

2.2 PUBLIC SUMMARY OF THE DOSSIER

SCOPE OF THE APPLICATION

The present dossier documents the compliance of AMP deaminase produced by *Aspergillus melleus* AE-DN with the criteria laid out in Regulation (EC) 1332/2008 on food enzymes, i.e.:

- the food enzyme is safe for consumers in its intended uses
- it fulfils a reasonable technological need in food processing
- its use does not mislead consumers.

EXISTING AUTHORIZATIONS OF THE FOOD ENZYME

The food enzyme object of this dossier has been used in food processing for over 30 years across the European Union and in other markets world-wide.

It has been evaluated for its safety and technological need and authorized by Denmark, France, China and Korea.

PRODUCTION METHOD

The food enzyme object of this dossier is produced by fermentation of the microorganism *Aspergillus melleus* AE-DN in pure culture. No foreign microorganisms are allowed to develop during the enzyme manufacturing process.

During the fermentation, run in fermentation trays, the microorganism is provided with nutrients, water and aeration. It develops and produces the food enzyme.

After the fermentation is over, the microorganism is eliminated from the fermentation media containing the food enzyme. This fermentation media is partially purified and concentrated, to maximize the enzyme contents.

The concentrate is then mixed with other ingredients, in order to stabilize it for its storage, transportation and use in the food industry.

The food enzyme preparation complies with international specifications (JECFA), ensuring absence of contamination by toxic substances or noxious microorganisms.

The whole production process is run according to the requirements of the European Food Law and Food Hygiene Regulation. Production premises are regularly inspected by authorities.

TOXICOLOGICAL STUDIES

The food enzyme object of the present dossier was subjected to several toxicological studies to confirm its safety for consumers. The mutagenicity studies showed that the food enzyme does not have the potential to damage the genetic material of living organisms, including mammals. The oral toxicity study showed that the food enzyme

does not exhibit signs of toxicity, up to doses that are several thousand times higher than those which are consumed via food.

CONCLUSIONS ON THE SAFETY OF THE FOOD ENZYME

Based on the safety of the production microorganism, on the toxicological studies, and on previous evaluations by official experts, it is concluded that the food enzyme object of this dossier is safe in its intended uses.

USES OF THE FOOD ENZYME IN FOOD PRODUCTION

The food enzyme catalyses the conversion of substrate, AMP into IMP. The food enzyme is typically used in the following food process:

Yeast processing

The transformation of substrate provides the following benefits, of interest during food processing:

Yeast processing: Improving the flavor of yeast extract by the conversion of insipid component (AMP) into sapid one (IMP).

The food enzyme is denatured at the end of the food manufacturing process. Therefore it cannot have any technological function anymore in final foods.

CONCLUSIONS ON THE TECHNOLOGICAL NEED OF THE FOOD ENZYME

This AMP deaminase has been used for over 30 years in above food production processes, which by itself demonstrate the technological need, together with the above listed benefits. The AMP deaminase from *Aspergillus melleus* object of the present dossier has itself been used for over 30 years in food processing.

THE USE OF THE ENZYME WILL NOT MISLEAD THE CONSUMERS

The enzyme does not perform any technological function in the final foods containing ingredients prepared with the help of this enzyme. Moreover, the food products prepared with the help of this AMP deaminase do not have other characteristics than what is expected by the consumer.

This enzyme has been used for the above described technological function in food processes for many years and has been specifically approved in many countries.

Considering the above, there are no reasons to believe that the use of AMP deaminase in food processing could be misleading for the consumer.

3 TECHNICAL DOSSIER

3.1 ADMINISTRATIVE DATA

3.1.1 APPLICANT

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3.1.2 MANUFACTURER

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3.1.3 PERSON RESPONSIBLE FOR THE DOSSIER

3.1.3.1 RESPONSIBLE PERSON

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3.1.3.2 CONTACT PERSON

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