Further proposals from Amfep on the tiered enzyme exposure assessment method

Amfep

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Agenda

How enzymes are used in food processing

Factors affecting the exposure model

Using the Factors in the tiered method

Next steps

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Enzyme use in food processing: a unique technical background

Enzymes are not added to final foods

They can be used at various stages of food processing, to manufacture ingredients or final foods

Diverse factors affect how much TOS can be expected to be ingested by mean and high consumers in all age groups

These factors must be used to ensure a realistic, refined exposure assessment

(be it based on the Budget Method or on the use of the Consumption Database)

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The suggested factors

Factor 1 **Enzyme use level**	The amount of enzyme (expressed as TOS) used in the processing of the food or food ingredient. The value can be set at Maximum[1] or Typical[4]
Factor 2 **Processing**	The amount of residues (TOS) remaining in the food/food ingredient after accounting for the effects of processing. The value can be set at Maximum[2] or Default[3].
Factor 3 **Ratio Raw Material to Final Food (RM/FF)**	The ratio between the amount of enzyme treated raw material and its presence in the final food as presented to the consumer. The value can be set at Default[3]
Factor 4 **Occurrence**	The percentage of food within a category that is produced with the specific enzyme taking among others production habits and market share into consideration. The value can be set at 100% or Default[3].
Not applicable to enzymes:	
Brand Loyalty	*Reflecting the likelihood that a specific enzyme treated food is chosen in a longer time thereby presenting the consumer for fixed values of enzyme treated food (factor 1 and/or 4) in the specific food.*

Notes

1 Maximum enzyme use levels (expressed as TOS) as reported in the submitted dossiers.
2 Maximum amount of TOS remains in the food/food ingredient after processing.
3 Default values based on agreed standard conservative assumptions, when no specific data are available.
4 Typical enzyme use levels (expressed as TOS) taking into account all enzyme use levels for specific applications.

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Using the factors in the tiered method

Tier 1 'Budget Method'

Factor	Value
Enzyme use levels	Maximum[1]
Processing	Maximum[2]
Ratio raw material to final food (RM/FF)	Default[3]
Occurrence	100%

Tier 2 'Budget Method' with standard factors

Energy intake	50 kcal/kg bw
Processed Food factor	50%

Factor	Value
Enzyme use levels	Maximum[1]
Processing	Maximum[2]
Ratio raw material to final food (RM/FF)	Default[3]
Occurrence	100%

Notes

1 Maximum enzyme use levels (expressed as TOS) as reported in the submitted dossiers.

2 Maximum amount of TOS remains in the food/food ingredient after processing.

3 Default values based on agreed standard conservative assumptions, when no specific data are available.

4 Typical enzyme use levels (expressed as TOS) taking into account all enzyme use levels for specific applications.

Tier 2a Comprehensive method

Factor	Value
Enzyme use levels	Typical[4]
Processing	Default[3]
Ratio raw material to final food (RM/FF)	Default[3]
Occurrence	Default[3]

Tier 2b Refined 'Budget Method' with standard factors

Energy intake	50 kcal/kg bw
Processed Food factor	50%

Factor	Value
Enzyme use levels	Typical[4]
Processing	Default[3]
Ratio raw material to final food (RM/FF)	Default[3]
Occurrence	Default[3]

Factor 1: Enzyme use levels

Actual enzyme use levels vary according to (a.o.)

- Raw material characteristics
- Process conditions (pH, temperature, time)
- Enzyme costs

Enzyme users optimize enzyme doses based on the most relevant constraints

Actual enzyme use levels are much lower than the maximum recommended dosages

Proposal for Factor 1

Tier 1 and Tier 2: Maximum use levels for all food categories

Tier 2a/b: Typical use levels for all food categories

Factor 2: Processing

Certain unit operations in food processes may eliminate the TOS

Examples

- Beverage alcohol production (distillation)
- Flavoring substance production (distillation)
- Grain processing (washing steps)
- Starch processing (ion exchange and carbon treatments)
- Oil degumming (washing, centrifugation, deodorisation)
- Sugar production (crystallisation and washing)
- All immobilized enzyme uses

Proposal for Factor 2

Amfep has developed a set of conservative default values for Factor 2, for each of the food processes listed in the Commission guidance document

Factor 3: Raw materials to final foods ratio

Enzymes are usually dosed relative to a raw material

The concentration of TOS in the final food depends on

- The amount of TOS present in the raw material (Factor 2)
- The amount of the raw material present in the recipe for the final food

The amount of raw material needed to produce a certain amount of food is the RM/FF ratio

Proposal for Factor 3

AMFEP has developed a set of conservative default values for Factor 3 which have been used in the submitted dossiers

Factor 4: occurrence

A given applicant cannot be expected to procure the whole market

Not all foods produced by a given process are produced:

- with the enzyme under consideration, or
- with enzymes, e.g.:
  - The technological need of enzymes is not always absolute: degumming of oil, protein processing, production of coffee, tea, sugar, wine is not systematically done with enzymes
  - Food standards may prevent the use of enzymes (e.g. Reinheitsgebot for German beer)
  - Local regulations may prevent the use of enzymes (e.g. ‘pain de tradition française’)

Proposal for Factor 4

Use validated (EU Commission and MS, food industry) production statistics to generate conservative estimates of the proportions of foods that are not produced with enzymes

Brand loyalty

Consumer brand loyalty does not influence the exposure assessment for food enzymes, since enzymes are not added to final foods

The supply chain is complex:

- Food manufacturers source food ingredients from several suppliers
- Food ingredients manufacturers source enzymes from several suppliers

Therefore even a brand-loyal consumer will not be exposed to the same food enzyme over a significant time period

Proposal for Brand loyalty

There is no need to consider consumer brand loyalty as a factor in enzyme exposure assessment

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Next steps: Amfep's suggestions

EFSA to use Amfep's expertise when refining the exposure assessment method

- General approach, decision criteria
- Use of factors
- Adapt the comprehensive model used in Tier 2a to enzyme exposure evaluation

The result must be an operational, realistic and predictable method, easily usable by applicants and EFSA