FOOD ADDITIVES INTAKE MODEL (FAIM) TEMPLATE - VERSION 1.0 - DECEMBER 2012

GENERAL INFORMATION

The purpose of the Food Additives Intake Model (FAIM) template is to provide a **screening tool for estimating chronic exposure to food additives**. It allows the user to estimate the mean and high level exposure to food additives for different population groups throughout several European countries. According to the 'Guidance for submission for food additive evaluations', published on July 2012 on EFSA website (EFSA, 2012), two scenarios can be applied, taking into account: (1) the Maximum Permitted Levels (MPLs) of use as set in the current EU legislation and (2) the levels of use as reported for existing food additives, if available, or as proposed, in the case of new applications. The model also provides information on the food groups contributing to the total mean exposure.

The FAIM template can be used for the estimation of 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.

NOMENCLATURE

The nomenclature used in the FAIM template is the one used in Commission Regulation (EU) N° 1129/2011[1] (Part D). Despite being published in November 2011, this regulation will apply from 1 June 2013. However, considering that this regulation includes all food additives of which conditions of use were previously authorised in Directive 94/35/EC on sweeteners, in Directive 94/36/EC on colours and in Directive 95/2/EC on food additives other than colours and sweeteners, the nomenclature used in Commission Regulation (EU) N° 1129/2011 is common for all types of food additives. For this reason it was chosen to link the consumption data available within EFSA (i.e. from the EFSA Comprehensive European Food Consumption Database) to the nomenclature used in this regulation.

FOOD CONSUMPTION DATA USED FOR DIETARY EXPOSURE ASSESSMENT

In 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been built from using existing national information on food consumption at a detailed level. Competent authorities in European countries provided EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011b)).

Overall, the food consumption data gathered by EFSA were collected using different methodologies (24-hour recall, 48-hour recall, food records taking into account different survey periods) and thus direct country-to-country comparison should be made with caution.

Summary statistics from the Comprehensive Database can be used as a **screening tool to assess chronic exposure to food additives**. Intake statistics were calculated based on individual consumption over the total survey period; surveys with only one day per subject were excluded.

[1] Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. OJ L 295, 12.11.2011, p.1.

Surveys with less than 60 subjects were considered as non-reliable to estimate high levels of exposure.

The mean consumption is calculated based on the whole population, whereas the high level consumption is calculated based on consumers-only. When the number of consumers per age class for a food category was above 60, the high level calculated was the 95th percentile. When the number of consumers per age class for a food category was below 60, the high level was estimated as the mean consumption of consumers-only. This is due to the minimum number of observations necessary to estimate the 95th percentile (EFSA, 2011b). **Consumption data in red font are based on 5 consumers or less and therefore should be handled with caution** (see 'Nb of consumers' sheet).

The Panel estimated chronic exposure for the following population groups: toddlers, children[2], adolescents, adults and the elderly[2]. Calculations were performed using individual body weights.

For the exposure assessment, food consumption data are available from 26 different dietary surveys carried out in 17 different European countries.

FOOD LIST

The "Foods list" worksheet shows to which Food Classification System (FCS) food category each FoodEx food item is linked to.

Consumption records of the Comprehensive database were codified according to the FoodEx classification system (EFSA, 2011a). In order to perform exposure estimates, the nomenclature from the FoodEx classification system has been linked mainly to the level 2, and for few foods up to level 3, of the Food Classification System (FCS) as presented in Commission Regulation (EU) N° 1129/2011, Part D.

However, the level of detail available on foods in the FoodEx nomenclature did not always match the exact description of the food item in the Regulation (EU) N° 1129/2011. Some foods presented in the Regulation could not be identified in the FoodEx nomenclature (e.g. description too precise (e.g. heat-treated milk products vs. non heat-treated milk products). Others represented a part of other foods and were not distinguishable from them (e.g. decorations and coatings). For this reason, these specific food groups could not be represented in the FAIM template. As a consequence:

- A few food groups could not be presented in the FAIM template:
    - 2.3 - Vegetable oil spray
    - 5.4 - Decorations, coatings and fillings
    - 6.6 - Batters
    - 6.7 - Pre-cooked or processed cereals

Not considering these foods in the exposure assessment could result in minor under-estimations.

Some adjustments were made:

- The FoodEx nomenclature does not allow to differentiate fermented milk products, non-heat-treated after fermentation from those heat-treated after fermentation, therefore, the corresponding food groups 1.2 and 1.3 in the legislation food categories were gathered into a '1.23 - Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)' food group in the FAIM template.

[2] The terms "Children" and "The elderly" correspond respectively to "other children" and the merged groups of the "elderly" and the "very elderly" as defined in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011b).

- Some food items were linked to a more detailed level. The "only energy-reduced or with no added sugar" restriction of the Regulation 1129/2011 has been considered and a distinction has been made between products with sugar and products with sweeteners for 3 main food groups: confectionary, chewing gum, non-alcoholic flavoured drinks.

Some food groups have many sub-groups below the level 2 of the Regulation 1129/2011 Food Classification System, such as fruits and vegetables, meat, and alcoholic beverages food groups. For this reason, when several MPLs and/or use levels exist for those sub-groups, the highest values should be inserted in the template to perform the exposure calculation, except when the product on which the highest level applies is a very specific product (niche product or country specific product, e.g. 'only edible external coating of *pasturmas*', 'only *dulce de membrillo*', …).

In the consumption values (as well as in the exposure results), actual zeroes are represented by empty cells. Values below 0.05 are rounded to zero and appear as such.

AGE CLASSES

The age classes are defined as indicated in the following table:

Population	Age range	Countries with food consumption surveys covering more than one day
Toddlers	from 12 up to and including 35 months of age	Bulgaria, Finland, Germany, The Netherlands
Children[2]	from 36 months up to and including 9 years of age	Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, The Netherlands, Spain, Sweden
Adolescents	from 10 up to and including 17 years of age	Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Spain, Sweden
Adults	from 18 up to and including 64 years of age	Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, The Netherlands, Spain, Sweden, UK
The elderly[2]	Older than 65 years	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

MPLS AND USE LEVELS

MPLs are set in the Commission Regulation (EU) 1129/2011. When considering a new food additive or extension of use of an already authorised food additive, the levels of use are provided by the applicant ('proposed used levels'), whereas for the re-evaluation of an already authorised food additive use levels as reported by industry can be used ('reported use levels'). All values have to be entered as **mg/kg of food** in accordance with the nomenclature defined in Commission Regulation (EU) N°1129/2011.

EXPOSURE CALCULATION WORKSHEETS BY AGE CLASS

Potential exposures for mean and high level consumers are automatically calculated for each food category and age class (toddlers, children, adolescents, adults and the elderly).

All the exposure estimates (described below) are expressed in **mg/kg body weight/day**.

- Mean values are calculated on all population, by age class and survey.

- High level values are calculated either for the 95th percentile of consumers-only, when the number of consumers is ≥ 60, or the mean of consumers-only when consumers < 60.

- Mean of the total estimated exposure from all contributing food sources are calculated by summing the mean of all mean intakes per food group.

- High level of the total estimated exposure from all contributing food sources: Although the intuitive approach to estimate the high level total estimated exposure from all food categories is to add up the high level of consumption for each separate category, this results in a large over-estimation since it assumes that high-level consumers of one food are also high level consumers of all the other food categories. However, it is very unlikely that individuals are high-level consumers of more than one food category when a limited number of food categories is used. One approach, proposed by the United Kingdom (European Commission, 1998) and also presented in the EFSA Guideline concerning the use of the Concise Database (EFSA, 2008) and in the guidance document on the "Use of the Comprehensive European Food Consumption database in exposure assessment" (EFSA, 2011b) which has been found to work reasonably well, is to estimate the total exposure from all food sources by assuming that an individual might be a high-level consumer of two food categories and would be an average consumer of the remaining food categories. In practice, this method consists in adding the 95th percentile of exposure, resulting from the two food categories contributing the most (calculated for consumers-only), to the mean exposure for the remaining categories (calculated for the total population). This approach has been tested using UK data for a range of pesticides and radionuclides (Pesticides Safety Directorate, 2004) and has been shown to give a reasonable approximation of the 97.5th percentile of exposure to the results obtained using the food consumption data at individual level.

  In the re-evaluation of food colours undertaken by the ANS Panel since 2009, the Panel decided to use a different approach for estimating high percentiles of exposure in which it is assumed that an individual might be a high-level consumer of one food category only and would be an average consumer of all the remaining food groups. In practice, this method consists 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). This approach has been tested with the FAIM template, for five different food additives, including preservatives, colours and sweeteners, and nutrient sources. In this trial, the exposure estimates calculated with the above-mentioned method were compared with the estimates obtained by using the food consumption data at the individual level (e.g. raw food consumption data by the individual consumer). The two methods yielded similar results. For this reason, to avoid excessively conservative estimates, this approach was preferred for the high-level exposure estimates.

  However, the Panel noted that its exposure estimates should be considered as being conservative as it is assumed that all processed foods contain the food additive under consideration added at the MPLs or the maximum reported use levels.

The FAIM template is a first approach to the exposure estimate. Therefore it is not necessarily the case that applicants need to alter proposed use levels or restrict food categories to ensure that the ADI is not exceeded. Indeed **a more detailed exposure assessment will be conducted by EFSA using the more disaggregated consumption data if the ADI will be exceeded**. The applicant may also provide a more refined exposure using appropriate data.

UNCERTAINTIES ANALYSIS:

According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised below:

Table 1: Qualitative evaluation of influence of uncertainties

Sources of uncertainties	**Direction** *
Consumption data: different methodologies / representativeness / under-reporting / misreporting / no portion size standard	+/-
Extrapolation from food consumption survey of few days to estimate long-term (chronic) exposure	+
Linkage between reported use levels and food items in the EFSA Consumption Database: uncertainties on which precise types of food the use levels refer.	+/-
Occurrence data: maximum reported use levels considered within a whole food category, exposure calculations based on the maximum reported use levels (when the product on which the highest level applies is a very specific product (e.g.niche product or country specific product), use of typical use levels when available and reliable).	+
Exposure model: uncertainty in possible national differences in use levels of food categories, dataset not fully representative of foods on the EU market	+/-

* + = uncertainty with potential to cause over-estimation of exposure;
- = uncertainty with potential to cause underestimation of exposure.

As a whole, the total estimated uncertainty from all sources should generally leads to an overestimation of the calculated exposures, thus providing conservative estimates.

SUMMARY PER AGE CLASS AND PER SURVEY

This table provides an overview of the results from the previous worksheets (calculation worksheets per age class and per survey) in order to summarise the mean and the high level exposures calculated with MPLs or use levels.

SUMMARY PER AGE CLASS

This table presents the range (minimum-maximum) of the total exposure per age class across the surveys, for the mean and the high level of exposures calculated with MPLs or use levels.

SUMMARY PER AGE CLASS IN PERCENTAGE OF THE ADI

This table presents the range (minimum-maximum) of the exposure per age class across the surveys in percentage of the ADI, for the mean and the high level of exposures calculated with MPLs or use levels.

MAIN FOOD CONTRIBUTION

All the food categories that contribute 5% or more to the estimated total exposure (given as a range of minimum-maximum percentage) are highlighted for each age class, for both MPLs and use levels.

For each food category, the number of surveys for which the food category contributes 5% or more to the total mean exposure is also given.

INSTRUCTIONS FOR USE:

Steps to follow:

1	In the "Concentration values" worksheet, insert in cell B3 the **name of the substance/food additive** for which the dietary exposure assessment should be performed. If any, please insert also the **ADI of the considered additive** (cell B4)**.**
2	**In the case of re-evaluation of an already authorised food additive**: in the "Concentration values" worksheet, please insert the MPLs values in the cells ranging C7:C72 for the food categories under consideration (scenario n.1). **Please note that values should be expressed in mg/kg or mg/L and that dots are used for decimal numbers.**
3	**In the case of re-evaluation/extension of use of an already authorised food additive or a new application:** in the "Concentration values" worksheet, please insert in the cells ranging D7:D72 the reported/proposed levels (scenario n.2). **Please note that values should be expressed in mg/kg or mg/L and that dots are used for decimal numbers.**
	When in doubt on the correct classification of a food item, please consult the worksheet "Foods list".
4	Once all food categories for which either MPLs, use levels or both are available, are filled, then go to the "Summary per age class & survey" worksheet. Here the results are provided: mean and high level of the exposure estimates, on the basis of both the MPLs and use levels, per survey and age class.
5	Once all MPLs and/or use levels are filled for the relevant food categories, it's possible to see the summarised results of the dietary exposure estimates per age class when going to the "Summary per age class" worksheet.
6	Go to the "Main food contribution" worksheet to see which food categories contribute the most to the total mean dietary exposure. Only the food categories which contribute more than 5% to the overall dietary exposure within a dietary survey are highlighted. The number of surveys in which the contribution of the food category is higher than 5% is also given per age class.
	Results in summary sheets are rounded to one or three decimals. It may be that more or less decimal numbers are needed depending on the results. The user is encouraged to play with the decimals increase/decrease cell format in order to see the results properly.

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