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EFSA Guidance on the Submission of a Dossier on Food Enzymes for Safety Evaluation: Technical data

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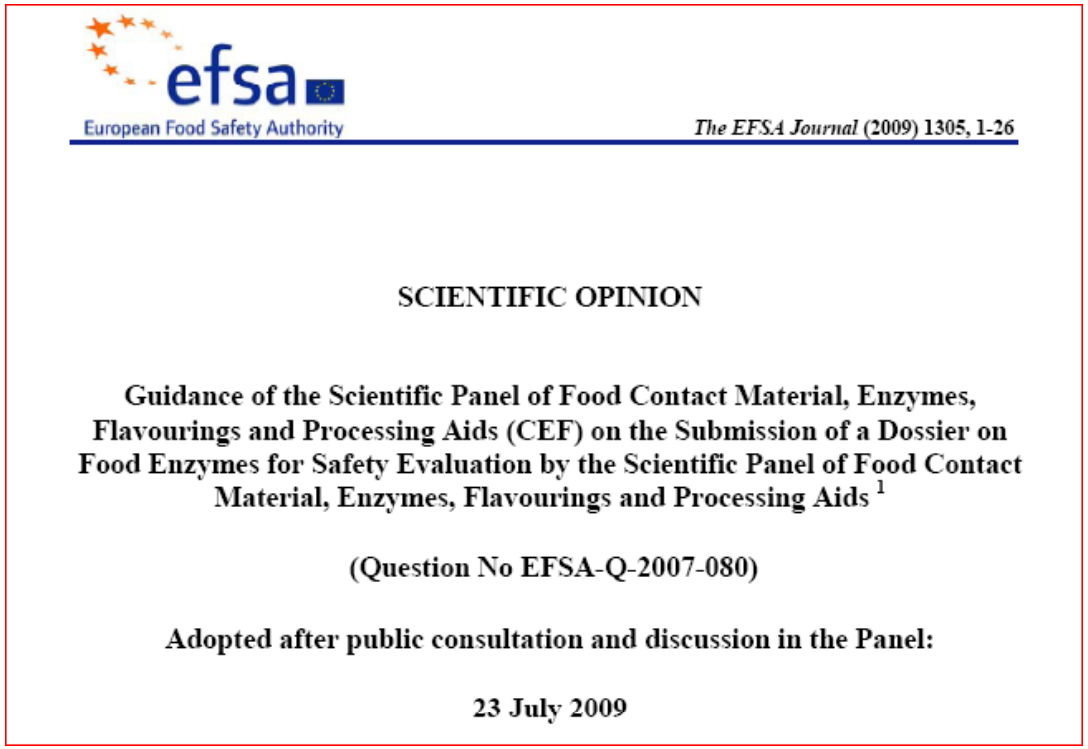
EFSA Info session on Food Enzymes
Parma, 17 January 2013

2009 Guidance document by the CEF Panel



European Food Safety Authority

The EFSA Journal (2009) 1305, 1-26

SCIENTIFIC OPINION

Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes for Safety Evaluation by the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids [1]

(Question No EFSA-Q-2007-080)

Adopted after public consultation and discussion in the Panel:

23 July 2009

http://www.efsa.europa.eu/en/efsajournal/pub/1305.htm

Technical data

Identity of the Food Enzyme

1. Name(s), Synonyms, Abbreviations and Classification(s)

- Common Name(s) and/or Trade Name(s) *(if applicable)*
- Enzyme Classification Number of Enzyme Commission of the International Union of Biochemistry and Molecular Biology (IUBMB) *(if applicable)*
- Chemical Name(s) *(if applicable)*
- Chemical Abstract Service (CAS) Registry Number *(if available)*
- European Inventory of Existing Chemical Substances Number (EINECS) or European List of Notified Chemical Substances Number *(ELINCS) (if available)*

Technical data

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Identity of the Food Enzyme

2. Chemical Composition

- Molecular mass and subunit structure; and amino acid sequence (if available)
- Chemical description including chemical purity and identity
- Information if modified by post translational or technological procedures
- Information if protein engineered, rational and nature of the modification
- Data on the batch-to-batch variability for the relevant parameters
- Data on the reproducibility for relevant parameters
- Any other useful information such as Total Organic Solids (TOS)

Technical data

European Food Safety Authority

Identity of the Food Enzyme

3. Proposed Chemical and Microbiological Specification

The proposed specifications should be submitted in a format modelled on recent EU or other internationally accepted specifications.

Technical data

Identity of the Food Enzyme

4. Properties of the Food Enzyme

- Information on the principal enzymatic activity
- The activity of the food enzyme under the conditions of the intended use and the influence of reaction conditions
- Any subsidiary/side activities
- Data on food enzyme stability

Technical data

Source Materials and Manufacturing Process

1. Production from animal sources

- Which animal tissue and information on previous consumption and if documented history of safe use
- Compliance with meat inspection requirements and handling in accordance with good hygienic practice
- Methods used to ensure absence of any risk of infectivity
- Data on non-infectivity based on the classification of the tissues in terms of their infectious titre in natural diseases

Technical data

Source Materials and Manufacturing Process

2. Production from plant and basidiomycete sources

- The part(s) of the plant or basidiomycete fruiting bodies/mycelia used
- Information on previous consumption and if documented history of safe use
- Methods used to ensure absence of any risk
- If a genetically modified plant or fungus is used, information on the organism in accordance with the GMO guidance document

Technical data

Source Materials and Manufacturing Process

3. Production from microbial sources

- Information about the strain used for food enzyme production
- For GMM, the presence of any factor(s) affecting the genetic stability of the producer strain
- Monitoring of production strain
- Production strain pathogenicity, toxigenicity and antimicrobial resistance

Technical data

Source Materials and Manufacturing Process

4. Manufacturing Process

- Description of key steps involved in the production process
- Description of operational limits including process controls and quality assurance procedures
- If used, information on the immobilisation procedure
- Other relevant information (i.e. nanotechnology?)

Technical data

Reaction and Fate in Food

- Fate of the food enzyme during food processing
- Behaviour of the food enzyme in the food matrix
- If needed, demonstrate the inactivation of both the principal and subsidiary/side enzymatic activities in the final food
- Information on possible adverse effects on nutrients
- Data on any possible effects on existing micro-organisms in food

Technical data

Case of Need and proposed Conditions of Use

- The technological need/purpose and intended use
- The mode of action and reactions catalysed
- The type of foodstuffs to be added to specific foods
- The amount of food enzymes to be added
- The conditions of its use in food processing

Technical data

Dietary Exposure

- Potential human exposure to the food enzyme and to any other constituent or by-product of concern

- A conservative technique such as the “budget method” should be used to assess potential dietary exposure in a standard adult of 60 kg bw. If needed, it should be adapted to consider the potential higher consumption in children.

- If food enzyme is proposed for products specifically designed for infants (0-12 months) or young children (12-36 months), *ad hoc* conservative exposure estimates must be produced.

Technical data

Existing authorisations and evaluations by other official bodies

- National authorities within the EU, i.e. French, Danish,…