Exposure Assessment of Food Enzymes

Ad-hoc meeting with industry association AMFEP
Parma, 18 August 2016

efsa
European Food Safety Authority

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Discussion item

1) Welcome and scope of this meeting
2) Food enzyme exposure estimation
   - EFSA approach
   - AMFEP proposals
3) Round-table discussion
   - Estimation tool development
   - Dossier evaluation
4) Closing remark and summary

EU Food Enzyme* risk assessment paradigm

Characterisation of food enzyme:

- Production organism,
- Raw materials
- Manufacturing process
- Chemical composition
- Physico-chemical properties

Identification of adverse effects to human health:

- NOAEL/BMDL

Potential hazardous compounds, e.g.

- Food enzyme itself
- Natural constituents and/or contaminants of the production organism and/or the raw materials
- Chemicals that are added initially and carried over during enzyme manufacturing process

Quantitative estimate of exposure to the collective of these compounds

- Taking into account the fate of the food enzyme during processing

Characterisation of any risk to consumers, associated with exposure

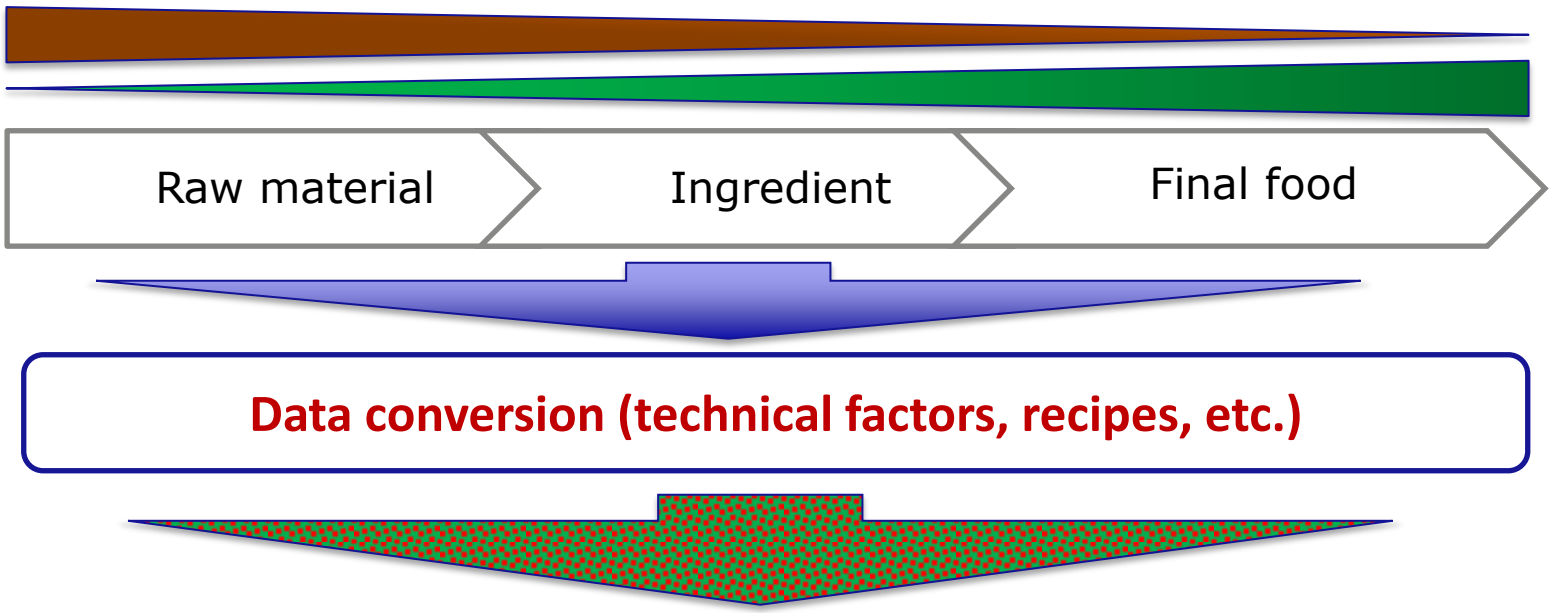
- MoE or
- Comparable intake from plant/animal sources & "history of safe use"

*as defined in Reg (EC) No 1332/2008
Reference: EFSA CEF Panel Guidance 2009

Challenge in food enzyme exposure assessment: data compatibility

Enzyme use level
[Applicant's dossier]

Food consumption data
[EFSA Comprehensive Database]



Simplified concept

Departure from the recommended Budget Method

- Risk assessment of EFSA shall cover general population in Europe
  - Budget method is likely to be conservative for adults, but not for toddlers.

	Comprehensive Database P95 min-max (g/kg bw per day)		Budget method (g/kg bw per day)
	Adults	Toddlers	
Total solids	20-30	62-92	50
Processed solids	9-18	33-68	25

- Dietary survey-based consumption data is now available in most EU countries, and for different age groups.
  - Measured versus extrapolated
  - More and more used in the assessment of regulated products (e.g. additives, pesticides)
  - Harmonised data collection methodology being implemented
  - Permits "drill down" (e.g. for refinement purposes)
- Process-based approach can be facilitated

Food Enzymes - Food Processes

EC guidance document to harmonise description of food processes in which food enzymes are intended to be used

- Baking processes
- Brewing processes
- Cereal-based processes
- Coffee processing
- Confectionery processing
- Dairy processing
- Distilled alcohol production
- Egg processing
- Fats and oils processing
- Flavouring production
- Fruit and vegetable processing
- Grain treatment and starch processing
- Protein processing
- Savoury snacks processing
- Sugar processing
- Tea processing as well as Herbal and fruit infusions processing
- Wine production
- Yeast processing

Source: EC Guidance document describing the food processes in which food enzymes are intended to be used

An example of Food Enzymes - Food Processes – Food Categories

Biscuits
Fine bakery wares
Confectionary

Baking process

Bread

Malt drink,
Soup cereal …

Dough

Pasta

Decorations, coatings, fillings

Grain

Flour

Cereal process

Soft drinks

Starch

Starch process

Starch hydrolysates
(e.g. glucose syrup)

Sauces
Jams
Jelly…

Bran/flake

Breakfast cereal
Muesli, snacks

Cereal process

Brewing process

Beer

Wort

Distilled alcohol

Cereal-based distilled alcohol

Simplified scheme showing main steps only

☆ = addition of food enzyme

Example of Technical factors (Brewing & Baking)

FoodEx code	FoodEx category	FAO conversion factor from FoodEx food group to raw material[(a)]	Recipe fraction	mg TOS/kg barley or flour
A.01.03.001.001	Wheat flour, brown	1	1	20
A.01.03.001.002	Wheat flour, durum	1	1	20
A.01.03.001.003	Wheat flour, white	1	1	20
A.01.03.001.004	Wheat flour, wholemeal	1	1	20
A.01.03.001.005	Graham flour	1	1	20
A.01.04	Bread and rolls	1	0.7	20
A.01.04.001	Wheat bread and rolls	1	0.7	20
A.01.04.005.007	Pita bread	1	0.7	20
A.01.07.001.004	Cheese cream cake	1	0.24	20
A.01.07.001.005	Cheese cream sponge cake	1	0.24	20
A.01.07.001.016	Croquembouche	1	0.25	20
A.01.07.001.019	Flan	1	0.5	20
A.01.07.001.020	Fruit cake	1	0.6	20
A.01.07.001.029	Profiterole	1	0.15	20
A.01.07.001.048	Baklava	1	0.15	20
A.01.07.002	Biscuits (cookies)	1	0.9	20
A.01.07.002.002	Biscuits, chocolate filling	1	0.81	20
A14.01	Beer and beer-like beverage	1.37	0.19	250
A.14.01.001	Beer, strong	1.37	0.19	250
A.14.01.002	Beer, regular	1.37	0.19	250
A.14.01.005	Beer-like beverages (malt drink)	1.37	0.19	250

BREWING & BAKING

The following assumptions were made in converting food as consumed to the raw material:

- Consumption of beer and beer-like beverages was converted to intake of raw barley grain, by assigning a factor of 0.19 to account for the amount of malted barley required to produce 1 L beer, and a factor of 1.37 to convert malted barley to barley grain.
- Consumption of bread was converted to intake of flour, generally assuming a 70% flour content in baked bread.
- Fine bakery ware was converted to intake of flour, taking into account a varying proportion of fillings, decorations and coatings (range 10–50%) and a varying degree of flour content, based on the type of pastry/dough (range 25–90%).

Example: Flour consumption from foods obtained from baking process

	Infants	Toddlers	Children	Adolescents	Adults	Elderly
	Range (min-max) of estimated exposure in g/kg bw per day across surveys per population group (number of surveys)					
Mean	0.3–2.8 (6)	2.2–6.2 (10)	2.9–6.0 (18)	1.5–3.9 (17)	1.1–2.4 (17)	1.1–2.0 (14)
P95	3.0–7.6 (5)	5.1–10.9 (7)	5.1–11.1 (18)	2.9–7.9 (17)	2.1–4.6 (17)	2.0–3.6 (14)

Way forward

- EFSA/Enzyme WG to calculate exposure for existing dossiers, using individual data from the Comprehensive Database

- EFSA/Enzyme WG to develop a process based estimation tool for future applications, based on summary statistics from the Comprehensive Database.

Round Table Discussion

Round-table Discussion

- Estimation tool development
  - Technical factors
  - Stakeholder engagement
- Dossier evaluation

Tool development

EFSA to develop a process based tool, based on summary statistics for future applications

- Publically accessible by all interested parties
- Validated by individual data extracted from the Comprehensive Database
- Allows the possibility to combine different usage data with the corresponding food process
- Same source of consumption data for screening and further refinement
- Necessary information to be derived from scientific sources, open sources and in collaboration with stakeholders

Dossier Evaluation

Development of the tool facilitates dossier evaluation

- The tool is food process based
- Information on food process (provided in the dossier) needs alignment with the harmonised definition of food process (EC guidance)
- Once a process evaluation is finalised, rapid assessment of applications cluster by process type would be possible
- Enzyme WG to calculate exposure for existing dossiers using Comprehensive Database, during the tool development

Summary

Two parallel activities

Finalisation of the statement		Assessment of FE applications
▪ The CEF Panel to revise the statement, taking account of comments / proposals received	EFSA to seek for input from stakeholders on technical information	▪ EFSA together with EC to define a work program
▪ EFSA to publish a technical report on the analysis of these comments		▪ The CEF Panel to assess received applications and adopt opinions

Thank you for your attention!

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