

Comments from the Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions.

Due date of submission – 31 January 2019

The Victorian Departments of Health and Human Services and Jobs, Precincts and Regions (the departments) welcome the opportunity to respond to this application to amend the Australia New Zealand Food Standards Code (the Code).

Application A1168 – Glucoamylase from GM *Aspergillus niger* as a processing aid (enzyme) – has been submitted by Novozymes Australia Pty Ltd. The Application seeks to permit the use of the enzyme glucoamylase from the fungus *Talaromyces emersonii* using a genetically modified strain of the ubiquitous environmental fungus *Aspergillus niger* as the production strain.

The function of glucoamylase is to convert starch to glucose, and it is used in the manufacture of syrups, beverages, cereal-based products, fruit products and vegetable products. While other preparations of glucoamylase are permitted in the Code, this will provide an alternative source. Food Standards Australia New Zealand (FSANZ) concludes that this enzyme performs its technological purpose and the classification as a processing aid is appropriate.

To address any public health and safety concerns relating to the use of this enzyme, it is understood from the FSANZ Risk and technical assessment report that:

- Glucoamylase produced using *A. niger* has a history of safe use in countries including Denmark, Canada, France, Brazil, China and Mexico.
- The production strain, *A. niger*, is not toxigenic or pathogenic and the final enzyme preparation is purified so that the production strain is no longer present. In fact, *A. niger* is often commonly used as a production strain for enzymes, with a number already permitted in the Code.
- The enzyme, glucoamylase, from other sources has been widely used in the food industry for decades.
- Glucoamylase produced using *A. niger* was shown not to be genotoxic (ability to damage genetic information), and did not produce adverse effects in rats administered glucoamylase produced in a related strain of *A. niger*.
- Using bioinformatics, no significant similarity was found between the amino acid sequence of this glucoamylase and known toxins.

However, the departments note an apparent inconsistency, such that:

- While the Call for submissions document and the executive summary of the Risk and technical assessment document states that bioinformatic analyses did not identify significant homology between the amino acid sequence of the glucoamylase and known allergens, section 3.4.5 of the Risk and technical assessment document describes significant homology to the glucoamylase Sch c 1 of *Schizophyllum commune*. The *S. commune* glucoamylase is described as a respiratory allergen rather than a food allergen, with no reports of allergic reactions to consumption of *S. commune*. The Risk and technical assessment document draws the conclusion that the homology between the glucoamylase in this application and the glucoamylase from *S. commune* does not represent a food safety hazard. However, the basis for this conclusion is the lack of evidence

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from the literature of allergic response from consumption of *S. commune* as a food in regions including Africa, Asia, the Indian subcontinent, and central America; no literature relating to food allergen potential from consumption of *S. commune* in countries comparable to Australia, with similar rates of food allergy, was cited.