

A Petition to Amend the Australia New Zealand Food Standards Code with a Serine endopeptidase Enzyme Preparation produced by *Trichoderma reesei*

EXECUTIVE SUMMARY

The present application seeks to schedule 18 - Processing Aids of the Australia New Zealand Food Standards Code (the Code) to approve a serine endopeptidase (protease) enzyme preparation from *Trichoderma reesei* produced by AB Enzymes GmbH for use as a processing aid in the manufacture of vegetable and animal protein hydrolysates (products), based upon the FSANZ food code:

- Meat, poultry and game products and dishes
- [Vegetable products and dishes](#)
- Fish and seafood products and dishes

Proposed change to Standard 1.3.3 - Processing Aids

The table schedule 18—9(3), Permitted processing aids various purposes, is proposed to be amended to include a genetically modified strain of *Trichoderma reesei* as permitted source for serine proteinase¹.

This application is submitted under a general assessment procedure.

¹ Food Standards Australia New Zealand (FSANZ) has prepared Proposal P276, in which the EC code listed in the Australia New Zealand Food Standards Code - Schedule 18 - Processing aids for serine proteinase 3.4.21.14 is no longer valid by IUBMB, and various other proteases are formerly recognized as 3.4.21.14, one of which is 3.4.21.65 (RF8963 - endopeptidase) [ENZYME - 3.4.21.65 Thermomycolin \(expasy.org\)](#).

Description of Enzyme Preparation

The food enzyme is a biological isolate of variable composition, containing the enzyme protein, as well as organic and inorganic material derived from the microorganism and fermentation process.

The main activity of the food enzyme is serine endopeptidase (██████████) —

Use of the Enzyme and Benefits

Like any other enzyme, the serine endopeptidase acts as a biocatalyst: with the help of the enzyme, a certain substrate is converted into a certain reaction product. It is not the food enzyme itself, but the result of this conversion that determines the effect in the food or food ingredient. After the conversion has taken place, the enzyme no longer performs a technological function.

The **substrates** for the enzyme are polypeptide protein chains which can be found in all living organisms and therefore occur naturally in nature and are a natural part of the human diet.

The **function** of the serine endopeptidase is to catalyse the hydrolysis of peptide bonds in proteins with preferential cleavage at Alanine, Tyrosine, and Phenylalanine in small molecule substrates.

Reaction products: as a result of the catalytic activity of the serine endo-peptidase, smaller proteins and peptides of variable lengths are formed. Being the result of protein catabolism, these

reaction products also naturally occur in all living organisms. Consequently, also the reaction product(s) occur(s) naturally in foods and adverse effects on nutrients are not to be expected.

Like most of the enzymes, the serine endopeptidase performs its technological function during food processing. The serine endopeptidase from *Trichoderma reesei* RF8963, object of this dossier, can theoretically be used as processing aid for partial or extensive hydrolysis of proteins from both animal and vegetable sources (e.g. casein, whey, gluten, and proteins from meat, fish, corn, soy, rice, peas, lentils etc.) but this specific enzyme **is intended to be used in protein processing, mainly in fish and meat processing.**

Safety Evaluation

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 thousand times higher than those which are consumed via food.

The product complies with the recommended purity specifications (microbiological and chemical requirements) of the FAO/WHO's Joint Expert Committee on Food Additives (JECFA) and the Food Chemicals Codex (FCC) for food-grade enzymes.

The product is free of production strain and recombinant DNA.

The safety of the serine endopeptidase preparation was confirmed by external expert groups, as follows:

- **Canada:** [5. List of Permitted Food Enzymes \(Lists of Permitted Food Additives\) - Canada.ca](#)
- [REDACTED]
- [REDACTED]
- **Brazil:** [Microsoft Power BI](#), (selection “serine endopeptidase”)
- **Mexico:** [ANEXO VI.pdf \(www.gob.mx\)](#), entry #76
- **USA:** [GRAS Notice 817 Agency Response Letter for Serine endopeptidase from Malbranchea cinnamomea produced in Trichoderma reesei \(fda.gov\)](#)

Conclusion

Based on the safety evaluation, AB Enzymes GmbH respectfully request the inclusion of serine endopeptidase from *Malbranchea cinnamomea* expressed in *Trichoderma reesei* in the table – 18-9(3) of schedule 18 - Permitted processing aids various purposes.