



EFSA Explanatory Note for the Guidance on the Submission of a Dossier on Food Enzymes

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EFSA Info session on Applications – Food Enzymes – Technical meeting with Applicants

Parma, 17. January 2013

Food Improvement Agents Package (FIAP)



Regulation (EC) No 1331/2008 on a common authorisation procedure for food additives, food enzymes and food flavourings

OJ L 354, 1-6 (2008)

Regulation (EC) No 1332/2008 of the European parliament and of the Council of 16. December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97

OJ L 354, 7-15 (2008)

Commission Regulation (EU) **No 234/2011**.. Implementation Regulation (EC) No 1331/2008 Establishing a common authorisation procedure for food additives, food enzymes and food flavourings

OJL 64/15 (2011)

Commission Implementation Regulation (EU) **No 562/2012** with regard to specific data required for risk assessment of food enzymes

OJL 168/21 (2012)



Key to authorisation

- Proof of food safety requires studies
- Data must be established
- Valid data are needed

No valid data, no risk assessment, no authorisation, no entrance to market

Safety evaluation of food enzymes Efsa Documents



Guidance of the CEF-Panel on the submission of a Dossier on Food Enzymes for Safety Evaluation...

EFSA Journal (2009) 1305, 1-26 http://www.efsa.europa.eu/en/efsajournal/pub/1305.htm

Explanatory Note for the Guidance of the CEF-Panel on the Submission of a Dossier on Food Enzymes

Supporting Publication 2011:177 http://www.efsa.europa.eu/en/supporting/pub/177e.htm

Guidance on the risk assessment of genetically modifed miroorganisms and their products intended for food and feed use

EFSA Journal 2011,9: 9(6): 2193

http://www.efsa.europa.eu/en/efsajournal/pub/2193.htm

Technical Report of EFSA



Explanatory Note for the Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes

Supporting Publication 2011; 177

Prepared by the working group on enzymes, Reviewing trial dossiers on amylase from B. licheniformis and amylase A. niger prepared by AMFEP

3.1.2 Chemical Composition



The following should be provided:

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Molecular mass, subunit structure, amino acid sequence (if available)

Comments/Explanation

today, it should be feasible to provide the amino acid sequence

Chemical description of the food Enzyme as tested...

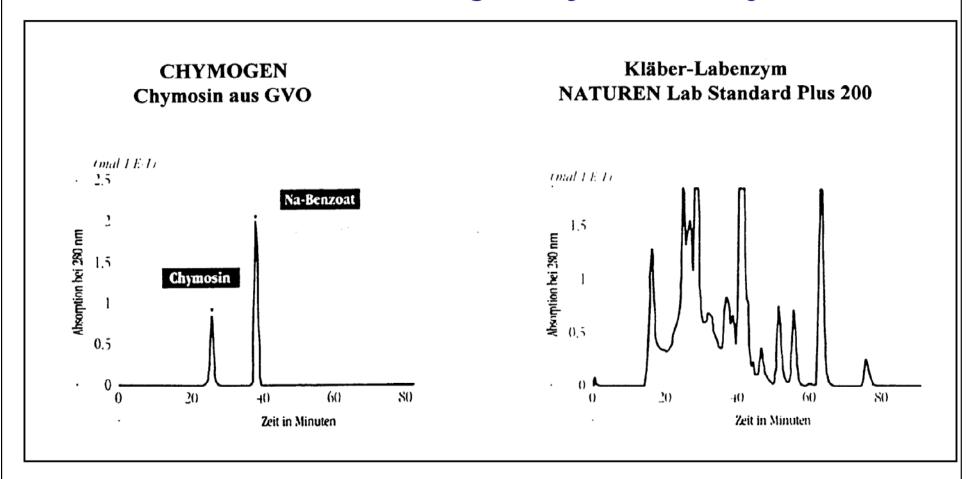
Degree purity and identity: prorelevant chromatographic or electrophoretic data

Impurities should be identified Analysis methods should be standardized/validated, provided in the annexes

3.1.2 Chemical Composition



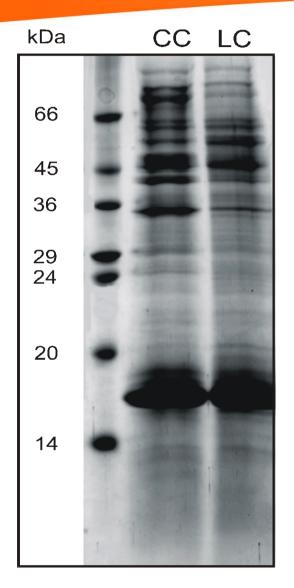
Demonstration of the homogeneity of an enzyme



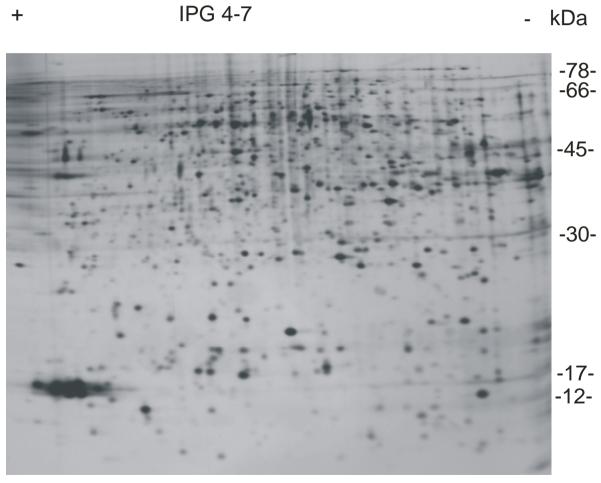
Chr. Hansen

Electrophoresis





Enzyme extracted from beans



3.1.2.1 Properties of the Food Enzyme



The following should be provided:

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Information on the principal enzymatic activity, specifying substrates, reaction products, cofactors

Any subsidiary / side activities Should be characterized, if Possible and where appropriate

Comments/Explanation

Information must refer to the specific characteristics of the food enzyme.

Determination methods for measurements of the enzyme activities should be provided. If Possible, correlation to international units should be made

Indicate also the presence of other significant enzyme activities present in the food enzyme

3.2.2 Manufacturing Process



The following should be provided:

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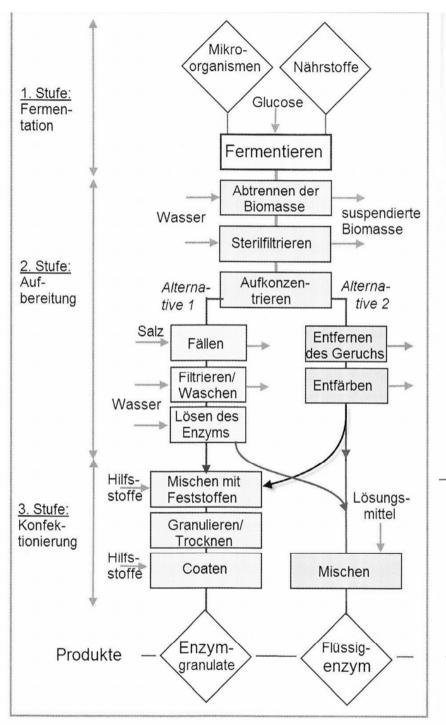
The production process for the food enzyme should be described as completely as possible. A flow chart diagram showing the most important steps in the process should accompany the description.

Comments/Explanation

Describe in detail the key steps Provided specifications of the agents and reagents used

No trivial textbook diagram

Identify critical steps in fermentation, recovery, separation, purification (HACCP)





Flow chart diagram

W. Rähse, (2012) Chem.Ing.Tech.84. 2152-2163

3.4 Case of Need and proposed Conditions of Use



The following should be provided:

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The type of food stuffs in which the food enzyme is intended to be used.

Comments/Explanation

The food categorization system ((EC) No 1665/2000 Annex III,) is not specifically developed for food enzymes. To assess consumer exposure and safety of margin it is necessary to identify the types of foods/food processes in which the enzyme is intended to be used.

4. Toxicological Data





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Comments/Explanation

i. Assessment of genotoxicity

The tested batch should be characterized. Evidence must be provided that the tested batch is representative for commercial food enzyme.

Original study reports must be provided and any effect detected must be reported and commented.

Dose selection must be justified.

ii. Assessment of systemic toxicity



Enzyme grouping

Waiving of toxicological testing

Commission Implementation Regulation (EU) No 562/2012

with regard to specific data required for risk assessment of food enzymes



Thank you for your attention

Questions?

Answers here!

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