

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

Due date of submission – 9 June 2022

The Victorian Departments of Health 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 A1238 – Serine endopeptidase from GM Trichoderma reesei seeks to permit the use of the serine endopeptidase, thermomycolin, derived from a genetically modified (GM) strain of *T. reesei*.

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

- Thermomycolin is an enzyme in the class of serine endopeptidases and is used to catalyse the hydrolysis of proteins in the manufacture and/or processing of meat, vegetable and seafood products.
- The enzyme is limited to performing a technological purpose during processing. It is also listed as an additive permitted at Good Manufacturing Practice (GMP) in Schedule 18 of the Code, and therefore meets the requirements of a processing aid.
- The proposed thermomycolin is produced from a GM strain of *T. reesei* containing the thermomycolin gene from *Malbranchea cinnamomea* (strain RF8963).
- The GM strain of *T. reesei* containing the thermomycolin gene has been assessed and found to be non-pathogenic and non-toxigenic. The genetic modification process which involved gene insertion is stable and of low allergy risk under the proposed conditions of use and exposure.
- The safety of *T. reesei* has previously been assessed by FSANZ, and the Code currently permits several organisms derived from the organism.
- The proposed enzyme has been approved for use as a processing aid in France, Denmark, Canada, Mexico, Brazil and the USA, where it has been determined as Generally Recognized as Safe (GRAS).
- Wheat is used in the production of the enzyme. 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*.
- Foods for sale that contain thermomycolin derived from GM *T. reesei* 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 an ingredient in a mixed food such as meat stock in a soup).

On the basis of the information above and FSANZ's conclusion that there are no identifiable hazards associated with thermomycolin derived from GM *T. reesei* under the proposed conditions of use, the departments support the progression of Application A1238.