

# Explanatory Statement

## 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1170 which sought approval for a steviol glycoside mixture (Reb MD) for use as an intense sweetener, produced from a GM *Saccharomyces cerevisiae*. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

## 2. Purpose

The Authority has approved a draft variation to insert new subsection S3—39 into Schedule 3 of the Code to permit Reb MD produced from fermentation to be used as a food additive in accordance with the Code's existing permissions and limits for steviol glycosides (including for steviol glycosides containing Reb MD).

## 3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

## 4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1170 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 2 April 2019 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Schedule 3 are likely to have a minor impact on business and individuals.

## 5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

## 6. Variation

Item [1] varies Schedule 3.

Item [1.1] varies the table to subsection S3—2(2). The variation amends that table to include in it references to ‘steviol glycosides from fermentation’ and to new section S3—39. The effect is that subsection 1.1.1—15(2) of Standard 1.1.1 will require a steviol glycosides preparation obtained from fermentation and that meets the criteria listed in subsection S3—39(1) to comply with the specifications listed in subsection S3—39(3) when that preparation is added to food or sold for use in food,

Item [1.2] inserts new section S3—39 into Schedule 3.

Subsection S3—39(1) will provide that the specifications imposed by subsection S3—39(3) will apply to a steviol glycosides preparation that: is obtained from fermentation; is not obtained from the leaves of the *Stevia rebaudiana* Bertoni plant; and contains a prescribed steviol glycoside.

Subsection S3—39(2) will provide a definition of the term ‘prescribed steviol glycoside’ that is used in subsection S3—39(1). The term is defined to mean rebaudioside MD derived from the following source: *Saccharomyces cerevisiae* strain CD15407 containing novel genes for the production of rebaudiosides.

The definition is in the form of a table in order to provide for the possibility that, in the future, other steviol glycosides may need to be added to the definition of ‘prescribed steviol glycoside’.

Subsection S3—39(3) will provide the specifications. These are for: description; assay; solubility; pH; total ash; loss on drying; residual solvents; arsenic; lead; cadmium; and mercury. The subsection also provides that the final product may be spray dried.

The effect of this amendment will be to permit rebaudioside MD that is obtained by fermentation, and not from the leaves of the *Stevia rebaudiana* Bertoni plant, to be used as a food additive in accordance with the existing food additive permissions in the Code for steviol glycosides, provided that the rebaudioside MD complies with the specifications listed in subsection S3—39(3).