

7 November 2016
[28–16]

Call for submissions – Application A1132

Broaden Definition of Steviol Glycosides (Intense Sweetener)

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 extracted from the *Stevia rebaudiana* Bertoni leaf and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 19 December 2016

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The [following supporting 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 claim 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 (CFs) 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 CF has also been proposed to be 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, is therefore applicable to all steviol glycosides in stevia leaf.

The Applicant intends to market steviol glycoside mixtures for use as intense sweeteners under the same conditions as those presently approved for steviol glycoside preparations and as such no new dietary exposure assessment was considered necessary for this Application.

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 poses any public health and safety concerns. It is expected that all steviol glycosides will be hydrolysed completely to steviol by gut microflora.

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

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 claims there are at least 40 different steviol glycosides that can be extracted, isolated and identified from the stevia leaf.

The purpose of the Application is 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 is 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 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 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 (Specification for rebaudioside M) and S3—32 (Specification for 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 its 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 submission) 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 list 10 specific steviol glycosides.

The European Food Safety Authority (EFSA) reviewed the safety of steviol glycosides in 2015, after an earlier assessment in 2010.

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 Columbia. 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 is being assessed under the General Procedure.

2 Summary of the assessment

2.1 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.

The Applicant intends to market steviol glycoside mixtures for use as intense sweeteners under the same conditions as those presently approved for steviol glycoside preparations and as such no new dietary exposure assessment was considered necessary for this Application.

No evidence was found to suggest that the expansion of the definition of steviol glycosides for use as 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.

2.2 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. In particular these relate to what drafting changes are required to the Code to reflect the conclusion that a steviol glycosides preparation may contain any steviol glycoside extracted from the stevia leaf, not just the current list of ten specific steviol glycosides. These drafting changes include a new specification and adding a new conversion factor for the additional steviol glycosides, for the calculation of steviol equivalence, which is how permissions for the addition of steviol glycosides as intense sweeteners are included in the Code. As well, the issues of analytical methods and food additive labelling are addressed.

2.2.1 Steviol glycosides specifications

Permissions for food additives are also linked to their specifications as listed in Schedule 3, due to section 1.1.1—15. The issue of steviol glycosides specifications is discussed in detail in section 2.4.1 of SD1.

The conclusion is that at this present time 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 along the same lines as this Application but this specification may not be finalised until 2018. That is because JECFA has requested further work and information be received by the end of 2017 which will be discussed at JECFA's mid-2018 meeting. Because of this delay, FSANZ needs to include new specifications to cover the requests of this Application in Schedule 3. The FSANZ specification could be removed when the JECFA tentative specification is made final, provided it covers all extracted steviol glycosides.

FSANZ is therefore proposing that a new specification be added to Schedule 3, (S3—36). 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 new proposed 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 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.

2.2.2 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 0.4. Minor steviol glycosides are typically no more than 5% of the total steviol glycosides content, so an approximation is reasonable. FSANZ agrees that this figure is reasonable and is proposing 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 thought 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.

2.2.3 Analytical methods

There are analytical methods available for the detection and quantification of steviol glycosides in food. These methods are based on High Performance Liquid Chromatography (HPLC). They should be 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.

2.2.4 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 prescribed 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, while 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 INS code of '960'. This name applies to any steviol glycosides preparation that meets the specification (see section 2.2.2) and so can apply to a blend of many different individual steviol glycosides. The existing additive naming requirements are considered sufficient for the proposed permission to add steviol glycosides as a group.

Aside from the ingredient labelling requirements, FSANZ does not consider any other labelling provisions in the Code would apply to this Application. The existing requirements for ingredient labelling will provide consumers with information to make informed choices about foods containing steviol glycosides.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called for to obtain the views of interested parties on the Application and the impacts of the regulatory options. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

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

Following consultation, the FSANZ Board will consider the proposed variation taking into account comments received through submissions. If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation (Forum). 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.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are not any relevant international standards and amending the Code to broaden the definition of steviol glycosides to permit all steviol glycosides extracted from the stevia leaf is unlikely to have a significant effect on international trade. This is because the amendments are voluntary and unlikely to have an impact on trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement was not considered necessary.

2.4 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:

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders. The benefits and costs associated with the proposed amendments to the Code have been considered based on regulatory impact principles. The level of analysis is commensurate to the nature of the Application and significance of the impacts.

A1132 is covered by the standing exemption from the Office of Best Practice Regulation (OBPR) 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.

However, FSANZ has undertaken a limited qualitative impact analysis.

Two regulatory options have been considered:

- (1) prepare a draft variation to the Code to permit a broadening of the definition of steviol glycosides for use as an intense sweetener
- (2) reject the Application.

The likely impacts of these options were considered but this is not intended to be an exhaustive, quantitative economic analysis. Rather, the qualitative effects of each option are described below, and are deliberately limited to broad areas such as trade and consumer choice.

Option 1 – prepare a draft variation to the Code

Sector	Costs or benefits
Consumers	Consumers seeking the use of intense sweeteners to replace sugar in various food categories will benefit by the use of steviol glycosides as a group. The Applicant claims that steviol glycoside preparations containing a broader definition allowing all steviol glycosides extracted from the stevia leaf provide improved flavour and taste benefits.
Industry	The Applicant indicates the food industry has expressed interest in steviol glycoside preparations with a broader number of steviol glycosides due to flavour benefits compared to current steviol glycosides preparations and allows for greater innovation. These benefits are the superior flavour and taste profile and less of the negative attributes found with current steviol glycosides preparations.
Governments	There should be little impact on government enforcement agencies since there are already ten steviol glycosides permitted to be added to various food categories. The addition of other minor steviol glycosides does not raise any public health and safety issues. Their presence in food can be analysed similarly to the currently permitted ones.

Option 2 – reject the Application

Sector	Costs or benefits
Consumers	There are no benefits to consumers with this option. They would not have the option of purchasing food products with reduced sugar content that would have a different and improved flavour profile which they might prefer to current steviol glycoside containing products.
Industry	Industry would not have access to new steviol glycoside preparations with claimed advantages of superior flavour and taste profile to be used in their reduced sugar products. They could be at a disadvantage compared to international competitors.
Governments	There would be no direct impacts on government agencies.

FSANZ considered that Option 1 to amend the definition of steviol glycosides is the preferred option and has prepared a draft variation to the Code.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has 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.

2.4.2.2 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 labelling requirements provide consumers with information about foods containing steviol glycosides to make informed food choices.

2.4.2.3 The prevention of misleading or deceptive conduct

No relevant issues were identified for this Application..

2.4.3 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 has 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 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 efficacy 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](#)² for the 'Addition to Food of Substances other than Vitamins and Minerals' 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.

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

3 Draft variation

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

4 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>

EFSA (2015) ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to food). Scientific opinion on the safety of the proposed amendment of the specifications for steviol glycosides (E 960) as a food additive. EFSA Journal 2015;13(12):4316, 29 pp. Available at <https://www.efsa.europa.eu/en/efsajournal/pub/4316>

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

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>

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Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – 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.

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.

Attachment B – Draft 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 prepared a variation to the Code.

2. Purpose

The purpose of the variation to the Code is 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 had to be added to Schedule 3, which covered preparations that included all steviol glycosides extracted from the stevia leaf. As well, a new conversion factor (CF) 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 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.3.1 and Schedule 3 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

6.1 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 of Schedule 15.

6.2 Schedule 3

Item 1 inserts a new entry into the table to subsection S3—2(2) in Schedule 3 for a new specification titled “steviol glycosides from *Stevia rebaudiana* Bertoni”. The reason a new specification is needed is because the current specifications for steviol glycosides preparations in the primary sources within S3—2 do not apply to all steviol glycosides extracted from the stevia leaf.

Item 2 inserts this new specification as S3—36 within Schedule 3. The specification criteria are similar to those for steviol glycosides in primary sources in S3—2.