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

Due date of submission – 23 January 2020

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 A1183 - Enzymatic production of Rebaudioside E from stevia leaf extract to permit an enzymatic conversion process to produce rebaudioside E. This rebaudioside E is a minor steviol glycoside produced through fermentation using a genetically modified strain of *Pichia pastoris* (*P. pastoris*).

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 for addition to a variety of foods in the Code.
- Internationally, steviol glycosides are permitted to be used as food additives in the European Union, Canada, United States of America (USA), South America, Asia, the Middle East and Africa.
- Currently the Code permits rebaudioside E production from *Stevia rebaudiana* Bertoni leaves by hot water extraction method.
- The Application A1183 proposes to use a microbial fermentation with a genetically modified yeast, *P. pastoris*, to manufacture rebaudioside E from purified stevia leaf extract through a method that has been previously assessed and approved by FSANZ for rebaudioside M and rebaudioside D.
- FSANZ's risk assessment has concluded that there are no safety risks either from the use of this rebaudioside E as a food additive or the production strain used in the manufacturing process.
- FSANZ's recommendations are not to distinguish steviol glycosides manufactured from plant extract or fermentation and use same INS (international numbering system) number 960 at this stage.
- FSANZ has recommended that permission for use of rebaudioside E as a food additive be included in the Code.

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 submissions to Application A1170, A1172 and A1176. Codex Alimentarius has already adopted a classification system to distinguish between steviol glycosides through the numbering system. The steviol glycosides produced from the plant (Stevia rebaudiana Bertoni) has INS 960a, which is different from those produced by fermentation (INS 960b). The labelling approach of Codex enables the source identification of steviol glycosides to provide adequate information relating to food to enable consumers to make informed choices; and enabling enforcement of any applicable consumer laws that might refer to 'natural' or leaf extracts. The departments strongly recommend that FSANZ adopts this classification system to distinguish steviol glycosides and align with international approaches. FSANZ's decision to wait until INS numbers are available for all methods is not practicable, it is more appropriate approach to align the Code with international changes and update as further development occurs.

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

It is also noted that an acceptable daily intake (ADI) of 0-4 mg/kg bodyweight for steviol glycosides was established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2009 and re-confirmed in 2016. Similar ADI for steviol glycosides was established by FSANZ in 2008. Over last few years, FSANZ has approved several applications for steviol glycosides but ADI data and permissions were not reviewed.

Before further progressing the Application A1183, the departments would like FSANZ to:

- consider aligning the labelling requirements with international approach;
- provide further information on Canada and Europe's position not approving the use of steviol glycosides from enzymatic conversion; and
- provide details of FSANZ's plan (if available) to review the ADI data and permissions for steviol glycosides.