

Food Additives Intake Model (FAIM) template

Version 2.1 - May 2024



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GENERAL INFORMATION

The purpose of the <u>Food Additives Intake Model</u> (FAIM) template is to provide a screening tool for estimating chronic dietary exposure to food additives. It allows users to estimate the mean and high-level exposure to food additives for different population groups throughout several European countries. The FAIM template can be used for the estimation of chronic exposure to a new food additive or exposure resulting from new uses of an already authorised food additive. Therefore, the FAIM template can be used as a first step in the dietary exposure assessment process by applicants, risk assessors as well as risk managers.

FOOD CONSUMPTION DATABASE

The <u>EFSA Comprehensive European Food Consumption Database</u> is used in the FAIM template to estimate dietary exposure for the following six population groups: infants (from 12 weeks of age), toddlers (also named young children), children, adolescents, adults and the elderly. The version of the Comprehensive Database used in the FAIM template version 2.1 is the one released in December 2022.

FOOD CATEGORIES

Consumption records are codified according to the food categories as presented in Annex II, Part D, of Regulation (EC) No 1333/2008. However, the level of detail available in the nomenclature of the EFSA Comprehensive Database (FoodEx2 classification system) (EFSA, 2015) did not always match the exact description. Some of the food categories, restrictions and/or exceptions presented in the Regulation could not be identified in the FoodEx2 nomenclature and consequently are not represented in the FAIM template (Nikolic et al, 2021). The list of the food categories available in the updated version of FAIM (Version 2.1) can be seen in Appendix A.

Some foods recorded in the Comprehensive Database are not described to an adequate level of detail. As a result, these foods may remain at a more general level of description (e.g., cheese without further detail) and therefore cannot be classified in the FAIM nomenclature with more precise levels of detail (e.g., the sub-categories 01.7.1 Unripened cheese, 01.7.2 Ripened cheese, etc). In such cases, these foods are classified under the parental food category (e.g., a cheese undetermined will be classified under the FC 01.7 Cheese and cheese products).

As a result, for an exposure assessment in which exposure from e.g., unripened cheese or any other specific category of cheese is estimated, also the undefined cheeses should be taken into account. This means that the occurrence levels (e.g., MPLs, use levels) should be assigned to both the sub-category e.g. FC 01.7.1 Unripened cheese and to the parental food category 01.7 Cheese and cheese products. In such a way, foods not detailed enough (e.g., cheese with no



further detail from the example, but which could potentially be an unripened cheese), will be also considered.

Some foods could not be classified in any food categories and are shown in the FAIM template as FC 99 Unclassified foods. This food category contains only 0.05% of all the foods available in the surveys. It is considered that this food category could not be considered in any exposure assessment (i.e., not attributing it an occurrence level).

OCCURRENCE LEVELS

Users of the FAIM template are required to input the levels of occurrence for the food additive under evaluation for each food category to be considered in the assessment of exposure. The occurrence levels can be "proposed use levels", in the case of a new food additive or for an extension of use of an already authorised food additive, "reported use levels" or analytical results, in the case of an evaluation of an already authorised food additive. The regulatory maximum level exposure scenario can be assessed by inputting the maximum levels from Regulation N°1333/2008, Annex II, Part E (named maximum permitted levels (MPLs) in EFSA opinions).

In case there is occurrence (use level, analytical level, MPL) in a parental food category (e.g., 14.1.4 Flavoured drinks), the tool does not automatically assign this occurrence level to the subcategories (e.g., 14.1.4.1 Flavoured drinks with sugar and 14.1.4.2 Flavoured drinks with sweetener). Consequently, the occurrence level of the parental food category must be assigned to all parental and sub-categories in which there is occurrence. Applied to the example, this means that the occurrence level must be entered for 14.1.4 Flavoured drinks, 14.1.4.1 Flavoured drinks with sugar and 14.1.4.2 Flavoured drinks with sweetener. All values have to be entered as mg/kg of food in accordance with the authorised uses as per Regulation (EC) N°1333/2008, Annex II, Part E.

EXPOSURE ASSESSMENT METHODOLOGY

The first version of the FAIM template was in the form of an Excel file which has been published on the EFSA website in December 2012. This template made use of summary statistics from the Comprehensive Database to estimate chronic dietary exposure in different population groups and EU countries. The method used to estimate high-level exposure from food consumption summary statistics consisted in adding the highest high level of exposure from one food category (calculated for consumers only) to the mean exposure values for the remaining categories (calculated for the total population).

In the current release of the FAIM template (Version 2.1), dietary exposure is calculated by multiplying, for each food category, the concentration levels inputted by the user with their respective consumption amount per kilogram of body weight for each individual in the Comprehensive Database. The exposure per food category is subsequently added to derive an individual total exposure per day. These exposure estimates are averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only one day per subject are excluded as they are considered as not adequate to assess repeated exposure. This is carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group. On the basis of these distributions, the mean and 95th percentile of exposure are calculated per survey



and population group. The 95th percentile of exposure is only calculated for those population groups where the sample size was sufficiently large to allow this calculation (EFSA, 2011).

REFERENCES

EFSA (European Food Safety Authority), 2011. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. The EFSA Journal, 2011, 34 pp.

European Food Safety Authority, 2015. The food classification and description system FoodEx2 (revision 2). EFSA supporting publication 2015: EN-804. 90 pp.

Nikolic M., Ioannidou S., Tard A., Arcella D., 2021. Mapping of FoodEx2 Exposure Hierarchy with the food categories of Annex II (part D) of Regulation (EC) No 1333/2008 on food additives. Zenodo 2021, https://doi.org/10.5281/zenodo.4461576



APPENDIX A

TABLE 1: LIST OF FOOD CATEGORIES AVAILABLE IN THE FAIM VERSION 2.1

FOOD CATEGORY	FOOD CATEGORY DESCRIPTION
01.1	Unflavoured pasteurised and sterilised (including UHT) milk
01.2	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation
01.4	Flavoured fermented milk products including heat-treated products
01.5	Dehydrated milk as defined by Directive 2001/114/EC
01.6.1	Unflavoured pasteurised cream (excluding reduced fat creams)
01.6.2	Unflavoured live fermented cream products and substitute products with a fat content of less than 20%
01.6.3	Other creams
01.7	Cheese and cheese products
01.7.1	Unripened cheese excluding products falling in category 16
01.7.2	Ripened cheese
01.7.4	Whey cheese
01.7.5	Processed cheese
01.7.6	Cheese products (excluding products falling in category 16)
01.8	Dairy analogues, including beverage whiteners
02.1	Fats and oils essentially free from water (excluding anhydrous milkfat)
02.2	Fat and oil emulsions mainly of type water-in-oil
02.2.1	Butter and concentrated butter and butter oil and anhydrous milkfat
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions
03	Edible ices
04.1	Unprocessed fruit and vegetables
04.1.1	Entire fresh fruit and vegetables
04.1.2	Peeled, cut and shredded fruit and vegetables
04.1.3	Frozen fruit and vegetables
04.2	Processed fruit and vegetables
04.2.1	Dried fruit and vegetables
04.2.2	Fruit and vegetables in vinegar, oil, or brine
04.2.3	Canned or bottled fruit and vegetables
04.2.4.1	Fruit and vegetable preparations excluding compote





FOOD	FOOD CATEGORY DESCRIPTION
CATEGORY 04.2.4.2	Compote, excluding products covered by category 16
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC
04.2.5.3	Other similar fruit or vegetable spreads
04.2.5.4	Nut butters and nut spreads
04.2.6	Processed potato products
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC
05.2	Other confectionery including breath freshening microsweets
05.2.1	Other confectionery with added sugar
05.2.2	Other confectionery without added sugar
05.3	Chewing gum
05.3.1	Chewing gum with added sugar
05.3.2	Chewing gum without added sugar
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4
06.1	Whole, broken, or flaked grain
06.2.1	Flours
06.2.2	Starches
06.3	Breakfast cereals
06.4	Pasta
06.4.1	Fresh pasta
06.4.2	Dry pasta
06.4.4	Potato Gnocchi
06.5	Noodles
06.6	Batters
06.7	Pre-cooked or processed cereals
07.1	Bread and rolls
07.2	Fine bakery wares
08.1	Fresh meat, excluding meat preparations as defined by Regulation (EC) No 853/2004
08.2	Meat preparations as defined by Regulation (EC) No 853/2004
08.3	Meat products
08.3.1	Non-heat-treated meat products
08.3.2	Heat-treated meat products
09.1.1	Unprocessed fish
09.1.2	Unprocessed molluscs and crustaceans
09.2	Processed fish and fishery products including molluscs and crustaceans



FOOD CATEGORY	FOOD CATEGORY DESCRIPTION
09.3	Fish roe
10.1	Unprocessed eggs
10.2	Processed eggs and egg products
11.1	Sugars and syrups as defined by Directive 2001/111/EC
11.2	Other sugars and syrups
11.3	Honey as defined in Directive 2001/110/EC
11.4	Table Top Sweeteners
11.4.1	Table Top Sweeteners in liquid form
11.4.2	Table Top Sweeteners in powder form
11.4.3	Table Top Sweeteners in tablets
12.1.1	Salt
12.2.1	Herbs and spices
12.2.2	Seasonings and condiments
12.3	Vinegars
12.4	Mustard
12.5	Soups and broths
12.6	Sauces
12.7	Salads and savoury based sandwich spreads
12.8	Yeast and yeast products
12.9	Protein products, excluding products covered in category 1.8
13.1.1	Infant formulae as defined by Directive 2006/141/EC
13.1.2	Follow-on formulae as defined by Directive 2006/141/EC
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC
13.1.4	Other foods for young children
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)
14.1.1	Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packed waters
14.1.2	Fruit and vegetable juices
14.1.2.1	Fruit juices as defined by Directive 2001/112/EC
14.1.2.2	Vegetable juices



FOOD CATEGORY	FOOD CATEGORY DESCRIPTION
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products
14.1.4	Flavoured drinks
14.1.4.1	Flavoured drinks with sugar
14.1.4.2	Flavoured drinks with sweetener
14.1.5.1	Coffee, coffee extracts
14.1.5.2	Other
14.2.1	Beer and malt beverages
14.2.2	Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol free counterparts
14.2.3	Cider and perry
14.2.4	Fruit wine and made wine
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008
14.2.7.1	Aromatised wines
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol
15.1	Potato-, cereal-, flour- or starch-based snacks
15.2	Processed nuts
16	Desserts excluding products covered in category 1, 3 and 4
17	Food supplements as defined in Directive 2002/46/EC
17.1	Food supplements supplied in a solid form, excluding food supplements for infants and young children
17.2	Food supplements supplied in a liquid form, excluding food supplements for infants and young children
99	Unclassified foods