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 A1172 which sought an amendment to Schedule 3 of the Code to prescribe a new specification for rebaudioside D (Reb D) produced by a particular enzymatic conversion method. The Authority considered the application in accordance with Division 1 of Part 3 of the FSANZ Act and prepared 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 standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to amend subsection S3—35(2) of Schedule 3 of the Code. The amendment includes in the specification provided by that subsection a reference to the enzymatic conversion method used to produce the A1172 applicant's Reb D. The amendment's effect permits Reb D produced by that production method to be used as a food additive in accordance with the existing permissions and limits for steviol glycosides (including containing Reb D) in the Code.

The Authority also prepared a draft variation to amend Schedule 18 of the Code to permit the use of the specific enzyme as a processing aid in the processing of the A1172 applicant's Reb D in accordance with Standard 1.3.3 of 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 A1172 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

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]

Item [1] amends Schedule 3 of the Code. The item adds a new paragraph (c) to the subsection S3—35(2).

The new paragraph S3—35(2)(c) includes a reference to the enzymatic conversion of purified stevia leaf extract to produce Reb D using a protein engineered enzyme that: contains both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and is sourced from *Pichia pastoris* strain UGT-A.

The effect of this amendment is to permit Reb D 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 steviol glycosides containing Reb D).

Item [2]

Item [2] will amends Schedule 18. The item inserts a new entry into the table to subsection S18—9(3). The effect of the new entry is to permit the use of a specific enzyme as a processing aid in the manufacture of Reb D for the following technological purpose: the conversion of purified stevia leaf extract to produce Reb D. The permitted enzyme is a protein engineered enzyme that: contains both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and is sourced from *Pichia pastoris* strain UGT-A. 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).

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