

Application A1176 – Enzymatic Production of Steviol Glycosides

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

Due date of submission – 8 October 2019

The Victorian Departments of Health and Human Services 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 A1176 – Enzymatic production of steviol glycosides seeks permission to include a novel enzymatic conversion process to produce steviol glycosides to amend the Code. The method uses three enzymes derived from three different genetically modified (GM) strains of *Escherichia coli* K-12 to produce steviol glycoside preparations.

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

- Steviol glycosides have applications as intense sweeteners or flavour enhancers and are permitted in the Code for addition to a variety of foods.
- Internationally, steviol glycosides are permitted to be used as food additives in the European Union, Canada, Asia, Central/South America, and Africa.
- The proposed enzymatic process uses two UDP-glucosyltransferases and a sucrose synthase to produce three different steviol glycoside preparations with high contents of Rebaudiosides M and/or D, or Rebaudioside (Reb) AM.
- The steviol glycosides preparations with high contents of Reb M and/or D, or Reb AM using the enzymatic conversion methods are not approved in Canada or Europe. We note that the steviol glycosides preparation with a high Reb M content has GRAS (Generally Recognised as Safe) status in the USA.
- The enzymes are sourced from genetically modified strains of *E. coli* K-12, a bacterium. *E. coli* K-12 is a non-pathogenic and model microbial strain for use in research and industry. This strain has a long history of safe use to produce food enzymes.
- FSANZ's risk assessment has concluded that there are no safety risks either from the use of Reb D, Reb M or Reb AM as food additives or the production strains used in the manufacturing process.
- FSANZ has recommended that permission for use of these enzymes as processing aids for production of Reb D, Reb M or Reb AM be expressly included in the Code. FSANZ also intends to vary Schedule 18 (Processing aids) to permit the use of the protein engineered enzymes UDP-glucosyltransferase and sucrose synthases, sourced from *E. coli* as processing aids to produce Reb D, Reb M or Reb AM.

The departments note the previously raised concerns about FSANZ's decision to delay the use of a numbering system to distinguish steviol glycosides from different sources, and different technologies in the responses to Application A1172. Codex Alimentarius has already adopted a classification system to distinguish steviol glycosides from fermentation through the INS number, 960b. The Codex's labelling approach enables the source identification of steviol glycosides and enforcement of any applicable consumer laws that might refer to 'natural' or leaf extracts. The departments recommend that FSANZ should more rapidly adopt this classification system to distinguish steviol glycosides and align with international approaches.

On the basis of the information above, the departments support the progression of Application A1176. However, we note from the Call for Submissions that the use of enzymatic conversion methods for steviol glycosides are not approved in Canada or Europe. The consideration of international standards is important when assessing Applications of this type, and FSANZ should have included information as to why these

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methods are not approved in those jurisdictions. Further details on this issue should be included in any future updates on this Application.