Challenges in the estimation of exposure to food enzymes

Karl-Heinz Engel
CEF Panel Member

Info Session on Applications – Food Enzymes – Technical meeting with stakeholders on refinement of exposure estimates

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CHALLENGES IN EXPOSURE ESTIMATION TO FOOD ENZYMES

1. • Harmonisation of food processes terminology and definitions
2. • Translation of food processes into specific food categories
3. • Establishment of conversion factors
4. • Fate of constituents of the food enzyme in the final food
5. • Summary statistics *vs.* individual consumption data

1. HARMONISATION OF TERMINOLOGY AND DEFINITIONS OF FOOD PROCESSES

- Harmonisation of the terminology and the definition of food processes is needed at the first stage of the evaluation.
- EC is working, in collaboration with industry, on a working document for the harmonisation of the terminology of food processes.
- Different sources of information for food technology can support this area such as text books, open and grey literature, and databases.
- Clarifications if needed from the applicants

2. TRANSLATION OF FOOD PROCESSES INTO SPECIFIC FOOD CATEGORIES

- It is imperative for each application to translate the proposed food processes into specific food categories from the FOODEX 1 classification.

- In many applications the proposed uses are mentioned as processes but not the related foods in which the food enzyme will end up.

- Different sources of information for food technology can support this area such as food industry, text books, open and grey literature, and databases.

GROSS INDICATIVE USES OF FOOD ENZYMES

Production of beer and other cereal based processes

The same ???

Production of cereal based distilled alcoholic beverages

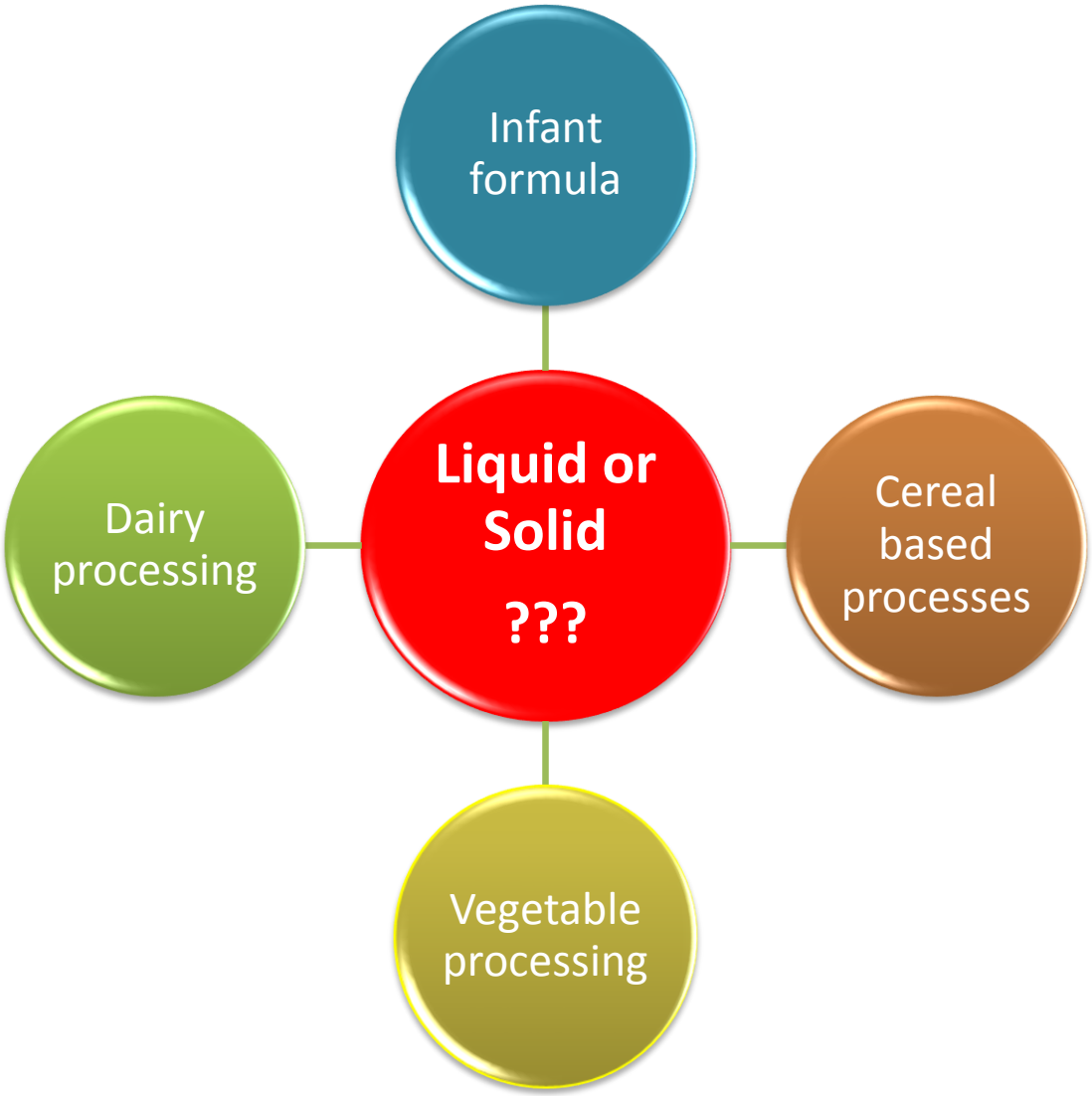
?

Milk and dairy processing

The same ???

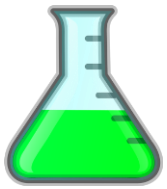
Milk processing

GROSS INDICATIVE USES OF FOOD ENZYMES



3. ESTABLISHMENT OF CONVERSION FACTORS: Pathway of FEs exposure

Food Enzyme → Substrate or raw material → Final food → Consumption



Occurrence → Consumption

3. ESTABLISHMENT OF CONVERSION FACTORS: Data requirements

Food Enzyme → Substrate or raw material → Final food → Consumption

Data ? **Data ?** **Data ?**

Applicant | **Industry Food Technology** | **EFSA DB**

Dose per substrate or raw material

Recipes for Related Foods

Dose per Final Food

CONVERSION FACTOR

Consumption data

Consumption data

Occurrence → **Consumption**

3. ESTABLISHMENT OF CONVERSION FACTORS: Affecting Parameters

Conversion factors for food enzymes are influenced by several parameters:

- Food processes in which they are used
- When the food enzyme is used during the process
- Target substrate on which the enzyme exerts its function
- Food categories covered by the food process

4. Fate of constituents of the food enzyme in the final food

Food Enzymes are not single substances but mixtures of active enzyme(s), by-products, contaminants, remainders of raw materials, etc.

SCF report (1991): "The combined information from the general specifications and this test battery (toxicological) make it possible to evaluate the **product** for the presence of both specific, well known toxins and unknown toxic compounds".

Considering the possible existence of unknown toxic compounds, proof of absence is *per se* not possible by analytical methods.

However, the assumption of the absence of food enzyme constituents in the final food may be acceptable in particular cases, where there is supporting sound scientific information available.

5. Summary statistics vs. individual consumption data

The EFSA Comprehensive European Food Consumption Database

The Comprehensive Food Consumption Database is a source of information on food consumption across the European Union (EU). It contains detailed data for a number of EU countries. The database plays a key role in the evaluation of the risks related to possible hazards in food in the EU and allows estimates of consumers' exposure to such hazards, a fundamental step in EFSA's risk assessment work. The database will also be relevant in future for other fields of EFSA's work, such as the assessment of nutrient intakes of the EU population.

- Guidance for the use of the EFSA Comprehensive European Food Consumption Database

EFSA used its food classification system 'FoodEx' to categorise all foods and beverages included in the Comprehensive Database.

- Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database

Summary statistics from the database ena ble quick screening for chronic and acute exposure to substances and organisms that may be found in the food chain. In the database, dietary surveys and food consumption data for each country are divided by category. These include: age, from infants to adults aged 75 years or older; food group (over 1,500) and type

5. Summary statistics vs. individual consumption data

EFSA has made publically available the summary statistics but not the individual data of the EFSA Comprehensive Consumption Database.

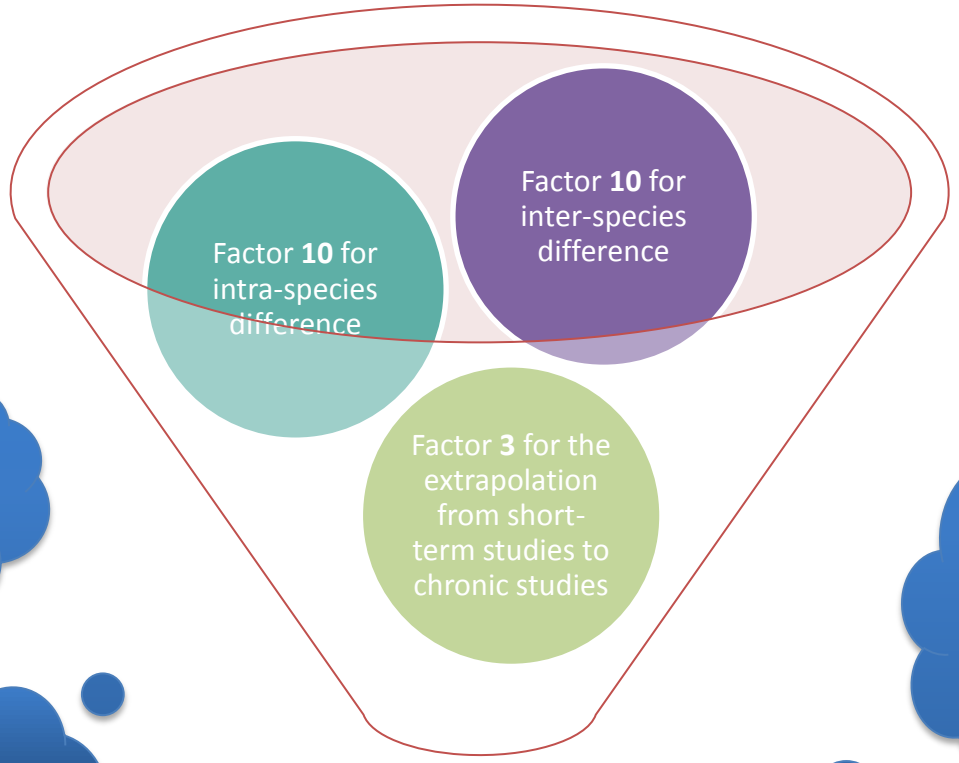
EFSA explores the possibility to develop sooner a possible model for the intake of food enzymes, similar to the Food additives Intake Model (FAIM).

Then a model template can be developed and used for the estimation of exposure to food enzymes as a first step in the dietary exposure assessment process by applicants, risk assessors as well as risk managers.

Infants special consideration – Milk consumption

- The budget method was developed without taking milk into consideration as food additives were not to be used in milk.
- In case of food enzymes that are not going to be present in milk and milk-based beverages this concept is compatible.
- However, there is a number of food enzymes that are to be present in these products; then special considerations should be made (e.g. use of Tier 2A)

MARGIN OF EXPOSURE = NOAEL / EXPOSURE



Expert judgement

Completeness and quality of data

Safety assessment on a case-by-case basis

MoE

Thank you !