

Discussion Draft, Prepared for February 2022 RAC Meetings

Definitions (333-333-1010)

- (1) “Adulterant” means chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or potential for addiction when added to psilocybin products.
- (2) “Batch” means a quantity of whole fungi from a harvest lot, or a quantity of psilocybin product from a process lot.
- (3) “Capsule” means a small soluble pill, tablet or container that contains liquid or powdered psilocybin product and is intended for human consumption.
- (4) “Chemical Synthesis” means the production of psilocybin using precursor ingredients rather than cultivation of fruiting bodies and mycelium.
- (5) “Dung” means unpasteurized animal, bird or bat feces. Dung does not include finished compost.
- (6) “Edible psilocybin product” means psilocybin extract or homogenized fungi that has been incorporated into a food item or potable beverage.
- (7) “Fruiting Bodies” means the spore producing organs of the fungi *Psilocybe cubensis*.
- (8) “Fungi” means the fruiting bodies or mycelium of the fungi *Psilocybe cubensis*
- (9) “Harvest Lot” means a specifically identified quantity of fungi that are cultivated and dried under the same conditions and harvested within a 12-hour period at the same location within the licensed premises.
- (10) “Homogenized fungi” means dried fruiting bodies or mycelium that have been homogenized by powdering or other techniques which uniformly distribute psilocybin throughout the product. Homogenized products may contain inactive ingredients such as binders, dilutants and carrying agents.
- (11) “Laboratory” means a laboratory licensed under Ballot Measure 109 (2020), Section 97
- (12) “Manufacturer” means a manufacturer licensed under Ballot Measure 109 (2020), Section 23
- (13) “Mycelium” means the fungal threads or hyphae of *Psilocybe cubensis*, including sclerotia.
- (14) “Process Lot” means homogenized fungi, psilocybin extract or edible psilocybin product of the same type that was processed at the same time using the same processing method, ingredients, and standard operating procedures.
- (15) “Psilocybin” means psilocybin or psilocin.
- (16) “Psilocybin extract” means solid or liquid psilocybin which has been extracted from fruiting bodies or mycelium of *Psilocybe cubensis*, and that may include, in addition to psilocybin and psilocin:
 - (a) Compounds and acids that were naturally derived from *Psilocybe cubensis*.
 - (b) Inactive ingredients that are used to form capsules, tinctures and other oral preparations.
- (17) “Psilocybin Tracking System” means the system for tracking psilocybin products required by Ballot Measure 109 (2020), Section 45.
- (18) “Psilocybin Product” means psilocybin-producing fungi, and mixtures or substances containing a detectable amount of psilocybin, including whole fungi, homogenized fungi, psilocybin extract and edible psilocybin products.
- (19) “Tincture” means a liquid containing psilocybin that consists of either:
 - (a) A non-potable solution of at least 25% non-denatured alcohol, that is exempt from the Liquor Control Act under ORS 471.035; or
 - (b) A non-potable solution comprised of glycerin, plant-based oil, syrup and other ingredients.
- (20) “Whole fungi” means dried fruiting bodies and sclerotia of *Psilocybe cubensis*, or portions thereof, that have not been homogenized.
- (21) “Wood Chips” mean substrates consisting primarily of wood products that have not been composted.

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Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c)

Psilocybin Production (333-333-2010)

(1) A Manufacturer may only cultivate or possess the fungi species *Psilocybe cubensis* on the licensed premises. Incidental possession of other species of fungi associated with employee meals is permitted.

(2) A Manufacturer is prohibited from:

- (a)** Using dung in cultivation and production of psilocybin products.
- (b)** Using wood chips as a growing medium in cultivation and production of psilocybin products.
- (c)** Producing psilocybin by using genetically modified organisms.
- (d)** Producing psilocybin by chemical synthesis.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c) and Section 23(1)

General Manufacturer Requirements (333-333-2020)

(1) A manufacturer must:

- (a)** Use equipment, counters and surfaces for processing that are food-grade and do not react adversely with any solvent being used.
 - (b)** Construct and maintain counters and surface areas in a manner that reduces the potential development of microbials, molds and unintended fungi and that can be easily cleaned.
 - (c)** Maintain the licensed premise in a manner that is free from conditions which may result in contamination of psilocybin products and that is suitable for safe and sanitary operations.
 - (d)** Store all psilocybin products in a locked area when not in use, including psilocybin products that require refrigeration,
 - (e)** Assign every process lot a unique identification number and enter this information into the Psilocybin Tracking System.
- (2)** A manufacturer may not produce, transfer or sell a psilocybin product that appeals to minors, including but not limited to:
- (a)** Product that are modeled after non-psilocybin products primarily consumed by and marketed to children; or
 - (b)** Products in the shape of an animal, vehicle, person or character.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c) and Section 23(1)

Manufacturer Endorsements (333-333-2030)

(1) A manufacturer may only produce and sell psilocybin products if the manufacturer has received an endorsement from the Authority for that type of product. Endorsement types are:

- (a)** Fungi cultivation;
- (b)** Psilocybin extraction; and
- (c)** Edible psilocybin production.

(2) An applicant for a manufacturer license must request an endorsement upon submission of an initial application but may also request to add or remove an endorsement at any time following licensure.

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- (3)** To apply for an endorsement, an applicant or licensee must submit a form prescribed by the Authority that identifies the proposed endorsement.
- (4)** Only one application and license fee are required regardless of how many endorsements an applicant or licensee requests or when the request is made.
- (5)** An individual manufacturer may hold multiple endorsements.
- (6)** The Authority may deny a manufacturer's request for an endorsement or revoke an existing endorsement if the manufacturer cannot or does not meet the requirements of these rules. If the Authority denies or revokes approval, the processor has a right to a hearing under ORS chapter 183.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 25

Statutes Implemented: Ballot Measure 109 (2020), Section 25

Pesticides and Fertilizers (333-333-2040)

- (1)** A manufacturer may only use pesticides in accordance with ORS Chapter 634 and OAR 603, division 57.
- (2)** In addition to other records required by these rules, a manufacturer who cultivates mycelium or fruiting bodies must maintain, at all times and on the licensed premises:
 - (a)** The material safety data sheet (MSDS) for all pesticides, fertilizers or other agricultural chemicals used in production;
 - (b)** The original label or a copy of the label for all pesticides, fertilizers or other agricultural chemicals used in production;
 - (c)** A log of all pesticides, fertilizers or other agricultural chemicals used in production. The log must include:
 - (A)** The information required to be documented by a pesticide operator in ORS 634.146; and
 - (B)** Unique identifying Information from the required Psilocybin Tracking System that identifies batches or lots to which the product was applied.
- (3)** Records required under section (2) of this rule shall be maintained for at least two years and shall be made available to the Authority upon request.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c) and Section 23(1)

Adulterants (333-333-2050)

- (1)** A licensee may not add to psilocybin products any chemical, drug, plant, or substance that has the effect of altering potency, intoxicating effect, duration of effect, toxicity or potential for addiction, including but not limited to monoamine oxidase inhibitors (MAOI's), beverage alcohol or cannabis. A psilocybin product that has added chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or addictiveness is considered adulterated.
- (2)** A licensee may not produce, store or transfer adulterated psilocybin products. In addition to the provisions of (1) of this rule, a psilocybin product may be considered adulterated if:
 - (a)** It bears or contains any poisonous or deleterious substance in a quantity rendering the psilocybin product a risk to human health;

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- (b)** It bears or contains any added poisonous or deleterious substance exceeding a safe tolerance if such tolerance has been established;
- (c)** It consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for human consumption;
- (d)** It is processed, prepared, packaged or held under improper time-temperature conditions or under conditions increasing the probability of contamination with excessive microorganisms or physical contaminants;
- (e)** It is processed, prepared, packaged, or held under unsanitary conditions increasing the probability of contamination or cross-contamination;
- (f)** It is held or packaged in containers composed, in whole or in part of any poisonous or deleterious substance rendering the contents potentially injurious to health;
- (g)** Any substance has been substituted wholly or in part;
- (h)** Damage or inferiority has been concealed in any manner; or
- (i)** Any substance has been added, mixed or packaged to make it appear a better or of greater value than it is.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c)

Psilocybin Extract Manufacturing Requirements (333-333-2060)

- (1)** A manufacturer with a psilocybin extraction endorsement may use only water, vegetable glycerin, acetic acids, ethanol and methanol as solvents in extraction. All other solvents are prohibited.
- (2)** A manufacturer with a psilocybin extraction endorsement may not use denatured alcohol.
- (3)** A manufacturer with a psilocybin extraction endorsement may not apply pressure or heat over 140 degrees Fahrenheit when manufacturing psilocybin extracts.
- (4)** If using methanol or ethanol, a manufacturer must process psilocybin extracts in a room with equipment, including all electrical installations that meet the requirements of the Oregon Structural Specialty Code, related Oregon Specialty Codes and the Oregon Fire Code.
- (5)** When producing a psilocybin extract that will be used in an edible psilocybin product, a manufacturer with a psilocybin extraction endorsement must process in a food establishment licensed by the Oregon Department of Agriculture and must comply with applicable provisions of OAR 603, division 21, division 24, division 25 and division 28.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c)

Psilocybin Extract Manufacturing Safety Procedures (333-333-2070)

- (1)** A manufacturer with a extraction endorsement must:
 - (a)** Work in an environment with proper ventilation, controlling all sources of ignition where flammable vapors may be present;
 - (b)** Use only potable water in processing; and
 - (c)** Have an emergency eye-wash station in any room in which solvents other than water are used.

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(2) A manufacturer with a psilocybin extraction endorsement must create and maintain a comprehensive training program that includes the hazards presented by all solvents used at the licensed premises as described in the material safety data sheet for each solvent.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c)

Psilocybin Edible Manufacturing Requirements (333-333-2080)

(1) A manufacturer with an edible psilocybin production endorsement may only process in a food establishment licensed by the Oregon Department of Agriculture (ODA) and must comply with the applicable provisions of OAR 603, division 21, division 24, division 25 and division 28.

(2) A manufacturer with an edible psilocybin production endorsement may not:

(a) Engage in processing at a location that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited-service restaurant, single event temporary restaurant, commissary, mobile unit, bed and breakfast, or warehouse licensed under ORS 624;

(b) Share a food establishment with another person or entity;

(c) Process food intended for commercial sale that does not contain psilocybin; or

(d) Use a psilocybin product to produce psilocybin edible psilocybin products unless that psilocybin product was processed or cultivated in a food establishment licensed by the ODA in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c)

Psilocybin Manufacturing Records (333-333-2100)

A manufacturer with a psilocybin extraction, or edible psilocybin production endorsement must create and maintain standard policies and procedures that include but are not limited to:

(1) Instructions and ingredients for making each psilocybin product;

(2) The procedure for making each process lot homogenous;

(3) If applicable, the procedure for purging and disposing of any solvent or other unwanted product from a psilocybin extract;

(4) Procedures for conducting necessary safety checks prior to commencing production of psilocybin products;

(5) Procedures for cleaning all equipment, counters and surfaces;

(6) Procedures for preventing growth of pathogenic organisms and toxin formations;

(7) Proper handling and storage of any solvent or other chemical used in processing in accordance with material safety data sheets and other applicable laws;

(8) Proper disposal of any waste produced during processing in accordance with applicable laws, rules and regulations;

(9) Appropriate use of any necessary safety or sanitary equipment; and

(10) Emergency procedures to be followed in case of fire, chemical spill or other emergency.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c)

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Allowable Psilocybin Product Types (333-333-2110)

- (1) A manufacturer with a fungi cultivation endorsement may produce whole fungi, mycelium and homogenized fungi.
- (2) A manufacturer with a psilocybin extraction endorsement may produce psilocybin extract.
- (3) A manufacturer with an edible psilocybin production endorsement product may produce edible psilocybin products
- (4) A manufacturer may only produce those psilocybin products for which they hold an endorsement.
- (5) Psilocybin products not included in this rule are prohibited and may not be manufactured, nor possessed by any licensee.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c) and Section 25

Psilocybin Product Delivery Methods (333-333-2120)

- (1) All psilocybin products must be designed to be consumed by a client orally.
- (2) Psilocybin products designed to be delivered to clients through any method other than orally, including but not limited to, transdermal patches, inhalers, nasal sprays, suppositories and injections, are prohibited.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c)

Statutes Implemented: Ballot Measure 109 (2020), Section 8(2)(c)