

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1273– Steviol glycosides as a food additive in Food for special medical purposes) Variation

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 A1273 which sought to amend the Code to permit the use of steviol glycosides as a food additive (intense sweetener) in Food for special medical purposes (FSMP), excluding any use in FSMP formulated for infants. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1273 – Steviol glycosides as a food additive in Food for special medical purposes) Variation*.

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the

international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending Schedule 15 of the Code to permit the use of steviol glycosides as a food additive (intense sweetener) in FSMP, excluding any use in FSMP formulated for infants.

4. Documents incorporated by reference

The approved draft variation in this instrument does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would prescribe identity and purity specifications for the food additive to be permitted in FSMP by the approved 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 JECFA Monographs 26 (2021)), and the United States Pharmacopeial Convention Food Chemicals Codex (13th edition, 2022). These include specifications for steviol glycosides. In addition, Schedule 3 also contains other specifications for specific types of steviol glycosides not covered by the specifications incorporated by reference in section S3—2.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1273 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 17 November 2023 for a four-week period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)¹. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised the Authority that a Regulatory Impact Statement was not required for the applications relating to food additives. This was because applications relating to permitting the use of food additives that have been determined to be safe were considered to be minor and deregulatory in nature as their use would be voluntary if the draft variation concerned is approved. Under the new approach, the Authority's assessment is that a regulatory impact statement is not required for this application.

6. Statement of compatibility with human rights

¹ Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies: <https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national>

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1273 – Steviol glycosides as a food additive in Food for special medical purposes) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Item [1] of the Schedule to the variation amends Schedule 15, by inserting a new item into the table to section S15—5, after the table item dealing with 'Saccharin' under the heading "13.5 Food for special medical purposes". The new table item consists of:

960	Steviol glycosides	75	Not for a *very low energy food. Not for a product formulated for infants.
		330	For a *very low energy food only.

The effect of this amendment is to permit the use of steviol glycosides (INS number 960) as a food additive in:

- a food for special medical purposes that is not a *very low energy food subject to an MPL of 75 mg/kg (as steviol equivalents) and the express condition that the steviol glycosides must not be added to or used in a product formulated for infants; and
- a food for special medical purposes that is a very low energy food up to an MPL of 330 mg/kg (as steviol equivalents).

'Very low energy food' is defined in Standard 1.1.2 as:

'a food for special medical purposes produced for consumption as part of a 'very low energy diet'.'

'Very low energy diet' is defined in Standard 1.1.2 as:

'a range of food for special medical purposes specially formulated for the dietary management of overweight and obesity and which provide the sole source of nutrition when consumed according to the directions for use on the label'.

Very low energy foods are formulated as a total diet replacement and to provide the sole source of nutrition for their consumer. As such, they are not suitable for infants. A product that was formulated for and sold for use by an infant as part of a 'very low energy diet' (i.e., as a total diet replacement and to provide a sole source of nutrition) would also be captured by the Code's definition of 'infant formula product', and therefore must comply with the Code's separate and different requirements that apply to infant formula products. The Code's definition of 'food for special medical purposes' also expressly provides that any product that meets the Code's criteria on what is an 'infant formula product' cannot be a 'food for special medical purposes'. This in turn means that an 'infant formula product' cannot be a very low

energy food. For this reason, the food additive permission provided by the approved draft variation for a 'very low energy food' does not expressly exclude 'products formulated for infants'.

The same rationale does not apply to a 'food for special medical purposes' that is not a 'very low energy food'. The Code allows for 'food for special medical purposes' that are not a 'very low energy food' to be formulated for partial feeding of infants. As such, if a product is not formulated and sold as the sole or principal liquid source of nourishment for infants, it would not be an infant formula product and regulated as such. For this reason, the food additive permission provided by the draft variation for 'food for special medical purposes' that are not a 'very low energy food' expressly excludes 'a product formulated for infants'.

The effect of the above is that the use of steviol glycosides (INS number 960) as food additive are not permitted in 'food for special medical purposes' formulated for infants.