

## 2.2. PUBLIC SUMMARY OF THE DOSSIER

### SCOPE OF THE APPLICATION

The present dossier documents the compliance of Aspergillopepsin I produced by *Trichoderma reesei* 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 a number of years 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) Mexico.

### PRODUCTION METHOD

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

*Trichoderma reesei* 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 (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 safety of food enzyme object of the present dossier is supported by toxicological studies conducted under the DuPont *Trichoderma reesei* Safe Strain Lineage. The toxicological studies confirm the safety of the food enzyme 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 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 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 the substrate proteins and peptides into protein fragments of various lengths, peptides and free amino acids, is present in many food raw materials and ingredients, and therefore the food enzyme is typically used in the following food processes:

- Potable alcohol production
- Protein processing

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

- Facilitate the production of peptides with better functional properties such as solubility (Cheng and Medina, 2012; Hasegawa *et al.*, 1988), emulsification, gelling and foaming (Whitehurst and Law, 2010; Uhlig, 1998)
- 'Predigestion' of the cereal proteins for optimal development of the fermentation
- Amylolytic enzymes have better access for the hydrolysis of the cereal starch granules.

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**

Aspergillopepsin I from various origins have been used for many years in above food production processes, which by itself demonstrate the technological need, together with the above listed benefits. The Aspergillopepsin I from *Trichoderma reesei* 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 Aspergillopepsin I is the degradation of the substrate in proteins in protein containing raw materials with the release of peptides and amino acids, resulting in improved processing properties of these materials.

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



Aspergillopepsin1 from various origins have been used in food processes for a number of years and has been specifically approved in many countries including France.

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