

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

Due date of submission – 28 July 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 A1219 – *Alpha-amylase from GM Bacillus licheniformis as a processing aid* seeks to permit the use of the enzyme alpha-amylase derived from a genetically modified (GM) strain of *B. licheniformis*.

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

- Alpha-amylase is an enzyme that catalyses the breakdown of starch to glucose and maltose. It is proposed to be used as an enzyme in brewing, potable alcohol production and starch processing and does not perform a function in the final food for sale. Thus, it meets the requirements of a processing aid under the Code.
- The proposed alpha-amylase marketed by Danisco New Zealand Ltd is produced by fermentation of genetically modified *Bacillus licheniformis* containing the alpha-amylase gene from *Cytophaga* species (strain JML 1584).
- Alpha-amylase has a history of safe use and is already listed as a permitted processing aid in the Code from plant sources and several microbial sources, including *B. licheniformis*.
- The risk assessment conducted by FSANZ determined that:
 - the GM host strain is neither pathogenic nor toxigenic, and
 - the genetic modification process which involved gene insertion is stable and with low or no allergy risk.
- Food for sale that contain alpha amylase derived from GM *B. licheniformis* as an ingredient will be subjected 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).
- The draft variation prepared by FSANZ proposes to list alpha amylase sourced from *B. licheniformis* containing the alpha amylase gene from *Cytophaga* species as an enzyme in Schedule 18 for the use as described, subject to the condition that the maximum permitted level of the enzyme is the amount consistent with Good Manufacturing Practice (GMP).

Based on the above information and FSANZ's conclusion that there are no public health and safety issues associated with alpha-amylase derived from GM *B. licheniformis*, the departments support the progression of Application A1219.