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Characterisation of food enzymes. Frequently missing information

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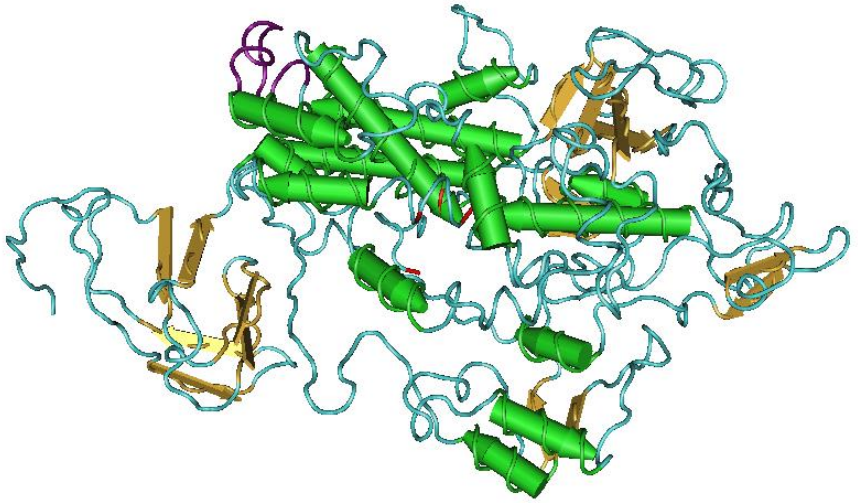
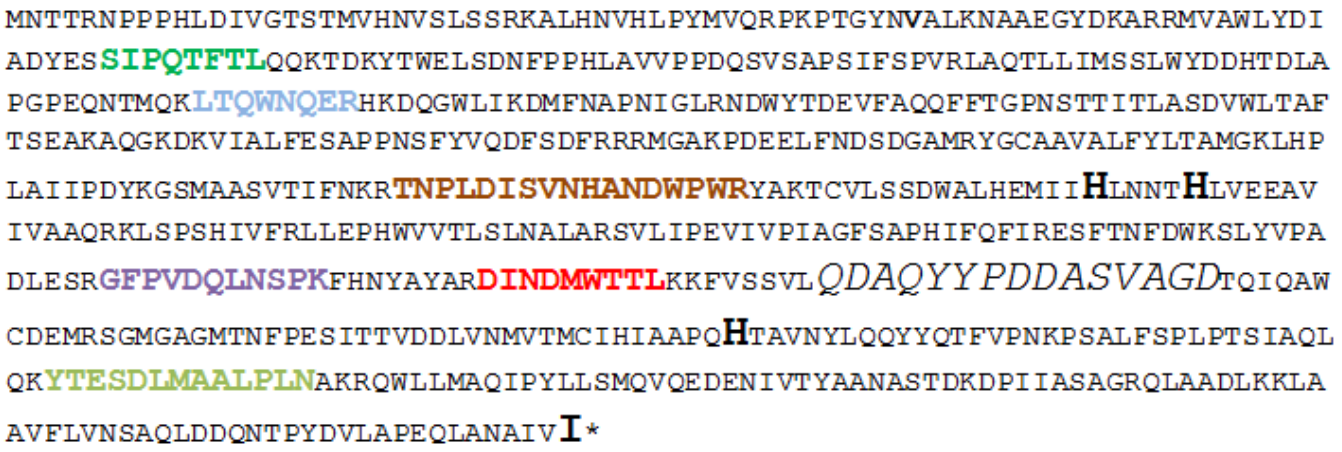
Overview – technical aspects of enzyme evaluation

- Information that is often missing or incomplete in applications
- Food enzyme vs. food enzyme preparation
- Immobilised enzymes
- Enzymes used as raw materials



Information often missing/incomplete in applications

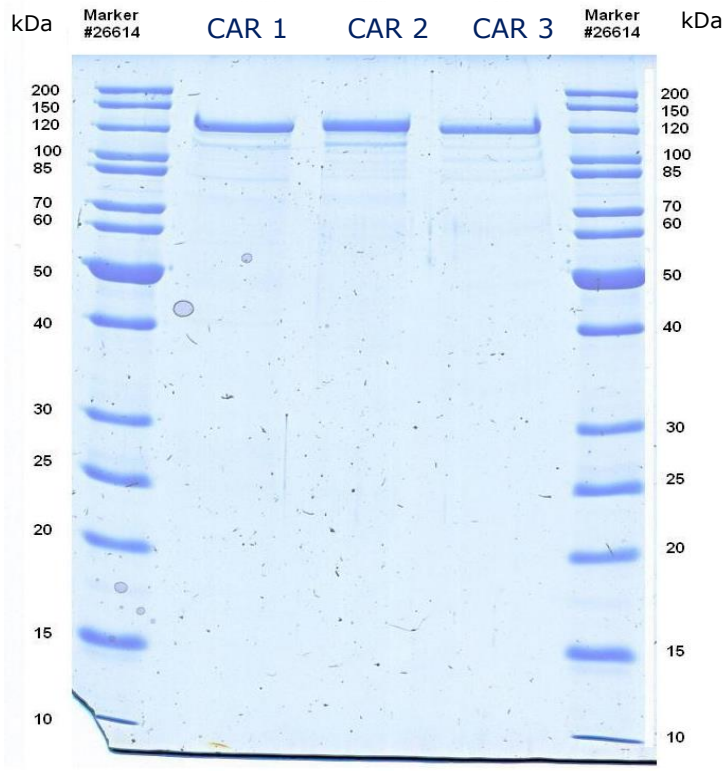
- Certificate of Analysis for all relevant chemical and microbiological parameters[1]
- Exact amino acid sequence of the FE under assessment
- Calculation of the molecular mass from the cDNA sequence



[1] According to the Guidance of the CEF Panel and Explanatory note for guidance.

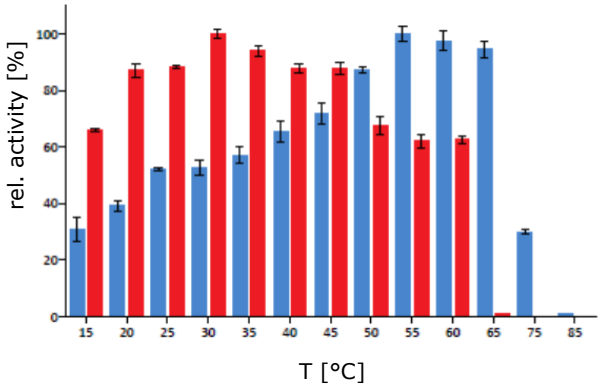
Information often missing/incomplete in applications

- SDS-PAGE analysis of at least 3 representative commercial batches and the tox batch(es)



Information often missing/incomplete in applications

- Specific list of raw materials (e.g. media components, antifoam agents, flocculants, etc.)
- Exact manufacturing process (including fermentation and downstream processing steps) subject to the evaluation
- LoD of analytical methods
- Data on the thermostability of the food enzyme



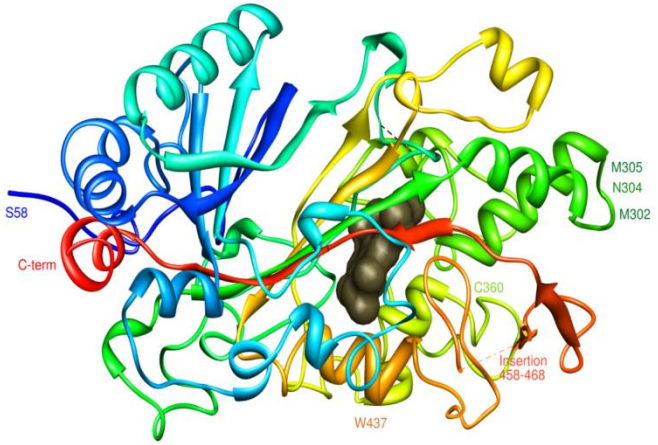
Food enzyme *vs*. food enzyme preparation

Article 3 of the Regulation (EC) No 1332/2008:

- '**Food enzyme**' means a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms:

  (i) containing one or more enzymes capable of catalysing a specific biochemical reaction
  (ii) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods.

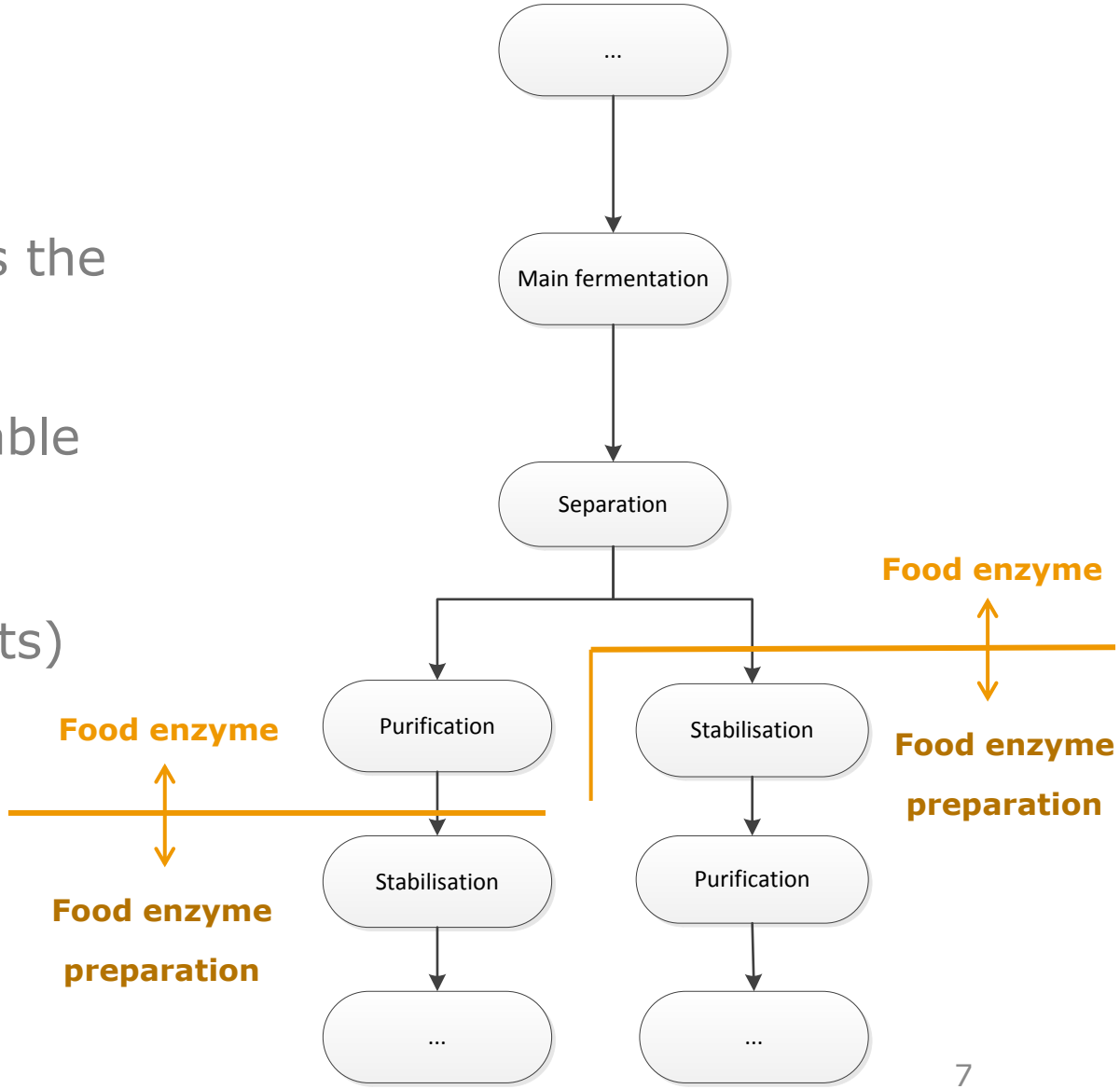
- '**Food enzyme preparation**' means a formulation consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.



Food enzyme *vs.* food enzyme preparation

Please specify:

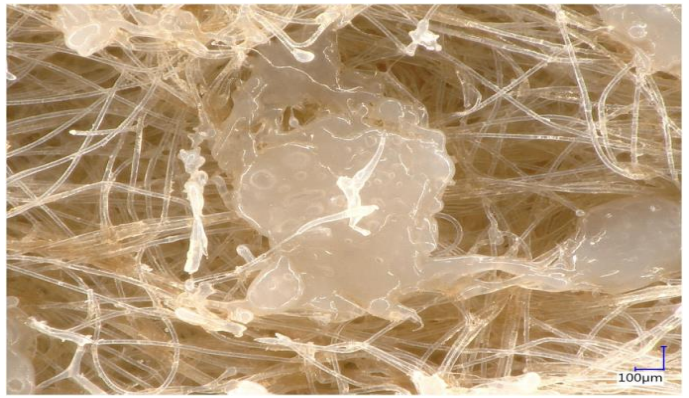
- at which point of the manufacturing process the samples analysed were taken (for chemical characterisation, purity data, absence of viable cells/DNA, etc.)
- type and amount of substances (e.g. diluents) added (if applicable)



Immobilised enzymes

Clear description of the immobilisation process, including:

- materials used (e.g. cross-linking agents, support materials)
- analytical data for the presence/absence of the food enzyme or any other substance of concern resulting from the raw materials used



Enzymes used as raw materials

For enzymes used as raw materials (e.g. lysozyme), the following data should be provided:

- a justification on their purpose
- fate and activity in the food enzyme and/or the final food

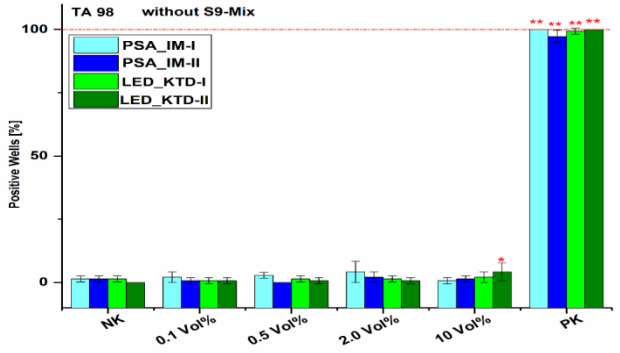
Commercial *vs*. tox batch

The batch(es) used for toxicological testing ("tox batch") should be a food enzyme[1]:

- representative of the commercial material (*i.e.*, not purer than the commercial batches, similar protein profiles)

or

- one of the representative commercial batches



[1] According to the Guidance of the CEF Panel and Explanatory note for guidance.

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