2.2 Public summary of the dossier

Scope of the application

Enzymes are found in all living organisms, be they microbes, plants, animals, or human beings. They are proteins (just like the constituents of our muscles for instance), therefore they are not living by themselves.

Enzymes sustain life by permitting all chemical reactions in our bodies to take place.

Enzymes can therefore also accelerate chemical reactions that take place for instance during the manufacturing of foods. In fact, many traditional foods such as bread would not exist without enzymes.

Food enzymes are regulated at the European level by Regulation (EC) 1332/2008. This text foresees that all food enzymes will be included in an European list, once they have been evaluated by the European Food Safety Authority (EFSA) for their safety, and by the European Commission and Member States for their technological need – ensuring that their use does not mislead consumers.

The present application concerns the food enzyme **serine protease produced by a genetically modified microorganism, *Fusarium venenatum***.

Existing uses, evaluations and authorisations of the food enzyme

The food enzyme object of the present dossier has been used for some years in various European Member States as well as other countries world-wide.

It has been evaluated for its safety and technological need and authorised by Denmark and France.

Production method

The food enzyme is produced by fermentation of the *Fusarium venenatum* microorganism.

Fusarium venenatum has been used for many years for the production of food enzymes.

The fermentation is run in pure culture, which means that no foreign, contaminating microorganisms are allowed to develop.

During the fermentation the microorganism is provided with nutrients such as sugars, proteins, and mineral salts. It multiplies and produces the food enzyme serine protease, object of the present dossier. The enzyme is excreted by the microorganism cells into the liquid fermentation medium.

After the fermentation is over the microorganism is separated from the liquid broth containing the enzyme. The broth is partially purified and concentrated to increase the enzyme contents.

Then the concentrate is formulated into a food enzyme preparation, which can be used by food manufacturers. This formulation involves diverse food ingredients and ensures that the enzyme is stable.

The food enzyme preparations comply with international specifications, 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 performed on the food enzyme

The food enzyme object of the present dossier was submitted to several toxicological studies to further ensure its safety for consumers.

Two mutagenicity studies showed that the food enzyme is unable to damage the genetic material of living organisms.

Two oral toxicological studies on rats (a 90-days study and a 25-days study), where groups of animals were given the food enzyme at very high doses, showed, that all dose levels were generally well tolerated. The highest enzyme dosage administered was in the 25-days rat study and corresponded to 3.6 gram of food enzyme dry extract per kilogram of body weight and per day.

In comparison, given the dosages of the food enzyme used in food manufacturing, the dosage tested in rats without any health concerns would correspond to a human being (including infants) needing to ingest over 116 times more food than usual before having eaten the same amount of enzyme as was provided to the rats. This is of course impossible.

Conclusions on the safety of the food enzyme

Based on the safety of the production microorganism and on the previous safety evaluations performed by official expert panels at the authorities in several countries it is concluded that the use of the food enzyme object of the present dossier is safe for consumers.

Uses of the food enzyme in food production

Protein processing

The serine protease object of the present dossier is used for partial or extensive hydrolysis of animal and vegetable proteins to be further used as ingredients in a variety of beverage and food products

The enzyme is added during the food production process, where it performs its function. In the final food product the enzyme protein is denatured by high temperature, which means that the enzyme does not have any action or any function in the final food.

Conclusions on the technological need of the food enzyme

Proteases have been used in food production processes since the 1970s, which by itself demonstrate their technological need. The serine protease object of the present dossier has itself been used for several years in food processing.

The use of the food enzyme will not mislead consumers

The enzyme is not functional in the final food, and in many cases the use of the enzyme does not result in effects on the final food.

In cases where there may be a noticeable effect on the final food it is likely that the same effect could be achieved by a similar process without the use of the enzyme.

In any case, the final food products or their characteristics are not different from what is expected by the consumer based on appearance or already available information from the product label.

In Denmark and France, where serine protease object of this dossier is specifically approved for the described application, the final foods do not bear any mention of the food enzyme or its effects.

Based on this the use of the serine protease does not mislead the consumer.