OBJECTIVE

Estimate chronic exposure to a food additive, for a particular/proposed use, for different population groups throughout the EU.

Rationale

Carry out an exposure estimation based on food consumption data

General Considerations

- **Aims of exposure assessment:**
  - estimate both the average exposure to a food additive and its distribution across the population (i.e. 95th percentile exposure) to be compared with tox data (namely ADI, if available)

- **New Assessment tool** (developed for the applicant)

  Food **A**dditives **I**ntake **M**odel **(FAIM)** – Template

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Exposure estimation

Two-scenario approach

➢ **Authorisation** of a new food additive **(Scenario 1)**

➢ **Modification** of proposed uses or use levels of an authorised food additive **(Scenario 2)**

New Exposure Assessment tool (FAIM)

➢ **Based on EFSA Comprehensive European Food consumption database**

Consumption Database
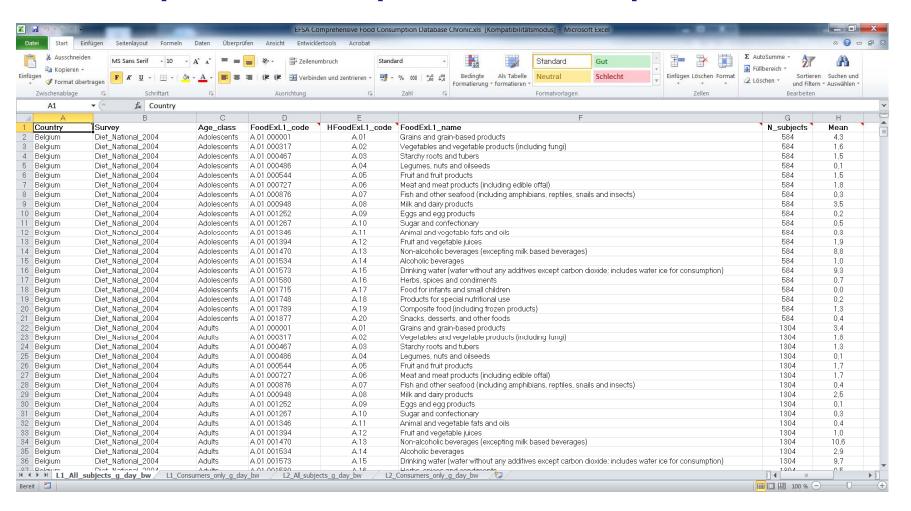
Background: **EFSA Comprehensive European Food Consumption Database**

➢ Data collected by EFSA (DATEX/DCM) including detailed information for a number of EU countries in refined food categories and specific population groups, also partly covering children.

➢ **To be downloaded from EFSA homepage:**
http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm
(data is included in the FAIM template, no separate download required)

Consumption database

EFSA Comprehensive European Food Consumption Database

Consumption Data

Background: **EFSA Comprehensive European Food Consumption Database**

Limits of this database

- Different methodologies used in different countries (24 h recalls, dietary records, food frequency questionnaires)

- No chronic consumption calculated for surveys using single 24 h recalls

- Sample size too small to calculate 95th percentile for some population groups or food categories

- Food categorisation is not completely congruent with EU regulations and directives

FAIM Template (1)

Rationale

- harmonisation of data submission
- more transparent
- user friendly
- no expertise required

Development of the FAIM template

➢ Matching of the food categorisation of the EFSA Comprehensive European Food Consumption Database (FoodEx) to the categorisation system of the EU Commission **Regulation 1129/2011** (FCS)

FAIM Template (2)

Development of the FAIM template

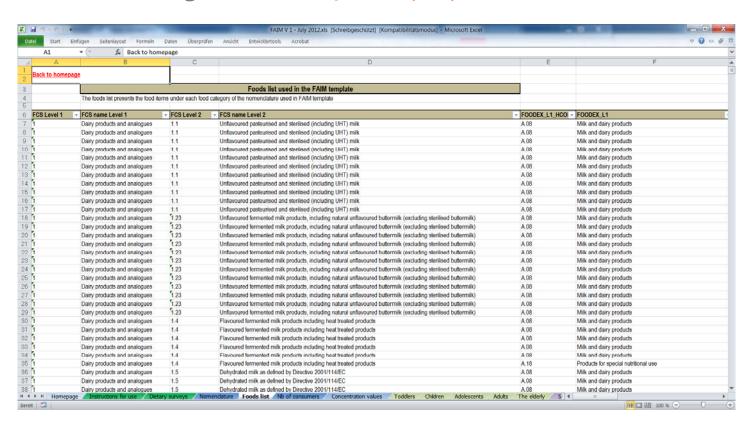➢ Matching of the food categorisation of the EFSA Comprehensive European Food Consumption Database (FoodEx) to the categorisation system of the EU Commission **Regulation 1129/2011** (FCS)

FAIM Template (3)

Development of the FAIM template
Matching food categorisation (FoodEx and FCS)

➢ **Testing on plausibility of matching FoodEx to FCS**

➢ **Testing on robustness of 95th percentiles**

FAIM Template (4)

PRINCIPLES OF EXPOSURE CALCULATIONS (via the template)

Mean exposure =   Σ [(Mean consumption food category x.y)

                 x   (MPL/proposed use level food category x.y)]

High level exposure =   (Consumption at 95th percentile of food category m.n with highest contribution to total mean exposure)

x

(MPL/proposed use level food category m.n)

+

Σ [(Mean consumption food category x.y)

x

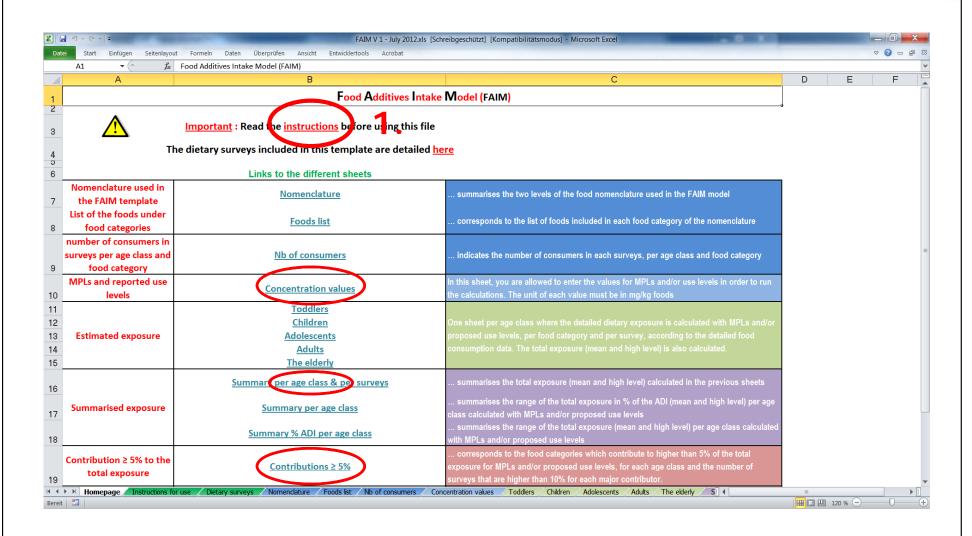(MPL/proposed use level food category x.y)]

–

(Mean consumption food category m.n)

x

(MPL/proposed use level food category m.n)]

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FAIM Template (5)

FAIM Template (6) - Instructions

Click to return to homepage

Scroll down to read all instructions

A	B
Back to homepage	

Instructions for use:

Important: Please respect the general rule that only cells highlighted in yellow in the "Concentration values" sheet (columns C and D as well as the name of the substance) should be filled! The other cells contain data, calculation formula or references. If you change the entries, the results might be incorrect.

For a full description of the model and the underlying assumptions please consult the following document:
(add here the link to the general information document on the website)
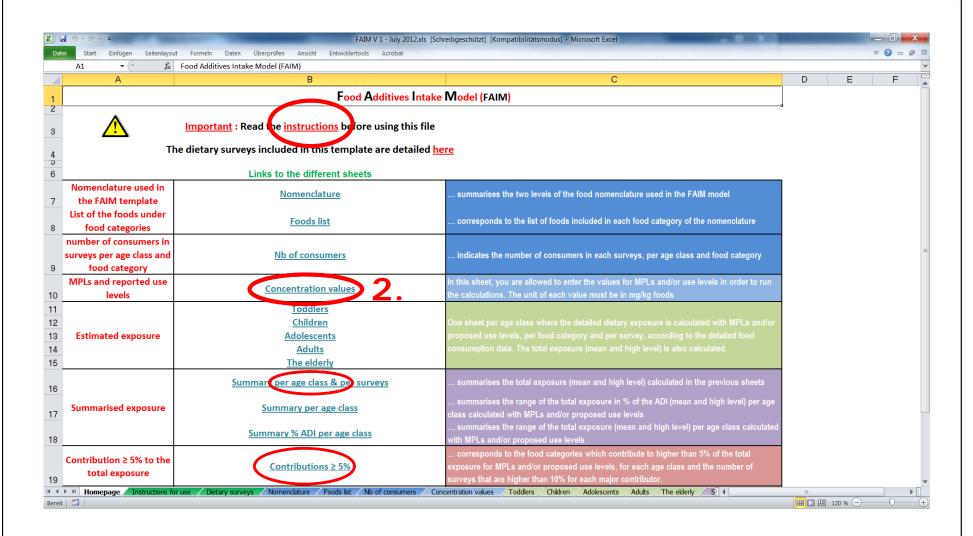
Please follow the following procedure:

1	In the "Concentration values" worksheet, insert in cell B2 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**
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 C6:C71 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 D6:D71 the reported/proposed levels. **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 "food 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 "Contrib ≥ 5%" 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

FAIM Template (8)

Screenshot of Excel spreadsheet "FAIM V 1 - July 2012.xls [Schreibgeschützt] [Kompatibilitätsmodus] - Microsoft Excel"

Cell A1: Back to homepage

	Name of the substance		xxx		Levels in beverages and foods	
	ADI (mg/kg bw/day)		y			
	FCS name Level 1		FCS name Level 2		MPL	Use levels
					mg/kg - mg/L*	mg/kg - mg/L*
7	1 - Dairy products and analogues	1.1 - Unflavoured pasteurised and sterilised (including UHT) milk				
8	1 - Dairy products and analogues	1.23 - Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)				
9	1 - Dairy products and analogues	1.4 - Flavoured fermented milk products including heat treated products				
10	1 - Dairy products and analogues	1.5 - Dehydrated milk as defined by Directive 2001/114/EC				
11	1 - Dairy products and analogues	1.6 - Cream				
12	1 - Dairy products and analogues	1.7.1 - Unripened cheese (excl cat 16)				
13	1 - Dairy products and analogues	1.7.2 - Ripened cheese				
14	1 - Dairy products and analogues	1.7.4 - Whey cheese				
15	1 - Dairy products and analogues	1.7.5 - Processed cheese				
16	1 - Dairy products and analogues	1.8 - Dairy analogues, including beverage whiteners				
17	2 - Fats and oils, and fat emulsions	2.1 - Fats and oils essentially free from water (excluding anhydrous milkfat)				
18	2 - Fats and oils, and fat emulsions	2.2 - Fat and oil emulsions mainly of type water-in-oil				
19	3 - Edible ices	3 - Edible ices				
20	4 - Fruit and vegetables	4.1 - Unprocessed fruit and vegetables				
21	4 - Fruit and vegetables	4.2 - Processed fruit and vegetables				
22	5.1 - Cocoa and Chocolate products as covered by Directive 2000/36/EC	5.1 - Cocoa and Chocolate products as covered by Directive 2000/36/EC				
23	5.2 - Other confectionery including breath refreshening microsweets	5.2.1 - Other confectionery with added sugar				
24	5.2 - Other confectionery including breath refreshening microsweets	5.2.2 - Other confectionery without added sugar				
25	5.3 - Chewing gum	5.3.1 - Chewing gum with added sugar				
26	5.3 - Chewing gum	5.3.2 - Chewing gum without added sugar				
27	6 - Cereals and cereal products	6.1 - Whole, broken, or flaked grain				
28	6 - Cereals and cereal products	6.2 - Flours and starches				
29	6 - Cereals and cereal products	6.3 - Breakfast cereals				
30	6 - Cereals and cereal products	6.4 - Pasta				
31	6 - Cereals and cereal products	6.5 - Noodles				
32	7 - Bakery wares	7.1 - Bread and rolls				

enter data for **new authorisation** (proposed use levels for each proposed food category)

(Scenario 1)

add data of use levels (if available) for **modification of authorisation**

(Scenario 2)

FAIM Template (9)

FAIM Template (10)

efsa — European Food Safety Authority

	MPL				Use levels			
	Range for mean across dietary surveys		Range for high level across dietary surveys		Range for mean across dietary surveys		Range for high level across dietary surveys	
	Min	Max	Min	Max	Min	Max	Min	Max
Toddlers	0,12	0,31	0,26	0,87	0,05	0,15	0,12	0,43
Children	0,04	0,27	0,15	0,51	0,02	0,13	0,07	0,26
Adolescents	0,02	0,08	0,07	0,20	0,01	0,04	0,04	0,10
Adults	0,01	0,05	0,04	0,12	0.000	0,02	0,02	0,06
The elderly	0,01	0,04	0,04	0,11	0.000	0,02	0,02	0,06

SUMMARY OF TOTAL ESTIMATED EXPOSURE (mg/kg bw/day)

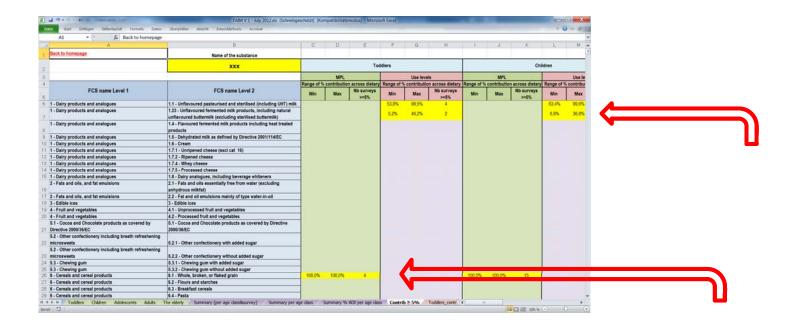Use the **data** as presented here for your application

AND

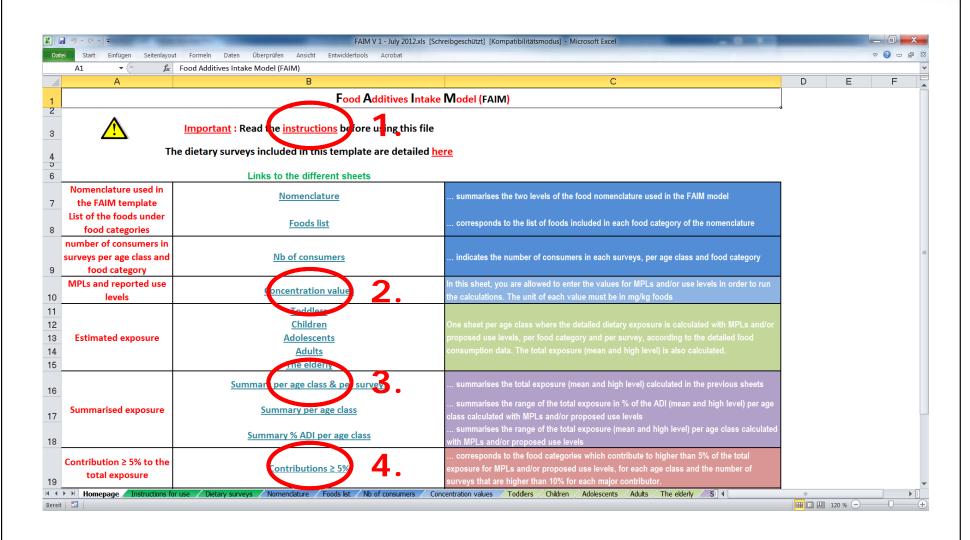provide the **FAIM template** with your data

FAIM Template (12)

Also indicate in your application those food categories contributing more than 5% to the total exposure of the additive.

The categories are automatically highlighted in the template

FAIM Template (13)

Applicants should submit exposure data using the **FAIM template** following its publication on the EFSA website