

4 November 2015
[28–15]

Approval Report – Application A1108

Rebaudioside M as a Steviol Glycoside Intense Sweetener

Food Standards Australia New Zealand (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.

On 29 June 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received nine submissions.

FSANZ approved the draft variation on 28 October 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 3 November 2015.

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

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

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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 (at Approval)

Executive summary

PureCircle Limited, based in Illinois in the United States of America (USA), submitted an Application seeking permission for a new steviol glycoside, rebaudioside M (abbreviated as Reb M), as a new intense sweetener. Permission was sought for Reb M to be another permitted steviol glycoside that can be added to an intense sweetener food additive preparation called '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 within the food additive group '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 sections 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 was currently no specification monograph that includes a reference to Reb M within general steviol glycosides specifications in Schedule 3.

Steviol glycosides are permitted food additives in the Codex Alimentarius General Standard for Food Additives, and in many countries including the USA, the European Union, Canada and many Asian, Central and South American countries. Reb M is considered Generally Recognized as Safe (GRAS) in the USA 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 Reb M.

Steviol glycosides 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 had previously conducted a dietary exposure assessment using the current permissions for steviol glycosides and therefore no dietary exposure assessment was necessary for this Application.

FSANZ's risk assessment concluded that Reb M's use as a food additive in accordance with the current permissions for steviol glycosides raised no public health and safety concerns.

FSANZ therefore approved a draft variation to add Reb M to the list of permitted steviol glycosides set out in subsection 1.3.1—4 (7) of the revised Code. The approved draft variation also inserts into Schedule 3 of the revised Code new specifications for the substance Reb M and steviol glycosides preparations containing Reb M. 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 (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.

The approved draft variation differs from the variation circulated with the Call for Submissions. The drafting was amended: to provide one specification for Reb M and a separate specification for a steviol glycoside mixture or preparation that contains Reb M; and to clarify how the general steviol glycosides specifications currently provided by Schedule 3 will apply.

With the Applicant's agreement, the approved draft variations are only for the revised Code since it comes into operation and replaces the current Code on 1 March 2016. It was felt unnecessary to also amend the current Code as the approved draft variation's anticipated gazettal date will be close to 1 March 2016.

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 the food additive called 'steviol glycosides' as an intense sweetener to different types of food refer to nine specific individual steviol glycosides (see section 2.1.1 of SD1 which explains the structures of these individual glycosides). The steviol glycosides intense sweetener preparation can be a blend of differing amounts of the individual steviol glycosides or it can be primarily one steviol glycoside.

The steviol glycoside applied for in this Application is called 'rebaudioside M' (abbreviated to 'Reb M' in this report, sometimes also called 'rebaudioside X'). The Application sought to have Reb M as a permitted steviol glycoside so it could be included in the current permissions for steviol glycosides addition to different food categories with specific maximum permitted levels. The Application was not seeking any additional permissions or changes to maximum permitted levels for the current steviol glycosides permissions. It also sought a specification for Reb M so it could be included along with the other permitted steviol glycosides since current specifications for steviol glycosides do not include Reb M. The Applicant has two preparations of Reb M; one that contains greater than 50% Reb M (the remainder being other permitted steviol glycosides) and the other more purified preparation, which contains greater than 95% Reb M.

The Applicant claimed that Reb M has a superior flavour profile, as well as greater sweetness intensity compared to other steviol glycosides. It claimed 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 compared to more abundant steviol glycosides.

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) (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 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 (subsections 1.1.1—15(1) and (2) of the revised Code). 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), the JECFA (Joint Food and Agricultural Organization/World Health Organization 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 in subsection 1.3.1—4(7) of the revised Code. 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.

With the Applicant's agreement, only draft variations for the revised Code were considered, since it comes into operation and replaces the current Code on 1 March 2016. It was felt unnecessary to also amend the current Code as the anticipated gazettal date is close to 1 March 2016.

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 food additive 'steviol glycosides' in the Code refers to the nine specific steviol glycosides detailed in the JECFA and FCC 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.

There are two 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 its GRAS notice No. GRN 512 for its 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 also consistent with one preparation 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 within Commission Regulation (EU) No. 231/2012; again it does not include Reb M.

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.

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.

Columbia and Nigeria also specifically permit Reb M. Nigeria permits Reb M at levels consistent with the maximum permitted levels established for steviol glycosides within 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 might be developed as 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

A number of issues were raised in submissions to the call for submissions. The approved draft variations were amended from those at the call for submissions to take account of the issues raised in submissions. Table 1 contains the issues raised and FSANZ's response.

Nine submissions were received, with eight supporting the draft variations and continuing with the assessment, while one submission tentatively supported the draft variations but raised a number of issues. Submissions were received from seven industry representatives, including the Applicant, one Government enforcement agency and a food technology association.

One submission queried aspects of the draft variation provided with the call for submissions (Attachment C). FSANZ has amended the drafting (see Attachment A).

The main amendment was to provide separate specifications for: a steviol glycoside preparation that contained only Reb M as the steviol glycoside; and steviol glycosides preparations that contain a mixture of Reb M with at least one other (already permitted) steviol glycoside. Both these specifications have their own Reb M specific requirements, as well as linking to other 'steviol glycosides' specifications (JECFA, FCC or European Commission) that contain other general steviol glycoside specifications.

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>FSANZ has written a specification for Reb M to be added into the Code (S3—31 of Schedule 3) separate from the JECFA specification for ‘Steviol glycosides’. Will JECFA amend or write a new specification for Reb M?</p>	<p>Food Technology Association of Australia (FTAA)</p>	<p>FSANZ cannot comment on what JECFA will do in relation to amending its current ‘steviol glycosides’ specification. FSANZ is aware there is interest from impacted stakeholders to request JECFA to amend the ‘steviol glycosides’ specification². It is important to re-state that because the current JECFA (or FCC or EU) steviol glycosides specification does not include reference to Reb M, FSANZ needed to include its own specifications specifically for Reb M, but it has done that by linking them to the current JECFA/FCC/EU steviol glycosides specifications. This is the approved draft variation. If the JECFA (or FCC or EU) steviol glycosides specification is amended to include reference to Reb M then the FSANZ specific specifications (S3—31 and S3—32) can be removed from the Code as they will not be needed.</p>
<p>More clarity and explanation required around the specification drafting. Is there a specific preparation and hence specific specification for Reb M? Or is the specification specific for steviol glycosides that can contain Reb M, along the same lines as the JECFA specification? The explanation in section 2.2.2 in the Call for Submissions provides some clarification but it has not been translated into the draft variation.</p>	<p>Food Technology Association of Australia (FTAA)</p>	<p>FSANZ has amended the specification drafting, which had combined the substance Reb M and steviol glycosides preparations containing Reb M into one specification. The amended draft variation now provides a definition for Reb M and then provides two separate specifications – one for steviol glycosides preparations that only comprise Reb M (ie, 95%) as the only steviol glycoside, and another specification for steviol glycosides preparations which contain Reb M as well as other already permitted steviol glycosides. The relevant section dealing with Reb M specifications in this report (section 2.3.2) has also been reworded.</p>
<p>Within the draft variation written as S3—31 subsection (3) cannot be compliant with subsection (2). This is because none of the specifications in sections S3—2 or S3—3 mention Reb M.</p>	<p>Food Technology Association of Australia (FTAA)</p>	<p>The drafting provides specifications for two substances: for a steviol glycosides preparation that only comprises Reb M (ie, 95%) and for a steviol glycosides preparation contain Reb M as well as other already permitted steviol glycosides. In both cases, the specifications in effect deem the latter to be a steviol glycoside to which the general steviol glycosides attributes written in the JECFA/FCC/EU specification apply. As such, the JECFA/FCC/EU specifications do not need to refer to Reb M.</p>

² Report of the Forty Seventh session of the Codex Committee on Food Additives (CCFA) REP15/FA paragraph 138 and Appendix XIII, http://www.codexalimentarius.org/input/download/report/924/REP15_FAe.pdf

Issue	Raised by	FSANZ response (including any amendments to drafting)
Will the INS number for Reb M also be 960, as for current steviol glycosides	Food Technology Association of Australia (FTAA)	Yes, the INS number 960 is linked to the general food additive 'steviol glycosides', not to any specific steviol glycoside. This is no different to the current situation in the Code. The Code sets out what INS number applies for the purposes of ingredient labelling statements. Section 1.2.4—7 of the revised Code sets out the requirements for labelling of food additives. Schedule 8 lists the food additive names and code numbers for ingredient labelling purposes. Steviol glycosides (INS 960) is listed in S8—2. Steviol glycoside permissions for food categories are provided in Schedule 15, while subsections 1.3.1—4(6) and 1.3.1—4(7) state how steviol glycosides are calculated. Reb M is listed in subsection 1.3.1—4(7) so is a permitted steviol glycoside.
Since there are no permissions for Reb M in other international jurisdictions, answers to the above questions should have been addressed in the original application and need to be addressed in this report (or requested in a second round call for submissions).	Food Technology Association of Australia (FTAA)	FSANZ has addressed the issues dealing with clarity of the drafting as discussed above. FSANZ does not believe there is any need to conduct another round of public comment.
The submitters agree with the proposed specification as outlined in SD1, section 2.6 and Table 1. However, they both recommend that the numbers of permitted steviol glycosides should be increased from 10 to 11 (note 1). Also note 2 incorrectly states that Reb E is one of the permitted 9 steviol glycosides in the JECFA specification for steviol glycosides.	International Stevia Council, Calorie Control Council, and PureCircle Limited (the Applicant)	The notes to Table 1 have been rectified in the amended SD1 for the Approval Report. Rebaudioside E (Reb E) is not currently permitted in the Code, nor is it listed in the JECFA or FCC specifications. FSANZ is not proposing to permit Reb E as part of this Application since it was not requested nor has FSANZ assessed Reb E; it has only assessed and permitted Reb M as per the Application. Because of this, the numbers as listed are correct and will not be changed.
Both submitters prefer using alternative food additive names for labelling, such as 'stevia leaf extract', which is used in the USA. They explain that this term is more recognised by consumers as indicating that the sweetener is from a natural source.	International Stevia Council, and Calorie Control Council	The labelling of steviol glycosides is dealt with in section 2.3.4 of this report. It is important to note that steviol glycosides preparations are classified as food additives (with the technological function of intense sweetener) and not as ingredients. The labelling of food additives is addressed by the relevant section of the Code (subsection 1.2.4—7 of the revised Code).
The NZBC Technical Advisory Group and Frucor noted that there does not appear to be any permissions to add steviol glycosides to fruit drinks (food category 14.1.2.2 in Schedule 1 of Standard 1.3.1 of the current Code, Schedule 15—5 of the revised Code), unlike similar beverages. They are investigating addressing this lack of permission via a separate application.	New Zealand Beverage Council (NZBC), and Frucor Beverages Limited	This comment is noted. It is also noted that permissions exist for their addition to low joule fruit and vegetable juice products (subcategory 14.1.2.2.2 in the revised Code) being a subcategory within 14.1.2.2. If permissions are sought for other types of beverages, then a new application to amend the Code would be required (as noted in the Frucor submission).

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Building on recent toxicity studies (references provided), the submitter (also the Applicant) notes that there are also other steviol glycosides that are currently not permitted or listed in the specifications that could also be covered by steviol glycoside permissions in the Code. These other steviol glycosides have now been well characterised and as examples are listed as Reb H, J, K, N and O.</p>	<p>PureCircle Limited (the Applicant)</p>	<p>FSANZ takes this information and the supplied references as a comment. Assessing and potentially approving other steviol glycosides not formally requested in the Application is outside the scope of FSANZ's assessment for this current Application. Alternative regulatory consideration of steviol glycosides or assessing and approving any new ones would require a new Application.</p>

2.2 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 raised no public health and safety concerns.

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1).

2.3 Risk management

The conclusion of the risk assessment of Reb M (section 2.2 and SD1) is that Reb M is as safe and suitable as the other nine currently permitted steviol glycosides for use as an intense sweetener food additive. There were, however, a number of risk management issues to consider, specifically how to add permissions into the Code and write specifications for Reb M and steviol glycoside preparations containing Reb M.

2.3.1 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. The permissions for these are 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).

As explained in section 1.3, steviol glycosides permissions are written as steviol equivalents. Only those nine steviol glycosides listed in subsection 1.3.1—4(7) in the revised Code are therefore permitted to be part of any steviol glycosides preparations used as intense sweeteners. For Reb M to also be permitted, an entry for Reb M and its steviol equivalents conversion factor must be added to this subsection. 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, i.e. the food additive 'steviol glycosides'.

The approved draft variation following the call for submissions reflecting 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 occurred. 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 and it is not present (or in negligible amounts) in commercial steviol glycoside preparations. Steviol is often included in steviol glycoside lists for structural elucidation purposes only. Therefore it has been removed from the list and Reb M added.

2.3.2 Reb M specification

Permissions for food additives are also linked to their specifications. The current steviol glycosides permissions are linked to the JECFA, FCC and European Commission specifications for steviol glycosides. The JECFA and FCC specification applies to the nine specifically named and identified steviol glycosides permitted by the Code in subsection 1.3.1—3(7) of the revised Code, but does not include Reb M. Therefore, an additional definition and then specification has been written for the substance Reb M (Schedule S3—31). This specification also applies to steviol glycoside preparations that only contain Reb M as the steviol glycoside. Separately, a new definition and then specification for a preparation of steviol glycosides containing Reb M along with other already permitted steviol glycosides has been written (Schedule 3—32). Both these specifications are also linked to other relevant specifications within the JECFA, FCC or European Commission for steviol glycosides.

Because the safety and technological purpose of Reb M is similar to the other permitted steviol glycosides, the new Reb M specification is linked to the existing 'steviol glycosides' specifications of JECFA, FCC or the European Commission. Any differences between Reb M and the generic steviol glycosides specifications are addressed in the new specifications 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 applies 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.

The Reb M specifications are provided in the draft variations at Attachment A. The intent of these new specifications for Reb M is that the unique properties of Reb M are included in Schedule S3—31, along with a specification for a steviol glycoside preparation that only contains Reb M as the steviol glycoside. Specifications for steviol glycoside preparations containing Reb M with other already permitted steviol glycosides are included in Schedule 3—32.

If the current JECFA, FCC or European Commission specifications for steviol glycosides are updated to include Reb M, then these two specifications in the Code will not be required and so can be removed.

2.3.3 Analytical methods

There are, and have been, analytical methods available for detecting and quantifying 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.

2.3.4 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.

3 Impact analysis

The Office of Best Practice Regulation (OBPR), in a letter dated 24 November 2010 (reference 12065), granted a standing exemption from the need for the OBPR to assess if a Regulatory Impact Statement is required for the approval of applications relating to food additives.

This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature. The exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Notwithstanding the above exemption, FSANZ conducted a limited cost benefit analysis for this Application. That analysis found that permitting Reb M as a new steviol glycoside had benefits to the various sectors of the food industry. These included manufacturers of processed foods who wish to use steviol glycosides or blends of intense sweeteners containing steviol glycosides as full or partial replacements for sugar. These benefits are potentially greater sweetness potency and superior flavour profile that more readily mimics sugar but with less of the different flavour notes of other intense sweeteners. No costs to different stakeholders were identified that overrode these benefits. Nor was any benefit in rejecting the Application identified. As explained above, the use of Reb M as a food additive in accordance with the current permissions for steviol glycosides raised no public health and safety concerns.

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 draft variation to the Code to permit the use of Reb M as a food additive in accordance with the current permissions for steviol glycosides.

4 Decision

The approved draft variations to the revised Code, as varied after consideration of submissions, is at Attachment A, with the related explanatory statement at Attachment B. The variations take effect on 1 March 2016. It was considered unnecessary to also amend the current Code as the anticipated gazettal date is expected to be close to 1 March 2016.

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

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

5 Risk communication

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 Food Standards 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 to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

The FSANZ Board considered the draft variation taking into account public comments received from the call for submissions.

The Applicant, individuals and organisations that made 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.

The FSANZ Board's decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation³ (the 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.

6 FSANZ Act assessment requirements

6.1 Section 29

6.1.1 Cost benefit analysis

As explained in section 3, FSANZ conducted a cost benefit analysis which concluded that the benefits that would arise from the proposed food regulatory measure will outweigh the costs to the community, Government or industry that may arise from that measure.

6.1.2 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. See section 3.

³ Convening as the Australia and New Zealand Food Regulation Ministerial Council

6.1.3 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 in both Australia and New Zealand.

6.1.4 Any other relevant matters

See below.

6.2 Subsection 18(1)

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

6.2.1 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.

6.2.2 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 2.3.4).

6.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this Application relevant to this objective.

6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ 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 with 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 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**

There are no issues identified with this Application relevant to this objective.

- **any written policy guidelines formulated by the Ministerial Council⁴**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*⁵ 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 determined that adding Reb M to the current list of permitted steviol glycosides was consistent with these specific order policy principles.

7 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/gsfaonline/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

European Commission (2012) Commission Regulations (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council, E 960 Steviol Glycosides, Off J Eur Union 55(L83):270-271. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0231&qid=1422417373325&from=EN> Accessed on 3 June 2015

Food Chemicals Codex (2014), 9th Edition, Steviol Glycosides, Rockville (MD): United States Pharmacopeial Convention (USP).

⁴ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

⁵ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Health Canada (2012) 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. <http://www.hc-sc.gc.ca/fn-an/consult/nom-adm-0002/index-eng.php> List of Permitted Sweeteners (current version, issued date 24 April 2014) <http://www.hc-sc.gc.ca/fn-an/securit/addit/list/9-sweetener-edulcorant-eng.php> Both accessed on 3 June 2015

JECFA (2010) Steviol Glycosides, in Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 10 (2010)), Geneva, Switzerland. Food and Agriculture Organization of the United Nations (FAO), Joint FAO/WHO Expert Committee on Food Additives (JECFA), Rome, Italy. <http://www.fao.org/ag/agn/jecfa-additives/specs/monograph10/additive-442-m10.pdf>. Accessed on 3 June 2015

US FDA (2013). GRAS Notice No. GRN 473 [Purified steviol glycosides with rebaudioside X as the principal component]. Submitted by PureCircle Ltd, Oak Brook (IL) to U.S. Food and Drug Administration (US FDA), on 24 April 2013. Releasable dossier and Agency Response Letter available at this link <http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=473> Accessed on 3 June 2015

US FDA (2014) GRAS Notice No GRN 512 [High purity Rebaudioside M]. Submitted by GLG Life Tech Corporation, Vancouver, British Columbia, Canada to the U.S. Food and Drug Administration (US FDA), on 28 April 2014. Releasable dossier and Agency Response Letter available at this link <http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=512> Accessed on 3 June 2015

Attachments

- A. Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
- B. Explanatory Statement
- C. Draft variation to the revised *Australia New Zealand Food Standards Code* (call for submissions)

Attachment A – Approved draft variation 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 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.

1 Name of instrument

This instrument is the *Food Standards (Application A1108 – Rebaudioside M as a Steviol Glycoside 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 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions – 2014 Revision.

Schedule

[1] **Standard 1.3.1** is varied by omitting paragraphs (g) to (j) of the definition of **CF** in subsection 1.3.1—4(7), and substituting

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

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

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

“			”
	rebaudioside M	section S3—31	”
“			”
	steviol glycoside mixtures including rebaudioside M	section S3—32	”

[2.2] inserting 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—comprise not less than 95% 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 one of the specifications that relate to steviol glycosides and that is listed in a primary source named in paragraph S3—2(1)(b), S3—2(1)(c) or S3—2(1)(d).

S3—32 Specification for steviol glycoside mixture including rebaudioside M

(1) In this section:

prescribed steviol glycosides are:

- (a) dulcoside A;
- (b) rebaudioside A;

- (c) rebaudioside B;
 - (d) rebaudioside C;
 - (e) rebaudioside D;
 - (f) rebaudioside F;
 - (g) rubusoside;
 - (h) steviolbioside; and
 - (i) stevioside.
- (2) This specification relates to a mixture that contains rebaudioside M and one or more prescribed steviol glycosides.
 - (3) The rebaudioside M and the prescribed steviol glycoside or glycosides must together comprise not less than 95% of the mixture on the dried basis.
 - (4) Subject to subsection (3), the mixture must also comply with one of the specifications that relate to prescribed steviol glycosides and that is listed in a primary source named in paragraph S3—2(1)(b), S3—2(1)(c) or S3—2(1)(d).”

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 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 approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation⁶, 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 *Legislative Instruments Act 2003*.

2. Purpose

The approved draft variation adds rebaudioside M to the list of permitted steviol glycosides that can be added as a food additive intense sweetener preparation to food or sold for use in food. It also includes new specifications in Schedule 3 of the Code for rebaudioside M and for a steviol glycoside mixture or preparation that includes rebaudioside M.

3. Documents incorporated by reference

The approved draft variation incorporates a number of specifications by reference to specific documents in force or existing at the commencement of the variation.

The incorporated specifications are contained in the specific editions of publications listed in section S3—2 of Schedule 3 of the Code. In general, these specifications and publications are referred to in order to provide further technical detail to support the provisions of the Code. These references by incorporation are consistent with the current practice in the Code, particularly Schedule 3 which itself already incorporates the specifications in these documents by reference.

The documents in question are:

- (a) The Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005), Food and Agriculture Organisation of the United Nations, Rome, as superseded by specifications published in any of the following:

⁶ convening as the Australia and New Zealand Food Regulation Ministerial Council

- (i) FAO JECFA Monographs 3 (2006);
 - (ii) FAO JECFA Monographs 4 (2007);
 - (iii) FAO JECFA Monographs 5 (2008);
 - (iv) FAO JECFA Monographs 7 (2009);
 - (v) FAO JECFA Monographs 10 (2010);
 - (vi) FAO JECFA Monographs 11 (2011);
 - (vii) FAO JECFA Monographs 13 (2012);
- (b) United States Pharmacopeial Convention (2014) Food chemicals codex. 9th ed, United States Pharmacopeial Convention, Rockville, MD.
- (c) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1108 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. A call for submissions (including the draft variation) occurred for a six-week consultation period.

A Regulation Impact Statement was not required because the approved draft variation 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

Item [1] varies Standard 1.3.1. The variation replaces paragraphs (g) to (j) of the definition of **CF** (Conversion Factor) in subsection 1.3.1—4(7).

Standard 1.3.1 and Schedule 15 permit the use of preparations of steviol glycosides ('steviol glycosides') as food additives intense sweeteners. Paragraph 1.3.1—4(6)(i) of Standard 1.3.1 requires that, for this purpose, steviol glycosides must be calculated as 'steviol equivalents' in accordance with subsection 1.3.1-4(7). The variation adds rebaudioside M to the list of steviol equivalents within that subsection. It also adds a conversion factor used to calculate a steviol equivalent for rebaudioside M. This in effect provides the permission for the use of rebaudioside M as a food additive.

The variation also removes the reference to steviol in paragraph (h) of the definition of **CF** (Conversion Factor) in subsection 1.3.1—4(7). This is because steviol is not itself a steviol glycoside, nor is it contained in commercial steviol glycoside preparations. It is the active non-sugar component of steviol glycosides. It was listed in the definition for illustrative purposes and is often added to lists of steviol glycosides for structural elucidation purposes only. It has a steviol equivalence of 1.00 and, as such, is not required.

Item [2] varies Schedule 3.

Item [2.1] varies the table to subsection S3—2(2). The variation amends that table to include in it references to: rebaudioside M; a steviol glycoside mixture or preparation that includes rebaudioside M; and new sections S3—31 and S3—32. The effect is that subsection 1.1.1—15(2) of Standard 1.1.1 will require those substances, when added to food or sold for use in food, to comply with the specifications listed for each by those new sections.

Item [2.2] inserts new sections S3—31 and S3—32 into Schedule 3.

New section S3—31 provides the specifications for rebaudioside M. Subsection S3—31(1) and S3—31(2) provides a definition and specifications for assay, chemical name and formula weight. Subsection S3—31(3) provide that rebaudioside M must also comply with one of the specifications that relate to steviol glycosides and that is listed in a primary source named in paragraph S3—2(1)(b), S3—2(1)(c) or S3—2(1)(d) of Schedule 3. Each of the primary sources named in those paragraphs contains a specification that relates to steviol glycosides that are comparable to rebaudioside M. Subsection S3—31(3) requires that rebaudioside M comply with one of those specifications subject to the requirements in subsection S3—31(2).

New section S3—32 provides the specifications for a steviol glycoside mixture or preparation that includes rebaudioside M. Subsections S3—32(1) and (2) provide that the specifications apply to a mixture that contains rebaudioside M and one or more of the steviol glycosides currently permitted by the Code in preparations of steviol glycosides for use as a food additive intense sweetener. Subsection S3—32(3) provides a content specification. That is, the rebaudioside M and the prescribed steviol glycoside or glycosides must together comprise not less than 95% of the mixture. Subsection S3—31(3) provides that rebaudioside M must also comply with one of the specifications that relate to steviol glycosides and that is listed in a primary source named in paragraphs S3—2(1)(b), S3—2(1)(c) or S3—2(1)(d) of Schedule 3.

Attachment C – Draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016) (call for submissions)



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.”