

2.2 PUBLIC SUMMARY OF THE DOSSIER

SCOPE OF THE APPLICATION

The present dossier documents the compliance of acid prolyl endopeptidase produced by a genetically modified strain of *Aspergillus niger* 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 nearly a decade across the European Union and in other markets world-wide.

It has been evaluated for its safety and technological need and authorized by (among others) Australia, China, Denmark, France and Russia.

PRODUCTION METHOD

The food enzyme object of this dossier is produced by fermentation of the microorganism *Aspergillus niger* in pure culture. *Aspergillus niger* has been used for many decades for the production citric acid and a wide variety of food enzymes and is globally regarded as a safe microorganism.

The *Aspergillus niger* strain used for the production of acid prolyl endopeptidase was genetically modified in order to more efficiently produce the enzyme. Therefore, the acid prolyl endopeptidase encoding gene which naturally occurs in *Aspergillus niger* was multiplied by means of self-cloning.

During the fermentation, run in closed tanks, the microorganism is provided with nutrients, water and aeration. It develops and produces the food enzyme. No foreign microorganisms are allowed to develop during the enzyme manufacturing process.

After the fermentation is over, the microorganism efficiently eliminated from the liquid broth containing the food enzyme. This broth 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 hundred times higher than those which are consumed via food.

The food enzyme is totally free of the genetically modified *Aspergillus niger* strain and DNA sequences of concern.

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, i.e. accelerates, the conversion of proteins and peptides into products smaller peptides. Proteins and peptides are present in many food raw materials and ingredients, and therefore the food enzyme may typically be used in the following food processes:

- Brewing
- Potable alcohol production
- Protein processing
- Starch processing

The transformation of proteins and peptides with the help of acid prolyl endopeptidase may provide the following benefits, of interest during food processing:

- Brewing:
 - Consistent beer stability, prevention of chill haze without loss of foam properties
 - Increased flexibility in the choice of raw materials (raw grain/malt ratio)
- Potable alcohol production:
 - Optimal fermentation, thereby reducing costs and waste
 - Increased flexibility in the choice of raw materials
- Protein processing:
 - Production of protein hydrolysates
- Starch processing:
 - Prevention of clogging of filters by proteins, thereby reducing chemicals needed for filter cleaning and thus reducing waste

The food enzyme has no technological function anymore in final foods.

CONCLUSIONS ON THE TECHNOLOGICAL NEED OF THE FOOD ENZYME

Acid prolyl endopeptidase has been used for nearly a decade in above mentioned food production processes, which by itself demonstrates their technological need, together with the above listed benefits.

THE USE OF THE ENZYME WILL NOT MISLEAD THE CONSUMERS

The effect of the enzymatic conversion with the help of acid prolyl endopeptidase is the degradation of proteins and peptides in raw materials (such as cereals) containing these substrates. This may result in improved processing properties of these raw materials.

Acid prolyl endopeptidase does not perform any technological function in the final beverages or foods containing ingredients prepared with the help of this enzyme. Moreover, the food products prepared with the help of acid prolyl endopeptidase do not have other characteristics than what is expected by the consumer.

Acid prolyl endopeptidase has been used for the above described technological function in food processes for many years and has been specifically approved in many countries including Denmark and France. There are no reasons to assume that the use of the food enzyme could lead to a food which would be misleading in terms of nature, freshness, the quality of the ingredients used or the nutritional quality of the final food. Enzymatic processes in general are per definition natural and they therefore do not influence the naturalness of the production process or the final food.

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