

20 February 2017
[06–17]

Approval report – Application A1132

Broaden Definition of Steviol Glycosides (Intense Sweeteners)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by PureCircle Limited to expand the definition of steviol glycosides for use as an intense sweetener to include all steviol glycosides present in the *Stevia rebaudiana* Bertoni leaf.

On 7 November, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received seven submissions.

FSANZ approved the draft variation on 8 February 2017. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 17 February 2017.

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

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Supporting document

The [following document](#)¹ which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical assessment report

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1132Definition-of-Steviol-Glycosides.aspx>

Executive summary

Steviol glycosides are permitted food additives in the Codex Alimentarius General Standard for Food Additives (GSFA), and in many countries including the USA, the European Union, Canada and many Asian, and Central and South American countries.

PureCircle Limited, based in Illinois in the United States of America (USA), submitted an Application to amend the current definition of steviol glycosides to include all minor steviol glycosides (potentially an extra 40) extracted from the *Stevia rebaudiana* Bertoni (stevia) leaf.

The addition of these minor steviol glycosides to the *Australia New Zealand Food Standards Code* (the Code) will be in addition to the 10 steviol glycosides currently listed. These minor steviol glycosides are stated by the Applicant to provide improved flavour and taste compared to the currently permitted steviol glycosides.

The function of steviol glycosides (INS 960) as a food additive, is as an intense sweetener, which is already permitted in various food categories with maximum permitted levels in section S15—5. Permissions for steviol glycosides are provided as “steviol equivalents” which are calculated using the equation in subsection 1.3.1—4(7). The calculation uses conversion factors which are provided for the different steviol glycosides in this subsection.

Permitted food additives also need to have an appropriate specification for identity and purity. Primary sources of specification for steviol glycosides are contained in the Code, but they do not apply to all steviol glycosides extracted from the stevia leaf. Therefore, a new specification which includes all minor steviol glycosides extracted from the stevia leaf has been drafted. A new conversion factor has also been added into the Code to capture all other steviol glycosides not already listed.

In vitro studies consistently showed the biotransformation of steviosides, rebaudiosides and dulcosides to steviol. This is in agreement with earlier studies conducted on stevioside and rebaudioside A which have been evaluated in previous FSANZ assessments. The existing Acceptable Daily Intake (ADI) of 0-4 mg/kg bodyweight, which is expressed on the basis of steviol equivalents, was therefore applicable to all steviol glycosides in stevia leaf.

No dietary exposure assessment was considered necessary because the steviol glycoside mixtures will be used under the same conditions as those presently approved in the Code.

No evidence was found to suggest that the expansion of the definition of steviol glycosides for use as sweeteners to include all steviol glycosides present in the stevia leaf posed any public health and safety concerns. It was expected that all steviol glycosides will be hydrolysed completely to steviol by gut microflora.

FSANZ concluded that broadening the definition and hence specification for steviol glycosides preparations to include any mixture of individual steviol glycosides extracted from the stevia leaf was justified. The same analytical methods currently used for steviol glycosides can be used to identify these other minor steviol glycosides. The current ingredient labelling requirements for steviol glycosides added to food as an intense sweetener food additive still apply; it can be listed as ‘steviol glycosides’ or with the code number ‘960’.

1 Introduction

1.1 The Applicant

The Applicant is PureCircle Limited, based in Illinois in the United States of America (USA). PureCircle Limited produces stevia ingredients, including steviol glycosides, for the food industry around the world.

1.2 The Application

Steviol glycosides are a family of steviol glycosides extracted from *Stevia rebaudiana* Bertoni (for the rest of the report called “stevia”) leaves. Ten specific steviol glycosides are permitted to be present, at a total content of at least 95% w/w, in steviol glycoside preparations that are permitted as intense sweetener food additives to be added to a wide variety of foods. The Application claimed there are at least 40 different steviol glycosides that can be extracted, isolated and identified from the stevia leaf.

The purpose of the Application was to amend the current definition, and therefore specification, of steviol glycoside preparations to not be limited to the current 10 steviol glycosides but all the various steviol glycosides that can be extracted from the stevia leaf. The justification was that the other minor steviol glycosides provide positive sensory attributes to the flavour and taste characteristics of food to which these steviol glycoside preparations have been added as intense sweeteners compared to just the currently permitted 10 steviol glycosides. They are claimed to reduce the unwanted taste characteristics associated with commercial steviol glycoside preparations used to replace sugar or in blends with other intense sweeteners, with or without sugar.

1.3 The current Standards

1.3.1 Australia and New Zealand

The intense sweetener food additive, ‘steviol glycosides’ (INS 960) has permissions to be added to various food categories with maximum permitted levels in the table to section S15—5 (Table of permissions of food additives) in Schedule 15 – Substances that may be used as food additives in the *Australia New Zealand Food Standards Code* (the Code). Subsection 1.3.1—4(6) of Standard 1.3.1 – Food additives require that:

steviol glycosides are calculated as steviol equivalents in accordance with subsection (7).

Subsection 1.3.1—4(7) provides the formula used to calculate steviol equivalents for a blend of different steviol glycosides. It lists the ten different steviol glycosides and their different conversion factors, along with the basic steviol structure itself which has a conversion factor of 1.00 (more explanation on conversion factors is provided in section 2.2.2 below). A steviol glycoside preparation may contain a blend of ten different steviol glycosides. A steviol glycosides preparation must contain greater than 95% on a dried weight basis of steviol glycosides.

All permitted food additives are also required to have a specification for identity and purity. Schedule 3 – Identity and purity contains primary sources of specifications in section S3—2. All the three primary sources have specification monographs for steviol glycosides:

- subparagraph S3—2(1)(b), the JECFA (Joint FAO/WHO Expert Committee on Food Additives) Combined Compendium of Food Additive Specifications
- subparagraph S3—2(1)(c), Food Chemicals Codex (FCC)

- subparagraph S3—2(1)(d), Commission Regulation (EU) No 231/2012.

The JECFA and FCC specifications apply to nine steviol glycosides, while the European Commission specification applies to these nine steviol glycosides, as well as rebaudioside E.

Additional specifications had been added to Schedule 3; being sections S3—31 (rebaudioside M) and S3—32 (steviol glycoside mixture including rebaudioside M) as an outcome of the Applicant's earlier Application A1108, which sought permission for rebaudioside M as a permitted steviol glycoside. These additional specifications were required because rebaudioside M was not listed in the JECFA, FCC or European Commission steviol glycosides specifications.

1.3.2 International and National Standards

There are broad permissions for the use of steviol glycosides as intense sweetener food additives in food regulations around the world. Permissions for steviol glycosides for some major international and country regulations are noted below. However, none currently permit the minor steviol glycosides.

1.3.2.1 Codex

The Codex Committee on Food Additives (CCFA) adopted permissions for the food additive "steviol glycosides" (with the food additive number of INS 960) as a sweetener in 2011 for a wide variety of food categories in the Codex Alimentarius General Standard for Food Additives (GSFA). The specifications for food additives in Codex are those of JECFA and the specification for 'steviol glycosides' (JECFA 2010) currently includes nine specific steviol glycosides.

The Applicant sought an assessment of a similar dossier of data to that supplied in this Application to JECFA, which conducted an assessment at JECFA's 82nd meeting in June 2016. The Summary Report of this meeting included a toxicological summary and new tentative specifications (JECFA 2016).

1.3.2.2 The United States of America

There is a large number (the Application lists 38 at the time of lodgement) of Generally Recognized as Safe (GRAS) notifications to the United States Food and Drug Administration (USFDA) for various steviol glycoside preparations used as sweeteners for a variety of food categories. The Applicant has a recent GRAS notification, GRN 619, which is comparable to this Application and which at the time of submission of this Application had not yet been reviewed by the USFDA.

The United States Pharmacopeial Convention Food Chemicals Codex (FCC) contains a specification for steviol glycosides. This specification includes the same nine steviol glycosides listed in the JECFA specification.

1.3.2.3 European Union

The European Commission has permitted the use of steviol glycosides as a sweetener in a variety of different foods under the Commission Regulation (EU) No. 1131/2011. This permission is for the general food additive 'steviol glycosides' with the European food additive designation E 960. The specification for steviol glycosides is provided within Commission Regulation (EU) No. 231/2012 and lists 10 specific steviol glycosides.

The European Food Safety Authority (EFSA) reviewed the safety of the proposed amendments to the specifications for steviol glycosides (including the addition of rebaudioside M) in 2015, after an earlier assessment of the safety of steviol glycosides in 2010. No new safety concerns were identified.

1.3.2.4 Canada

Canada has permitted the use of steviol glycosides as a sweetener food additive in a variety of different foods since 2012, after Health Canada reviewed its safety (Health Canada 2012).

The Applicant has also submitted an application that is similar to this Application, seeking broader permissions for steviol glycosides to Health Canada.

1.3.2.5 Other countries

Steviol glycosides (as a generic group, as well as different types of extracts) are permitted as sweeteners (food additive) in a wide variety of other countries. In Asia, steviol glycosides are permitted in Japan, India, South Korea, China, Malaysia, Indonesia, Singapore and Taiwan. In Central and South America, forms of steviol glycosides are permitted in Brazil, Argentina, Paraguay, Uruguay, Mexico, Peru and Colombia. Other countries that permit steviol glycosides are Israel, Russia, Switzerland, Turkey and Ukraine.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Public submissions on the Call for Submissions document were sought from 7 November to 19 December 2016, after FSANZ assessed the Application. Seven submissions were received; four from industry and industry associations, two from government agencies and one from a public health association which all supported the progression of the Application. A submitter sought confirmation that the JECFA specification to be finalised in the future is likely to align with the specification proposed by FSANZ. This issue is addressed in Section 2.3.1 of this report.

No issues were raised relating to the draft variation or the SD1, so they are unchanged from the Call for Submissions.

2.2 Risk assessment

FSANZ conducted a risk assessment on broadening the definition of steviol glycosides preparations to include all steviol glycosides extracted from the stevia leaf, which is provided as SD1.

In vitro studies consistently showed the biotransformation of steviosides, rebaudiosides and dulcosides to steviol. This is in agreement with earlier studies conducted on stevioside and rebaudioside A which have been evaluated in previous FSANZ assessments. The existing Acceptable Daily Intake (ADI) of 0–4 mg/kg bodyweight, which is expressed on the basis of steviol, is therefore applicable to all steviol glycosides in stevia leaf.

No dietary exposure assessment was considered necessary since the Applicant's steviol glycoside mixtures will be used under the same conditions as those presently approved in the Code.

No evidence was found to suggest that the expansion of the definition of steviol glycosides for use as a sweetener to include all steviol glycosides present in the stevia leaf poses any public health and safety risks. It is expected that all steviol glycosides will be hydrolysed completely to steviol by gut microflora.

The food technology assessment concludes that broadening the definition and hence specification for steviol glycosides preparations to include any mixture of individual steviol glycoside compounds extracted from the stevia leaf is justified. The same analytical methods currently used for steviol glycosides can be used to identify these other steviol glycoside compounds.

2.3 Risk management

The risk assessment concluded that expanding the definition of permitted steviol glycosides for use as a food additive in accordance with the existing permissions for steviol glycosides raised no public health and safety concerns.

However, there are some risk management issues to consider which are dealt with in the following sections.

2.3.1 Steviol glycosides specifications

Permissions for food additives are linked to their specifications as listed in Schedule 3, due to section 1.1.1—15. Steviol glycosides specifications are discussed in section 2.4.1 of SD1, which concludes that there are no primary or secondary sources of specifications in Schedule 3 for the food additive steviol glycosides that permit any extracted steviol glycoside from the stevia leaf. Current JECFA, FCC and European specifications all have a defined list of identified steviol glycosides. At its June 2016 meeting, JECFA established a new tentative specification, titled "Steviol glycosides from *Stevia rebaudiana* Bertoni". However, this specification may not be finalised until 2018 because JECFA has requested further work and information (analytical method and analysis results from commercial samples). This work is due to JECFA by the end of 2017 and will be discussed at JECFA's meeting mid-2018. Because there are no current specifications in Schedule 3 that address the Applicant's steviol glycosides preparations, FSANZ needed to develop a new specification to be added to Schedule 3. Providing the final JECFA specification covers all extracted steviol glycosides and is consistent with the FSANZ specification, then the FSANZ specification can be removed at a later date.

The draft variation contains this new specification, being S3—35. This specification consists of the following:

- It is based on the basic structure of the current JECFA, FCC and European steviol glycosides specifications but is broader to include any steviol glycoside extracted from the stevia leaf. For this reason, structures of individual steviol glycosides have not been provided in the new specifications.

- The title is commensurate with the tentative JECFA specification to make it explicit that the steviol glycosides are extracted from the stevia leaf, as there is new technology available to produce steviol glycosides in other ways such as via fermentations.
- Includes a definition explaining that the steviol glycosides are obtained by hot water extraction processes from the stevia leaf with subsequent purification involving ion-exchange resins and recrystallisation from methanol or aqueous ethanol.
- Other specification criteria are a description of the powder, assay of the minimum percentage of steviol glycosides on the dried basis, solubility, pH, and specific purity limits. All these requirements are the same as those in the current JECFA, FCC and European specifications.

The new specification is provided in the draft variation at Attachment A.

2.3.2 Steviol conversion factors

As explained in section 1.3.1, permissions for steviol glycosides are based on steviol equivalents which are calculated using the equation and conversion factors (CFs) in subsection 1.3.1—4(7). There are CFs for the ten currently permitted steviol glycosides. The CFs are used to convert steviol glycosides to the active component, being steviol and are related to the ratio of the molecular weights of steviol to the steviol glycoside. The Application proposed that the CF for the other minor steviol glycosides be assigned as 0.33, being a median figure between the CFs for the various additional minor steviol glycosides, which are in general between 0.25 and 0.40. Minor steviol glycosides are typically no more than 5% of the total steviol glycosides content, so an approximation is reasonable. FSANZ agreed that this figure was reasonable and has included an additional CF of 0.33 for all other steviol glycosides in subsection 1.3.1—4(7) (see Attachment A).

Since CFs for the ten major individual steviol glycosides are already listed in the Code it was not appropriate to provide a single general CF for all steviol glycosides mixtures. Individual steviol glycosides producers and suppliers can determine the appropriate CF for their specific commercial preparations so food manufacturers know the steviol equivalents and can make appropriate dosing calculations to ensure they comply with the maximum permitted levels in the Code.

2.3.3 Analytical methods

There are analytical methods available for detecting and quantifying steviol glycosides in food. These methods are based on High Performance Liquid Chromatography (HPLC). They are able to be readily adapted to analyse for different types of steviol glycosides in food since the active ingredient is the steviol moiety, which is found in all steviol glycosides. Some references to steviol glycoside analytical methods are provided in section 2.3 of SD1.

2.3.4 Labelling

Substances used as food additives are required to be declared in the statement of ingredients on the label of most packaged foods. Standard 1.2.4 – Information requirements – statement of ingredients, requires food additives to be declared by their class name followed by the food additive name or code number in brackets.

Schedule 7 – Food additive class names (for statement of ingredients) provides the list of food additive class names for labelling purposes and includes the class name ‘sweetener’. Schedule 8 – Food additive names and code numbers (for statement of ingredients) provides the lists of food additive names and code numbers.

These lists refer to ‘steviol glycosides’ which has the code number ‘960’. This name applies to any steviol glycosides preparation that meets the specification (see section 2.3.1) and so can apply to a blend of different individual steviol glycosides. The existing food additive naming requirements are considered sufficient for the proposed permission for the use of all steviol glycosides extracted from the stevia leaf as food additives.

3 Decision

The draft variation as proposed following assessment was approved with minor amendments. The amendments relates to the consecutive numbering of the new specification added into Schedule 3. The completion of the assessment of this Application will proceed that of another application and so S3—36 has needed to be renumbered to S3—35. The variation takes effect on gazettal. The approved draft variation 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.

The draft variation on which submissions were sought is at Attachment C.

4 Risk communication

4.1 Consultation

Consultation is a key part of FSANZ’s standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on the Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ’s social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions were called for to obtain the views of interested parties on the Application and the impacts of the regulatory options.

The Applicant, individuals and organisations that made submissions on this Application were notified at each stage of the assessment. Subscribers and interested parties were also notified via email about the availability of reports for public comment.

The FSANZ Board’s decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code via the Notification Circular and on the FSANZ website.

5 FSANZ Act assessment requirements

5.1 Section 29

5.1.1 Consideration of costs and benefits

A1132 is covered by the standing exemption from the Office of Best Practice Regulation which applies to food additives (reference number 12065).

This exemption is that a Regulation Impact Statement is not required for applications relating to food additives, as they are machinery in nature and their use is voluntary.

Notwithstanding the above exemption, FSANZ conducted a limited cost benefit analysis for this Application (summary provided in the Call for Submissions). That analysis found that expanding the definition of steviol glycosides for use as an intense sweetener to include all steviol glycosides extracted from the *Stevia rebaudiana* Bertoni leaf had benefits to consumers and food manufacturers who wish to use steviol glycosides as intense sweeteners. These benefits include superior flavour and taste profile of the steviol glycosides preparations which are of benefit to both consumers and the food industry using these preparations. No costs to different stakeholders were identified that overrode these benefits. Nor was any benefit in rejecting the Application identified.

FSANZ concluded that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure. Therefore, the preferred option was to prepare a variation to the Code to expand the definition of steviol glycosides for use as an intense sweetener to include all steviol glycosides extracted from the *Stevia rebaudiana* Bertoni leaf.

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. The only measure available to permit the use of the other steviol glycosides present in the stevia leaf is to amend the Code as requested and assessed.

5.1.3 Any relevant New Zealand standards

Standard 1.3.1 and Schedule 3 apply in both Australia and New Zealand.

5.1.4 Any other relevant matters

Other relevant matters are considered below.

5.2. Subsection 18(1)

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

5.2.1 Protection of public health and safety

FSANZ had undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns with expanding the definition of steviol glycosides for use as an intense sweetener to include all steviol glycosides present in the stevia leaf.

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

The existing ingredient labelling provisions in the Code for substances used as food additives apply to steviol glycosides. These existing labelling provisions will continue to allow consumers to identify whether steviol glycosides have been added to a packaged food.

5.2.3 The prevention of misleading or deceptive conduct

No relevant issues were identified for this Application.

5.3 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 risk analysis which is provided in SD1. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information including scientific literature was also used in assessing the Application.

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

Section 1.3.2 above details the various permissions for the use of steviol glycosides in food regulations around the world. As indicated previously, the Applicant is seeking the same permissions requested in this Application in other international (via JECFA and CCFA) and national regulations. Therefore, permitting this Application will help ensure consistency in the regulation of steviol glycosides between Australia and New Zealand and other international and national standards.

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

The variation is voluntary and as such is not expected to have any impact on the efficiency or competitiveness of the food industry.

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

FSANZ did not identify any relevant issues relating to this consideration.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The [Policy Guideline for the Addition to Food of Substances other than Vitamins and Minerals](#)² 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
- no nutrition, health or related claims are to be made in regard to the substance.

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

FSANZ determined that amending the Code to broaden the definition of steviol glycosides to permit all steviol glycosides extracted from the stevia leaf was consistent with these specific order policy principles.

6 References

Commission Regulation (EU) No. 1131/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides. Available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1131&from=EN>

Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives, E 960 Steviol Glycosides, pages 270-271. Available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0231&from=EN>

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FAO (2010) Online Edition: "Combined Compendium of Food Additive Specifications". Steviol Glycosides. Monograph 10. Available at <http://www.fao.org/ag/agn/jecfa-additives/details.html?id=898>
Also found in Compendium of Food Additive Specifications FAO Monograph 10 (2010), FAO, Rome.

Health Canada (2012a). *Information and Consultation Document on Health Canada's Proposal to Allow the Use of the Food Additive Steviol Glycosides as a Table-Top Sweetener and as a Sweetener in Certain Food Categories*. Ottawa (ON): Health Canada, Bureau of Chemical Safety, Food Directorate, Health Products and Food Branch. Available at: <http://www.hc-sc.gc.ca/fn-an/consult/steviol/document-consultation-eng.php>

Health Canada (2012b). *Notice of Modification to the Lists of Permitted Food Additives to Enable the Use of Steviol Glycosides as a Table-Top Sweetener and as a Sweetener in Certain Food Categories*. Ottawa (ON): Health Canada, Bureau of Chemical Safety, Food Directorate, Health Products and Food Branch. Available at: <http://www.hc-sc.gc.ca/fn-an/consult/nom-adm-0002/index-eng.php>

JECFA 2016, 82nd Joint FAO/WHO Expert Committee on Food Additives (JECFA) meeting – Food additives. Summary and conclusions, 7-16 June 2016, Geneva, Switzerland. Issued 21 June 2016. Available at <http://www.fao.org/3/a-bl839e.pdf>

United States Pharmacopeial Convention (2014) Food Chemicals Codex. 9th ed, United States Pharmacopeial Convention, Rockville, MD, Steviol glycosides. Available at <http://online.foodchemicalscodex.org/online/pub/index?fcc=10&s=0&oYr=2016&oMo=6&oDa=1>

WHO 2016, WHO Technical Report Series; no. 1000. Evaluation of certain food additives: Eighty-second report of the Joint FAO/WHO Expert Committee on Food Additives, Geneva, Switzerland Available at <http://apps.who.int/iris/bitstream/10665/250277/1/9789241210003-eng.pdf>

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

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



Food Standards (Application A1132 – Broaden Definition of Steviol Glycosides (Intense Sweetener)) Variation

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 Standards Management Officer]

Standards Management Officer
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.

Attachment B – 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 A1132 which seeks to expand the definition of steviol glycosides for use as an intense sweetener to include all steviol glycosides present in the *Stevia rebaudiana* Bertoni leaf. 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, 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 the variation to the Code to broaden the definition of steviol glycosides to permit the use of all steviol glycosides extracted from the *Stevia rebaudiana* Bertoni leaf as additives. The current specifications for steviol glycosides contained in the primary monographs in S3—2 are defined to apply only to a limited number of listed steviol glycosides and not to all possible steviol glycosides. Therefore a new specification for steviol glycosides has been added to Schedule 3, which covers preparations that included all steviol glycosides extracted from the stevia leaf. As well, a new conversion factor was added to the list in subsection 1.3.1—4(7) to capture all the other steviol glycosides.

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 A1132 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 7 November 2016 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.3.1 and Schedule 3 is 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

6.1 Variation to Standard 1.3.1

Item [1] varies paragraph 1.3.1—4(7)(j) of Standard 1.3.1 relating to the conversion factor **CF** for different steviol glycosides. The effect of the change is to introduce a conversion factor for any other steviol glycoside not already listed. Conversion factors are used to calculate steviol equivalents, which is how permissions for adding steviol glycosides to different food categories are listed in the table to section S15—5 in Schedule 15.

6.2 Variation to Schedule 3

Item [2.1] inserts a new reference for steviol glycosides from *Stevia rebaudiana* Bertoni into the table to subsection S3—2(2). This is needed as the current specifications for steviol glycoside preparations in the primary sources within S3—2 do not apply to all steviol glycosides extracted from the stevia leaf.

Item [2.2] inserts a new specification as S3—35. The specification criteria are similar to those for steviol glycosides in primary sources in subsection S3—2(1).

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



Food Standards (Application A1132 – Broaden Definition of Steviol Glycosides (Intense Sweetener)) Variation.

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 Standards Management Officer]

Standards Management Officer
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 A1132 – Broaden Definition of Steviol Glycosides (Intense Sweetener)) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Standard 1.3.1** is varied by omitting paragraph 1.3.1—4(7)(j), substituting

- (j) stevioside—0.40;
- (k) any other steviol glycoside—0.33.

[2] **Schedule 3** is varied by

[2.1] inserting the following into the table to subsection S3—2(2), in alphabetical order

steviol glycosides from *Stevia rebaudiana* Bertoni section S3—36

[2.2] inserting the following after section S3—35

S3—36 Specification for steviol glycosides from *Stevia rebaudiana* Bertoni

- (1) This specification relates to a steviol glycosides preparation obtained from the leaves of the *Stevia rebaudiana* Bertoni plant.
- (2) The preparation must be obtained from the leaves of the *Stevia rebaudiana* Bertoni plant by the following extraction processes. The leaves are extracted with hot water and the extracts are purified using ion-exchange resins followed by recrystallisation from methanol or aqueous ethanol. The final product may be spray dried.
- (3) The preparation may contain different individual steviol glycosides.
- (4) The specifications are the following:
 - (a) Description—white to light yellow powder, approximately 200 to 300 times sweeter than sucrose;
 - (b) Assay—not less than 95% of steviol glycosides on the dried basis;
 - (c) Solubility—freely soluble in water;
 - (d) pH—between 4.5 and 7.0 (1% solution);
 - (e) Total ash—not more than 1%;
 - (f) Loss on drying—not more than 6% (105°C, 2 hour);
 - (g) Residual solvents:
 - Not more than 200 mg/kg methanol
 - Not more than 5000 mg/kg ethanol
 - (h) Arsenic—not more than 1 mg/kg;
 - (i) Lead—not more than 1 mg/kg;
 - (j) INS number—960.