

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

Due date of submission – 10 November 2022

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

Application A1252 - *Glucoamylase from GM Aspergillus niger (gene donor: Penicillium oxalicum) as a processing aid* seeks to permit the use of the enzyme glucoamylase derived from a genetically modified (GM) strain of *A. niger*.

From the Food Standards Australia New Zealand (FSANZ) Assessment report it is understood that:

- Glucoamylase breaks down starch to release glucose to produce various products such as alcohol (ethanol) and amino and organic acids. It is proposed to be used as a processing to aid in baking processes, brewing processes and starch processing for the production of starch hydrolysates, including glucose syrups.
- Glucoamylase from GM sources is already listed as a permitted processing aid in the Code, including GM *A. niger* with other gene donors. This enzyme is considered a protein engineered variant, as it differs in its amino acid composition from the original.
- The protein engineered variant of the glucoamylase enzyme is produced by a GM strain of *A. niger* containing the glucoamylase gene from *P. oxalicum*.
- The *A. niger* strain (BO 1 lineage) has a history of use in enzyme production and is not considered pathogenic nor toxigenic.
- The gene insert from *P. oxalicum* has been shown to be stably integrated into the genome of the production strain.
- Foods for sale that contain glucoamylase derived from GM *A. niger* as an ingredient will be subject to the GM labelling requirements under the Code. However, GM labelling requirements will not apply if the food containing the enzyme is not a food for sale itself (for example, if the enzyme is present in the beer used in the batter for a battered fish product).
- Wheat is used in the production of the granulated form of the enzyme for use in bakery processes. Any food for sale containing the enzyme where wheat is present will be subject to mandatory declaration requirements as outlined in Standard 1.2.3 - Information requirements – warning statements, advisory statements, and declarations.
- The enzyme glucoamylase was assessed against protein homology data and not shown to be congruent with the amino acid sequences of any known food allergens.
- The proposed enzyme has been assessed for safety by the Danish Veterinary and Food Administration and approved for use.
- FSANZ determined there are no safety concerns with the use of this enzyme for this technological purpose at levels consistent with Good Manufacturing Process.

On the basis of the information above and FSANZ's conclusion that there are no public health and safety issues associated glucoamylase derived from GM *A.niger*, the departments support the progression of Application A1252.