26 March 2024
286-24

Approval report – Application A1273

Steviol glycosides as a food additive in Food for special medical purposes

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Nestlé Australia Limited and Nestlé New Zealand Limited to permit steviol glycosides as a food additive (intense sweetener) in Food for Special Medical Purposes.

On 17 November 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 13 March 2024. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 26 March 2024.

This report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website:

SD Risk and Technical Assessment

Executive summary

Nestlé Australia Limited and Nestlé New Zealand Limited applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the addition of the food additive 'steviol glycosides' to Food for Special Medical Purposes (FSMP).

The primary reason for the requested amendment is to align the Code with international permissions, including the European Union and with provisions listed in the Codex Alimentarius standard. The proposed use of steviol glycosides is consistent with its typical function as an intense sweetener. Relevant identity and purity specifications are included in the Code.

FSANZ has previously assessed an extensive toxicological database on steviol glycosides, which has identified no safety concerns or a need to amend the Acceptable Daily Intake (ADI) established by FSANZ in 2008 of 0-4 mg/kg bw for steviol glycosides, expressed as steviol equivalents. This was confirmed as a part of the current assessment.

Under the current assessment for the use of steviol glycosides in FSMP, FSANZ's estimated dietary exposure assessment established that separate maximum permitted levels were required to ensure that exposures to steviol glycosides remained below the ADI for FSMP that are 'very low energy foods' and all 'other FSMP' as set out below:

- for very low energy foods produced for consumption as part of a very low energy diet, the maximum permitted level of the food additive is 330 mg/kg (as steviol equivalents),
- for all other FSMP, the maximum permitted level of the food additive is 75 mg/kg (as steviol equivalents), with no permission in FSMP formulated for infants (0 – 12 months).

Following assessment and the preparation of the draft variation, FSANZ called for submissions regarding the draft variation. FSANZ received four submissions. One submitter fully supported the draft variation. Three submitters noted imports of other FSMP may be impacted by the draft variation because the maximum permitted level for steviol glycosides for other FSMP is lower than international provisions. FSANZ acknowledges this concern, however, as stated above, a lower maximum permitted level for other FSMP is required to ensure intakes are below the ADI.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the Code.

The effect of the approved draft variation will be to:

- permit the food additive for use in the manufacture of FSMP in accordance with the Code, subject to the conditions that:
    - for very low energy foods produced for consumption as part of a very low energy diet, the maximum permitted level of the food additive is 330 mg/kg (as steviol equivalents),
    - for all other FSMP, the maximum permitted level of the food additive is 75 mg/kg (as steviol equivalents), with no permission in FSMP formulated for infants (0 – 12 months).

1 Introduction

1.1 The applicant

The applicant is Nestlé Australia Limited and Nestlé New Zealand Limited (Nestlé), a food manufacturer, importer and marketer.

1.2 The application

The applicant sought to amend the Australia New Zealand Food Standards Code (the Code) to permit steviol glycosides as a food additive (intense sweetener) in Food for Special Medical Purposes (FSMP).

The purpose of the application is to align the Code with international permissions, including those in place under European Union (EU) Regulations, and with provisions listed in the relevant Codex Alimentarius (Codex) standard.

The applicant has requested a maximum permitted level (MPL) of 330 mg/kg (as steviol equivalents), excluding any use in FSMP for infants aged under 12 months.

Infant is defined in section 1.1.2—2 of the Code as follows: Infant means a person under the age of 12 months.

1.3 The current Standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Food for special medical purposes

Standard 2.9.5 – Food for special medical purposes regulates the sale, composition and labelling of foods specially formulated for the dietary management of individuals with certain diseases, disorders or medical conditions. FSMP are required when the dietary management of individuals cannot be easily or completely achieved with other dietary modification including the use of other special purpose foods. FSMP includes formulated dietary products that are intended for use as the sole source of nutrition, either consumed orally or through an enteral route (e.g. naso-gastric tube), as well as specialised supplementary formulated products. Food regulated by this standard is intended to be used under medical supervision. Due to the specialised nature and purpose of these foods, this standard also includes a restriction on the premises at which, and the persons by whom, FSMP may be sold to consumers.

Many FSMP are imported into Australia and New Zealand. In order to limit the impost on manufacturers and therefore ensure continued supply of these products to Australia and New Zealand, the existing compositional and labelling requirements in Standard 2.9.5 harmonise where possible with overseas regulations.

By definition, a FSMP cannot be an Infant Formula Product or a food specially formulated for the dietary management of overweight and obesity and which is not a very low energy food. Very low energy foods and very low energy diets (VLED) are FSMP defined and regulated within Standard 2.9.5. For the purposes of this call for submissions report, these foods are referred to as ‘VLED’. All other FSMP are referred to as ‘other FSMP’ in this report.

A number of intense sweeteners are already permitted to be used in the manufacture of FSMP, however steviol glycosides are not included.

1.3.2 Permitted use

When steviol glycosides are added to food as an intense sweetener, they are regulated as food additives.

Paragraph 1.1.1—10(6)(a) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a food additive' unless that substance's use as a food additive is expressly permitted by the Code.

Section 1.3.1—3 provides which substances are permitted to be used as a food additive in food. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

Section 1.1.2—11 defines the expression 'used as a food additive'. Subsection 1.1.2—11(1) provides that a substance is 'used as a food additive' in relation to a food if both of the following conditions are met: the substance is added to the food to perform one or more technological functions listed in Schedule 14; and the substance is identified in subsection 1.1.2—11(2) – this includes (among other things) a substance identified in the table to section S15—5 as a permitted food additive.

Schedule 14 lists the permitted technological purposes of food additives. The table to section S14—2 provides that use as an intense sweetener is a permitted technological purpose.

Schedule 15 lists the specific food additive permissions for different classes of foods. Item 13.5 in the table to subsection S15—5 lists the permitted food additives for Food for special medical purposes. This list includes *Additives permitted at GMP*. These are listed in Schedule 16. Several intense sweeteners are included in Schedule 16.

The MPLs for steviol glycosides are calculated as 'steviol equivalents' in accordance with subsection 1.3.1—4(7) (see paragraph 1.3.1—4(6)(i)). Sub-section 1.3.1—4(7) sets out how to calculate steviol equivalents based on the ratio of the various glycosides that make up the steviol glycosides preparation used in food.

1.3.3 Identity and purity requirements

Paragraph 1.1.1—15(1)(a) 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.

Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)), and the United States Pharmacopeial Convention (2022) Food chemicals codex (13th edition). These include specifications for steviol glycosides. In addition, Schedule 3 contains a number of specifications for steviol glycosides, over and above the steviol glycosides listed in subsection S3—2(1) of Schedule 3.

1.3.4 Labelling requirements

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code applying to the sale of that food.

Standard 2.9.5 sets out specific labelling requirements that apply for FSMP. Unless the

contrary intention appears in the standard, the labelling provisions in Part 1.2 (labelling and information requirements) of the Code do not apply.

The most relevant labelling provisions in Standard 2.9.5 that apply to this application are those relating to the declaration of ingredients. Paragraph 2.9.5—9(1)(e) requires that FSMP for sale in a package must bear a label that provides information on ingredients in accordance with the following requirements of section 2.9.5—11:

- a statement of ingredients that complies with the Code; or
- information that complies with Articles 18, 19, 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; or
- information that complies with 21 CFR § 101.4.

Standard 2.9.5 does not require the provision of ingredient information on FSMP that are not in a package, or on the inner package or transportation outer of an FSMP (subsections 2.9.5—8(1), 2.9.5—8(3), 2.9.5—8(4)).

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

The application sought to amend the Code to align with international permissions, as many FSMP products are imported into Australia and New Zealand from other countries. As FSMP are intended to be consumed by limited population groups, consumers often rely on accessing FSMP from countries outside of Australia and New Zealand.

Codex

Codex STAN 192-1995 (also referred to as the General Standard for Food Additives, or GSFA) contains food additive listings by food category[2]. The GSFA contains provisions for the use of steviol glycosides in a range of foods and maximum permitted limits. The following food categories and provisions are relevant to this application:

- **13.3 Dietetic foods intended for special medical purposes (excluding products of food category 13.1 – Infant formulae, follow-up formulae, formulae for special medical purposes for infants):** Steviol glycosides: maximum 350 mg/kg.

  FSANZ notes that an age range is not specified. However, the Codex permission for steviol glycosides in Codex Category 13.3 products do not extend to products for infants and products for young children that fall under one of the 13.1 food categories.

- **13.4 Dietetic formulae for slimming purposes and weight reduction**: Steviol glycosides: maximum 270 mg/kg.

  FSANZ notes that this food category is broader than Standard 2.9.5 in the Code, as some products may fall under Standard 2.9.3 – Division 2 (Formulated meal replacements).

[2] GSFA Online Food Categories

European Union

Food additives approved in the 27 EU Member States are listed in Annex II of Regulation (EC) No 1333/2008[3,4,5]. This Regulation is supported by a database for ease of searching. The relevant provisions are summarised below.

- **13.2 Dietetic foods for special medical purposes (excluding products of food category 13.1.5):** Steviol glycosides: maximum 330 mg/kg.

  Refer to table 1 below for information regarding food category 13.1.5.

- **13.3 Dietary foods for weight control intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet):** Steviol glycosides: maximum 270 mg/kg.

  FSANZ notes that this food category is broader than Standard 2.9.5 in the Code, as some products may fall under Standard 2.9.3 – Division 2 (Formulated meal replacements).

Food category 13.1.5 (shown below in Table 1) includes dietary foods for infants and young children, and human breast milk fortifiers. Under the EU Regulation intense sweeteners (including steviol glycosides) are not permitted to be added to foods in these categories.

While the European Food Safety Authority (EFSA) has published an opinion for the addition of sucralose to food category 13.1.5.2 (FSMP for young children aged 12 – 36 months), no permission for the use of sucralose in this product category has yet been incorporated into EU law.[6]

Table 1: EU Regulation food category 13.1.5

Food category	*Inclusions*
13.1.5	Dietary foods for infants and young children for special medical purposes as defined by Commission Directive 1999/21/EC and special formulae for infants This category covers foods for particular nutritional uses specially processed or formulated and intended for the dietary management of infants and young children and to be used under medical supervision.
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants This category covers dietary foods for infants for special medical purposes and special formulae such as premature infant formulae, hospital discharge formulae, low and very low birth weight formulae, and human breast milk fortifiers.
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC

[3] Database (europa.eu)
[4] EU Rules (europa.eu)
[5] Consolidated TEXT: 32008R1333 — EN — 05.10.2023 (europa.eu)
[6] Safety of the proposed extension of use of sucralose (E 955) in foods for special medical purposes in young children | EFSA (europa.eu)

	This category covers foods specially processed or formulated and intended for the dietary management of babies and young children, to be used under medical supervision. This includes for example the dietary management of infants and young children with metabolic or gastrointestinal disorders, or single or multiple food allergies or intolerances (e.g. cow's milk protein allergy, protein mal-absorption) and for general tube feeding. Baby foods are foodstuffs destined to children of at least 4 months (see Article 8 of Commission Directive 2006/125).

Other countries

Singapore and Turkey expressly permit the addition of steviol glycosides to FSMP. Singapore permits steviol glycosides up to 175 mg/kg. Turkey permits up to 330 mg/kg (excluding products for infants and young children).

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

For the reasons outlined in this report, the draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal and is at Attachment A. The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 17 November 2023. The consultation period was four weeks.

Four submissions were received - one from government, two from industry (Ingredion and the New Zealand Food and Grocery Council), and one from the Australian Institute of Food Science and Technology (AIFST). All submitters supported the proposed MPL of 330 mg/kg (as steviol equivalents) for VLED. NZFS supported the proposed MPL of 75 mg/kg (as steviol equivalents) for other FMSP, to manage potential risk associated with the variations in medical requirements. However, both industry organisations and the AIFST were concerned that the lower MPL for other FSMP could restrict imports and was overly conservative.

Responses to the issues raised in submissions are summarised in Table 1 below.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Fully supports the proposed draft variation	New Zealand Food Safety (NZFS)	Noted
Support the proposed draft variation and MPL of 330 mg/kg (as steviol equivalents) for VLED, but noted concerns regarding other FSMP (see below)	Australian Institute of Food Science and Technology (AISFT) Ingredion New Zealand Food and Grocery Council (NZFGC)	Noted
Disappointed at the departure (from international levels) of the proposed MPL for other FSMP, which may impact future imports and innovation.	AIFST	Noted. The MPL for other FSMP is based on a safety assessment combined with a dietary exposure assessment. See also responses below.
Noted that MPL for other FSMP will result in issues for imported products and limit the availability of such FSMP to Australia and New Zealand consumers for dietary management of specific medical conditions.	AIFST Ingredion	Noted. As stated above, the lower MPL for other FSMP is based on a safety assessment combined with a dietary exposure assessment. The numerical MPLs in legislation or established by Codex are not a target, rather they are an upper level. Actual use levels are not the same as MPLs, and in practice other FSMP available internationally are produced with levels of steviol glycosides lower than the MPL requested by the applicant.

Issue	Raised by	FSANZ response
Noted that imports of other FSMP may be impacted by the lower MPL (75 mg/kg)	AIFST Ingredion NZFGC	The lower MPL for other FSMP is based on a safety assessment. An MPL of 75 mg/kg ensures that 'other FSMP' users will not have dietary exposures that exceed the ADI regardless of differing medical requirements, intended populations and directions of use.
Noted that for other FSMP it is not clear why the scenario of 'usual use levels' was not applied for the dietary exposure**.**	AIFST NZFGC	Adoption of the MPL regulatory approach is consistent with the statutory objective set for FSANZ of protecting public health and safety and reflects that FSMPs are used by a vulnerable population and can provide the sole source of nutrition for a lifetime. The MPL regulatory approach takes account of consumers who may only be able to use or tolerate one specific product with a concentration at the maximum permitted level. Modelling also confirmed that the 'usual use level scenario' would result in some products exceeding the ADI.
Stated that for other FSMP, it is not often the case that FSMP are used as a sole source of nutrition for a lifetime. The ADI is for whole of life and is not based on a limited (temporary) exposure.	AIFST	Other FSMP can be a sole source of nutrition for a lifetime. This scenario must therefore be accounted for. The ADI being for lifetime exposure means that it is conservative and highly protective during shorter exposures. See also responses above.
Disappointed at the departure (from international levels) of the proposed MPL for other FSMP, but nevertheless support.	NZFGC	Noted. See responses above.

2.2 Risk assessment

FSANZ undertook an assessment to determine whether the food additive achieves the requested technological purpose in the quantity and form proposed to be used, and to determine if there are any public health and safety concerns (refer to the Supporting Document (SD)).

The food technology assessment concluded that the use of steviol glycosides as a food additive in FSMP is consistent with its typical technological function as an intense sweetener. The evidence presented by the applicant provided adequate assurance that the use of steviol glycosides, in the quantity and form proposed to be used, is technologically justified and is effective in achieving its stated purpose. VLED have a greater technological need for intense sweeteners than other FSMP due to their highly prescriptive and restricted composition, and need to reduce the energy value. Relevant identity and purity specifications are included in the Code.

FSANZ has previously assessed an extensive toxicological database on steviol glycosides, which has identified no safety concerns or a need to amend the Acceptable Daily Intake (ADI) established by FSANZ in 2008 of 0 - 4 mg/kg bw for steviol glycosides, expressed as steviol. The applicant submitted a number of recent reviews on the toxicity of steviol glycosides which for the reasons stated in the SD did not raise any concerns regarding the safety of steviol glycosides, nor provide any new toxicity information that has not previously been assessed by FSANZ. For the reasons stated in the SD, FSANZ again determined there was no need to amend the established ADI.

FSANZ conducted dietary exposure assessments to estimate the level of chronic exposure to steviol glycosides (expressed as steviol equivalents) from VLED and other FSMP.

When used at the proposed MPL, estimated dietary exposures from VLED did not exceed the ADI, whereas estimated dietary exposures for adults, adolescents and children from other FSMP when used as a sole source of nutrition exceeded the ADI. A lower maximum use level of steviol glycosides for other FSMP could result in exposures that do not exceed the ADI, if other FSMP is used as a sole source of nutrition. The highest use level of steviol glycoside (expressed as steviol equivalents) that would not result in dietary exposures from other FSMP exceeding the ADI is 75 mg/kg.

2.3 Risk management

2.3.1 Risk management options

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of four weeks.

The risk management options available to FSANZ following the call for submissions are to either:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Having regard to the submissions received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (see Attachment A).

The approved draft variation will permit steviol glycosides to be used as a food additive:

- in very low energy foods produced for consumption as part of a VLED, subject to a MPL of 330 mg/kg; and
- in all other types of FSMP, subject to a MPL of 75 mg/kg and an express condition that the steviol glycosides cannot be added to a product formulated for infants.

2.3.2 Public health and safety considerations of steviol glycosides in FSMP

The risk and technical assessment reported in the SD concluded that the use of this food additive is technologically justified as an intense sweetener in FSMP (both VLED and other FSMP). There are no public health and safety concerns with using steviol glycosides as a food additive in the manner requested in the application (maximum 330 mg/kg) for VLED. For other FSMP there are no such concerns with using steviol glycosides as a food additive at a MPL of 75 mg/kg.

2.3.3 Permitted use and conditions in VLED

As explained in the Call for Submissions, Standard 2.9.5 was amended in 2022 by Application *A1230 – Very Low Energy Diets*, to impose requirements on VLEDs as FSMP. These amendments set nutrient composition and labelling requirements for VLED, but did not set specific food additive permissions.

FSANZ acknowledges that the use of intense sweeteners within VLED has been previously discussed within Proposal *P242 – Foods for Special Medical Purposes* (P242) and that the permission is now commonly used internationally. Due to the prescriptive composition and limited energy content of VLED, FSANZ considers the addition of steviol glycosides as an alternative to existing intense sweeteners is favourable from both a composition and consumer compliance viewpoint. The addition of steviol glycosides will allow manufacturers to achieve the desired flavour and level of sweetness without additional sugar. In practice this would allow for better utilisation of the prescriptive composition, for example increased content of essential nutrients and decreased sugar content. In addition, consumer compliance to VLED total diet replacement plans are typically low and generally do not extend beyond two to three weeks. Improved palatability of the products could aid compliance and in turn benefit clinical results.

VLED are specifically formulated to satisfy the nutrient requirements of people when used as the sole source of nutrition in the dietary management of overweight and obesity. VLED are required to contain a label statement to the effect that VLED are not recommended for pregnant, nursing or lactating women or use by infants, children, adolescents and elderly, other than under medical supervision. In addition, the only products that can provide sole source of nutrition to infants are infant formula products. This is captured by the definitions in Standard 1.1.2. Because of this the approved draft variation does not require an additional condition statement listed in column four of schedule 15--5 (regarding use by infants) against the MPL for VLED.

The dietary exposure to steviol glycosides from VLED was estimated for adults aged between 18 and 65 years to be 80% of the ADI. This was modelled in alignment with the intensive level of the total diet replacement plan estimated (details are noted in section 3.4.4 of the SD). As VLEDs are used as sole source of nutrition for a short period and typically have lower rates of compliance, FSANZ considers this exposure to be conservative, with minimal risk to public health and safety of VLED users (further details are provided in section 3.4.4 of the SD).

2.3.4 Permitted use and conditions in other FSMP

2.3.4.1 Other FSMP

As noted in section 1.3.1, FSMP include formulated dietary products that are intended for use as the sole source of nutrition (consumed orally or through an enteral route) and as a partial source of nutrition through specialised supplementary formulated products. FSMP are often multipurpose as they are prescribed for the dietary management of certain diseases, disorders or medical conditions. In practice this means FSMP can be formulated for broader use across a population and have flexible directions of use. For example many enteral feeds are formulated for a large age range (4 - 14 years) and can also be used as an Oral Nutrition Supplement (ONS) as partial or sole source of nutrition. Therefore, establishing one MPL for steviol glycosides for the 'other FSMP' product category is difficult due to the variations in medical requirements, intended population and directions of use.

Based on the conclusions of the SD, FSANZ considers permitting the addition of steviol glycosides to other FSMP (excluding FSMP formulated for infants under 12 months of age) is appropriate based on the technological justification and potential to aid consumer compliance. Extensively formulated foods are typically associated with metallic tastes and unusual flavours due to the addition of vitamin and mineral nutrient preparations. The addition of intense sweeteners, including steviol glycosides, has the ability to mask these flavours and tastes, while maintaining the nutritional profile and macronutrient ranges of the FSMP. As noted above, increasing the desirability of these products may increase consumer compliance and in turn benefit clinical outcomes.

Based on the dietary modelling (refer to section 3.4.3 of the SD), the maximum permitted level for other FSMP will be 75 mg/kg, instead of 330 mg/kg as requested by the applicant. An MPL of 75 mg/kg ensures that 'other FSMP' users will not have dietary exposures that exceed the ADI regardless of differing medical requirements, intended populations and directions of use.

The maximum permitted level of 75 mg/kg also mitigates risks associated with the younger populations exceeding the ADI. As consumers of FSMP are already considered a vulnerable population, it is a public health priority to ensure their products remain safe and suitable. For example, formulas for cow's milk protein allergy and/or phenylketonuria for consumers aged one year and above are captured within this category and can be used as sole source of nutrition.

2.3.4.2 FSMP formulated for infants

The applicant has excluded FSMP formulated for infants under 12 months of age from the permission requested.

By definition a FSMP cannot be an infant formula product. However, the FSMP definition does not exclude medical purpose products based on the age they are intended. Therefore, according to the definition, an FSMP can include medical purpose products for infants other than infant formula products as defined in Standard 1.1.2 of the Code. For example, Standard 2.9.1 does not include modulatory products such as human milk fortifiers and pre-term supplementary products for infants as these do not meet the definition for an infant formula product. Therefore, these products are captured by Standard 2.9.5. As these medical purpose products for infants are captured by Standard 2.9.5, FSANZ considers the exclusion of FSMP formulated for infants under 12 months of age an appropriate condition statement for inclusion in S15—5 of the approved draft variation. The condition statement requested by the applicant aligns with the EU Regulation, which does not allow the addition of steviol glycosides to *dietary foods for babies and young children for special medical purposes*,

dietary foods for infants for special medical purposes and special formulae for infants and *dietary foods for infants and young children for special medical purposes.*

FSANZ notes that the proposed condition statement regarding infants does not align with Codex STAN 192-1995 (see section 1.4 above). This difference can be attributed to the way food additive provisions are listed within food categories and how the food categories are captured. Codex STAN 192-1995 clearly notes that all infant products are captured within food category 13.1 (Infant formulae, follow-up formulae, formulae for special medical purposes for infants), and all other FSMP are regulated separately. As discussed in the preceding paragraph, Standard 2.9.5 can regulate medical purpose products formulated for infants that are not captured by Standard 2.9.1. Due to this difference FSANZ cannot achieve complete alignment with the provisions noted in Codex. However, trade implications are not anticipated, as intense sweeteners are not known to be used or required in FSMP formulated for infants.

As the condition statement was requested by the applicant, the dietary exposure assessment in the SD has not included infants under 12 months of age within the assessment. The dietary exposure assessment noted assumptions regarding the composition and consumption of FSMP, due to their varying nature, purpose and application of use (further details are provided in section 3.4.4 of the SD).

2.3.5 Labelling

In accordance with existing FSMP labelling provisions (see section 1.3.4 above), steviol glycosides will be required to be listed as a food additive in ingredient information on an FSMP label. Ingredient labelling information is only required when the FSMP is sold in a package .

FSMP labelling requirements permit ingredients to be declared in one of three ways:

- a statement of ingredients that complies with the Code
- information that complies with Articles 18, 19, 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers
- information that complies with 21 CFR § 101.4.

Listing steviol glycosides as an ingredient in accordance with the Code would require steviol glycosides to be identified in the statement of ingredients using the class name ‘sweetener’ (as listed in Schedule 7) followed in brackets by either the food additive name ‘steviol glycosides’ or the International Numbering System (INS) code number 960 (as listed in Schedule 8). European and United States ingredient declaration requirements differ from the Code requirements. In the case of European regulations, steviol glycosides can be declared with code numbers E960a, E960b, E960c and E960d. The United States does not permit the use of code numbers, but does allow for the use of ‘sweetener’ in the ingredient name, provided the common food additive name (e.g. ‘steviol glycosides’) is also included.

2.3.6 Risk management conclusion

Having considered all aspects of the assessment against the statutory requirements, the risk management conclusion was to permit the voluntary addition of steviol glycosides to FSMP. FSANZ considers permission for the addition of steviol glycosides to FSMP will provide further flexibility for formulating products and a greater range of products to consumers.

Under the approved draft variation, the permissions would be subject to MPLs for steviol

glycosides (as steviol equivalents) in FSMP as follows:

- VLED – 330 mg/kg
- Other FSMP (not for FSMP formulated for infants) – 75 mg/kg

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions were invited on a draft variation which was released for public comment between 17 November 2023 and 11 December 2023. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on applications to amend the Code. All submissions are considered as part of the decision making process by FSANZ. All comments are valued and contribute to the rigour of our assessment.

Documents relating to A1273, including the received submissions, are available on the FSANZ website.

The draft variation was considered for approval by the FSANZ Board having regard to all the submissions made during the call for submissions period.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[7]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for the applications relating to food additives. This is because applications relating to permitting the use of food additives that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the application is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

[7] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considers permitting the use of steviol glycosides as a food additive (intense sweetener) in FSMP.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the potential positives and negatives of moving away from the status quo by permitting the food additive.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

Costs and benefits of permitting the use of this food additive

Industry may benefit from being able to use this food additive as an intense sweetener in FSMP. Due to the voluntary nature of the permission, industry will only use the food additive where they believe a net benefit exists for them in terms of cost savings or improvement to the quality of their product to make it more appealing to consumers.

If industry were to experience cost savings as a result of using the food additive, industry may pass on some of the cost savings onto consumers.

Consumers of FSMP where the food additive is intended to be added may benefit from greater accessibility of these products or a better quality product.

Permitting the use of this food additive may result in a small, inconsequential cost to government in terms of an addition to the current range of food additives that are already monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting steviol glycosides as a food additive in FSMP most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety and dietary exposure assessment (refer to the SD) which is summarised in section 2.2. The safety assessment concluded there are no public health and safety concerns in permitting steviol glycosides as a food additive (intense sweetener) in FSMP at a MPL of 330 mg/kg in VLED, and at a MPL of 75 mg/kg in other FSMP (excluding use in other FSMP formulated for infants).

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

As discussed in section 2.3.5, the existing labelling provisions for declaring food additives on FSMP will apply. These will require provision of information to consumers to enable informed choices about foods containing steviol glycosides.

2.5.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this application relevant to this objective.

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the food technology, hazard and dietary exposure assessment (refer to the SD). The applicant submitted supporting information, including scientific studies, product information and relevant literature, as part of their application. FSANZ also had regard to other technical information including scientific literature in assessing the application.

- **the promotion of consistency between domestic and international food standards**

As summarised in section 1.4 above, Regulation EU 1131/2011 provides permission for the use of steviol glycosides as a food additive in a range of foods. The regulation includes permission to add steviol glycosides to the food categories relevant to this application (at a maximum permitted level of 330 mg/kg steviol equivalents for the category equivalent to other FSMP, and 270 mg/kg for the category equivalent to VLED). The permission does not extend to products for infants aged under 12 months of age or for young children (aged 12 – 36 months).

This permission and condition of use applies to all countries in the EU.

Codex's GSFA contains permission for use of steviol glycosides in a range of foods, including for FSMP at a maximum permitted level of 350 mg/kg. The Codex maximum permitted level for VLED is 270 mg/kg.

The approved draft variation will promote consistency with international provisions, by

including a new permission in the Code for the addition of steviol glycosides to FSMP. Complete alignment with international regulations would not be possible, as definitions for product categories vary and because of the outcome of FSANZ's safety and dietary exposure assessment for 'other FSMP'.

- **the desirability of an efficient and internationally competitive food industry**

The effect of the proposed amendments to the Code will be to allow FSMP imported into Australia and New Zealand to contain steviol glycosides. As above, complete alignment is not achieved with the MPL provisions in Codex and in place under EU Regulations. If FSMP are imported from a EU member state, and the actual use level of the steviol glycosides is at or below the MPL proposed under this application, trade would be facilitated.

In this way, Australia and New Zealand will remain competitive with other international markets.

- **the promotion of fair trading in food**

A new permission in the Code would promote trade and commerce in the food industry, on the basis that it provides consistency between Australia and New Zealand, and globally.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

The Ministerial Policy Guideline on the *Addition of substances other than vitamins and minerals*[8] includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose, and
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ's assessment is that permitting steviol glycosides in FSMP would be consistent with the Ministerial Policy Guideline and the specific order principles for 'technological function' as a food additive. Setting two different MPLs would be consistent with the specific order principle 'the addition of the substance to food is safe for human consumption'.

The Ministerial Policy Guideline on the *Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods*[9] states the composition of special purpose food should be consistent with the intended purpose. Based on our assessment, FSANZ considers that the Policy Guideline has been met.

3 References

FSANZ (2012) Final assessment report. Proposal P242 Foods for Special Medical Purposes.

[8] Policy guideline on the addition of substances other than vitamins and minerals | Food Regulation
[9] Policy guideline on intent of Part 2.9 of the Food Standards Code – Special purpose foods | Food Regulation

FSANZ, Canberra. Available online at: Proposal P242 - Foods for Special Medical Purposes | Food Standards Australia New Zealand

FSANZ (2022) Application A1230 Very Low Energy Diets (VLED). FSANZ, Canberra. Available online at: A1230 - Very Low Energy Diets (VLED) | Food Standards Australia New Zealand

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*

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

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1273 – Steviol glycosides as a food additive in Food for special medical purposes) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 15—Substances that may be used as food additives

[1] Section S15—5 (table, numbered heading "*13.5 Food for special medical purposes*", after the table item dealing with 'Saccharin')

Insert:

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.

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 sunsetting 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 sunsetting 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 sunsetting 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.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA) [10]. 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

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

[10] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

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.