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[9-11]

APPLICATION A1037 STEVIOL GLYCOSIDES – INCREASE IN PERMITTED USE LEVELS APPROVAL 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 in plain soy beverages up to 100 mg/kg. The Applicant claims the increased levels are required to provide a more acceptable taste profile for consumers and has provided sensory analyses to support this claim.

This Application was assessed under the General Procedure with one round of public consultation.

The specific objectives in considering this Application were to:

- protect public health and safety in relation to the proposed increase to permissions for steviol glycosides in a range of foods
- ensure adequate information relating to steviol glycosides is provided to consumers to enable informed choice

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, and complies with relevant Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications.

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. A pre-market assessment of the safety and suitability of steviol glycosides at the increased levels is required prior to approval of an increase in levels 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 eighteen 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 recent notifications are for general use at levels determined by good manufacturing practices. Europe currently does not have harmonised permissions for steviol glycosides, although rebaudioside A is approved for use in France and stevioside has been evaluated by the European Union's Scientific Committee for Food (SCF) most recently in 1999. The European Food Safety Authority (EFSA) issued a positive opinion of the safety of steviol glycosides in April 2010 and published revised exposure estimates in January 2011.

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.

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 to predict exposure for consumers who may always choose the same product every time. These assumed brand loyalty for water-based flavoured beverages and flavoured milk products (including yoghurt). 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.

The general labelling requirements of the Code, including the mandatory declaration of food additives, will provide adequate information to consumers regarding foods containing steviol glycosides. Steviol glycosides must be declared in the ingredient list by the class name 'sweetener' followed by its specific name 'steviol glycosides' or additive number. Based on the risk assessment findings, no additional mandatory labelling is proposed.

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 were 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, entries for steviol glycosides under items 3 (ice confection sold in liquid form), 5.2 (low joule chewing gum), 11.4 (tabletop sweeteners) and 14.1.3 (brewed soft drink) in Schedule 1 will be removed as permission for these categories is conferred by entries in the superior category. 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.

In response to submissions received to the Assessment Report, some minor rounding of two existing steviol glycoside permissions, items 1.2.2 (fermented milk products and renneted milk products) and 4.3.6 (fruit and vegetable preparations including pulp) in Schedule 1, has also been undertaken.

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.

Decision

To approve variations to Standard 1.3.1 – Food Additives to permit an increase to the maximum permitted level of steviol glycosides in the proposed foods.

Reasons for Decision

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 may provide 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 were invited on the Assessment Report between 15 December 2010 and 9 February 2011. Comments were specifically requested on the scientific aspects of the Application, including the technological function, dietary exposure and any information relevant to the safety assessment of steviol glycosides at the proposed use levels. Comments were also sought on any impact resulting from consequential drafting amendments to steviol glycoside permissions.

A total of eleven submissions were received as a result of the public consultation; a summary of which is included at **Attachment 3**.

As this Application was assessed as a general procedure, there was one round of public comment following release of the Assessment Report. Submissions received were considered in developing this Approval Report with main issues raised specifically addressed.

Amendments to Draft Variations after Consultation

In response to submissions received on the Assessment Report, minor rounding of the MPLs for two existing steviol glycoside permissions has been undertaken. It is acknowledged that the MPL for items 1.2.2 – Fermented milk products and renneted milk products and 4.3.6 – Fruit and vegetable preparations inc pulp (176 and 208 mg/kg, respectively) may be overly precise and rounding these values to 175 and 210 mg/kg, respectively, is unlikely to impact on the overall dietary exposure to steviol glycosides. Amendments were also made to correct minor errors identified in the steviol equivalents calculation and example provided in draft variations advised at Assessment. The draft variation to update primary reference sources in Standard 1.3.4 – Identity and Purity has been deleted, as amendments to this standard will be undertaken as a result of Proposal P1013 Code Maintenance IX. The amended variations contained in this Report reflect these changes and a simplified format.

CONTENTS

INTRODUCTION	2
1. THE ISSUE / PROBLEM	2
2. BACKGROUND.....	2
2.1 <i>Current Standard</i>	2
2.2 <i>Previous assessment</i>	3
2.3 <i>International regulations</i>	3
2.4 <i>Technological function</i>	5
3. OBJECTIVES	5
4. QUESTIONS TO BE ANSWERED	6
RISK ASSESSMENT.....	6
5. RISK ASSESSMENT SUMMARY	7
5.1 <i>Technological Justification</i>	7
5.2 <i>Safety Assessment</i>	7
5.3 <i>Dietary Exposure Assessment</i>	8
5.4 <i>Risk Assessment Conclusion</i>	10
5.5 <i>Evaluation of an alternate exposure approach</i>	10
RISK MANAGEMENT	12
6. ISSUES	12
6.1 <i>Addressing the objectives</i>	12
6.2 <i>Additional amendments</i>	13
7. OPTIONS	15
8. IMPACT ANALYSIS	15
8.1 <i>Affected Parties</i>	15
8.2 <i>Benefit Cost Analysis</i>	16
8.3 <i>Comparison of Options</i>	16
COMMUNICATION AND CONSULTATION STRATEGY	16
9. COMMUNICATION	16
10. CONSULTATION.....	17
10.1 <i>Public Consultation</i>	17
10.2 <i>Issues raised in submissions</i>	17
10.3 <i>World Trade Organization (WTO)</i>	21
CONCLUSION.....	21
11. CONCLUSION AND DECISION	21
11.1 <i>Reasons for Decision</i>	22
12. IMPLEMENTATION AND REVIEW.....	22
ATTACHMENT 1A - DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (AT APPROVAL)	23
ATTACHMENT 1B - DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (AT ASSESSMENT)	26
ATTACHMENT 2 - EXPLANATORY STATEMENT OF DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	32
ATTACHMENT 3 - SUMMARY OF PUBLIC SUBMISSIONS ON THE ASSESSMENT REPORT	33

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 for plain soy beverages to 100 mg/kg.

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 notified 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	Ice cream 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 2008 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 countries¹ 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. Recommendations for steviol glycosides provisions in the General Standards of Food Additives (GSFA) were considered at the 43rd Session of the Codex Committee on Food Additives (CCFA) in March 2011.

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 and the European Union (EU) Scientific Committee for Food (SCF) evaluated the use of stevioside as a sweetener in 1984, 1988, 1989 and 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's) 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. It was noted, however, that based on conservative estimates of steviol glycosides exposure in both adults and children, the ADI would likely be exceeded at the maximum proposed use levels.

Consequently, the EC requested that EFSA conduct a revised exposure assessment for steviol glycosides based on revised uses and levels of steviol glycosides submitted by the petitioners. Revisions included reductions in levels for 16 food uses; 15 food uses were removed altogether; 12 food uses remained unchanged, while three new food uses were included. The methodology adopted was the same as in the previous opinion of the ANS Panel (2010). For children, consumption data was obtained from the EXPOCHI² consortium (data from Belgium, France, The Netherlands, Spain, Czech Republic, Italy, Finland, Germany, Greece, Cyprus, Sweden) and the United Kingdom (UK) National Dietary and Nutrition Survey (NDNS), while exposure for adults was based only on the UK population (NDNS survey). Due to uncertainties in estimating consumption of non-alcoholic flavoured drink, estimates for high consumer children in the revised assessment were corrected based on the EFSA Comprehensive database.

EFSA released its revised exposure assessment in January 2011. The revised exposure estimates differ only slightly from the exposure estimates given in the previous opinion and although the corrected exposure for the upper range of high level exposure (95th/97.5th percentile) in children decreased slightly, high consumer children are still above the ADI for some European countries³. As with the previous exposure estimates, the revised exposure estimates should also be considered as conservative. A number of factors contributed to the uncertainties in the final exposure estimates, including differences in consumption data survey design and reporting, limitations in the EXPOCHI food categorisation system and the assumption that all processed foods and beverages contained steviol glycosides at the maximum proposed use levels.

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 eighteen⁴ 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. 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 notified GRAS determinations for the use of steviol glycosides in foods.

² Individual food consumption data and exposure assessment studies for children

³ The dietary exposure assessment conducted for this Application is noted in section 5.3

⁴ GRAS Notices 252, 253, 275, 278, 282, 287, 303, 304, 318, 323, 329, 337, 348, 349, 354, 365, 367 and 369

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 artificially-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 Monograph 10 (2010) superseding previous monographs. These specifications outline the purity of steviol glycosides as being not less than 95% of the total amount of the nine named steviol glycosides, with the major glycosides present being stevioside and rebaudioside A. The previous monograph (Monograph 5) named seven glycosides (not including rebaudioside D and F).

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 JECFA Monograph 10 specification.

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

The primary objective of most relevance to the assessment of this Application is the protection of public health and safety. In order to specifically address this, FSANZ has performed a risk assessment to determine if there are any public health and safety concerns associated with the proposed use.

The risk assessment has been based on the best available scientific evidence and considers the following 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. Submitted taste trial results support the claim that higher steviol glycoside maximum limits are required to produce consumer-acceptable sweetened products for ice cream and various flavoured drinks (specifically soft drinks, which have 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.

To assume that all foods with a permission to add steviol glycosides contains it at the maximum permitted level (MPL) leads to a gross overestimation of dietary exposure. This is due to: the broad range of foods included, plus their use as ingredients in mixed foods; actual use levels may be below maximum permitted levels; steviol glycosides may not be used in all the permitted food categories and it assumes that no other intense sweeteners are used. Indeed, the assessment conducted by EFSA (see section 2.3), which used this approach, resulted in conservative estimates of exposure.

A more realistic scenario was indicated by JECFA who undertook dietary exposure assessments for steviol glycosides 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

Consistent 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 DIAMOND's 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 still 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 (i.e. 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 for Australian and New Zealand consumers 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.
- 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.
- The brand loyal scenarios assume 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.

Based on broadly protective assumptions that are likely to lead to a considerable overestimation of dietary exposure, FSANZ concludes 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 are 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 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.

5.5.2 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.

Risk Management

6. Issues

6.1 Addressing the objectives

The legislative objectives that FSANZ is required to meet when developing or varying a food standard are noted in section 3. FSANZ considers the primary objective of most relevance to this Application is the protection of public health and safety. The other two have less direct relevance although are also taken into consideration.

6.1.1 Risk to public health and safety

FSANZ concludes that approval of the proposed increased levels of steviol glycosides in the specified foods does not pose a risk to public health and safety for Australian and New Zealand consumers.

6.1.2 Providing adequate information to enable informed choice - Labelling

Labelling provisions are included within the Code to protect public health and safety and to provide adequate information to enable consumers to make informed choices.

Food additives must be labelled in accordance with clause 8 of Standard 1.2.4. Under this clause, a food additive must be declared in the statement of ingredients by class of additive followed by the additive's specific name or code number in brackets. The current labelling provisions included in the Code are considered appropriate and no other mandatory labelling is considered necessary.

6.1.3 Prevention of misleading and deceptive conduct

FSANZ has considered this objective and concludes there are no misleading or deceptive conduct aspects to this assessment.

6.1.4 Consistency with Policy Guidelines

As noted in section 3, FSANZ is required to have regard to the Policy Guideline on the Addition of Substances other than Vitamins and Minerals to foods. Since the purpose for addition of steviol glycosides to food falls under 'Technological Function', regard has been given particularly to the specific order policy principles for 'Technological Function'.

It has been determined that: the Applicant provided a clear stated purpose, steviol glycosides are safe for human consumption, there is a clear technological function and steviol glycosides are added in a quantity and form which is consistent with delivering the stated purpose.

6.2 Additional amendments

6.2.1 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 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. Standard 1.3.4 will be amended to include reference to the Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 10 (2010) in clause 2 as a result of the concurrent Proposal, P1013 Code Maintenance IX, which is expected to be considered by the Ministerial Council in mid-2011.

Therefore, the amendments to Standard 1.3.4 advised at Assessment stage of this Application have been removed.

6.2.2 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 glycosides assessment which permitted use of steviol glycosides in a broad range of specified foods at specified maximum levels. Therefore, in undertaking this application, FSANZ has 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** to this Report.

Food additive permissions in Schedule 1 are hierarchical in nature. Therefore, if a 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.

In regard to steviol glycosides, 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	Ice cream 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.

6.2.3 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 most recent JECFA specification states a total purity of 95% of nine named 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 and apply to all preparations of steviol glycosides which comply with relevant specifications.

As 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 equivalents level 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 equivalents

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.

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: Approve the draft variations to 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 are not considered to have any significant impacts, therefore they 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 imposed 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 potential benefits for the food industry and consumers without imposing significant costs for government agencies, consumers or manufacturers.

Communication and Consultation Strategy

9. Communication

FSANZ developed and applied a basic communication strategy to this Application. The strategy involved 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 standards 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 are notified at each stage of the Application. The decision of the FSANZ Board to approve the variations to the Code has been notified 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 directly and via the FSANZ website.

10. Consultation

10.1 Public Consultation

The Assessment Report was notified for public comment between 15 December 2010 and 9 February 2011. As this Application was assessed under a General Procedure, only one round of public comment was applicable.

Comments were 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.

In total, eleven submissions were received on the Assessment Report. A summary of the submissions is provided in **Attachment 3**.

Submissions were received from a range of stakeholders including: industry associations (5), professional associations (1), government agencies (3) and industry (2). All submissions supported the proposed increased levels of steviol glycosides, the simplification and clarification of existing steviol glycoside permissions and provision of guidance for determining steviol equivalents.

Submitters' comments have been taken into account in preparing the Approval Report, with specific issues discussed below.

10.2 Issues raised in submissions

10.2.1 Rounding of existing steviol glycoside permissions

Queensland Health suggested permissions for steviol glycosides need only be expressed to a realistic value; for example, to two significant figures, claiming values expressed to three significant figures are meaningless from a toxicological viewpoint and unrealistic for product formulation. NZFSA also proposed minor rounding of some existing steviol glycosides permissions, for example, 176 mg/kg to 175 mg/kg.

10.2.1.1 Response

There are six categories in Schedule 1 of Standard 1.3.1 where the MPL for steviol glycosides is expressed to three significant figures.

Category	Description	Maximum level mg/kg
1.1.2	Liquid milk products and flavoured liquid milk	115
1.2.2	Fermented milk products and rennetted milk products	176
4.3.6	Fruit and vegetable preparations inc pulp	208
13.3	Formula meal replacements & supplementary foods	175
13.4	Formulated supplementary sports foods	175
14.1.2.2	Fruit and vegetable juices products	125

Certain aspects of toxicology can be quite precise; generally this is not the case for ADIs, which is reflected by their expression as one significant figure (e.g. 4 mg/kg bw/day not 3.9 or 4.1) and sometimes two significant figures when above 10 (e.g. 25 mg/kg bw/day). FSANZ therefore acknowledges little difference exists in MPL values expressed to two or three significant figures from a toxicological viewpoint.

There is the potential, however, to significantly impact on the dietary exposure for steviol glycosides if MPLs were amended, particularly in those food groups with high consumption levels. For example, flavoured milk products were identified in the DEA as one of the major contributors to steviol glycosides exposure for children aged 2–6 years, and amending the MPL upwards could significantly increase the overall dietary exposure to steviol glycosides for this population group. Any impact, especially on industry, from rounding down the MPL would need to be determined through consultation; however no further consultation opportunities are available under the current assessment procedure (general).

Queensland Health also suggests expressing MPLs to three significant figures is unrealistic from a product formulation perspective. However, no information has been received from industry to suggest that existing MPLs are unrealistic; nor have any requests been received suggesting a change is necessary.

Schedule 1 of Standard 1.3.1 contains a number of permissions, other than those for steviol glycosides, where the MPL is expressed to three significant figures. Therefore, FSANZ does not consider rounding MPLs for steviol glycoside permissions to two significant figures as warranted.

FSANZ does however accept the MPLs for items 1.2.2 – Fermented milk products and rennetted milk products and 4.3.6 – Fruit and vegetable preparations including pulp (176 and 208 mg/kg, respectively) may be overly precise. Minor rounding of these values to 175 and 210 mg/kg, respectively, is likely to have minimal impact on the overall dietary exposure of steviol glycosides. The draft variations at **Attachment 1A** reflect these amendments.

10.2.2 Permission in Ready-To-Drink (RTD) alcoholic beverages

Sugar Australia suggests including a direct permission for steviol glycosides in item 14.3 – Alcoholic beverages, not included in item 14.2, instead of relying on the indirect permission to add steviol glycosides to RTD alcoholic beverages conferred by clause 7 of Standard 1.3.1.

10.2.2.1 Response

RTD alcoholic beverages are mixtures of spirits and water based beverages and/or fruit juices. Sugar Australia is correct in stating that permission for addition of steviol glycosides to these beverages is conferred by the carryover principle.

The carryover principle defined under clause 7 of Standard 1.3.1⁵ permits a mixed food, in this case a RTD alcoholic beverage, to contain the food additives (i.e. steviol glycosides) permitted in the individual food (i.e. soft drink or fruit juice), at levels in proportion with the amount of that individual food present in the final mixed food.

FSANZ does not accept the arguments presented in the submission that including a direct permission would remove ambiguity and interpretation of steviol glycosides permissions, reduce unnecessary complication in product formulation or align permissions for steviol glycosides with other intense sweeteners such as aspartame and sucralose in RTD alcoholic beverages.

Aspartame and sucralose are permitted in RTD alcoholic beverages up to GMP levels because they are listed as Schedule 2 food additives. Steviol glycosides however, are not included in Schedule 2 and may only be added to foods at defined levels where expressly permitted in Schedule 1. As such, a permission could only be given via inclusion of a sub-category for RTD alcoholic beverages under item 14.3. This may well result in more confusion and interpretation issues as no definition of what constitutes a RTD alcoholic beverage currently exists. Further, it is considered impractical to give specific food additive permissions for mixed foods when permissions are already conferred by the carryover principle.

FSANZ therefore considers it unnecessary to include a permission for steviol glycosides in RTD alcoholic beverages under item 14.3.

10.2.3 Typographic error in steviol equivalents calculation

The Food Technology Association of Australia (FTAA) noted an error in the example calculation for determining steviol equivalents provided in the draft variations.

10.2.3.1 Response

FSANZ thanks the FTAA and has made the necessary amendments; these are reflected in the draft variations provided at **Attachment 1A**.

10.2.4 Purity specifications

Two submitters (FTAA and Sugar Australia) questioned the relevance of including reference to specifications for the Applicant's steviol glycosides preparation in the Report. It was suggested the revised steviol glycosides permissions could be interpreted as only applying to those steviol glycosides preparations with greater than 90% rebaudioside A levels.

⁵ The carry over principle is defined in clause 7 of Standard 1.3.1 –Food Additive as-“Other than by direct addition, a food additive may be present in any food as a result of carryover from a raw material or an ingredient, provided that the level of the food additive in the final food is no greater than would be introduced by the use of the raw material or ingredient under proper technological conditions and good manufacturing practice”.

10.2.4.1 Response

FSANZ notes the concerns raised and would like to provide clarification.

Applications to amend food additive permissions in the Code require a pre-market safety assessment to assess the safety, suitability and technological function of the additive in the proposed foods. Data and information requirements to support the application are contained in Parts 3.1 – General information and 3.3.1 – Food Additives of FSANZ’s Application Handbook. These requirements state that the data and information supplied should be based on a representative sample of the commercial product on which approval is sought. Further, the additive should be described as completely as possible, including sufficient compositional data to enable accurate identification. In this case, a detailed description of the composition and purity of the steviol glycosides within the Applicant’s preparation was provided.

Substances added to foods must also comply with relevant identity and purity standards. Having a detailed description of the additive allows a comparison between the particular additive and relevant standards to determine compliance. Clause 2 of Standard 1.3.4 currently references JECFA monographs up to Monograph 5 (2008) as a primary source of specifications for substances added to food. As discussed in sections 2.4 and 6.1.1, the steviol glycosides preparation which is the subject of this Application, would not comply with Monograph 5, but would with Monograph 10 (yet to be included in the Code).

Further, although assessment is made on a particular steviol glycosides preparation, permissions in the Code apply to all steviol glycosides preparations that comply with identity and purity specifications as noted in Standard 1.3.4.

Amendments have been made to sections 2.4, 6.1.1 and 6.1.3 to make this clearer.

10.2.5 EFSA report on exposure estimates

The Department of Health, Victoria (Vic Health) suggested FSANZ consider the EFSA Journal (2011; 9(1):1972), published in January 2011, “Revised exposure assessment for steviol glycosides for the proposed uses as a food additive”.

10.2.5.1 Response

FSANZ has noted the report cited by Vic Health (see section 2.3).

The revised exposure assessment conducted by EFSA was based on revisions to the uses and levels of steviol glycosides as provided by the petitioners. The same methodology was employed as used in the previous ANS Panel opinion, with exposure for children (aged 1–14 years) based on consumption data from 11 European countries and the UK, while for adults, only UK data was used. In the revised assessment, a correction factor was also applied to the intake of non-alcoholic flavoured drinks for high consumer children.

For children, EFSA estimated mean dietary exposure from 0.4–6.4 mg/kg bw/day, with corrected exposure estimates at the 95th percentile from 1.0–12.7 mg/kg bw/day. UK adults were estimated to have a mean dietary exposure of 1.9–2.3 mg/kg bw/day and 5.6–6.8 mg/kg bw/day for high consumers (97.5th percentile). Revised exposure estimates differ only slightly from the exposure estimates given in the previous opinion and although the upper range estimated for high consumer children decreased from 17.2 in the previous opinion to 12.7 mg/kg bw/day, exposures are still above the ADI for several countries.

As with the previous exposure estimates, EFSA also advised the revised exposure estimates should be considered as conservative. A number of factors contributed to the uncertainties in the final exposure estimates, including differences in consumption data survey design and reporting, limitations in the EXPOCHI food categorisation system and the assumption that all processed foods and beverages contained steviol glycosides at the maximum proposed use levels (including all beverages and not only energy-reduced beverages as proposed by the applicants).

Caution should be exercised when comparing dietary exposure assessments. As discussed in section 5.3, assuming all foods with a permission for steviol glycosides actually contain it at the maximum permitted level, greatly overestimates dietary exposure.

Whilst of interest, the EFSA outcome is based on different permissions, intake data and populations. It does not change FSANZ's conclusion (section 5.3) that based on the broadly protective assumptions used in the DEA, no public health and safety issues are associated with the proposed increases in the maximum permitted levels of steviol glycosides.

10.3 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 was not considered necessary.

Conclusion

11. Conclusion and Decision

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.

The 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.

Approving the substance as a food additive requires the presence of the substance to be listed in ingredient lists on food packages. This labelling requirement enables consumers to have adequate information to make informed purchase choices.

FSANZ has concluded there are no misleading or deceptive conduct aspects to this assessment.

The relevant Ministerial Council Policy Guideline has been addressed in this assessment. The technological function of using the substance has been articulated and assessed as being met. Its use as proposed has been assessed as being safe and suitable.

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 1A**.

Decision

To approve variations to Standard 1.3.1 – Food Additives to permit an increase to the maximum permitted level of steviol glycosides in the proposed foods.

11.1 Reasons for Decision

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

The FSANZ Board's decision has been notified to the Ministerial Council. Following notification, the proposed draft variations to the Code are expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

ATTACHMENTS

- 1A. Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)
- 1B. Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)
2. Explanatory Statement of Draft Variations to the *Australia New Zealand Food Standards Code*
3. Summary of issues raised in public submissions

Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)

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

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 equivalents

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 $100 \times 0.40 = 40$ 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 $(0.9 \times 0.4 + 0.05 \times 0.40 + 0.05 \times 0.33) \times 100$ mg/kg = 39.65 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:

$$0.90 \times (160/0.40) + (0.05 \times (160/0.40)) + (0.05 \times (160/0.33))$$

$$= 404 \text{ mg/kg}$$

[1.3] *omitting from Schedule 1, under item 3 Ice cream and edible ices, the sub-item Reduced and low fat ice cream and edible ices*

[1.4] *omitting from Schedule 1, the entry for Steviol glycosides (calculated as steviol equivalents) in each of the sub-items listed in the Table to this item*

Table to Item [1.4]

3	Ice confection sold in liquid form
5.2	low joule chewing gum
11.4.1	Tabletop sweeteners – liquid preparation
11.4.2	Tabletop sweeteners – tablets or powder or granules packed in portion sized packages
14.1.3.1	Brewed soft drink

[1.5] *omitting from Schedule 1, the words Steviol glycosides (calculated as steviol equivalents) wherever appearing in the sub-items listed in the Table to this item, substituting Steviol glycosides*

Table to Item [1.5]

1.1.2	Liquid milk products and flavoured liquid milk
4.3.2	Fruits and vegetables in vinegar, oil, brine or alcohol
4.3.4	low joule chutneys, low joule jams and low joule spreads
5.1	Chocolate and cocoa products
5.2	Sugar confectionary
6.3	Processed cereal and meal products
7.1	fancy breads
7.2	Biscuits, cakes and pastries
11.4	Tabletop sweeteners
13.3	Formula meal replacements and formulated supplementary foods
13.4	Formulated supplementary sports foods
14.1.2.1	Fruit and vegetable juices
14.1.2.2	low joule fruit and vegetable juice
14.1.5	Coffee, coffee substitutes, tea, herbal infusions and similar products
20.2	custard mix, custard powder and blanc mange powder
20.2	jelly
20.2	dairy and fat based desserts, dips and snacks
20.2	sauces and toppings (including mayonnaises and salad dressings)

[1.6] *omitting from Schedule 1, under each of the sub-items listed in Column 1 of the Table to this item, the Additive Name and Max Permitted Level for additive Steviol glycosides (calculated as steviol equivalents), substituting the Additive Name in Column 2 of the Table to this item and the Max Permitted Level in Column 3 of the Table to this item*

Table to Item [1.6]

Column 1		Column 2	Column 3
Sub-Item		Additive Name	Max Permitted Level
1.2.2	Fermented milk products and renneted milk products	Steviol glycosides	175 mg/kg
3	Ice cream and edible ices	Steviol glycosides	200 mg/kg
4.3.6	Fruit and vegetable preparations including pulp	Steviol glycosides	210 mg/kg

14.1.3	Water based flavoured drinks	Steviol glycosides	200	mg/kg
14.1.4	Formulated Beverages	Steviol glycosides	200	mg/kg

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

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

Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)

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

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 $100 \times 0.40 = 40$ 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 $(0.9 \times 1.00 + 0.05 \times 0.40 + 0.05 \times 0.33) \times 100$ 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:

$$(0.90 \times (160/0.40)) + (0.05 \times (160/0.40)) + (0.05 \times (160/0.33)) = 404 \text{ mg/kg}$$

[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
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substituting –

960	Steviol glycosides	115	mg/kg
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[1.4] *omitting from* Schedule 1, *under sub-item* 1.2.2 Fermented milk products and renneted milk products –

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

960	Steviol glycosides	176	mg/kg
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[1.5] *omitting from* Schedule 1, *under item* 3 Ice cream and edible ices –

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

960	Steviol glycosides	200	mg/kg
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[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
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[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
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[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
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substituting –

960	Steviol glycosides	160	mg/kg
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[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
	<i>substituting –</i>			
	960	Steviol glycosides	450	mg/kg
[1.10]	<i>omitting from</i> Schedule 1, <i>under sub-item</i> 4.3.6 Fruit and vegetable preparations including pulp –			
	960	Steviol glycosides (calculated as steviol equivalents)	208	mg/kg
	<i>substituting –</i>			
	960	Steviol glycosides	208	mg/kg
[1.11]	<i>omitting from</i> Schedule 1, <i>under sub-item</i> 5.1 Chocolate and coca products			
	960	Steviol glycosides (calculated as steviol equivalents)	550	mg/kg
	<i>substituting –</i>			
	960	Steviol glycosides	550	mg/kg
[1.12]	<i>omitting from</i> Schedule 1, <i>under sub-item</i> 5.2 Sugar confectionery –			
	960	Steviol glycosides (calculated as steviol equivalents)	1100	mg/kg
	<i>substituting –</i>			
	960	Steviol glycosides	1100	mg/kg
[1.13]	<i>omitting from</i> Schedule 1, <i>under item</i> 5.2 low joule chewing gum –			
	960	Steviol glycosides (calculated as steviol equivalents)	1100	mg/kg
[1.14]	<i>omitting from</i> Schedule 1, <i>under sub-item</i> 6.3 Processed cereal and meal products –			
	960	Steviol glycosides (calculated as steviol equivalents)	250	mg/kg
	<i>substituting –</i>			
	960	Steviol glycosides	250	mg/kg
[1.15]	<i>omitting from</i> Schedule 1, <i>under sub-item</i> 7.1 fancy breads –			
	960	Steviol glycosides (calculated as steviol equivalents)	160	mg/kg
	<i>substituting –</i>			
	960	Steviol glycosides	160	mg/kg
[1.16]	<i>omitting from</i> Schedule 1, <i>under sub-item</i> 7.2 Biscuits, cakes and pastries –			
	960	Steviol glycosides (calculated as steviol equivalents)	160	mg/kg

substituting –

960	Steviol glycosides	160	mg/kg
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[1.17] *omitting from* Schedule 1, *under sub-item* 11.4. Tabletop sweeteners –

960	Steviol glycosides (calculated as steviol equivalents)	GMP	
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substituting –

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

960	Steviol glycosides (calculated as steviol equivalents)	GMP	
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[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	
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[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
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substituting –

960	Steviol glycosides	175	mg/kg
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[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
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substituting –

960	Steviol glycosides	175	mg/kg
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[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
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substituting –

960	Steviol glycosides	50	mg/kg
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[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
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substituting –

960	Steviol glycosides	125	mg/kg
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[1.24] *omitting from* Schedule 1, *under sub-item* 14.1.2.2 soy bean beverage (plain or flavoured) –

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
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substituting –

960	Steviol glycosides	200	mg/kg
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[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
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[1.27] *omitting from* Schedule 1, *under sub-item* 14.1.4 Formulated Beverages –

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

960	Steviol glycosides	200	mg/kg
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[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
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substituting –

960	Steviol glycosides	100	mg/kg
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[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
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substituting –

960	Steviol glycosides	80	mg/kg
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[1.30] *omitting from* Schedule 1, *under sub-item* 20.2 jelly –

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

960	Steviol glycosides	260	mg/kg
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[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
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substituting –

960	Steviol glycosides	150	mg/kg
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[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
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substituting –

960	Steviol glycosides	320	mg/kg
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[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

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.

Item [1.3]

This item removes the sub-item under item 3, Reduced and low fat ice cream and edible ices, as the revised maximum permitted level for steviol glycosides in item 3 Ice cream and edible ices is now almost equivalent to the level in this sub-category.

Item [1.4]

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

Item [1.5]

This item removes the reference to 'calculated as steviol equivalents' from each entry as an outcome of item 1.1.

Items [1.6] and [1.7]

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

Attachment 3

Summary of Public Submissions on the Assessment Report

In total, eleven submissions were received during the public consultation period for the Assessment Report.

Submissions were received from five industry associations, one professional association, three jurisdictions (Queensland, Victoria and New Zealand) and two industry members. All submissions supported the Application; supporting the proposed increased levels of steviol glycosides, the redrafting for simplification and clarity of existing steviol glycoside permissions and including guidance for determination of steviol equivalents.

A summary of the submissions is provided in the Table below.

Submitter	Group	Comments
Coca Cola South Pacific	Industry	<ul style="list-style-type: none"> Support the Application Supports both the increased levels and instructions and calculation for calculating steviol equivalents States these amendments will assist manufacturers to comply with MPL
Queensland Health (QLD Health)	Government	<ul style="list-style-type: none"> Supports Option 2 – permit increased levels Suggests further simplification of steviol glycoside permissions in that MPL be rounded to two significant figures i.e. 115 mg/kg be rounded to 120 mg/kg <ul style="list-style-type: none"> States that the third significant figure is meaningless from a toxicological viewpoint, and Unrealistic degree of precision for food manufacturers when formulating foods
Department of Health, Victoria (Vic Health)	Government	<ul style="list-style-type: none"> Supports progression of the Application subject to any further information becoming available Recommends FSANZ review EFSA's revised exposure estimates for steviol glycosides published in January 2011
Australian Food and Grocery Council (AFGC)	Industry body	<ul style="list-style-type: none"> Supports the Application States the proposed levels provides industry with the necessary flexibility and opportunity for product innovation and development, and Harmonises with international standards providing greater opportunities for trade and range of products available to consumers
Australian Beverages Council Ltd (ABCL)	Industry body	<ul style="list-style-type: none"> Supports the Application Promotes consistency with international permissions Cites permissions by USFDA, AFSSA, EFSA, CCFA as consistent with those proposed in the Application for water based beverages (200 mg/kg <i>c.f.</i> 198 mg/kg), Supports the rationalisation and simplification of existing permissions and instructions for calculating steviol equivalents
Calorie Control Council	Industry body	<ul style="list-style-type: none"> Supports the Application Urges FSANZ to act expeditiously in approving the recommendations
Complementary Healthcare Council of Australia (CHC)	Industry body	<ul style="list-style-type: none"> Supports the Application In principle support for increased levels noting safety and risk assessment data provided.

Submitter	Group	Comments
Food Technology Association of Australia (FTAA)	Professional association	<ul style="list-style-type: none"> • Supports the Application • Notes the statement, “The preparation which is the subject of this Application comprises 95% of nine steviol glycosides, with Rebaudioside A accounting for over 95% of those present” and comments that this is interpreted as meaning this preparation contains 90% of Rebaudioside A • Further notes, specifications contained in JECFA monographs, as cited in the Assessment Report, only make reference to total purity (95%) and not to any minimum levels of Rebaudioside A • Suggests any change in permitted levels should be independent of the purity of the steviol glycosides, other than they should comply with the JECFA specifications • Notes the conversion factor stated in the second example in the draft variations is incorrect
International Sweeteners Association (ISA)	Industry body	<ul style="list-style-type: none"> • Supports the Application • Welcomes simplification of existing permissions and provision of clarity and guidance in determining steviol equivalents
New Zealand Ministry of Agriculture and Forestry (MAF)	Government	<ul style="list-style-type: none"> • Supports the Application • Satisfied on technological justification and agrees there are no public health or safety concerns • Suggests that some existing permission could be subject to minor rounding, i.e. 176 mg/kg to 175 mg/kg
Sugar Australia Pty Ltd and GLC Life Tech Corporation	Industry	<ul style="list-style-type: none"> • Supports the Application • Supports proposed increased levels • Supports redrafting for simplification and clarity of existing steviol glycoside permissions • Requests removal of the reference to the purity specification of the steviol glycoside preparation • For clarity, requests it be made explicit that permissions apply to all steviol glycoside preparations which meet the JECFA specifications • Requests the indirect permission for ready-to-drink alcoholic mix beverages be replaced with a direct permission