

# 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.

FSANZ accepted Application A1108 which seeks permission for rebaudioside M to be added to the list of permitted steviol glycosides used as intense sweeteners. 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<sup>1</sup>, 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 *Legislative Instruments Act 2003*.

## 2. Purpose

The approved draft variation adds rebaudioside M to the list of permitted steviol glycosides that can be added as a food additive intense sweetener preparation to food or sold for use in food. It also includes new specifications in Schedule 3 of the Code for rebaudioside M and for a steviol glycoside mixture or preparation that includes rebaudioside M.

## 3. Documents incorporated by reference

The approved draft variation incorporates a number of specifications by reference to specific documents in force or existing at the commencement of the variation.

The incorporated specifications are contained in the specific editions of publications listed in section S3—2 of Schedule 3 of the Code. In general, these specifications and publications are referred to in order to provide further technical detail to support the provisions of the Code. These references by incorporation are consistent with the current practice in the Code, particularly Schedule 3 which itself already incorporates the specifications in these documents by reference.

The documents in question are:

- (a) The Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005), Food and Agriculture Organisation of the United Nations, Rome, as superseded by specifications published in any of the following:

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<sup>1</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

- (i) FAO JECFA Monographs 3 (2006);
  - (ii) FAO JECFA Monographs 4 (2007);
  - (iii) FAO JECFA Monographs 5 (2008);
  - (iv) FAO JECFA Monographs 7 (2009);
  - (v) FAO JECFA Monographs 10 (2010);
  - (vi) FAO JECFA Monographs 11 (2011);
  - (vii) FAO JECFA Monographs 13 (2012);
- (b) United States Pharmacopeial Convention (2014) Food chemicals codex. 9<sup>th</sup> ed, United States Pharmacopeial Convention, Rockville, MD.
- (c) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives.

#### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1108 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. A call for submissions (including the draft variation) occurred for a six-week consultation period.

A Regulation Impact Statement was not required because the approved draft variation to Standard 1.3.1 and 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 Standard 1.3.1. The variation replaces paragraphs (g) to (j) of the definition of **CF** (Conversion Factor) in subsection 1.3.1—4(7).

Standard 1.3.1 and Schedule 15 permit the use of preparations of steviol glycosides ('steviol glycosides') as food additives intense sweeteners. Paragraph 1.3.1—4(6)(i) of Standard 1.3.1 requires that, for this purpose, steviol glycosides must be calculated as 'steviol equivalents' in accordance with subsection 1.3.1-4(7). The variation adds rebaudioside M to the list of steviol equivalents within that subsection. It also adds a conversion factor used to calculate a steviol equivalent for rebaudioside M. This in effect provides the permission for the use of rebaudioside M as a food additive.

The variation also removes the reference to steviol in paragraph (h) of the definition of **CF** (Conversion Factor) in subsection 1.3.1—4(7). This is because steviol is not itself a steviol glycoside, nor is it contained in commercial steviol glycoside preparations. It is the active non-sugar component of steviol glycosides. It was listed in the definition for illustrative purposes and is often added to lists of steviol glycosides for structural elucidation purposes only. It has a steviol equivalence of 1.00 and, as such, is not required.

Item [2] varies Schedule 3.

Item [2.1] varies the table to subsection S3—2(2). The variation amends that table to include in it references to: rebaudioside M; a steviol glycoside mixture or preparation that includes rebaudioside M; and new sections S3—31 and S3—32. The effect is that subsection 1.1.1—15(2) of Standard 1.1.1 will require those substances, when added to food or sold for use in food, to comply with the specifications listed for each by those new sections.

Item [2.2] inserts new sections S3—31 and S3—32 into Schedule 3.

New section S3—31 provides the specifications for rebaudioside M. Subsection S3—31(1) and S3—31(2) provides a definition and specifications for assay, chemical name and formula weight. Subsection S3—31(3) provide that rebaudioside M must also comply with one of the specifications that relate to steviol glycosides and that is listed in a primary source named in paragraph S3—2(1)(b), S3—2(1)(c) or S3—2(1)(d) of Schedule 3. Each of the primary sources named in those paragraphs contains a specification that relates to steviol glycosides that are comparable to rebaudioside M. Subsection S3—31(3) requires that rebaudioside M comply with one of those specifications subject to the requirements in subsection S3—31(2).

New section S3—32 provides the specifications for a steviol glycoside mixture or preparation that includes rebaudioside M. Subsections S3—32(1) and (2) provide that the specifications apply to a mixture that contains rebaudioside M and one or more of the steviol glycosides currently permitted by the Code in preparations of steviol glycosides for use as a food additive intense sweetener. Subsection S3—32(3) provides a content specification. That is, the rebaudioside M and the prescribed steviol glycoside or glycosides must together comprise not less than 95% of the mixture. Subsection S3—31(3) provides that rebaudioside M must also comply with one of the specifications that relate to steviol glycosides and that is listed in a primary source named in paragraphs S3—2(1)(b), S3—2(1)(c) or S3—2(1)(d) of Schedule 3.