

Info session in support of the public consultation

31 March 2021

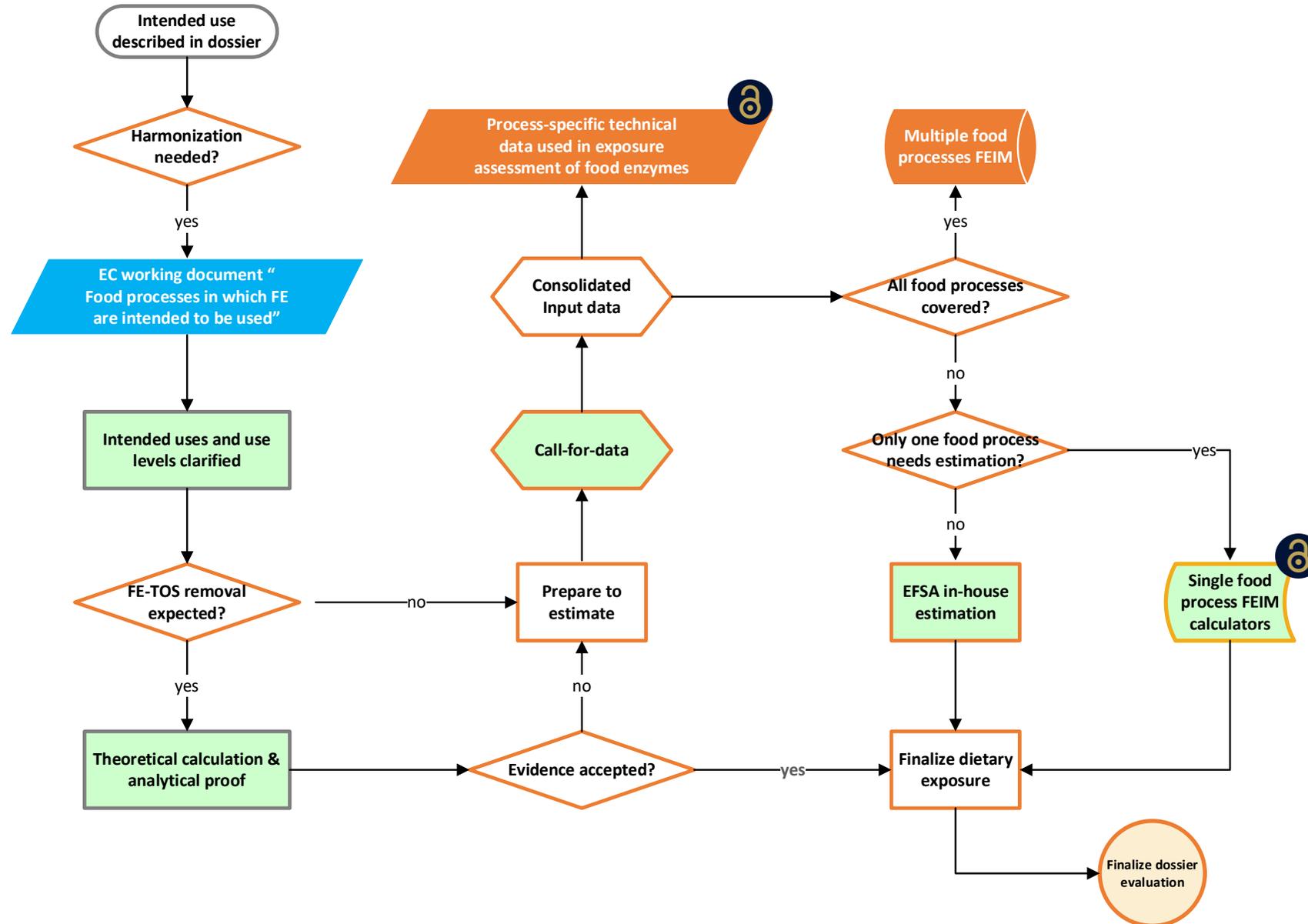
Food Enzyme Intake Model

Food Enzymes Team

FIP Unit

Trusted science for safe food

Dietary Exposure to Food Enzymes



Intended Use and Use Level

Raw material \neq substrate

Food manufacturing process	Raw material to which the food enzyme is added	Recommended use level of the food enzyme
Food process 1 (e.g., baking processes)	Raw material 1 (e.g., flour)	Maximum use level 1 (e.g., 50 mg TOS/kg flour)
Food process 2 (e.g., egg processing)	Raw material 2 (e.g., whole egg)	Maximum use level 2 (e.g., 50 mg TOS/kg whole egg)

Annex E - Food manufacturing processes and estimation of dietary exposure to the food enzyme TOS

Activity unit/kg raw material x mg TOS/activity unit
 = mg TOS/kg raw material
The calculation step(s) is to be included in the dossier

EC working document describing food processes in which food enzymes are intended to be used



EFSA document “Process-specific technical data used in exposure assessment of food enzymes”

1. Baking processes
2. Brewing processes
3. Cereal-based processes
4. Distilled alcohol production
5. Grain treatment and starch processing
 - a) Grain treatment for the production of starch and gluten fractions
 - b) Starch processing for glucose syrups production and other starch hydrolysates
6. Coffee processing
 - a) Coffee bean demucilation
 - b) Coffee processing
7. Egg processing
8. Fats and oils processing
 - a) Degumming of fats and oils
 - b) Modification of fats and oils by interesterification
 - c) Modification of fats and oils by hydrolysis (tbc)
9. Refined and unrefined sugar production
10. Manufacture of speciality carbohydrates
11. Wine and wine vinegar production



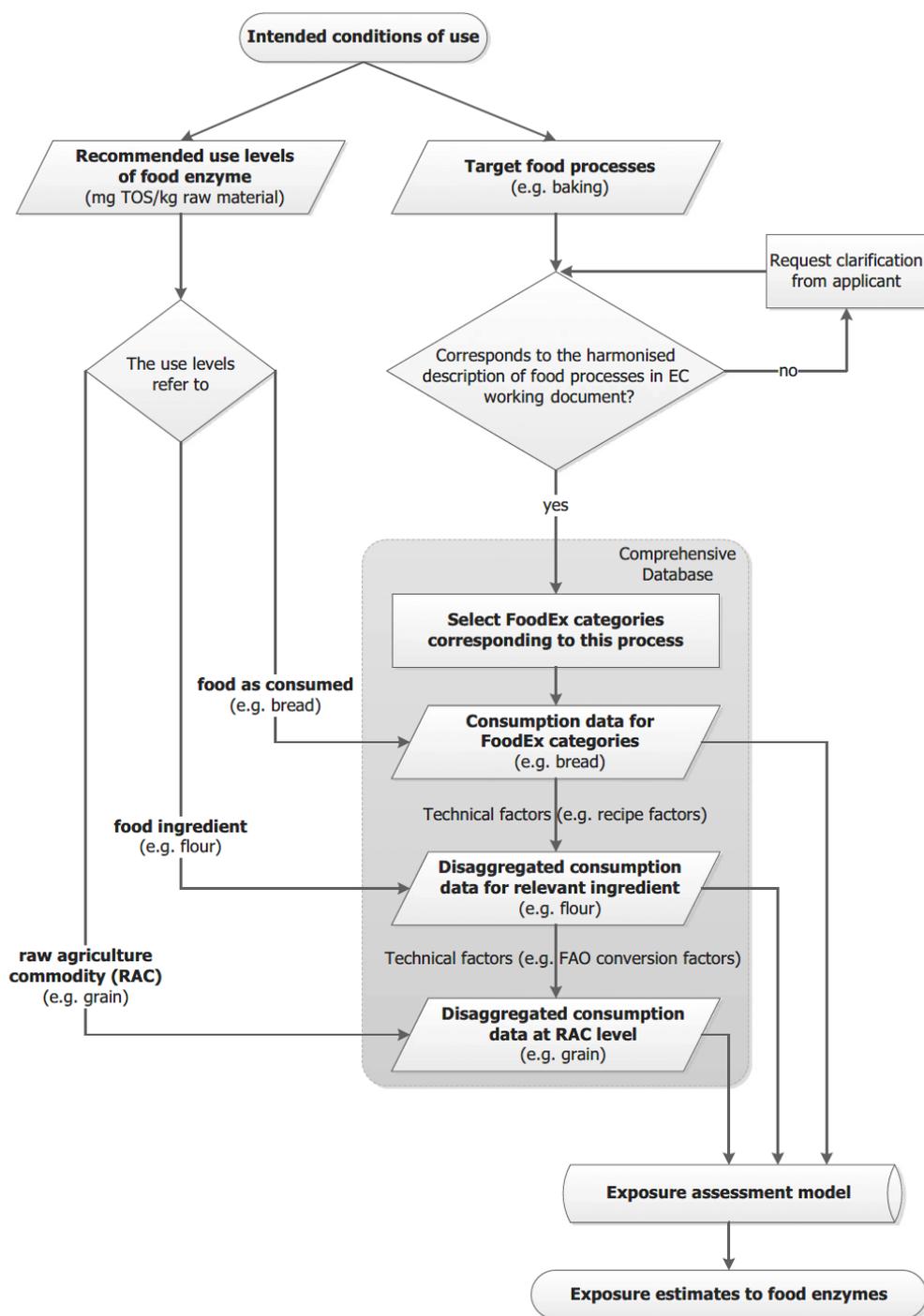
12. Fruit and vegetable processing
13. Tea processing & Herbal and fruit infusions processing
14. Milk processing
 - a) Lactose reduction
 - b) Production of cheese and by-products
 - c) tbc
15. Flavouring production
 - a) Flavouring production via distillation
 - b) Flavour enhancement *in situ*
 - c) Flavouring production as such (tbc)
16. Yeast processing
17. Protein processing
 - a) Protein hydrolysates for infant and follow-or
 - b) tbc
18. Meat and fish products processing
19. Confectionary processing
20. Coffee substitutes processing
21. Savoury snack processing



PENDING

It is generally assumed that the entire FE-TOS is transferred into the food produced, unless evidence is available to prove the contrary.

- ❑ For several food processes, upon invitation of EFSA, associations of the enzyme manufacturers and food manufacturers have provided evidence. This includes
 - Technical information about the removal in the concerned food processes,
 - Theoretical calculation of the carry-over into foods produced,
 - Analytical data along the food production steps and/or in foods produced,
 - Explanation why the analysed parameter(s) is relevant for the FE-TOS.
- ❑ EFSA evaluated the validity of these evidence and used them in the dossier evaluation. → **Annex E in the new guidance**
- ❑ An applicant can provide own data or can be requested to provide such data to support individual dossiers.
Note that ≥ 3 samples
- ❑ To ensure that advances in technological processes are accounted for in the future, EFSA will periodically review the validity of the evidence supporting the waiver.



Translation from Food Processes to Input Data for estimation

- Process specific FoodEx food categories
 - Hierarchy level L2, L3 or L4 as appropriate
- Technical factors
 - To combine the use levels and consumption data
- EFSA collates these input data and consult the interested parties via call-for-data on the web

Features of the Comprehensive Consumption Database in presentation II

All calls are accessible at EFSA website ([HERE](#))

- 1st Call: **Baking processes; brewing processes**
November 2016 - January 2017
- 2nd Call: **Cereal-based processes; savoury sacks processing**
November 2017 - February 2018
- 3rd Call: **Protein components in infant formulae and follow-on formulae**
February - May 2019
- 4th Call: **Wine production; coffee processing**
June - September 2019
- 5th Call: **Fats and oils processing for interesterification**
February - September 2020
- 6th Call: **Egg processing; refined sugar production (molasses as a by-product)**
May - August 2020
- **Preparation of new calls:** dairy processing, flavouring production, fruit and vegetable processing, etc.

Transparency, consistency and equal treatment

Food Groups & Technical Factors

FoodEx hierarchical code	FoodEx matrix description	FoodEx hierarchical level	f1 (converting molasses to sugar beet or to sugar cane)	f2 (average fraction of molasses in respective FoodEx category)	f3 (Percentage of FoodEx category containing molasses)
A.01.06.001	Cereal flakes	3	40	0.04	0.03
A.01.06.002	Muesli	3	40	0.001	0.03
A.01.06.003	Cereal bars	3	40	0.001	0.01
A.01.07.001.020	Fruit cake	4	40	0.01	0.25
A.01.07.001.024	Gingerbread	4	40	0.1	1.00
A.01.07.001.044	Lebkuchen	4	40	0.1	1.00
A.01.07.002.008	Speculaas	4	40	0.1	1.00
A.10.04.001	Candies, with sugar	3	40	0.001	0.01
A.10.04.011	Liquorice candies	3	40	0.001	0.13

Example

f1 - Conversion factor converting the food or ingredient consumed into the raw material to which food enzymes are directly added

f2 - Ingredient fraction reflecting the amount of ingredient in the food as consumed in which the food enzyme is present

f3 - Fraction of food items containing the ingredients of interest within the total food category

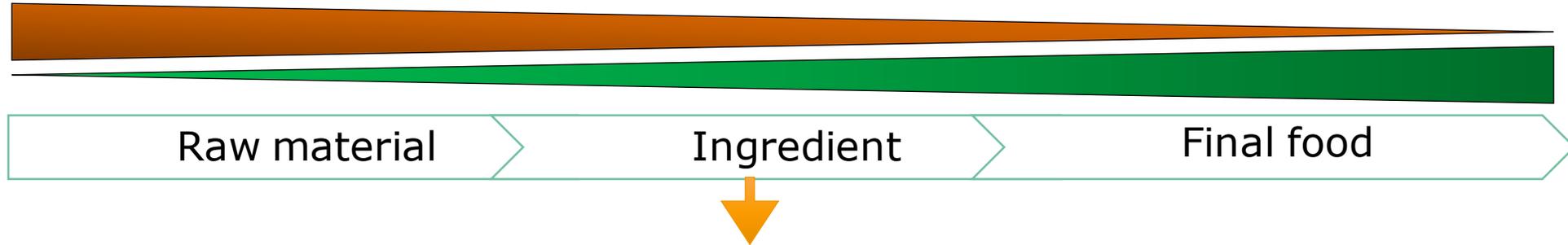
- When $f3 = 1$, this factor does not appear in a call-for-data

f3 is GNPD assisted

- Process specific FoodEx food categories are selected from the Comprehensive Database
- Selection is influenced by:
 - Raw material to which FE is added
 - Ingredient search on GNPD Database from Mintel
 - RPC (Raw Primary Commodity) database search
 - Other open sources
- Subject to feedback mechanism via open call for stakeholders prior to finalisation of individual process evaluation and process specific tool

Enzyme use level
[Applicant's dossier]

Food consumption data
[EFSA Comprehensive Database]



**Factors
f1 & f2**

- Data conversion (recipes, ingredient fractions, technical factors (e.g. concentration, dilution, yield), conversion from processed to raw, etc.)
- Various sources (e.g. FAO, RPC, open sources) – subject to feedback mechanism via open call



TOS per final food x consumption of final food

TOS per ingredient x consumption of ingredient

TOS per raw material x consumption of raw material

- Factor f3 is only used in those cases when only a certain percentage of food products within a larger food category are likely to contain the food enzyme.
- This factor is derived by using the Mintel Global New Products Database.
- Factor f3 represents the fraction of food items containing the ingredient of interest (as declared on the product label) within the total food category searched.

For example, only a certain fraction of biscuits within the overall category of “biscuits with cream filling” are likely to contain coffee.

$$\text{Factor f3} = \frac{\text{the number of biscuits declaring coffee as ingredient}}{\text{the total number of biscuits listed in the food category}}$$



Commission Implementing Regulation (EU) No 562/2012

Explanation to the Article

(4) With regard to the toxicological properties of enzyme preparations, the SCF guidelines indicated that food enzymes which are derived from edible parts of (non-genetically modified) plants and animals are generally considered as posing no health problems. According to the guidelines no special documentation for safety needs to be supplied provided that the potential consumption under normal use does not lead to an intake of any components which is larger than can be expected from normal consumption of the source as such, and provided that satisfactory chemical and microbiological specifications can be established.

(5) The European Food Safety Authority ("the Authority") has also indicated in its guidance on data requirements for the evaluation of food enzyme applications that the justification for not supplying toxicological data for food enzymes from edible parts of animals and non genetically modified plants may include a documented history on the safety of the source of the food enzymes, the composition and the properties of the food enzyme as well as its use in food which demonstrates no adverse effects on human health when consumed in a comparable way, supported by any existing toxicological studies. Therefore, the enzyme application for food enzymes from such edible sources should not be required to include toxicological data.

Two sets of intake estimate: FE-TOS, SMT-equivalent

	Exposure to the FE-TOS from foods produced through a food process	Intake of source material TOS equivalent
Concentration data	TOS in raw material (e.g. vegetable peels)	Plant source: vegetable peels
	Provided in dossier	Edible from literature, recipe, etc
Consumption data	EFSA comprehensive Database (Individual food consumption data, six age groups)	
Food selection	Foods produced from intended processes	Foods containing or produced from the vegetable
Technical factors	f1, f2	f1, f2, enzyme yield factor
	Consolidated via open call-for-data	The yield factor is provided by an applicant. It refers to the amount (x kg) of food enzyme typically obtained from the amount (y kg) of the vegetable peels.

When the food enzyme is used in a **single** food process

- **Use FEIM calculators** (available at https://zenodo.org/search?page=1&size=20&q=FEIM*&file_type=xls)
- **Report the result in a table format**

When the FEIM calculator is not available

- **Applicants to provide as much details on the process**
 - Specific raw material, food groups, use levels and yield factors, etc.
- **These details will aid EFSA to estimate and to develop additional calculators.**

When the food enzyme is used in two or more food processes that requires calculation

- **EFSA will calculate the combined exposure**