

2.2 PUBLIC SUMMARY OF THE DOSSIER

SCOPE OF THE APPLICATION

The present dossier documents the compliance of Protein-glutaminase produced by *Chryseobacterium proteolyticum* AE-PG 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 8 years.

It has been evaluated for its safety and technological need and authorized by France and the U.S.A.

PRODUCTION METHOD

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

Chryseobacterium proteolyticum AE-PG has been used for 8 years for the production of food enzymes.

During the fermentation, run in closed tanks, 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 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 over a hundred 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, i.e. accelerates, the conversion of substrate protein into deamidated protein. Protein is present in many food raw materials and ingredients, and therefore the food enzyme is typically used in the following food processes:

- Baking and pasta/noodle making
- Dairy processing
- Meat and fish processing
- Protein processing
- Grain processing
- Yeast processing

The transformation of substrate protein may provide the following benefits, of interest during food processing:

- Baking and pasta/noodle making: Improving dough softness
- Dairy processing: Improving texture of final food
- Meat and fish processing: Improving texture of food and food ingredient
- Protein processing: Improving physical properties of food and food ingredient
- Grain processing: Improving physical properties of food and food ingredient
- Yeast processing: Improving functional properties of the yeast products

The food enzyme is removed, denatured or under ineffective circumstances at (or before) 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

Protein-glutaminase object of the present dossier has been used for 8 years in above food production processes, which 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 Protein-glutaminase is the conversion of the substrate, various proteinic food raw materials, resulting in improvement of the properties of food or food ingredient.

Protein-glutaminase 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 Protein-glutaminase do not have other characteristics than what is expected by the consumer.

Protein-glutaminase has been used for the above described technological function in food processes for many years and has been specifically approved in France and USA.

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