

2.2. PUBLIC SUMMARY OF THE DOSSIER

SCOPE OF THE APPLICATION

The present dossier documents the compliance of Subtilisin produced by *Bacillus subtilis* 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

Subtilisin¹ from *Bacillus subtilis* have been used in food processing for many years across the European Union and in other markets world-wide.

They have been evaluated for their safety and technological need and authorized by (among others) Brazil, Canada, China, France and Mexico.

PRODUCTION METHOD

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

Bacillus subtilis has been used for decades 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 (FAO/WHO, 2006), 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.

¹ Most positive lists mention the general name 'protease' and do not differentiate between the various proteases.

TOXICOLOGICAL STUDIES

The food enzyme is produced by a microorganism which has been granted by the European Food Safety Authority the status of "Qualified Presumption of Safety" (QPS), which means that products from this microorganism (e.g. food enzymes) are exempted from toxicological studies for their use in food processing.

CONCLUSIONS ON THE SAFETY OF THE FOOD ENZYME

Based on the safety of the production microorganism (QPS) 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 the substrate proteins and peptides into protein fragments of various lengths, peptides and free amino acids. Proteins and peptides are present in many food raw materials and ingredients, and therefore the food enzyme is typically used in the following food process:

- Protein processing.

The transformation of the substrate proteins and peptides may provide the benefits, of interest during food processing:

- Improve processes - better, quicker and more stable processes,
- Better process control,
- Improved yield.

The food enzyme is either removed or denatured at (or before) the end of the food manufacturing process or the substrate for the enzymatic reaction is depleted. Therefore it cannot have any technological function anymore in final foods.

CONCLUSIONS ON THE TECHNOLOGICAL NEED OF THE FOOD ENZYME

Subtilisin from various origins has been used for many years in the above food production process, which by itself demonstrates the technological need, together with the above listed benefits. The Subtilisin from *Bacillus subtilis* object of the present dossier has itself been used for several years in food processing.

THE USE OF THE ENZYME WILL NOT MISLEAD THE CONSUMER

The effect of the enzymatic conversion with the help of Subtilisin is the degradation of the substrate in plant and animal raw materials, resulting in:

- Improved processing of these materials in the production of final foods:
 - Better, quicker and more stable processes,
 - Better process control,
 - Improved yield.
- Improved properties of the final foods:
 - Better functional properties of produced peptides,

- Increased protein content in food,
- Improved digestibility and reduced allergen potential (especially in milk products).

Subtilisin 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 Subtilisin do not have other characteristics than what is expected by the consumer.

Subtilisins¹ have been used for the above described technological function in food processes for many years and have been specifically approved in many countries including France.

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

¹ Most positive lists mention the general name 'protease' and do not differentiate between the various proteases.