FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

15 December 2010
[25-10]

APPLICATION A1037
STEVIOL GLYCOSIDES – INCREASE IN PERMITTED USE LEVELS
ASSESSMENT REPORT

Executive Summary

Food Standards Australia New Zealand (FSANZ) received an Application from Cargill, Incorporated on 28 October 2009. The Application seeks approval to increase the allowed maximum permitted level (MPL) of steviol glycosides (expressed as steviol equivalents) in ice cream, water based beverages, brewed soft drinks, formulated beverages and flavoured soy beverages up to 200 mg/kg and up to 100 mg/kg in plain soy beverages. The Applicant suggests the increased levels are required to provide a more acceptable taste profile for consumers and provide sensory analyses to support this.

Steviol glycosides are high intensity sweeteners extracted from the *Stevia rebaudiana* (Bertoni) plant. Rebaudioside A and stevioside are typically identified as the principal sweetening constituents and are accompanied by smaller amounts of other steviol glycosides. The preparation that is the subject of this Application comprises not less than 95% of nine steviol glycosides, with rebaudioside A accounting for over 95% of those present.

Food additives, which include intense sweeteners, are regulated under Standard 1.3.1. Schedule 1 of the Standard details permissions for the addition of steviol glycosides to a broad range of foods at specified maximum permitted levels. To approve an increase in levels, a pre-market assessment of the safety and suitability of steviol glycosides at the increased levels is required prior to approval being granted.

Steviol glycosides are permitted for use as a sweetener in a number of Asian and South American countries. They have also been the subject of fourteen independent Generally Recognised As Safe (GRAS) determinations notified to the United States Food and Drug Administration (USFDA) since 2008. The majority of the GRAS notifications are for specified foods at specific use levels; however the most recent notifications are for general use at levels determined by good manufacturing practices. Europe currently does not have harmonised permissions for steviol glycosides, however, rebaudioside A is approved for use in France; stevioside has been evaluated by the Scientific Committee for Food (SCF) most recently in 1999 and the European Food Safety Authority (EFSA) issued a positive opinion of the safety of steviol glycosides in April 2010.

An acceptable daily intake (ADI) of 0-4 mg/kg bodyweight, expressed as steviol equivalents, was established by FSANZ in 2008, JECFA in 2009 and EFSA in 2010.

The Application is being assessed under the General Procedure.

Risk Assessment

The risk assessment considered the technological justification and safety of increased maximum permitted levels of steviol glycosides for the specified foods, including consideration of a dietary exposure assessment.

The dietary exposure assessment modelled three scenarios, a 30% market share scenario and two 'brand loyal' scenarios - water based flavoured beverages and flavoured milk products (including yoghurt) to predict exposure for consumers who may always choose the same product every time.

Commensurate with JECFA's recommendation, a 30% market share scenario was considered in FSANZ's previous steviol glycosides assessment and confirmed as an appropriate, realistic scenario for the purpose of this assessment. It should be noted that a 30% market share scenario still results in a very protective overestimation of dietary exposure.

The 30% market share scenario assumes that for all food with permission for addition of steviol glycosides, thirty per cent actually contains steviol glycosides. Limitations in data for dietary exposure assessments mean it is not possible to predict consumers' preferences and behaviours in relation to food selection. A reasonable assumption is to assume that 'brand loyal' consumers may always choose the same product within a food category that may contain steviol glycosides, but it is unrealistic to assume that consumers would be brand loyal across a number of, or all, food categories.

In addition to the use of the proxy value for the purposes of modelling that all other foods, where permitted, contain steviol glycosides at 30% of the MPL (30% market share scenario), all foods in the 'brand loyal' categories were assumed to contain 100% of the MPL and they were assumed to always be selected by the consumer.

These scenarios overestimate the number of foods containing steviol glycosides and the levels of steviol glycosides in the foods. The modelling assumes steviol glycoside levels in foods used as ingredients are carried over to mixed foods; that all foods permitted to have steviol glycosides added do in fact contain them and that no other intense sweeteners are used. In reality the estimated amount of identified foods that may be intensely sweetened (where permitted) is shared by a number of permitted intense sweeteners.

These are broadly protective assumptions that are likely to lead to a considerable overestimation of dietary exposure.

Conclusions

The proposed increases in the maximum permitted levels of steviol glycosides in ice cream and selected beverages are technologically justified and supported by taste trials as providing a more acceptable taste profile to consumers.

Toxicological and other relevant data published subsequent to the original FSANZ assessment raise no concerns regarding the safety of steviol glycosides and do not indicate a need to change the existing ADI of 0-4 mg/kg bw/day, expressed as steviol equivalents.

Dietary exposure assessment, based on a 30% market share scenario for broad food groups at maximum levels specified, indicated that estimated dietary exposures to steviol glycosides were less than 60% of the ADI for both mean and 90th percentile exposures for all population groups assessed, including children.

Using a scenario to represent 'brand loyal' consumers of water based flavoured drinks, 90th percentile estimated dietary exposures were 110% of the ADI for Australian children aged 2-6 years and 100% of the ADI for New Zealand children aged 5-14 years. A further scenario considered 'brand loyal' consumers of flavoured milk products (including yoghurt) which are the highest contributor to steviol glycosides exposure for Australian children aged 2-6 years. This scenario predicted that estimated mean and 90th percentile dietary exposures for Australian children aged 2-6 years were approximately 55% and 100% of the ADI, respectively.

The 30% market share scenario and subsequent 'brand loyal' consumer scenarios are based on very conservative assumptions that are likely to lead to a considerable overestimation of dietary exposure. On this basis, the small exceedance of the ADI found for the high consuming individuals in the brand loyal scenario are not considered to be of concern. Estimates of exposure from the market share scenario, which is also a conservative estimate, are below the ADI. Therefore it is concluded there are no public health and safety concerns associated with the proposed increases in the maximum permitted levels in ice cream and certain beverages.

Additional Amendments

The Code is currently quite complicated in terms of how permissions for steviol glycosides (expressed as steviol equivalents) are given in Schedule 1 of Standard 1.3.1. In undertaking this application, additional drafting amendments are proposed to rationalise and simplify existing permissions for steviol glycosides and provide clarity and guidance around steviol equivalents.

As noted in section 6.1 of this Report, it is proposed to delete certain steviol glycosides permissions under items 3, 5.2, 11.4 and 14.1.3 in Schedule 1 of Standard 1.3.1. It is also proposed to clarify and provide instructions on how steviol glycosides are calculated as steviol equivalents in the Standard and include in subclause 5(2) of the Standard that steviol glycosides shall be calculated as steviol equivalents thereby removing the need to include this for every steviol glycosides permission in Schedule 1.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

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

- No other measures (available to the Authority or not) would be more cost-effective than a variation to Standard 1.3.1

- Any relevant New Zealand standards

- Any other relevant matters

Preferred Approach

To prepare draft variations to Standards 1.3.1 – Food Additives and 1.3.4 – Identity and Purity to permit an increase to the maximum permitted level of steviol glycosides in the proposed foods.

Reasons for Preferred Approach

An amendment to the Code approving an increase to the permitted levels of steviol glycosides (expressed as steviol equivalents) in the proposed foods in Australia and New Zealand is proposed on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that use of steviol glycosides as proposed does not raise any public health and safety concerns.

- Use of steviol glycosides as an intense sweetener in the proposed foods at the requested maximum permitted level is technologically justified as sensory analysis indicates a more acceptable taste profile is produced which would be expected to provide some benefits to food manufacturers and consumers.

- Approving an increase to the maximum permitted level of steviol glycosides in the proposed foods would not impose significant, if any, costs for government agencies, consumers or manufacturers as it is an already permitted food additive and provides potential benefits.

- The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

Consultation

Public submissions are now invited on this Assessment Report. Comments are specifically requested on the scientific aspects of this Application, including the technological function, dietary exposure and any information relevant to the safety assessment of steviol glycosides at the proposed use levels. Comments are also being sought on any impact resulting from consequential drafting amendments to steviol glycoside permissions.

As this Application is being assessed as a general procedure, there will be one round of public comment. Submissions to this Report will be considered in developing the Approval Report.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies,

research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked 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 using the Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5636

CONTENTS

SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at:

http://www.foodstandards.gov.au/foodstandards/applications/applicationa1037stev4605.cfm

SD1: Risk Assessment Report

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from Cargill, Incorporated on 28 October 2009. The Application seeks approval to amend Schedule 1 of Standard 1.3.1 – Food Additives to increase the level of steviol glycosides (expressed as steviol equivalents) permitted for use in ice cream, water based beverages, brewed soft drinks, formulated beverages and flavoured soy beverages to 200 mg/kg and to 100 mg/kg for plain soy beverages.

The Applicant claims the new use levels are supported by sensory testing of prepared formulations and are comparable to levels requested for the same food categories within the European Union. Likewise, they suggest these levels would be acceptable within the United States (US) as a consequence of the numerous self-Generally Recognised As Safe (GRAS) determinations which support levels consistent with good manufacturing practices (GMP).

Steviol glycosides (steviol conjugated with glucose, xylose, and/or rhamnose) are high intensity sweeteners extracted from the *Stevia rebaudiana* (Bertoni) plant. Rebaudioside A and stevioside are typically identified as the principal sweetening constituents and are accompanied by smaller amounts of other steviol glycosides. The preparation which is the subject of this Application comprises not less than 95% of nine steviol glycosides, with rebaudioside A accounting for over 95% of the steviol glycosides present.

A comprehensive database of the latest pre-clinical and clinical steviol glycoside publications has been provided to support the safety assessment and corroborate the previous FSANZ conclusion that steviol glycosides are safe for human consumption within specified food categories at defined use levels.

1. The Issue / Problem

The Applicant seeks to increase the currently permitted maximum level for steviol glycosides (expressed as steviol equivalents) in ice-cream; water based flavoured drinks; brewed soft drinks; formulated beverages and plain and flavoured soy beverages.

Food additives, which include intense sweeteners, are required to undergo a pre-market safety assessment prior to being included or amended in Standard 1.3.1.

Consideration of the safety of increased or varied dietary exposure to steviol glycosides, as well as assessing the technological justification for the requested increased use levels is required before any permission may be granted.

2. Background

2.1 Current Standard

Food additives used in the manufacture of food are regulated under Standard 1.3.1, which describes a food additive as:

Any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5.

Steviol glycosides fall under the Schedule 5 functional class of intense sweetener.

Schedule 1 of the Standard contains permissions for the addition of steviol glycosides to a range of foods at specified maximum levels. The foods and levels relevant to this Application are detailed below:

Category	Description	Maximum level mg/kg
3	Icecream and Edible Ices	64
14.1.4.4	Soy bean beverage (plain or flavoured)	
	Plain	65
	Flavoured	175
14.1.3	Water based flavoured drinks	160
14.1.3.1	Brewed soft drink	160
14.1.4	Formulated Beverages	160

2.2 Previous assessment

FSANZ previously assessed and subsequently approved an application for steviol glycosides in 2008. The Application (A540) was submitted by the Plant Sciences Group, Central Queensland University and Australian Stevia Mills Pty Ltd requesting approval for use of steviol glycosides as an intense sweetener in a wide variety of foods. Following a comprehensive risk assessment, FSANZ established an Acceptable Daily Intake (ADI) of 4 mg/kg bw/day, concluding no public health and safety issues existed that would preclude approval being granted. It was also concluded that use of steviol glycosides as an intense sweetener in the proposed foods at the prescribed levels was technologically justified. Permissions were subsequently included in Standard 1.3.1 for addition of steviol glycosides (expressed as steviol equivalents) in a broad range of foods at specified maximum levels.

At the time of FSANZ's assessment, use of steviol glycosides as a sweetener in food was not approved in the United States of America (USA) or Europe, but was approved in Japan and a number of other countries (see section 2.3).

2.3 International regulations

Permissions for use of steviol glycosides as an intense sweetener in a range of foods have existed for several years in a number of countries. As noted in the dossier, Japan has used stevia as its main non-sucrose sweetener for more than 30 years and a number of other countries[1] also allow its use.

The safety of steviol glycosides was reviewed by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) in 2000, 2004, 2005, 2007 and most recently in 2009. At its 63rd meeting in 2004, a temporary ADI of 2 mg/kg bw/day was established; the Committee also specified a need for additional safety studies to be undertaken. Following the submission and evaluation of additional data, the Committee at its 69th meeting in 2009, revised the ADI to 4 mg/kg bw/day and removed the temporary designation.

Europe currently does not have harmonised permissions for the use of steviol glycosides as a sweetener in food. Rebaudioside A however, has been authorised for use in France since 2009, while the Scientific Committee for Food (SCF) evaluated the use of stevioside as a sweetener in 1984, 1988 and 1989. The most recent opinion dates from June 1999.

[1] China, Malaysia, Switzerland, Taiwan, Turkey, Ukraine, Russia, Korea, Brazil, Paraguay, Mexico, Peru, Argentina, Indonesia and Israel

At the request of the European Commission (EC), the European Food Safety Authority's (EFSA) Panel on Food Additives and Nutrient Sources added to Food (ANS) assessed the safety and suitability of steviol glycosides as a sweetener used in food categories specified by three petitioners. EFSA released its opinion in April 2010 which, following consideration of data on stability, degradation products, metabolism and toxicology, established an ADI for steviol glycosides (expressed as steviol equivalents) of 4 mg/kg bw/day. They also concluded that steviol glycosides complying with JECFA specifications are not carcinogenic, genotoxic or associated with any reproductive or development toxicity.

In the USA, steviol glycosides have been permitted for use in dietary supplements since 1995. Their use as a sweetener in food has also been the subject of fourteen[2] independent GRAS determinations notified to the United States Food and Drug Administration (USFDA) since 2008. The majority of the notifications relate to preparations of purified rebaudioside A, or rebaudioside A in combination with stevioside, for use in specified foods at defined levels. The most recent notifications (GRAS Notice 348; 349, filed with the USFDA in August 2010) are for use as a general-purpose sweetener in foods, excluding meat and poultry products and infant formulas, at levels determined by good manufacturing practice, as well as use as a table top sweetener.

At the time of writing, eleven "no-objection" letters had been issued by the USFDA in relation to self-GRAS determinations for the use of steviol glycosides in foods.

2.4 Technological function

Steviol glycosides are a non-caloric intense sweetener and are natural components of the leaves of *Stevia rebaudiana* (Bertoni).

Water extracts of *S. rebaudiana* have been used as a sweetener in some Asian and South American countries for a number of years. Commercially purified extracts contain up to ten different glycosides of steviol, each with steviol as a common central component of its molecular structure. Stevioside, rebaudioside A, rebaudioside C and dulcoside A are the main steviol glycosides, with stevioside and rebaudioside A generally comprising around 80% of the extract. The other six minor glycosides present usually constitute less than 5% of the total extract.

The principal sweetening glycoside in the Applicant's preparation is rebaudioside A, which they report corresponds to greater than 95% of the glycosides present. They claim their preparation has a sweetening potency approximately 200 to 300 times that of sucrose.

The main purpose of using steviol glycosides in foods is to enhance taste and sweetness without needing to use high calorie sweeteners (such as sucrose, glucose, fructose, honey) or man-made chemical intense sweeteners. Steviol glycosides are claimed to have wide use in a range of foods due to their flavour and sweetness profile, along with their high stability. In 2005, the Codex Alimentarius assigned steviol glycosides the food additive number INS 960.

Updated specifications for steviol glycosides were prepared by JECFA in 2010 and published in FAO JECFA Monographs 10 (2010). The Applicant has developed their own in-house HPLC analytical methods for the identification and quantification of steviol glycosides in food and beverage matrices. Chemical analyses of three commercial batches were submitted which demonstrate conformance to the relevant JECFA specification.

[2] GRAS Notices 252, 253, 275, 278, 282, 287, 303, 304, 318, 323, 329, 337, 348 and 349.

3. Objectives

The objective of this Assessment is to determine whether it is appropriate to amend Schedule 1 of Standard 1.3.1 to increase the permitted maximum levels of steviol glycosides in the proposed foods.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The Ministerial Council Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals* includes policy principles in regard to substances added to achieve a solely technological function such as food additives and processing aids. According to these guidelines, permissions 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.

4. Questions to be answered

For this Application, FSANZ has considered the following risk assessment questions:

- Are the proposed increases in maximum permitted levels in selected foods consistent with achieving the stated purpose?

- Is there a need to change the ADI of 0-4 mg/kg bodyweight established previously by FSANZ?

- If the maximum permitted levels of steviol glycosides are increased in the proposed foods, would the resulting exposure for all consumers pose an unacceptable risk for public health and safety?

RISK ASSESSMENT

In addition to information supplied by the Applicant, other available resource materials including published scientific literature and general technical information were used in this assessment.

5. Risk Assessment Summary

The risk and technical assessment has considered the safety and suitability associated with increasing the maximum permitted level of steviol glycosides in the proposed foods. The summary and conclusion from this assessment (Supporting Document 1) are presented below.

5.1 Technological Justification

The Applicant has requested an increase to the maximum currently permitted amounts of steviol glycosides to be added to some foods and beverages. They claim results of taste analyses performed for a number of foods using the currently permitted limits produce product that is not sweet enough.

Steviol glycosides are 200 to 300 times sweeter than sucrose with the relative sweetness of individual glycosides varying. Rebaudioside A is sweeter than stevioside (300 times compared with 250 times sucrose respectively) and is associated with a more palatable taste profile, which is very relevant as the Applicant's commercial product is predominantly composed of rebaudioside A.

The Applicant has proposed that increased levels of steviol glycosides are required in the specified foods to provide a commercially acceptable product. Taste trial results submitted support the claim that higher steviol glycoside maximum limits are required to produce consumer accepted sweetened products for ice cream and various flavoured drinks (specifically soft drinks, which has been used to justify amended limits for other drinks).

FSANZ accepts the submitted data which supports increased maximum permitted levels of steviol glycosides in the proposed foods. The use of steviol glycosides as an intense sweetener, in the specified foods at the proposed amounts, is technologically justified.

5.2 Safety Assessment

The hazard assessment considered whether new toxicological or other data indicate a need to change the existing ADI.

No new unpublished studies were provided by the Applicant. A published paper described three *in vitro* and two *in vivo* genotoxicity studies on rebaudioside A. No mutagenic or clastogenic activity was evident in these assays. As discussed in previous assessments by FSANZ, JECFA and EFSA, the weight of evidence from an extensive database indicates that steviol glycosides are unlikely to be genotoxic.

The Applicant submitted several published reviews and studies which have been considered by JECFA but which were not published at the time of FSANZ's previous assessment.

The additional published toxicokinetics, metabolism, toxicity, and human data on steviol glycosides adds to the extensive database available for the hazard assessment of steviol glycosides. There were no findings in these publications which would indicate a need to change the ADI of 0-4 mg/kg bw/day, expressed as steviol equivalents, which was established by FSANZ in 2008.

5.3 Dietary Exposure Assessment

5.3.1 Introduction

FSANZ conducted a dietary exposure assessment (DEA) for steviol glycosides based on the information provided by the Applicant (see section 4 of SD1). Dietary exposure was estimated for the addition of steviol glycosides to foods according to existing permissions and the requested increased levels proposed by the Applicant.

The DEA models exposure to steviol glycosides based on broad food groupings assigned within the FSANZ dietary modelling program, DIAMOND. Where existing and proposed amended permission for steviol glycosides was given to a food classification code, all foods within that group were deemed to contain steviol glycosides at the specified level. Permissions were also carried over to mixed foods where the food has been used as an ingredient. Assumptions used in the DEA are detailed in section 4.1.5 of SD1.

Assuming all foods with a permission for steviol glycosides contains it at the maximum permitted level (MPL) grossly overestimates dietary exposure due to the broad range of foods with permissions, the maximum level may not be used, steviol glycosides may not be used in all food categories and the assumption that no other intense sweeteners are used.

Dietary exposure assessments for steviol glycosides were undertaken by JECFA at both its 63rd and 69th meetings (see section 4.4 of SD1). The assessments considered similar food categories to those included in this DEA, although most foods contained steviol glycosides at much higher levels. It was also assumed that steviol glycosides would completely replace all dietary sugars (total sugars and honey) used in or as food. Exposure estimates ranged between 1-5 mg/kg bw/day, although this was acknowledged by the Committee as being highly conservative and noted actual intakes would likely be 20-30% of these values.

5.3.2 '30% Market Share' scenario

Commensurate with the JECFA recommendation, a 30% market share scenario was considered in FSANZ's previous steviol glycosides assessment, and is confirmed as an appropriate, realistic scenario for the purpose of this assessment.

The 30% market share scenario assumes that for all food with permission for addition of steviol glycosides, thirty per cent actually contains steviol glycosides. In addition to use in broad food groups, it discounts the use of any other sweeteners currently available in the market, where in reality the estimated thirty per cent of identified foods that may be intensely sweetened (where permitted) is shared by a number of permitted intense sweeteners. Due to the limitations of the data collected in the national nutrition surveys and DIAMONDs capabilities, 30% of the MPL is used as a proxy to represent 30% market share.

Based on a 30% market share scenario for broad food groups, the estimated dietary exposure to steviol glycosides was less than 60% ADI for both mean and 90th percentile exposures for all population groups assessed.

It should be noted that a 30% market share scenario results in a very protective overestimation of dietary exposure.

5.3.3 'Brand loyal' scenarios

Given data limitations in dietary exposure assessments, it is not possible to predict consumers' preferences and behaviours in relation to food selection. It is reasonable to assume that 'brand loyal' consumers may always choose the same product within a food category that may contain steviol glycosides, but it is unrealistic to assume that consumers would be brand loyal across a number of, or all, food categories. Therefore, two separate consumer behaviour scenarios (water based flavoured beverages and flavoured milk products including yoghurt) were modelled to predict exposure for 'brand loyal' consumers (ie: those consumers who may always choose the same product every time).

In addition to the use of the proxy value for the purposes of modelling that all other foods, where permitted, contain steviol glycosides at 30% of the MPL, all foods in the 'brand loyal' categories were assumed to contain 100% of the MPL and they were assumed to always be selected by the consumer.

For 'brand loyal' consumers of water based flavoured drinks, the estimated dietary exposures for those consumers at the 90th percentile consumption level were 110% of the ADI for Australian children aged 2-6 years and 100% of the ADI for New Zealand children aged 5-14 years.

For 'brand loyal' consumers of flavoured milk products (including yoghurt) – the highest contributor to steviol glycosides exposure for Australian children aged 2-6 years – the estimated mean and 90th percentile dietary exposures were approximately 55% and 100% of the ADI, respectively.

5.3.4 Major food groups

Overall the dietary exposure assessment indicated that water based flavoured drinks (soft drinks, cordials, formulated beverages) were the major contributor for all the population groups assessed, except for Australian children aged 2-6 years, ranging from 36% (Australian children aged 7-16 years) to 41% (New Zealand children aged 5-14 years) of total steviol glycosides exposure. The greatest contributors to total steviol glycosides exposure for Australian children aged 2-6 years were flavoured milk products (21%) followed by water based flavoured drinks (19%). In addition to water based flavoured drinks, tabletop sweeteners were also major contributors for Australians aged 17 years and above (20%) and the New Zealand population aged 15 years and above (22%).

5.3.5 Conclusion

It should be noted that both the 30% market share scenario and subsequent 'brand loyal' consumer scenarios overestimate the number of foods containing steviol glycosides and the levels of steviol glycosides in the foods. The modelling assumes steviol glycoside levels in foods used as ingredients are carried over to mixed foods, that all foods permitted to have steviol glycosides added do in fact contain them and that no other intense sweeteners are used. In reality the estimated amount of identified foods that may be intensely sweetened (where permitted) is shared by a number of permitted intense sweeteners. These are broadly protective assumptions that are likely to lead to a considerable overestimation of dietary exposure. On this basis, the small exceedance of the ADI found for the high consuming individuals in the brand loyal scenario are not considered to be of concern. Estimates of exposure from the market share scenario, which is also a conservative estimate, are below the ADI.

Therefore it is concluded there are no public health and safety concerns associated with the proposed increases in the maximum permitted levels in ice cream and certain beverages.

5.4 Risk Assessment Conclusion

The Risk and Technical Assessment concluded that:

- The proposed increases in the maximum permitted levels of steviol glycosides in ice cream and selected beverages are technologically justified and supported by sensory analyses as providing a more acceptable taste profile to consumers.

- Limited new data on the toxicity of steviol glycosides indicate no need to change the existing ADI of 0-4 mg/kg bw/day, expressed as steviol equivalents.

- For all groups of Australian and New Zealand consumers assessed (including children), estimated dietary exposures were well below the ADI for the 30% market share scenario. This scenario assumes that 30% of all foods with a permission to add steviol glycosides actually contain it.

- For 'brand loyal' consumers of water based flavoured drinks, estimated 90th percentile dietary exposures were 110% of the ADI for Australian children aged 2-6 years and 100% of the ADI for New Zealand children aged 5-14 years. This scenario assumes that 30% of all foods with a permission to add steviol glycosides actually contain it and that in addition, within the water based beverages and flavoured milk products categories, consumers chose the same product every time and that this product contains steviol glycosides at the maximum permitted level.

- For 'brand loyal' consumers of flavoured milk products (including yoghurt), which are the highest contributor to steviol glycosides exposure for Australian children aged 2-6 years, the estimated mean and 90th percentile dietary exposures were approximately 55% and 100% of the ADI, respectively.

- Based on broadly protective assumptions that are likely to lead to a considerable overestimation of dietary exposure, there are no public health and safety issues associated with the proposed increases in the maximum permitted levels of steviol glycosides.

5.5 Evaluation of an alternate exposure approach

As discussed in section 5.3, the results of the DEA are likely to considerably overestimate actual exposure (see section 4.1.5 of SD1) because they:

- overestimate the number of foods containing steviol glycosides
- overestimate the levels of steviol glycosides in those foods
- assume that steviol glycoside levels in foods used as ingredients are carried over to mixed foods
- assume that no other intense sweeteners are used.

In addition to the assumptions in the 30% market share scenario, the 'brand loyal' scenarios further assume that those foods contain 100% of the MPL and are always chosen by the consumers.

Alternative dietary exposure assessments such as those using substitution of one intense sweetener for another, where accurate dietary intake data is available, may provide a more realistic estimate of exposure. Similarly, accurate data on market share and concentration levels of steviol glycosides in food may also provide more realistic exposure estimates.

5.5.1 Substitution method

The Applicant provided a study by Renwick (2008) which uses published data on dietary exposures to approved intense sweeteners, such as aspartame, from post-market surveillance studies conducted in the US, Canada, EU and Australia, to predict the maximum likely intake of rebaudioside A.

The intense sweetener intake data analysed was sourced mainly from studies using specifically designed food diaries combined with actual use levels or approved levels in the food. These intake estimates were then converted to sucrose equivalents by multiplying the daily intakes, expressed in mg specific sweetener/kg body weight into mg sucrose/kg body weight. Using sucrose equivalents as a common denominator then allows substitution with a novel sweetener by dividing the sucrose equivalents by the relative sweetness for that intense sweetener. Assuming a relative sweetness for rebaudioside A of 200 times that of sucrose and complete replacement of other intense sweeteners, the dietary exposure to rebaudioside A was then predicted. It should be noted that steviol glycoside preparations with a relative sweetness of 300 would be 66% of the level calculated using a relative sweetness of 200.

The predicted dietary exposure to rebaudioside A for the general population for average and high consumers was 1.3 mg/kg bw/day and 3.4 mg/kg bw/day respectively. Exposures for children for average and high consumers were 2.1 mg/kg bw/day and 5.0 mg/kg bw/day respectively. Converting these to steviol equivalents corresponds to mean and high exposures for the general population of 0.4 and 1.1 mg/kg bw/day (11% and 28% ADI respectively) and 1.7 mg/kg bw/day (41% ADI) for high consuming children.

Australian and New Zealand data were also included in Renwick's analysis. Four hundred consumers were selected for inclusion based on a pre-screening survey as having higher than average intakes of sweeteners. The 90th percentile exposure in this high consumer group was estimated to be 3.4 mg/kg bw/day (85% of the ADI) but would grossly overestimate the 90th percentile exposure in the general population.

Use of a substitution method to estimate dietary exposure has an advantage over other methods as it is based on actual intake of intensely sweetened foods thereby giving more realistic intake estimates.

5.5.4 Market exposure

The risk assessment identified limitations in available data to accurately predict dietary exposure to steviol glycosides. There are limited data currently available on market share for intensely sweetened products and the proportion of this claimed by each of the currently permitted intense sweeteners.

Data from a screener survey on consumption of intense sweeteners in Australia and New Zealand conducted by FSANZ in 2003 indicated that carbonated soft drinks were the highest consumed intensely sweetened food category, with 27% of screener survey respondents (n=3529) reporting consumption of an intensely sweetened soft drink in the last seven days. The 2009 Grocery Guide shows diet and no calorie products account for approximately 35% of the carbonated/still beverage market.

The DEA was based on the assumption that 30% of the food in every specified food category contains steviol glycosides and that it was the only intense sweetener used. This overestimates the market penetration for steviol glycosides as the market for intensely sweetened products is shared by a number of currently permitted intense sweeteners.

Therefore this supports the conclusion that the exposure estimates used to compare to the ADI are conservative.

FSANZ is seeking data and information relating to actual market share for steviol glycosides.

Risk Management

6. Issues raised

The risk assessment concludes that the proposed increased levels of steviol glycosides to be added to the specified foods do not pose a public health and safety risk and are technologically justified.

Current labelling provisions included in the Code to protect public health and safety and provide adequate information to enable consumers to make informed choices are considered appropriate.

6.1 Additional amendments

6.1.1 Specifications

In 2010, JECFA prepared an updated specification for steviol glycosides which supersedes the previous specification issued in 2008. The revised specification is published in FAO JECFA Monograph 10 (2010).

The Code references earlier JECFA monographs up to monograph 5 (2008) as a primary source of specifications for substances added to food in clause 2 of Standard 1.3.4 – Identity and Purity. As an outcome of this Application, Standard 1.3.4 will be amended to include reference to the revised specifications for steviol glycosides, namely inclusion of the Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 10 (2010) in clause 2.

Amendments to Standard 1.3.4 have also been identified in Proposal P1013 – Code Maintenance IX. Consideration of whether to retain the draft variations pertaining to Standard 1.3.4 will therefore be addressed at the approval stage for this Application.

6.1.2 Existing permissions

The Code is currently quite complicated in terms of how permissions for steviol glycosides (expressed as steviol equivalents) are given in Schedule 1 of Standard 1.3.1. The current drafting was the outcome of FSANZ's previous steviol glycoside assessment which permitted use of steviol glycosides in a broad range of specified foods at specified maximum levels. Therefore, in undertaking this application, we have taken the opportunity to rationalise and simplify existing permissions for steviol glycosides and address the issue of calculating steviol equivalents. An explanatory summary of the proposed amendments is included at Attachment 2 of this Report.

Food additive permissions in Schedule 1 are hierarchical in nature. Therefore if permission exists for a particular food additive to be added to a food in a higher level category, that permission also applies to all subordinate levels within that same category. Permission in a lower level, where there is also permission in the superior category, is only necessary if a requirement exists to have a higher maximum permitted level.

Within Schedule 1 there are some categories which contain the same maximum permitted levels for both the superior and subordinate levels. This is unnecessary. It is proposed to delete the subordinate category entries where permission is conveyed by an entry in the superior level. Categories identified include item 5.2 – sugar confectionary and 11.4 – tabletop sweeteners.

This Application seeks approval to increase the maximum permitted level of steviol glycosides (expressed as steviol equivalents) in 14.1.3 – Water based flavoured drinks and 14.1.3.1 – Brewed soft drink up to 200 mg/kg. There is no need for an entry in 14.1.3.1 when permission for the requested increased level is conferred through permission in 14.1.3. Therefore, it is proposed to delete the entry for steviol glycosides in 14.1.3.1– Brewed soft drink in Schedule 1.

Currently, category 3 – Ice cream and edible ices, contains three separate permissions for steviol glycosides (expressed as steviol equivalents).

Category	Description	Current Maximum level mg/kg	Requested Maximum level mg/kg
3	Icecream and Edible Ices	64	200
	Ice confection sold in liquid form	115	
	Reduced and low fat ice cream and edible ices'	208	

Approving the requested increase to the maximum permitted level of steviol glycosides for ice cream and edible ices (200 mg/kg) would then either exceed or be almost equivalent to the maximum permitted levels in the other two subcategories – 'Ice confection sold in liquid form' (115 mg/kg) and 'Reduced and low fat ice cream and edible ices' (208 mg/kg).

It is proposed to delete the entries for 'Ice confection sold in liquid form' and 'Reduced and low fat ice cream and edible ices', in category 3 of Schedule 1, therefore having a maximum permitted level for steviol glycosides of 200 mg/kg applicable to all ice cream and edible ices.

FSANZ is seeking comment regarding the impact, if any, associated with amending existing permissions for steviol glycosides contained within Schedule 1 of Standard 1.3.1.

FSANZ is also seeking data and information on steviol glycosides usage in the food categories where permissions currently exist, and data on actual levels used.

6.1.3 Determining steviol equivalents

Steviol glycosides are a mixture of different glycosides. The ratio of the various glycosides that make up the different steviol glycosides preparations used as a sweetener in food therefore differs.

The JECFA specification includes nine glycosides with stevioside and rebaudioside A as the principal glycosides. Other glycosides include rebaudioside B, rebaudioside C, rebaudioside D, rebaudioside F, dulcoside A, rubusoside and steviolbioside which are generally present in preparations of steviol glycosides at levels lower than stevioside or rebaudioside A.

As all steviol glycosides have one steviol molecule as their central component, JECFA considered the best way to quantify them was in terms of their steviol component (which is also the active sweetening component). Permissions for steviol glycosides are therefore expressed in the Code in terms of steviol equivalents. However, the Code currently does not provide any guidance for calculating steviol equivalents.

It is proposed to clarify and provide instructions on how steviol glycosides are calculated as steviol equivalents in Standard 1.3.1, as outlined below.

To calculate the steviol equivalent levels for a steviol glycoside, the following calculation is used -

$$[SE] = CF \times [SG]$$

Where –

CF = Conversion Factor as listed in the Table for the corresponding steviol glycosides
[SG] = concentration of individual steviol glycoside
[SE] = concentration as steviol glycosides

Steviol glycoside	Conversion factor
Steviol	1.00
Stevioside	0.40
Rebaudioside A	0.33
Rebaudioside B	0.40
Rebaudioside C	0.33
Rebaudioside D	0.28
Rebaudioside F	0.34
Dulcoside A	0.40
Rubusoside	0.50
Steviolbioside	0.50

It is also proposed to provide advice in subclause 5(2) of Standard 1.3.1 that steviol glycosides shall be calculated as steviol equivalents, thereby removing the requirement to include this for every steviol glycoside permission in Schedule 1.

FSANZ is seeking comment on the instructions and calculation given for determining steviol equivalents.

7. Options

As food additives require pre-market approval, it is not appropriate to consider non-regulatory options. Consequently, two regulatory options have been identified for this Application:

Option 1: Reject the Application

Option 2: Amend Standard 1.3.1 to allow an increase in the maximum permitted levels of steviol glycosides in the proposed foods.

Option 2 includes the minor changes to the drafting in relation to steviol glycosides as discussed in section 6.1. These changes are being made for clarity and to update references, are not considered to have any significant impacts and so are not considered further below.

8. Impact Analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendment to the Code have been analysed using regulatory impact principles.

In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this Application indicated a low or negligible impact. The Office of Best Practice Regulation has advised that the Application appears to be of a minor or machinery nature; notified approval of the preliminary assessment (RIS ID: 11635) and further advised that a Regulatory Impact Statement (RIS) is not required.

8.1 Affected Parties

The affected parties may include:

- those sectors of the food industry wishing to manufacture and market the food products subject to the Application
- consumers of food products which contain steviol glycosides
- government agencies with responsibility for compliance and enforcement of the Code.

8.2 Benefit Cost Analysis

8.2.1 Option 1

This is the *status quo* and requires no amendment to the Code.

- Food manufacturers may be disadvantaged through limited ability to innovate and access market opportunities for the development of products containing higher levels of steviol glycosides.
- Consumers may be disadvantaged through the inability to access products containing steviol glycosides with a more acceptable taste profile.
- There is no identified impact on government agencies.

8.2.2 Option 2

- Allows the food industry more choice when formulating products containing steviol glycosides.
- Consumers may benefit by access to foods which contain steviol glycosides that have a more acceptable taste profile.
- Food additive permissions are voluntary, therefore there should be no additional costs imposed on industry or consumers.

- There is not predicted to be any significant cost impost on jurisdictions to determine compliance with the proposed amendment compared with current monitoring and compliance activities as existing enforcement methods remain suitable.

8.3 Comparison of Options

Option 1 appears to provide no benefits to industry, consumers or government. It denies industry the ability to innovate and access identified market opportunities, while also denying consumers access to products with more acceptable/improved taste profiles.

Option 2 does not appear to impose any significant costs on industry, consumers or government. Potential benefits may exist for both industry and consumers in terms of more choice in available products; increased innovation and market opportunities for industry and improved taste profiles in products sweetened with steviol glycosides.

In considering the costs and benefits associated with both options, Option 2 would be the preferred option as it conveys benefits for the food industry and consumers without imposing significant costs for government agencies, consumers or manufacturers.

Communication and Consultation Strategy

9. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying interested parties and email alert subscribers to the availability of the assessment reports for public comment and placing the reports on the FSANZ website.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ assessment reports.

The Applicant, individuals and organisations making submissions on this Application will be notified at each stage of the Application. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify its decision to the Ministerial Council. If a request to review the decision is not made by the Ministerial Council, the variation will be gazetted. Stakeholders (including the Applicant) and submitters will be advised of the notification and gazettal and directly on the FSANZ website.

10. Consultation

FSANZ is seeking comment from the public and other interested stakeholders to assist in assessing this Application. Once the public comment period has closed there will be no further round of public comment.

Comments are sought in relation to scientific aspects of the Application including the technological function, dietary exposure assessment and any safety considerations, as well as information relating to any potential costs or benefits associated with increasing the permitted levels of steviol glycosides in the proposed foods.

FSANZ is seeking data and information relating to actual market share for steviol glycosides.

FSANZ is seeking comment regarding the impact, if any, associated with amending existing permissions for steviol glycosides contained within Schedule 1 of Standard 1.3.1.

FSANZ is also seeking data and information on steviol glycosides usage in the food categories where permissions currently exist, and data on actual levels used.

FSANZ is seeking comment on the instructions and calculation given for determining steviol equivalents.

10.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations 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.

Amending the Code to allow an increase in already permitted levels of steviol glycosides in certain foods is unlikely to have a significant effect on international trade as the proposed variations to the Code constitute minor technical changes.

Notification to WTO under FSANZ's obligations under either the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements is not considered necessary.

Conclusion

11. Conclusion and Preferred Option

This Application has been assessed against the requirements of section 29 of the FSANZ Act with FSANZ recommending the proposed draft variations to Standard 1.3.1.

This Report concludes that an increase in the maximum permitted levels of steviol glycosides in the proposed foods is technologically justified and does not pose a public health and safety risk.

An amendment to the Code giving permission for an increase in permitted maximum levels of steviol glycosides in the proposed foods in Australia and New Zealand is recommended on the basis of the available scientific information.

The proposed draft variations are provided in **Attachment 1**.

Preferred Approach

To prepare draft variations to Standards 1.3.1 – Food Additives and 1.3.4 – Identity and Purity to permit an increase to the maximum permitted level of steviol glycosides in the proposed foods.

11.1 Reasons for Preferred Approach

An amendment to the Code to increase the permitted levels of steviol glycosides (expressed as steviol equivalents) in the proposed foods in Australia and New Zealand is proposed on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that use of steviol glycosides as proposed does not raise any public health and safety concerns.

- Use of steviol glycosides as an intense sweetener in the proposed foods at the requested maximum permitted level is technologically justified and would be expected to provide some benefits to food manufacturers and consumers.

- Approving an increase to the maximum permitted level of steviol glycosides in the proposed foods would not impose significant, if any, costs for government agencies, consumers or manufacturers as it is an already permitted food additive.

- The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

12. Implementation and Review

Following the consultation period for this document an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board. The FSANZ Board's decision will then be notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Explanatory Statement of Draft Variations to *the Australia New Zealand Food Standards Code*

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Subsection 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

Commencement: on gazettal

[1] ***Standard 1.3.1*** *is varied by –*

[1.1] *inserting in subclause 5(2) after the entry for* sorbic acid –

steviol glycosides shall be calculated as steviol equivalents in accordance with the formula used in subclause 3.

[1.2] *inserting after subclause 5(2) –*

(3) To calculate the steviol equivalent levels for a steviol glycoside, the following calculation is used –

$$[SE] = CF \times [SG]$$

where –

CF = *Conversion Factor as listed in the Table for the corresponding steviol glycoside*
[SG] = *concentration of individual steviol glycoside*
[SE] = *concentration as steviol glycoside*

Table to clause 5(3)

Column 1	Column 2
Steviol glycoside	**Conversion factor**
Steviol	1.00
Stevioside	0.40
Rebaudioside A	0.33
Rebaudioside B	0.40
Rebaudioside C	0.33
Rebaudioside D	0.28
Rebaudioside F	0.34
Dulcoside A	0.40
Rubusoside	0.50
Steviolbioside	0.50

Examples:

Example of calculation of steviol equivalents for a single glycoside:

A preparation of 100 mg/kg of Rebaudioside B contains 100 x 0.40 = 40 mg/kg steviol equivalents.

Example of calculation of steviol equivalents for a mixture of glycosides:

For a preparation containing 100 mg/kg of a mixture of 90% Stevioside, 5% Rebaudioside B and 5% Rebaudioside A, the steviol equivalent is (0.9 x 1.00 + 0.05 x 0.40 + 0.05 x 0.33) x 100 mg/kg= 93.65 mg/kg

Example of calculation for maximum permitted level of a steviol glycoside preparation:

To calculate the maximum permitted level of a steviol glycoside preparation which contains 90% Stevioside, 5% Rebaudioside B and 5% Rebaudioside A, in a food where the permission is 160 mg/kg (steviol equivalents).

To determine the equivalence for this preparation:

(0.90 x (160/0.40)) + (0.05 x (160/0.40)) + (0.05 x (160/0.33))
= 404 mg/kg

[1.3] *omitting from* Schedule 1, *under sub-item* 1.1.2 Liquid milk products and flavoured liquid milk –

960	Steviol glycosides (calculated as steviol equivalents)	115	mg/kg

substituting –

960	Steviol glycosides	115	mg/kg

[1.4] *omitting from* Schedule 1, *under sub-item* 1.2.2 Fermented milk products and rennetted milk products –

960	Steviol glycosides (calculated as steviol equivalents)	176	mg/kg

substituting –

960	Steviol glycosides	176	mg/kg

[1.5] *omitting from* Schedule 1, *under item* 3 Ice cream and edible ices –

960	Steviol glycosides (calculated as steviol equivalents)	64	mg/kg

substituting –

960	Steviol glycosides	200	mg/kg

[1.6] *omitting from* Schedule 1, *under sub-item* 3 Ice confection sold in liquid form –

960	Steviol glycosides (calculated as steviol equivalents)	115	mg/kg

[1.7] *omitting from* Schedule 1, *under item* 3 Ice cream and edible ices, *the sub-item* –

Reduced and low fat ice cream and edible ices

960	Steviol glycosides (calculated as steviol equivalents)	208	mg/kg

[1.8] *omitting from* Schedule 1, *under sub-item* 4.3.2 Fruits and vegetables in vinegar, oil,

brine or alcohol –

960	Steviol glycosides (calculated as steviol equivalents)	160	mg/kg

substituting –

960	Steviol glycosides	160	mg/kg

[1.9] *omitting from* Schedule 1, *under sub-item* 4.3.4 low joule chutneys, low joule jams and low joule spreads –

960	Steviol glycosides (calculated as steviol equivalents)	450	mg/kg

substituting –

960	Steviol glycosides	450	mg/kg

[1.10] *omitting from* Schedule 1, *under sub-item* 4.3.6 Fruit and vegetable preparations including pulp –

960	Steviol glycosides (calculated as steviol equivalents)	208	mg/kg

substituting –

960	Steviol glycosides	208	mg/kg

[1.11] *omitting from* Schedule 1, *under sub-item* 5.1 Chocolate and coca products

960	Steviol glycosides (calculated as steviol equivalents)	550	mg/kg

substituting –

960	Steviol glycosides	550	mg/kg

[1.12] *omitting from* Schedule 1, *under sub-item* 5.2 Sugar confectionery –

960	Steviol glycosides (calculated as steviol equivalents)	1100	mg/kg

substituting –

960	Steviol glycosides	1100	mg/kg

[1.13] *omitting from* Schedule 1, *under item* 5.2 low joule chewing gum –

960	Steviol glycosides (calculated as steviol equivalents)	1100	mg/kg

[1.14] *omitting from* Schedule 1, *under sub-item* 6.3 Processed cereal and meal products –

960	Steviol glycosides (calculated as steviol equivalents)	250	mg/kg

substituting –

960	Steviol glycosides	250	mg/kg

[1.15] *omitting from* Schedule 1, *under sub-item* 7.1 fancy breads –

960	Steviol glycosides (calculated as steviol equivalents)	160	mg/kg

substituting –

960	Steviol glycosides	160	mg/kg

[1.16] *omitting from* Schedule 1, *under sub-item* 7.2 Biscuits, cakes and pastries –

960	Steviol glycosides (calculated as steviol equivalents)	160	mg/kg

substituting –

960	Steviol glycosides	160	mg/kg

[1.17] *omitting from* Schedule 1, *under sub-item* 11.4. Tabletop sweeteners –

960	Steviol glycosides (calculated as steviol equivalents)	GMP

substituting –

960	Steviol glycosides	GMP

[1.18] *omitting from* Schedule 1, *under sub-item* 11.4.1 Tabletop sweeteners – liquid preparation –

960	Steviol glycosides (calculated as steviol equivalents)	GMP

[1.19] *omitting from* Schedule 1, *under sub-item* 11.4.2 Tabletop sweeteners – tablets or power or granules packed in portion sized packages –

960	Steviol glycosides (calculated as steviol equivalents)	GMP

[1.20] *omitting from* Schedule 1, *under sub-item* 13.3 Formula meal replacements and formulated supplementary foods –

960	Steviol glycosides (calculated as steviol equivalents)	175	mg/kg

substituting –

960	Steviol glycosides	175	mg/kg

[1.21] *omitting from* Schedule 1, *under sub-item* 13.4 Formulated supplementary sports foods –

960	Steviol glycosides (calculated as steviol equivalents)	175	mg/kg	

substituting –

960	Steviol glycosides	175	mg/kg	

[1.22] *omitting from* Schedule 1, *under sub-item* 14.1.2.1 Fruit and vegetable juices –

960	Steviol glycosides (calculated as steviol equivalents)	50	mg/kg	

substituting –

960	Steviol glycosides	50	mg/kg	

[1.23] *omitting from* Schedule 1, *under sub-item* 14.1.2.2 low joule fruit and vegetable juice products –

960	Steviol glycosides (calculated as steviol equivalents)	125	mg/kg	

substituting –

960	Steviol glycosides	125	mg/kg	

[1.24] *omitting from* Schedule 1, *under sub-item* 14.1.2.2 soy bean beverage (plain or favoured) –

960	Steviol glycosides (calculated as steviol equivalents)	65	mg/kg	Plain soy bean beverage only
960	Steviol glycosides (calculated as steviol equivalents)	175	mg/kg	Flavoured soy bean beverage only

substituting –

960	Steviol glycosides	100	mg/kg	Plain soy bean beverage only
960	Steviol glycosides	200	mg/kg	Flavoured soy bean beverage only

[1.25] *omitting from* Schedule 1, *under sub-item* 14.1.3 Water based flavoured drinks –

960	Steviol glycosides (calculated as steviol equivalents)	160	mg/kg	

substituting –

960	Steviol glycosides	200	mg/kg	

[1.26] *omitting from* Schedule 1, *under sub-item* 14.1.3.1 Brewed soft drink –

960	Steviol glycosides (calculated as steviol equivalents)	160	mg/kg	

[1.27] *omitting from* Schedule 1, *under sub-item* 14.1.4 Formulated Beverages –

960	Steviol glycosides (calculated as steviol equivalents)	160	mg/kg

substituting –

960	Steviol glycosides	200	mg/kg

[1.28] *omitting from* Schedule 1, *under sub-item* 14.1.5 Coffee, coffee substitutes, tea, herbal infusions and similar products –

960	Steviol glycosides (calculated as steviol equivalents)	100	mg/kg

substituting –

960	Steviol glycosides	100	mg/kg

[1.29] *omitting from* Schedule 1, *under sub-item* 20.2 custard mix, custard power and blanc mange power –

960	Steviol glycosides (calculated as steviol equivalents)	80	mg/kg

substituting –

960	Steviol glycosides	80	mg/kg

[1.30] *omitting from* Schedule 1, *under sub-item* 20.2 jelly –

960	Steviol glycosides (calculated as steviol equivalents)	260	mg/kg

substituting –

960	Steviol glycosides	260	mg/kg

[1.31] *omitting from* Schedule 1, *under sub-item* 20.2 dairy and fat based desserts, dips and snacks –

960	Steviol glycosides (calculated as steviol equivalents)	150	mg/kg

substituting –

960	Steviol glycosides	150	mg/kg

[1.32] *omitting from* Schedule 1, *under sub-item* 20.2 sauces and toppings (including mayonnaises and salad dressings) –

960	Steviol glycosides (calculated as steviol equivalents)	320	mg/kg

substituting –

960	Steviol glycosides	320	mg/kg

[2] ***Standard 1.3.4*** *is varied by omitting subclause 2(a), substituting*

(a) Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 (2005) as superseded by specifications published in FAO JECFA Monographs 3 (2006) and FAO JECFA Monographs 4 (2007) and FAO JECFA Monographs 5 (2008) and FAO JECFA Monographs 10 (2010), Food and Agricultural Organisation of the United Nations. Rome; or

Attachment 2

Explanatory Statement of Draft Variations to the *Australia New Zealand Food Standards Code*

Apart from increasing the maximum permitted levels of steviol glycosides in the proposed foods in Schedule 1 of Standard 1.3.1, the draft variations allow simplification of existing permissions; clarify how steviol glycosides are calculated as steviol equivalents and update references in Standard 1.3.4.

Item [1.1]

This item inserts text into subclause 5(2) of Standard 1.3.1 to express that steviol glycosides shall be calculated as steviol equivalents, removing the requirement to include this for every steviol glycoside permission in Schedule 1.

Item [1.2]

This item inserts an equation for determining the steviol equivalents for various steviol glycosides. A table containing conversion factors for each steviol glycoside and worked examples demonstrating various forms of the calculation are also included.

Items [1.3] to [1.4], [1.8] to [1.12], [1.14] to [1.17], [1.20] to [1.23], [1.28] to [1.32]

These items remove the reference to ‘calculated as steviol equivalents’ from each entry as an outcome of item 1.1.

Items [1.5], [1.24] to [1.25], [1.27]

These items omit the reference to ‘calculated as steviol equivalents’ and increase the maximum permitted levels.

Items [1.6], [1.7]

These items simplify permissions for steviol glycosides in category 3 Ice cream and edible ices. The entry for steviol glycosides under sub-item 3 Ice confection sold in liquid form and the sub-item 3 Reduced and low fat ice cream and edible ices have been deleted as the revised maximum permitted level for steviol glycosides in item 3 Icecream and edible ices now either exceeds or is almost equivalent to the levels in the sub-categories.

Items [1.13], [1.18] to [1.19], [1.26]

These items omit the entry for the sub-item as permission for addition of steviol glycoside to these foods is conferred by the superior category.

Item [2]

This item updates the reference to the most recent JECFA Monograph.