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 A1157 which sought an amendment to Schedule 3 of the Code to prescribe a new specification for rebaudioside M (Reb M) produced by a particular enzymatic conversion method. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

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 draft variation of a standard.

2. Purpose

The purpose of the variations is to permit the use as a food additive of Reb M produced using the enzymatic conversion method detailed in Application A1157. To this end, the variations amends the specification for Reb M provided by S3—35(2) of Schedule 3 of the Code by inserting a reference to that enzymatic conversion method. The variations also amend Schedule 18 of the Code to permit the use as processing aids of the specific enzymes used in that enzymatic conversion method. The effect of the variations is to permit the use of Reb M produced by that method to be used as a food additive in accordance with the existing permissions and limits for steviol glycosides (including containing Reb M) in the Code.

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 A1157 included one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary. Submissions were called for on 20 July 2018 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations 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]

Item [1] amends Schedule 3 of the Code. The item omits S3—35(2) and substitutes new subsection S3—35(2) and (2A).

The new subsection S3—35(2) includes a reference to the enzymatic conversion of purified stevia leaf extract to produce Reb M using protein engineered enzymes that: contain both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and are sourced from both of the following; a *Pichia pastoris* strain expressing UGT-A, and a *Pichia pastoris* strain expressing both UGT-B1 and UGT-B2.

The new subsection S3—35(2A) restates the proviso in the current subsection S3—35(2) that the final product may be spray dried.

The effect of this amendment is to permit Reb M produced using this method to be used as a food additive in accordance with the existing food additive permissions in the Code for steviol glycosides (including containing Reb M).

Item [2]

Item [2] amends Schedule 18. The item inserts a new entry into the table to subsection S18—9(3). The effect of the new entry would be to permit the use of specific enzymes as a processing aid in the manufacture of Reb M for the following technological purpose: the conversion of purified stevia leaf extract to produce Reb M. The permitted enzymes are protein engineered enzymes that: contain both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and are sourced from both of the following; a *Pichia pastoris* strain expressing UGT-A, and a *Pichia pastoris* strain expressing both UGT-B1 and UGT-B2. The permission includes the condition that the maximum permitted amount used as a processing aid must be consistent with Good Manufacturing Practice (as defined by section 1.1.2—2(3) of the Code).