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Supporting document 1

Food technology, hazard and dietary assessment– Application
A1149

Addition of Steviol glycosides to fruit drinks

Executive summary

FSANZ has assessed an application from the Australian Beverages Council Ltd (ABCL) to amend the Australia New Zealand Food Standards Code (the Code) to permit the addition of steviol glycosides to fruit drinks at a maximum permitted level (MPL) of 200 mg/kg steviol equivalents.

Steviol glycosides provide a technological purpose as an intense sweetener and are already permitted in a range of foods at various maximum permitted levels, including levels consistent with good manufacturing practice. The food technology assessment concludes that the use of steviol glycosides as a food additive in fruit drinks is technologically justified in the quantity and form proposed.

An acceptable daily intake (ADI) of 0-4 mg/kg bw for steviol glycosides, expressed as steviol, was established by Food Standards Australia New Zealand (FSANZ) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FSANZ 2008, JECFA 2009). Toxicological and other relevant data published subsequent to FSANZ's previous assessments of steviol glycosides raised no concerns regarding the safety of steviol glycosides and did not indicate a need to amend the ADI.

FSANZ estimated dietary exposure to steviol glycosides (expressed as steviol equivalents) based on maximum permitted levels in specific foods and using the most recent Australian and New Zealand nutrition survey consumption data. Initial results showed dietary exposures exceeded the ADI at the 90th percentile, so FSANZ collected concentration data from the food industry based on actual use levels and market share. A refined dietary exposure estimate based on this industry use data was undertaken for baseline exposure, then including the requested extension of use in fruit drinks at an MPL of 200 mg/kg.

The mean and 90th percentile dietary exposures across the population groups assessed for the *Refined baseline* ranged between 1.4-1.8 mg/kg bw/day and 2.2-3.5 mg/kg bw/day, respectively. For the *Refined extension of use* scenario including fruit drinks, dietary exposures were 1.5-1.9 mg/kg bw/day and 2.3-3.8 mg/kg bw/day, respectively. The increase in dietary exposure by permitting use of steviol glycosides in fruit drinks is 0.1 mg/kg bw/day at the mean and 0.1-0.4 mg/kg bw/day at the 90th percentile.

Dietary exposure as a proportion of the ADI for the *Refined baseline* at the mean and 90th percentile ranged between 35-45% and 55-90%, respectively across all population groups

assessed. For the *Refined extension of use* scenario, dietary exposures at the mean and 90th percentile were between 35%–45% of the ADI and between 60%–95% of the ADI, respectively, across the population groups assessed. Estimated dietary exposures on average only increase by up to 5% of the ADI between the *Refined baseline* and extension of use in fruit drinks scenarios. Therefore the impact of permitting the use of steviol glycosides in fruit drinks on the dietary exposure to steviol glycosides is small.

Based on the dietary exposure assessment, the ADI will not be exceeded by permitting the extension of use of steviol glycosides to fruit drinks at the MPL of 200 mg/kg steviol equivalents.

FSANZ concludes that there are no public health and safety concerns from the extension of use of steviol glycosides in fruit drinks at the proposed levels of addition.

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1 Introduction

FSANZ received an application from the Australian Beverages Council Ltd (ABCL) to permit the addition of steviol glycosides to fruit drinks at a maximum permitted level of 200 mg/kg steviol equivalents.

Currently, permissions exist in a range of foods, including beverages, to use steviol glycosides as an intense sweetener but not in fruit drinks.

The technological purpose of steviol glycosides is as an intense sweetener where it can be used alone or in conjunction with other intense sweeteners to replace and reduce the sugar content in fruit drinks.

Steviol glycosides are purified extracts obtained from the leaves of the plant *Stevia rebaudiana* Bertoni.

2 Food technology assessment

2.1 Previous FSANZ food technology assessments

FSANZ has previously completed food technology assessments for other applications relating to the use of steviol glycosides and are summarised in Table 1.

Previous food technology assessments were consistent in concluding that steviol glycosides, when used as a food additive in the form and quantity proposed, provide the technological purpose as an intense sweetener.

Table 1 Previous applications to FSANZ for steviol glycosides (FSANZ, 2008, 2011, 2015, 2017, 2018)

Year	Application	Purpose	Summary of outcome and change to the Code
2008	A540 Steviol glycosides as sweeteners	To permit steviol glycosides as a food additive – intense sweetener in a range of foods at max permitted levels/levels of good manufacturing practice.	Approved - amended Standards 1.2.4 and 1.3.1 - permitted in a range of foods at max permitted levels/levels of good manufacturing practice.
2011	A1037 Steviol glycosides – increase in permitted use levels	To increase maximum permitted levels to 100 and 200 mg/kg in a range of foods to improve the taste profile.	Approved - amended Standard 1.3.1 to permit an increase in maximum permitted levels for a range of foods.
2015	A1108 Rebaudioside M (Reb M) as a Steviol glycoside intense sweetener	To include Reb. M as a component of steviol glycosides mixtures used as an intense sweetener.	Approved – amended Standard 1.3.1 and Schedule 3.
2017	A1132 Broaden definition of steviol glycosides (intense sweetener)	To expand the definition of steviol glycosides for use as an intense sweetener to include all steviol glycosides	Approved – amended Standard 1.3.1 and Schedule 3.

Year	Application	Purpose	Summary of outcome and change to the Code
		present in the <i>Stevia rebaudiana</i> leaf.	
2018	A1157 Enzymatic production of Reb. M	To permit Reb. M produced by an enzymatic biosynthesis method.	Awaiting decision on FSANZ Board recommendation from the Australia and New Zealand Ministerial Forum on Food Regulation

2.2 Objective for the food technology assessment

The objective of the food technology assessment is to determine whether steviol glycosides used as a food additive in the form and quantity proposed achieves the technological purpose as an intense sweetener in fruit drinks.

2.3 Chemical and physical properties

The purified extract from the leaves of *Stevia rebaudiana* Bertoni contain different glycosides of steviol, referred to as steviol glycosides. Each of the glycosides contains steviol as a common central component of its molecular structure and then different sugar moieties (glucose, rhamnose, fructose, deoxyglucose xylose, galactose, arabinose and xylose) forming the glycoside. Figure 1 provides the structural formula for steviol and related glycosides (JECFA 2017b).

Steviol glycosides are categorised into 7 different groups based on the type of glycosidic residues linked to the steviol backbone. These groups and common names for steviol glycoside components are summarised in Table 2 (JECFA 2017b).

Commercial steviol glycoside preparations are white to light yellow powders that are soluble in 50:50 ethanol and water mixtures and are odourless or have a slight odour (FAO 2016).

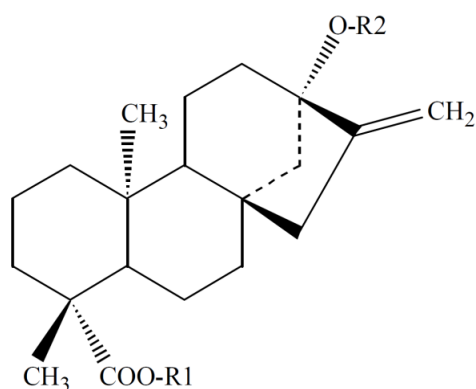


Figure 1 Structural formula for steviol and related glycosides

Table 2 Steviol glycoside groups and components (JECFA 2017b)

Group 1 Steviol + Glucose (SvGn)
Steviolmonoside, Steviolmonoside A, Rubososide, Steviolbioside, Stevioside, Stevioside A, Stevioside B, Rebaudioside B, Rebaudioside G, Rebaudioside E, Rebaudioside A, Rebaudioside A2, Rebaudioside D, Rebaudioside L, Rebaudioside I, Rebaudioside I2, Rebaudioside I3, Rebaudioside Q, Rebaudioside Q2, Rebaudioside Q3, Rebaudioside M, 5 additional related SvGn
Group 2 Steviol + Rhamnose + Glucose (SvR1Gn)
Dulcoside A, Dulcoside C, Rebaudioside C, Rebaudioside C2, Rebaudioside N, Rebaudioside O, Rebaudioside O2, Rebaudioside K, Rebaudioside S, Rebaudioside K2, Rebaudioside H, Rebaudioside J
Group 3 Steviol + Xylose + Glucose (Steviol + Xylose + Glucose (SvX1Gn)
Stevioside F, Rebaudioside F, Rebaudioside F2, Rebaudioside F3, Rebaudioside R, Rebaudioside U2, Rebaudioside T, Rebaudioside V2, Rebaudioside V
Group 4 Steviol + Arabinose + Glucose (SvA1Gn)
Rebaudioside U, Rebaudioside W, Rebaudioside W2, Rebaudioside W3, Rebaudioside Y
Group 5 Steviol + Galactose + Glucose (SvGa1Gn)
Rebaudioside T1
Group 6 Steviol + Fructose + Glucose (SvFruGn)
Rebaudioside A3
Group 7 Steviol + -De-oxy glucose + Glucose (SvdG1Gn)
Stevioside D, Stevioside E, Stevioside E2

2.4 Technological purpose

From information assessed in previous applications; A540, A1037, A1038, A1108, A1132, A1157 (FSANZ 2008, 2011, 2015, 2017, 2018) the technological purpose of steviol glycosides as an intense sweetener in a range of foods was concluded to be appropriate.

In summary, steviol glycosides:

- can be used in new product development and/or reformulation to produce reduced calorie, reduced sugar/added sugar foods including beverages
- are 200 to 300 times sweeter than sucrose and have been used for a number of years as a non-caloric intense sweetener in a range of foods
- include components of steviol glycosides which can be used alone or in conjunction with other intense sweeteners or sugar to provide sweetness in food
- are heat and acid stable

2.5 Technological justification

Steviol glycosides are already permitted for addition to food in a range of food classes; including fruit juice at 50 mg/kg, low joule fruit and vegetable juice at 125 mg/kg and water-based flavoured beverages at 200 mg/kg. Although low joule fruit and vegetable juice products can contain steviol glycosides they are less palatable because of the low level of juice used to formulate these products. The applicant considers that these drinks are not popular with consumers.

In FSANZ's assessment of application A1037 (FSANZ 2011) consumer preference studies confirmed that acceptable sweetness levels for consumers in cola and fruit flavoured drinks using steviol glycosides required a 10% sucrose equivalent, equating to approximately 200 mg/kg steviol equivalents. Above this level, the bitterness intensity increased and there was no significant increase in consumer liking.

The applicant states that steviol glycosides at a maximum permitted level of 200 mg/kg steviol equivalents in fruit drinks will meet Australian and New Zealand consumer palatability preferences. This would provide equivalent sweetness to the levels permitted in water-based flavoured beverages and fruit juice.

The application also confirms there is a consumer preference for steviol glycosides as plant-based intense sweeteners compared with other permitted intense sweeteners used in fruit drinks. e.g. aspartame, acesulphame potassium, alitame and aspartame-acesulphame salt.

Water-based beverages containing 200 mg/kg steviol glycosides and higher levels of sugar are popular with consumers in international markets. Steviol glycosides in these products allow for 30-50% reduction in sugar. There are some low joule fruit and vegetable juices and water-based beverages available in New Zealand and Australian markets that have a 50% reduction in sugar due to the use of steviol glycosides. These are currently described and named as food classes that already permit steviol glycosides, but are more correctly described as 'fruit drinks.'

2.6 The manufacturing process

The production of steviol glycosides from the leaves of the *Stevia rebaudiana* plant generally follows the same basic steps with some variation at the later stages of purification and separation. This was included in application A540 and A1037 (FSANZ 2008, 2011 and more recently by JECFA (FAO 2016).

The conventional extraction method involves the crushing of stevia leaves and extraction with hot water. The extract is purified using ion-exchange chromatography along with other purification steps including filtration and crystallisation.

The 2016 JECFA assessment mentions extraction of Rebaudiosidase A (95% Reb A) from fermentation of a non-toxic and non-pathogenic GM source (FAO 2016). The use of enzymatic extraction can be used to concentrate specific steviol glycosides and may also be more efficient than conventional methods in terms of yields (Gonzalez et al, 2014).

2.7 Product specifications

There are international specifications for steviol glycosides established in the Combined Compendium of Food Additive Specifications (JECFA 2017b). These state that the composition of the preparation must consist of at least 95% steviol glycosides. These specifications are an accepted primary source of specifications in section S3-2(1)(b) of the

Code.

The Code itself contains specifications in section S3-2(1)(a) for steviol glycosides. These specifications include aspects of steviol glycosides not previously included in JECFA specifications.

Steviol glycosides have been assigned the food additive number INS 960.

2.7.1 Calculating steviol equivalent or steviol levels

Since previous FSANZ hazard assessments identified that all steviol glycosides are metabolised to steviol in animals and humans, the ADI is expressed in terms of steviol equivalents (JECFA uses the term 'expressed as steviol'). This allows for variability in the individual glycosides in mixtures of steviol glycoside extracts. Therefore, conversion factors are needed to convert the different steviol glycosides to steviol.

The equation and conversion factor is related to the ratio of molecular weights of the steviol to the steviol glycoside are included in section S1.3.1-4(7) of the Code.

2.8 Analytical method for detection

Analytical methods are available for the detection and quantification of steviol glycosides in food since preparations of steviol glycosides have been commercialised and permitted as intense sweeteners for several years. These have been based on High Performance Liquid Chromatography (HPLC). Such analytical methods were mentioned in assessment of applications A1037, A1108, A1132 (FSANZ 2011, 2015, 2017). These also refer to the European Food Safety Authority (EFSA) scientific opinion on steviol glycosides in 2010 (EFSA 2010). Two HPLC analytical methods have been published (Geuns et al 2008, Gardana et al 2010). The most recent JECFA report includes a validated HPLC-ultraviolet (UV) method for the assay of steviol glycosides that exist in smaller quantities (JECFA 2017a). These methods should be applicable for analysis of all types of steviol glycosides added to foods.

2.9 Product stability

FSANZ and JECFA concluded that steviol glycosides are thermally and hydrolytically stable for use in foods, including acidic beverages like fruit drinks under normal processing and storage conditions (FSANZ 2015, 2017, 2018, FAO 2016).

2.10 Food technology conclusions

Steviol glycosides provide a technological purpose as an intense sweetener and are already permitted in a range of foods at various maximum permitted levels, including levels consistent with good manufacturing practice. The food technology assessment concludes that the use of steviol glycosides as a food additive in fruit drinks, is technologically justified in the quantity and form proposed.

3 Hazard assessment

3.1 Previous FSANZ hazard assessments

FSANZ first assessed steviol glycosides in application A540 (FSANZ 2008) and established an ADI of 0-4 mg/kg bw, expressed as steviol. At that time, ten steviol glycosides were

known; stevioside, dulcoside, steviolbioside, rubudioside, and rebaudiosides A, B, C, D, E and F.

FSANZ updated the hazard assessment of steviol glycosides in applications A1037, A1108 and A1132 (FSANZ 2011, 2015, 2017) but did not find reason to change the ADI established in 2008.

In application A1157 FSANZ again reviewed the available toxicological and other relevant data on steviol glycosides published subsequent to FSANZ's previous assessments. This review was part of the evaluation of an application to permit rebaudioside M (Reb M) from a novel production method using enzymes sourced from genetically modified strains of *Pichia pastoris* (FSANZ, 2018). The available data raised no concerns regarding the safety of steviol glycosides and did not indicate a need to amend the ADI of 0-4 mg/kg bw.

3.2 Objectives for the hazard assessment

FSANZ has recently assessed new toxicological and other relevant data on the safety of steviol glycosides, as part of application A1157 (FSANZ 2018). A further literature search in August 2018 did not identify any additional new studies, but the applicant provided details of acute toxicity studies with a rebaudioside A preparation, and one human clinical study that have not been previously assessed by FSANZ. These studies are reviewed below.

3.3 Toxicological data

3.3.1 Acute studies in animals

The application makes reference to four acute toxicity studies on a preparation of rebaudioside A (98%) derived from *Stevia rebaudiana*. The study reports are included in a 2012 US FDA Generally Recognised as Safe (GRAS) notification (Mini Star International 2012). The reports provide details of acute oral and dermal toxicity studies in rats, and skin and eye irritation studies in rabbits. Only the acute oral toxicity study is reviewed below, as the other studies are not relevant to dietary exposure.

3.3.1.1 Acute oral toxicity study in rats (Mini Star International 2012) Regulatory status: GLP; Conducted according to OECD Test Guideline 425

The test substance, identified as Stevia Leaf 98% Reb-A Powder Extract, Batch no. 20100910 from Ministar International Inc, was administered to female Sprague Dawley rats as a 50% w/w mixture in water by oral gavage. Animals were observed for mortality, signs of gross toxicity and behavioural changes during the first few hours after dosing and at least once daily thereafter for 14 days. Body weights were recorded prior to administration of the test substance and again on Days 7 and 14 following dosing. All rats were killed at the end of the 14-day observation period and gross necropsies were performed on all animals. The study was conducted in accordance with the Up and Down Procedure, in which single animals were dosed sequentially with increasing doses ranging from 175-5000 mg/kg bw. Two additional animals were administered 5000 mg/kg bw.

All animals survived until the end of the 14-day observation period, gained body weight and appeared active and healthy. No signs of gross toxicity, adverse pharmacological effects or abnormal behaviour were observed. No gross abnormalities were observed at necropsy.

The acute oral LD₅₀ of Stevia Leaf 98% Reb-A Powder Extract was greater than 5000 mg/kg bw in female rats under the conditions of this study.

3.3.2 Other studies

3.3.2.1 *Effects on food intake, satiety and postprandial glucose and insulin levels (Anton et al. 2010)*

The effects of stevia, aspartame and sucrose on food intake, satiety and blood glucose/insulin levels were compared in a group of human volunteers. Two sets of individuals aged 18-50 years were recruited: 19 lean individuals (Body Mass Index [BMI] 20.0-24.9 kg/m²) and 12 obese individuals (BMI 30-39.9 kg/m² with a waist circumference of ≥ 36 inches for females and ≥ 40 inches for males). All participants completed three test days, each starting after a 12-hour fast. Participants consumed a standard 469 kcal breakfast in the morning, and then 20 minutes prior to lunch and dinner they were given a 400 g preload of tea and crackers with cream cheese sweetened with stevia (290 kcal), aspartame (290 kcal) or sucrose (493 kcal). The order in which the preloads were given was balanced, and participants were blinded to the type of sweetener used. Food intake (kcal) was directly measured using ISO 9001 scales, and visual analogue scores (VAS) were used to assess subjective ratings of hunger, satiety, fullness and hedonic ratings of food. Participants provided blood samples immediately before and 20 minutes after consuming the first preload, and at 30, 60 and 120 minutes after the test lunch meal. Based on previous studies it was determined that a sample size of 30 participants would allow detection of the following measures with > 80% power: 1) a mean difference between test conditions of 60 kcal of food consumed at the test lunch meal; 2) a mean difference of 83 kcal at the dinner meal; 3) a mean difference of 6 ratings points for VAS ratings of hunger; and 4) a mean difference of 15 rating points for VAS ratings of satiety. A repeated measures design was used to test if food intake, hunger and satiety or postprandial glucose and insulin levels differed as a function of the three different sweeteners in the preload meal.

Participants consumed significantly less food (kcal) over the entire day in the stevia and aspartame conditions compared to the sucrose condition (mean difference between sucrose and stevia conditions: 300 kcal, $p < 0.001$; sucrose and aspartame conditions: 334 kcal, $p < 0.001$). There was no significant difference in food consumption between the stevia and aspartame conditions. Food intake at lunch and dinner did not differ significantly between the three test conditions when the preload was excluded from the analysis, indicating that discretionary food intake did not differ between the conditions. Reported hunger and satiety levels did not differ between the three conditions at any time point. Based on an area under the curve analysis, postprandial blood glucose levels were significantly lower in participants consuming stevia compared to those given sucrose ($p < 0.01$), and postprandial insulin levels were significantly lower in the stevia condition compared to both the aspartame ($p = 0.04$) and sucrose ($p = 0.003$) conditions. No adverse events were reported during the trial.

The study authors concluded that participants who consumed lower calorie preloads containing stevia or aspartame did not compensate by eating more lunch or dinner compared to when they consumed higher calorie preloads containing sucrose. They also reported similar levels of satiety. In addition, stevia preloads reduced postprandial blood glucose and insulin levels.

3.4 Assessments by other agencies

3.4.1 Joint FAO/WHO Expert Committee on Food Additives (JECFA)

JECFA reviewed the safety of steviol glycosides at their 51st, 63rd, 68th, 69th and 82nd meetings. A temporary ADI of 0 to 2 mg/kg bw was established at the 63rd meeting, which was subsequently replaced with a full ADI of 0 to 4 mg/kg bw, expressed as steviol, for steviol glycosides at the 69th meeting. A re-evaluation of steviol glycosides at the 82nd

meeting, in 2016, confirmed this ADI (FAO/WHO 2016).

3.4.2 Health Canada

Health Canada expanded their definition of steviol glycosides to include Reb M in 2016, in recognition of the common metabolic fate of steviol glycosides; that is, hydrolysis to steviol, conjugation by glucuronidation and urinary excretion (Health Canada 2016). More recently Health Canada further expanded their definition of steviol glycosides to include all steviol glycosides found in *Stevia rebaudiana* Bertoni (Health Canada 2017).

3.4.3 United States Food and Drug Administration (FDA)

Since the beginning of 2016, 13 GRAS notices for steviol glycosides have been submitted to the US FDA. The FDA has responded with no questions concerning the GRAS status of 11 of these products, and two responses are pending.

3.5 Hazard assessment discussion and conclusion

Recent assessments by FSANZ and JECFA have confirmed that all steviol glycosides undergo the same metabolic pathway to steviol, which is then glucuronidated and excreted in the urine. A single ADI, expressed as steviol, is therefore appropriate for all steviol glycosides.

The assessment of steviol glycosides in application A1157 identified a small number of genotoxicity studies, studies in laboratory rodents and studies in human volunteers of steviol glycosides that have been published since application A1132 was assessed by FSANZ. For the present assessment, no further new studies were identified, but the Applicant provided details of two studies not previously reviewed by FSANZ; an acute oral toxicity study with a rebaudioside A preparation, and a study in humans of effects of stevia on food intake and postprandial glucose and insulin levels. None of these studies indicate a need to change the existing ADI of 0-4 mg/kg bw, expressed as steviol.

In conclusion, the available data do not raise concerns regarding the safety of steviol glycosides. The existing ADI of 0-4 mg/kg bw, expressed as steviol, previously established by FSANZ continues to be appropriate.

4 Dietary exposure assessment

4.1 Objective for the dietary exposure assessment

The objective for the dietary exposure assessment was to estimate population exposure to steviol glycosides based on currently permitted levels in foods, and the proposed extension of use in fruit drinks.

4.2 Approach to the dietary exposure assessment

Dietary exposure assessments at FSANZ are conducted using a tiered approach. The first assessment is conducted using the worst case assumptions and the least amount of resources, and refinements made following this assessment if needed.

Dietary exposure assessments require concentration data of the chemical of interest in food, and consumption data of those foods collected through national nutrition surveys. Details of the steviol glycoside concentration data, and food consumption data used in this dietary

exposure assessment are outlined below. The dietary exposure assessment for steviol glycosides was undertaken using FSANZ's dietary modelling computer program Harvest¹, and compared to the ADI of 0-4 mg/kg bw. As food additive permissions in the Code apply to both Australia and New Zealand, dietary exposure assessments were undertaken for both countries.

A summary of the general FSANZ approach to conducting the dietary exposure assessment for this Application is at Appendix 1. A detailed discussion of the FSANZ methodology and approach to conducting dietary exposure assessments is set out in *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009).

4.2.1 Food consumption data used

The food consumption data used for the dietary exposure assessments were:

- **2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS):** one 24-hour food recall survey of 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% of respondents (ABS, 2014). Only those respondents who had two days of food consumption data (n=7,735) were used in this assessment.
- **2008–09 New Zealand Adult Nutrition Survey (2008 NZ ANS):** one 24-hour recall of 4,721 New Zealanders aged 15 years and above, with a second 24-hour recall undertaken for 25% of respondents. (Ministry of Health 2011a; Ministry of Health 2011b). Only the first day of food consumption data was used in this assessment.
- **2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS):** one 24-hour food recall covering 3,275 New Zealand school children aged 5-14 years, with 25% of respondents also completing a second 24-hour recall. Only the first day of food consumption data was used in this assessment.

Dietary exposure assessments based on food consumption data from national nutrition surveys provide the best estimation of actual consumption of a food and the resulting estimated dietary exposure for the Australian and New Zealand populations. The design of these nutrition surveys and the key attributes, including survey limitations, are set out in Appendix 1.

One day of food consumption data for each of the NZ surveys were used for the dietary exposure assessment whereas the average of two days of data from the 2011-12 NNPAS was used for Australia. This was due to the proportion of respondents with a second day of data and the availability of sample weights for the two day sample. The two day average exposures better reflect longer term estimates of dietary exposure and therefore are a better estimate of chronic dietary exposure.

The hazard identification and characterisation did not identify any population sub-groups with specific safety considerations in relation to dietary exposure to steviol glycosides. In addition, the food categories in which steviol glycosides are currently permitted, and the category fruit drinks for which the applicant seeks an extension of use, are consumed by all of the Australian and New Zealand populations. Therefore the dietary exposure assessments were conducted for the general Australian and New Zealand populations based on the dietary survey data available. These age groups, along with the number of respondents of each survey are listed in Table 3.

¹ Harvest is FSANZ's custom-built dietary modelling program that replaced the previous program, DIAMOND, which does the same calculations just using a different software program.

Table 3 Population groups used in the dietary exposure assessment Country	Nutrition survey	Age group	No. respondents (Day 1 only)	No. respondents (Day 1 and 2)
Australia	2011-12 NNPAS	2 years and above	n/a	7,735
New Zealand	2002 NZ CNS	5 – 14 years	3,275	n/a
	2008 NZ ANS	15 years and above	4,721	n/a

4.2.2 Estimating dietary exposure to steviol glycosides

Steviol glycosides dietary exposures were calculated for each individual consumer in the national nutrition surveys using their individual food consumption records. The Harvest program multiplied the specified concentrations of steviol glycosides for an individual food by the amount of the food that an individual consumed in order to estimate the exposure to steviol glycosides from each food. Once this had been completed for all of the foods specified to contain steviol glycosides, the total amount of steviol glycosides consumed from all foods was summed for each individual. Where results are expressed on a body weight basis, each individual's body weight was used. Mean and 90th percentile (P90) dietary exposures were then derived from the individuals' ranked exposures. Estimated dietary exposures for the population on a body weight basis were compared to the ADI for risk characterisation purposes.

A Harvest food-additive model was most appropriate for this dietary exposure assessment as nutrition survey foods consumed are grouped as per the food category codes in Schedule 15 of the Code and concentrations of steviol glycosides are assigned to these relevant codes. The food category codes in Schedule 15 of the Code (where permission for steviol glycosides are listed) in some instances vary from the codes in Harvest. Therefore, to match the permissions to the specific consumption data the corresponding codes needed to be matched. The Schedule 15 food category code and the corresponding Harvest code are listed in Table 4.

4.2.3 Initial estimate of baseline dietary exposure to steviol glycosides

For this application the dietary exposure assessment was conducted in two tiers. The first dietary exposure assessment for steviol glycosides was conducted using the Maximum Permitted Levels (MPLs) in the Code. This dietary exposure assessment scenario is referred to as the '*Baseline*' scenario. The concentration values used for this initial assessment are listed in Table 4.

Estimated dietary exposures were compared to the ADI of 0-4 mg/kg bw. Estimated *Baseline* mean dietary exposure to steviol glycosides across all Australian and New Zealand population groups assessed ranged from 55-85% of the ADI, and 90th percentile exposures ranged between 95-160% of the ADI (Appendix 2, Table 2.1). The highest 90th percentile exposure of 170% ADI was for New Zealand children 5-14 years. The exposure estimates derived from this scenario are conservative since it assumes that all foods in every category contain steviol glycosides at the MPL and the consumer will continuously (over a lifetime) be

exposed to steviol glycosides at these levels. This is not likely to be the case in reality.

4.2.4 Refined estimate of dietary exposure to steviol glycosides

In order to determine a more realistic estimate of dietary exposure, more specific concentration data were required. Therefore, a request was made to the food industry in Australia and New Zealand for use levels of steviol glycosides. The collection of industry data was facilitated by the Applicant, the Australian Food & Grocery Council and New Zealand Food & Grocery Council. This dietary exposure assessment scenario is referred to as the 'Refined' Scenario. The concentration values used for this initial assessment are listed in Table 3. A '*Refined baseline*' assessment was undertaken as was a '*Refined extension of use*' scenario where the requested permission for fruit drinks was also included and evaluated.

The *Refined* dietary exposure was estimated using a weighted concentration of steviol glycosides for each food derived from: (1) industry use information, concentration data (reported maximum use level) and the products market share for the particular food category; market share was obtained from industry or Euromonitor (Euromonitor International 2018); (2) where industry data were not available, or a portion of the market share unaccounted for, the MPL was used for the whole category or the remaining portion respectively and (3) extension of use to fruit drinks at 200 mg/kg.

Table 4 Food classifications and concentrations of steviol glycosides used in the dietary exposure assessment for baseline and refined scenarios

Food standards category code	Food standards category name	Harvest classification code	Harvest classification name	Concentration used in dietary exposure assessment scenario (mg/kg)*		Proportion of market share industry data provided for (%)
				Baseline	Refined**	
1.1.2	Liquid milk products and flavoured liquid milk	1.1.2	Liquid milk prod & flav liquid milk	115	79.0	40.8
1.2.2	Fermented milk products and renneted milk products	1.2.2	Ferm & renn milk prod, flavoured	175	148.4	15.2
3	Ice cream and edible ices	3	Ice cream & edible ices	200	66.2	66.9
4.3.2	Fruits and vegetables in vinegar, oil, brine or alcohol	4.3.2	Fruits & veges in vinegar/oil/brine/alcohol	160	149.8	6.4
4.3.4.1	Low joule chutneys, low joule jams and low joule spreads	4.3.4.2	Fruit & vege spreads (low joule), jams	450	448.7	0.3
4.3.6	Fruit and vegetable preparations including pulp	4.3.6	Fruit & vegetable preparations including pulp	210	146.0	30.5
5.1	Chocolate and cocoa products	5.1	Chocolate & cocoa products	550	426.8	22.4
5.2	Sugar confectionery	5.2	Sugar confectionery	1100	900.9	18.1
6.3	Processed cereal and meal products	6.3	Processed cereal & meal products	250	94.8	62.1
7.1.1	Fancy breads	7.1.4	Fancy breads	160	160	0
7.2	Biscuits, cakes and pastries	7.2	Biscuits, crackers, cakes, pastries & scones	160	151.4	5.4
11.4	Tabletop sweeteners	11.4	Tabletop sweeteners	400000	400000	0
13.3	Formulated meal replacements and formulated supplementary foods	13.3	Formula meal replacements & formulated supp foods	175	145.3	17

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Food standards category code	Food standards category name	Harvest classification code	Harvest classification name	Concentration used in dietary exposure assessment scenario (mg/kg)*		Proportion of market share industry data provided for (%)
				Baseline	Refined**	
13.4	Formulated supplementary sports foods	13.4	Formulated supplementary sports foods	175	175	0
14.1.2.1	Fruit and vegetable juices	14.1.2.1	Fruit & vegetable juices	50	16.1	74.1
14.1.2.2.1	Fruit Drink	14.1.2.2.1	Fruit Drink		200**	
14.1.2.2.2	Low joule fruit and vegetable juice products	14.1.2.2.2	Low joule fruit & vegetable juice products	125	115.4	30
14.1.2.2.3	Soy bean beverage (plain or flavoured)	14.1.7.2	Soy beverage, flavoured	200	126.4	36.8
		14.1.7.1	Soy beverage, unflavoured		126.4	
14.1.3	Water based flavoured drinks (Australia)	14.1.3	Water based flavoured drinks	200	52.9	91
14.1.4	Formulated Beverages	14.1.4	Formulated beverages	200	186	7
14.1.5	Coffee, coffee substitutes, tea, herbal infusions and similar products	14.1.5	Coffee (or substitute), tea, herbal infusion & similar	100	55.1	44.9
20.2.0.1	Custard mix, custard powder and blancmange powder	20.2.1.1.3.2	Desserts, dairy, no choc/coffee; custard & blanc mange mix/powd	80	80	0
		20.2.1.1.1.2	Desserts, dairy, choc; custard & blanc mange mix/powd	80	80	0
20.2.0.2	Jelly	20.2.1.2.3.1	Desserts, no-dairy, no choc/coffee; jelly	260	30.9	91.3
20.2.0.3	Dairy and fat based desserts, dips and snacks	20.2.1.1	Desserts, dairy	150	83.1	44.6
		20.2.1.2	Desserts, no-dairy		83.1	
		20.2.6.3	Dips & spreads		83.1	

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Food standards category code	Food standards category name	Harvest classification code	Harvest classification name	Concentration used in dietary exposure assessment scenario (mg/kg)*		Proportion of market share industry data provided for (%)
				Baseline	Refined**	
		20.2.6.3.1	Dips, dairy or fat based		83.1	
		20.2.6.3.2	Dips, not dairy or fat based		0	
		21.2.6.3.1	Dips & spreads, homemade, contains dairy		83.1	
20.2.0.4	Sauces and toppings (including mayonnaises and salad dressings)	20.2.6.1	Sauces & syrups, sweet	320	251.7	21.9
		20.2.7	Mayo and salad dressing		251.7	
		20.2.6.2	Gravy, sauces & condiments		251.7	

* As steviol equivalents.

** *Refined* scenario used a weighted concentration based on industry use data, and market share data from Industry and Euromonitor 2018.

° Extension of use requested by applicant. The concentration of 200 mg/kg was only used in the '*Refined extension of use*' scenario.

4.2.5 Brand loyalty

The *Refined* assessment is based on weighted concentrations of steviol glycosides that would be indicative of likely concentrations and therefore exposures to steviol glycosides from across the whole diet over a lifetime. Consumers can be brand loyal when it comes to selecting and consuming foods. An assessment of selected foods that are frequently consumed, are commonly selected based on brand, and contribute to the estimated dietary exposures was undertaken to determine how much of them could be consumed on a daily basis before exceeding the ADI. This was compared to high consumption amounts for the foods reported from nutrition surveys to determine if exceeding the ADI would be likely.

4.2.6 Assumptions and limitations of the dietary exposure assessment

The aim of the dietary exposure assessment was to make the most realistic estimation of dietary exposures to steviol glycosides as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the estimated dietary exposure was not an underestimate of exposure.

Assumptions made in the dietary exposure assessment included:

- If less than 100% of the market was represented by industry data, or industry data were not provided for a food category, the remaining market share proportion was assigned the MPL in the Code. The MPLs were used for the portion of the category for which no industry data was available as it could not be assumed that concentration data from one company is representative of all foods in the category.
- If there were data for both Australia and New Zealand, generally the higher of the two was used for the dietary exposure assessments for both countries on the assumption that food manufactured in either country could be imported, sold and consumed in the other. If data for only one country was available, then this value was assigned for both countries. The final concentrations that were assigned to each of the permitted food categories were then used in the dietary exposure assessment.
- The category tabletop sweeteners is permitted at Good Manufacturing Practice (GMP) in Schedule 15 of the Code, therefore in the absence of industry data a concentration of 400,000 mg/kg was assigned based on data from industry obtained in a previous assessment of steviol glycosides (FSANZ 2011).
- Where industry concentration data were provided and it was not specified as to the form of the steviol glycosides, it was assumed that the concentration was as steviol equivalents. If the actual concentration was in fact for steviol glycosides, the concentration used in the dietary exposure assessment would be a worst case scenario as the amount of steviol equivalents would be lower.

In addition to the specific assumptions made in relation to this dietary exposure assessment, there were a number of limitations:

- When less than 100% of the market was represented by industry provided data the remaining proportion was assigned the MPL to derive a weighted concentration. Where there were no industry data the MPL was used. This results in a mixture of maximum and actual use levels being used in the dietary exposure assessment which has likely skewed the real percentage of food contributors to steviol glycoside dietary exposures.
- Due to uncertainties or gaps arising from the limited amount of industry data on steviol glycoside use or non-use, and product market share, the remaining proportion of market share was assigned the MPL, thus the concentrations used were conservative and may have led to an overestimation of the actual dietary exposure to steviol glycosides.

- As only one day of food consumption survey data are available from New Zealand nutrition surveys, the estimated exposures are likely to be over-estimated (particularly at the high percentiles of exposure) given that two days of survey data has been established as more appropriate for estimating long term consumption and therefore dietary exposure.

4.3 Dietary Exposure Assessment Results

4.3.1 Estimated Dietary exposure to steviol glycosides

All estimates of dietary exposure to steviol glycosides are expressed as steviol equivalents. The estimated dietary exposures to steviol glycosides were calculated for 'consumers' of steviol glycosides only, that is only the respondents in the survey population that have been exposed to steviol glycosides as a result of consuming a food in which it is permitted to be used. For this assessment, all survey respondents were consumers of steviol glycosides (see Appendix 2, Table 2.1) given the broad range of commonly consumed foods in which they are permitted to be used. The estimates of exposure were reported on a per kilogram body weight basis using each individual's body weight, and expressed as a percentage of the ADI.

For the initial *Baseline* scenario (i.e. steviol glycoside concentrations at the MPL) the mean and 90th percentile of estimated exposures for Australian and New Zealand consumers ranged from 2.2-3.3 mg/kg bw/day (55-80% of the ADI) and 3.9-6.5 mg/kg bw/day (95-160% of the ADI), respectively (full results in Appendix 2, Table 2.1). As discussed above, the initial *Baseline* based on MPLs exceeded the ADI, and a refined dietary exposure assessment was undertaken, therefore this *Baseline* scenario will not be discussed further in this report.

For the *Refined* scenario (i.e. refined dietary exposure assessment using industry use and market share data), the *Refined baseline* mean and 90th percentile estimated exposures for Australian and New Zealand consumers ranged from 1.4-1.8 mg/kg bw/day and 2.2-3.5 mg/kg bw/day, respectively. For the *Refined extension of use* scenario the estimated dietary exposures at the mean and 90th percentile would be 1.5-1.9 mg/kg bw/day and 2.3-3.8 mg/kg bw/day, respectively. It was estimated that the increase in dietary exposure by permitting use of steviol glycosides in fruit drinks is 0.1 mg/kg bw/day at the mean and 0.1-0.4 mg/kg bw/day at the 90th percentile.

Detailed results of estimates of exposure to steviol glycosides for all scenarios and population groups assessed can be found at Appendix 2, Table 2.1.

4.3.2 Foods where steviol glycosides are permitted that contribute to exposure

The major food contributors to the estimated dietary exposures to steviol glycosides were calculated for each *Refined* scenario and population group assessed.

The foods that were major contributors to the total estimate of steviol glycoside dietary exposure (providing ≥5%) were calculated from consumers' mean intake from all foods included in the *Refined* scenario. These results should be interpreted with caution given the weighted nature of the concentration data used for the assessment that included a varying proportion of industry use levels and MPLs across the foods included. This may skew the foods contributing to the dietary exposure and may not truly reflect the contributors in reality.

There was little difference in the percent contributions for each of the food groups to total dietary exposure between the *Refined baseline* and *Refined extension of use* scenarios (up to 2% only for the highest contributing foods). So only the results for the *Refined extension of*

use scenario are reported here.

The category 'tabletop sweeteners' was the largest contributor to total steviol glycoside exposure for the Australian population 2+ years (31%), and second largest contributor for New Zealand population 15+years (18%). In the absence of more recent industry use data for steviol glycosides in this category, the assigned concentration of 400,000 mg/kg based on industry data from a previous steviol glycosides application for 100% of the consumption in this category was applied, and therefore likely to overestimate and skew the contributing exposure to steviol glycosides than is likely in reality. The major contributors to steviol glycoside exposure for New Zealand children 5-14 years were 'water based beverages' at 18%, and for New Zealand adults 15+ years was 'Coffee (or substitute) tea, herbal infusion & similar' at 34%. Two food categories that were major contributors across all population groups were 'Water based beverages' and 'Gravy sauces and condiments'.

With the exception of water-based beverages, the percent of the market share for which industry data were provided for the major contributing food categories was less than 45% of the total market share for their respective category, as noted in Table 3. Therefore, interpreting the results of major food contributors needs to be done with caution. This is because weighted concentrations were used where less than 100% of the market was represented by industry data and the remaining proportion assigned the MPL, or the MPL was used for the whole category where industry data were unavailable, which are likely to skew the proportions derived which may be different in reality.

Several other food categories were major contributors to total steviol glycoside exposure for the different population groups. The major contributing food categories and their contribution to total dietary exposure are presented in Figure 2. Further details of the contributions to dietary exposure of all food categories where steviol glycosides are permitted can be found in Appendix 2, Table 2.2.

The estimated contribution to dietary exposure from fruit drinks ranged from 3-7% of total exposure to steviol glycosides for all populations assessed in the *Refined extension of use* scenario.

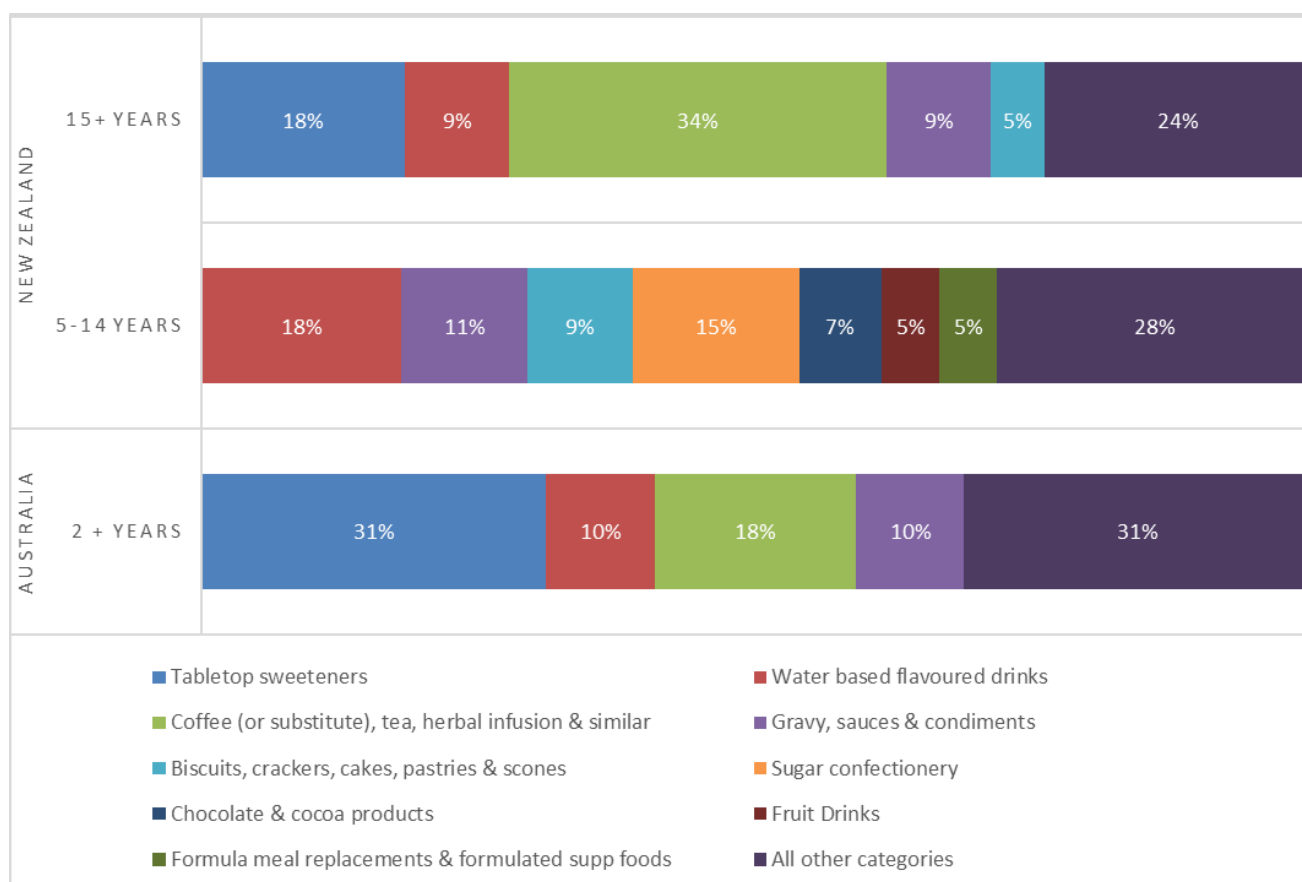


Figure 2 Major ($\geq 5\%$) contributing food categories to steviol glycoside dietary exposure for Australia and New Zealand population groups for the Refined extension of use scenario

4.4 Dietary exposure assessment summary

FSANZ determined a *Refined* estimate of dietary exposure to steviol glycosides based on the most recent Australian and New Zealand nutrition survey consumption data and information on reported use levels by industry. As industry data were not available for all products manufactured, nor complete information on whether steviol glycosides are used or not, several assumptions needed to be made to determine a concentration of steviol glycosides used in the assessment. The data gaps and assumptions made are likely to mean that the refined estimate is still an overestimation of the actual exposure to steviol glycosides.

The mean and 90th percentile of dietary exposures to steviol glycosides across the population groups assessed for the *Refined baseline* ranged from 1.4-1.8 mg/kg bw/day and 2.2-3.5 mg/kg bw/day, respectively. For the *Refined extension of use scenario*, exposures were 1.5-1.9 mg/kg body weight/day and 2.3-3.8 mg/kg body weight/day, respectively.

The highest contributing food category to steviol glycoside exposure differed for each population group assessed. ‘Tabletop sweeteners’, ‘water-based beverages’ and ‘Coffee (or substitute) tea, herbal infusion & similar’ were among the highest contributors to steviol glycoside exposure. However contributors should be interpreted with caution given a weighted concentration was used in the dietary exposure assessment, and may skew the proportions derived such that they may be different in reality. Fruit drinks at the proposed MPL did not contribute substantially to the total steviol glycoside estimated dietary exposure (3-7%).

The *Refined baseline* estimated exposures remain conservative and are not considered the most refined estimate of actual dietary exposures as it would be unlikely that all foods within each permitted food category would contain steviol glycosides at maximum concentrations provided by industry or at the MPL where industry data were not provided. In addition, it is unlikely that all foods consumed from permitted food categories would always contain steviol glycosides. Hence, the exposure estimates are unlikely to reflect usual dietary exposures from steviol glycoside-containing foods.

5 Risk characterisation and conclusion

The *Refined* estimated dietary exposures to steviol glycosides did not exceed the ADI for all the population groups assessed both at baseline and if the proposed use in fruit drinks was approved (refer to Figure 3).

Dietary exposure for the *Refined baseline* at the mean and 90th percentile ranged between 35-45% and 55%–90% of the ADI, respectively, across the population groups assessed. For the *Refined extension of use* scenario, dietary exposures at the mean and 90th percentile would be between 35%–45% and between 60%–95% of the ADI, respectively, across all of the population groups assessed. Estimated dietary exposures on average only increase by up to 5% of the ADI between the *Refined baseline* and *Refined extension of use* to fruit drinks scenarios. Therefore the impact of permitting the use of steviol glycosides in fruit drinks on the dietary exposure to steviol glycosides is very small.

The population with the highest exposures were 5-14 year New Zealand population. Their estimated dietary exposure at the 90th percentile was 90% of the ADI for the *Refined baseline* and 95% of the ADI for the *Refined extension of use* scenario. However as discussed above given the concentration data used and only one day of consumption data, the estimate is conservative and exposure in all population groups assessed would likely be lower in reality.

A brand loyalty assessment was undertaken for water based beverages as they contributed to dietary exposure to steviol glycosides. They can therefore be frequently consumed in large quantities due to brand loyalty. Based on the MPL of 200 mg/kg and assuming an average body weight of 70 kg, a person would need to consume 1400 g/day of water based beverages before exceeding the ADI. The 90th percentile consumption for a single day for Australians 2 years and above is 1125 g/day; for New Zealand children 5-14 years it is 830 g/day and for New Zealand adults is 1170 g/day. Therefore it is unlikely that brand loyal high consumers over a lifetime would consume enough to exceed the ADI.

Based on the dietary exposure assessment, it is anticipated that the ADI will not be exceeded by permitting the extension of use of steviol glycosides to fruit drinks at the MPL of 200 mg/kg steviol equivalents.

There are no public health and safety concerns from the extension of use of steviol glycosides in fruit drinks at the proposed level.

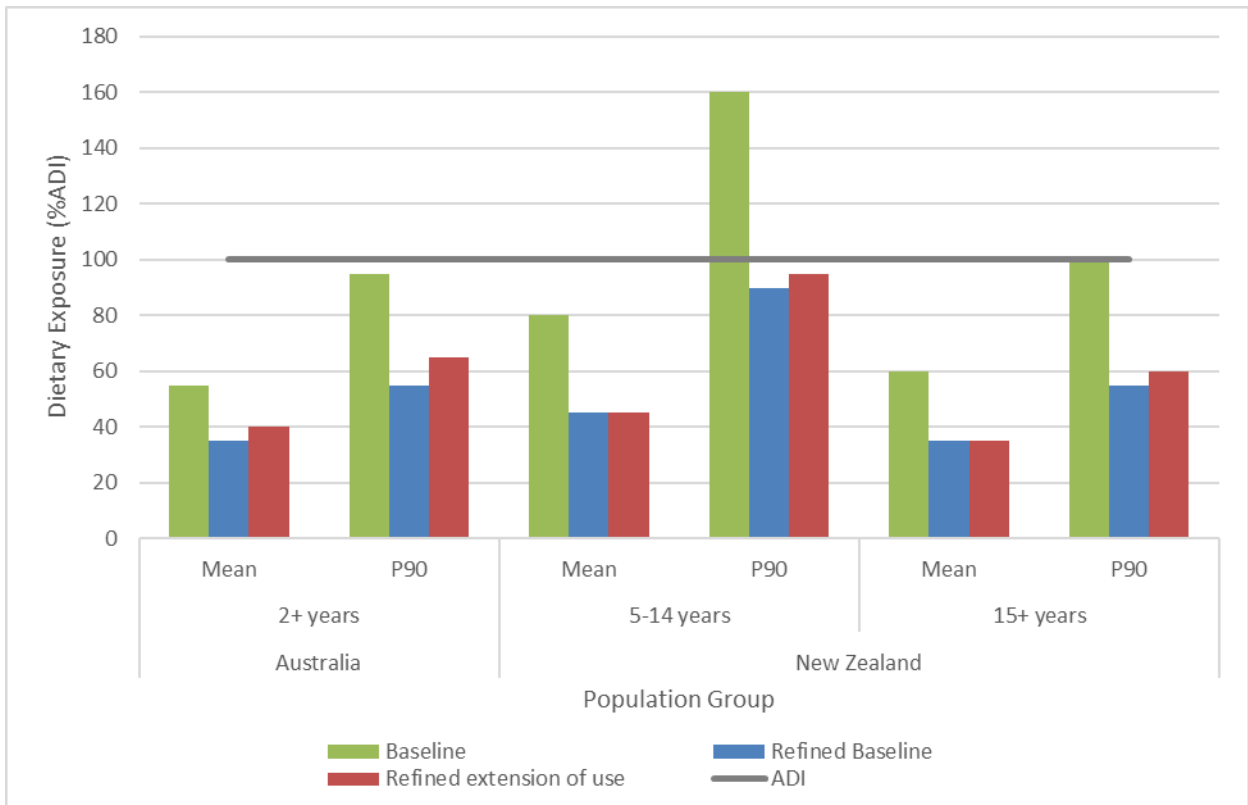


Figure 3 Estimated consumer dietary exposures to steviol glycosides for Australian and New Zealand population groups as a percentage of the Acceptable Daily Intake

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Appendix 1 Dietary Exposure Assessments at FSANZ

A dietary exposure assessment is the process of estimating how much of a food chemical a population, or population sub group, consumes. Dietary exposure to food chemicals is estimated by combining food consumption data with food chemical concentration data. The process of doing this is called 'dietary modelling', where:

Dietary exposure = food chemical concentration x food consumption

FSANZ's approach to dietary modelling is based on internationally accepted procedures for estimating dietary exposure to food chemicals. Different dietary modelling approaches may be used depending on the assessment, the type of food chemical, the data available and the risk assessment questions to be answered. In the majority of assessments FSANZ uses the food consumption data from each person in the national nutrition surveys to estimate their individual dietary exposure. Population summary statistics such as the mean exposure or a high percentile exposure are derived from the ranked individual person's exposures from the nutrition survey.

An overview of how dietary exposure assessments are conducted and their place in the FSANZ Risk Analysis Process is provided on the FSANZ website at:

<http://www.foodstandards.gov.au/science/riskanalysis/Pages/default.aspx>

FSANZ has developed a custom-built computer program 'Harvest' to calculate dietary exposures. Harvest replaces the program 'DIAMOND' that had been used by FSANZ for many years. Harvest has been designed to replicate the calculations that occurred within DIAMOND using a different software package.

Further detailed information on conducting dietary exposure assessments at FSANZ is provided in *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009), available at:

http://www.foodstandards.gov.au/science/exposure/documents/Principles%20_%20practices%20exposure%20assessment%202009.pdf

1.1 Food consumption data used

The most recent food consumption data available were used to estimate steviol glycoside exposures for the Australian and New Zealand populations. The national nutrition survey data used for these assessments were:

- The 2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS)
- The 2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS)
- The 2008-09 New Zealand Adult Nutrition Survey (2008 NZ ANS).

The design of each of these surveys varies somewhat and key attributes of each are set out below. Further information on the national nutrition surveys used to conduct dietary exposure assessments is available on the FSANZ website at

<http://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureandin4438.aspx>.

1.1.1 2011–12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS)

The 2011–12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS), undertaken by the Australian Bureau of Statistics, is the most recent food consumption data for Australia. This survey includes dietary patterns of a sample of 12,153 Australians aged from 2 years and above. The survey used a 24-hour recall method for all respondents, with 64% of respondents (n=7,735) also completing a second 24-hour recall on a second, non-consecutive day. The data were collected from May 2011 to June 2012 (with no enumeration between August and September 2011 due to the Census). Only those respondents who had two days of food consumption data were used to estimate dietary exposures for this assessment. The Day 1 and 2 average provides the best estimates of dietary exposures for Australians aged 2 years and above. Consumption and respondent data from the survey were incorporated into the Harvest program from the Confidentialised Unit Record Files (CURF) data set (ABS 2014). These data were weighted during the calculations undertaken in Harvest.

1.1.2 2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS)

The 2002 NZ CNS was a cross-sectional and nationally representative survey of 3,275 New Zealand children aged 5–14 years. The data were collected during the school year from February to December 2002. The survey used a 24-hour food recall and provided information on food and nutrient intakes, eating patterns, frequently eaten foods, physical activity patterns, dental health, anthropometric measures and nutrition-related clinical measures. It was also the first children's nutrition survey in New Zealand to include a second day diet recall data for about 15% of the respondents, and dietary intake from both foods (including beverages) and dietary supplements. Only the Day 1 24-hour recall data for all respondents (excluding supplements) were used for this assessment. These data were weighted during the calculations undertaken in Harvest.

1.1.3 2008-09 New Zealand Adult Nutrition Survey (2008 NZ ANS)

The 2008 NZ ANS provides comprehensive information on the dietary patterns of a sample of 4,721 respondents aged 15 years and above. The survey was conducted on a stratified sample over a 12-month period from October 2008 to October 2009. The survey used a 24-hour recall methodology with 25% of respondents also completing a second 24-hour recall. The information collected in the 2008 NZ ANS included food and nutrient intakes, dietary supplement use, socio-demographics, nutrition related health, and anthropometric measures. Only the Day 1 24-hour recall data for all respondents (excluding supplements) were used for this assessment. These data were weighted during the calculations undertaken in Harvest.

1.2 Limitations of dietary exposure assessments

Dietary exposure assessments based on 2011-12 NNPAS, 2002 NZ CNS and 2008 NZ ANS food consumption data provide the best estimation of actual consumption of a food and the resulting estimated dietary exposure assessment for the Australian population aged 2 years and above, as well as the New Zealand populations aged 5–14 years and 15 years and above, respectively. However, it should be noted that national nutrition survey data do have limitations. Further details of the limitations relating to dietary exposure assessments undertaken by FSANZ are set out in the FSANZ document, *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009).

Appendix 2 Dietary Exposure Assessment Results

Table 2.1. Estimated mean and P90 dietary exposure [§] to steviol glycosides, expressed as steviol equivalents, for Australia and New Zealand

				Baseline Exposure [¶]				Refined Baseline [‡]				Refined extension of use Exposure			
Country	Age group (years)	Survey respondents (n)	consumers to respondents ratio(%)	Mean		90th percentile		Mean		90th percentile		Mean		90th percentile	
				mg /kg bw/day	Percent of ADI (%)	mg/kg bw/day	Percent of ADI (%)	mg/kg bw/day	Percent of ADI (%)	mg/kg bw/day	Percent of ADI (%)	mg/kg bw/day	Percent of ADI (%)	mg/kg bw/day	Percent of ADI (%)
Australia	2+ [□]	7735	100	2.2	55	3.9	95	1.4	35	2.2	55	1.5	40	2.6	65
New Zealand	5-14 ^ψ	3275	100	3.3	80	6.5	160	1.8	45	3.5	90	1.9	45	3.8	95
	15+ [*]	4721	100	2.3	60	4.1	100	1.4	35	2.2	55	1.5	35	2.3	60

[§] Individual respondents' exposures are divided by their own body weight before deriving mean and P90 dietary exposures.

[¶] Baseline exposure scenario was derived using the Maximum Permitted Levels listed in Schedule 15 of the Food Standards Code.

[‡] Refined exposure scenario was derived using a weighted concentration calculated from industry use and market share data, with the proportion of market share where industry did not provide data the MPL was assigned. Fruit drinks were not included in the refined baseline assessment, and were included in the refined extension of use scenario.

[□] Derived using the Australian 2011-12 NNPAS (2 day average exposure).

^ψ Derived using the NZ CNS 2002 (Day 1 only).

^{*} Derived using the NZ ANS 2008 (Day 1 only).

Table 2.2. Foods contributing to total dietary exposure to steviol glycosides for the *Refined extension of use Dietary Exposure Scenario*

Harvest Classification Code	Harvest Classification Name	Contribution to total dietary exposure (%)		
		Australia	New Zealand	
		2+ years [∞]	5-14 years ^ψ	15+ years [*]
1.1.2	Liquid milk prod & flav liquid milk	1	5	3
1.2.2	Ferm & renn milk prod, flavoured	3	3	2
11.4	Tabletop sweeteners	31	1	18
13.3	Formula meal replacements & formulated supp foods	3	5	2
13.4	Formulated supplementary sports foods	1	0	0
14.1.2.1	Fruit & vegetable juices	1	1	1
14.1.2.2.1	Fruit drink	7	5	3
14.1.2.2.2	Low joule fruit & vegetable juice products	0	0	0
14.1.3	Water based flavoured drinks	10	18	9
14.1.4	Formulated beverages	0	2	0
14.1.5	Coffee (or substitute), tea, herbal infusion & similar	18	2	34
14.1.7.1	Soy beverage, unflavoured	1	0	1
14.1.7.2	Soy beverage, flavoured	0	0	0
20.2.1.1	Desserts, dairy	1	4	1
20.2.1.1.1.2	Desserts, dairy, choc; custard & blanc mange mix/powd	0	0	0
20.2.1.1.3.2	Desserts, dairy, no choc/coffee; custard & blanc mange mix/powd	0	0	0
20.2.1.1.3.2.1	Desserts, dairy, no choc/coffee; custard mix, dry	0	0	0
20.2.1.2	Desserts, no-dairy	0	0	0
20.2.1.2.3.1	Desserts, no-dairy, no choc/coffee; jelly	0	0	0
20.2.6.1	Sauces & syrups, sweet	0	0	0
20.2.6.2	Gravy, sauces & condiments	10	11	9

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Harvest Classification Code	Harvest Classification Name	Contribution to total dietary exposure (%)		
		Australia	New Zealand	
		2+ years [∞]	5-14 years ^ψ	15+ years [*]
20.2.6.2.5	Gravy, sauces & condiments, contains dairy, concentrate	0	0	0
20.2.6.3	Dips & spreads	0	0	0
20.2.6.3.1	Dips, dairy or fat based	0	0	0
20.2.6.3.2	Dips, not dairy or fat based	0	0	0
20.2.6.3.3	Spreads, dairy or fat based	0	0	0
20.2.6.3.4	Spreads, not dairy or fat based	0	0	0
20.2.7	Mayonnaise & salad dressings	1	1	1
21.2.6.3.1	Dips & spreads, homemade, contains dairy	0	0	0
3	Ice cream & edible ices	1	2	0
4.3.2	Fruits & veges in vinegar/oil/brine/alcohol	0	0	0
4.3.4.2	Low joule chutneys, jams & spreads	0	0	0
4.3.6	Fruit & vegetable preparations including pulp	0	2	1
5.1	Chocolate & cocoa products	3	7	3
5.2	Sugar confectionery	2	15	4
6.3	Processed cereal & meal products	1	3	1
7.1.4	Fancy breads	0	1	0
7.2	Biscuits, crackers, cakes, pastries & scones	4	9	5
Grand Total		100	100	100

[∞] Derived using the Australian 2011-12 National Nutrition Physical Activity Survey (2 day average exposure).

^ψ Derived using the New Zealand National Children's Nutrition Survey 2002 (Day 1 only).

^{*} Derived using the New Zealand Adult Nutrition Survey 2008 (Day 1 only).

All % contributions are expressed as a percentage of the total dietary exposure summed for all respondents for all food