Joint dossiers

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Trusted science for safe food

efsa
European Food Safety Authority

Legal basis

Possibility of developing joint dossiers derives from:

Reg. (EU) No 562/2012 *amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes*

Legal basis

Article 1:

5. Food enzymes may be grouped under one application provided that they have **the same catalytic activity**, **are processed from the same source material** (e.g. at species level) and **with a substantially same production process**, and have been obtained from:

(a) edible parts of plants or animals intended to be or reasonably expected to be ingested by humans; or

(b) micro-organisms having the status of Qualified Presumption of Safety; or

(c) micro-organisms which have been used in the production of food enzymes that have been evaluated and authorised by the competent authorities in either France or Denmark.

Legal basis

However, the preamble to Reg. (EU) No 562/2012 states:

8) With regard to grouping of specified food enzymes in one application, the Authority has already indicated in its guidance on data requirements for the evaluation of food enzyme applications that specified food enzymes with the same catalytic activity, produced by the same micro-organism **strain** and by the substantially same manufacturing process may be grouped in one application, even if as a rule each individual food enzyme must be assessed.

Number of joint dossiers

- **Microbial products**
  - Bacteria – 6
  - Filamentous fungi/yeasts – 10
- **Plants** – 2 (proteases: papain and bromelain)
- **Animals** – 3 (lipase, lysozyme, rennet)

Food enzymes from non-GM microorganisms

- The risk assessment is always made considering the production **strain**
- In principle each assessment requires strain-specific data on the origin, manufacture, characterisation, toxicology and exposure
- Therefore it is difficult to see how the contents of the joint dossiers would differ from the individual submissions.

Food enzymes from plants & animals

- The risk assessment is made considering the plant/animal species from which the food enzyme is extracted
- Each assessment requires data on the individual manufacturing process and characteristics of the food enzyme
- Allergenicity assessment is generic and no other toxicological studies are envisaged
- Exposure to the food enzyme is related to the food-equivalent and is generic.

Conclusion: there is sufficient generic information to allow risk assessment of joint dossiers

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