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

Due date of submission – 13 September 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 A1220 – *Beta-amylase from GM* Bacillus licheniformis *as a processing aid* seeks to permit the enzyme beta-amylase derived from a genetically modified (GM) strain of *B. licheniformis* for use in starch processing in the production of maltose syrup.

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

- Beta-amylase is an enzyme used in starch processing to produce maltose for syrups. It does not perform a function in the final food for sale and meets the requirements of a processing aid under the Code.
- The proposed beta-amylase is derived from a genetically modified strain of *B. licheniformis* containing the beta-amylase gene from *Priestia flexa* (previously classified as *Bacillus flexus*).
- Beta-amylase has a history of safe use and there are several plant and non-GM microbial sources of beta-amylase approved for use in the Code.
- The safety of *B. licheniformis* has previously been assessed by FSANZ and the Code currently permits several enzymes derived from the organism.
- The risk assessment conducted by FSANZ determined that the genetic modification process which involved gene insertion is stable and that the enzyme is safe under the proposed conditions of use.
- Foods for sale that contain beta-amylase derived from GM *B. licheniformis* 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 used to produce maltose syrup which is then used as an ingredient in confectionary).

The departments note the sequence homology assessment identified a 44.7% identity with a known food allergen (Tri a 17, derived from wheat) over an 80 amino acid window, which is above the 35% threshold suggested to indicate potential allergenicity. However, based on the lower degree of homology identified over the full-length sequence, and the expected negligible presence of residual enzyme due to production methods, FSANZ concluded the enzyme was unlikely to pose any allergenic concerns in food.

The departments recognise the assessment of allergen potential in GM foods is evolving, and appropriate sequence length and cut-offs when assessing homology remains an issue for debate[1]. Codex guidelines[2] recognise no single criterion can predict allergenicity and on this basis, recommend a stepwise approach that draws on evidence and data from

[1] EFSA Panel on Genetically Modified Organisms 2022. Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology. *EFSA Journal*, 20 (1), p. e07044.

[2] Codex Alimentarius Commission 2003. Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants. CAC/GL 45-2003.

multiple sources to assess allergen potential in newly expressed proteins. The departments support this approach and suggest further data for the enzyme, such as protein digestibility or immunological assays should be considered given the sequence homology assessment indicated potential for allergenicity. We note that the purification processes in the manufacture of the enzyme do not reduce potential safety hazards as the presence of allergens even at minute levels can elicit an allergenic response in some individuals. The departments support the progression of Application A1220 in principle but request further data to provide adequate assurance on the potential allergenicity of the enzyme.