

A Petition to Amend the Australia New Zealand Food Standards Code with a Polygalacturonase Enzyme Preparation produced by *Aspergillus oryzae*

The present application seeks to schedule 18 - Processing Aids of the Australia New Zealand Food Standards Code (the Code) to approve a polygalacturonase¹ enzyme preparation from *Aspergillus Oryzae* produced by AB Enzymes GmbH for use as a processing aid in:

- Fruit juices/products
- Vegetable juices/products
- Coffee processing
- Flavouring production
- Wine production

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 *Aspergillus Oryzae* as permitted source for polygalacturonase EC 3.2.1.15.

This application is submitted under a general assessment procedure.

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.

¹ AB Enzymes has also submitted to FSANZ the Pectin esterase enzyme preparation from *Aspergillus Oryzae* which is used in conjunction with the polygalacturonase described in this dossier.



The main activity of the food enzyme is polygalacturonase

Property	Requirement	
Activity	min.	75,000 PGU/mg
Appearance	Brown liquid	
Density	1.1 g/ml	

Use of the Enzyme and Benefits

The main activity of the *Aspergillus oryzae* AR-183 enzyme preparation is polygalacturonase (IUBMB 3.2.1.15). Polygalacturonase is a pectinolytic enzyme that breaks down pectin, and is found abundantly in plants, microorganisms, and animals.

In general, the technological need of the enzymatic conversion of pectin with the help of polygalacturonase can be described as: degradation of a component (the substrate pectin) which causes technical difficulties due to its high viscosity and gelling properties in processing of raw materials containing this component.

As described above, polygalacturonase is naturally present in fruit and vegetable raw materials. The natural enzymatic conversion of pectin in such materials is of technological benefit in several industrial food manufacturing processes, like fruits and vegetables processing, wine production, and oil extraction, etc.

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 polygalacturonase preparation was confirmed or is under consideration by external expert groups, as follows:

Approved:

- Denmark
- France

Under evaluation:

- EFSA
- USA
- Brazil

Conclusion

Based on the safety evaluation, AB Enzymes GmbH respectfully request the inclusion of polygalacturonase from *Aspergillus tubigiensis* expressed in *Aspergillus oryzae* in the table – 18-9(3) of schedule 18 - Permitted processing aids various purposes.