

Comments from the Victorian Department of Health and Human Services and the Victorian Department of Economic Development, Jobs, Transport and Resources.

Due date of submission – 24 May 2018

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

Application A1146 – Thermolysin (Protease) as a Processing Aid (Enzyme) has been submitted by Amano Enzyme Inc., and seeks permission to use an enzyme (protease) produced and purified from *Anoxybacillus caldiproteolyticus*.

From the Food Standards Australia New Zealand (FSANZ) Assessment report and the documentation provided by Amano Enzyme Inc. it is understood that:

- The purpose of the enzyme is to act as a processing aid, used to improve physiological properties and organoleptic properties in the manufacture and/or processing of dairy, egg, meat, fish, yeast, protein products and flavourings.
- The enzyme, thermolysin, is proposed to be sourced from a bacterium *A. caldiproteolyticus* strain TP-7.
- The source organism is not toxigenic or pathogenic.
- *A. caldiproteolyticus* has a long history of safe use overseas as the production organism for a number of enzyme processing aids.
- The enzyme is inactivated during processing (heat sensitive), and thus meets the requirements of a processing aid under the Code¹.
- FSANZ concluded that there are no public health and safety issues associated with the enzyme from this specific strain for the general population.
- The FSANZ assessment report has identified a potential hazard for consumers who may be sensitive to fish protein as no allergenic threshold is known. Tuna products (known allergens) are used in the fermentation media to produce the processing aid, therefore it is required to be declared under section 1.2.3—4 of Standard 1.2.3.
- Protease from *A. caldiproteolyticus* (former name *Geobacillus stearothermophilus*) has been approved for use in France and listed in Inventory of Processing Aids (IPA) maintained by the Codex Alimentarius.

The departments acknowledge that no public health and safety concerns for general population were raised by FSANZ in its safety assessment of this Application. On this basis, the departments support the progression of Application A1146.

¹ 'a substance that is used as a processing aid in relation to a food is a reference to a substance that is used during the course of processing:

- (a) to perform a technological purpose in the course of processing; and
- (b) does not perform a technological purpose in the food for sale '