

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 A1207 which sought an amendment to the Code to permit the use of rebudioside M (Reb M) produced from fermentation by a genetically modified *Saccharomyces cerevisiae* (*S. cerevisiae*) strain, as a food additive intense sweetener. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation)¹, 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 sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to the table to subsection S3—39(2) of the Code to permit Reb M to be used as a food additive (an intense sweetener) in accordance with the Code.

3. Documents incorporated by reference

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

Existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the food additive to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as food additives to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2017), the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition) and the Commission Regulation (EU) No 231/2012, specifications for food additives. These include specifications for this food additive.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1207 included one round of public consultation following an

¹ The Forum name change took effect on 21 February 2021 following a decision by Ministers.

assessment and the preparation of a draft variation and associated report. Submissions were called for on 21 October 2020 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit food additives (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional food additives (including new methods of manufacture of existing food additives) is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a new version of a food additive to the food supply that has been determined to be safe. The use of the approved food additive is also voluntary.

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 inserts a new entry into the table to subsection S3—39(2), which lists ‘prescribed steviol glycosides’ for the purposes of specifications in subsection S3—39(3).

The new entry is ‘Rebaudioside M’ derived from ‘*Saccharomyces cerevisiae* strain Y63348 containing novel genes for the production of rebaudiosides’. In other words, Reb M derived from this source will be a prescribed steviol glycoside and specifications in subsection S3—39(3) will apply to this Reb M.

The effect of this amendment will be to permit Reb M that is derived from this source, 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 Reb M complies with the specifications listed in subsection S3—39(3).