete viral genome, without deletion or substitution, is excised from the recombinant molecule could conceivably lead to infection. In particular, circular DNA genomes, cleaved with a single cut restriction enzyme and ligated to a prokaryotic vector, provide such a condition; however, for accurate excision one must postulate the unlikely eventuality of the recombinant molecule being brought in contact with the same restriction enzyme used during the insertion of the DNA segment into the vector. Complete viral genomes could also be generated from a recombinant molecule in the case of oligomers of viral DNA inserts; a complete copy of the viral DNA could then be generated by intramolecular recombination. Full length linear DNA molecules inserted into a vector by oligo dA-oligo dT tailing or by addition of other linker molecules would be unlikely to excise accurately terminating genomes.

Given that it is conceptually possible to generate infectious molecules from recombinant DNA containing the complete genome of DNA viruses, it is important to assess the factors that would result in such infectious DNA causing disease. The probability that the excised molecules would infect host cells is of course relatively low in view of the inefficiency of infection by naked DNA (Ito, 1960; Burnett and Harrington, 1968; McCutchan and Pagano, 1968; Mayne et al., 1971; Graham and van der Eb, 1973; Sol and van der Noordaa, 1977). Another important factor in such a scenario is the susceptibility of neighboring cells to the virions produced by a cell infected with the infectious DNA. If the surrounding cells were not sensitive to the virus itself, the initially infected cell, producing virions, could not spread this infection to other cells or tissues; in the absence of virus spread there would be no risk other than the possible transformation of a small number of cells, in the case of oncogenic viruses, as discussed above. Only if the host was sensitive to the virus would spread occur; this would not be different from infection with the virus itself and would not generally represent a unique biohazard. Futher study of this type of viral DNA insert would be extremely useful.

Recapitulation. It should be noted that these model scenarios were not constructed from an anthropocentric viewpoint, but apply generally to any model in which vertebrates are colonized by the *E. coli* carrying the recombinant molecule.

To recapitulate, even assuming a worst case situation, this analysis leads us to conclude that cloning the subgenomic segments of nononcogenic viruses, the complete genome of negative strand RNA viruses, and any part of the genome of segmented viruses carries no risk of generating a biohazard. Second: It is possible to construct conceivable but extremely unlikely sets of circumstances resulting in a biohazard from the cloning of the transforming segment of oncogenic viruses. And, third: It is possible to envisage feasible biohazard scenarios from cloning of the complete genome of DNA viruses or the entire genome of plus strand RNA viruses but even these carry little possibility of risk. When this analysis is combined with the immense unlikelihood of generating this worst case scenario in the first place, given good laboratory practice and the safety inherent in use of approved *E. coli* K-12 host-vector systems (Gorbach, 1978), the group felt strongly justified in concluding from available scientific information that viral genomes or fragments thereof, cloned in *E. coli* K-12 using approved plasmid or phage vectors pose no more risk than work with the infectious virus or its nucleic acid and in most, if not all cases, clearly present less risk. In fact, the Workshop participants agreed that cloning of viral DNA in *E. coli* K-12 may provide a unique opportunity to study with greatly reduced risks the biology of extremely pathogenic and virulent viruses.

The group also agreed that the cloning of cDNA copies of viroids in *E. coli* K-12 should be postponed until more information is available about their molecular and cellular biology.

Recommendation. Based on these considerations the participants of the U.S.-EMBO Workshop concluded that the use of P2 (NIH guidelines) or CI (Williams report) containment measures, in conjunction with an EK1 host-vector system should provide adequate containment for cloning any viral genome or fragment thereof and recommended this as the minimum con-

tainment levels for recombinant DNA experiments involving eukaryotic viral DNA inserts. However, if the virus itself must be handled at higher levels of physical containment it seems prudent at the present time to use the more stringent containment conditions. It was emphasized that containment practices must include adequate training and the use of high quality microbiological technique.

EXPERIMENTS WITH EUKARYOTIC HOST-VECTORS

1. Vertebrate host-vector systems in which viral DNA vectors are used to propagate other DNA segments.

The workshop participants endorsed the portion of the NIH guidelines that describes the features required for an animal virus to be used as a cloning vector (i.e., the first portion of section III.B.3.a. of the draft version, revised NIH guidelines for recombinant DNA research). The following is our recommended version of this section:

Because this work will be done almost exclusively in tissue culture cells, which have no capacity for propagation outside the laboratory, the primary focus for containment is the vector; it should be pointed out that the risk of laboratory acquired infection as a consequence of tissue culture manipulations is very low. Given good microbiological practices, the most likely mode of escape of recombinant DNAs from a physically contained laboratory is carriage by an infected human; thus the vector with an inserted DNA segment should have little or no ability to replicate or spread in humans. Further, a recombinant virus should not inadvertently pose a threat to any species.

For use as a vector in a vertebrate host cell system, an animal viral DNA molecule ideally should display the following properties:

(a) It should not consist of the whole genome of any agent that is infectious for humans or that replicates to a significant extent in human cells in tissue culture.

(b) It should be derived from a virus whose epidemiological behavior and biological properties are well understood.

(c) Its functional anatomy should be known—that is, there should be a clear idea of the location within the molecule of:

(i) The sites at which DNA synthesis originates and terminates;

(ii) The sites that are cleaved by restriction endonucleases;

(iii) The template regions for the major gene products.

(d) It should be defective when carrying an inserted DNA segment; that is, propagation of the recombinant DNA as a virus must be dependent upon the presence of a complementing helper genome. In almost all cases this condition would be achieved automatically by the manipulations used to construct and propagate the recombinants. In addition, the amount of DNA encapsidated in the particles of most animal viruses is defined within fairly close limits. The insertion of sizeable foreign DNA sequences, therefore, generally demands a compensatory deletion of viral sequences. It may be possible to introduce very short insertions (50-100 base pairs) without rendering the viral vector defective. In such a situation, the requirement that the viral vector be defective is not necessary.

If possible the helper virus genome should:

(i) Be integrated into the genome of a stable line of host cells (a situation that would effectively limit the growth of the vector recombinant to such cell lines); or

(ii) Consist of a defective genome, or an appropriate conditional lethal mutant virus, making vector and helper dependent upon each other for propagation.

However, neither of these stipulations is a requirement.

The group discussed at length the possibility that use of eukaryotic vectors under these conditions could pose a threat to the community or environment, but could not envisage a plausible set of circumstances whereby a risk to the community could develop. Given the extent of the genetic deletion required to satisfy the conditions stated above and in table 2, and the constraints that encapsidation places on the size of an inserted gene segment, the workshop participants saw no way that the experiments could generate a competent virus containing new genetic information sufficient to code for a functional gene product. The group tried to conceive of ways by which a recombinantional event between the defective recombinant genome and the helper genome or the genome of an indigenous virus in an exposed laboratory worker might generate nondefective viral recombinants, but as mentioned, was unable to identify any.

The possibility that a defective recombinant genome might be maintained in nature through complementation by a helper virus was considered too unlikely to be a cause for concern, given the absence of any precedent in animal virology. The group considered the adeno-associated viruses, which are defective parvoviruses maintained in nature, to be a unique case in that they are known to integrate into host cells and to have at least 33 different potential helpers (human adenoviruses) available.

Having considered the use of the genomes of different DNA animal viruses to propagate DNA sequences from different sources, the group proposed the following recommendations:

TABLE 2

Viral Vector DNA	Precaution Level Depending on Source of Foreign DNA		
	prokaryotic	eukaryotic	viral
polyoma virus — all or part	L or M	L	CbC
SV40 — unconditionally defective by deletion of all or part of the sequences of any of the genes	L or M	M	CbC
adenoviruses 2 and 5 — incapacitated by deletion of at least two capsid genes	L or M	L	CbC
murine adenovirus strain FL — all or part+	L or M	L	CbC
Herpes simplex virus — incapacitated by a large deletion	CbC	CbC	CbC

L corresponds to a containment level approximately equivalent to P2.

M corresponds to a containment level approximately equivalent to P3.

Prokaryotic sequences that are known not to contain toxigenic genes may be cloned in *L* conditions: otherwise *M* conditions should be used.

+ Before this viral DNA can be used as a vector, further information is required about its host-range, particularly its interactions with cultured primate cells.

CbC these experiments should be assessed by the appropriate committees on a "Case by Case" (CbC) basis.

The group recommended that further work on the biological properties of recombinants formed between the genomes of two animal viruses should be carried out as a matter of some importance. The workshop participants discussed the possibility that new viral agents might be created with novel biological properties (e.g. host range, tissue tropism, pathogenicity) not found in either parent. Several model experiments were proposed to test this possibility. The group recommended that research in this area proceed cautiously with each case being considered on its individual merits and even if the model experiments suggest little cause for concern, continued careful surveillance of new recombinants should be maintained.

2. *Vertebrate host-vector systems in which recombinant DNAs are used to transform cells.* In these types of experiments viral DNAs carrying a foreign DNA segment will be used to transform cells in culture and in the process, integrate the recombinant DNA into the host cell chromosome. Some transformation systems are nonpermissive for progeny virus production and pose no possibility of producing laboratory infections. Other transformation systems are semi-permissive and, in addition to the appearance of transformed cells, allow the production of low titers of infectious virus.

When recombinant DNAs are used to transform cells which do not yield significant quantities of infectious virus (e.g. SV40 in murine cells, polyoma virus in rat or hamster cells, adenovirus 2 and 5 in rat cells) *L* conditions are generally sufficient; for viruses which do not infect humans, there need be no requirement that the vector be disabled. *M* conditions should be used if the system is semipermissive (i.e., virus is produced, in low titer) and the virus is capable of infecting humans (e.g. SV40 in human cell cultures). It was agreed that the DNA to be cloned must not be derived from another animal virus.

The use of viral genes as selective markers offers exciting and important possibilities for experiments involving cloning in eukaryotic cells. Possibly the best of such markers would be the herpes simplex virus thymidine kinase gene. We recommend that special emphasis be given to cloning in prokaryotic systems a small fragment (<5KB) of herpes viral DNA which contains the sequences of this gene. Once available, the purified segment could be ligated to any chosen piece of DNA and cells transformed by the recombinant could easily be selected by virtue of the presence of thymidine kinase.

3. *Baculoviruses as vectors.* The group discussed the use of baculoviruses (large DNA-containing insect viruses) for cloning genes in invertebrate cells and concluded that our knowledge of the molecular and cellular biology of these viruses is too limited to allow any general recommendations. Proposals to use these viruses should be considered case by case. The group also recommended, however, that because of the potential exploitation of these viruses as biological pesticides (two have already been licensed for this purpose) and as vectors in recombinant DNA experimentation, high priority should be given to studies of their basic virology, genetics, and molecular biology.

4. *Cauliflower Mosaic Virus as a vector for cloning genes in plant cells.* The only known plant viruses which could serve as vectors for cloning genes in plants and plant cell protoplasts are Cauliflower Mosaic Virus (CaMV) and its close relatives, which have relaxed circular double stranded DNA genomes with a molecular weight of 5×10^6. The genomes of these viruses are not known to integrate into host chromosomes, or to pick up cellular genes. CaMV is spread in nature by aphids, in which it survives for a few hours. Spontaneous mutants of CaMV that are not transmitted by aphids arise frequently; these mutants fail to make a transmission factor essential for aphid transmission.

The viruses in the CaMV group have narrow host ranges and are relatively difficult to transmit mechanically to plants. For this reason, they are most unlikely to be accidentally transmitted from spillage of purified preparations of the virus.

The workshop participants recommended that for use as a vector with intact plants, a strain should be selected which is not transmitted by aphids The ability to produce local lesions in an appropriate host would be an advantage in maintaining the integrity of the strain. The plants should be grown in either a greenhouse or plant growth cabinet which is insect-proof Soil, plant pots and unwanted infected plant materials should be removed from the greenhouse or cabinet in sealed insect proof containers and sterilized. It is not necessary to sterilize run-off water from the infected plants as this is not a plausible route for secondary infections. Infected plant materials to be used for further research, which have to be removed from the greenhouse or cabinet, should be maintained under insect proof conditions. These measures provide an entirely adequate degree of containment and are similar to those required in many countries for licensed handling of "exotic" plant viruses.

CaMV or its DNA may also be useful as a vector to introduce genes into plant protoplasts. The fragility of plant protoplasts combined with the properties of CaMV mentioned above provides adequate safety. Since the group envisaged no risks to the environment from use of the CaMV protoplast system, no special containment was recommended.

Appendix E

TABLE 1

Risk of Illness in Laboratory Workers and of Spread of Viruses to the Environment

Agent	Genome	Severity of Disease in Adult Humans	Risk of Laboratory Infection	Transmission into Community or Environment	Community or Environmental Impact
Lassa Fever Virus	RNA - Negative strand, segmented	4+	H	L - H	H
Variola Virus	DNA - Linear, double stranded	4+	H (If not vaccinated)	L - H	H
*Yersinia pestis (Plague bacterium)		4+	H	L - H	L - H
Yellow Fever Virus (Wild type)	RNA - Positive strand	3+	H (If not vaccinated)	Dependent on presence of vector (H	
*Rickettsia prowazeki (Typhus agent)		3+	H	L	0
Hepatitis B Virus	DNA - Circular, partially single stranded	3+	L to H	L	0 - L
*Vibrio cholerae (Cholera bacterium)		2+ - 3+	L	L	0 to L
Influenza Virus (Novel epidemic strain)	RNA - Negative strand, segmented	1+ - 2+	L	H	H
Epstein-Barr Virus	DNA - Linear, double stranded	2+	L	L	0
Polio virus (wild)	RNA - Positive strand	0 - 3+	L	L	0 to L
Coxsackie Viruses	RNA - Positive strand	0 - 2+	L	L	0 to L
Herpes simplex virus	DNA - Linear, double stranded	1+	L	L	0
*Shigella sonnei		1+	L	L	0
Vesicular stomatitis virus	RNA - Negative strand	1+ - 2+	H	L	L for humans; H for certain animals.
Adenovirus 2 or 5	DNA - Linear, double stranded	0 - 1+	0 - L	L	0
Adeno-SV40 Hybrid Viruses (Nondefective)	DNA - Linear, double stranded	0 - 1+	0 - L	L	0
Vaccinia virus	DNA - Linear, double stranded	1+	L	L	0
Human Papilloma virus	DNA - Circular, double stranded	1+	L	L	L to 0
Influenza Virus (PR8)	RNA - Negative strand, segmented	0	0	0	0
*Bacteroides sp.		0 - 1+	0	L	0
Adeno-associated virus	DNA - Linear, single stranded	0	L	L	0
BK Virus	DNA - Circular, double stranded	0	L	0	0
Simian Virus 40 (SV40)	DNA - Circular, double stranded	0	L to H (?)	0 to L(?)	0
Sindbis virus (Lab. adapted)	RNA - Negative strand**	0 - 1+	0	Dependent on presence of vector (0-L)	
Semliki Forest Virus	RNA - Negative strand**	0 - 1+	0	Dependent on presence of vector (0-L)	
Reoviruses	RNA - Double stranded, segmented	0	0 to 1+	0	0
Rous sarcoma virus	RNA (Retrovirus)	0	0	0	0
Murine leukemia sarcoma viruses	RNA	0	0	0	0
Feline leukemia viruses	RNA	0	0	0	0
Polyoma virus	DNA - Circular, double stranded	0	0	0	0

* Non-viral agents.

** Ed. note: This should read "RNA-Positive strand."

H = High probability; L = Low probability.

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APPENDIX F.—REPORT OF THE VIRUS WORKING GROUP SPONSORED BY THE RECOMBINANT DNA ADVISORY COMMITTEE

On April 6–7, 1978, a working group of American virologists met in a public meeting at the National Institutes of Health to: (1) Review the report of the U.S.-EMBO workshop to assess risks for recombinant DNA expriments involving the genomes of animal, plant, and insect vectors and (2) Translate the conclusions of the U.S.-EMBO report into recommended physical and bilogical containment levels for consideration by the RAC for incorporation into the revised NIH guidelines for recombinant DNA research. The 19 scientists in attendance (see attached roster) had expertise in clinical infectious disease; epidemiology of viral disease; medical and diagnostic virology; the biology of virus infection; biochemical virology; viral immunology; and plant, insect, and veterinary viruses. Six of the participants (Drs. Ginsberg, Choppin, Martin, Rowe, Summers, and Wagner) had attended the U.S.-EMBO workshop.

REVIEW OF THE U.S.-EMBO WORKSHOP REPORT

The working group discussed the U.S.-EMBO workshop report section by section and recommended the following amendments:

(1) Page 10, line 17—delete "then modifies" and insert "is thought to modify."

(2) Page 16, lines 6-8—The working group did not understand the scientific basis behind this short paragraph which singled out viroids from other RNA plant viruses and which would postpone work in this area. Deletion of these three lines was recommended following a discussion about the potential risks attending the cloning of cDNA copies of viroids in *E. coli* K12.

(3) Table 1.

(a) Yellow fever virus—Add "L (if vaccinated)" under Risk of Laboratory Infection and change "(H)" to "(L-H)" under Community or Environmental Impact.

(b) Epstein-Barr Virus—Change "2+" to "0-2+" under Severity of Human Disease.

After reviewing the U.S.-EMBO report the working group unanimously endorsed: (1) The classification of viruses with respect to their ability to cause disease in laboratory workers and their impact on the environment; (2) The analysis and recommendations for cloning viral DNA's in *E. coli* K12; and (3) The analysis and recommendations for the use of viral DNA's as vectors in eukaryotic cells.

IMPLEMENTATION OF THE U.S.-EMBO REPORT

A. Cloning Eukaryotic Viral DNA in *E. coli* K12 Host-Vector Systems.

After considerable discussion, the working group recommended physical and biological containment conditions for experiments involving the cloning of viral DNA in *E. coli* K12 as shown in table 1. The group classified the viral DNA for such experiments in three categories: (1) Virion DNA of DNA viruses; (2) cDNA copies of virion RNA of RNA viruses; and (3) Intracellular forms of viral DNA including integrated genomes, and DNA from productively infected cells. The viral DNA to be cloned was then subclassified into whether it represented the entire viral genome or a purified subgenomic segment thereof. Subgenomic segments were further subdivided on the basis of whether they contained intact transforming genes or not (see table 1). In addition, the working group also assigned physical and biological containment levels for cDNA copies of cellular mRNA's for each class of viral DNA insert (see table 1).

1. In its deliberations, the working group was impressed with the safeguards afforded by a ban on mouth-pipetting for recombinant DNA experiments involving *E. coli* K12 host-vectors. The group felt that the only plausible way *E. coli* K12 could gain entry into laboratory workers was by oral ingestion. The analysis contained in the U.S.-EMBO report was predicated on the remote possibility that *E. coli* K12, containing eukaryotic viral DNA, would be swallowed and the viral DNA insert would be delivered to a tissue in the body which ordinarily would be inaccessible to the virus. A prohibition of mouth pipetting would clearly prevent this sequence of events from even beginning. The working group therefore recommended that no mouth pipetting be allowed at any level of physical containment (including P1) when working with *E. coli* K12.

2. The group was struck by the inherent safety afforded by nonmobilizable plasmids and felt they represented an additional level of containment when used with *E. coli* K12. Accordingly, the working group recommended the use of *E. coli* K12 in conjunction with non-mobilizable plasmid vectors (referred to in table 1 as EK1NM) for several categories of experiments.

3. The virus working group extensively discussed the use of class III (CDC) and "moderately oncogenic" (NCI) viral DNA's in *E. coli* K12 host vector systems. The group concluded that vesicular stomatitis virus (VSV), which is a widely studied negative-strand RNA virus, is classified as a class III agent because of its ability to produce disease in animals; VSV is not an important human pathogen (see table 1 of U.S.-EMBO report). The working group agreed that VSV possessed all of the safety features of other negative-strand RNA viruses (see U.S.-EMBO report) and strongly recommended that cloning of VSV cDNA be permitted because of its importance as a model virus in studies of the molecular biology of virus infection. The working group also considered the 9 viruses classified as moderately oncogenic by NCI (Appendix B) and concluded that the only potential biohazard associated with their use involved the propagation of the viruses themselves during the preparation of reagents/substrates for use in recombinant DNA experiments. None of these agents produces human disease or has been associated with human malignancy. The virus working group endorsed the inclusion of these agents as sources of eukaryotic viral DNA for cloning in *E. coli* K12 and recommended that NCI guidelines be followed for work involving the viruses themselves.

B. Viral DNA Vectors in Eukaryotic Cells.

The working group discussed the physical containment levels appropriate for different eukaryotic viral DNA vectors and prepared a list of four animal viruses and two plant viruses as candidate vectors. In each case the group made recommendations regarding physical containment conditions for productive or non-productive virus-cell interactions. The virus working group, like the participants of the U.S.-EMBO workshop, were concerned about alterations in host range and tissue tropism that might occur following the insertion of foreign viral DNA sequences into eukaryotic viral DNA vectors and were unable to specify containment levels for this type of DNA recombinant. The group agreed that experiments of this type could yield useful information about viral pathogenesis and recommended that each be evaluated by the recombinant DNA Molecule Program Advisory Commitee on a "case-by-case" (CBC) basis. The working group also recognized its inability to identify all possible viral vectors and therefore included a category which encompassed other potential viral DNA vectors whose use could also be evaluated on a "case-by-case" basis.

The virus working group regarded the use of DNA vectors prepared from CaMV and BGMV as posing virtually no biohazard to plants or the ecosystem and recommended a minimum of physical containment. The group extensively discussed the use of baculovirus DNA as vectors, and, despite their certification as registered pesticides, considered the available information about their host range, persistence, and basic biology to be too rudimentary at the present time. A "case-by-case" evaluation was therefore recommended.

The virus working group unanimously endorsed the elimination of the requirement pertaining to the functional anatomy of viral DNA vectors (page 49602, third column, (iii)) since these features are related in no way to the inherent safety of a potential vector. These criteria for candidate vectors were retained in the final recommendations, however, as desirable, although not required features.

It should be noted that the recommendations of the virus working group impact on two other sections of the Revised Guidelines for Recombinant DNA Research.

(1) Section III B 1a(1)(g) can be eliminated because it is now covered in section III B 1b(1).

(2) Section III A should be amended to read "pathogenic organisms in classes 3, 4, and 5 except vesicular stomatitis virus;" the prohibition of moderate risk oncogenic viruses should be deleted.

The recommendations made by the virus working group were based on the best and most current available scientific considerations. The containment levels proposed for cloning eukaryotic

viral DNA inserts in prokaryotic systems pertain *only* to *E. coli* K12 and its derivatives. The working group agreed with the participants of the U.S.-EMBO Workshop that eukaryotic viral genomes cloned in *E. coli* K12 posed less risk in nearly all cases than work with the infectious virus itself.

Recombinant DNA Molecule Program Advisory Committee Working Group on Report of the U.S.-EMBO Workshop to Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant and Insect Viruses, National Institutes of Health, Conference Room 9, Building 31C, Bethesda, Md. 20014, April 6-7, 1978, 9 a.m

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TABLE 1. Recommended Containment for Cloning of Viral DNA in E. coli K12 Host-Vector Systems

Virus Class	Type of Viral DNA Segment to be Cloned: Subgenomic[1] — Non-transforming Segments	Subgenomic[1] — Segments containing an entire transforming gene	Genomic[2] — Non-segmented genome	Genomic[2] — Segmented genome	cDNA from cellular mRNA[3]
DNA	All P1[4]+EK1	All P2+EK1NM[5]			
Non-transforming viruses					
AAV, MVM, Mouse Adeno			P1+EK1		P1+EK1
Other			P1+EK1NM		P1+EK1
Transforming viruses					
Herpes saimiri and H.ateles[6]			P2+EK2 or P3+EK1		
Other			P2+EK1NM		
RNA					
Retroviruses	All P1+EK1	All P2+EK1NM			All P2+EK1NM
Gibbon and woolly monkey			P2+EK2 or P3+EK1		
Other			P2+EK1NM		
Negative strand RNA	P1+EK1		P1+EK1	P1+EK1	P1+EK1
Plus strand RNA	P1+EK1				
Type 1 and 2 Sabin polio, 17D yellow fever vaccine strains			P1+EK1		P1+EK1
Other			P2+EK1NM		P2+EK1NM
Double stranded RNA	P1+EK1			P1+EK1	P1+EK1

1 ≥ 99% pure (i.e., less than 1% of the DNA consists of intact viral genomes), otherwise as for whole genomes.

2 Integrated genomes to be cloned at containment as for shotgun experiments on uninfected cells.

3 ≥ 99% pure, otherwise as for shotgun with uninfected cells.

4 For the purposes of this chart, P1 is defined as including a ban on mouth pipetting.

5 EK1NM means K-12 with non-mobilizable plasmid vectors.

6 These viruses have been classified by NCI as "moderate risk oncogenic viruses," and NCI recommends that the viruses be handled under the equivalent of P3 containment.

TABLE 2. Recommended Containment for Recombinant DNA Research Using Eukaryotic Viral Vectors

Vector DNA	Productive Virus-Cell Interactions						Non-Productive Virus-Cell Interactions
	Type of DNA Insert						
	Prokaryotic		Eukaryotic			Eukaryotic Viral	
	Shotgun	Purified	Shotgun		Purified		
			Natural Host	Other			
1. Polyoma							
Intact Genome	P2	P2	P2	P3	P2	CBC*	P2
Deleted Genome	P2	P2	P2	P3	P2	CBC	P2
2. SV40							
Intact Genome	--	--	--	--	--	---	P2
Deleted Genome	P2	P2	P2	P3	P3	CBC	P2
3. Human Ad2+Ad5							
Deleted Genome	P3	P3	P3	P3	P3	CBC	P2
4. Mouse Adenovirus (Strain FL)							
Intact Genome	CBC	CBC	CBC	CBC	CBC	CBC	P2
Deleted Genome	P2	P2	P2	P2	P2	CBC	P2
5. Insect Viruses	CBC	CBC	CBC	CBC	CBC	CBC	--
6. Plant Viruses (CaMV and BGMV)	P1	P1	P1	P1	P1	CBC	--
Plants and Potentially Propagated Plant Parts	Insect-Proof Growth Cabinet or Controlled-Access Insect-Proof Greenhouse.					CBC	--
7. All other potential Viral Vectors	CBC	CBC	CBC	CBC	CBC	CBC	CBC

* CBC - Case by case to be decided by RAC

(1) *Viruses of Eukaryotes.*

(a) *DNA viruses.*

1. *Nontransforming viruses.*

(a) *Adeno-associated viruses, minute virus of mice, and mouse adenovirus strain FL.*—P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with the whole genome, subgenomic DNA segments, or cDNA copies of cellular mRNA.*

(b) *Other viruses.*

(i) P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with purified subgenamic segments or cDNA copies of cellular mRNA.*

(ii) P1 physical containment including no mouth pipetting + an EK1 host vector, which, in the case of a plasmid, must be non-mobilizable shall be used for DNA recombinants produced with the whole genome.

2. *Transforming viruses.*

(a) *Herpes saimiri and herpes ateles.*

(i) P1 physical containment including no mouth pipetting + an EK1 host vector shall be used for DNA recombinants produced with purified nontransforming subgenomic DNA segments or cDNA copies of cellular mRNA.*

(ii) P2 physical containment + an EK1 host vector which, in the case of a plasmid, must be non-mobilizable, shall be used for DNA recombinants produced with purified subgenomic DNA segments containing an entire transforming gene.

(iii) P3 physical containment + an EK1 host-vector or P2 + EK2 shall be used for DNA recombinants produced with the whole genome.

(b) *Other viruses.*

(i) P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with purified non-transforming subgenomic DNA segments or cDNA copies of cellular mRNA.*

(ii) P2 physical containment + an EK1 host-vector which, in the case of a plasmid, must be non-mobilizable, shall be used for DNA recombinants produced with the whole genome or purified subgenomic DNA segments containing an entire transforming gene.

(b) *RNA viruses.*

1. *Retroviruses.*

(a) *Gibbon ape and woolly monkey viruses.*

(i) P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with purified non-transforming subgenomic DNA segments.

(ii) P2 physical containment + an EK1 host-vector which, in the case of a plasmid, must be non-mobilizable, shall be used for DNA recombinants produced with purified subgenomic DNA segments containing an entire transforming gene or cDNA copies of cellular mRNA.*

(iii) P2 physical containment + an EK2 host-vector shall be used for DNA recombinants produced with the whole genome.

(b) *Other viruses*

(i) P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with purified non-transforming subgenomic DNA segments.

(ii) P2 physical containment + an EK1 host-vector which, in the case of a plasmid, must be non-mobilizable, shall be used for DNA recombinants produced with purified subgenomic DNA segments containing an entire transforming gene, the whole genome, or cDNA copies of cellular mRNA.*

2. *Negative strand viruses.*—P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with the whole genome, subgenomic DNa segments or purified cDNA copies of cellular mRNA.*

3. *Plus-strand RNA viruses.*

(a) *Types 1 and 2 Sabin poliovirus and strain 17D (Theiler) of yellow fever virus.*—P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with the whole genome, subgenomic DNA segments or purified cDNA copies of cellular mRNA.*

(b) *Other viruses*

(i) P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with purified subgenomic DNA segments.

(ii) P2 physical containment + an EK1 host-vector which, in the cse of a plasmid, must be nonmobilizable, shall be used for DNA recombinants produced with the whole genome or purified cDNA copies of cellular mRNA.*

4. *Double-stranded segmented RNA viruses.*—P1 physical containment including no mouth pipetting + an EK1 host vector shall be used for DNA recombinants produced with mixtures of subgenomic segments, a specific subgenomic segment, or purified cDNA copies of cellular mRNA.*

5. *Viroids.*—P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with the whole genome, subgenomic DNA segments or cDNA copies of cellular mRNA.*

(c) *Intracellular viral DNA.*—Physical and biological containment specified for shotgun experiments involving uninfected eukaryotic cellular DNA [sec. B.1.a.(1)] shall be used for DNA recombinants produced with integrated viral DNA or viral genomes present in infected cells.

3. *Experiments with Eukaryotic host-vectors.*

a. *Vertebrate host-vector systems.*—Because this work will be done almost exclusively in tissue culture cells, which have no capacity for propagation outside the laboratory, the primary focus for containment is the vector; it should be pointed out that risk of laboratory acquired infection as a consequence of tissue culture manipulations is very low. Given good microbiological practices, the most likely mode of escape of recombinant DNAs from a physically contained laboratory is carriage by an infected human; thus the vector with an inserted DNA segment should have little or no ability to replicate or spread in humans. Further, a recombinant virus should not inadvertently pose a threat to any species.

For use as a vector in a vertebrate host cell system, an animal viral DNA molecule should display the following properties:

(a) It should not consist of the whole genome of any agent that is infectious for humans or that replicates to a significant extent in human cells in tissue culture. If the recombinant molecule is used to transform non-permissive cells (i.e. cells which do not produce infectious virus particles), this is not a requirement.

(b) It should be derived from a virus whose epidemiological behavior and host range are well understood.

(c) In permissive cells, it should be defective when carrying an inserted DNA segment; (i.e. propagation of the recombinant DNA as a virus must be dependent upon the presence of a complementing helper genome). In almost all cases this condition would be achieved automatically by the manipulations used to construct and propagate the recombinants. In addition, the amount of DNA encapsidated in the particles of most animal viruses is defined within fairly close limits. The insertion of sizeable foreign DNA sequences, therefore, generally demands a compensatory deletion of viral sequences. It may be possible to introduce very short insertions (50-100 base pairs) without rendering the viral vector defective. In such a situation, the requirement that the viral vector be defective is not necessary except in those cases in which the inserted DNA encodes a biologically active polypeptide.

It is desired but not required that the functional anatomy of the vector be known—that is, there should be a

*The cDNA copy of cellular mRNA must be 99 percent pure; otherwise, physical and biological containment specified for shotgun experiments involving uninfected eukaryotic cellular DNA [sec. B.1.a.(1)] shall be used.

clear idea of the location within the molecule of:

(a) The sites at which DNA synthesis originates and terminates.

(b) The sites that are cleaved by restriction endonucleases.

(c) The template regions for the major gene products.

If possible the helper virus genome should:

(i) Be integrated into the genome of a stable line of host cells (a situation that would effectively limit the growth of the vector recombinant to such cell lines), or

(ii) Consist of a defective genome, or an appropriate conditional lethal mutant virus, making vector and helper dependent upon each other for propagation.

However, neither of these stipulations is a requirement.

(1) *Polyoma virus.*

(a) *Productive virus-cell interactions.*

1. Defective or intact polyoma virus genomes, with appropriate helper, if necessary, can be used in P2 conditions to *propagate* DNA sequences from:

(*a*) Bacteria of class 1 or class 2 (see appendix B), or their phages or plasmids, except for species of bacteria that produce potent polypeptide toxins.

(*b*) From mice.

(*c*) From other eukaryotic organisms that do not produce potent polypeptide toxins, provided the DNA segment is purified.

2. Defective or intact virus genomes with appropriate helper, if necessary, can be used in P3 conditions for shotgun experiments to *propagate* DNA sequences from eukaryotic organisms, provided the DNA is obtained from uninfected cells such as embryonic or tissue culture cells.

3. Experiments involving the use of defective polyoma virus genomes to *propagate* DNA sequences from eukaryotic viruses will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by that committee.

(b) *Non-productive virus-cell interactions.*—Defective or intact polyoma virus genomes can be used as vectors in P2 conditions to *transform* nonpermissive cells in culture.

(2) *Simian virus 40.*

(a) *Productive virus-cell interactions.*

1. SV40 DNA, rendered unconditionally defective by a deletion in an essential gene, with appropriate helper, if necessary, can be used in P2 conditions to *propagate* DNA sequences from:

(*a*) Bacteria of class 1 or class 2 (see appendix B), or their phages or plasmids, except for species of bacteria that produce potent polypeptide toxins.

(*b*) Uninfected African green monkey kidney cells.

2. SV40 DNA, rendered unconditionally defective by a deletion in an essential gene, with an appropriate helper, if necessary, can be used in P3 conditions to *propagate* DNA sequences from eukaryotic organisms (shotgun experiments or purified DNA) provided the DNA is obtained from uninfected cells such as embryonic or tissue culture cells.

3. Experiments involving the use of defective SV40 genomes to *propagate* DNA sequences from eukaryotic viruses will be evaluated by the Recombinant DNA Molecular Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by that committee.

(b) *Non-productive virus-cell interactions.*—Defective or intact SV40 genomes can be used as vectors in P2 conditions to *transform* nonpermissive cells in culture.

(3) *Human adenoviruses 2 and 5.*

(a) *Productive virus-cell interactions.*

1. Human adenoviruses 2 and 5, rendered unconditionally defective by deletion of at least 2 capsid genes, with appropriate helper(s), if necessary, can be used in P3 conditions to *propagate* DNA sequences from:

(*a*) Bacteria of class 1 or class 2 (see appendix B) or their phages or plasmids except for species of bacteria that produce potent polypeptide toxins.

(*b*) Eukaryotic organisms (shotgun experiments or purified DNA) provided the DNA is obtained from uninfected cells such as embryonic or tissue culture cells.

2. Experiments involving the use of unconditionally defective human Ad 2 and 5 genomes to *propagate* DNA sequences from eukaryotic viruses will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by that committee.

(b) *Non-productive virus-cell interactions.*—Defective or intact human Ad 2 and 5 genomes can be used as vectors in P2 conditions to *transform* non-permissive cells in culture.

(4) *Murine adenovirus strain FL.*

(a) *Productive virus-cell interactions.*

1. Unconditionally defective murine adenovirus strain, FL genomes, with appropriate helper, if necessary, can be used in P2 conditions to *propagate* DNA sequences from:

(*a*) Bacteria of class 1 or class 2 (see appendix B) or their phages or plasmids except for species of bacteria potent polypeptide toxins.

(*b*) Eukaryotic organisms (shotgun experiments or purified DNA) provided the DNA is obtained from uninfected cells such as embryonic or tissue culture cells.

2. Experiments involving the use of intact murine adenovirus strain FL genomes to *propagate* DNA sequences from prokaryotic or eukaryotic organisms will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by that committee.

3. Experiments involving the use of unconditionally defective murine adenovirus strain FL genomes to *propagate* DNA sequences from eukaryotic viruses will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by that committee.

(b) *Non-productive virus-cell interactions.*—Defective or intact murine adenovirus strain FL genomes can be used as vectors in P2 conditions to *transform* non-permissive cells in culture.

(5) *All other potential viral vectors.*

(a) Experiments involving the use of viral DNA vectors consisting of 25 percent or less of the viral genome shall be used:

1. In P2 conditions to *transform* nonpermissive cells in culture.

2. Under physical containment conditions to be determined by the Recombinant DNA Molecule Program Advisory Committee to *propagate* DNA sequences from prokaryotic or eukaryotic organisms.

(b) Experiments involving the use of other intact or defective virus genomes to *propagate* DNA sequences from prokaryotic or eukaryotic organisms (and viruses) or as vectors to *transform* non-permissive cells will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by that committee.

The Recombinant DNA Molecule Program Advisory Committee will also review all experiments involving the use of virus vectors in animals and the physical containment conditions appropriate for such studies.

b. *Invertebrate host-vector systems in which insect viruses are used to propagate other DNA segments.*—As soon as information concerning the nature of the host range, infectivity, persistence and integration in vertebrate and invertebrate cells becomes available, experiments involving the use of baculo-viruses to propagate

DNA sequences will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by the committee. Experiments should be done in established invertebrate cell lines and should follow, where appropriate, criteria recommended for vertebrate viral DNA vectors [Sec. 3.a.(a-c)].

c. *Plant host-vector systems.*—The DNA plant viruses which could currently serve as vectors for cloning genes in plants and plant cell protoplasts are Cauliflower Mosaic Virus (CaMV) and its close relatives, which have relaxed circular double stranded DNA genomes with a molecular weight of 4.5×10^6, and Bean Golden Mosaic Virus (BGMV) and related viruses with small ($<10^6$ daltons) singled-stranded DNA genomes. These viruses are not known to integrate into host chromosomes, or to incorporate cellular genes into their genomes. CaMV is spread in nature by aphids, in which it survives for a few hours. Spontaneous mutants of CaMV that are not transmitted by aphids arise frequently; these mutants fail to make a transmission factor essential for aphid transmission. BGMV is spread in nature by whiteflies, in which it survives for several days to three weeks; certain other single-stranded DNA plant viruses are transmitted by leafhoppers, in which the viruses persist for days or weeks. Single-stranded DNA plant viruses are thought not to replicate in their insect vector.

The DNA plant viruses have narrow host ranges and are relatively difficult to transmit mechanically to plants. For this reason, they are most unlikely to be accidentally transmitted from spillage of purified preparations of the virus.

When these viruses are used as vectors with intact plants, the plants should be grown in either a limited access greenhouse or plant growth cabinet which is insect-proof, preferably with positive air pressure, and in which an insect fumigation regime is maintained. Soil, plant pots and unwanted infected plant materials should be removed from the greenhouse or cabinet in sealed insect proof containers and sterilized. It is not necessary to sterilize run-off water from the infected plants as this is not a plausible route for secondary infection. Infected plant materials to be used for further research, which have to be removed from the greenhouse or cabinet, should be maintained under insect proof conditions. These measures provide an entirely adequate degree of containment and are similar to those required in many countries for licensed handling of "exotic" plant viruses.

The viruses or their DNA may also be useful as a vector to introduce genes into plant protoplasts. The fragility of plant protoplasts combined with the properties of the viruses mentioned above provide adequate safety. Since no risk to the environment from the use of the DNA plant virus/protoplast system is envisaged, no special containment is recommended.

Experiments involving the use of plant virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under containment conditions recommended by that committee.

Appendix G.—Report of a Workshop on Risk Assessment of Agricultural Pathogens

Conducted by: Recombinant DNA Molecule Program Advisory Committee.

Sponsored by: U.S. Department of Agriculture, National Science Foundation, and National Institutes of Health, March 20-21, 1978.

Contents

INTRODUCTION

An assessment of risk involved in recombinant DNA research on plant and insect pathogens necessarily entails consideration of different concerns than those applied to risk assessment of research with pathogens of man and animals. This fundamental difference provided the basis on which the recommendations of our committee were formulated.

There was a consensus amongst the committee members that working with plant pathogens and baculoviruses in recombinant DNA studies presents no more hazard than that which exists in current laboratory studies with the pathogens themselves. It is significant that to the best of our knowledge there have been no cases recorded in which laboratory studies with cultures of plant pathogens have resulted in illness in man or animals exposed to these organisms. Neither is there a documented case in which laboratory studies with cultures have resulted in an escape resulting in an outbreak of disease in plants growing under natural conditions.

We believe that any potential risk that might arise from studies involving plant pathogens is now adequately covered by existing federal and state quarantine regulations. These have evolved to enable government to deal with the practicalities of plant disease control (Gram, E., 1960, Chapter 9, pp. 314-356 in "Plant Pathology, An Advanced Treatise", J. G. Horsfall and A. E. Dimond, eds., vol. 3, Acad. Press., New York). They take precedence over any other regulations since they determine whether or not an investigator has access to a particular pathogen.

With plants, resistance to disease is the rule, susceptibility is the exception. Thus, the common occurrence of resistance poses an important barrier to the successful establishment of potential pathogens. There is no pathogen that is highly virulent on all plant species. Rather, the majority of pathogens are restricted to a relatively small number of host plants and within these specific susceptible hosts varietal variation in resistance is usually present. Breeding for disease resistance has provided a means for effecting relatively rapid changes in varieties. In the United States today, approximately 95 percent of the acreage in crops of economic importance is planted to varieties that carry resistance to one or more major diseases. This is one of the key factors in the productivity of American agriculture. Even when a particularly destructive new race or strain of a plant pathogen arises, it is possible to change the available varieties and to reduce or minimize the threat within the space of two or three years. This was the case when a virulent strain of the pathogen that causes *Helminthosporium* leaf blight spread throughout the corn growing area of the United States in 1970 and it was necessary to discontinue the growing of those hybrids that carried the factor for male sterility which also conferred susceptibility to the disease (Ullstrup, A. J., 1972, Ann. Rev. Phytopath. 10:37-50).

Virulent plant pathogens commonly are contained in nature because for their very survival and dissemination within a region, or for an epidemic to develop, they require specific environmental factors (Colhoun, J., 1973, Ann. Rev. Phytopath. 11:343-364). For example, bacterial wilt caused by *Pseudomonas solanacearum* rarely occurs north of the Mason-Dixon line. The causal bacterium is sensitive to low temperatures and has a relatively high optimum temperature for growth. Even when introduced inadvertently into Northern states it does not overwinter in the soil or affect susceptible crops the following year (Kelman, A., 1953, N. Carolina Agr. Exp. Sta. Bull. 99, 194p).

In considering hypothetical risks of recombinant DNA research on plant pathogenic organisms our committee considered the following questions:

1. Will the introduction of recombinant DNA from a specific plant pathogen in *E. coli* K12 lead to the development of strains with enhanced virulence to man or animals?

2. Will strains of *E. coli* be converted into plant pathogens?

3. Will the use of plant pathogens as HV systems result in hazards to plants?

With the relatively minor reservations documented below, the committee agreed that the answer to all three questions was "No". First we would point out that there is no evidence that genetic information transferred from plant pathogenic organisms would enhance the capability of strains of *E. coli* to harm man, animals or plants. There are a very small number of possible exceptions to this generalization. These include a few species of bacteria which have been found in association with plants or which have been described as weak or minor plant pathogens and which may be closely related to forms causing disease in man. Also, plant pathogens such as the ergot fungus, and certain molds that produce aflatoxins on stored plant products are likely to be banned on the grounds that they produce potent, albeit non-polypeptide, toxins.

Provided that the use of plant pathogens as HV systems is not undertaken with the objective of deliberately creating forms with increased virulence and host range beyond that which occurs by natural genetic exchange (these are expressly prohibited by the guidelines) we see no hazard from such systems to plants.

1. Without dissent, the committee agreed on a classification of plant pathogens on the basis of hazard to agriculture.

We have placed all plant pathogens into a single class with two subgroups. This reflects our opinion that recombinant DNA research with plant pathogens has a negligible risk. The two subgroups take account of existing federal and state quarantine regulations. We propose that this classification be appendix C in the guidelines.

HAZARD CLASSIFICATION OF PLANT PATHOGENS

Class 1A—Plant pathogens not in class 1B.

Class 1B—All organisms that are subject to quarantine restrictions for any of the following reasons:

(i) Plant pathogens not known to occur in the United States.

(ii) Plant pathogens that are not widely distributed throughout the ecological range of their hosts.

(iii) Plant pathogens subject to federal or state eradication or suppression programs.

All plant pathogens require state and federal (USDA[1]) permits for shipment across state lines.

2. *Specific recommendations.* The lack of an accepted definition of exchangers caused us some difficulty in our discussions. A majority of the committee favor a liberal definition that would exclude all gram negative bacteria from the guidelines. However, since this decision has still to be made by the RAC and Dr. Fredrickson some of our recommendations had to reflect two alternatives: (i) On the basis that most gram negative forms would be excluded we present rationale for including gram negative plant pathogens in this exclusion; (ii) on the basis that prokaryotic exchangers might be defined in a less liberal fashion, or that there might be a long lag period before plant pathologists can present evidence satisfying whatever exchange criteria are established, we present rationale for adopting minimal containment levels for all phytopathogenic bacteria namely P1+EK2 or P2+EK1.

III B 1a. Shotgun experiments using the *E. coli* K12 host-vector systems.

(2) Prokaryotic DNA recombinants. (p. 49602 FR 42 No. 187, Sept. 27, 1977). We propose that the minimum containment levels adopted for other bacteria be applicable to phytopathogenic bacteria, namely P1+EK2 or P2+EK1.

(i) Modify line 7 to read; "biochemical, genetic, and/or pathogenic properties.

(ii) Delete the words "and plant pathogens" from line 5 of the second paragraph.

Rationale: Plant pathogenic bacteria include diverse organisms principally in the genera *Agrobacterium, Corynebacterium, Erwinia, Pseudo- monas,* and *Xanthomonas.* A number of the plant pathogenic species are soil-inhabitants and are widely distributed throughout the United States. In general they cause economic loss only when environmental conditions are favorable and available control practices are not used. A number of bacteria that cause foliage diseases can exist as epiphytes on a variety of non-host plants as well as on their susceptible hosts. Other bacteria such as the pathogen that causes halo blight of beans are seed-transmitted, do not survive in soil for long periods of time and can be controlled by the use of pathogen-free seed. The mechanisms by which plant pathogenic bacteria produce disease in plants may involve enzymes which attack substrates in plants such as pectic compounds. Such enzymes would not be harmful to man or animals. Similarly certain growth promoting compounds and compounds that interfere with specific physiological functions in plants, e.g. polysaccharides that block movement of water, are not known to cause injury to man.

Certain bacteria which are not known to cause disease in plants but which are commonly present as epiphytes on leaves (Leben, C., 1965 Ann. Rev. Phytopath. 3:209-230) have been associated with diseases of man, i.e. *Erwinia herbicola* also designated as *Enterobacter agglomerans* (Starr, M. P. and Chatterjee, A. R., 1972, Ann. Rev. Microbiol. 26:389-426). However, there is a diversity of strains that have been obtained from plants and there is no conclusive evidence that the types widespread in plants are the same strains associated with certain infections in man.

Similarly it has been reported that a bacterium similar to a pathogen of onions (*Pseudomonas cepacia*) has been associated with a disease of man (Ederer, G. M. & Matsen, J. M., 1972, J. Infect. Dis. 125:613-618; Snell, J. J. S., Hill, L. R., LaPage, S. P. & Curtis, M. A., 1972, Internat. Symp. Systemat. may not have useable vectors.

III.B. 3c. Plant host-vector systems. (p. 49603).

(i) Delete second paragraph. "Whole plants or plant * * * at this time".

Rationale: This paragraph is confusing. Its intent was to define practical size or scale limits to physical containment rather than limits to biological containment. The committee concluded that the discussion of physical containment in the preceding paragraph makes this redundant.

(ii) Delete last sentence of fourth paragraph "However, if the source of the DNA is itself pathogenic * * * shall be carried out under P3 conditions" and substitute: "If the vector is an unmodified virus the experiments shall also be carried out under P2 conditions".

Rationale: This committee has reassessed the risk to man, animals, and plants from plant pathogenic agents. In this context we are concerned principally with the risk of DNA from plant pathogens to plants. This paragraph now reflects our lowered assessment of these risks.

(iii) Delete paragraph five. Experiments on * * * are not met.

Rationale: As for (ii).

(iv) Modify final paragraphs to read "* * * permit a decrease of one step in the physical containment to P1."

Rationale: The survival of plant protoplasts (see table 1) and undifferentiated cultured plant cells outside their laboratory environment is zero because of their extremely exacting growth requirements and fragility.

[1]Address to obtain application to import or move a plant pest or pathogen: Plant Importation and Technical Support Staff, Plant Protection and Quarantine Programs, Animal and Plant Health Inspection Service, USDA, Federal Center Building, Hyattsville, Md. 20782.

II.D. a. HV-1 (p. 49600).

This committee proposes that the Recombinant Advisory Committee consider allowing the construction of modified HV-1 systems with conjugation proficient plasmids in addition to other recombinant molecules of prokaryotic origin under one step higher physical containment providing that all the DNA segments in the cell are derived from organisms which exchange DNA by natural physio-Lower Eukaryotes (p. 9601)(e)2. Insert the words—

The remainder of the species in this class, including plant pathogenic or symbiotic fungi that do not produce potent toxins: P2+EK1 or P1+EK2.

Rationale: There is no demonstrable risk either to man or plants from cloning such DNA in *E. coli.* Also the present wording which refers to disease causing microorganisms could be interpreted to call for an unreasonably high containment level for these plant pathogens.

(f) Plants. (p. 49601). Delete the words "carries a known pathogenic micro-organism or"

Rationale: The risk to man or plants from DNA of a plant pathogen is not comparable to the risk of cloning DNA which codes for a potent polypeptide toxin. We have covered this risk elsewhere.

II.D. Biological containment—Host vector systems. a.2. Other prokaryotes (p. 49600).

We endorse the La Jolla Working Group Draft: (Insert III-3). "Experiments that are exempt from these guidelines". In the event that sections (iii) and (iv) are not adopted we propose the following:

Self-cloning of bacterial plant pathogens and symbionts:

(i) The use of an indigenous plasmid or bacteriophage shall be exempt from the guidelines.

(ii) The use of a foreign vector (a non-indigenous plasmid or bacteriophage) from an organism which exchanges DNA by natural physiological processes shall require P2 containment.

Rationale: Many self-cloning experiments with agriculturally significant gram-negative bacteria could be more readily and safely carried out by using well characterized *E. coli* plasmid vectors. Some plants pathogens and symbionts Bacteriol., 22:-138). *Pseudomonas aeruginosa,* a pathogen of man, conversely, Has been reported to cause a leaf-spot of tobacco but is considered a minor and inconsequential pathogen of plants (Cho, J. J., Schroth, M., Mason, M N, Komino, S. D. and Green, S. K., 1975 Phytopath. 65:425-431). These three bacteria should be governed by regulations applicable to human pathogens.

In our opinion it is a mistake to equate prokaryotic plant pathogens with Class 2 human pathogens as is done in the revised guidelines. The minimum containment level for those that have been extensively characterized as to pathogenic and other properties should be consistent with that adopted for other prokaryotes namely, P1+EK2 or P2+EK1.

III B1b(1)(d) Viruses of plants (p. 49602). Change to P2+Ek1 or P1+Ek2.

Rationale: Because of their fastidious modes of transmission and restrictive host ranges, DNA plant viruses were considered to present a minimal risk to animals or agriculture when used in shotgun experiments with the *E. coli* K-12 host vector systems.

III B 3b Pesticide baculoviruses (p. 49603).

(1) Remove sentences "Two viruses are presently registered * * * tussock moth".

Rationale: Footnote No. 7 in the September, 1977, draft describes the baculovirus pesticides that have been registered to date. The second sentence of the September, 1977, draft is therefore repetitive. Also, it should be made clear that any baculovirus that is registered by the EPA may be used as a vector since EPA registration is an ongoing process and other baculoviruses may eventually be registered which could be more useful for vector work.

(2) Remove the sentence "However, much still needs to be learned" and rewrite the final sentence of first paragraph to read "However, information is needed on the nature of the host range specificity, particularly the infectivity and persistence of the viral DNA in invertebrate and vertebrate cell cultures."

Rationale: The original sentence, "However much still needs to be learned," introduces ambiguity. The background information that was agreed to be essential in 1977 was information on the host specificity, particularly infectivity of viral DNA in vertebrate cell cultures.

(3) Substitute for the last paragraph in this section: When such background information is available, and if it confirms the narrow host range specificity, a baculovirus vector may be used for cloning DNA segments derived from the host insect, from another Environmental Protection Agency registered baculovirus, from an EK1 bacterium of from DNAs cloned in an EK1 bacterium (with the exception of any cloned DNA derived from an animal virus other than an EPA registered baculovirus), using P2 physical containment. Cloning of other classes of DNA is not envisioned for the exploratory phases of this work, but may be considered on a case-by-case basis in the future.

Rationale: The term "EK1 bacterium" was originally meant to include any DNA cloned in an EK1 bacterium, not simply *E. coli* K-12 DNA. Of particular interest in this category are Lepidopteran genes already cloned in *E. coli* K-12 such as the *B. mori* silk gene and the chorion genes of *A. polyphemus.* Also, it would be of interest to extract baculovirus DNA cloned in EK1 with a plasmid vector and test infectivity and/or effects in insect cell cultures. Such experimentation is also relevant to safety assessment of EK1 hosts.

Rationale: The revised guidelines explicitly prohibit conjugative plasmids and generalized transducing phages in EK-1 and HV-1 Systems. It is implicit that these elements shall not be introduced subsequent to cloning. This precludes host range tests unless they are carried out under more stringent physical containment. It also prevents plasmid promoted mobilization to introduce recombinant molecules back to the *original* DNA source organism or its mutants. Plant pathogens and Rhizobia are often non-transformable. This will effectively preclude complementation tests for traits not expressed in the cloning host such as plant pathogenicity in EK hosts. In effect, this creates a dilemma. In the proposed revisions of the drafted guidelines self-cloning in plasmids will be excluded even though the recombinant DNA can be mobilized out of the host strain into other prokaryotes. On the other hand, DNA cloned from the donor prokaryotes into a different recipient prokaryote cannot be mobilized by a conjugative plasmid back into the original donor, despite the fact that it is receiving its own DNA by this procedure. If the "exchanger" list is based on plasmid exchange these arguments are irrelevant.

We have listed in table 2 our suggestions for prokaryotic exchangers that are either plant pathogens or symbionts (Rhizobium) together with evidence for such exchange.

TABLE 1

SURVIVAL DATA OF PLANT PROTOPLASTS

(S-T. Liu, S. H. Fernandez, N. Schwinghamer, C. I. Kado,
Department of Plant Pathology, University of California
Davis, CA 95616 - March 16, 1978)

Source	Growth Conditions: Medium	Supplemented phyto-hormones	Temperature (° C)	Cell density (/ml)	Cell wall formation	Period of survival (days)	Fraction surviving (%)
(Vigna sinensis)							
Cowpea	G/D[1]	yes	25	$>10^6$	yes	10	10
Cowpea	G/D	no	25	$>10^6$	no	0	0
Cowpea	0.45 M Mannitol 1% agar (sealed)	no	25	$>10^6$	no[2]	0	0
Cowpea	0.45 M Mannitol 1% agar (unsealed)	no	25	$>10^6$	no[3]	0	0
Cowpea	2% water agar	no	25	$>10^6$	no (lysis)	0	0
Cowpea	sterile soil[4]	no	25	$>10^6$	no (lysis)	0	0
Cowpea	unsterile lab bench top	no	25	$>10^6$	no[5]	0	0
(Nicotiana tabacum)							
Tobacco	S/T-III[6]	yes	22	$>10^6$	yes	>21	63[6]
Tobacco	S/T-III	no	22	$>10^6$	no	0	0
(Vinca rosea)							
Periwinkle	M/S[7]	yes	22	$>10^5$	yes	6	1
Periwinkle	M/S	no	22	$>10^5$	no	0	0
(Brassica rapa)							
Turnip	B5[8]	yes	28	10^3-10^4/cm^2	yes[9]	0	0
Turnip	B5 (without sugars)	yes	28	10^3-10^4/cm^2	yes[9]	0	0
Turnip	M/S	yes	28	10^3-10^4/cm^2	yes[9]	0	0
Turnip	G/D	yes	28	10^3-10^4/cm^2	yes[9]	0	0
Turnip	B/M[10]	yes	28	10^3-10^4/cm^2	yes[9]	0	0

[1]Grashoff, P. and C. Doy (1972) Planta 107, 161-170
[2]Dried completely in 12 hours
[3]Dried completely in 3 hours
[4]UC potting mix
[5]Dried in 5-30 min.
[6]Shepard, J.F. and R.E. Totten (1975) Plant Physiol. 55, 689-694
[7]Murashige, T. and F. Skoog (1962) Physiol. Plantarum 15, 473-497
[8]Gamborg, O.L., R.A. Miller, and K. Ojima (1968) Expt. Cell. Res. 50, 151-158
[9]Protoplast first allowed to regenerate cell walls before plating on media indicated
[10]Braun, A.C. and H.N. Wood (1962) Proc. Natl. Acad. Sci. U.S.A. 48, 1776-1782

TABLE 2

Available evidence for exchange among bacterial plant pathogens and symbionts (prepared by C. I. Kado)

			plasmid exchange	chromosomal exchange
Agrobacterium	×	Erwinia	-	-
	×	Pseudomonas	1	-
	×	Xanthomonas	23	-
	×	Rhizobium	12,20	29
	×	E. coli	15,10,17,27	-
Erwinia	×	Pseudomonas	18,11	27
	×	Xanthomonas	23	-
	×	Rhizobium	-	-
	×	E. coli	5,7,8,14,21,27	19,9,13
Pseudomonas	×	Xanthomonas	23	-
	×	Rhizobium	15,6,28	3
	×	E. coli	15,11,26,22	-
Xanthomonas	×	Rhizobium	-	-
	×	E. coli	23	-
Rhizobium	×	E. coli	6,28,16,2,4,25	24

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RECOMBINANT DNA MOLECULE PROGRAM ADVISORY COMMITTEE, WORKSHOP ON RISK ASSESSMENT OF AGRICULTURE PATHOGENS

National Science Foundation, Conference Room 338, 1800 G Street NW., Washington, D.C. 20550, March 20-21, 1978, 9 a.m.

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Federal Register

FRIDAY, JULY 28, 1978
PART V

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

EXEMPTION FROM PREEMPTION OF STATE AND LOCAL HEARING AID REQUIREMENTS

Applications

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 808]

[Docket No. 77N-0333]

EXEMPTION FROM PREEMPTION OF STATE AND LOCAL HEARING AID REQUIREMENTS

Applications for Exemption

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: In response to applications from several States, this proposal would exempt certain State and local hearing aid device requirements from Federal preemption. The Federal Food, Drug, and Cosmetic Act preempts State and local medical device requirements that are different from or in addition to Federal requirements. The act also provides that the agency may, by regulation, exempt State and local device requirements from preemption. Elsewhere in this issue, the agency gives notice of an opportunity for interested persons to request an oral hearing on these proposed regulations.

DATES: Comments by September 26, 1978. The Commissioner proposes that the final regulation based on this proposal shall be effective 30 days after its publication in the REGISTER REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305) Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Joseph M. Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: The Commissioner of Foods and Drugs, in a final regulation published in the FEDERAL REGISTER of February 15, 1977 (42 FR 9286), established professional and patient labeling and conditions for sale of hearing aids. Since this regulation became effective on August 25, 1977, any State and local hearing aid requirement that is different from or in addition to the requirements established by the FDA regulations is preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)).

The Food and Drug Administration issued final regulations, published in the FEDERAL REGISTER of May 2, 1978 (43 FR 18661), establishing procedures for considering applications for exemption from preemption. In these regulations, the Commissioner announced his determination that section 521 of the act does not preempt certain types of State and local requirements. The following requirements relating specifically to hearing aids are not preempted: (1) Requirements with respect to the licensing of hearing aid dispensers, audiologists, and physicians; (2) requirements that are substantially identical to the FDA requirements governing the labeling and conditions for sale of hearing aids; and (3) requirements established by Federal, State, or local agencies to control the expenditures of public funds for purchasing hearing aids and hearing health care services for the hearing impaired.

These regulations also established procedures for considering applications filed under section 521(b) of the act. Section 521(b) provides that FDA may, by regulation issued after notice and an opportunity for an oral hearing, exempt a State or local medical device requirement from preemption under such conditions as the Commissioner may prescribe if the requirement is (1) more stringent than an FDA requirement applicable to the device under the act, or (2) required by compelling local conditions and compliance with it would not cause the device to be in violation of any requirement applicable under the act.

Shortly after the FDA hearing aid regulation became effective, several States applied for exemption from preemption for their hearing aid requirements. Realizing that many other State and local governments had requirements similar to those for which applications had been filed, the Commissioner, in a notice published in the FEDERAL REGISTER of October 18, 1977 (42 FR 55648), invited all State and local governments to file within 30 days applications for exemption from preemption for requirements governing labeling and conditions for sale of hearing aids. The purpose of the notice was to expedite the consideration of these applications by encouraging simultaneous submissions by affected State and local governments. As a result of this notice, 19 applications are now pending. The Commissioner is now proposing action on each of these applications in this consolidated proceeding.

EFFECT OF EXEMPTION

The Commissioner emphasizes that when FDA grants an exemption to a State or local requirement (when FDA reinstates a preempted State or local law), the granting of the exemption does not in any manner affect FDA requirements under the act, such as the FDA regulations mentioned earlier relating to labeling and conditions for sale of hearing aids. The FDA requirements continue in full force and effect regardless of whether comparable or related State or local requirements are preempted or exempted from preemption.

The Commissioner also notes that many State requirements do not apply to all sales of hearing aids, as the FDA requirements do. For example, some State requirements apply only to sales to minors; other State requirements specifically do not apply to sales of replacement hearing aids. If such requirements are more stringent than the FDA requirements, they may be exempted from preemption. If an exemption is granted, these State or local requirements are in addition to and not in lieu of the FDA requirements. Therefore, a person engaged in the sale or distribution of hearing aids must comply with both sets of requirements to be in compliance with both State and Federal law.

THE FDA HEARING AID REGULATIONS

In ruling on these applications, the Commissioner has compared each of the State requirements to FDA hearing aid requirements in §§ 801.420 and 801.421 (21 CFR 801.420, 801.421).

Section 801.420 requires a manufacturer or distributor of a hearing aid to provide a user instructional brochure to accompany each hearing aid. This brochure must contain certain information for the hearing aid dispenser and user and instructions for use of the hearing aid. Section 801.421 (b) and (c) requires the manufacturer and hearing aid dispenser to make the brochure available to a prospective user. The dispenser is required to give a prospective user an opportunity to read the brochure and to review the brochure with the prospective user.

Section 801.421 also prohibits a hearing aid dispenser from selling a hearing aid unless the prospective user has presented to the dispenser a statement signed by a licensed physician stating that the patient's hearing loss has been evaluated medically, and that the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the 6 months preceding the sale. An informed adult, 18 years of age or older, may waive the medical evaluation requirement by signing a written statement. The hearing aid dispenser is prohibited from actively encouraging the prospective user to waive medical evaluation.

GENERAL ISSUES

Many of the State requirements are similar and involve a number of recurring issues. Later sections of this preamble will address individual State or local requirements. The following dis-

cussion of the recurring issues and the Commissioner's reasons for their resolution generaly will not be repeated in the discussion of the individual State laws.

1. *Medical evaluation.* The Commissioner has determined that good hearing health care practice requires that persons with hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. A medical evaluation by a physician is necessary to determine the cause of, and the pathology associated with, a patient's hearing loss. Because a medical evaluation often includes an interpretation of a medical history, a physical examination, and laboratory and X-ray studies, an examination by other than a licensed physician will not satisfy this need. Therefore, the Commissioner is proposing to deny exemption from preemption for any State or local requirement that does not require a medical evaluation by a licensed physician.

2. *Audiological evaluation.* In the final FDA regulation on labeling and conditions for sale of hearing aids, the Commissioner rejected suggestions that an audiological evaluation be made a condition to the sale of a hearing aid. The Commissioner concluded that the public record did not justify requiring an audiological evaluation to determine hearing aid candidacy. The Commissioner also noted that such a requirement would create an additional barrier to the receipt of a hearing aid in those areas of the country where audiological services are scarce and could increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification. However, several States with mandatory audiological evaluation requirements have pointed out in their applications that audiological services are not scarce in their jurisdictions. These States also claim that the cost of audiological evaluation is generally covered by medical insurance so as not to represent a direct additional cost to the patient.

Although audiological examinations may be covered by insurance as a number of States claim, the Commissioner is not persuaded that this provides a basis for granting an exemption from preemption. The consumer ultimately pays for these examinations, if not directly, then through increased insurance premiums. Furthermore, the Commissioner has not seen any additional information which would justify requiring an audiological evaluation to determine hearing aid candidacy. Therefore, the Commissioner is proposing to deny exemption from preemption for State laws requiring audiological evaluation for adults before the sale of a hearing aid.

However, as noted in the FDA hearing aid regulation under § 801.420(c)(3), the Commissioner believes that a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation because hearing loss may cause problems in language development and the educational and social growth of a child. Although the FDA regulation encourages, but does not require, audiological evaluation for children, the Commissioner believes that State requirements for audiological evaluation for children are more stringent than, and consistent with, the Federal requirement. Therefore, the Commissioner is proposing to grant exemption from preemption for such requirements.

3. *Waiver of medical evaluation.* The Federal regulation permits a prospective hearing aid user 18 years of age or older to waive the medical evaluation requirement provided the hearing aid dispenser: (1) Informs the prospective user that exercise of the waiver is not in the user's best health interest; (2) does not actively encourage the user to waive; and (3) affords the prospective user the opportunity to sign a waiver statement. This waiver provision acknowledges that some persons have religious or personal beliefs against a medical evaluation. The provision also allows for the rare circumstance in which an individual would have great difficulty in obtaining a medical evaluation because of the lack of a physician in the area.

The FDA regulation (§ 801.420(c)(2)) also requires that the User Instructional Brochure contain a statement warning hearing aid dispenser to advise the prospective user to consult promptly with a licensed physician if the dispenser determines that the prospective user has any one of eight medical conditions. A prospective user may waive medical evaluation whether or not any one of the eight conditions is present. The Commissioner, however, expects hearing aid dispensers to urge prospective users exhibiting any of these conditions to consult a physician.

The Commissioner believes that, in general, an informed adult who has religious or personal objections to medical examination should be permitted to waive the medical evaluation requirement. Therefore, he is proposing to deny exemption from preemption for those State and local requirements that either do not permit any waiver of a medical evaluation requirement, or permit a waiver only for religious reasons. However, the Commissioner strongly believes that a medical examination should be an integral part of the hearing aid selection process for most adults and an absolute requirement, as provided in § 801.421(a)(2), for persons who are less than 18 years old. Therefore, the Commissioner, in deference to the judgment of the States, is proposing to grant exemptions from preemption for those State and local requirements that do not permit a waiver when certain medical conditions are found to exist in the prospective purchaser. Such a requirement is more stringent than the FDA requirement and is consistent with the FDA policy of encouraging a medical evaluation as a condition to the purchase of a hearing aid.

4. *Six-month requirement.* The FDA regulation in § 801.421(a)(1) requires that a medical evaluation be made no more than 6 months before the purchase of a hearing aid. This period is sufficiently long to give the purchaser time to shop for a hearing aid and yet is sufficiently short to decrease the likelihood of substantial changes in the prospective user's medical condition.

Some States have requested an exemption for requirements which provide that a medical evaluation must take place less than 6 months before the sale of the hearing aid. These States assert that, in their jurisdictions, hearing health care services are readily available and, therefore, it is reasonable to require an examination within a shorter period of time. The Commissioner generally agrees with this position. Therefore, he is proposing to grant an exemption from preemption for those State requirements that provide that the medical evaluation must take place less than 6 months before the sale of a hearing aid; the basis for the exemption is that such requirements are more stringent than the FDA requirement.

Other States do not establish any time period within which a medical examination must occur. Apparently in those States it is not a violation of State law for a hearing aid dispenser to sell a hearing aid even though the prospective user has not received a medical evaluation for many years. The Commissioner reiterates that all FDA requirements remain in force when a State statute is less stringent or silent with respect to a particular requirement. When the State requirement is more stringent, the Federal requirement continues regardless of whether the more stringent requirement is exempted from preemption. Of course, compliance with a particular State requirement that is more stringent than the FDA requirement will also assure compliance with the comparable FDA requirement.

To summarize, under Federal law a medical examination must, unless lawfully waived, take place no longer than 6 months before the purchase of a hearing aid. Where the Commissioner

grants an exemption for a State law that establishes a shorter time period, then under State law the shorter time period is a valid State requirement.

5. *Sales receipt.* Many State laws require a hearing aid dispenser to provide the purchaser with a receipt containing certain information. Most of the required information concerns the terms of sale. Such requirements are not preempted by section 521(a) of the act because they do not relate to the safety and effectiveness of hearing aids. Therefore, they are not candidates for exemption from preemption.

Some State laws, however, require that the receipt contain certain information with respect to the safety or effectiveness of the hearing aids. For such requirements, the Commissioner is proposing to grant exemption from preemption provided that the requirement does not conflict with any requirement under FDA regulation.

Many State laws also require that the receipt include a statement as to whether the hearing aid is new, used, or reconditioned. Section 801.420(c)(5) requires that, if a hearing aid is "used" (as defined in § 801.420(a)(6)), or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag physically attached to the hearing aid. Most of the State laws, however, do not define the term "used hearing aid." The Commissioner is proposing to exempt from preemption State laws that require a sales receipt to state whether the hearing aid is new, used, or reconditioned, provided that the State applies the Federal definition of "used hearing aid" when enforcing the requirement. Such requirements will be exempted on the basis that they impose an additional and more stringent requirement.

6. *Recordkeeping.* Section 801.421(d) requires a hearing aid dispenser to maintain a copy of the physician's medical evaluation statement or the signed waiver for at least 3 years from the date of sale. The Commissioner is proposing to exempt from preemption those more stringent State requirements that provide that these records must be kept for a longer period, because such requirements may assist the States in enforcing the medical evaluation requirements.

Individual State or Local Requirements

Following are discussions of the sections of State hearing aid laws and regulations that are subject 521 of the act:

Arizona

Arizona Revised Statute 36-1901.7. This section provides that unethical conduct for a hearing aid dealer includes:

(s) Fitting and dispensing of a hearing aid when dealing with a child 14 years of age or under, without first ascertaining whether the child has been examined by an otolaryngologist, including an otologic and audiologic examination, for his recommendation within 90 days prior to the fitting. If such not be the case, a recommendation to do so must be made and this fact shall be recorded as provided by regulation. The provisions of this subdivision shall not apply to the replacement of any hearing aid within 1 year of its purchase.

(t) Fitting and dispensing of a hearing aid to any individual who has a significant air bone gap or an apparent unilateral sensorineural hearing loss without first ascertaining that the individual has been examined by an otolaryngologist and received an otological and audiologic examination within the preceding 6-month period. If such not be the case, the individual shall sign an agreement as provided by regulation, stating the person has been informed of possible correction of his hearing loss by surgical or medical means, and that a hearing loss of this nature could be caused by serious and life threatening disease. The provisions of this subdivision shall not apply to the replacement of any hearing aid within 1 year of its purchase.

Subsection (s) and its implementing regulation (A.C.R.R. R9-16-303) are less stringent than the FDA requirements because they would allow the parent or guardian of a child 14 years of age or under to waive the medical evaluation requirement for the child. These provisions would allow the dispensing of a hearing aid to a child without any medical examination. Therefore, the Commissioner is proposing to deny exemption from preemption for these requirements.

Subsection (t) and its implementing regulation (A.C.R.R. R9-16-304) require that a prospective hearing aid user with a significant air bond gap or apparent unilateral sensorineural hearing loss be examined by an otolaryngologist and receive an otologic and audiologic examination within 6 months before the sale of a hearing aid. An informed adult may sign a written waiver of these requirements. As stated above in the discussion of general issues, the Commissioner is proposing to deny exemption from preemption for audiological evaluation requirements for adults. However, because the Arizona statute permits a waiver of this requirement, the Commissioner believes that the reasoning given above does not apply. The Commissioner is proposing to exempt these requirements from preemption because they are more stringent than the FDA requirements.

California

Business and Professions Code § 3365.6:

No hearing aid shall be sold by an individual licensed under this chapter, to a person 16 years of age or younger, unless within the preceding 6 months a recommendation for a hearing aid has been made by both a board-certified, or a board-eligible physician specializing in otolaryngology, and by an audiologist certified by the American Speech and Hearing Association. A replacement of an identical hearing aid within one year shall be an exception to this requirement.

This section is more stringent than the FDA regulation because it requires that a prospective hearing aid user 16 years of age or younger be examined by an otolaryngologist and an audiologist before the sale of a hearing aid. Therefore, the Commissioner is proposing that this section be exempted from preemption. The Commissioner advises, however, that in order for a sale to be in compliance with Federal law, it must meet all the requirements of the FDA regulation. Thus, with specific reference to the "replacement" provision in the final sentence of § 3365.6, if a "replacement" constitutes a new sale, and is not simply a warranty-type substitution of one hearing aid for another, all requirements of the FDA regulation must be met including a medical examination within the preceding 6 months.

The Commissioner is also proposing to exempt from preemption California's Health and Safety Code, section 26463(m), which prohibits the advertising of any device represented to have any effect in diseases or disorders of the ear. The Commissioner especially seeks comments on this provision because to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent than the FDA requirements. However, if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be preempted by section 521(a) of the act.

The Commissioner notes that the proposal here is independent of an earlier application for exemption for other provisions of California law (see Federal Register of February 15, 1977, 42 FR 9186, 9226). That matter is pending. When the proposed regulation was issued on the earlier application, the FDA hearing aid regulation had not yet gone into effect and, therefore, California laws relating to hearing aids were not preempted. Because California laws relating to labeling and conditions of sale of hearing aids that are in addition to or different from the FDA requirements are now preempted, it is necessary to include these provisions in the current proceeding.

Connecticut

Connecticut General Statutes 20-403:

Anyone who has a history of (1) Visible congenital or traumatic deformity of the ear; (2) Active drainage from the ear within the previous 90 days; (3) Sudden, or rapidly

progressive, hearing loss within the previous 90 days; (4) Acute or chronic dizziness; (5) Unilateral hearing loss of sudden or recent onset within the previous 90 days; (6) audiometric air-bone gap equal to, or greater than, 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz; (7) visible evidence of cerumen accumulation, or a foreign body in the ear canal; and (8) pain or discomfort in the ear within the previous 60 days shall be advised by the hearing aid dealer, as defined herein, to consult a physician or an otolaryngologist, as defined herein, prior to fitting of the hearing aid. A written statement, stating the consumer has been advised of such, shall accompany any sale of a hearing aid.

The Commissioner is proposing to exempt this section from preemption. The section is more stringent than the FDA regulation because it requires the hearing aid dispenser to advise the prospective purchaser in writing to consult a physician if certain medical conditions are found to exist.

The FDA regulation only requires that the User Instructional Brochure contain a statement warning hearing aid dispensers to advise a prospective hearing aid user to consult a physician if these medical conditions are found to exist.

Connecticut General Statutes 20-404. This section provides that a hearing aid dealer license may be suspended for unethical conduct including:

(6) Selling a hearing aid to a person under the age of 18 without prior ear examination by an otolaryngologist and an audiological examination performed or supervised by an audiologist.

The Commissioner is proposing to exempt this section from preemption. It is more stringent than the FDA regulation because it requires that a child be examined by an otolaryngologist and an audiologist, while the FDA regulation only requires that the child be examined by a licensed physician.

DISTRICT OF COLUMBIA

Act 2-79, Sec. 5:

Sec. 5 Special Provisions.

(a) No registrant shall fit, offer for sale, or sell a hearing aid to a person unless, within the preceding three (3) Months, the person has received a medical clearance after an examination by an otolaryngologist and a hearing test evaluation.

(b) No registrant shall sell a hearing aid not conforming to the hearing test evaluation required without prior consultation and written approval from the signer of the hearing test evaluation.

(c) Sections 5(a) and 5(b) of this act do *not apply to*—

(1) The purchase of an identical hearing aid within two (2) years of the date that the purchaser receives the original aid; and

(2) The purchase of parts, attachments or accessories of the telephone designed to aid the hearing-impaired.

(d) If a prospective hearing aid user has a bona fide religious belief which precludes him or her from having a medical examination as required in section 5(a) of this act, the prospective hearing aid user may waive the medical examination requirement: *Provided*, That the prospective hearing aid user signs the following statement, printed in ten (10)-point type:

"My religious beliefs require that I waive the medical examination and the hearing aid evaluation required by the 'Hearing Aid Dealer and Consumers Act of 1977' for the purchase of a hearing aid. I voluntarily waive the medical examination, notwithstanding the fact that I have been advised by

Hearing Aid Dispenser's Name ————

that my best health interest would be served if I had a medical evaluation by a physician who is an ear specialist."

No registrant shall seek to induce a prospective hearing aid user to execute such a waiver.

This section is more stringent than the FDA requirements in several respects. First, it requires that the prospective purchaser be examined by an otolaryngologist and not just a licensed physician. Second, it requires that the prospective purchaser receive a hearing test evaluation in addition to a medical examination. Third, the section requires the prospective purchaser to obtain a medical examination and hearing test evaluation within 3 months before the sale of the hearing aid. Finally, this section allows a waiver of the medical evaluation requirement only for a person who has a bona fide religious belief which precludes a medical examination.

As stated above in the discussion of general issues, the Commissioner is proposing to exempt this section from preemption to the extent that it requires a medical examination by an otolaryngologist with 3 months before the sale of the hearing aid. However, as also stated above, the Commissioner is proposing to deny exemption for the requirement of a hearing test (audiological) evaluation before the sale of a hearing aid.

The provision that the prospective purchaser may waive the medical examination requirement only for a bona fide religious belief is also more stringent than the FDA regulation, which permits a waiver for personal or religious reasons. Moreover, the provision does not refer to the existence of certain medical conditions or otherwise provide a basis for denying an adult the right to decide whether to seek or to waive a medical examination. However, because it substantially narrows the grounds under which an adult may waive a medical examination, the Commissioner is proposing to deny exemption from preemption for the District of Columbia provision that a purchaser may waive the medical examination requirement only for religious reasons. As a result, the Federal waiver provision will apply in the District of Columbia; that is, any informed adult, 18 or over, may waive the medical evaluation requirement.

The Commissioner notes that section 5(c) of the District of Columbia act exempts from the coverage of sections 5(a) and 5(b) the "purchase of an identical hearing aid within two (2) years" of the original purchase. To be in compliance with Federal law, however, each sale must satisfy all the requirements of the FDA regulation including a medical examination within the preceding 6 months. Where there is simply a warranty-type substitution of one hearing aid for another and not a new purchase, the FDA regulations relating to conditions of sale do not apply.

FLORIDA

Florida Statutes § 468.135(5):

Medical Clearance: If, upon inspection of the ear canal with an otoscope, in the common procedure of a hearing aid fitter, and upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client shall be instructed to see a physician, and a hearing aid shall not be fitted until medical clearance is obtained for the condition noted. Any person with a significant difference between bone-conduction and air-conduction hearing must be informed of the possibility of medical correction.

Florida Administrative Code § 10D-48.25(26):

The registrant shall not fit or sell a hearing aid to any individual when any of the following conditions are found to exist, either from observation by the registrant, or on the basis of information furnished by the prospective hearing aid user, without first receiving a written medical clearance for the condition noted. Such written statement shall be attached to the buyer's sales contract. A copy of such statement shall be retained by the registrant at his place of business for no less than three (3) years.

(a) Visible, congenital or traumatic deformity of the ear;

(b) History of, or active drainage from the ear within the previous ninety (90) days;

(c) History of sudden or rapidly progressive hearing loss within the previous ninety (90) days;

(d) Acute or chronic dizziness;

(e) Unilateral hearing loss of sudden or recent onset within the previous ninety (90) days;

(f) Any hearing loss in which there is a 15 db or greater difference between the air-conduction threshold and the bone-conduction threshold at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz;

(g) Visible evidence of cerumen accumulation or a foreign body in the ear canal;

(h) Pain or discomfort in the ear.

The statute and its implementing regulation are more stringent than the FDA regulation because of the requirements that a prospective user exhibiting one of several medical conditions obtain a written medical clearance. Moreover, the section does not contain a waiver provision, whereas the FDA regulation allows for a waiver. The Commissioner notes, however, that Florida law does not specify

a time period before a sale during which the medical examination must have taken place. Therefore, the Commissioner is proposing that the Florida statute and the implementing regulation be exempted from preemption. The Commissioner advises, however, that the medical examination must take place within 6 months before the sale of the hearing aid in order for the sale to be in compliance with the FDA regulation.

KENTUCKY

Kentucky Revised Statutes § 334.200:

Requirements for sale or dispensing of hearing aids.—(1) It is unlawful for an individual licensed under this chapter to sell or dispense a hearing aid to any person unless within the preceding ninety (90) days:

(a) The person has been examined by and received a written, signed, and dated approval for a hearing aid from a duly licensed physician. The written approval shall include, but not be limited to, a statement that the person examined has no known ear diseases or conditions of the ear which might make the fitting and wearing of a hearing aid useless, or harmful to the person's health, or which might interfere with the proper fitting and wearing of a hearing aid; and,

(b) The person has received a hearing aid evaluation, and a written, signed, and dated recommendation for a hearing aid from a physician or an audiologist licensed or authorized to practice audiology pursuant to KRS 334A. The written recommendation may take the form of a specific recommendation as to the make and model of a hearing aid or may include a listing of specifications for a hearing aid.

(c) Any person eighteen (18) years of age or older may elect to sign a waiver to the requirements of subsections (a) and (b) of this section before the purchase of a hearing aid. The waiver shall be on a separate sheet of paper, shall be read to the prospective purchaser of a hearing aid, and shall recite: "I am eighteen (18) years old or older, and I voluntary sign this waiver which indicates that I do not wish to have a hearing aid evaluation by a physician or an audiologist prior to purchasing this hearing aid(s)."

These requirements are more stringent than the FDA regulation in two respects: The prospective user of a hearing aid must have been examined by a licensed physician within 90 days before the sale, and the Kentucky statute requires a prospective user to receive an audiological evaluation by a licensed physician or audiologist in addtion to a medical clearance. As stated in the discussion of general issues above, the Commissioner is proposing to deny exemption from preemption for audiological evaluation requirements. However, because the Kentucky statute permits a waiver of the requirements, the Commissioner believes that the reasoning given above does not apply. Therefore, he is proposing to grant exemption from preemption for this entire section.

MAINE

Maine Revised Statute Annotated 1658-D, 1658-E:

§ 1658-D *Medical or audiological examination.* 1. *Minors.* No dealer may sell or furnish a hearing aid to a person of 18 years of less without a written statement, signed by a physician with specialized training in the field of otolaryngology or by an audiologist, that such person has had an ear or hearing examination within 90 days of the purchase of furnishing of a hearing aid and that a hearing aid is recommended for such person.

2. *Adults.* The department shall by regulation list and define certain medical conditions affecting hearing. If a dealer has notice of the existence of any one or more of such conditions in the case of a prospective purchaser of a hearing aid, whether by the dealer's observation of the prospective purchaser or by information furnished by the prospective purchaser, fitting of the hearing aid shall be delayed until the purchaser has had an ear or hearing examination administered by a physician with specialized training in the field of otolaryngology or by an audiologist who, as a result of such examination, recommends in writing a hearing aid for the prospective purchaser.

§ 1658-E *Persons and practices not affected.* This chapter is not intended to prevent any person from engaging in the practice of measuring human hearing, provided that such person does not intend to sell hearings aids and accessories unless under the direct supervision of a licensee.

This chapter does not apply to a person who is a physician or osteopath duly licensed under the laws of the State of Maine.

Persons holding a master's or doctoral degree from an accredited university program which includes at least 24 credits in audiology at the graduate level and 150 supervised clinical hours in clinical audiology may test or measure human hearing but shall not demonstrate, with the intent to sell, hearing aids and accessories, except ear molds.

Nothing in this chapter shall be construed to require an ear or hearing examination by a physician or audiologist of a person who objects thereto on the ground that such examination conflicts with the tenets and practices of a church or religious denomination of which he is a member or adherent.

Section 1658-D is less stringent than the FDA regulation in its requirements for both minors and adults because it permits the sale of a hearing aid on the recommendation of an audiologist without a medical evaluation by a licensed physician. Although the last sentence of section 1658-E may be more stringent than the FDA waiver provision because it applies only to those who object to examination by a physician or audiologist for religious reasons, the effect of this provision is to require that only those persons who do not object for religious reasons be examined by a licensed physician or an audiologist. Therefore, the Commissioner is proposing to deny exemption from preemption for section 1658-D and the last sentence of section 1658-E.

The Commissioner has determined that the first three sentences of section 1658-E are not preempted because they are licensing provisions, and therefore, not requirements with respect to a device within the meaning of section 521 of the act.

Maine also requests an exemption from preemption for section 1658-C, which requires a hearing aid dispenser to give a notice containing certain information to the purchaser at the time of sale. Most of the provisions of this section are not requirements with respect to a device within the meaning of section 521 of the act, and, therefore, are not preempted. Section 1658-C(3)(c), however, requires that the notice contain a statement as to whether the hearing aid is new, used, or reconditioned. This provision is preempted because it is different from the requirements of the FDA regulation. However, as indicated in the general discussion above, the Commissioner is proposing to exempt from preemption this portion of section 1658-C. As a result, if the exemption is granted, none of the section will be preempted.

MINNESOTA

Minnesota Statutes §§ 145.43 and 145.44:

§ 145.43 *Hearing aids; restrictions on sales.* Subdivision 1. Definition. "Hearing aid" means any instrument or device designed for or represented as aiding defective human hearing, and its parts, attachments, or accessories, including but not limited to ear molds. Batteries and cords shall not be considered parts, attachments, or accessories of a hearing aid.

Subdivision 2. Prescription or written recommendation required. No hearing aid shall be sold by any person in this State except upon the prescription or other written and signed recommendation of an authorized person who is neither employed by, or in a business relationship with, a seller of hearing aids. For purposes of this section, "authorized person" means an audiologist, otolaryngologist, otologist, or licensed medical doctor. "Audiologist" means an individual who holds a master's degree or doctor's degree in audiology from a college or university that is fully accredited by the North Central Association of Colleges and Secondary Schools or an equivalent accrediting association. Any person selling a hearing aid as provided in this section shall maintain for not less than one year, in a file under the name of the person to whom the hearing aid was sold, a true copy of the prescription or other written recommendation, as provided herein, upon which such sale was made. Nothing in this act shall apply to a sale solely limited to either repair services or replacement parts, or both, for a hearing aid already owned by a consumer or to the sale of a replacement hearing aid to an aid already owned by a consumer.

§ 145.44 *Conditions requiring consultation of doctor or audiologist; waiver of sale restrictions.* Subdivision 1. When a hearing aid vendor finds the following conditions in any person either by observation or being told by said person, said vendor shall not fit or sell a hearing aid until that person has

consulted with a licensed medical doctor or audiologist:

(1) Visible congenital or traumatic deformity of the ear.

(2) History of, or active drainage from the ear within the previous 90 days.

(3) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(4) Acute or chronic dizziness.

(5) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(6) Significant air-bone gap.

Subdivision 2. Adults under 60 years who are legally competent may be exempted from the provisions of §145.43, subdivisions 2 and 3, if they sign a waiver acknowledging that they have been provided a copy of this law printed in large typeface (at least 14-point) and that the law has been read aloud to them by the hearing aid vendor. A copy of the signed waiver will be kept on file for three years from the date of sale.

Section 145.43 is less stringent than the FDA requirements because it allows the dispensing of a hearing aid upon the recommendation of an audiologist alone. Therefore, the Commissioner is proposing to deny exemption from preemption for this section.

Similarly, subdivision 1 of §145.44 will allow the sale of a hearing aid upon the recommendation of an audiologist alone. Although the waiver provision in subdivision 2 of §145.44 is limited to adults under 60 years of age, the effect of this provision is merely to require that children and adults 60 years of age and older be examined by a physician or an audiologist. Therefore, §145.44 is less stringent than the FDA requirements because it does not require examination by a physician. The Commissioner is proposing to deny exemption from preemption for this section.

MISSISSIPPI

Mississippi Code 73-14-3(g). This section defines "unethical conduct" for hearing aid dealers. Included in this definition is the following:

(9) Dispensing and selling a hearing aid to a child under the age of ten (10) years who has not been examined and cleared for hearing aid use by a board of eligible or certified otolaryngologists or evaluated by an audiologist certified by the American Speech and Hearing Association unless stated as unnecessary for further evaluation by either within a ninety-day period.

This requirement is less stringent than the FDA regulation because it would allow the sale of a hearing aid to a child under the age of 10 upon the recommendation of an audiologist alone. Therefore, the Commissioner is proposing to deny exemption from preemption for this section.

NEBRASKA

Nebraska Revised Statutes 71-4712(2)(c). This section prohibits unethical conduct in hearing aid dealers including:

(vi) Fitting and selling a hearing aid to a child under the age of sixteen who has not been examined and cleared for hearing aid use within a six-month period by an otolaryngologist. The provisions of this subdivision shall not apply to the replacement with an identical model of any hearing aid within one year of its purchase;

(vii) Selling a hearing aid to any individual who has a significant air bone gap or a unilateral sensorineural hearing loss unless that individual has been examined by an otolaryngologist within a six-month period or has signed a statement in duplicate, also signed by the retailer, that he has been informed that he may have a medically or surgically remediable hearing loss and should seek the advice of an otolaryngologist. One copy of such statement shall be filed with the department. The provisions of this subdivision shall not apply to the replacement with an identical model of any hearing aid within one year of its purchase.

Subdivision (vi) is more stringent than the FDA requirement because it requires examination and clearance by an otolaryngologist while the FDA regulation requires examination and clearance by any licensed physician. Similarly, subdivision (vii) is more stringent than the FDA requirement because it requires that an individual with a significant air bone gap or a unilateral sensorineual hearing loss be examined by an otolaryngologist or sign a waiver of that requirement. Therefore, the Commissioner is proposing to exempt these requirements from preemption.

The Commissioner advises, however, that in order for a sale to be in compliance with Federal law, it must also meet all the requirements of the FDA regulation. Thus, with specific references to the replacement provision in the final sentences of subdivisions (vi) and (vii), if a "replacement" constitutes a new sale and not simply a warranty-type substitution of one hearing aid for another, all requirements of the FDA regulation must be met, including a medical examination within the preceding 6 months.

NEW JERSEY

New Jersey Statutes Annotated 45:9A-24, 25: 45:9A-24. *Written recommendation to consult licensed physician; conditions; signature for receipt; list of physicians.*

Whenever any of the following conditions are found to exist either from observations by the licensee or on the basis of information furnished by the prospective hearing aid user, a licensee shall, prior to fitting and selling a hearing aid to any individual, suggest to that individual in writing that his best interests would be served if he would consult a licensed physician specializing in diseases of the ear or if no such licensed physician is available in the community then to a duly licensed physician:

(a) Visible congenital or traumatic deformity of the ear,

(b) History of, or active drainage from the ear within the previous 90 days,

(c) History of sudden or rapidly progressive hearing loss within the previous 90 days,

(d) Acute or chronic dizziness,

(e) Unilateral hearing loss of sudden or recent onset within the previous 90 days,

(f) Significant air-borne gap.

A person receiving the written recommendation to purchase a hearing aid shall sign a receipt for the same.

The licensee shall provide the prospective hearing aid user with a list of at least three physicians specializing in diseases of the ear, practicing in the area, and their addresses or if none are practicing in the area, then a list of at least three physicians and their addresses.

45:9A-25 *Sale of hearing aid to person under 18.* No hearing aid shall be sold by an individual licensed under this chapter, to a person less than 18 years of age unless within the preceding 6 months a recommendation for a hearing aid has been made by a board-certified, or a board-eligible physician specializing in otolaryngology, or by an audiologist certified by the American Speech and Hearing Association after examination and diagnosis by a board-certified or board-eligible otolaryngologist. A replacement or an identical hearing aid within one year shall be an exception to this requirement.

Section 45:9A-24 is more stringent than the FDA regulation because it requires the hearing aid dispenser to advise the prospective purchaser to consult an otolaryngologist or other licensed physician if any of the listed conditions is found to exist. The Federal regulation requires only that the User Instructional Brochure contain a statement warning hearing aid dispensers to advise a prospective hearing aid user to consult a physician if certain medical conditions are found to exist. Therefore, the Commissioner is proposing to exempt this section from preemption.

Section 45:9A-25 is more stringent than the FDA regulation because it prohibits the sale of a hearing aid to a person under the age of 18 without a recommendation by an otolaryng- ologist or by an audiologist after the prospective user has been examined by an otolaryngologist, while the Federal regulation only requires, examination by a licensed physician. Therefore, the Commissioner is proposing to exempt this section from preemption.

The Commissioner notes that the New Jersey requirement does not apply to the sale of a replacement or identical hearing aid within 1 year. The Commissioner reiterates that if a "substitution" is in reality a new sale, all requirements of the FDA regulation, including the medical examination provisions, must be met.

New Jersey also requests an exemption from preemption for section 45:9A-23, which requires the dispenser to make certain statements to the purchaser and to give to the purchaser a receipt containing certain information. Most of the provisions of this section are not requirements with respect to a device within the meaning of section 521 of the act and therefore are not preempted. Section 45:9A-23(b)(4), however, requires that the receipt

must include a statement as to whether the hearing aid is used or reconditioned. This provision is preempted because it is different from the Federal requirements. As indicated in the discussion of general issues above, the Commissioner is proposing to exempt this provision from preemption. As a result, the entire section will not be preempted.

NEW MEXICO

New Mexico Statutes Annotated 67-36-16F prohibits: F. Selling or fitting of the first hearing aid of any child under sixteen (16) years of age, who has not been examined and cleared for the aid by both an otolaryngologist and an audiologist, certified competent by the American Speech and Hearing Association.

This provision is more stringent than the FDA regulation for the situations to which it applies because it requires examination and clearance by both an otolaryngologist and an audiologist. Therefore, the Commissioner is proposing that this provision. be exempted from preemption.

NEW YORK

New York General Business Law Article 37: § 784 *Special provisions.* 1. No hearing aid shall be sold to any individual unless within the preceding six months the individual as been examined by an otolaryngologist or a licensed audiologist, and a written recommendation for a hearing aid has been made by such physician or audiologist except, however, that this subdivision shall not apply to any individual who signs a written waiver based upon a religious objection: *Provided, however,* That any licensed physician may conduct such pure tone and speech audiometry and issue a written recommendation for a hearing aid if neither an otorhinolaryngologist nor licensed audiologist is available or if the hearing impaired individual is unable to reach such otorhinolaryngologist or licensed audiologist by reason of physical incapacity or infirmity and such reason is attested to on the written recommendation by the licensed physician who conducted the pure tone and speech audiometry; except however, that this subdivision shall not apply to any other individual over the age of sixteen who has undergone his first pure tone and speech audiometry, and has received his first written recommendation and has purchased his first hearing aid and who within the preceding three years has been examined by an otorhinolaryngologist or a licensed audiologist or other licensed physician pursuant to the provisions of this subdivision and to whom a written recommendation has been issued by such otorhinolaryngologist, licensed audiologist or other licensed physician. This subdivision does not apply to the replacement of parts or accessories or to the replacement of a hearing aid resulting from the loss, damage or theft of the individual's hearing aid occurring within the preceding three years of the individuals' examination by an otorhinolaryngologist or a licensed audiologist or other licensed physician pursuant to the provisions of this subdivision and the issuance of a written recommendation by such otorhinolaryngologist, licensed audiologist or other licensed physician.

This provision is less stringent than the FDA regulation because it allows the sale of a hearing aid on the recommendation of an audiologist alone. Therefore, the Commissioner is proposing to deny exemption from preemption for this provision and its implementing regulations.

New York also requests exemption from preemption for section 785-a(3) and its implementing regulations, which require the dispenser to give the purchaser an itemized receipt containing certain information. Most of the provisons of this section are not requirements with respect to a device within the meaning of section 521 of the act and therefore are not preempted. Sections 785-a(3) and 191.11(a) of the implementing regulations, however, require that this receipt contain a statement as to whether the hearing aid is new, used, or reconditioned. This provision is preempted because it is different from the Federal requirements. As indicated in the discussion of general issues above, the Commissioner is proposing to exempt this provision from preemption. As a result, the entire section will not be preempted.

The Commissioner has also determined that section 785-a(4), which requires the dispenser to give the purchaser a 30-day return privilege, is not preempted because it is a consumer protection provision beyond the scope of § 801.421 of the FDA regulations.

OHIO

Ohio Revised Code 4747.09: Sec. 4747.09 Each licensed hearing aid dealer or fitter shall furnish each person supplied with a hearing aid a receipt showing the licensee's signature, the number of his license certificate, the complete address of his place of business, a complete description of the make and model of hearing aid furnished, the full terms of sale, including the terms of guarantee, if any, and if the hearing aid sold is not new, the receipt shall also be clearly marked "used" or "reconditioned," whichever is applicable.

Each receipt shall also bear, in type no smaller than that used in the body of the receipt, the following legend: "the purchaser is advised that any examination, fitting, recommendation, or representation made by a licensed hearing aid dealer or fitter in connection with the sale of this hearing aid is not an examination, diagnosis, or prescription made by a person licensed to practice medicine in this state and therefore must not be regarded as medical opinion or advice."

Each licensed hearing aid dealer or fitter shall, when dealing with a child sixteen years of age or less, ascertain whether such child has been examined by an otolaryngologist prior to being fitted for a hearing aid. If the licensee determines that such examination has not taken place, he shall recommend to the person legally responsible for the custody of such child that such examination take place and shall so state on a waiver to be specified by the Board.

This provision is less stringent than the FDA requirements because it requires only that the hearing aid dispenser advise the parent or guardian that the child should be examined by an otolaryngologist and apparently allows the parent or guardian to waive this examination for the child. Therefore, the Commissioner is proposing to deny exemption from preemption for this section.

The first two sentences of this section require the dispenser to give to each purchaser a receipt containing certain information. Most of the information required does not relate to the safety or effectiveness of hearing aids and therefore the requirements are not requirements with respect to a device within the meaning of section 521 of the act and are not preempted. The requirement, however, that the receipt be clearly marked "used" or "reconditioned" is preempted because it is different from the Federal requirements. As indicated in the discussion of general issues above, the Commissioner is proposing to exempt this section from preemption. As a result, all of the provisions with respect to the receipt will not preempted.

OREGON

Oregon Revised Statute § 694.136 provides that a person registered to deal in hearing aids may have the certificate of registration revoked for several reasons including the following:

(6) Fitting or dispensing a hearing aid for use by any person without first determining through direct observation and personal interview whether any of the following conditions exist and, if so determined, failing to refer the person to a licensed medical physician specializing in diseases of the ear or if no such licensed physician is available in the community, to any licensed medical physician:

(a) Visible congenital or traumatic deformity of the ear;

(b) History of, or active drainage from, the ear within the previous 90 days;

(c) History of sudden or rapidly progressive hearing loss within the previous 90 days;

(d) Acute or chronic dizziness;

(e) Unilateral hearing loss of sudden or recent onset within 90 days;

(f) Significant air-bone gap (greater than or equal to 15 decibels, American National Standards Institute, 500, 1,000 and 2,000 Hz average); or

(g) Any other condition that the division may by rule establish.

However, if the person or the parents or guardians of the person refuse for good cause, to seek medical opinion, the person dealing in hearing aids shall obtain from the person or the parents or guardian of the person a certificate to that effect in a form as prescribed by the division. It is a violation of this subsection for any person dealing in hearing aids or his employees and putative agents, upon making such required referral for medical opinion, to in any manner whatsoever disparage or discourage a prospective hearing aid user from seeking such medical opinion prior to the fitting

and dispensing of a hearing aid. Nothing required to be performed by a person dealing in hearing aids under this subsection means that the person is engaged in the diagnosis of illness or the practice of medicine or any other activity prohibited by the provisions of ORS 694.036, 694.095 and this section.

(7) Fitting or dispensing a hearing aid for use by any person under 16 years of age unless within 90 days of such sale the child has been referred:

(a) To an otolaryngologist for examination and for a recommendation of corrective measures which may be required; or

(b) To a properly licensed medical physician for like examination and recommendation; or

(c) To an audiologist licensed by the State of Oregon for an evaluation of the child's hearing and for a recommendation of corrective measures which may be required: *Provided,* That the child is also examined by a properly licensed medical physician who gives approval for possible hearing aid use.

If the parents or guardian of such person refuse for good cause to seek medical opinion, the person dealing in hearing aids shall obtain from such parents or guardian a certificate to that effect in a form prescribed by the division. However, the replacement of an identical hearing aid within one year is not subject to this subsection.

Subsection (6) is less stringent than the FDA regulation because it apparently permits the parent or guardian of a minor 16 or 17 years of age to waive the medical examination requirement for the child. Therefore, the Commissioner is proposing to deny exemption from preemption for this subsection.

Subsection (7) also provides that the parent or guardian of the child may waive the medical evaluation requirement for the child. To this extent, subsection (7) is less stringent than the FDA requirement. The Commissioner is proposing to deny exemption from preemption for this subsection.

Oregon also requests exemption from preemption for section 694.036 which requires the dispenser to give the purchaser a receipt containing certain information. Most of the provisions of this section are not requirements with respect to a device within the meaning of section 521 of the act. However, section 694.036(e) requires that this receipt contain a statement as to whether the hearing aid is new, used, or reconditioned. This provision is preempted because it is different from the Federal requirements. As indicated in the discussion of general issues above, the Commissioner is proposing to exempt this section from preemption. As a result, none of section 694.036 will be preempted.

PENNSYLVANIA

35 Purdon's Statutes § 6700:

Section 402. *Referral to physician.* Whenever any of the following conditions are found to exist either from observations by the registrant or on the basis of information furnished by the prospective hearing aid user, a registrant shall, prior to fitting and selling a hearing aid to any individual, suggest to that individual in writing that his best interests would be served if he would consult a licensed physician specializing in diseases of the ear, or if no such licensed physician is available, then to a duly licensed physician:

(1) Visible congenital or traumatic deformity of the ear.

(2) Active drainage from the ear within the previous 90 days or history of this symptom.

(3) Sudden or rapidly progressive hearing loss within the previous 90 days.

(4) Acute or chronic dizziness.

(5) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(6) Visible evidence of cerumen accumulation or a foreign body in the ear canal.

(7) Significant air-bone gap, when generally acceptable standards have been established.

(8) Pain in the ear within the previous 90 days.

Whenever any of the aforementioned conditions are found to exist either from observations by the registrant or on the basis of information furnished by the prospective hearing aid user, the registrant shall not sell or fit a hearing aid to such person without a written recommendation from a licensed physician that a hearing aid may be beneficial to such person.

Section 403. *Medical examination.* No hearing aid is to be sold to any individual unless, wrthin the preceding six months, the individual has been examined by an otologist or otolaryngologist or any licensed physician, and a written recommendation has been made by such physician that the use of a hearing aid may be beneficial to the physician's patient.

This section does not apply to (i) the replacement of parts or accessories or of a worn out or damaged hearing aid, or (ii) any individual who signs a written waiver as set forth in this section. The waiver form must be in at least 10 point type. The waiver must be read and explained in such a manner that the purchaser will be thoroughly aware of the consequences of signing the waiver. The waiver form shall read as follows:

"I have been advised that my best interests would be served if I had a medical examination by an otologist or otolaryngologist or any licensed physician before my purchase of a hearing aid.

(Registrant's Name)_____

has fully and clearly informed me of the value of such medical examination. After such explanation, I voluntarily sign this waiver. I choose not to seek a medical examination before the purchase of the hearing aid."

(Signature of Registrant)_____

(Signature of Purchaser)_____

Section 506. Sale to Minors. No hearing aid shall be sold by an individual registered under this act to a person 18 years of age or younger, unless within the preceding 6 months a recommendation for a hearing aid has been made by a physician specializing in otolaryngology or otology. A replacement of an identical hearing aid within 6 months shall be an exception to this requirement.

Section 402 is more stringent than the FDA requirement because it prohibits the hearing aid despenser from selling a hearing aid when certain medical conditions are found to exist, unless the prospective user receives a written recommendation from a licensed physician; no waiver of this requirement is permitted. The Commissioner is proposing to exempt this section from preemption.

Section 403 is not preempted because it is substantially identical in most respects to the FDA requirements in that it requires that the prospective user obtain medical clearance within 6 months before the sale of a hearing aid and permits an informed adult to waive this requirement.

The Commissioner advises, however, that in order for a sale to be in compliance with Federal law, it must also meet all the requirements of the FDA regulation. Thus, with specific reference to the replacement provision in the first sentence of the second paragraph of section 403, if a "replacement of parts or accessories or of a worn out or damaged hearing aid" constitutes a new sale and not simply a warranty-type replacement of parts or substitution of one hearing aid for another, all requirements of the FDA regulation must be met including a medical examination within the preceding six months.

The requirement in section 506 that a prospective hearing aid user 18 years of age or younger must be examined by an otolaryngologist or otologist is more stringent than the FDA requirement of examination by any licensed physician. Also, section 506 does not permit anyone 18 years of age to waive the requirement while the FDA regulation permits a waiver for those 18 years of age or older. The Commissioner is proposing to exempt section 506 from preemption because it is more stringent than the Federal regulation.

TEXAS

Vernon's Civil Statutes. Article 4566. Section 14:

(d) Every license must, when dealing with a child 10 years of age or under, ascertain whether the child has been examined by an otolaryngologist for his recommendation within 90 days prior to the fitting. If such is not the case, a recommendation by the licensee to do so must be made and this fact noted on the bill of sale required in subsection (b) of this section.

This section is less stringent than the FDA requirements because it requires only that the hearing aid dispenser recommend that the child be examined by an otolaryngologist and apparently would allow the dispenser to sell the hearing aid even though the child has not been medically examined. The Commissioner is proposing to deny exemption from preemption for this section.

Texas also seeks exemption from preemption for section 14(b), which requires the dispenser to give to the pur-

chaser a bill of sale containing certain information. Most of the information required by this section does not relate to the safety or effectiveness of hearing aids and therefore these provisions are not preempted. However, section 14(b) requires that the bill of sale include a statement as to whether the hearing aid is new, used, or rebuilt. This provision is preempted because it is different from the Federal requirements. As indicated in the discussion of general issues above, the Commissioner is proposing to exempt this provision from preemption. As a result, none of section 14(b) will be preempted.

WASHINGTON

Revised Code of Washington 18.35.110:

§ 18.35.110 *Grounds for suspension of licensee.* Any person licensed under this chapter may have his license suspended for a fixed period or be placed on probation by the department for any of the following causes:

* * * * *

(2)(e)(i) Whenever any of the following conditions are found or should have been found to exist either from observations by the licensee or on the basis of information furnished by the prospective hearing aid user, prior to fitting and dispensing a hearing aid to any such prospective hearing aid user, failing to advise that prospective hearing aid user in writing that he should first consult a licensed physician specializing in diseases of the ear or if no such licensed physician is available in the community then to any duly licensed physician:

(A) Visible congenital or traumatic deformity of the ear;

(B) History of, or active drainage from the ear within the previous ninety days;

(C) History of sudden or rapidly progressive hearing loss within the previous ninety days;

(D) Acute or chronic dizziness;

(E) Unilateral hearing loss of sudden or recent onset within ninety days;

(F) Significant airbone gap (when generally acceptable standards have been established);

(G) Any other conditions that the department may by rule establish: *Provided,* That it shall be a violation of this subsection for any licensee or his employees and putative agents upon making such required referral for medical opinion to in any manner whatsoever disparage or discourage a prospective hearing aid user from seeking such medical opinion prior to the fitting and dispensing of a hearing aid: *And provided further,* That no such referral for medical opinion need be made by any licensee in the instance of replacement only of a hearing aid which has been lost or damaged beyond repair within one year of the date of purchase: *And provided further,* That nothing in this section required to be performed by a licensee shall mean that the licensee is engaged in the diagnosis of illness or the practice of medicine or any other activity prohibited by the provisions of this code;

(ii) Fitting and dispensing a hearing aid to any person under eighteen years of age who has not been examined and cleared for hearing aid use within the previous six months by a physician specializing in otolaryngology except in the case of replacement instruments or except in the case of the parents or guardian of such person refusing, for good cause, to seek medical opinion; *Provided,* That should the parents or guardian of such person refuse, for good cause, to seek medical opinion, the licensee shall obtain from such parents or guardian a certificate to that effect in a form as prescribed by the department;

(iii) Fitting and dispensing a hearing aid to any person under eighteen years of age who has not been examined by a clinical audiologist for his recommendations during the previous six months, without first advising such person or his parents or guardian in writing that he should first consult a clinical audiologist.

Subsection (2)(e)(i) is less stringent than the FDA regulation because it requires only that the hearing aid dispenser advise the prospective user to consult an otolaryngologist or other licensed physician if one of the listed conditions is found to exist and apparently allows the sale of the hearing aid without a medical evaluation or a written waiver of a medical evaluation. Therefore, the Commissioner is proposing to deny exemption from preemption for this requirement.

Subsection (2)(e)(ii) is less stringent than the FDA regulation because it allows the parent or guardian of a child under the age of 18 to waive the medical evaluation requirement for the child. Therefore, the Commissioner is proposing to deny exemption from preemption for this requirement.

Subsection (2)(e)(iii), if it is considered to be in addition to the FDA medical evaluation requirement, is more stringent than the FDA requirement because it imposes an additional requirement of examination by an audiologist for a prospective hearing aid user under the age of 18. The Commissioner is proposing to exempt subsection (2)(e)(iii) from preemption.

WEST VIRGINIA

West Virginia Code § 30-26-14:

Section 30-26-14 *Matters to be ascertained-by licensee prior to the sale or fitting of hearing aids.* (a) Every licensee engaged in the practice of dealing in or fitting of hearing aids shall, prior to the sale or the fitting of a hearing aid intended to be worn or used by any person, first ascertain whether such person has within the preceding six months been examined for the defective or impaired hearing condition sought to be relieved by an otolaryngologist or other duly licensed physician. If such person has been so examined, the licensee shall, prior to the sale or fitting of such hearing aid, determine the recommendations and consult with such otolaryngologist or physician. If such person has not been so examined, the licensee shall not proceed to the sale or fitting of a hearing aid until after such person has been so examined.

(b) Prior to the sale of a hearing aid, every licensee shall be required to advise in writing, in the manner and form prescribed by the board, the person to whom he intends to sell or fit with such hearing aid that such person's best interest would be served by consulting an otolaryngologist or other physician specializing in diseases of the ear, or any other physician duly licensed to practice medicine in this State, if any of the following conditions are found upon examination of such person:

(1) Visible congenital or traumatic deformity of the ear;

(2) History of active ear discharge within the previous ninety days;

(3) History of a sudden or rapidly progressive hearing loss within the previous ninety days;

(4) Acute or chronic dizziness;

(5) Unilateral hearing loss of sudden or recent onset within the previous ninety days; or

(6) Significant air-bone gap.

(c) A copy of any writing or form required to be given to a prospective purchaser or other person by the terms of this section shall be retained in the records of the licensee for a period of seven years following the issuance of each writing.

Subsection (a) is more stringent than the Federal regulation because it does not permit the prospective user to waive the medical evaluation requirement. However, as stated above, the Commissioner believes that informed adults should be permitted to waive the medical evaluation requirement if the prospective user has religious or personal objections to a medical evaluation. Therefore, the Commissioner is proposing to deny exemption from preemption for this subsection. As a result, the Federal waiver provision will apply in West Virginia; that is, any informed adult, 18 or older, may waive the medical evaluation requirement.

Subsection (b) of this section is more stringent than the Federal regulation because it requires the hearing aid dispenser to consult a physician if one of six warning signs is present. The Federal regulation (§ 801.420(c)(2)) requires that the user instructional brochure contain a statement warning hearing dispensers to advise the prospective user to consult promptly a physician if one of eight conditions is observed in the prospective user. Since the West Virginia statute requires the dispenser to advise the prospective user in writing, it is more stringent than the Federal requirement and the Commissioner is proposing to exempt it from preemption.

Subsection (c) of this section is more stringent than the Federal requirement because it requires the hearing aid dispenser to maintain for 7 years copies of the physician's clearance statement and the written warnings required by subsection (b), while the Federal regulation requires the dispensers to maintain copies of medical clearance statements and waivers for only 3 years. Therefore the Commissioner is proposing to exempt subsection (c) from preemption.

COMMENT

The Commissioner has made his decisions on these applications based on the plain meaning of the language of the requirements. The Commissioner invites comments on whether he has interpreted these requirements correctly and on whether these requirements are interpreted or applied differently by the States. The Commissioner also invites comments on those State statutes that require mandatory audiological evaluation and those that also limit waiver of the medical evaluation requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that part 808 be amended as follows:

1. In §808.1 by adding a new paragraph (f) as follows:

§808.1 Scope.

* * * * *

(f) The Federal requirement will apply at all times regardless of whether the State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement will apply to those circumstances not covered by the State or local requirement.

2. In §808.55 *California* by adding new paragraphs (a) (13) and (14) as follows:

§808.55 California.

(a) * * *

(13) Business and Professions Code, sections 3365 and 3365.6.

(14) Health and Safety Code, section 26463(m).

* * * * *

3. In subpart C by adding new §§808.53, 808.57, 808.59, 808.67, 808.69, 808.73, 808.74, 808.77, 808.80, 808.81, 808.82, 808.85, 808.87, 808.88, 808.93, 808.97, 808.98, and 808.101 as follows:

§808.53 Arizona.

(a) The following Arizona medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

(1) Arizona Revised Statutes, chapter 17, §36-1901.7(t).

(2) Arizona Code of Revised Regulations, title 9, article 3, section R9-16-304.

(b) The following Arizona medical device requirements are preempted by section 521 of the act and have been denied an exemption from preemption:

(1) Arizona Revised Statutes, chapter 17, §36-1901.7(s).

(2) Arizona Code of Revised Regulations, title 9, article 3, section R9-16-303.

§808.57 Connecticut.

The following Connecticut medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: Connecticut General Statutes, sections 20-403 and 20-404.

§808.59 Florida.

The following Florida medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

Florida statutes, §468.135(f) and Florida Administrative Code, §10D-48.25(26), on the condition that the medical evaluation required by thse sections take place no more than 6 months before the sale of the hearing aid.

§808.67 Kentucky.

The following Kentucky medical device requirement is enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: Kentucky Revised Statutes, section 334.200(1).

§808.69 Maine.

(a) The following Maine medical device requirement is enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: Maine Revised Statutes, title 32, section 1658-C, on the condition that, in enforcing this requirement, Maine applies the definition of "used hearing aid" in §801.420(a)(6) of this chapter.

(b) The following Maine medical device requirements are preempted by section 521 of the act and have been denied an exemption from preemption: Maine Revised Statutes, title 32, section 1658-D and the last sentence of section 1658-E.

§808.73 Minnesota.

The following Minnesota medical device requirements are preempted by section 521 of the act and the Commissioner of Food and Drugs has denied an exemption from preemption for these requirements: Minnesota Statutes, §§145.43 and 145.44.

§808.74 Mississippi.

The following Mississippi requirement is preempted by section 521 of the act and the Commissioner of Food and Drugs has denied an exemption from preemption for this requirement: Mississippi Code, section 73-14-3(g)(9).

§808.77 Nebraska.

The following Nebraska medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: Nebraska Revised Statutes, sections 71-4712(2)(c) (vi) and (vii).

§808.80 New Jersey.

The following New Jersey medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

(1) New Jersey Statutes Annotated, section 45:9A-23, on the condition that New Jersey, in enforcing this requirement, applies the definition of "used hearing aid" in §801.420(a)(6) of this chapter.

(2) New Jersey Statutes Annotated, sections 45:9A-24 and 45:9A-25.

§808.81 New Mexico.

The following New Mexico medical device requirement is enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: New Mexico Statutes Annotated, section 67-36-16(F).

§808.82 New York.

(a) The following New York medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

(1) General business law, article 37, section 785-a(3).

(2) Official Compilation of codes, rules and regulations of the State of New York, chapter V, title 19, subchapter G, §§191.10 and 191.11, on the condition that New York, in enforcing this requirement, applies the definition of "used hearing aid" in §801.420(a)(6) of this chapter.

(b) The following New York medical device requirements are preempted by section 521(a) of the act and the Commissioner of Food and Drugs has denied an exemption from preemption:

(1) General business law, article 37, section 784.

(2) Official compilation of codes, rules and regulations of the State of New York, chapter V, title 19, subchapter G, §§ 191.6, 191.7, 191.8, and 191.9.

§ 803.85 Ohio.

The following Ohio medical device requirement is enforceable notwithstanding section 521(a) of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: Ohio Revised Code, § 4747.09; for the last two sentences, with respect to medical examination of children, on the condition that Ohio, when enforcing this requirement, applies the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

§ 808.87 Oregon.

(a) The following Oregon medical device requirements are enforceable notwithstanding section 521(a) of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: Oregon Revised Statutes, § 694.036.

(b) The following Oregon medical device requirements are preempted by section 521 of the act and the Commissioner of Food and Drugs has denied an exemption from preemption: Oregon Revised Statutes, §§ 694.136 (6) and (7).

§ 808.88 Pennsylvania.

The following Pennsylvania medical device requirements are enforceable notwithstanding section 521(a) of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: 35 Purdon's Statutes 6700, section 402; section 504(4) on the condition that Pennsylvania, when enforcing this requirement, applies the definition of "used hearing aid" in § 801.420(a)(6) of this chapter; section 506; and section 507(2).

§ 808.93 Texas.

(a) The following Texas medical device requirement is enforceable notwithstanding section 521(a) of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: Vernon's Civil Statutes, Article 4566, section 14(b), on the condition that Texas, when enforcing this requirement, applies the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following Texas medical device requirement is preempted by section 521(a) of the act and the Commissioner of Food and Drugs has denied an exemption from preemption: Vernon's Civil Statutes, Article 4566, section 14(d).

§ 808.97 Washington.

(a) The following Washington device requirement is enforceable notwithstanding section 521(a) of the act because the Commissioner of Food and Drugs has granted an exemption from preemption: Revised Code of Washington 18.35.110(2)(e)(iii), on the condition that it is enforced in addition to the applicable requirements of this chapter.

(b) the following Washington medical device requirements are preempted by section 521(a) of the act and the Commissioner of Food and Drugs has denied an exemption from preemption: Revised Code of Washington 18.35.110(2) (i) and (ii).

§ 808.98 West Virginia.

The following West Virginia medical device requirement is preempted by section 521(a) of the act and the Commissioner of Food and Drugs has denied an exemption from preemption: West Virginia Code, section 30-26-14.

§ 808.101 District of Columbia.

(a) Except as provided in paragraph (b) of this section, the following District of Columbia medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act: Act 2-79, section 5 and section 6, on the condition that the District of Columbia, in enforcing the requirement in section 6(a)(5), applies the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following District of Columbia medical device requirement is preempted by section 521(a) of the act and the Commissioner of Food and Drugs has denied an exemption from preemption: Act 2-79 to the extent that it requires a hearing test evaluation for adults 18 years or older and does not allow adults to waive the medical evaluation requirement for personal, as well as religious reasons.

Interested persons may, on or before September 26, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received commments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economnic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: July 20, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 78-20862 Filed 7-27-78; 8:45 am]

Federal Register

FRIDAY, JULY 28, 1978
PART VI

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

■

MILK IN TEXAS AND CERTAIN OTHER MARKETING AREAS

Decision on Proposed Amendments to Marketing Agreements and Orders

[3410-02]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Parts 1071, 1073, 1097, 1102, 1104, 1106, 1108, 1120, 1126, 1132, 1138]

[Docket Nos. AO-231-A45, etc.]

MILK IN THE TEXAS AND CERTAIN OTHER MARKETING AREAS

Decision on Proposed Amendments to Marketing Agreements and Orders

7 CFR Parts	Marketing area	Docket Nos.
1071	Neosho Valley	AO-227-A34
1073	Wichita, Kans	AO-173-A35
1097	Memphis, Tenn	AO-219-A34-RO1
1102	Fort Smith, Ark	AO-237-A28-RO1
1104	Red River Valley	AO-208-A28
1106	Oklahoma Metropolitan	AO-210-A41
1108	Central Arkansas	AO-243-A52-RO1
1120	Lubbock-Plainview, Tex	AO-328-A21
1126	Texas	AO-231-A45
1132	Texas Panhandle	AO-262-A30
1138	Rio Grande Valley	AO-335-A26

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This decision would provide for a "base-excess" plan for paying producers under 11 southwestern Federal milk orders, beginning October 1, 1978. The plan was proposed by a major cooperative association at a public hearing held in April 1977. Under the plan, each producer's average daily delivery of milk during September through December (October through December for 1978 only) would be his established base. In the following March through July, each producer would be paid a higher uniform base price for milk deliveries up to his base, and a lower price for any excess milk. During August through February, producers would receive the blend price for all their deliveries. The intent of the plan is to provide an incentive to producers to even out their milk production during the year.

DATE: See supplementary information under "Referendum Order to Determine Producer Approval."

FOR FURTHER INFORMATION CONTACT:

Robert F. Groene, Marketing Specialist, Daily Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-4824.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notices of hearing: Issued February 11, 1977, published February 14, 1977 (42 FR 9674); issued March 3, 1977, published March 25, 1977, published March 31, 1977 (42 FR 17130). Notice of extension of time for filing briefs: Issued May 18, 1977, published May 23, 1977 (42 FR 26217).

Notice of recommended decision: Issued December 20, 1977, published December 29, 1977 (42 FR 65088). Notices of extension of time for filing exceptions: Issued January 20, 1978, published January 26, 1978 (43 FR 3568); issued February 15, 1978, published February 22, 1978 (43 FR 7327).

Preliminary Statement

A public hearing was held upon proposed amendments to the marketing agreements and to the orders regulating the handling of milk in the aforesaid marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice (7 CFR 900), at Irving, Tex., on April 5-8, 1977, pursuant to notices thereof.

Upon the basis of the evidence introduced at the hearing and the record thereof, the Deputy Administrator, Program Operations, on December 20, 1977, filed with the Hearing Clerk, U.S. Department of Agriculture, his recommended decision containing notice of the opportunity to file written exceptions thereto.

The material issues, findings and conclusions, rulings, and general findings of the recommended decision are hereby approved and adopted and are set forth in full herein with the following modifications:

Index of Changes

1. Under the heading "1. The need for a common base-excess plan in the 11 markets," paragraphs 1 and 3 are revised, two new paragraphs are added following paragraph 3, two new paragraphs are added following paragraph 12, paragraphs 13 and 36 are revised, one paragraph is added following paragraph 40, one paragraph is added following paragraph 44, paragraph 45 is revised, one paragraph is added following paragraph 56, three paragraphs are added following paragraph 58, two paragraphs are added following paragraph 63, three paragraphs are added following paragraph 64, one paragraph is added following paragraph 72, paragraph 76 is revised, one paragraph is added following paragraph 83, two paragraphs are added following paragraph 85, on paragraph is added following paragraph 87, one paragraph is added following paragraph 88, and forty-seven paragraphs are added following paragraph 89.

2. Under the heading "2. Order provisions implementing the base-excess plan," paragraph 1 is revised, in paragraph 10 the number "1" is changed to "10," one paragraph is added following paragraph 10, two paragraphs are added following paragraph 17, paragraph 26 is revised, eleven paragraphs are added following paragraph 30, and one paragraph is added following paragraph 31.

The material issues on the record of the hearing relate to:

1. The need for a common base-excess plan in the 11 markets, and
2. Order provisions implementing the base-excess plan.

Findings and Conclusions

The following findings and conclusions on the material issues are based on evidence presented at the hearing and the record thereof:

1. *The need for a common base-excess plan in the 11 markets.* A common base and excess plan for distributing returns for milk among producers should be provided under each of the 11 orders included in this proceeding. The plan should be made effective on October 1, 1978.

A base-excess plan is a means of apportioning among producers on the basis of their deliveries of milk to handlers the money due them from such handlers. The plan in no way affects the cost of milk purchased by handlers. Producers in total receive the same amount of money under a base-excess plan as they would receive under a blend price payment procedure. The plan is designed to encourage production in the fall months of seasonally low production and to discourage excess production in the spring months of seasonally high production.

Except for the initial base-making period in 1978, the base-excess plan adopted herein would provide that each producer under the 11 orders would receive a daily base equal to the average of his daily deliveries of milk to all handlers under such orders

during the 4-month period of September through December. The daily base of a producer who delivered less than 90 days' production to all handlers under such orders during the 4-month period would be computed by dividing his total deliveries during such period by 90. This base would then be used during the following months of March through July to determine how much of the producer's milk is to be priced at the base and excess prices. The quantity of milk which a producers delivers during each of the months of March through July which is in excess of his base milk for the month would be paid for at the excess price, which would be the Class III price for the month. The quantity of milk not in excess of the producer's base milk would be paid for at the base price.

For the initial base-making period in 1978, a base for each producer would be established by adding the pounds of producer milk delivered by him under each of the 11 orders during the months of October through December and dividing such amount by the number of days' production represented by such producer milk or by 60, whichever is greater.

The quantity of milk which a producer delivers during each of the months of March through July which is in excess of his base milk for the month would be paid for at the excess price, which would be the Class III price for the month. The quantity of milk not in excess of the producer's base milk would be paid for at the base price.

The base price for each market using marketwide pooling would be determined by subtracting the total value of all excess milk in the market from the total pool obligation of all handlers and dividing the resulting amount by the pounds of base milk. The base prices for milk received by individual handlers in the Memphis, Tenn., and Fort Smith, Ark., orders, which provide for individual handler pooling, would be determined by subtracting the total value of all excess milk received at the plant of each handler from the total obligation of such handler to producers and dividing the resulting amount by the pounds of base milk.

Eight of the 11 orders under consideration provide that producers shall receive a blend price during all months of the year. The three other orders under consideration (Memphis, Fort Smith, and Central Arkansas) presently provide for a base-excess plan for paying producers. The base-forming months in the three orders are September through January and the base-paying months are March through July. The base-excess plans of the three orders provide for the computation of a producer's daily base by dividing the total deliveries of such producer to handlers regulated under the three orders by the number of days in such period beginning with the first day during September-January milk was delivered to handlers regulated under one of the orders, but not less than 120 days. During the base-and-excess payment period a producer's daily base is multiplied by the number of days in the month to obtain a monthly base, which is used to determine how much of the producer's deliveries is base milk and excess milk.

The producer's base and excess milk is apportioned among handlers, and ultimately among the three orders, according to the percentage that the producer's deliveries to each handler is of his total deliveries to handlers regulated under the three orders.

The value of excess milk under the Central Arkansas, Fort Smith, and Memphis orders is computed by assigning excess milk in series, beginning with Class III milk, to the producer milk in each class and multiplying the quantities of milk so assigned to each class by the respective class prices. The total value of the excess milk is then divided by the total pounds of excess milk and the answer is rounded to the nearest cent. Under the Central Arkansas order, 4 cents per hundredweight is deducted to maintain a reserve in the producer-settlement fund.

Under the Central Arkansas order, which provides for marketwide pooling, the base price is computed by subtracting the total value of the excess milk from the total obligation of pool handlers and dividing the resulting amount by the pounds of base milk. The resulting price is reduced between 4 and 5 cents to maintain a reserve in the producer-settlement fund.

Under the Fort Smith and Memphis orders, which are individual handler pool orders, the base price for each handler is computed by subtracting the value of the excess milk received by the handler from his total obligation to producers and dividing such amount by the quantity of base milk.

It should be noted that in computing the base and excess prices adjustments are made for purposes of applying location adjustments and funding the advertising and promotion programs. These adjustments to the prices received by producers are necessary during all months and do not affect the operation of the base-excess plan.

The Southern Region Division of Associated Milk Producers, Inc. (AMPI), proposed that a base plan for the 11 orders be made effective September 1, 1977. The Southern Region Division markets the milk of its members to handlers located in a seven-state area who are regulated under the 11 orders under consideration. The cooperative proposed a base plan patterned after the provisions of the base plan in the Central Arkansas order. Under its proposal, milk from an individual producer that is received as producer milk during the base-forming months by handlers fully regulated under any of the 11 orders would be used to compute a base for such producer. The producer's base would be computed by dividing the total pounds of milk delivered to such handlers during September-December by the number of days in such period beginning with the first day on which milk was first received from such producer, but not less than 90 days.

Proponent proposed that producers receive base and excess prices for their deliveries during the months of February through July. The excess price would be the Class III price for the month. The value of base milk in the individual markets would be determine by subtracting from the total obligation of pool handlers the value of the excess milk. To determine the base price, the value of the base milk would be divided by the quantity of base milk, and the resulting amount would be reduced between 4 and 5 cents to provide a reserve in the producer-settlement fund.

AMPI contended that a common base plan should be adopted in each of the 11 markets to provide an incentive for all producers in these markets to bring their seasonal milk production pattern more in line with the fluid milk needs of handlers. Proponent pointed out that since August 1968 it had been using a somewhat different type of base plan as a means of making payment to its member producers under the 11 orders. The cooperative indicated that the objective of its payment plan was to provide its members with an incentive to gear their production to the demand of handlers for Class I milk, including a reserve milk supply.

AMPI claimed that its plan was reasonably successful for a number of years during which the "vast majority" of producers in the 11 markets were members of AMPI. The cooperative contended, however, that the effectiveness of its payment plan in terms of meeting the needs of the markets had diminished in recent years as a result of the cooperative's position that a production incentive plan could be applied equitably to its members only if the plan were to apply on a marketwide basis. Accordingly, AMPI requested that the orders be amended to provide all producers under the 11 orders with the incentive to improve the seasonal pattern of their milk production.

Proponent claimed that a sufficient supply of milk is not available in the 11 markets during the fall months to meet the Class I requirements of han-

dlers. It contends that the proposed plan will increase production during the fall months, thereby assuring handlers of an adequate supply of milk during such period. Proponent contends also that the production leveling aspect of the plan will diminish the large reserve milk supplies during the spring and summer months.

The cooperative stated that because supplies are inadequate in the fall it has been necessary for it to acquire milk from outside the 11-market area in supplying the fluid milk needs of handlers. Proponent indicated, however, that it has not been able to procure sufficient milk from outside sources and thus has been forced to allocate its available supply among the handlers supplied by the cooperative.

Proponent contends that it has the primary burden of maintaining a reserve milk supply for the 11 markets and of allocating the available milk supplies to handlers for Class I and Class II uses. AMPI alleges that it bears a disproportionate share of the costs of maintaining a reserve milk supply. It pointed out that some producers in the 11 markets bear none of the expenses of maintaining the reserve milk supply because of the milk procurement practices of certain handlers. These handlers buy milk from producers who deliver all of their milk production to such handlers on six or seven days during the week. These same handlers then buy supplemental milk supplies from AMPI on only those days of the week when their plants bottle milk. The cooperative then has the responsibility of marketing on the remaining days of the week the milk production of the cooperative's members who deliver to such handlers.

Proponent indicated that because of the cooperative's role in handling the reserve milk supply its members have had their pay prices for milk reduced to cover the cost of such operations. During the fall months, the cooperative pointed out, its members have had to bear the costs of shifting milk from market to market to meet the fluid milk requirements of handlers. During the spring months the cooperative's members have had the expense of moving to manufacturing plants that milk which is surplus to the fluid milk requirements of handlers.

Proponent contended that the proposed plan should be adopted in each of the 11 orders because the procurement area of the handlers regulated by such orders constitutes one area of reserve milk supply for the 11 markets. Proponent indicated that most, if not all, of its member milk associated with its Southern Region Division is disposed of in the 11 markets and that 1,307 of its 4,895 members associated with the 11-market area were pooled during October 1976 under more than one of the 11 orders. Because of this intermingling of producers among the 11 markets, proponent contended that the plan should be adopted on a common basis under all 11 orders so that the milk delivered by a producer to one or more of the 11 markets is taken into account in the computation of his base and in the payment for base and excess milk.

A cooperative association opposed the adoption of a base-excess plan on the basis that such plans do not level production during the year. Opponent claimed instead that the plan would provide an incentive for producers to expand production annually. The cooperative argued that additional quantities of milk are not needed in these 11 markets because Class I utilization in 1976 ranged from a low of 58 percent in the Wichita market to a high of 88 percent in Central Arkansas. It contended that the plan would cause dairy farmers to participate in a "race for base," i.e., make an extra effort to increase milk production during the base-forming months. It alleged that such efforts would result in too much production in the fall months and add to the excess reserve milk supplies in other months.

The cooperative's representative contended that dairy farmers located on the fringe of the production areas might shift to another market if the base-excess payment plan resulted in a lower per hundredweight return than the blend price received by neighboring dairy farmers shipping to other Federal order markets. Thus, the cooperative was concerned that the proposed payment plan might result in disorderly marketing conditions.

The cooperative contended further that the plan would restrict the movement of producers from one market to another. It indicated that a producer would not want his milk moved to a market outside the 11 markets during the base-forming period since he would not earn a base for that production. During the spring months it would not be feasible for producers to shift to the 11 markets from other markets since they would not have a base and, thus, would not be eligible to receive the base price for their milk. The cooperative also stated that the plan would present administrative and enforcement problems for the market administrator. It suggested that, in order to obtain additional base, dairy farmers would add water to milk, borrow milk cows from a dairy farmer shipping to a manufacturing plant, or exchange milk with another dairy farmer.

Several proprietary plant operators, cooperatives, and producers expressed opposition to a common base-excess plan on the basis that such plan would restrain outside milk supplies from entering the 11 markets. They contended that, because only dairy farmers who begin delivering milk to one of the 11 markets in either August or September would be able to earn a base reflecting their average daily production during the fall months, the proposed plan would preclude other dairy farmers from entering the markets during other months of the year. Several also were concerned that cooperatives that deliver to handlers regulated by an order other than the 11 under consideration could tend to keep their members from joining cooperative's supplying the 11 markets by having them sign membership contracts expiring in months other than August or September.

A large number of producers testified individually in opposition to a base-excess plan, indicating that the plan should not be adopted for various reasons, including the following:

a. The plan is sought by AMPI to increase milk production so that the cooperative can operate its manufacturing facilities throughout the year.

b. The plan is a means of restricting entry of new producers to the market, or forcing independent producers to join AMPI.

c. More producer milk is not needed during the fall months because producers currently receive the Class III price for a portion of their milk during the fall.

d. Cows calving in September and October will produce more milk in the spring months relative to the preceding fall months if good pasture is available for grazing during the spring.

e. It takes from 3 to 5 years to change the milk production pattern of a herd through breeding practices.

f. Moving a cow from one herd to another herd to build base would decrease the yearly milk production of that cow by 2,000 pounds.

g. The Dairy Herd Improvement Association claims that a cow calving in the fall will yield $110-$114 more net return than a cow calving in the spring months, in which case such a return in itself provides sufficient incentive for fall production.

h. The base plan would be an extreme hardship on those producers whose dairy herd is or has been affected by Bang's or other diseases affecting milk production.

i. July and August are not good months for a cow to have a calf due to high daytime temperatures and an infestation of flies.

j. The blend price, which is usually higher in the fall months than in the spring months, provides sufficient incentive to produce additional milk in the fall months.

Several handlers opposed the adoption of a base-excess plan in the 11 markets. One handler stated that his seasonal pattern of Class I sales in the Corpus Christi area is contrary to that of other handlers in other markets. He indicated that his Class I sales are greater in the spring than in the fall because of the tourist trade and that the proposed base-excess plan would not be compatible with this sales pattern. The handler claimed that such a plan would discourage new dairy farmers from entering the market, that it would decrease the local producer milk supply and force a greater reliance on milk supplies from the northern part of the United States, and that consumers would be forced to pay a higher price for milk. The handler also argued that a base-excess plan would help the proponent cooperative gain additional market control.

Another handler opposed the adoption of a base-excess plan on the basis that the seasonal fluctuation in milk production in the 11 markets is not significant, pointing out that in the spring of 1975 and 1976 milk production was 114 and 110 percent, respectively, of production in the immediately following fall months. The handler also noted that a base-excess plan was terminated in the North Texas order in 1963 because milk production had increased 85 percent in a 10-year period of time while Class I sales had increased only 41 percent.

Several handlers with own-farm production opposed the application of the proposed base-excess plan to their own-farm production and suggested the following alternatives if such a plan is adopted: (1) delay the effective date of the plan for 2 years, (2) exempt own-farm production from the base-excess plan, and (3) exempt from the base plan that portion of own-farm production equivalent to the amount of packaged milk sold to consumers.

A common base-excess plan should be included in each of the 11 markets under consideration. The base plans will provide a means of encouraging a more level seasonal production pattern in the 11 markets so that there will be a better seasonal coordination of milk supplies with the Class I demand.

Milk production in the 11-market area fluctuates seasonally, with supplies increasing in the spring and declining in the fall. Such changes are portrayed, for example, in the producer delivery data for 1975 and 1976 that were included in the record. In the spring of 1975, average daily deliveries of producer milk reached 109 percent of the average daily deliveries for 1975 and 1976 combined. For 1976, this figure was 108 percent. Similar downward swings occurred in the fall, with average daily deliveries dropping to 92 percent in 1975 and 95 percent in 1976 of the 2-year daily average.

Although it was argued by some that such seasonal fluctuations in production are not severe, such changes are much more meaningful when viewed in terms of the somewhat opposite swings in Class I sales. When supplies were lower in the fall, average daily Class I sales fluctuated upward to 107 percent in 1975 and 105 percent in 1976 of the average daily Class I sales for the 2-year period. During the heavy production months, sales dropped off considerably. In 1975, average daily Class I sales in the 11-market area were only 90 percent of the 2-year daily sales average. In 1976, the amount was 92 percent.

When the production and sales data are put together, it is quite evident that production is not in seasonal balance with the Class I sales of regulated handlers. In 1975, the relationship of average daily producer deliveries to the 2-year average of daily Class I sales ranged from a low of 121 percent in October and November to a high of 144 percent in May. Similarly, in 1976, this relationship ranged from 125 percent in November to 142 percent in April.

It is recognized that the production-sales data do not portray the same seasonal relationship for each of the 11 markets individually. However, the producer delivery data for each market do not necessarily reflect the seasonal production patterns of individual producers. This is because producers are shifted extensively from market to market by the proponent cooperative in balancing the fluid milk needs of handlers throughout the entire 11-market region. For this reason, the only meaningful analysis of producer delivery data is that which is based on producer deliveries for all 11 markets combined.

A number of parties contended in their exceptions to the recommended decision that there is no seasonal shortage of milk in the 11 markets but merely daily shortages of milk resulting from the 4- and 5-day bottling schedules of handlers. It is true that daily variations in the quantity of milk demanded by handlers tend to accentuate milk shortages during the fall months. However, there is little reason to expect that the bottling schedules of handlers will change significantly, and the milk shortages that result from such bottling schedules pose a supply problem for those cooperatives committed to supplying the fluid milk needs of handlers.

Because of the seasonal changes in production and Class I sales, it has been necessary for the proponent cooperative to take various actions in response to the marketing problems that arise from such seasonal changes. Such actions have centered on obtaining adequate supplies of milk for handlers' fluid needs during the fall and disposing of excess supplies during the spring and early summer.

For example, in the fall of 1976 the cooperative found it necessary to acquire substantial quantities of milk from outside the 11-market area. About 22 million pounds of supplemental milk were obtained from the Central Arizona Federal order market, for instance. Most of this was needed to meet the fluid milk requirements of handlers in the Dallas/Fort Worth, Houston, and San Angelo areas of the Texas market. Also, supplemental milk was moved into the 11-market area from Missouri, primarily for use by handlers in the Memphis market. In most cases, the supplemental supplies moved into the 11-market area were not moved directly to the shortage areas but instead were used to supply handlers nearest the out-of-area source in order to minimize transportation costs. Supplies regularly associated with the 11-market area were then redirected (in what proponent referred to as a "stairstepping" arrangement) to the shortage areas. Even with the acquisition of out-of-area milk supplies, the proponent cooperative was not always able to fulfill the needs of handlers and was forced to allocate its limited supplies to its regular buyers.

Additional efforts by the proponent cooperative to balance the Class I needs of handlers include the shifting of producers from one market to another within the 11-market area. Such efforts are directed primarily toward having sufficient supplies available for the Texas market. Relative to the number of producers on the Texas market in February 1977, the following numbers of additional producers were associated with the Texas market in the immediately preceding months: 551 in September, 539 in October, 458 in November, 669 in December and 492 in January. Such additional numbers resulted largely from the proponent cooperative's shifting of producers, which was done in part to implement the "stairstepping" arrangement referred to earlier in connection with the out-of-area supplies and also to redirect the movement of milk supplies within the 11-market area to the areas of greatest need.

In addition to its balancing activities necessitated by seasonal shortages in milk production, the proponent cooperative also handles much of the excess milk that results from the seasonal increases in milk production. The major outlets in the 11-market area for reserve milk supplies are manufacturing plants operated by proponent. Such plants are located at Sulphur Springs and Muenster, Tex.;

Tulsa and Oklahoma City, Okla.; and Hillsboro, Kans. Milk supplies not needed at distributing plants are redirected to these plants for surplus disposal. At times, the proponent cooperative assumes the handling of a somewhat greater proportion of the surplus in the 11-market area than would normally be associated with its share of the area's total producer milk. It is not unusual for some handlers to buy milk on a regular basis from producers not belonging to a cooperative association and then obtain supplemental milk from the cooperative on heavy bottling days. Also some handlers purchase milk from the cooperative only during the fall months when the supplies of milk are traditionally short in these 11 markets.

In his exceptions, a party held that there is no evidence on the record that AMPI bears the "burden" of surplus disposition. The record reveals, however, that proponent cooperative handles the reserve requirements and the related surplus disposition for handlers who receive milk produced by nonmembers on 7 days a week and rely on the cooperative to supply milk on a lesser number of days. To the extent that proponent cooperative handles a disproportionate share of the market surplus, it bears the "burden" of surplus disposition in the market.

In carrying out the various balancing activities associated with the seasonal fluctuations in milk production, the proponent cooperative incurs operating costs that are passed on to its members through reduced returns from the sale of their milk. As a marketing organization attempting to obtain the highest possible returns for its members, the cooperative has sought to reduce such costs. For a number of years, the cooperative has operated a type of base plan among its own members for the purpose of tailoring production on the part of these producers to meet the fluid needs of the 11 markets. The effectiveness of the plan in reducing balancing costs has been limited, however, because the cooperative's balancing activities are affected also by the production pattern of other producers in the 11-market area. Also, there has been some reluctance on the part of the cooperative's members to impose an effective production incentive plan on themselves when other producers in the 11 markets are not operating under a similar plan. As an aid to minimizing the costs of marketing the milk of its members, the cooperative is seeking the adoption of a common base-excess plan under the 11 orders.

It is in the interest of orderly marketing that a base-excess plan be applicable under each of the 11 orders under consideration. Such plans are specifically authorized by the act as a marketing arrangement that producers may use under a Federal order. It is recognized that not all producers who would be affected by the adopted base plan favor its use. Nevertheless, considerable weight must be given to the fact that a very significant number of producers in each of the markets believe that such a plan can materially aid in the marketing of their milk. The proponent cooperative alone represents roughly three-fourths of the producer milk in the 11 markets combined, and about 85 percent or more of the producer milk in 8 of the 11 individual markets. In the other three markets—Wichita, Rio Grande Valley, and Texas—the proponent cooperative markets at least two-thirds or more of the milk in each market. In view of the seasonal fluctuations in milk production and the attendant marketing problems for these producers, the adoption of a common base-excess plan for the 11 markets is appropriate.

Opposition to the proposed base plan was limited primarily to the Texas market, which has about half of the milk in the 11-market area. It is in the Texas market, however, where the proponent cooperative is heavily engaged in balancing activities associated with the seasonal swings in production, and where it is significantly affected by the fluctuating production of producers outside its membership. The fact that there was opposition to the base plan should not be an overriding consideration in this case in determining whether or not the proposal should be adopted.

The base plan for each order should permit the interchange of producers among all 11 markets without affecting their establishment of base or payments for base milk. Such an arrangement is now applicable under the central Arkansas, Fort Smith, and Memphis orders. A similar arrangement is needed for the 11-market area because of the extensive and continuing shifting of producers among the individually regulated markets. Such shifts occur largely in connection with the proponent cooperative's balancing activities referred to earlier. Under the "stairstepping" arrangement, for example, producers associated with the Rio Grande Valley market may be redirected to the Texas Panhandle and Lubbock-Plainview markets. Producers associated with the latter two markets might then be redirected to the Texas market. Similarly, producers may be shifted from the Wichita market to the Oklahoma metropolitan market, and then from the latter market to the Texas market. In October 1976, for example, 1,307 of the proponent cooperative's 4,895 member-producers on the 11 markets that month were producers under more than one of the 11 orders.

A producer representative and a handler regulated under the Memphis order, which permits deliveries by producers to central Arkansas, Fort Smith, and Memphis markets to be used in the computation of a producer's base, opposed a comparable provision for the 11 markets. Both stated that such a provision is not authorized in the Act.

There is nothing in the Act stating that a base-excess plan in a market cannot include deliveries by producers to plants regulated under another Federal order in determining the quantities of base milk of an individual producer. As indicated, the Memphis, central Arkansas, and Fort Smith orders all presently contain such provisions.

The handler also opposed the inclusion of the central Arkansas, Fort Smith, and Memphis orders in the proposed 11-market base plan. He was not opposed, however, to the continuation of the present base plan in each of the three orders or in an order merging the three orders. It was his position that the three markets receive their milk supply from a common production area. Others testifying at the hearing argued that the Lubbock-Plainview market should not be included since that market is a growth area and additional class I milk is needed from one year to the next.

These arguments are not persuasive. These markets are an integral part of the area being supplied by the proponent cooperative. For the reasons already set forth, recognition should be given to the cooperative's request that a base plan be adopted in these and nearby markets for the purpose of aiding it in the marketing of its members' milk.

Various parties suggested that is would not be appropriate to limit the computation of a producer's base to deliveries only within the 11 markets. They noted that one or more of the 11 markets draw milk from a production area that also serves markets outside of these 11 markets. They pointed out that a dairy farmer residing in such common production area would be disadvantaged unless his total production is used in computing his average daily base.

Producers in the 11 markets who are not members of a cooperative usually deliver their milk to the same handler throughout the month. Consequently, their total production for the month would be used in computing their base. Producers who are members of a cooperative association which markets the milk of its members under one of the 11 markets and a market outside of the 11 markets could be affected. Such

producer would not be disadvantaged in the computation of his base if at least three-fourths of his production were delivered during the basemaking period to one of the 11 markets. The plan provides that a producer who delivers milk at least 90 days out of the 122 days during September through December would receive a base equal to his average daily production. Such provision will permit a limited interchange of producers between the 11 markets and other Federal order markets.

Several parties noted that climatic conditions and production patterns vary throughout the 11 markets. For that reason, they suggsted that whatever months are used as the basemaking and basepaying months for the 11-market area might not be appropriate for each of the individual orders.

The production area of each of the 11 orders is in reality a part of a common production area used to supply the needs of all 11 markets. It is for this reason that the 11 markets must be considered on a combined basis in establishing the basemaking and basepaying months.

In their exceptions to the recommended decision, several parties argued that if the 11-market area is in fact a common production area the 11 orders should be combined into one order. This proceeding does not provide the forum for deciding whether there should be only one order or 11 orders. Such a decision would have to be made on the basis of a hearing held for that purpose.

A number of those who testified were concerned that the adoption of a base plan would result in a "race for base." They contended that the adoption of the plan would result in excessive fall production, thereby reducing the level of the blend price in the fall months. They alleged also that the plan would increase milk production during the flush months and thus increase total milk production rather than level milk production throughout the year.

There is no means of foretelling how producers will react to a common base plan in the 11 markets. If a "race for base" occurs and results in excess fall production or in a large increase in milk production annually, marketing conditions can be reviewed at such time.

Several parties filed exceptions to the finding in the recommended decision that "there is no means of foretelling how producers will react to a common base plan in the 11 markets." They pointed out that the experience that the Department has had with base plans in other markets, particularly north Texas, should have caused the Department to conclude that adoption of the plans would lead to chaotic marketing conditions. They also held that the decline in the number of base plans under Federal orders during the period from 1967-1977 was further evidence of the failure of base-excess plans as a feasible marketing tool.

It is true that there has been a decline in the number of orders with base-excess plans. In some instances, the base plans were terminated because they resulted in an increase in yearly milk production. These past events, however, provide no conclusive evidence that producers within the 11-market area will react in a similar manner to the adoption of the proposed base-excess plans.

In this regard, parties excepting to the recommended decision held that base plans in the 11 markets will increase rather than decrease reserve milk supplies during the spring and summer months. If producers attempt to increase fall milk production by expanding their present herd size, then it is likely that milk production will increase during the spring and summer months. However, if producers change the production of their current herds to conform with the production pattern that a base-excess plan attempts to achieve (by expanding fall milk production and decreasing milk production during the flush months), the increase in reserve milk supplies that exceptors anticipate should not result during the spring and summer months.

Several parties claimed that the proposed base-excess plans could result in only nonmember producers receiving base and excess prices. They contended that because a cooperative association has the privilege of reblending its proceeds, the association would not be required to pay its members upon the basis of their deliveries of base milk and excess milk.

Proponent cooperative indicated that it intends to pay its members using the base-excess payment plan. It was not revealed on the record what payment procedures other cooperatives would use. Irrespective of the payment procedures utilized by cooperatives during the months when base and excess prices are paid, the payment that the cooperative association receives from the producer-settlement fund for all of its member producer milk will reflect the respective quantities of its member producer milk that is base milk and excess milk. For that reason members of a cooperative association will find it advantageous to produce milk with the same seasonal pattern as other producers. Otherwise, the prices received by the cooperative's producers could decline relative to the prices received by other producers as a group during the months of March through July.

Opponents of the base plan argued that such a plan would restrict the entry of new producers into the 11-market area during certain times of the year since new producers would not have a base and would receive only the excess price for their milk. It was claimed that such restrictiveness was a restraint of trade in violation of § 608c(5)(G) of the act.

It is recognized that any base-excess plan will tend to provide a disincentive at certain times of the year for producers to come onto the market, either as new producers who have just started dairying or as producers who have been shipping to other markets outside the 11-market area. This is why it is necessary to establish a common base plan for the 11 markets that permits the interchange of producers within this area. Nevertheless, the time when producers just coming onto the 11 markets would be adversely affected the most would be during the base-paying months. This is when supplies are customarily in excess of the class I requirements of handlers and handlers normally would not be seeking new producers. The influx of new producers at this time would be expected to be minimal.

The use of a base-excess plan under the order is not in violation of § 608c(5)(G) of the act. The latter provision specifies that an order shall not prohibit or in any manner limit the marketing in a Federal order area of milk produced in any production area in the United States. Congress, in providing specific authorization in the act for base-excess plans, did not intend that their use be nullified by § 608c(5)(G) of the act.

Exceptors reiterated claims made at the hearing and in post-hearing briefs that the proposed base plan is in violation of § 608c(5)(G) of the act. For the reasons already indicated, such claims are not valid and do not warrant a denial of the proposal for base plans in the 11 markets.

Exceptors held that the adoption of the base plans would allow AMPI to "manipulate" an order through "pool loading" i.e., shifting unneeded milk supplies from one market to another for the purpose of depressing the returns to producers in the second market who are not members of the cooperative. Neither the exceptions nor the record provide a basis, however, for concluding that base plans would facilitate socalled pool loading. It appears instead that a cooperative's ability to load a pool would be weakened by the adoption of the proposed base plans. If, for example, a cooperative were to bring additional milk supplies onto one of the 11 markets during the basepaying months from dairy farmers not regularly associated with the 11 markets, such dairy farm-

ers would receive only the excess price for their milk. Thus, it seems likely that a base plan would deter a cooperative from loading a pool rather than facilitating such action.

As outlined earlier, producers testifying against a base-excess plan raised numerous reasons as to why such a plan should not be adopted. Much of the opposition centered on the difficulties and additional expense that producers would experience in adjusting their production operations under a base plan.

In their exceptions, certain parties held that the base plans would insulate AMPI from competition for membership by making it more difficult for a producer to switch cooperatives while at the same time qualifying for a full base. As the recommended decision pointed out, there are some disincentives under a base plan which might deter a new producer from entering the 11 markets under consideration during certain months of the year. To the extent that these disincentives exist, a dairy farmer who markets his milk outside the 11 markets might be deterred from joining a cooperative that markets its milk entirely within the 11 markets. However, a producer under one of the 11 orders who is a member of a cooperative could transfer to any other cooperative in the area during any month of the year and continue to market his milk under one of the 11 orders without any loss of base as a result of such transfer. This would be possible since a base is earned by the producer and not by the cooperative of which the producer is a member. Thus, the transfer of a producer from one cooperative to another would not affect the ability of the producer to earn a full base, as suggested in the exceptions.

In other exceptions, it was contended that the Department was insensitive to "competitive considerations" in adopting the base plans. This is not the case. Consideration has been given to the extent to which the base plans might tend to limit a cooperative's ability to compete for members and market outlets for milk. The claims are without merit.

Also, approximately 200 individuals, primarily dairy farmers, submitted comments to the Department opposing the base-excess plans. For the most part, the individuals reiterated the same objections voiced by dairy farmers at the hearing. Some of the 200 individuals also signed the exceptions filed by Concerned Dairymen, a group of dairy farmers opposed to the adoption of uniform base-excess plans. Approximately 500 individuals signed such exceptions.

It is recognized that producers may need to make some added expenditures and special adjustments in their operations under the adopted base-excess plan if they desire to maximize their returns under the plan. As indicated, the purpose of the plan is to encourage a more level seasonal pattern of production. Seasonal fluctuations in production occur because this production pattern is normally the least costly and most natural production pattern for farmers. Any change in this normal production pattern comes about only through the special efforts of farmers, which usually entails added costs and operating difficulties. Farmers are not inclined to change their production pattern in the absence of any special incentive. The purpose of the base plan is to provide this incentive.

Questions arose at the hearing concerning the application of an 11-market uniform base-excess plan under the Texas order in conjunction with that order's "dairy farmer for other markets" provision. The "dairy farmer for other markets" provision provides that a cooperative or pool plant operator may not pool milk of a dairy farmer on the Texas market during the months of February through July if the cooperative association or pool plant operator caused milk from the same dairy farmer to be associated with another market anytime during the immediately preceding months of September through November. The provision is intended to preclude the association of reserve supplies of surrounding Federal order markets with the Texas market during the months of February through July when the milk is not needed if the producers involved were not on the Texas market during the fall months when supplies are customarily short.

The application of the "dairy farmer for other markets" provision in conjunction with the base-excess plan could cause a dairy farmer who earned base during the months of September through December not to receive the base price on any of his milk delivered to the Texas market during the base-paying months of March through July. Under that provision a dairy farmer who is a "dairy farmer for other markets" could not qualify as a producer. As a consequence, the dairy farmer would not be eligible to have his milk priced under the order and thus would have no assurance of what price he would receive for his milk. If the order required such dairy farmer to be paid the base price on any of his deliveries to the Texas market, such payment would conflict with the "dairy farmer for other markets" provision and defeat the purpose of that provision.

The "dairy farmer for other markets" provision, however, would not peclude producers delivering to a plant which was a nonpool plant under the Texas order during the months of September-November but which is a pool plant during the next March-July period from benefiting under the base-excess plan. Also, an individual dairy farmer could shift to the Texas market from any of the other 10 markets during March-July and retain his earned base provided that he does not deliver milk at a plant operated by the same handler to whom he shipped milk during the preceding September-November period.

The operators of pool plants with own-farm production and dairy farmers whose herds consist soley of registered dairy animals should not be accorded an exemption, from the base-excess provisions of the orders. At the hearing, several such individuals set forth varying reasons why their operations should be treated differently than those of other producers. However, if an exemption were granted, it would not comfort with the purpose of the base-excess plan, which is to encourage all producers on the 11 markets to even out their production during the year.

Three producer representatives and a handler representative urged that a uniform base-excess plan not be adopted in the 11 markets because of the declining use of base-excess plans. They pointed out that the number of Federal order markets with a base-excess plans has declined from 23 markets in 1967 to 5 in 1977. It was claimed that from 1963 to 1971 base-excess plans were discontinued in five orders because the plans had provided an incentive for excessive production relative to class I needs, especially during the base-forming months.

Whether or not base-excess plans should be applicable in the 11 markets under consideration must be based on the record evidence of the current hearing as it relates to present marketing conditions in these markets. As described previously in this decision, the record evidence in this proceeding justifies the use of a base-excess plan in each of the 11 markets.

A cooperative association and a handler opposed the adoption of a base-excess plan on the basis that proponent did not develop studies on the impact of the proposed plan on the markets involved and thus provided for the record only limited evidence regarding its proposal. The relevant point here is not the extent to which proponent studied the issue at hand but rather whether or not the evidence in the record adequately supports the adoption of the proposal. As already indicated, the record does justify the use of a common base-excess plan for the 11-market area.

Exceptors reiterated previous contentions that AMPI presented no studies or data which would indicate that a

base plan would improve the seasonal production pattern. For the reasons just cited, their arguments are without merit.

One cooperative association maintained that the "economic incentive to obtain base creates a major administrative burden in policing the plan." Its representative alleged that many farmers would be tempted to expand their production during the fall months by adding water to milk, borrowing cows from dairymen shipping to grade B manufacturers, and exchanging milk with someone who is not pooled in the market, for example. In support of his argument that the plan would be an administrative burden, the cooperative's representative indicated that the decline in the number of base plans under Federal orders was the best evidence of the deficiencies of such plans.

Speculation by the cooperative's representative that the base plan provisions would create an administrative burden is not sufficient reason for denying implementation of the proposed plan. Furthermore, none of the potential problems cited would be an administrative burden for the market administrator in computing bases. The market administrator would rely on the handlers who receive the producers' milk to report the amount of milk pooled by each producer during the month. Additionally, none of the reasons set forth by opponent for terminating base plans were related to the administration of such plans. The need for the base plan in the 11 markets as a means of leveling production throughout the year overrides any potential administrative problem noted at the hearing that might arise in the operation of the base plan.

Several cooperative associations alleged they would not be able to obtain as members dairy farmers who are members of other cooperatives operating outside the 11-market area unless the members' contracts expired in either August or September. They indicated that, if the members' contract expired at any other time, a dairy farmer would be reluctant to change cooperatives since he would be at a disadvantage in becoming a producer on one of the 11 markets. They noted that if the dairy farmer entered the market in October–December, he would not be able to obtain a base equal to his average daily deliveries in the base-making period. If he entered the market during March–July, he would receive the excess price for his milk during such period of time.

The manager of one cooperative was concerned that, if a base-excess plan were adopted, a cooperative which presently has a 30-day contract with its members would begin signing its members to 1-year contracts expiring in months other than August or September to discourage any shifting of members to other cooperatives.

It is recognized that the proposed base plan could be a disincentive for dairy farmers in other areas to become producers under 1 of the 11 orders, and that dairy cooperatives supplying the 11 markets could have some difficulty in obtaining new members. However, this presumably would be a limited problem since dairy farmers usually maintain their membership in a cooperative over a period of years and do not switch membership from one cooperative to another. In any event, the inability of a cooperative to obtain new members readily should not be an overriding consideration in deciding whether a base-excess plan should be adopted.

Counsel for 30 dairy farmers contended that the proposed base-excess plans should not be adopted because present marketing conditions in the markets are in conformity with § 602(4) of the act. He contended that the proposed plans would result in conditions that are contrary to this.

Section 602(4) states that it is the declared policy of Congress for the Secretary to establish and maintain such orderly marketing conditions as will provide an orderly flow of the supply to market throughout its normal marketing season to avoid unreasonable fluctuations in supplies and prices. As one of the means of obtaining this objective, the act specifically provides for the adoption of base-excess plans in Federal order markets. The record of this proceeding indicates that the use of base-excess plans in the 11 markets would, in fact, foster orderly marketing as contemplated under § 602(4) of the act.

This representative for 30 dairy farmers also claimed that the hearing was improperly called. He contended that § 608c (3) and (17) of the act permits hearings to be called only under two conditions: (1) The Secretary may call a hearing if he has reason to believe that the issuance of an order will tend to effectuate the declared policy of the act; and (2) the Secretary is required to call a hearing under specified conditions when one-third or more of the producers as defined in an order apply as individuals and in writing for a hearing. The representative thus concluded that a hearing could not be called to consider a proposal submitted by a cooperative association on behalf of producers.

This is not the case. The act does not preclude parties in the industry, such as a cooperative association, from petitioning for a hearing. The Secretary may call a hearing either on his own volition or at the request of other parties if he concludes that the proposed change would tend to effectuate the declared policy of the act.

Moreover, the Department's "Rules of Practice and Procedure Governing Proceedings to Formulate Marketing Agreements and Marketing Orders" (7 CFR part 900) specifically provide for the submission of proposals by persons other than the Secretary. Section 900.3 states that a "marketing agreement or a marketing order may be proposed by the Secretary or by any other person."

The motion by a cooperative association to render the entire hearing void and the motion by another cooperative association to reconvene the hearing at a later date because proponent altered provisions of its proposal at the hearing are denied. No statutory or administrative rules preclude appropriate revisions of a proposal at the hearing. Furthermore, the hearing notice stated that the purpose of the hearing was to receive evidence with respect to the economic and marketing conditions which relate to the proposed amendments and any appropriate modifications thereof. Thus, interested parties were given the opportunity to modify the proposed base-excess plan during the course of the hearing to the extent that no new issue outside the scope of the hearing was raised. In fact, as described elsewhere in this decision, several handler witnesses did propose certain modifications.

Exceptors reiterated claims made at the hearing and in post-hearing briefs that a modification at the hearing of a provision contained in the notice of hearing did not allow sufficient time to introduce testimony in opposition to the modification. There was no indication in the exceptions, however, of what significant market information may have been precluded from the record. In the absence of such a showing, it cannot be concluded that exceptors have a valid complaint.

Two cooperative associations claimed that the administrative law judge erred in not dismissing the hearing on the proposed base-excess plans. These cooperatives maintained that because proponent had submitted a revision to its original proposal and the Department had issued a revised notice of hearing reflecting the revision, proponent and the Department were involved in an ex parte communication which is prohibited by the "Government in the Sunshine Act."

The communications which took place between proponent and Department officials in this instance involved the receipt of revisions from proponent to previously submitted proposals and the Department's acknowledgement of the receipt of such revisions. The initial proposals had been accepted by the Department for considera-

tion at a hearing and had been set forth in a hearing notice. The revised proposals represented modifications of the initial proposals that could have been made during the course of the hearing. Because such changes were made available to the Department prior to the hearing, it was possible to provide the industry with advance notice of the modifications intended to be supported at the hearing. In the absence of the communications which took place, interested parties would have had to wait until the hearing to be made aware of the modifications. The communications involved were made a part of the record of this proceeding. Such communications provided no basis for dismissing the hearing and the administrative law judge acted properly in not doing so. Interested parties were not disadvantaged through these communications but in fact were aided by virtue of having advance notice of the modifications that the proponent cooperative was making in its initial proposals. This afforded all interested parties the opportunity to safeguard their interests through full participation in all aspects of the rulemaking proceeding, which is the very thrust of the regulations on ex parte communications.

Exceptors reitereated their contention that the presiding officer's rejection of a motion to require AMPI to show cause why the plan should not be dismissed under "Government in the Sunshine Act" was in error. The views expressed by exceptors were fully considered in the recommended decision and, as noted, are without merit.

One of the exceptors further stated that all ex parte communications between any party and the Department subsequent to the hearing should be made available to all interested parties. A number of letters were received by Department officials from persons opposed to the base plan and from other individuals on behalf of persons opposed to the plan. Such letters and the Department's replies to them have been made a part of the official record in this proceeding and are available for viewing by the public.

Counsel for a cooperative association objected to the Department's failure to disclose the basis for its prehearing conclusion that the proposed uniform base-excess plans would tend to effectuate the purposes of the act. Such disclosure, however, is not required.

Following a public hearing, the Secretary may adopt only those proposals considered at the hearing that, if supported by the record evidence, would tend to effectuate the purposes of the act. It would be useless, then, to include in the hearing notice proposals that obviously would not be consistent with the act and thus could not be adopted. For this reason, the Department must make a preliminary evaluation of all proposals submitted to it for consideration at a hearing to determine if the proposals would carry out the intent of the act. The Department is not required to reveal publicly the various considerations involved in making an affirmative determination on the proposals. It should be emphasized, though that the inclusion of a proposal in a hearing notice in no way means that the proposal will be adopted. The adoption of a proposal by the Secretary must be based solely on the evidence presented at the hearing.

In his exceptions, counsel reiterated his objection to the Department's failure to disclose the basis for its prehearing conclusion that the uniform base-excess plans would tend to effectuate the purposes of the act. For the reasons just noted, the objection is not valid.

Counsel for the cooperative association alleged also that § 554(d) of the Administrative Procedure Act precludes an employee of the Department who investigated the initial proposal and participated in the hearing from being involved in the subsequent decisionmaking process. This is not the case. There is no requirement that those employees involved in the decisionmaking process in a rulemaking proceeding must not have participated in other activities related to the proceeding.

In his exceptions, counsel restated his previous contention. However, he provided no additional basis for such contention in renewing his objection. As indicated, Counsel's claim is without foundation.

Two cooperative associations and a handler maintained that the base-excess plan did not have the support of producers and would not be approved if dairy farmers were to vote individually on the proposal. The record does not indicate how each producers feels about the proposal. Testimony at the hearing, however, indicated that the proposal was supported by the proponent cooperative, which represents a major portion of the producers that would be affected. The act provides that a cooperative association may vote on behalf of its members. If a cooperative elects to vote in this manner, which is commonly referred to as "bloc voting," the Department is required to accept the cooperative's vote as the approval or disapproval of all its producer-members, even if some members do not support the vote. In this case, an affirmative vote by the proponent cooperative apparently would assure the approval of the proposed base-excess plan in all 11 markets because proponent represents more than two-thirds of the producers in the 9 marketwide pool orders and three-fourths of the producers in the 2 individual-handler pool orders.

Exceptors reiterated contentions made at the hearing and in post-hearing briefs that AMPI should not be allowed to bloc vote on the base plans because a considerable number of its members are opposed to the plans. Exceptors' positions have been fully considered but for the reasons just cited cannot be accepted.

An exceptor noted that the Secretary failed to consider a "Louisville" seasonal incentive payment plan to level production in lieu of the base-excess plan. Consideration of such a plan was not within the scope of this hearing since a Louisville plan was not proposed by any party.

One exceptor held that proponent had narrowed the scope of the statistics offered at the hearing to the point that proponent had not set forth a realistic, factual representation of the actual marketing situation. For that reason, exceptor requested a reopening of the hearing "so that additional statistical material, of a broader based sampling, may be presented and thereby show that the desired effects enunciated by proponent may in fact be emerging through the present program * * *."

The arguments for reopening the hearing are not persuasive. The initial hearing provided ample opportunity for all parties to present whatever statistics they believed would be relevant to the issue under consideration. Any reopening of the hearing would need to be based on a strong demonstration that any new information submitted would be of a very significant nature and would be likely to change the outcome of the proceeding. The arguments set forth in the exceptions do not provide such a demonstration. Accordingly, the request to reopen the hearing is denied.

In his exceptions, a party requested that the Department inform each producer prior to his voting on a base plan of how it intends to curb abuses of the base plan. Exceptor did not specify, however, any particular abuse that he believed might occur. Any abuses of the base plan can be reviewed, of course, through the hearing procedure.

This exceptor also requested a listing of all producers who might be voting on a base plan so that those opposed to the base-excess plan could ascertain the eligibility under the Act of each potential voter. The task of determining the eligibility of voters in this circumstance is delegated to the referendum agent whom the Secretary selects to conduct the vote among producers. Such voting eligibility is determined in accordance with the Department's rules as set forth in 7 CFR Part 900.

Counsel for a cooperative which was opposed to the adoption of the proposed uniform base plans requested in his exceptions that official notice be taken of the following items:

1. The Texas Milk Market Report of December 1977 which was published by the Market Administrator of the Texas order;

2. Base Plans in U.S. Milk Markets: Development, Status, and Potential (Market Research Report No. 957, USDA, ERS);

3. Notice by AMPI to "All Handlers Regulated Under Texas Marketing Area Order No. 1126," dated April 22, 1977.

The request for official notice of the three items is denied. The rules governing this proceeding specify that "interested persons shall be given adequate notice, at the hearing or subsequent thereto, of matters so noticed and shall be given adequate opportunity to show that such facts are inaccurate or are erroneously noticed." Taking official notice of the above items in this final decision would preclude interested parties from having an opportunity to comment through exceptions on any of the information contained in these several items.

Counsel for this cooperative also requested rulings on 18 proposed findings of fact which he set forth in his post-hearing brief and which in his opinion were not ruled upon in the recommended decision. The proposed findings and the Department's rulings are as follows:

(1) "The base-excess plans in the North Texas, Red River, Lubbock-Plainview, Northern Louisiana, and New Orleans orders were discontinued because of excessive production depressing the blend price to the farmer in a 'race for base'."

The reason why the base-excess plans were discontinued in the five orders were set forth in the final decision or termination order relative to the discontinuation of such plans in the respective orders. In some cases, a "race for base" was indicated as a partial reason for discontinuing the base plan.

(2) "The AMPI base-excess plan for 11 federal market orders covers precisely an area where AMPI holds oligopolistic control of milk supply."

The members of the Southern Region Division of AMPI market their milk primarily, if not entirely, in the 11 markets for which base-excess plans were proposed. The extent to which AMPI markets milk in the 11-market area was set forth specifically on the record. The percent of the producer milk marketed in each of the 11 markets by AMPI varied from more than 2/3 to 100 percent of the total producer milk in the respective markets. It is noted that in the Texas market, where about half of the milk in the 11-market area is priced, there are a number of cooperatives as well as a large number of nonmember producers who market their milk individually. Whether or not AMPI has "oligopolistic" control of the milk supply in the 11-market area need not be determined in this proceeding.

(3) "The eleven-market area draws milk supply from production areas that serve adjoining markets which AMPI does not control."

As noted earlier, one or more of the 11 markets draw milk from a production area that also serves markets outside of these 11 markets. Also, the record indicates that one of such production areas serves the St. Louis-Ozarks market in which members of AMPI, according to one of its spokesmen, represent less than 2 percent of the producers on the market.

(4) "Seasonality of milk production for the fluid market (spring production over fall) of 15 percent or less reflects effective management in achieving reasonably even production."

This proposed finding is discussed in the response to the following proposed finding.

(5) "The 11-market area as a whole had, in 1976, seasonality of production of 9.5 percent, spring over fall production, and 13.8 percent in 1975, which seasonality is well within reasonable and achievable limits of effective management."

Changes in production in the 11-market area from fall to spring must be viewed in light of class I sales during such periods to gain some persepective of the problem of meeting the fluid milk requirements of handlers. The production changes from fall to spring are accentuated by somewhat opposite swings in class I sales. In 1975, the relationship of average daily producer deliveries to the 2-year average of daily class I sales ranged from a low of 121 percent in October and November to a high of 144 percent in May. Similarly, in 1976, this relationship ranged from 125 percent in November to 142 percent in April. Thus, it is evident that the production pattern in the 11-market area is not in line with the sales pattern of regulated handlers.

(6) "It is not probable that a base-excess plan would materially improve upon the present seasonality of production."

It is not possible to determine the extent to which producers may change their production pattern in respone to the payment incentives of a base plan. In the case of those producers with relatively level production, there is not likely to be much change. The record indicates, however, that a number of producers have substantially greater production in the spring than in the fall. A base-excess plan can be expected to provide an incentive for these producers to take steps to level out their production.

As indicated earlier, it is recognized that the seasonal swings in production for the 11-market region are not unusually severe. It must be kept in mind, of course, that a type of base plan has been operated by the proponent cooperative for a number of years, with the plan applying to a very large proportion of the producers in the 11 markets. This undoubtedly has had some leveling effect on milk production in this region. Because of this, the opportunity for a further leveling of production is perhaps somewhat less than might otherwise have been the case. It is desirable, of course, that any initiative gained toward evening out production not be lost. A base plan under the orders should maintain the leveling of production already achieved plus encouraging further production changes for the markets as a whole, particularly since the base plans would apply to producers who have not been subject to any seasonal payment incentive plan.

It also must be kept in mind that the production data for the 11-market region include data for three markets in which base-excess plans have been in effect under the orders for a number of years. The regional data thus are influenced by the leveling effects of those three plans.

(7) "A reasonable reserve supply of fluid milk over Class I sales is 15 to 20 percent."

The exact amount of reserve milk supply needed for each of the 11 markets, or for the 11-market area as a whole, cannot be determined from this record.

(8) "Reserves of fluid milk to accommodate plants, receiving milk four or five days a week only, occasion a 14 percent reserve for each day of non-receipt. The cost of this reserve is of economic benefit to the handlers so operating and is not a cost of marketing properly to be borne by producers through a diminution of their blend price."

It is recognized that daily balancing costs of this nature are properly chargeable to fluid milk distributors. Nevertheless, this does not diminish the desirability of encourging producers to bring their production on a seasonal basis more in line with the fluid milk needs of the market.

(9) "The 11-market area has an adequate reserve supply of fluid milk to meet the reasonable needs of handlers in the market."

This finding is contrary to the record evidence, which indicates that milk supplies during the fall are not adequate to meet the Class I demand of handlers.

(10) "AMPI does not disproportionately bear the burden of carrying the reserve supply for the 11-market area. In fact, many of the markets dominated by AMPI draw upon reserves pooled upon the Texas and Wichita markets thereby depressing the blend price to nonmembers and imposing the burden of reserves for markets monopolized by AMPI on the nonmembers serving the Texas and Wichita markets."

The manner in which AMPI bears a disproportionate share of the reserve milk for the Texas market was discussed earlier in this decision. With respect to the other point in the proposed finding, it is noted that the "diary farmer for other markets" provision of the Texas order was adopted specifically to assure that the Texas market would not carry the reserve milk supplies for other markets.

(11) "The base-excess plan would stimulate a 'race for base' in the fall base-forming period."

This proposed finding was discussed earlier in this decision.

(12) "Added production stimulated in the fall would depress the blend price paid in the fall causing loss of income to the farmers."

If it is assumed that the only variable in this instance is the quantity of milk produced, it is true that an increase in production would lower the average blend price. However, this presumably would be offset by an improvement in producer pay prices in the spring and summer months as a result of less production (in response to the base plan incentive).

(13) "Increased fall production will stimulate increased spring production because baseholders will strive to obtain full payment for the base acquired in the fall and because of natural factors of breeding and pasturage, thereby depressing the blend price to the farmers in the spring."

To obtain full payment in the spring months for base earned during the fall months, a producer would need to produce only as much milk in the spring months as he produced in the fall months. The base plan would provide a disincentive (through the payment of the surplus price) for any production in excess of a producer's base. It does not follow, therefore, that an increase in fall production will necessarily result in a proportionate increase in spring production.

(14) "The proposed base-excess plan would create an economic barrier to the entry of new producers except for entry during the months of August and September."

As indicated earlier, it is recognized that any base-excess plan will tend to provide a disincentive at certain times of the year for producers to come onto the market.

(15) "The fall of the year is the most expensive time for a new producer to enter into dairy farming."

Several producers testified that this was true in the areas in which they were located. In such areas, a dairy farmer who began operations in the fall months might have to make a large cash outlay to purchase feed for his cows until such time as they could be placed on pasture the next spring and until he could raise his own feed grains. In a "dry lot" operation, it does not seem likely that the cost of the beginning operations in the fall months would differ materially from beginning operations at any other time of the year.

(16) "The base-excess plan would make it difficult for new and young dairy farmers to enter the dairy business in the 11-market area."

As noted earlier, there may be a disincentive for producers to come onto the market at certain times of the year. Those disincentives apply to all producers whether they are new or experienced and whether they are young or old.

(17) "The base-excess plan may lend itself to manipulation to strengthen the oligopolistic control of the market by AMPI."

The provisions of an order are intended to promote the orderly marketing of milk and must carry out the intent of the act. If it is believed at any time that such provisions, including the base plans adopted herein, are not meeting these requirements, a review of such provisions at a hearing may be sought.

(18) "In a free vote by individual dairy farmers, the base-excess plan would probably not be adopted."

There is no basis on the record for establishing that a base plan would be adopted or defeated if individual dairy farmers were permitted to cast their votes on the proposed amended orders. As pointed out elsewhere in the decision, cooperatives have the option to bloc vote for their members.

2. *Order provisions implementing the base-excess plan.* Except for the interim provisions established for 1978 that are described later, the base-excess plan adopted in this decision would establish a base for each producer by adding the pounds of producer milk delivered by him under each of the 11 orders during September through December (the base-forming period) and dividing such amount by the number of days' production represented by such producer milk or by 90, whichever is greater. Under usual conditions, a producer would deliver milk throughout the base-forming period (122 days). It is possible that a producer would not deliver milk to any of the 11 markets for a limited number of days during the base-forming period (perhaps because of a temporary suspension of a health permit, or shipments to a market other than the 11 markets). The 32-day grace period provided herein should accommodate most situations in which a producer's milk would be withheld from delivery to one of the 11 markets.

Requiring a producer to supply one or more of the 11 markets in the base-forming months in order to earn a full base provides an incentive for him to ship to these markets instead of other markets. This will tend to assure that sufficient milk is available to supply handlers in the 11 markets during the fall months when production is lowest relative to the demand for Class I milk. A producer who delivers at least 90 days' production during the four-month base-forming period to the 11 markets can be considered as being primarily associated with this 11-market area. A producer who delivers less than 90 days' production should have his base determined by dividing his total producer milk in the base-forming period by 90. This will assure that a producer who may have been supplying the Class I needs of a market other than the 11 markets for a substantial part of the base-forming period will receive a base that reflects his contribution as a producer supplying the needs of the 11 markets in such period.

Dairy farmers who deliver to a plant that becomes a pool plant under one of the 11 orders after the beginning of the base-forming period should be assigned bases in the same manner as if they had been producers under these orders during the base-forming period. Their bases would be calculated from their deliveries to that plant in the preceding September-December period.

It is expected that when such a plant acquires pool plant status it will add Class I sales to the market comparable to such sales in prior periods when it was not a pool plant. It is appropriate, therefore, that those dairymen who have been supplying the plant have bases computed for them according to their deliveries to the plant in the base-forming period.

As proposed by the cooperative advocating the base plan, the months of September through December should be used as the base-forming period. It is during these months that milk production tends to be at its lowest level throughout the year. The need for encouraging more level production during this period is accentuated by the tendency for Class I sales to swing upward during this same period.

In addition to these four months, January is also now being used as one of the base-making months under the Central Arkansas, Fort Smith, and Memphis orders. Data for the 11 mar-

kets for 1975 and 1976 indicate that milk production during January exceeded Class I disposition by approximately the same amount that milk production exceeded Class I disposition during the months of September through December. Thus, the use of January as a base-making month would not be inappropriate in the 11 markets. The production leveling effects of a base plan, however, can be sufficiently achieved through the use of the four-month base-making period advocated by the proponent cooperative. Moreover, the shorter time period will provide producers somewhat more flexibility in accommodating to the operation of the base plan.

The base-paying months should be the months of March through July. Presently, these months are used as the base-paying months under the Central Arkansas, Fort Smith, and Memphis orders. Proponent cooperative, however, supported the use of February through July as the base-paying months.

The period of March through July is when milk production tends to be at its highest level during the year and when the base plan should be encouraging a more level seasonal production pattern. This is particularly so since within this period there is usually a seasonal decline in Class I sales.

Data for 1975 and 1976 which the cooperative relied on in support of its proposal does not support the use of February as one of the base-paying months. Producer receipts for such month on an daily basis were less than the daily average for each calendar year. There is no need to be discouraging the production of milk during this month.

Producers would establish new bases each year. The bases would be computed by the market administrator of the respective orders to be effective in the following March through July (the base-paying period). By February 10 of each year, the market administrator would notify each producer and the handler reveiving his milk of the producer's base. The market administrator would notify a cooperative, if so requested by the cooperative, of the base established by its member producers.

The recommended decision provided that the market administrator would notify each producer of his new base by February 1. Upon further review, it appears questionable whether this deadline can be reasonably met due to the large number of producers involved and the extent of the intermarket shipments of milk by individual producers. Accordingly, the respective orders should provide that the producers must be notified of their new base no later than February 10.

Base milk would mean the producer milk of a producer in each month of March through July that is not in excess of an amount equal to the producer's base multiplied by the number of days in the month. Excess milk would mean the producer milk of a producer in each month of March through July in excess of the producer's base milk for the month. Excess milk would also include all the producer milk in March through July of a producer who has no base.

Since the base a producer receives would be determined by the quantity of milk shipped in the base-forming months, he would have an incentive to maximize his shipments in September through December. In these months production for the market is normally shortest relative to Class I needs. This would not be the case in the base-paying months when production for the market is substantially more than its fluid milk requirements. In these months a producer would receive, in effect; only the manufacturing milk value for his production in excess of his base milk for the month and thus would be encouraged to limit his production during such period.

The base-excess plan proposed herein provides that milk sold by a producer during March-July which is in excess of his base would be priced at the Class III price. The quantity of producer milk sold during the same months which does not exceed the producer's base would be priced at the base price. The base price for milk for each marketwide pool order would be determined by subtracting the value of the excess milk delivered by producers under such order from the total value of all milk delivered by producers and dividing such amount by the pounds of base milk delivered by producers. The precise level of the base price would depend upon the classified use of milk in the market and the percentage of base milk in the market.

The base price for producer milk received by individual handlers under the Memphis, Tennessee and Fort Smith, Arkansas orders would be determined by subtracting the total value of all excess milk received at the plant of each handler from the handler's total obligation to producers and dividing such amount by the pounds of base milk. The base price for milk received by individual handlers would vary according to the classified use value of the handler's producer milk and the percentage of base milk received by the handler.

The base and excess prices adopted herein were proposed by proponent cooperative. A handler regulated under the Memphis order objected in his brief to the proposed method of pricing and requested that the base and excess prices be patterned after those in the Central Arkansas, Fort Smith and Memphis orders. Under such orders the excess price is usually a blend of the Class III, Class II and Class I prices. Opponent noted that, if the excess price is the Class III price as proposed herein, the base price would exceed the Class I price. It was his position that such base price would be improper.

Under the base plan provisions adopted herein, the base price for the month would exceed the Class I price whenever the quantity of excess milk is greater than the amount of producer milk utilized for Class II and Class III uses. However, if the quantity of excess milk were less than the amount of producer milk utilized in Class II and Class III uses, the base price would be less than the Class I price but would exceed the weighted average price.

Those who opposed pricing excess milk at the Class III price level offered no basis for their conclusion that a base price higher than the Class I price would be improper. Furthermore, pricing of excess milk at the Class III price will provide a greater incentive for a producer to even out his production than by pricing excess milk at the higher level suggested by opponents of the proposed pricing method. It is concluded, therefore, that excess milk should be priced at the Class III price level.

An exceptor reiterated a contention made at the hearing and in his post-hearing brief that the excess price should be a blend of the class I, class II, and class III prices according to the pro rata use of the excess milk in such classes. He indicated that unless such change is made the base price could conceivably exceed the class I price. Exceptor held that a base price higher than the class II price would be improper but failed to indicate a basis for such opinion.

The arguments advanced in the exceptions provide no basis for revising the recommended decision in this regard.

Proponent requested that the location adjustment for producer milk apply only to the base milk delivered by a producer. The cooperative noted that the application of a location adjustment to the excess price would reduce such price (the Class III price) below the value of milk in manufacturing uses. Proponent contended that it would be inappropriate to pay producers less than the Class III price for milk.

Milk for manufacturing uses has practically the same value to milk processors wherever located. This is reflected under the order program through the use of a uniform surplus price in virtually all orders which is equal to the average price per hun-

dredweight for the month of manufacturing grade milk f.o.b. plants in Minnesota and Wisconsin. It a location adjustment were applied to the excess price, it would result in an excess price at various plant locations that is less than the value of manufacturing grade milk delivered to those same plant locations. Such pricing would not be consistent with the location value of milk for manufacturing uses. Consequently, the location adjustment for producer milk should apply only to the base milk delivered by a producer.

The Central Arkansas order presently provides for a 4-cent deduction in the computation of the excess price. The money accumulated from the 4-cent deduction is added to the producer-settlement fund reserve.

The producer-settlement fund is a necessary adjunct of the Central Arkansas order and all orders with marketwide pooling. It is maintained by the market administrator for the purpose of accumulating payments from pool handlers whose utilization of milk in Class I uses is in excess of the marketwide average. Disbursements from the fund are made to those pool handlers whose utilization of milk in Class I uses is less than the marketwide average. A portion of the funds accumulated (4 to 5 cents per hundredweight) is retained each month as a reserve. This reserve is maintained to provide funds for the market administrator to pay handlers in the event an audit adjustment, for example, results in money due a handler.

It is concluded that a reserve deduction of 4 to 5 cents should continue to apply to each hundredweight of base milk under the Central Arkansas order. The same deduction should apply to base milk under the other marketwide pool orders under consideration. There is no need, however, to apply a 4-cent deduction, as under the Central Arkansas order, in computing the excess price under such orders. In most instances excess milk will be classified as Class III milk. The 4-cent reduction could result in excess milk being priced to the producer, in effect, at less than the Class III price under the order. There is no justification on this record for pricing any milk at less than the Class III price.

Proponent proposed that the base transfer rules of the base-excess plan permit the transfer of all or any part of the base by a producer only in the event of death of the baseholder or upon termination of milk production and the complete dispersal of the herd. In the case of a jointly held base, it was proposed that, upon termination of the joint ownership, the base be apportioned among the joint holders.

Limitations on base transfers are necessary, according to proponent, to prevent circumvention of the purpose of the base plan and to insure that the plan will provide producers with the incentive to increase their production of milk during the base-forming months. Proponent indicated that the proposed base transfer rules are not intended to prevent a producer who transfers his base upon the complete dispersal of his herd from immediately resuming production in the same or another area. Such producer would be free to reenter production and earn a base during the next base-forming period. Proponent noted that if the producer should reenter production during any period other than the base-forming period, then all milk that he markets would be priced as excess milk.

One handler and a cooperative association proposed that producers be permitted to transfer any portion of their base to other producers at any time.

Bases should be transferable in their entirety or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base). Such transfer, which could be made from one market to another, will facilitate the transfer of property when a baseholder dies or when the farm of a baseholder is sold. In addition, the transfer of base will facilitate adjustments by those producers desiring to expand or contract their operations and will make it easier for new producers to enter the market during the base-paying period.

A 100-pound minimum on transfers of base is provided herein (unless the transfer involves the remaining portion of a producer's base) as a means of limiting the administrative work that could be connected with the frequent transfer of only a few pounds of base for a producer. The transfer of such minimum amounts would provide only minimal benefit for the producers involved and increase the cost of administering the program. The 100-pound minimum herein provided will aid in reducing the administrative expense involved in the transfer of bases without limiting to any significant extent the practical transferability of bases among producers.

As provided herein, a base may be transferred to be effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application would be required to be on a form approved by the market administrator and signed by a baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, it would be required that the application be signed by all joint holders or their heirs. These provisions will minimize the possibility of a misunderstanding between the parties involved concerning transfers.

The base established by a partnership may be divided between partners on any basis agreed on in writing by them if written notification of the agreed upon division, signed by each partner, is received by the market administrator prior to the first day of the month in which the division is to be effective. This will facilitate the division of the assets of a partnership that is dissolved during the base-paying period. The division of the base will in no way affect the total quantity of base milk in the pool, irrespective of the manner in which the division of the base is made between the partners.

Bases assigned to producers who supplied a plant which was not a pool plant under one of the 11 markets in the base-forming period but which becomes a pool plant prior to or during the following base-paying period should not be transferable. Such restriction is necssary to deal with those instances in which a plant regularly associated with another market becomes regulated under one of the 11 orders for only a single or several months before shifting back to the originating market or to another market outside the 11-market area under consideration. In those instances in which a plant becomes newly regulated and remains as a pool plant during all of the base-paying period, the producers delivering to that plant would want to retain their bases in order to receive a base price for such milk. If, however, the plant were to lose its pool plant status before the end of the base-paying period, producers delivering milk to such plant would have no need for the bases and would offer such bases for sale. It would not be appropriate to permit the transfer of bases in such instance snce Class I sales in the market would be reduced by the amount of the plant's Class I sales in the month the plant lost its pool plant status while the aggregate producer bases for the month would remain inflated by the bases that had been assigned to the producers associated with such plant. If producers were permitted to purchase such bases, they would benefit by receiving a greater share of the value associated with the Class I sales in these 11 markets at the expense of other producers in these markets who did not choose to buy addtional base.

AMPI excepted to the base rules adopted in the recommended decision. The cooperative argued that the unlimited transfer of base would frustrate the purpose and objective of the base plan by reducing the incentive for producers to increase production during the base-forming period and

would enable producers to circumvent the base plan and other order provisions. In particular, AMPI stated that "producers with wide seasonal production patterns who fail to increase production during the base-forming months will be able to cover and market as base milk all or part of their excess production by simply purchasing sufficient base from other producers."

It is possible that some producers will make little or no attempt to alter their seasonal production pattern but instead will purchase additional base to cover what otherwise would be "excess" production. It would be largely a matter of economics, of course, as to whether a producer is better off to build his own base or purchase base. The more that producers choose not to build their bases but rely instead on purchased base, the more likely that the value of base will increase. This should dampen any substantial reliance on purchased base and, thus, give producers a greater incentive to build their own base rather than buy it.

AMPI also argues that the unlimited transfer of base will encourage producers to transfer their bases to other producers during March through July and market their milk to plants regulated under orders outside of the 11-market area where they would be able to receive the blend price for all their milk. Moreover, AMPI states, a cooperative could organize the transfer of base of its members to other members having excess milk. The cooperative could then market the milk of the members from whom base was transferred to plants regulated under non-base-excess orders. Thus, it is argued, the cooperative would be able to draw the base price on more of its member milk being marketed under the 11 base-excess plan orders than would otherwise be the case, while at the same time depressing the blend price levels under the other orders.

It is recognized that the potential for these situations exists. From a practical standpoint, however, it is questionable whether much milk would shift to markets outside the 11-market area during the March-July period. This is the time in most markets when handlers are seeking ways to dispose of milk that is surplus to their fluid needs rather than seeking additional supplies. Presumably, there would be little opportunity for cooperatives or individual producers in the 11-market area to find continuing outlets for milk in outside markets.

Another possible problem cited by AMPI is that the unlimited transfer of bases could nullify the "dairy farmer for other markets" provision of the Texas order. In short, that order provides that if a dairy farmer is not a "producer" under the order throughout the months of September through November he cannot qualify as a "producer" under the order during the following months of February through July. It is claimed by AMPI, however, that a person who could not qualify as a producer under the Texas order in this situation nevertheless could have earned a base under that order in the fall months which he could sell to producers on the Texas market. The cooperative contends that the sale of base in this case would undermine the purpose of the "dairy farmer for other markets" provision.

The purpose of the "dairy farmer for other markets" provision is to keep milk not regularly associated with the Texas market from being "dumped" there in the heavy production months when the milk is not needed elsewhere. The base transfer provisions adopted herein would not nullify this basic purpose. In most cases, dairy farmers who were not on the Texas market during the entire September-November period still would not be able to have their milk pooled under the Texas order during the February-July period.

A final argument made by AMPI is that a cooperative, such as itself, whose members supplied 100 percent of the producer milk pooled under one of the 11 base-excess plan orders could circumvent the provisions by arranging for the transfer of base from those producers to members with excess production on one or more of the other 10 orders. In that event, it was claimed, the cooperative representing 100 percent of the producer milk under the order would continue to draw the same total dollar value on member milk marketed under that order during March through July, while at the same time increasing its members' total returns under the other orders where the cooperative represents less than 100 percent of the producers.

There is no doubt that AMPI could arrange for the transfer of base among its members on the 11 markets in the manner described so as to enhance its returns at the expense of other producers. However, if this were to occur, the purpose of the base plan in the affected markets would be seriously undermined. The continued use of the base plans in this case would need to be seriously questioned.

In his exceptions, a handler urged that an individual dairy farmer who shifts from outside the 11-market area to one of the 11 markets during any of the months of October through July be accorded a full base. This presumably would parallel the arrangement adopted herein whereby a producer who is associated with a plant that becomes newly pooled under one of the 11 orders during such month would be accorded a full base, as determined from prior marketings.

This situation is not comparable to one in which a dairy farmer becomes a new producer on one of the 11 markets as a result of a plant shifting from one market to another. In such instance, the plant that becomes newly regulated adds Class I sales to the market. It is appropriate that the producers supplying such plant should receive bases based upon their delivery of milk during the immediately prior base-making period.

This should not be the case with producers who may come onto the market on an individual basis. As provided herein, such a producer who enters one of the 11 markets during the period of October-December will earn a base proportionate to the number of days that he delivers milk during the 3-month period, i.e. his total deliveries would be divided by 90 days. A producer who enters the market during the period of January-July will not earn a base at all. This in in recognition of the fact that such producer would be entering the market during a period when additional milk is normally not needed to supply the fluid market.

It is necessary that the reporting sections of the orders be revised to require handlers under the 11 orders to submit reports to the market administrator of the amounts of producer milk and base milk received from each producer at each plant location. Cooperative associations in their role as handlers should report the quantities of producer milk and base milk delivered by their members to each pool plant and non-pool plant under the respective order as well as the producer milk deliveries of each member under the other 10 orders. The reporting by cooperatives under each of the orders of individual member deliveries in the 11 markets will facilitate the computation under the individual orders of the base milk of members delivering milk under more than one order.

Because of the time required to complete the remaining procedures in this proceeding, the proposed amended orders adopted herein, if approved by producers, could not be made effective until October 1, 1978. Therefore, it is necessary to provide a shorter base-making period for 1978 than would otherwise be the case. As provided herein, a base for each producer would be established by adding the pounds of producer milk delivered by him under each of the 11 orders during October through December 1978 and dividing such amount by the number of days' production represented by such producer milk or by 60, whichever is greater. The base established for each producer during the October-December 1978 period would then be used in

determining the payments to producers during the base-paying months of March through July 1979.

RULINGS ON PROPOSED FINDINGS AND CONCLUSIONS

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

GENERAL FINDINGS

The following findings and determinations are made for each of the orders in this proceeding. They supplement those that were made when the orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth below.

(a) The tentative marketing agreement and the order, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(b) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing area, and the minimum prices specified in the tentative marketing agreement and the order, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(c) The tentative marketing agreement and the order, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial and commercial activity specified in, a marketing agreement upon which a hearing has been held.

RULINGS ON EXCEPTIONS

In arriving at the findings and conclusions, and the regulatory provisions of this decision, each of the exceptions received was carefully and fully considered in conjunction with the record evidence. To the extent that the findings and conclusions, and the regulatory provisions of this decision are at variance with any of the exceptions, such exceptions are hereby overruled for the reasons previously stated in this decision.

MARKETING AGREEMENT AND ORDER

Annexed hereto and made a part hereof are two documents, a Marketing Agreement regulating the handling of milk, and an Order amending the orders regulating the handling of milk in the marketing areas specified above, which have been decided upon as the detailed and appropriate means of effectuating the foregoing conclusions.

It is hereby ordered, That this entire decision, except the attached marketing agreement, be published in the FEDERAL REGISTER. The regulatory provisions of the marketing agreement are identical with those contained in the orders as hereby proposed to be amended by the attached order which is published with this decision.

REFERENDUM ORDER TO DETERMINE PRODUCER APPROVAL; DETERMINATION OF REPRESENTATIVE PERIOD; AND DESIGNATION OF REFERENDUM AGENTS

It is hereby directed that referenda be conducted and completed on or before the 30th day from the date this decision is issued, in accordance with the procedure for the conduct of referenda (7 CFR 900.300 et seq.), to determine whether the issuance of each of the attached orders as amended and as hereby proposed to be amended, regulating the handling of milk in each of the aforesaid marketing areas, is approved or favored by producers, as defined under the terms of each of the orders (as amended and as hereby proposed to be amended), who during the representative period were engaged in the production of milk for sale within the aforesaid marketing area.

The representative period for the conduct of such referenda is hereby determined to be January 1978.

The agents of the Secretary to conduct such referenda are hereby designated to be Richard E. Arnold for Parts 1071, 1073, 1104, 1106, 1120, 1132, and 1138; C. E. Dunham for Part 1126; and Charles S. McDonald for Parts 1097, 1102, and 1108.

(An Impact Analysis relative to this decision is available from the Deputy Administrator for Marketing Program Operations, Agricultural Marketing Service.)

Dated: July 23, 1978.

P. R. "BOBBY" SMITH,
Assistant Secretary for Marketing Services.

Order[1] *amending the orders, regulating the handling of milk in the Neosho Valley, Wichita, Kans.; Memphis, Tenn., Fort Smith, Ark.; Red River Valley, Oklahoma Metropolitan, Central Arkansas, Lubbock-Plainview, Tex.; Rio Grande Valley, Texas Panhandle, and Texas marketing areas.*

FINDINGS AND DETERMINATIONS

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of each of the aforesaid orders and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings.* A public hearing was held upon certain proposed amendments to the tentative marketing agreements and to the orders regulating the handling of milk in the aforesaid marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice and procedure (7 CFR Part 900).

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said orders as hereby amended, and all of the terms and conditions, thereof, will tend to effectuate the declared policy of the act;

(2) The parity prices of milk, as determined pursuant to section 2 of the act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the said marketing areas, and the minimum prices specified in the orders as hereby amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(3) The said orders as hereby amended regulate the handling of milk in the same manner as, and are applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held.

Order relative to handling. It is therefore ordered that on and after the effective date hereof the handling of milk in the aforesaid marketing areas shall be in conformity to and in compliance with the terms and conditions of each of the orders, as amended, and as hereby amended, as follows:

The provisions of the proposed marketing agreement and order amending the orders contained in the recommended decision issued by the Deputy

[1] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

Administrator, Program Operations, on December 20, 1977, and published in the FEDERAL REGISTER on December 29, 1977 (42 FR 65088) shall be and are the terms and provisions of this order, amending the orders, and are set forth in full herein with the following modifications:

1. In section 90 of all 11 orders, a non-substantive, clarifying change in language has been made.

2. Sections 92 (a) and (b) of all 11 orders have been revised.

3. In section 94 of all 11 orders, the announcement of base has been changed from February 1 to February 10.

PART 1071—MILK IN THE NEOSHO VALLEY MARKETING AREA

1. In §1071.31, paragraph (a) (2) and (4) is revised as follows:

§1071.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

* * * * *

2. In §1071.32, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§1071.32 Other reports.

* * * * *

(b) In addition to the reports required pursuant to paragraphs (a) and (c) of this section and §§1071.30 and 1071.31, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

(c) Each handler who receives milk from producers shall report to the market administrator on or before the 7th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in §1071.92.

3. Section 1071.61 is revised as follows:

§1071.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat content as follows:

(1) Combine into one total the values computed pursuant to §1071.60 for all handlers who filed the reports prescribed by §1071.30 for the month and who made the payments pursuant to §§1071.71 and 1071.73 for the preceding month;

(2) Add an amount equal to the total value of the location adjustments computed pursuant to §1071.75;

(3) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to §1071.60(f); and

(6) Subtract not less than 4 cents nor more than 5 cents per hundredweight.

(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraphs (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1071.62 is revised as follows:

§1071.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) The 12th day after the end of each month the applicable uniform prices for such month.

§1071.71 [Amended]

5. Section 1071.71(a)(2)(i) is amended by changing the word "price" to "prices."

6. Section 1071.71(a)(2)(ii) is amended by changing the words "uniform price" to "weighted average price."

7. In §1071.73, the introductory text of paragraph (b) is revised as follows:

§1071.73 Payments to producers and to cooperative associations.

* * * * *

(b) On or before the 17th day after the end of each delivery period, for all milk (or base milk and excess milk) received during such delivery period from such producer at not less than the applicable uniform price(s) for such delivery period subject to the following adjustments:

* * * * *

§1071.74 [Amended]

8. Section 1071.74 is amended by changing the words "uniform price" to "uniform prices."

9. Section 1071.75 is revised as follows:

§1071.75 Plant location adjustments for producers and on nonpool milk.

(a) For producer milk received at a pool plant the uniform price and the uniform price for base milk shall be adjusted according to the location of the pool plant at the rates set forth in §1071.52.

(b) The weighted average price applicable to other source milk shall be adjusted at the rates set forth in §1071.52, except that the adjusted weighted average price plus 5 cents shall not be less than the Class III price.

§1071.76 [Amended]

10. Section 1071.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."

11. A new center head "Base-Excess Plan" and five new sections (§§1071.90 through 1071.94) are added immediately following §1071.86 as follows:

BASE-EXCESS PLAN

§ 1071.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1071.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1071.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1071.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1071.92 that is delivered under this order at each respective plant location.

§ 1071.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in cess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1071.92.

§ 1071.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1108, 1126, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1071.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1071.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

1071.121 [Amended]

12. Section 1071.121(b) is amended by changing all references to "§ 1071.61(d)" to read "§ 1071.61(a)(4)."

PART 1073—MILK IN THE WICHITA, KANS., MARKETING AREA

1. In § 1073.31, paragraph (a) (2) and (4) is revised as follows:

§ 1073.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

* * * * *

2. Section 1073.32 is revised as follows:

§ 1073.32 Other reports.

(a) Each handler who receives milk from producers shall report to the market administrator on or before the 8th day after the end of each of the months of March through July the following information.

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1073.92.

(b) In addition to the reports required pursuant to paragraph (a) of this section and §§ 1073.30 and 1073.31, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

3. Section 1073.61 is revised as follows:

§ 1073.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight of milk of 3.5 percent butterfat content as follows:

(1) Combine into one total the values computed pursuant to § 1073.60 for all handlers who filed the reports prescribed by § 1073.30 for the month and who made the payments pursuant to § 1073.71 for the preceding month;

(2) Deduct the amount of the plus adjustments and add the amount of the minus adjustments, which are applicable pursuant to § 1073.75;

(3) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to § 1073.60(f); and

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a)(1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1073.62 is revised as follows:

§ 1073.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) the 12th day after the end of each month the applicable uniform prices for such month.

§ 1073.71 [Amended]

5. Section 1073.71(a)(2)(i) is amended by changing the word "price" to "prices."

6. Section 1073.71(a)(2)(ii) is amended by changing the words "uniform price" to "weighted average price."

7. In § 1073.73 paragraphs (a) and (d)(2) are revised as follows:

§ 1073.73 Payments to producers and to cooperative associations.

* * * * *

(a) On or before the second working day following the 12th day after the end of the month during which the milk was received, to each producer for whom payment is not made pursuant to paragraph (c) of this section, at not less than the uniform price(s) computed for such producer's deliveries of milk (or base milk and excess milk) adjusted by the butterfat differential and location adjustments computed pursuant to §§ 1073.74 and 1073.75, and less the amount of the payment made pursuant to paragraph (b) of this section. If by such date such handler has not received full payment pursuant to § 1073.72, he may reduce his total payments uniformly to all producers by not more than the amount of the reduction in payment by the market administrator. He shall, however, complete such payments pursuant to this paragraph not later than the date for making such payments next following receipt of the balance from the market administrator.

* * * * *

(d) * * *

(2) In making final settlement, the value of such milk at the appropriate uniform prices adjusted pursuant to §§ 1073.74 and 1073.75, less payment made pursuant to paragraph (d)(1) of this section.

§ 1073.74 [Amended]

8. Section 1073.74 is amended by changing the words "uniform price" to "uniform prices."

9. Section 1073.75 is revised as follows:

§ 1073.75 Plant location adjustments for producers and on nonpool milk.

(a) For producer milk received at plants located outside Zone 1 the uniform price and the uniform price for base milk shall be increased or decreased by an adjustment for each such plant at the rates specified in § 1073.52(a).

(b) For purposes of computations pursuant to §§ 1073.71(a)(2)(ii) and 1073.72, the weighted average price shall be adjusted at the rates set forth in § 1073.52, applicable at the location of the nonpool plant(s) from which the milk was received, except that the adjusted weighted average price plus 5 cents shall not be less than the Class III price.

§ 1073.76 [Amended]

10. Section 1073.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."

11. A new center head "Base-Excess Plan" and five new sections (§§ 1073.90 through 1073.94) are added immediately following § 1073.86 as follows:

BASE-EXCESS PLAN

§ 1073.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1073.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1073.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1073.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1073.92 that is delivered under this order at each respective plant location

§ 1073.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1073.92.

§ 1073.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1108, 1126, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1073.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such

base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1073.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1073.121 [Amended]

12. Section 1073.121(b) is amended by changing all references to "§ 1073.61(d)" to read "§ 1073.61(a)(4)."

PART 1097—MILK IN THE MEMPHIS, TENN., MARKETING AREA

1. In § 1097.31, paragraph (a)(3) is revised as follows:

§ 1097.31 Payroll reports.

(a) * * *

(3) The total pounds of milk received from such producer and for the months of March through July the total pounds of milk and the pounds of base milk of such producer delivered to each fluid milk (pool) plant (and diverted to each plant that is not a fluid milk [pool] plant) under any of the orders specified in § 1097.92;

* * * * *

2. Section 1097.61, paragraph (b) is revised as follows:

§ 1097.61 Computation of uniform price for each handler (including uniform prices for base milk and excess milk).

* * * * *

(b) For each month of March through July, the market administrator shall compute for each handler with respect to producer milk, a uniform price for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a)(1) through (4) of this section subtract, for each handler, an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk received by such handler as producer milk and bulk milk received from a handler described in § 1097.9(c); and

(ii) Divide the resulting amount by the total hundredweight of such handler's base milk and deduct any fraction of a cent.

3. Section § 1097.75 is revised as follows:

§ 1097.75 Plant location adjustments for producers.

In making payment pursuant to § 1097.73, for milk received the uniform price and the uniform price for base milk shall be adjusted according to the location of the fluid milk plant where such milk was received at the rate provided pursuant to § 1097.52.

4. Section 1097.90 is revised as follows:

§ 1097.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1097.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1097.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1097.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1097.92 that is delivered under this order at each respective plant location.

5. Section 1097.91 is revised as follows:

§ 1097.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1097.92.

6. Section 1097.92 is revised as follows:

§ 1097.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the toal pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1108, 1126, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

7. Section 1097.93 is revised as follows:

§ 1097.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base

signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

8. Section 1097.94 is revised as follows:

§ 1097.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1097.95 [Revoked]

9. Section 1097.95 is revoked.

PART 1102—MILK IN THE FORT SMITH, ARK., MARKETING AREA

1. In § 1102.31, paragraphs (b) and (d) are revised as follows:

§ 1102.32 Payroll reports.

* * * * *

(b) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(d) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

2. In § 1102.32, paragraph (a)(2) is revised as follows:

§ 1102.32 Other reports.

(a) * * *

(2) The total pounds of milk and butterfat and the pounds of base milk of such producer delivered to each approved (pool) plant (and diverted to each plant that is not an approved [pool] plant) under any of the orders specified in § 1102.92.

* * * * *

3. In § 1102.61, paragraph (b) is revised as follows:

§ 1102.61 Computation of uniform price for each handler (including uniform prices for base milk and excess milk).

* * * * *

(b) For each month of March through July, the market administrator shall compute for each handler with respect to milk received from producers, a uniform price for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducing 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraphs (a) (1) through (3) of this section, subtract, for each handler, an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of such handler's excess milk; and

(ii) Divide the resulting amount by the total hundredweight of such handler's base milk, and deduct any fraction of a cent.

4. Section 1102.75 is revised as follows:

§ 1102.75 Plant location adjustments for producers.

For producer milk received at an approved plant the uniform price and the uniform price for base milk shall be reduced according to the location of the approved plant at the rates set forth in § 1102.52.

5. Section 1102.90 is revised as follows:

§ 1102.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1102.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk as defined under any order specified in § 1102.92 from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1102.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1102.92 that is delivered under this order at each respective plant location.

6. Section 1102.91 is revised as follows:

§ 1102.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1102.92.

7. Section 1102.92 is revised as follows:

§ 1102.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn., Fort Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1126, 1108, 1120, 1132, and 1133 respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

8. Section 1102.93 is revised as follows:

§ 1102.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market ad-

ministrator prior to the first day of the month on which such division is to be effective.

9. Section 1102.94 is revised as follows:

§ 1102.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1102.95 [Revoked]

10. Section 1102.95 is revoked.

PART 1104—MILK IN THE RED RIVER VALLEY MARKETING AREA

1. In § 1104.31, paragraph (a) (2) and (4) is revised as follows:

§ 1104.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

* * * * * *

2. In § 1104.32 paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§ 1104.32 Other reports.

* * * * *

(b) In addition to the reports required pursuant to §§ 1104.30 and 1104.31 and paragraphs (a) and (c) of this section, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

(c) Each handler who receives milk from producers shall report to the market administrator on or before the 7th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1104.92.

3. Section 1104.61 is revised as follows:

§ 1104.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight of milk of 3.5 percent butterfat content as follows:

(1) Combine into one total the values computed pursuant to § 1104.60 for all handlers who filed the reports prescribed by § 1104.30 for the month and who made the payments pursuant to §§ 1104.71 and 1104.73 for the preceding month;

(2) Add an amount equal to the total value of the location adjustments computed pursuant to § 1104.75;

(3) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to § 1104.60(f); and

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraphs (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1104.62 is revised as follows:

§ 1104.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) The 12th day after the end of each month the applicable uniform prices for such month.

§ 1104.71 [Amended]

5. Section 1104.71(a)(2)(i) is amended by changing the word "price" to "prices."

6. Section 1104.71(a)(2)(ii) is amended by changing the words "uniform price" to "weighted average price."

7. In § 1104.73, the introductory text of paragraph (a)(2) (immediately preceding subdivision (i)), and paragraphs (b) (1)(ii) and (3)(ii) are revised as follows:

§ 1104.73 Payments to producers and to cooperative associations.

(a) * * *

(2) On or before the 15th day of the following month, an amount equal to not less than the applicable uniform price(s), as adjusted pursuant to §§ 1104.74 and 1104.75, multiplied by the hundredweight of milk (or base milk and excess milk) received from such producer during the month, subject to the following adjustments:

* * * * *

(b) * * *

(1) * * *

(ii) Submit to the cooperative association on or before the 10th day of each month written information which shows for each member-producer (*a*) the total pounds of milk received during the preceding month, (and for the months of March through July the pounds of base milk), (*b*) the total pounds of butterfat contained in such milk, (*c*) the number of days of production included in such receipts, and (*d*) the amounts withheld by the handler in payment for supplies sold; and

* * * * *

(3) * * *

(ii) In making final settlement, the value of such milk at the appropriate uniform price(s), as adjusted pursuant to §§ 1104..74 and 1104.75, less the amount of partial payment made for such milk.

§ 1104.74 [Amended]

8. Section 1104.74 is amended by changing the words "uniform price" to "uniform prices."

9. Section 1104.75 is revised as follows:

§ 1104.75 Plant location adjustments for producers and on nonpool milk.

(a) In making payments to producers pursuant to § 1104.73 for producer milk received at a pool plant, the uniform price and the uniform price for base milk shall be reduced according to the location of the pool plant at the rate set forth in § 1104.52(a);

(b) For the purpose of computations pursuant to §§ 1104.71 and 1104.72, the weighted average price plus 5 cents shall be adjusted at the rate set forth in § 1104.52(a) applicable at the location of the nonpool plant from which the milk was received (but not to be less than the Class III price); and

(c) In making payments to producers pursuant to § 1104.73 for producer milk diverted from a pool plant to a nonpool plant, the uniform price and the uniform price for base milk shall be reduced according to the location of the nonpool plant at which the milk is received at the rate set forth in § 1104.52(a).

§ 1104.76 [Amended]

10. Section 1104.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."

11. A new center head "Base-Excess Plan" and five new sections (§§ 1104.90 through 1104.94) are added immediately following § 1104.86 as follows:

BASE-EXCESS PLAN

§ 1104.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1104.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1104.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1104.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1104.92 that is delivered under this order at each respective plant location.

§ 1104.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1104.92.

§ 1104.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1097, 1102, 1104, 1106, 1108, 1120, 1126, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of day's production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the baseforming period shall be calculated as if the plant were a pool plant under such orders for the entire baseforming period. A base thus assigned shall not be transferable.

§ 1104.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1104.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1104.121 [Amended]

12. Section 1104.121(b) is amended by changing all references to "§ 1104.61(d)" to read "§ 1104.61(a)(4)."

PART 1106—MILK IN THE OKLAHOMA METROPOLITAN MARKETING AREA

1. In § 1106.31, paragraph (a)(2) and (4) is revised as follows:

§ 1106.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

* * * * *

2. In § 1106.32, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§ 1106.32 Other reports.

* * * * *

(b) In addition to the reports required pursuant to §§ 1106.30 and 1106.31 and paragraphs (a) and (c) of this section, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

(c) Each handler who receives milk from producers shall report to the market administrator on or before the 7th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1106.92.

3. Section 1106.61 is revised as follows:

§ 1106.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat content as follows:

(1) Combine into one total the values computed pursuant to § 1106.60 for all handlers who made the reports prescribed in § 1106.30 and who made the payments pursuant to §§ 1106.71 and 1106.73 for the preceding month.

(2) Add the aggregate of the values of all allowable location adjustments to producers pursuant to § 1106.75.

(3) Add not less than one-half of the cash balance on hand in the producer-settlement fund less the total amount of the contingent obligations to handlers pursuant to § 1106.72.

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents.

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to § 1106.60(f).

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraphs (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1106.62 is revised as follows:

§ 1106.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) The 12th day after the end of each month the applicable uniform prices for such month.

§ 1106.71 [Amended]

5. Section 1106.71(a)(2)(i) is amended by changing the word "price" to "prices."

6. Section 1106.71(a)(2)(ii) is amended by changing the words "uniform price" to "weighted average price."

7. In § 1106.73, paragraphs (a) and (d)(1)(ii)(*a*) are revised as follows:

§ 1106.73 Payments to producers and to cooperative associations.

* * * * *

(a) On or before the 15th day after the end of the month during which the milk (or base milk and excess milk) was received, to each producer to whom payment is not made pursuant to paragraph (d) of this section, at not less than the applicable uniform price(s) for such month, as adjusted pursuant to §§ 1106.74 and 1106.75, and less the amount of the payment made pursuant to paragraph (b) of this section: *Provided,* That if by such date such handler has not received full payment pursuant to § 1106.72, he may reduce his total payments to all producers uniformly by not more than the amount of reduction in payment from the market administrator; he shall, however, complete such payments pursuant to this paragraph not later than the date for making such payments next following receipt of the balance from the market administrator;

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(*a*) The total pounds of milk received during the preceding month and for the months of March through July the pounds of base milk;

* * * * *

§ 1106.74 [Amended]

8. Section 1106.74 is amended by changing the words "uniform price" to "uniform prices."

9. Section 1106.75 is revised as follows:

1106.75 Plant location adjustments for producers and on nonpool milk.

(a) In making payments to producers pursuant to § 1106.73 for producer milk received at a pool plant, the uniform price and the uniform price for base milk shall be reduced according to the location of the pool plant at the rates set forth in § 1106.52;

(b) For the purpose of computations pursuant to §§ 1106.71 and 1106.72, the weighted average price plus 5 cents shall be adjusted at the rates set forth in § 1106.52 applicable at the location of the nonpool plant from which the milk was received (but not to be less than the Class III price); and

(c) In making payments to producers pursuant to § 1106.73 for producer milk diverted from a pool plant to a nonpool plant, the uniform price and the uniform price for base milk shall be reduced according to the location of the nonpool plant at which the milk is received at the rates set forth in § 1106.52.

§ 1106.76 [Amended]

10. Section 1106.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."

11. A new center head "Base-Excess Plan" and five new sections (§§ 1106.90 through 1106.94) are added immediately following § 1106.86 as follows:

BASE-EXCESS PLAN

§ 1106.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1106.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1106.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1106.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1106.92 that is delivered under this order at each respective plant location.

§ 1106.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1106.92.

§ 1106.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market adminis-

trator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097 1102, 1108, 1126, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1106.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1106.94 Announcement of established bases.

On or before February 10, of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1106.121 [Amended]

12. Section 1106.121(b) is amended by changing all references to "§ 1106.61(d)" to read "§ 1106.61(a)(4)."

PART 1108—MILK IN THE CENTRAL ARKANSAS MARKETING AREA

1. In § 1108.31, paragraph (a)(2) and (4) is revised as follows:

§ 1108.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net volume paid.

* * * * *

2. Section 1108.32(a)(1) is revised as follows:

§ 1108.32 Other reports.

(a) * * *

(1) On or before the seventh day of each month of April through August, for each producer for the preceding month:

(i) The name and address or other appropriate identification of each producer; and

(ii) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1108.92;

* * * * *

3. In § 1108.61, the introductory text of paragraph (a) (immediately preceding subparagraph (1)), and paragraph (a)(6) and (b) are revised as follows:

§ 1108.61 Computation of uniform price (including weighted average price and base and excess prices).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk containing 3.5 percent butterfat content as follows:

* * * * *

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraphs (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1108.75(a) is revised as follows:

§ 1108.75 Plant location adjustments for producers and on nonpool milk.

(a) The uniform price and the uniform price for base milk to be paid for producer milk received at a pool plant located 60 miles or more from the County Courthouse in Arkadelphia, Ark., the County Courthouse in Forrest City, Ark., or the State Capital in Little Rock, Ark., whichever is nearer by the shortest highway distance, as determined by the market administrator, shall be reduced according to the distance of the plant from the respective buildings designated above at the rate of 1.5 cents for each 10 miles or residual fraction thereof.

* * * * *

5. Section 1108.90 is revised as follows:

§ 1108.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1108.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1108.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under

any other order specified in § 1108.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1108.92 that is delivered under this order at each respective plant location.

6. Section 1108.981 is revised as follows:

§ 1109.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1108.92

7. Section 1108.92 is revised as follows:

§ 1108.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1108, 1126, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

8. Section 1108.93 is revised as follows:

§ 1108.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the base-holder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

9. Section 1108.94 is revised as follows:

§ 1108.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§§ 1108.95 and 1108.96 [Revoked].

10. Sections 1108.95 and 1108.96 are revoked.

PART 1120—MILK IN THE LUBBOCK-PLAINVIEW, TEX., MARKETING AREA

1. In § 1120.31, paragraph (a) (2) and (4) is revised as follows:

§ 1120.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

* * * * *

2. In § 1120.32, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§ 1120.32 Other reports.

* * * * *

(b) In addition to the reports required pursuant to § 1120.30 and § 1120.31 and paragraphs (a) and (c) of this section, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

(c) Each handler who receives milk from producers shall report to the market administrator on or before the 8th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1120.92.

3. Section 1120.61 is revised as follows:

§ 1120.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat content as follows:

(1) Combine into one total the values computed pursuant to § 1120.60 for all pool handlers who made the reports prescribed in § 1120.30 for the month and who have made the payments required pursuant to § 1120.71 for the preceding month;

(2) Add an amount equal to the sum of the deductions to be made for location adjustments pursuant to § 1120.75;

(3) Add an amount equal to not less than one-half the unobligated balance on hand in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in such computations;

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to § 1120.60(f); and

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administra-

tor shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1120.62 is revised as follows:

§ 1120.62 Announcement of uniform prices and butterfat differential.

The market admininstrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) The 10th day after the end of each month the applicable uniform prices for such month.

§ 1120.71 [Amended]

5. Section 1120.71(a)(2)(i) is amended by changing the word "price" to "prices."

6. Section 1120.71(a)(2)(ii) is amended by changing the words "uniform price" to "weighted average price."

7. In § 1120.73, the introductory text of paragraph (a)(2) (immediately preceding subdivision (i)), and paragraph (d)(3) are revised as follows:

§ 1120.73 Payments to producers and to cooperative associations.

(a) * * *

(2) On or before the 15th day after the end of each month for milk (or base milk and excess milk) received during such month, an amount computed at not less than the uniform price(s) per hundredweight pursuant to § 1120.61 as adjusted pursuant to § 1120.74; and less

* * * * *

(d) * * *

(3) The daily and total pounds and the average butterfat content of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

§ 1120.74 [Amended]

8. Section 1120.74 is amended by changing the words "uniform price" to "uniform prices."

9. Section 1120.75 is revised as follows:

§ 1120.75 Plant location adjustments for producers and on nonpool milk.

(a) The uniform price and the uniform price for base milk to be paid for milk which is received from producers at pool plants located either outside the State of Texas or within the State but north of the counties of Parmer, Castro, Swisher, Briscoe, Hall, and Childress and 100 miles or more from the city hall of Lubbock, Tex., by the shortest hard-surfaced highway distance as determined by the market administrator shall be reduced at the rate set forth in the table contained in § 1120.52 according to the location of the pool plant at which such milk was received from producers; and

(b) For purposes of computations pursuant to §§ 1120.71 and 1120.72 the weighted average price plus 5 cents shall be adjusted at the rates set forth in § 1120.52 applicable at the location of the nonpool plant from which the milk was received (but not to be less than the Class III price).

§ 1120.76 [Amended]

10. Section 1120.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."

11. A new center head "Base-Excess Plan" and five new sections (§§ 1120.90 through 1120.94) are added immediately following § 1120.86 as follows:

BASE-EXCESS PLAN

§ 1120.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1120.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1120.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1120.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1120.92 that is delivered under this order at each respective plant location.

§ 1120.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1120.92.

§ 1120.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kansas; Red River Valley; Oklahoma Metropolitan; Memphis, Tennessee; Fort Smith, Arkansas; Central Arkansas; Texas; Lubbock-Plainview, Texas; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1097, 1104, 1106, 1102, 1108, 1126, 1120, 1132 and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60 whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1120.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held

jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1120.94 Announcement of established bases.

On or before February 10 each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1120.121 [Amended]

12. Section 1120.121(b) is amended by changing all references to "§ 1120.61(d)" to read "§ 1120.61(a)(4)."

PART 1126—MILK IN THE TEXAS MARKETING AREA

1. In § 1126.32 paragraph (b)(2) is revised as follows:

§ 1126.32 Other reports.

* * * * *

(b) * * *

(2) The total pounds of producer milk received from such producer, its average butterfat content and for the months of March through July the total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1126.92;

* * * * *

2. Section 1126.61 is revised as follows:

§ 1126.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat content at pool plants at which no location adjustment applies as follows:

(1) Combine into one total the values computed pursuant to § 1126.60 for all handlers who filed the reports prescribed in § 1126.30 for the month and who made the payments pursuant to § 1126.71 for the preceding month;

(2) Add not less than one-fourth of the unobligated balance in the producer-settlement fund;

(3) Add the aggregate of all minus location adjustments and subtract the aggregate of all plus location adjustments pursuant to § 1126.75;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to § 1126.60(f); and

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

3. Section 1126.62 is revised as follows:

§ 1126.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) The 13th day after the end of each month the applicable uniform prices for such month.

§ 1126.71 [Amended]

4. Section 1126.71(b)(4) is amended by changing the words "uniform price" to "weighted average price."

5. In § 1126.73 the introductory text of paragraph (b) (immediately preceding subparagraph (1)), and paragraph (d)(2) are revised as follows:

§ 1126.73 Payments to producers and to cooperative associations.

* * * * *

(b) Subject to paragraphs (c) through (f) of this section, the market administrator shall pay each producer on or before the 18th day after the end of each month for milk (or base milk and excess milk) for which payment pursuant to § 1126.71(b) has been received by the market administrator or offset pursuant to § 1126.71(d). Such payment shall be at the applicable uniform price(s) for the month, subject to the following adjustments:

* * * * *

(d) * * *

(2) The total pounds and, with respect to final payments, the average butterfat content of the milk for which payment is being made and for the months of March through July the pounds of base milk;

* * * * *

§ 1126.74 [Amended]

6. Section 1126.74 is amended by changing the words "uniform price" to "uniform prices."

7. Section 1126.75 is revised as follows:

§ 1126.75 Plant location adjustments for producers and on nonpool milk.

(a) In making the payments required pursuant to § 1126.73, the uniform price and the uniform price for base milk for the month shall be adjusted by the amounts set forth in § 1126.52 according to the location of the plant where the milk being priced was received.

(b) For purposes of computing the value of other source milk pursuant to § 1126.71, the weighted average price shall be adjusted by the amount set forth in § 1126.52 that is applicable at the location of the nonpool plant from which the milk was received, except that the adjusted weighted average price plus 5 cents shall not be less than the Class III price.

§ 1126.76 [Amended]

8. Section 1126.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."

9. A new center head "Base-Excess Plan" and five new sections (§§ 1126.90 through 1126.94) are added immediately following § 1126.86 as follows:

BASE-EXCESS PLAN

§ 1126.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1126.92 in each of

the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1126.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1126.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1126.92 that is delivered under this order at each respective plant location.

§ 1126.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1126.92.

§ 1126.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Vally; Oklahoma metropolitan; Memphis, Tenn.; Fort Smith, Ark.; central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle: and Rio Grande Valley marketing areas (parts 1071, 1073, 1097, 1102, 1104, 1106, 1108, 1120, 1126, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1126.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1126.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1126.121 [Amended]

10. Section 1126.121(b) is amended by changing all references to "§ 1126.61(d)" to read "§ 1126.61(a)(4)."

PART 1132—MILK IN THE TEXAS PANHANDLE MARKETING AREA

1. In § 1132.31, paragraph (a) (2) and (4) is revised as follows:

§ 1132.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

* * * * *

2. In § 1132.32, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§ 1132.32 Other reports.

* * * * *

(b) In addition to the reports required pursuant to §§ 1132.30 and 1132.31 and paragraphs (a) and (c) of this section, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

(c) Each handler who receives milk from producers shall report to the market administrator on or before the seventh day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1132.92.

3. Section 1132.61 is revised as follows:

§ 1132.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat content f.o.b. pool plants located within 100 miles of the city hall of Amarillo, Tex., as follows:

(1) Combine into one total the values computed pursuant to § 1132.60 for all handlers who made the reports prescribed in § 1132.30 for such month, except those in default of payments required pursuant to § 1132.71 for the preceding month.

(2) Add an amount equal to the sum of the location adjustments to be made pursuant to § 1132.75;

(3) Add an amount equal to one-half of the unobligated cash balance in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of produce milk; and

(ii) The total hundredweight for which a value is computed pursuant to § 1132.60(f); and

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administra-

tor shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price:

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1132.62 is revised as follows:

§ 1132.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The fifth day after the end of each month the butter differential for such month; and

(b) The 10th day after the end of each month the applicable uniform prices for such month.

§ 1132.71 [Amended]

5. Section 1132.71(a)(2)(i) is amended by changing the word "price" to "prices."

6. Section 1132.71(a)(2)(ii) is amended by changing the words "uniform price" to "weighted average price."

7. In § 1132.73, the introductory text of paragraph (b) (immediately preceding subparagraph (1)), and paragraphs (c)(3), (4)(ii), and (d)(2) are revised as follows:

§ 1132.73 Payments to producers and to cooperative associations.

* * * * *

(b) On or before the 15th day after the end of each month, for milk (or base milk and excess milk) received during such month, an amount computed at not less than the applicable uniform price(s) per hundredweight, subject to the butterfat differential computed pursuant to § 1132.74, and plus or minus adjustments for errors made in previous payments to such producer; and less

* * * * *

(c) * * *

(3) Each handler who receives milk from a cooperative association which collects payments for its members pursuant to paragraph (c)(1) of this section shall on or before the 20th of each month, furnish such association information showing the daily and total pounds of milk received from each of the association's member producers for the first 15 days of such months, on or before the fifth day after the end of each month, such information for the 16th through the end of such month and, for the months of March through July, on or before the seventh day after the end of each month, the pounds of base milk.

(4) * * *

(ii) On or before the 13th day of the following month, in final settlement, the value of such milk received during the month, at the applicable uniform price(s) as adjusted pursuant to §§ 1132.74 and 1132.75, less the amount of payment made pursuant to paragraph (c)(4)(i) of this section.

(d) * * *

(2) The daily and total pounds and the average butterfat content of milk received from such producer, and for each of the months of March through July, the pounds of base milk;

* * * * *

§ 1132.74 [Amended]

8. Section 1132.74 is amended by changing the words "uniform price" to "uniform prices."

9. Section 1132.75 is revised as follows:

§ 1132.75 Plant location adjustments for producers and on nonpool milk.

(a) In making payment pursuant to § 1132.73 the uniform price and the uniform price for base milk to be paid for milk which is received from producers at a pool plant located 100 miles or more from the city hall, Amarillo, Tex., by the shortest hard-surfaced highway distance as determined by the market administrator shall be reduced at the rate set forth in the following schedule according to the location of the pool plant where such milk is received from producers:

	Rate per hundredweight (cents)
Distance from the Amarillo City Hall (miles):	
100 but less than 110	15.0
For each additional 10 mi or fraction thereof an additional	1.5

(b) For purposes of computations pursuant to §§ 1132.71 and 1132.72, the weighted average price plus 5 cents shall be adjusted at the rates set forth in § 1132.52 applicable at the location of the nonpool plant from which the milk was received (but the resulting price shall not be less than the class III price.)

§ 1132.76 [Amended]

10. Section 1132.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."

11. A new center head "Base-Excess Plan" and five new sections (§§ 1132.90 through 1132.94) are added immediately following § 1132.86 as follows:

BASE-EXCESS PLAN

§ 1132.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1132.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1139.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1132.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1132.92 that is delivered under this order at each respective plant location.

§ 1132.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1132.92.

§ 1132.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kansas; Red River Valley; Oklahoma Metropolitan; Memphis, Tennessee; Fort Smith, Arkansas; Central Arkansas; Texas, Lubbock-Plainview Texas; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1108, 1126, 1120, 1132, and 1138, respectively; of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is

greater: *Provided*, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60 whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1132.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1132.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1132.121 [Amended]

12. Section 1132.121(b) is amended by changing all references to "§ 1132.61(d)" to read "§ 1132.61(a)(4)."

PART 1138—MILK IN THE RIO GRANDE VALLEY MARKETING AREA

1. In § 1138.31, paragraph (a)(2) and (4) is revised as follows:

§ 1138.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

* * * * * *

2. Section 1138.32 is revised to read as follows:

§ 1138.32 Other reports.

(a) Each handler who receives milk from producers shall report to the market administrator on or before the 8th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1138.92.

(b) In addition to the reports required pursuant to paragraph (a) of this section and §§ 1138.30 and 1138.31, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

3. Section 1138.61 is revised as follows:

§ 1132.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat, content as follows:

(1) Combine into one total the values computed pursuant to § 1138.60 for all handlers who filed the reports prescribed by § 1138.30 for the month and who made the payments pursuant to §§ 1138.71 and 1138.73 for the preceding month;

(2) Add an amount equal to the sum of the deductions for location adjustments computed pursuant to § 1138.75;

(3) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to § 1138.60(f); and

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a)(1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1138.62 is revised as follows:

§ 1132.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) The 12th day after the end of each month the applicable uniform prices for such month.

§ 1138.71 [Amended]

(5) Section 1138.71(a)(2)(i) is amended by changing the word "price" to "prices."

6. Section 1138.71(a)(2)(ii) is amended by changing the words "uniform price" to "weighted average price."

7. In § 1138.73, the introductory text of paragraph (b) (immediately preceding subparagraph (1)), and paragraphs (d)(2), (e)(2), and (f)(1) are revised as follows:

§ 1138.73 Payments to producers and to cooperative associations.

* * * * *

(b) On or before the 16th day after the end of each month, for milk (or

base milk and excess milk) received during such month, an amount computed at not less than the applicable uniform price(s) per hundredweight as adjusted pursuant to §§ 1138.74 and 1138.75, plus or minus adjustments for errors made in previous payments to such producers and less

* * * * *

(d) * * *

(2) The total pounds and the average butterfat content of milk received from such producer and during the months of March through July the pounds of base milk;

* * * * *

(e) * * *

(2) In making final settlement, the value of such milk at the applicable uniform price(s) as adjusted pursuant to §§ 1138.74 and 1138.75 less the amount of partial payment made on such milk.

(f) * * *

(1) The days of delivery, the total pounds of milk, and the average butterfat test of milk received from such producer during the month and during the months of March through July the pounds of base milk;

* * * * *

§ 1138.74 [Amended]

8. Section 1138.74 is amended by changing the words "uniform price" to "uniform prices."

9. Section 1138.75 is revised as follows:

§ 1138.75 Plant location adjustments for producers and on nonpool milk.

(a) For producer milk received at pool plants located in Zones II and III or at pool plants located outside the marketing area and more than 100 miles, as determined by the market administrator, from the nearest of the county courthouses in El Paso County, Tex., or Bernalillo, or Santa Fe Counties, N. Mex., there shall be deducted from the uniform price and the uniform price for base milk an adjustment for each such plant for milk at the rates specified pursuant to § 1138.52.

(b) For purposes of computations pursuant to §§ 1138.71 and 1138.72, the weighted average price shall be adjusted at the rates set forth in § 1138.52 applicable at the location of the nonpool plant from which the milk was received, except that the adjusted weighted average price plus 5 cents shall not be less than the Class III price.

§ 1138.76 [Amended]

10. Section 1138.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."

11. A new center head "Base-Excess Plan" and five new sections (§§ 1138.90 through 1138.94) are added immediately following § 1138.86 as follows:

BASE-EXCESS PLAN

§ 1138.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1138.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1138.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1138.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1138.92 that is delivered under this order at each respective plant location.

§ 1138.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1138.92.

§ 1138.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1108, 1126, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater: *Provided,* That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 60 whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1138.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1138.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1138.12112 [Amended]

12. Section 113.121(b) is amended by changing all references to "§ 1138.61(d)" to read "§ 1138.61(a)(4)."

[FR Doc. 78-20963 Filed 7-27-78; 8:45 am]

FRIDAY, JULY 28, 1978
PART VII

DEPARTMENT OF LABOR

Employment and Training Administration

■

STANDARD FOR BENEFIT PAYMENT PROMPTNESS— UNEMPLOYMENT COMPENSATION

Revised Regulation

Federal Register

[4510-30]

Title 20—Employees' Benefits

CHAPTER V—EMPLOYMENT AND TRAINING ADMINISTRATION, DEPARTMENT OF LABOR

PART 640—STANDARD FOR BENEFIT PAYMENT PROMPTNESS—UNEMPLOYMENT COMPENSATION

Revised Regulation

AGENCY: Employment and Training Administration, Labor.

ACTION: Final rule.

SUMMARY: The Secretary of Labor's Standard for Benefit Payment Promptness requires that State unemployment compensation laws provide for the payment of unemployment benefits with the greatest promptness that is administratively feasible, and sets forth criteria for first payments of unemployment benefits that will be deemed to meet the Standard. Part 640 is amended so that the criteria for promptness of first payments of unemployment benefits will become progressively more stringent. Changes are made also to provide for appropriate corrective action when a State's performance falls below the criteria for promptness.

EFFECTIVE DATE: August 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Lawrence E. Weatherford, Administrator, Unemployment Insurance Service, Employment and Training Administration, U.S. Department of Labor, 601 D Street NW., Washington, D.C. 20213. Telephone: 202-376-7032.

SUPPLEMENTARY INFORMATION: On November 22, 1977, the proposal to revise the Standard for Benefit Payment Promptness—Unemployment Compensation, in Part 640, Chapter V, Title 20 of the Code of Federal Regulations, was published in the FEDERAL REGISTER at 42 FR 59952. Corrections of errors in the publication of November 22, 1977, were published in the FEDERAL REGISTER at 42 FR 62159 dated December 9, 1977.

SUMMARY OF PROPOSED CHANGES

In the document published on November 22, 1977, the Department of Labor proposed to make the following changes in part 640:

1. Change the standard as it applies to States which do not require a waiting period.

2. Change the measurement period from the 12-month period ending June 30 to the 12-month period ending March 31.

3. Change the standard by introducing higher and graduated criteria to be achieved over a 3-year period.

COMMENTS RECEIVED

Comments were invited on the proposed revision to part 640 with a closing date of December 22, 1977. Responses were received within the time limit from 33 State agencies, two Department of Labor regional offices, five legal aid and legal services organizations in four States, and the National Governors' Association. One response was received after the time limit. While the last response cannot be considered, it did not contain comments substantially different from those received within the time limit.

All of the responses received within the time limit have been considered. Many of the comments received were similar to comments submitted when part 640 was first proposed and published on March 5, 1976. The most significant comments related to (a) the effective dates of the more stringent performance criteria, (b) the proposed higher criteria levels of performance, and (c) establishment of separate criteria applicable to agent State performance.

The comments received and changes made in the proposal are discussed below.

1. NONWAITING WEEK STATES

All parties responding to this proposal except one favored allowing nonwaiting week States 21 days instead or 14 days after the end of the first compensable week to make first payments under the intrastate and interstate criteria. The single respond- ent not favoring the extension from 14 to 21 days proposed that a nonwaiting week State that is meeting the current criteria (80 percent and 60 percent) within 14 days should be required to continue to do so. The Department does not consider it feasible nor equitable to develop and enforce separate rules for a few States.

No change is made in this proposal, except that the first measurement period for the higher criteria will, as explained below, be the period beginning with the month following the effective date of this final regulation and ending on March 31, 1979, instead of March 31, 1978.

For the measurement period ending March 31, 1978, the present criteria will apply with only a change from 14 days to 21 days in the time limits for nonwaiting week States to make first payments. Thus, although the present criteria are retained through March 31, 1978, the change with respect to nonwaiting week States is incorporated to accomplish this improvement at the earliest feasible time.

2. CHANGE OF MEASUREMENT PERIOD

Several States objected to the retroactive application of the amendment to the Standard, which set more stringent criteria for achievement beginning with the 12-month period ending March 31, 1978. The States would not have reasonable time to plan their operations or to take appropriate action to meet the goal. Accordingly, to afford States enough lead time to gear up to meet the performance criteria, the measurement period for applying the present criteria of 80 percent for intrastate first payments and 60 percent for interstate first payments is retained for the 12-month period ending March 31, 1978. The first measurement period for the new criteria of 83 percent and 65 percent, respectively, is changed from the 12-month period ending on March 31, 1978, to the 12-month period ending on March 31, 1979, but in order to avoid retroactive effect the first measurement period for the period ending March 31, 1979, will begin with the month following the effective date of this final regulation instead of April 1, 1978. In addition, the measurement period for the second step in the higher criteria (87 percent and 70 percent) is changed from the 12-month period ending on March 31, 1979, to the 12-month period ending on March 31, 1980.

3. HIGHER AND GRADUATED CRITERIA

State responses generally reflected concern with the prospect of their meeting the proposed higher criteria.

Reports of accomplishment through February 1978, show that 43 States are exceeding the current intrastate criterion of performance and 31 States are exceeding the current interstate criterion calculated with allowance of 21 days for making first payments in nonwaiting week States. These results reflect the substantial effort States are making to improve their performance. This demonstrated effort, combined with continued improvements in automated systems, strongly indicates that the proposed higher criteria are attainable goals, as is more fully explained in the proposal.

In addition, the advances in the effective dates of the higher criteria make these goals more readily attainable. Further, the increased criteria of 90 percent and 75 percent proposed for the 12-month period ending March 31, 1980, have been deleted. This deletion was made because the effective date of the increased criteria would have been advanced to March 31, 1981, and analysis of available information indicates that a valid projection so far into the future cannot be made at this time.

Studies as conducted in 17 States have been completed in the remaining States. Results of the later studies were consistent with the results of the

earlier studies: Factors identified as uncontrollable and their adverse effect on benefit payment promptness were very similar in both series of studies.

Accordingly, no change is made in the higher criteria except as explained above.

4. ENFORCEMENT PROVISIONS

The enforcement provisions have been amended to allow the Department of Labor flexibility in applying the appropriate remedial steps to specific situations rather than applying all remedial steps to all situations of noncompliance.

The fact that a State does not meet the applicable intrastate or interstate criterion within a prescribed measurement period does not necessarily mean failure to meet the Secretary's standard.

The standard requires substantial compliance with a requirement for the greatest promptness that is administratively feasible. A State that has met the specified percentage of first payment criteria in a measurement period will be deemed to be in substantial compliance for that period. When a State has not met those criteria, however, a determination is then needed of whether or not the State has evidenced the requisite substantial compliance. Such a determination requires an inquiry into the circumstances that prevented the State from reaching the specified criteria. If that inquiry demonstrates that the State has achieved the greatest promptness reasonably attainable in its circumstances, the State may be considered to be in substantial compliance. On the other hand, when a State does not meet specified criteria due to circumstances that it could have avoided by taking corrective action and persists in such omissions, a compliance question would be presented. To clarify this, additions to § 640.3 set forth the meaning of the greatest promptness that is administratively feasible and the test of substantial compliance that will be applied.

5. OTHER COMMENTS

Comments were received recommending that the standard require 100-percent compliance within a specified number of days, and that the standard by omitting this requirement did not adequately protect the rights of individual claimants. Another commentor recommeded that the standard require States to either make payment or a determination in all cases within a specified number of days. There are various factors categorized as uncontrollable delays which make it virtually impossible for States to issue 100 percent of their first payments at a prescribed interval. Theoretically, achievement of 93 percent of intrastate first payments and 78 percent of interstate first payments in 35 days would be equivalent to near 100-percent performance as the accomplishment would include instances of uncontrollable delays. It is felt that the criteria set forth in the final rule afford adequate protection to the individual claimants. However, § 640.1 is changed to express the importance of promptness in determining eligibility.

A substantial number of States commented on the adverse effect of poor agent State performance on benefit payment promptness. The Department of Labor has made detailed recommendations to all States concerning procedures for processing interstate claims, and feels that implementation of said recommendations would produce substantial improvement in interstate benefit payment promptness. Therefore, no change is made in the regulation in this respect.

SUMMARY OF CHANGES IN FINAL RULE

Based upon comments received in response to the November 22, 1977, document, and other data accumulated since that date, the changes to 20 CFR Part 640, dated July 23, 1976, are summarized as follows:

1. The effective date of the first higher criteria will be the period ending March 31, 1979, and the second increase in the criteria will be the 12-month period ending March 31, 1980. The proposed third increase to have been effective for the 12-month period ending March 31, 1980, is deleted.

2. Nonwaiting week States are allowed 21 days to meet the criteria, effective for the period ending March 31, 1978.

3. The period over which the benefit payment promptness is to be measured is changed from the 12-month period ending June 30 to the 12-month period ending March 31.

4. Enforcement provisions are modified to allow the Department of Labor needed flexibility in the application of remedial steps.

5. Sections 640.1 and 640.3, relating to purpose and interpretation of Federal law requirements, are clarified by added provisions.

6. Other minor clarifying and technical changes are made.

NOTE.—The Department of Labor has determined that this document does not contain a major proposal requiring the preparation of an economic impact statement under Executive Order 11949 and applicable authority.

This document was prepared under the direction and control of Lawrence E. Weatherford, Adminsitrator, Unemployment Insurance Service, Employmemt and Training Administration, U.S. Department of Labor, 601 D Street NW., Washington, D.C. 20213, telephone 202-376-7032.

Accordingly, part 640 of chapter V of title 20, Code of Federal Regulations, is revised as set forth below.

Signed at Washington, D.C., on July 25, 1978.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

Sec.
640.1 Purpose and scope.
640.2 Federal law requirements.
640.3 Interpretation of Federal law requirements.
640.4 Standard for conformity.
640.5 Criteria for compliance.
640.6 Review of State compliance.
640.7 Benefit payment performance plans.
640.8 Enforcement of the standard.
640.9 Information, reports and studies.

AUTHORITY: Sec. 1102, Social Security Act (42 U.S.C. 1302); Secretary's order No. 4-75, dated April 16, 1975 (40 FR 18515) (5 U.S.C. 553). Interpret and apply secs. 303(a)(1) and 303(b)(2) of the Social Security Act (42 U.S.C. 503(a)(1), 503(b)(2)).

§ 640.1 Purpose and scope.

(a) *Purpose.* (1) Section 303(a)(1) of the Social Security Act requires, for the purposes of title III of that act, that a State unemployment compensation law include provision for methods of administration of the law that are reasonably calculated to insure the full payment of unemployment compensation when determined under the State law to be due to claimants. The standard in this part is issued to implement section 303(a)(1) in regard to promptness in the payment of unemployment benefits to eligible claimants.

(2) Although the standard applies to the promptness of all benefit payments and the criteria apply directly to the promptness of first benefit payments, it is recognized that adequate performance is contingent upon the prompt determination of eligibility by the State as a condition for the payment or denial of benefits. Accordingly, implicit in prompt performance with respect to benefit payments is the corresponding need for promptness by the State in making determinations of eligibility. However, applicable Federal laws provide no authority for the Secretary of Labor to determine the eligibility of individuals under a State law.

(b) *Scope.* (1) The standard in this part applies to all State laws approved by the Secretary of Labor under the Federal Unemployment Tax Act (section 3304 of the Internal Revenue Code of 1954, 26 U.S.C. 3304), and to the administration of the State laws.

(2) The standard specified in § 640.4 applies to all claims for unemployment compensation. The criteria for State compliance in § 640.5 apply to first payments of unemployment compensation under the State law to eligi-

ble claimants following the filing of initial claims and first compensable claims.

§ 640.2 Federal law requirements.

(a) *Conformity.* Section 303(a)(1) of the Social Security Act, 42 U.S.C. 503(a)(1), requires that a State law include provision for:

Such methods of administration * * * as are found by the Secretary of Labor to be reasonably calculated to insure full payment of unemployment compensation when due.

(b) *Compliance.* Section 303(b)(2) of the Social Security Act, 42 U.S.C. 503(b)(2), provides in part that:

Whenever the Secretary of Labor, after reasonable notice and opportunity for hearing to the State agency charged with the administration of the State law, finds that in the administration of the law there is:
(1) * * *
(2) a failure to comply substantially with any provision specified in subsection (a) of this section;

the Secretary of Labor shall notify such State agency that further payments will not be made to the State until the Secretary of Labor is satisfied that there is no longer any such * * * failure to comply.

Until he is so satisfied, he shall make no further certification to the Secretary of the Treasury with respect to such State * * *.

§ 640.3 Interpretation of Federal law requirements.

(a) *Section 303(a)(1).* The Secretary interprets section 303(a)(1) of the Social Security Act to require that a State law include provision for such methods of administration as will reasonable insure the full payment of unemployment benefits to eligible claimants with the greatest promptness that is administratively feasible.

(b) *Section 303(b)(2).* (1) The Secretary interprets section 303(b)(2) of the Social Security Act to require that, in the administration of a State law, there shall be substantial compliance with the provision required by section 303(a)(1).

(2) The greatest promptness that is administratively feasible will depend upon the circumstances in each State that impacts upon its performance in paying benefits. Factors reasonably beyond a State's control may cause its performance to drop below the level of adequacy expressed in the table below as criteria for substantial compliance applicable to all States. Where it is demonstrated that failure to meet the criteria of adequacy is attributable to factors reasonably beyond the State's control and, in light of those factors, the State has performed at the highest level administratively feasible, it will be considered that the State is in substantial compliance with the Standard for conformity. Whether or not the State is in substantial compliance, the remedial provisions of §§ 640.7 and 640.8 will be applicable when the pertinent criteria are not met.

§ 640.4 Standard for conformity.

A State law will satisfy the requirement of section 303(a)(1), if it contains a provision requiring, or which is construed to require, such methods of administration as will reasonably insure the full payment of unemployment benefits to eligible claimants with the greatest promptness that is administratively feasible.

§ 640.5 Criteria for compliance.

The criteria in the schedule below shall apply in determining whether, in the administration of a State law, there has been substantial compliance with the provision required by section 303(a)(1) in the issuance of benefit payments to eligible claimants for the first compensable weeks of unemployment in their benefit years:

	Percentage of first payments issued—days following end of first compensable week		
	14 days, waiting week States	21 days, nonwaiting week States[1]	35 days, all States
Intrastate claims			
Performance to be achieved for the 12-mo. period ending:			
Mar. 31, 1978.....	80	80	.....
Mar. 31, 1979.....	[2]83	[2]83	[2]90
Mar. 31, 1980, and thereafter.....	87	87	93
Interstate claims			
Performance to be achieved for the 12-mo. period ending:			
Mar. 31, 1978.....	60	60	.....
Mar. 31, 1979.....	[2]65	[2]65	[2]75
Mar. 31, 1980, and thereafter.....	70	70	78

[1]A nonwaiting week State is any State whose law does not require that a non-compensable period of unemployment be served before the payment of benefits commences.
[2]Beginning with the month following the effective date of this revised regulation.

A State will be deemed to comply substantially, as set out in §§ 640.2(b) and 640.3(b), if its average performance, for the period of review, meets or exceeds the applicable criteria set forth above.

§ 640.6 Review of State compliance.

(a) *Annual reviews.* The administration of each State law shall be reviewed annually for compliance, as set out in §§ 640.2(b) and 640.3(b). Annual reviews shall be for the 12-month period ending on March 31 of each year. An annual review with respect to any State shall be based upon the monthly reports of performance submitted to the Department by the State agency, any special reports of performance submitted to the Department by the State agency, any benefit payment performance plan applicable to the period being reviewed, any study or anylysis of performance relevant to the period being reviewed, and any other audit, study, or analysis as directed by the Department of Labor.

(b) *Periodic review.* The administration of any State law may be reviewed at any other time, when there is reason to believe that there may be failure of compliance as set out in §§ 640.2(b) and 640.3(b). Such a review shall be based upon the same elements as may be required for an annual review.

§ 640.7 Benefit payment performance plans.

(a) *Annual plan.* An annual benefit payment performance plan shall be submitted by a State agency to the Department of Labor when average performance over a 12-month period ending on March 31 of any year does not meet the criteria specified in § 640.5. An annual plan shall be submitted by July 31 following the applicable March 31, and shall be a plan for the fiscal year that begins on the succeeding October 1. An annual plan shall be subject to continuing appraisal during the period it is in effect, and shall be subject to modification from time to time as may be directed by the Department of Labor after consultation with the State agency.

(b) *Periodic plan.* A periodic benefit payment performance plan shall be submitted by a State agency when directed by the Department of Labor. A periodic plan may be in addition to, or a modification of an annual plan and may be required even though an annual plan covering the same period is not required. A periodic plan shall be subject to continuing appraisal during the period it is in effect, and shall be subject to modification from time to time as may be directed by the Department of Labor.

(c) *Content of plan.* An annual plan or periodic plan shall set forth such corrective actions, performance and evaluation plans, and other matters as the Department of Labor directs, after consultation with the State agency.

§ 640.8 Enforcement of the standard.

(a) *Action by the Department of Labor.* When a State agency fails, for an extended period, to meet the standard set forth in § 640.4 or the criteria specified in § 640.5, or fails to show

satisfactory improvement after having submitted a benefit payment performance plan of action, the Department of Labor shall pursue any of the following remedial steps that it deems necessary before considering application of the provisions of § 640.2:

(1) Initiate informal discussion with State agency officials pursuant to § 601.5(b) of this chapter.

(2) Conduct an evaluation of the State's benefit payment processes and analyze the reasons for the State's failure to meet the standard.

(3) Recommend specific actions for the State to take to improve its benefit payment performance.

(4) Request the State to submit a plan for complying with the standard by a prescribed date.

(5) Initiate special reporting requirements for a specified period of time.

(6) Consult with the Governor of the State regarding the consequences of the State's noncompliance with the standard.

(7) Propose to the Governor of the State and on an agreed upon basis arrange for the use of expert Federal staff to furnish technical assistance to the State agency with respect to its payment operations.

(b) *Action by the Assistant Secretary.* If, after all remedial steps have been exhausted, a State fails to take appropriate action, or otherwise fails to meet the standard specified in § 640.4, the Assistant Secretary for Employment and Training shall, after taking all factors into consideration, recommend to the Secretary of Labor that appropriate notice be sent to the State agency and that an opportunity for a hearing be extended in accordance with section 303(b) of the Social Security Act.

§ 640.9 Information, reports and studies.

A State shall furnish to the Secretary of Labor such information and reports and make such studies as the Secretary decides are necessary or appropriate to carry out this part.

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