

29 June 2015
[13–15]

Call for submissions – Application A1108

Rebaudioside M as a Steviol Glycoside Intense Sweetener

FSANZ has assessed an Application made by PureCircle Limited to permit rebaudioside M to be added to the current list of permitted steviol glycosides used as intense sweeteners 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) 10 August 2015

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 document which informed the assessment of this Application is available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/A1108-RebaudiosideM-SteviolGlycosideIntenseSweetener.aspx>

SD1 Risk and Technical Assessment Report

Executive summary

PureCircle Limited, based in Illinois in the United States of America, submitted an Application seeking permission for a new steviol glycoside, rebaudioside M (abbreviated as Reb M), as a new intense sweetener. The request is that Reb M be permitted to be added to the same food categories and at the same maximum permitted levels as the currently permitted steviol glycosides.

The permitted food additive called 'steviol glycosides' (food additive number INS 960) is a group of different individual steviol glycosides. There are currently nine permitted specific steviol glycosides in the food additive 'steviol glycosides' provided via subsection 1.3.1—4(7) of the revised *Australia New Zealand Food Standards Code* (the Code) (subclause 5(3) of Standard 1.3.1 of the current Code).

Permitted food additives also need to have an appropriate specification for identity and purity. Appropriate specification monographs are within the references in S3—2 and S3—3 of Schedule 3 of the revised Code (clauses 2 and 3 of Standard 1.3.4 of the current Code). There is currently no specification monograph for Reb M in Schedule 3.

Steviol glycosides are permitted food additives in the Codex Alimentarius General Standard for Food Additives (GSFA), along with many countries including the United States, the European Union, Canada and many Asian, and Central and South American countries. Reb M is considered Generally Recognized as Safe (GRAS) in the United States and is specifically permitted in Columbia and Nigeria. The Applicant has a current application for Reb M with Health Canada.

FSANZ carried out a risk assessment on the use of Reb M as a permitted form of steviol glycoside compared to the currently permitted steviol glycosides. It was concluded that Reb M is similar in chemical structure and sweetness intensity to other currently permitted steviol glycosides. The production of Reb M preparations, analytical methods, specifications and stability are also similar to other steviol glycosides.

As for other steviol glycosides, Reb M is hydrolysed completely to steviol by gut microflora. The existing acceptable daily intake (ADI) for steviol glycosides of 0-4 mg/kg bodyweight, which is expressed on the basis of steviol, therefore applies to rebaudioside M.

Reb M-containing preparations are intended for use in the same food categories and at the same use-levels already permitted for other steviol glycoside products. FSANZ has previously conducted a dietary exposure assessment using the current permissions for steviol glycosides and therefore no dietary exposure assessment was necessary for this Application.

It was concluded that the use of Reb M as a food additive in accordance with the current permissions for steviol glycosides raises no public health and safety concerns. FSANZ therefore proposes to add Reb M to the list of permitted steviol glycosides in subsection 1.3.1—4(7) of the revised Code. A new specification needs to be written for Reb M in Schedule 3 of the revised Code. The proposed draft variation is only for the revised Code since it comes into operation and replaces the current Code on 1 March 2016. FSANZ believes it is unnecessary to also amend the current Code as the expected gazettal date is expected to be close to 1 March 2016. The assumed gazettal date is provided the Board eventually approves the variation and no review of that decision is requested by Ministers.

Steviol glycosides are currently required to be declared in the list of ingredients on the label of most packaged foods in accordance with section 1.2.4—7 of the revised Code (clause 8 of Standard 1.2.4 of the current Code). The specific steviol glycoside used (for example, Reb M) is not required to be declared, noting that ‘steviol glycosides’ can be a blend of different individual steviol glycosides.

1 Introduction

1.1 The Applicant

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

1.2 The Application

Steviol glycosides are a family of different specific steviol glycosides extracted from the stevia plant (*Stevia rebaudiana* (Bertoni)) leaves. Current permissions for adding steviol glycosides as an intense sweetener to different types of food refer to nine specific steviol glycosides. The steviol glycoside involved in this Application is called 'rebaudioside M' (abbreviated to 'Reb M' in this summary, sometimes also called 'rebaudioside X'). The Application seeks to have Reb M as a permitted steviol glycoside so it can be included in the current permissions for steviol glycoside addition to different food categories with specific maximum permitted levels. The Application is not seeking any additional permissions or changes to maximum permitted levels for the current steviol glycoside permissions. It also seeks a specification for Reb M so it can be included along with the other permitted steviol glycosides. The Applicant has two preparations of Reb M; one that contains greater than 50% Reb M and the other more purified preparation, which contains greater than 95% Reb M.

The Applicant claims that Reb M has a superior flavour profile, as well as greater sweetness intensity compared to other steviol glycosides. It claims foods containing Reb M have a less bitter taste and that Reb M provides a liquorice taste profile that lingers and in levels used, has a closer profile to sucrose (which intense sweeteners replace). Reb M can also be used with other intense sweeteners to provide synergistic sweetness closer to sucrose and to reduce flavour notes from other intense sweeteners that differ from sucrose. Reb M naturally occurs in much lower concentrations in the stevia leaf than other steviol glycosides so different extraction and purification steps are required.

1.3 The current Standard

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 in Schedule 15 of the revised *Australia New Zealand Food Standards Code* (the revised Code) commencing on 1 March 2016 (Schedule 1 of Standard 1.3.1 of the current Code). Subsection 1.3.1—4(6) of the revised Code (subclauses 5(2) and 5(3) of Standard 1.3.1 of the current Code) requires 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 nine different steviol glycosides and their different conversion factors, along with the basic steviol structure itself which has a conversion factor of 1.00. Reb M is not one of the steviol glycosides listed (so therefore it is not a permitted steviol glycoside). A steviol glycoside preparation may contain a blend of different steviol glycosides.

All permitted food additives are also required to have a specification for identity and purity. Schedule 3 of the revised Code contains primary sources of specifications in section S3—2 (clause 2 of Standard 1.3.4 in the current Code). The three primary sources have specification monographs for steviol glycosides. They are:

- subparagraph S3—2(1)(b), being 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 the same nine steviol glycosides that are listed and so permitted via subsection 1.3.1—4(7). The European Commission specification applies to the nine listed steviol glycosides as well as rebaudioside E. Reb M is not listed in any of these specifications (nor any of the secondary sources in section S3—3 of Schedule 3), and so is not covered by a Schedule 3 specification monograph.

1.3.1 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. However, as noted above the term ‘steviol glycosides’ in the Code refers to the nine specific steviol glycosides detailed in the JECFA and Food Chemicals Codex specifications, of which Reb M is not one. Permissions for steviol glycosides (in general as well as any specific permission for Reb M) for some major international and country regulations are noted below.

1.3.1.1 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’ does not include Reb M. However, the 47th session of the CCFA in 2015 has required that JECFA give priority to the re-evaluation of this specification with a view to increasing its scope, including the incorporation of Reb M into the specification.

1.3.1.2 The United States of America

There is a large number 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.

Importantly for this Application, there are a couple that relate specifically to Reb M. GRAS Notice No. GRN 473 submitted by the Applicant to this Application (PureCircle Ltd) for the use of Reb M as a sweetener in a variety of different foods received a ‘no questions’ notification from the USFDA on 2 December 2013. This notification refers to Reb M preparations containing greater than 50% Reb M (the same as one of the Reb M preparations of this Application).

Another company, GLG Life Tech Corporation (based in Vancouver, British Columbia, Canada), has also received a USFDA letter of ‘no objection’ on 22 October 2014, to their GRAS petition GRN 512 for their high purity Reb M (purity of greater than 95% Reb M) for use as a sweetener for a variety of food categories. The high Reb M content and purity of their product is consistent with that of the current Application.

Reb M preparations for both these GRAS notifications meet both the JECFA and FCC general specifications for steviol glycosides, noting neither specifically mention Reb M.

1.3.1.3 The 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 specifications for steviol glycosides are provided in Commission Regulation (EU) No. 231/2012. Reb M is not one of the permitted steviol glycosides.

1.3.1.4 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. These permissions do not include Reb M.

The Applicant has also submitted an application (similar to this application) to Health Canada seeking approval for Reb M as a permitted sweetener. At this stage of FSANZ's assessment process the Health Canada assessment has not been completed.

1.3.1.5 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, though usually without specific reference to Reb M. 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. These countries do not specifically permit Reb M as one of the permitted steviol glycosides.

Columbia and Nigeria also specifically permits Reb M. Nigeria permits Reb M at levels consistent with the maximum permitted levels established for steviol glycosides in the Codex GSFA.

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.

There are currently no permissions in the Code to use Reb M as a permitted form of steviol glycoside, as part of a steviol glycoside preparation, for use as an intense sweetener food additive. Therefore, consideration has been given to assessing this Application to determine if it warrants a variation to 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 the use of Reb M as a steviol glycoside intense sweetener which is provided as SD1. The conclusions of this assessment are provided below.

Reb M is similar in chemical structure and sweetness intensity to other currently permitted steviol glycosides. The production of Reb M preparations, analytical methods, specifications and stability are similar to other steviol glycosides. Reb M occurs naturally in the leaves of the stevia plant at much lower concentrations than several other steviol glycosides so specific concentration and purification steps are required to produce preparations containing high concentrations of Reb M.

As for other steviol glycosides, Reb M is hydrolysed completely to steviol by gut microflora. The existing acceptable daily intake (ADI) for steviol glycosides of 0-4 mg/kg bodyweight, which is expressed on the basis of steviol, therefore applies to Reb M.

Preparations containing Reb M are intended for use in the same food categories and at the same use-levels already permitted for other steviol glycoside products. FSANZ has previously conducted a dietary exposure assessment using the current permissions for steviol glycosides and therefore no dietary exposure assessment was necessary for this Application.

It was concluded that the use of Reb M as a food additive in accordance with the current permissions for steviol glycosides raises no public health and safety concerns.

2.2 Risk management

The conclusion of the risk assessment of Reb M (section 2.1 and SD1) is that Reb M is as safe and suitable a steviol glycoside as the other nine currently permitted steviol glycosides for use as an intense sweetener food additive. There are therefore a number of risk management issues to consider, specifically how to add permissions into the Code.

2.2.1 Permissions for Reb M

Both the hazard assessment and the food technology assessment concluded that Reb M is comparable to other already permitted steviol glycosides (listed in subsection 1.3.1—4(7) of Standard 1.3.1 in the revised Code, Table to subclause 5(3) of Standard 1.3.1 in the current Code).

Steviol glycoside permissions are written as steviol equivalents. For Reb M to also be permitted for use, an entry for Reb M and its steviol equivalents conversion factor needs to be added to subsection 1.3.1—4(7). The conversion factor is 0.25 (see explanation for how this figure is derived from section 2.7 of SD1). No other changes to permissions for Reb M were requested by the Application; that is, the same permissions for Reb M were sought to those existing for the other permitted steviol glycosides. The proposed drafting to reflect Reb M permissions is provided at Attachment A for the revised Code.

A consequential change to the current variation in subsection 1.3.1—4(7) of the revised Code for the list of conversion factors (CF) has been proposed. Currently steviol, which is the basic active component of steviol glycosides, is listed with a conversion factor of 1.00. It is not a steviol glycoside itself so it is proposed that it be removed.

2.2.2 Reb M specification

Permissions for food additives are also linked to their specifications. The current steviol glycoside permissions are linked to the JECFA, FCC and European Commission specifications for steviol glycosides. The JECFA specification applies to nine specifically named and identified steviol glycosides but does not include Reb M. Therefore, an additional specification for Reb M needed to be written into the Code (Schedule 3 of the revised Code).

Because the safety and technological purpose of Reb M is similar to the other permitted steviol glycosides it was decided to link the new Reb M specification to the existing, and readily available, JECFA specification. Any differences between Reb M and the generic steviol glycosides JECFA specification needed to be addressed in the new specification added to the Code. These Reb M specific differences are noted below.

- The assay for the JECFA steviol glycosides specification is that not less than 95% of the product consists of the total of nine named steviol glycosides on the dried basis. For Reb M this same intent should apply but now the total steviol glycoside content should be not less than 95% of the named ten steviol glycosides (the current nine plus Reb M) on a dried basis.
- The chemical name, CAS number, chemical formula and molecular formula weight are provided in a consistent form to that provided in the JECFA specification for steviol glycosides.

Reb M is noted to have different water solubilities to other steviol glycosides. However, water solubilities is not deemed a relevant criterion for specifications so this will not be addressed. Water solubilities are important for food manufacturers to ensure complete incorporation of the intense sweetener preparation in the food matrix but this information should be supplied in technical data sheets.

The proposed Reb M specification is provided in the draft variations at Attachment A. If the current JECFA, FCC or European Commissions specifications for steviol glycosides are updated to include Reb M, then this specification in the Code can be removed.

2.2.3 Analytical methods

There are, and have been, 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 Reb M 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 2.4 of SD1.

2.2.4 Labelling

Steviol glycosides are currently required to be declared in the list of ingredients on the label of most packaged foods in accordance with subsection 1.2.4—7 of the revised Code (clause 8 of Standard 1.2.4 of the current Code). This requires the class name *sweetener* to be declared followed by the prescribed name *steviol glycosides*, or code number *960* in brackets. The specific steviol glycoside (for example, Reb M) or blend of steviol glycosides used is not required to be declared, which is the current situation. These existing labelling provisions will continue to allow consumers to identify whether steviol glycosides have been added to a packaged food.

2.3 Risk communication

FSANZ has developed a basic communication strategy for this Application.

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 draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

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 Regulation¹ (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 in the national press and on the FSANZ website.

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 permit Reb M as a new steviol glycoside to be used as an intense sweetener is unlikely to have a significant effect on international trade as allowing a new form of steviol glycoside will liberalise trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures 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.

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

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.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to determine whether a Regulation Impact Statement is 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 revised Code to permit and develop a specification for Reb M as a new steviol glycoside
- (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 revised 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 Reb M, being a new steviol glycoside, has a superior flavour profile to other steviol glycosides which offers consumers benefit.
Industry	The Applicant indicates the food industry has expressed interest in using Reb M due to flavour benefits it offers compared to other steviol glycosides and it supports innovation. These benefits are the increased sweetness potency, so more sugar can be replaced, and the superior flavour profile.
Governments	There should be little impact on government enforcement agencies since there are already nine steviol glycosides permitted to be added to various food categories. This is just another one. It's 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 a new steviol glycoside with claimed advantages of increased sweetness potency and superior flavour 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 permit and develop a specification for Reb M as a new steviol glycoside is the preferred option and has prepared draft variations to the revised 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

There are no relevant New Zealand only Standards; Standard 1.3.1 and Schedule 3 of the revised Code apply to both Australia and New Zealand.

2.4.1.4 Any other relevant matters

See 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 relating to using Reb M as an additional permitted steviol glycoside used as an intense sweetener.

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

No issues have been identified. In accordance with existing labelling provisions, steviol glycosides are required to be declared in the list of ingredients on the label of most packaged foods (see section 2.2.4).

2.4.2.3 The prevention of misleading or deceptive conduct

No issues were identified for this Application relevant to this objective.

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 1.3.1 details the current permissions for Reb M in different countries as well as the active regulatory work being undertaken by other international agencies in regard to assessing Reb M as a new steviol glycoside. Permitting this Application will ensure consistency between the Code and other international food standards.

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

Reb M is proposed as an additional permitted steviol glycoside to be used as an intense sweetener. It is claimed to have technological advantages of greater sweetening potency and superior flavour profile compared to other steviol glycosides. These attributes provide the food industry with potential advantages for developing reduced sugar products that are acceptable to consumers, and so make the products and industries more competitive and efficient.

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

Reb M is a new alternative steviol glycoside which some food industries in Australia and New Zealand may wish to evaluate and use in their products. It is currently permitted in some other countries and its permission is being actively sought in other countries. Permitting its use in Australia and New Zealand would support fair trading for both food manufacturers and retailers.

- **any written policy guidelines formulated by the Ministerial Council²**

The Policy Guideline 'Addition to Food of Substances other than Vitamins and Minerals'³ 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 adding Reb M to the current list of permitted steviol glycosides is consistent with these specific order policy principles.

3 Draft variation

The proposed draft variation is only for the revised Code since it comes into operation and replaces the current Code on 1 March 2016. FSANZ believes it is unnecessary to also amend the current Code as the expected gazettal date is expected to be close to 1 March 2016 provided the Board eventually approves the variation and no review of that decision is requested by Ministers.

² Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

³ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

The draft variation to the revised Code is at Attachment A and the related draft explanatory statement is at Attachment B. The variation is intended to take effect on 1 March 2016.

An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments (FRLI).

4 References

Codex Alimentarius (2014) General Standard for Food Additives, CODEX STAN 192-1995 (Revision 2014), Steviol Glycosides in Table one, pages 201-203
http://www.codexalimentarius.net/gsaonline/docs/CXS_192e.pdf. Accessed on 3 June 2015

European Commission (2011) Commission Regulation (EU) No 1131/2011 of 11 November amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides. Off J Eur Union 54(L295):205-211.
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0205:0211:EN:PDF> Accessed on 3 June 2015

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Attachments

- A. Draft variations to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
- B. Draft Explanatory Statement

Attachment A – Draft variations to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)



Food Standards (Application A1108 – Rebaudioside M as a Steviol Glycoside 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 Standard commences on the date specified in clause 2 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**.

1 Name of instrument

This instrument is the *Food Standards (Application A1108 – Rebaudioside M as a Steviol Glycoside Intense Sweetener) Variation*.

2 Commencement

This instrument commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions —2014 Revision.

3 Variation of Standard 1.3.1

Schedule 1 varies the *Australia New Zealand Food Standards Code* – Standard 1.3.1 – Food additives.

4 Variation of Schedule 3

Schedule 2 varies the *Australia New Zealand Food Standards Code* – Schedule 3 – Identity and purity

Schedule 1 – Variation of Standard 1.3.1

[1] Omit paragraphs (g) to (j) of the definition of **CF** in subsection 1.3.1—4(7), substitute

- “
- (g) rebaudioside M—0.25;
 - (h) rubusoside—0.50;
 - (i) steviolbioside—0.50;
 - (j) stevioside—0.40.”

Schedule 2 – Variation of Schedule 3

[1] Insert after section S3—30

“S3—31 Specification for rebaudioside M

- (1) In this section:
rebaudioside M means the chemical with the Chemical Abstracts Service Registry Number 1220616-44-3 and the formula $C_{56}H_{90}O_{33}$.
- (2) For rebaudioside M, the specifications are the following:
 - (a) assay—not less than 95% of the total of the steviol glycosides named in the JECFA steviol glycosides specification and rebaudioside M, on the dried basis;
 - (b) Chemical name—Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester;
 - (c) Formula weight—1,291.3.
- (3) Subject to subsection (2), rebaudioside M must comply with a monograph specification in section S3—2 or section S3—3 that relates to steviol glycosides.”

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 A1108 which seeks permission for rebaudioside M to be added to the list of permitted steviol glycosides used as intense sweeteners. The Authority considered the Application in accordance with Division 1 of Part 3 and has proposed a draft variation.

2. Purpose

The Authority has proposed that rebaudioside M be added to the list of permitted steviol glycosides. To do this rebaudioside M is proposed to be added to subsection 1.3.1—4(7) of the Code used to calculate steviol equivalents. This is how steviol glycosides are permitted to be added as intense sweeteners to a variety of food categories in the table to section S15—5 in Schedule 15. No new specific permissions are needed for rebaudioside M in section S15—5. Since there are no specifications for rebaudioside M in any of the monographs in Schedule 3 (S3—2 and S3—3), a new specification has been written to be added into Schedule 3.

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 A1108 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (including the draft variations) will occur for a six-week consultation period.

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 Variation to Standard 1.3.1

Item 1 of Schedule 1 of the draft variation amends paragraphs (g) to (j) of the definition of **CF**

(Conversion Factor) in subsection 1.3.1—4(7) of Standard 1.3.1.

The effect of this amendment is to include rebaudioside M in the list of permitted steviol glycosides that can be added to specific food categories as an intense sweetener food additive. It does this by adding rebaudioside M and its conversion factor used to calculate steviol equivalents to the list within subsection 1.3.1—4(7) to the revised Code. The permissions for adding steviol glycosides to food exist in the table to section S15—5 of Schedule 15 of the revised Code. No changes are required in this Schedule.

6.2 Variation to Schedule 3

Item 1 of Schedule 2 of the draft variation inserts a new section S3—31 into Schedule 3 of the revised Code.

The new subsection adds a specification for rebaudioside M to Schedule 3. This specification is linked to the current JECFA specification for steviol glycosides, noting that the JECFA specification does not specifically mention rebaudioside M, but refers to nine other comparable steviol glycosides.