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

Intense sweeteners review

Steviol glycosides risk assessment

March 2023

Executive Summary

In 2017 a joint New Zealand Ministry for Primary Industries (MPI)/FSANZ Operational Research Project (ORP) was initiated to review all intense sweeteners permitted in the Australia New Zealand Food Standards Code (the Code). Phase 1 included conducting new or reviewing previous dietary exposure assessments, reviewing relevant ingredient databases and an investigation of consumption data from nutrition surveys.

As the first stage of a tiered approach to the risk assessment, the added sugars replacement screening model was used where all added sugar was assumed to be replaced by each sweetener based on relative sweetness. This method found that only steviol glycosides and cyclamates showed potential to exceed the Acceptable Daily Intake (ADI) for each sweetener. A review of previous dietary exposure assessments performed by FSANZ was then conducted to determine whether other studies had similar conclusions to the added sugars replacement screening model or if there were issues identified with any other intense sweeteners. Of the intense sweeteners investigated cyclamates was the only intense sweetener for which dietary exposure estimates exceeded the ADI (just above the ADI at the high percentile).

For this project, an updated dietary exposure assessment for cyclamates was undertaken based on Maximum Permitted Levels from the Code, no exceedance of the ADI was observed. A refined dietary exposure assessment conducted for steviol glycosides as part of the risk assessment for Application A1149 Steviol Glycosides in Fruit Drinks also found no exceedance. In the assessment for A1149, although estimated dietary exposures for high consuming children approached the ADI (95%), these were based on conservative assumptions.

A review of ingredient databases found steviol glycosides were the most frequently used sweetener in intense sweetened foods in both Australia and New Zealand, with sucralose and cyclamates used less frequently. An investigation into the reported consumption of intense sweetened foods in the 2011-12 Australian and 2002 and 2008 New Zealand National Nutrition Surveys showed that 23% of Australians aged 2 years and above, 11% of New Zealand children aged 5-14 years and 14% of New Zealand adults aged 15 years and above consumed at least one intense sweetened food.

At the conclusion of Phase 1, a number of options for further investigation were considered. It was decided that as a result of the evidence from Phase 1, and public health and safety issues not being identified for the majority of sweeteners, the next stage would consist of an analytical survey for steviol glycosides only. These data could then be used for a refined dietary exposure assessment.

Commencing in 2020, an analytical survey was conducted for steviol glycosides with the objective of determining the concentrations at which they are present in a variety of foods in Australia and New Zealand. These concentrations were subsequently used in a refined dietary exposure assessment for steviol glycosides for Australian and New Zealand populations.

A hazard assessment confirmed the ADI of 0-4 mg/kg bw/day. The estimated dietary exposures to steviol glycosides were well below the ADI (<50%) for the Australian and New Zealand populations assessed. Based on the current evidence available, no public health and safety issues were identified as a result of the risk assessment.

Acknowledgments

Food Standards Australia New Zealand (FSANZ) would like to acknowledge the following agencies for their contributions to the intense sweeteners review and steviol glycoside risk assessment.

The New Zealand Ministry for Primary Industries (MPI) provided input into the design and execution of the risk assessment. MPI also provided funding for sample purchasing and analysis.

The Institute of Environmental Science and Research (ESR) undertook the development and validation of the analytical method for steviol glycosides, purchased all New Zealand samples and analysed all food and beverage samples containing steviol glycosides.

Contents

Background

In 2012 Food Standards Australia New Zealand (FSANZ) made a commitment to monitor two newly approved intense sweeteners: steviol glycosides (assessed in Application A1037 Steviol glycosides: Increase in permitted use levels (FSANZ 2010)) and Advantame (assessed in Application A1034 Advantame as a high intensity sweetener (FSANZ 2011)). This was proposed to be done by obtaining concentration data from analysis or manufacturers' use data and undertaking a dietary exposure assessment (DEA). The scope of this project also included a review of the other nine sweeteners permitted in the Australia New Zealand Food Standards Code (the Code). A joint New Zealand MPI (Ministry for Primary Industries)/FSANZ Operational Research Project (ORP) was commenced in 2017 to cover this work.

Phase 1 of the ORP (Initial Scoping and Research) included conducting new or reviewing previous dietary exposure assessments, reviewing relevant ingredient databases and an investigation of consumption data from nutrition surveys.

Dietary exposure assessment work included an added sugars replacement screening assessment based on the relative sweetness of the intense sweeteners, a review of previously conducted dietary exposure assessments and conducting updated refined dietary exposure assessments. There were no exceedances of health based guidance values for any intense sweeteners for the updated assessments, however estimates of dietary exposure were approaching the Acceptable Daily Intake (ADI) for steviol glycosides for some population groups. Further details of these results can be found in Appendix 1, Tables A1.1, A1.2 and A1.3.

Through a supermarket scan in Australia and review of a New Zealand product database, it was found the intense sweetener used in the highest number of products was steviol glycosides (refer to Appendix 1, Table A1.4).

In an investigation into the reported consumption of intense sweetened foods in the 2011-12 Australian and 2002 and 2008 New Zealand National Nutrition Surveys, 23% of Australians aged 2 years and above, 11% of New Zealand children aged 5-14 years and 14% of New Zealand adults aged 15 years and above consumed at least one intense sweetened food. In Australia, the age group with the highest proportion of consumers was older adults aged 70 years and above (30%) (refer to Appendix 11, Table A1.5).

At the conclusion of Phase 1, a number of options for further investigation were considered. It was decided that as a result of the evidence from Phase 1, and that public health and safety issues were not identified for the majority of the intense sweeteners, the next stage would consist of an analytical survey for steviol glycosides only. These data could then be used for a refined dietary exposure assessment.

Commencing in 2020, an analytical survey was conducted for steviol glycosides with the objective of determining the concentrations at which they are present in a variety of foods. The analytical survey reported full results for each product as the concentrations of each steviol glycoside and also the concentration of total steviol glycosides and steviol equivalents. These data are used in the DEA contained in this assessment, and a summary is provided in Table A2.1.

Hazard Assessment

FSANZ established an ADI for steviol glycosides of 0-4 mg/kg bw/day steviol equivalents in 2008, as a part of application A540 (FSANZ 2008). The ADI was derived by applying a 100-fold safety factor to the No Observed Effect Level (NOEL) of 970 mg/kg bw/day (equivalent to 383 mg/kg bw/day steviol) identified in a two-year study in rats. FSANZ has since updated the hazard assessment for steviol glycosides as part of 10 other applications, of which the most recent is A1222 – Steviol glycosides from Yarrowia lipolytica (FSANZ 2021). These assessments did not identify a need to change the ADI initially established by FSANZ in 2008.

Briefly, all steviol glycosides identified to date share the same metabolic pathway. Steviol glycosides are deglycosylated by microflora in the colon. The remaining steviol core is absorbed into the body and conjugated to steviol glucuronide in the liver. Steviol glucuronide is predominantly excreted in the urine. A recent systematic review concluded that glycosides are not carcinogenic by either genotoxic or nongenotoxic mechanisms (Chappell et al. 2021). The steviol glycosides assessed by FSANZ to date do not exhibit significant homology with known allergens, and there are no case reports of allergy in association with use of highly purified steviol glycosides (Urban et al. 2015).

Dietary Exposure Assessment

Objectives

The objectives of this dietary exposure assessment were to estimate population dietary exposures to steviol glycosides and identify the major food group contributors for Australian and New Zealand population groups.

Approach to the dietary exposure assessment

Dietary exposure assessments require data on the concentration of the chemical of interest in the food requested and consumption data for the foods that have been collected through a national nutrition survey. 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 Harvest[1] and compared to the ADI of 0-4 mg/kg bw/day (steviol equivalents). As food additive permissions in the Food Standards 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/project is on the FSANZ website[2]. A detailed discussion of the FSANZ methodology and approach to conducting dietary exposure/intake assessments is set out in Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2009).

[1] https://www.foodstandards.gov.au/science/exposure/Pages/fsanzdietaryexposure4439.aspx
[2] https://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureandin4438.aspx

Food consumption data

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

- **2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS)**, a one day 24-hour recall of 3,275 New Zealand school children aged 5-14 years, with a second 24-hour recall undertaken for 15% of respondents (New Zealand Ministry of Health 2003)
- **2008-09 New Zealand Adult Nutrition Survey (2008 NZ ANS**), a one day 24-hour recall of 4,721 New Zealanders aged 15 years and above, with a second 24-hour recall undertaken for 25% of respondents (New Zealand Ministry of Health 2011a,b)
- **2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS)**, a one 24-hour food recall of 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% of respondents (Australian Bureau of Statistics (ABS) 2015).

The design of these nutrition surveys vary and the key attributes of each, including survey limitations are in the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2009).

Two days of consumption data were averaged (to better estimate longer term food consumption and dietary exposures) for Australia using the 2011-12 NNPAS, while consumption amounts and dietary exposure estimates for New Zealand were based on a single day of nutrition survey data. Food contributors to dietary exposures for both Australia and New Zealand were also based on a single day of nutrition survey data.

Population groups assessed

The hazard assessment did not identify any population sub-groups with specific safety considerations in relation to dietary exposure to steviol glycosides. In addition, the food classes in which steviol glycosides are currently permitted 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 from each survey are listed in Table 1.

Table 1 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	12,153	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

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 class codes in Schedule 15 of the Code and concentrations of steviol glycosides are assigned to these relevant codes. The food class 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 class code and the corresponding Harvest code are listed in Appendix 2, Table A2.1.

Steviol glycoside concentration data

Commencing in 2020, an analytical survey was conducted for steviol glycosides with the objective of determining the concentrations at which they are present in a variety of commercially available foods in Australia and New Zealand. The survey was not designed for compliance purposes. The survey sampled 123 products from across 25 food classes with samples purchased in Australia and New Zealand. The sampling list was developed by FSANZ using the food classes with current permissions for steviol glycoside in Schedule 15 of the Code, considering the major contributing food categories to steviol glycoside dietary exposure in the FSANZ assessment of A1149 (FSANZ 2019), and food classes where industry use concentration data were unavailable.

The concentrations of the thirteen major steviol glycosides identified by the International Stevia Council (ISC) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as being most significant in food products were measured by the Institute of Environmental Science and Research (ESR) in New Zealand. The analytical method for the determination of steviol glycosides developed and validated by ESR was derived from the JECFA method guidance (FAO/WHO 2020) and aligns closely with the now published JECFA method (FAO/WHO, 2021). However, the method was modified and the concentrations of the steviol glycosides were determined by high-performance liquid chromatography with mass spectrometric detection (LC-MSMS) following sample clean-up and preparation.

Steviol glycoside concentration data from this analytical survey were used in this dietary exposure assessment, along with the Maximum Permitted Levels (MPL) in the Code. Analytical concentrations of steviol glycosides were provided in the 'as purchased' and 'as consumed' forms of each food with a dilution factor used to convert the 'as purchased' concentration to 'as consumed' where relevant, e.g. for beverage powders, cordials, yoghurt mix, jelly mix, biscuit and cake mixes. These dilution factors were derived from the manufacturer's recommended preparation instructions on the product packaging. For the purpose of this dietary exposure assessment, concentration data for the 'as consumed' form of each food were used, except where the food was reported eaten or was used in recipes in the undiluted form. The analysed foods were grouped according to the classes in Schedule 15 of the Code and the Harvest classification system and mean concentrations for each group calculated.

Mean concentrations were used for each food as these were considered to be representative of concentrations of steviol glycosides that a person would consume over a lifetime. This is

appropriate for a food chemical that has an ADI and a chronic dietary exposure assessment is required. As food additive permissions in the Food Standards Code apply to both Australia and New Zealand, and that for some classes there were few products available at the time of sampling, all concentration data were included in calculating the mean concentrations used in the DEA for both countries.

Concentrations of steviol equivalents were used in the dietary exposure assessment. This is because the MPLs in the Code are expressed in this way and it also allows a direct comparison of the estimated dietary exposure with the ADI. Details of the concentration data used in the dietary exposure assessment are in Appendix 2, Table A2.1. There were no concerns identified with analytical concentrations of steviol glycosides compared with MPLs in the Code.

Scenarios used in the dietary exposure assessment

For this assessment, analytical data were not available for all food classes for which there is permission for steviol glycosides in the Code (e.g. 7.1.1 Fancy breads). This was because at the time of sampling (November 2020 to January 2021) there were no products identified from these classes in Australia or New Zealand that contained stevia or steviol glycosides as an ingredient. As products in these food classes may contain steviol glycosides, different scenarios were modelled to account for the potential contribution of these food classes to total dietary exposure.

Three scenarios were assessed:
- *Baseline* – analytical data and MPLs
- *Refined* – analytical data and zero concentration for food groups with no analytical data
- *Refined Market Uptake* – as for Refined with 30% market uptake assumed.

Each scenario is outlined in further detail below.

In the most conservative approach, referred to as the *Baseline* scenario, all classes for which there were no analytical data were given the MPL in the Code. For food classes for which there were analytical data, the mean concentration was applied to all foods within each class. This approach overestimates dietary exposure as it assumes that all foods within each class for which there is a permission to contain steviol glycosides do contain steviol glycosides, and that all foods within classes where there were no analytical data contain steviol glycosides at the MPL.

In a less conservative approach, referred to as the *Refined* scenario, all classes for which there were no analytical data were given the concentration of zero for steviol glycosides. For food classes for which there were analytical data, the mean concentration was applied to all foods within each class with some classes (e.g. water based flavoured drinks) divided into sub classes. This approach may also produce an overestimation of the estimated dietary exposure as it assumes that all foods within each class for which there is permission and use of steviol glycosides identified, contain steviol glycosides at the mean concentration.

In the least conservative approach, referred to as the *Refined-Market Uptake* scenario, the same concentrations were applied as in the *Refined* scenario, with a 30% market uptake adjustment applied to each concentration as a way of assuming that 30% of products within each class contain steviol glycosides. This approach is consistent with that used internationally by JECFA (2004) and in the assessment of A1037 (FSANZ 2010), and although less conservative is still likely to provide an overestimation of actual dietary exposure.

A brand loyalty assessment was not undertaken for this risk assessment. Brand loyalty assessments are used to assess if someone who always consumes one brand of a food at a

high amount that has the highest concentration within that class would have any issues in terms of public health and safety. A brand loyalty assessment was undertaken for steviol glycosides as part of A1149 (FSANZ 2019) based on the MPLs. That assessment did not identify any issues, and as concentrations obtained via the analytical survey were less than the MPLs, a brand loyalty assessment was deemed to not be necessary for this risk assessment.

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:

- In the *Baseline* scenario all foods in classes for which there is permission in the Code for steviol glycosides contain steviol glycosides.
- In the *Baseline* scenario all foods in classes for which there is permission in the Code but for which there are no analytical data, contain steviol glycosides at the MPL.
- In the *Refined* and *Refined – Market Uptake* scenarios, all foods in classes for which there are analytical data contain steviol glycosides.
- In the *Refined* and *Refined – Market Uptake* scenarios, all foods in classes for which there are no analytical data do not contain steviol glycosides.
- Steviol glycoside concentrations in foods available in Australia are the same as in foods available in New Zealand and vice versa.
- 1 mL = 1 g.
- Where a food has a specified steviol glycoside concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. flavoured yoghurt in smoothies.
- There are no changes in steviol glycoside concentrations due to cooking e.g. baking cakes and biscuits.
- There are no other contributions to steviol glycoside dietary exposure, for example through the use of dietary supplements or medicines.

These assumptions, particularly the first two listed, are likely to lead to a considerable overestimate for steviol glycoside dietary exposure, as together they assume that every food in every specified food class contains steviol glycosides. For example, there is permission for fruit and vegetable juices to contain steviol glycosides to a MPL of 50 mg/kg. Products in this class include fresh, sweetened, fortified and concentrated, pure and blended fruit and vegetable juices. Only the sweetened versions of these products are likely to contain steviol glycosides. However for the purposes of the dietary exposure assessment, every juice in this class is assumed to contain steviol glycosides.

Limitations of this dietary exposure assessment include:

- In the *Baseline* scenario, where there were no analytical concentration data available for classes where there is permission for steviol glycosides the MPL was used. This results in a mixture of maximum and actual concentration data being used in the dietary exposure assessment which has likely skewed the real percentage of food contributors to steviol glycoside dietary exposures.
- Foods were mostly analysed in the ‘as purchased’ form. Therefore for foods where cooking would be required prior to consumption (i.e. biscuit and cake mixes), any

changes in individual steviol glycoside concentrations as a result of this process were not accounted for in the dietary exposure assessment.
- As only one day of food consumption data are available from New Zealand nutrition surveys, the estimated dietary exposures are likely to be overestimated (particularly at the high percentiles of exposure) given that two days of survey data is more appropriate for estimating longer term consumption and therefore dietary exposure.
- The market has changed since the sampling of foods for analysis for this assessment was conducted, with new products and different formulations available. Products available in Australia and New Zealand today may be different to those included in the analytical program.

In addition to the specific assumptions made and limitations identified in relation to this dietary exposure assessment, there are a number of limitations associated with the nutrition surveys from which the food consumption data used for the assessment are based. A discussion of these limitations is included in Section 6 of the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2009).

Dietary exposure assessment results

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 or has an assigned concentration. For this assessment, almost all survey respondents were consumers of steviol glycosides (see Appendix 2, Table A2.2) given the broad range of commonly consumed foods in which they are permitted to be used. In Table A2.2 the proportion of consumers is reported as the weighted[3] proportion of consumers to respondents for all surveys.

The estimates of dietary 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 *Baseline* scenario the mean and 90th percentile of estimated dietary exposures for Australian and New Zealand consumers ranged from 0.5-0.9 mg/kg bw/day (10-20% of the ADI) and 0.8-1.7 mg/kg bw/day (20-40% of the ADI), respectively.

For the *Refined* scenario the mean and 90th percentile of estimated dietary exposures for Australian and New Zealand consumers ranged from 0.4-0.7 mg/kg bw/day (10-15% of the ADI) and 0.7-1.4 mg/kg bw/day (15-35% of the ADI), respectively.

For the *Refined-Market Uptake* scenario the mean and 90th percentile of estimated dietary exposures for Australian and New Zealand consumers ranged from 0.1-0.2 mg/kg bw/day (3-5% of the ADI) and 0.2-0.4 mg/kg bw/day (5-10% of the ADI), respectively.

Detailed results of the estimates of dietary exposure to steviol glycosides for all scenarios and population groups assessed can be found at Appendix 2 Table A2.2, and Figure 4.

[3] Survey sample weighting factors are used to adjust the results of surveys to better reflect the results that would have been obtained if a truly representative sample from the population had been able to be obtained, and to make population based estimations of results.

Food groups where steviol glycosides are permitted that contribute to dietary exposure

The major food contributors to the estimated dietary exposures based on day one of each survey were calculated for each scenario and for each population group assessed.

The foods that were major contributors to the total estimate of steviol glycoside dietary exposure (providing ≥5%) were calculated from consumers exposure from all foods included in the scenarios. These results should be interpreted with caution given the assumptions and limitations of the concentration data used for the assessment including the use of MPLs across some of the foods included. This mixture of MPLs and analytical concentrations within the one scenario may skew the foods contributing to the dietary exposure and may not truly reflect the contributors in reality.

There was no difference in the percent contributions for each of the food groups to total dietary exposure between the *Refined* and *Refined – Market Uptake* scenarios, so only the results for the *Baseline* and *Refined* scenarios are reported here.

For the *Baseline* scenario the food group 'Coffee (or substitute), tea, herbal infusion & similar' was the largest contributor to total steviol glycoside exposure for the Australian population aged 2 years and above (17%), and the New Zealand population aged 15 years and above (27%). Assuming that these foods (which are highly consumed by adult population groups) contribute the most to steviol glycoside exposure is unrealistic. Analytical data were collected for powdered coffee/tea/beverage sachet style products and this concentration was assigned to all tea and coffee, including regular brewed, therefore will be an overestimate of the consumption of steviol glycoside containing products. In addition the use of tabletop sweeteners in tea and coffee where reported in the national surveys is accounted for in food class 11.4 – Tabletop sweeteners. Across all population groups and all scenarios assessed, tabletop sweeteners contribute 5% or less to total steviol glycoside dietary exposure. The major contributors to steviol glycoside dietary exposure for New Zealand children aged 5-14 years were 'Water based flavoured drinks' and 'Biscuits, crackers, cakes, pastries & scones', both at 17%. These food groups were also major contributors for the Australian population aged 2 years and above and New Zealand adults aged 15 years and above.

For the *Refined* scenario the food groups 'Water based flavoured drinks' and 'Coffee (or substitute), tea, herbal infusion & similar' were the largest contributors to total steviol glycoside exposures for the Australian population aged 2 years and above (both 19%). 'Water based flavoured drinks' was also the largest contributor for New Zealand children aged 5-14 years (24%). For the New Zealand population aged 15 years and above, the food group 'Coffee or substitute, tea, herbal infusion & similar' was the largest contributor to steviol glycoside exposures at 31%, followed by 'Gravy, sauces and condiments' at 19%. Within the food class of 'Water based flavoured drinks', brewed soft drinks contributed less than 1% of total exposure to steviol glycosides for all Australian and New Zealand population groups. Electrolyte drinks contributed 1% to total steviol glycoside exposure for the Australian population aged 2 years and above, and less than 1% to total steviol glycoside exposure for both New Zealand population groups.

Several other food categories were major contributors to total steviol glycoside exposure for the different population groups assessed. Further details of the contributions to dietary exposure of all food categories where steviol glycosides are permitted or used for the *Baseline* and *Refined* scenarios can be found in Appendix 2 Tables A2.3 and A2.4, and Figures 1 to 3.

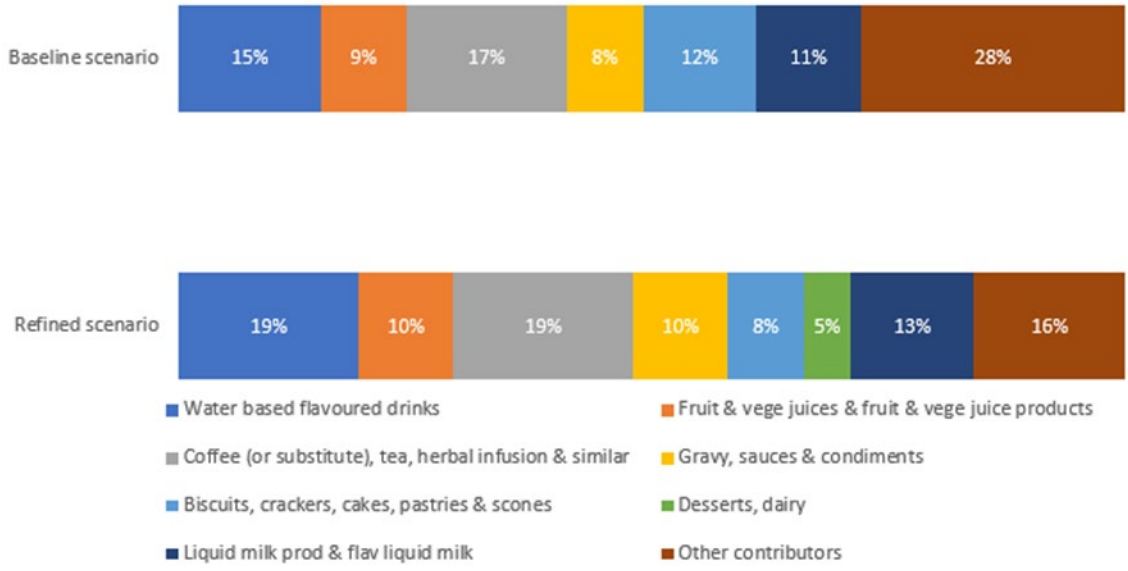

Figure 1 Major (≥5%) contributing food categories to steviol glycoside dietary exposure for the Australian population aged 2 years and above for the *Baseline* and *Refined* scenarios

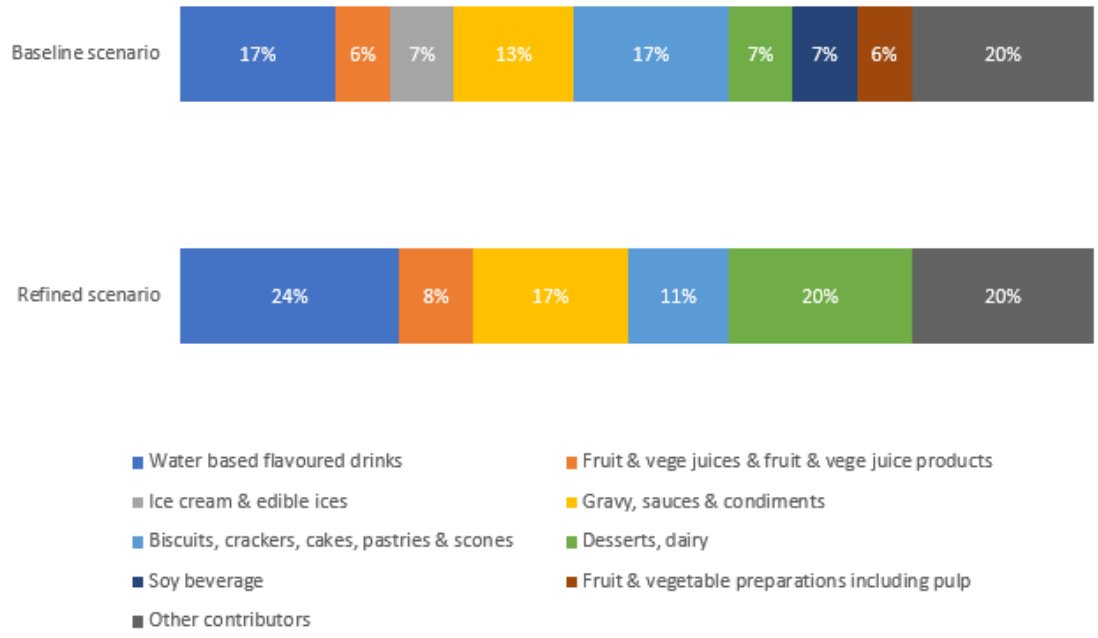

Figure 2 Major (≥5%) contributing food categories to steviol glycoside dietary exposure for the New Zealand population group aged 5-14 years for the *Baseline* and *Refined* scenarios

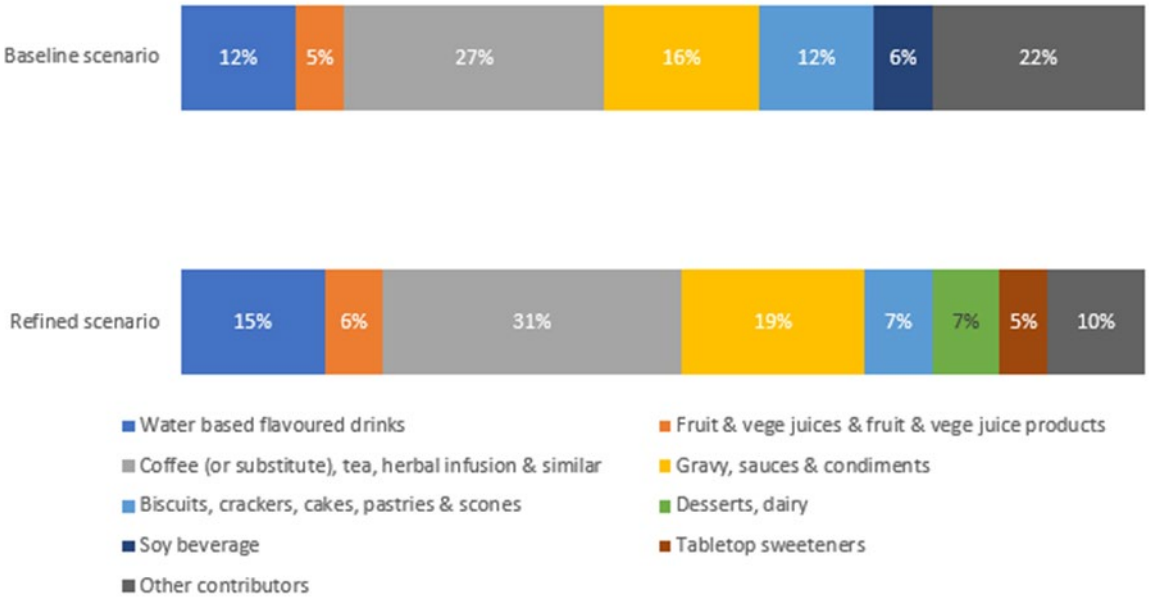

Figure 3 Major (≥5%) contributing food categories to steviol glycoside dietary exposure for the New Zealand population group aged 15 years and above for the *Baseline* and *Refined* scenarios

Risk characterisation and conclusion

Across all three scenarios, the estimated dietary exposures to steviol glycosides were well below the ADI for all the population groups assessed.

Dietary exposure for the *Baseline* scenario at the mean and 90th percentile ranged between 10-20% and 20-40% of the ADI, respectively, across the population groups assessed (Figure 4). For the *Refined* scenario, dietary exposures at the mean and 90th percentile were between 10-15% and 15-35% of the ADI, respectively across the population groups assessed. For the *Refined-Market Uptake* scenario, dietary exposures at the mean and 90th percentile were between 3-5% and 5-10% of the ADI, respectively, across the population groups assessed.

Water based flavoured drinks were a major contributor to total steviol glycoside exposures for all scenarios and population groups assessed (12-24%).

Based on the current evidence available for this assessment, there are no public health and safety concerns identified from the current use of steviol glycosides in the Australian and New Zealand food supply.

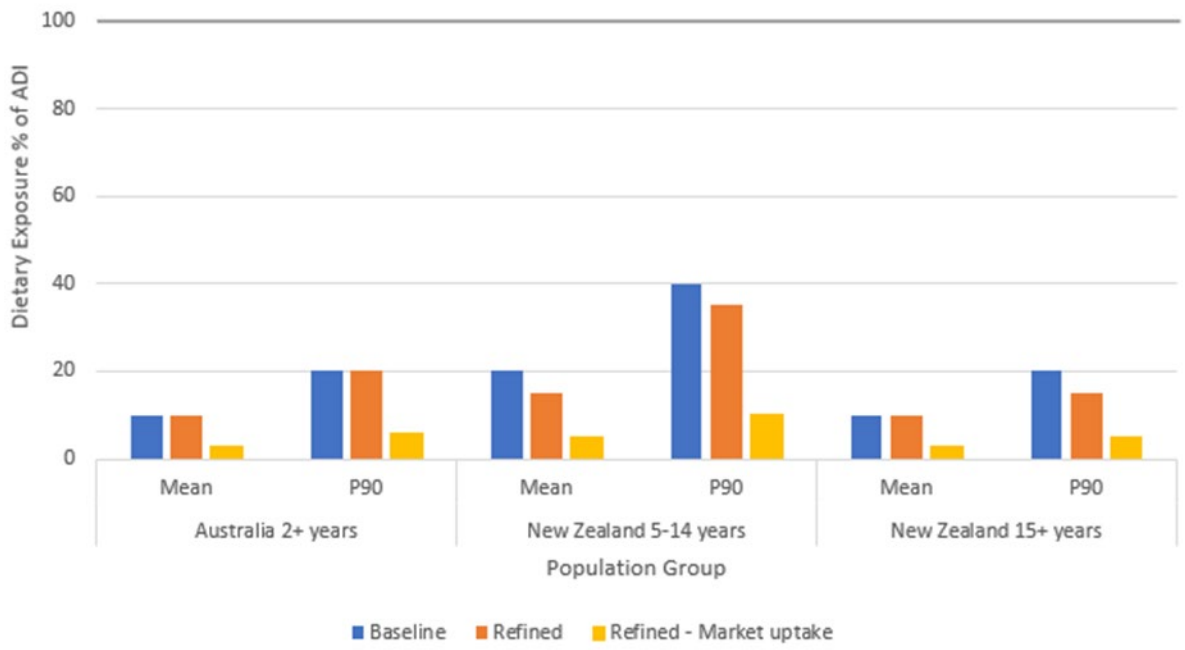

Figure 4 Estimated consumer dietary exposures to steviol glycosides for Australian and New Zealand population groups as a percentage of the Acceptable Daily Intake

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Appendix 1

Phase 1 of the Intense Sweeteners Review Operational Research Project (ORP) included conducting new or reviewing previous dietary exposure assessments, reviewing relevant ingredient databases and an investigation of consumption data from nutrition surveys. The findings from Phase 1 were used to inform the direction of Phase 2 (analytical survey of steviol glycosides).

Further details of the dietary exposure assessments undertaken during Phase 1 of the ORP are as follows:

- A tiered dietary exposure assessment approach was used to estimate dietary exposure to intense sweeteners. Initially, an added sugars replacement screening model[4] was conducted. This method assumed the replacement of the usual intake of added sugar, derived from national nutrition surveys[5, 6], with an intense sweetener based on its relative sweetness. This method found that estimates of dietary exposure for cyclamates and steviol glycosides, out of the twelve sweeteners assessed, exceeded the Acceptable Daily Intake (ADI) (refer to Table A1.1).
- A review of previous dietary exposure assessments conducted by FSANZ[7,8,9,10]was conducted to determine whether other studies had similar conclusions to the added sugars replacement screening model or if there were issues identified with any other intense sweeteners. FSANZ found that of the intense sweeteners investigated cyclamates was the only intense sweetener for which exposure estimates exceeded the ADI (refer to Table A1.2), however was only just exceeding the ADI and only at the high percentile.
- Using only the food groups where each sweetener is permitted in the Code, refined DEAs were then conducted for cyclamates and steviol glycosides. The refined dietary exposures were below the ADI for both cyclamates and steviol glycosides at the mean and 90th percentile of exposure (refer to Table A1.3). Estimates of dietary exposure to steviol glycosides were up to 95% of the ADI for high consuming children.
- To investigate the current use of intense sweeteners in products in the Australian and New Zealand food supply an online supermarket scan was conducted for Australia, and review of Nutritrack data from the University of Auckland Nutriweb packaged food

[4]https://www.foodstandards.gov.au/media/SiteAssets/Pages/posters/FSANZ2018_SweetenersNSAConferencePosters.pdf
[5] Australian Bureau of Statistics (2016) Australian Health Survey: Consumption of added sugars, 2011-12. https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/4364.0.55.011~2011-12~Main%20Features~Key%20Findings~1
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database was conducted for New Zealand to identify products that contain intense sweeteners. In both Australia and New Zealand, steviol glycosides was the most frequently used intense sweetener in foods and beverages (refer to Table A1.4).

- The final part of Phase 1 of the ORP was an assessment of the proportions of respondents to the 2011-12 Australian and 2002 and 2008 New Zealand National Nutrition Surveys who reported consuming intense sweetened foods and/or beverages. In Australia, 23% of the population aged 2 years and above, and in New Zealand, 11% and 14% of the population aged 5-14 years and 15 years and above, respectively, reported consuming a food containing intense sweeteners (refer to Table A1.5).

Table A1.1 Estimated dietary exposure to intense sweeteners using an added sugars replacement screening model [a]

Intense sweetener	Relative sweetness to sucrose	ADI [b] (mg/kg bw/day)	Percent of ADI (%) [c]			
			Australia [d] (Female, Male)		New Zealand [e] (Female, Male)	
			Mean	P90	Mean	P90
Acesulphame-potassium	200	15	15, 25	40, 50	25, 25	45, 50
Aspartame	180	40	10,10	15, 20	10, 10	20, 20
Aspartame-acesulphame salt [f]	350	37.1	0, 6	0, 10	6, 6	10, 10
Advantame	20000	5	1, 1	1, 1	1, 1	1, 1
Alitame	2000	1	35, 40	60, 75	35, 40	65, 75
Cyclamates	30	11	210*, 240*	380*, 450*	220*, 250*	410*, 460*
Monk fruit extract	250 - 400	Not specified	–	–	–	–
Neotame	8000	2	4, 5	8, 9	4, 5	8, 10
Saccharin	300	5	45, 55	85, 100	50, 55	90, 100
Steviol glycosides	200	4	85, 100	160*, 190*	90, 100	170*, 190*
Sucralose	600	15	8, 9	15, 15	8, 9	15, 15
Thaumatin	2000	Not specified	–	–	–	–

[a] Screener method assumes replacement of all added sugars with sweetener at its relative sweetness to sucrose.
[b] Acceptable Daily Intake; upper end of the ADI range.
[c] The upper end of the ADI range used for the calculation.
Mean - exposure for respondents, P90 - 90th percentile exposure for consumers only.
[d] Intake of added sugars is the Usual Intake derived from the 2011-12 National Nutrition and Physical Activity Survey of the Australian population 2 years and above, and [e] the 2008 NZ Adult Nutrition Survey of New Zealand population 15 years and above.
[f] Aspartame-acesulphame salt does not have a specific ADI. The salt dissociates into aspartame and acesulphame which have been assessed separately and had an ADI determined for each. The ADI of 31.7 is based on the ADI of each intense sweetener and accounts for the 2:1 ratio of aspartame and acesulphame to form the aspartame-acesulphame salt.
**Indicates an exceedance of the ADI.*

Table A1.2. Estimated dietary exposure to intense sweeteners (IS) as a percentage of the Acceptable Daily Intake (ADI)[7, 8, 9]

	Percent of ADI (%)							
	2003 IS Survey [a]				1995 IS Survey [a]		Proposal P150 [b]	
	Australia		New Zealand		Australia		Australia	
Intense sweetener	Mean	P90	Mean	P90	Mean	P90	Mean	P95
Acesulphame-potassium	3	6	2	6	<0.5	3	36	99
Aspartame	6	14	4	10	6	23	3	12
Aspartame-acesulphame salt [a]	–	–	–	–	–	–	–	–
Advantame	–	–	–	–	–	–	–	–
Alitame	–	–	–	–	–	–	22	91
Cyclamates	20	75	14	68	8	107 *	4	107 *
Neotame	–	–	–	–	–	–	–	–
Saccharin	7	31	4	15	3	56	3	66
Steviol glycosides	–	–	–	–	–	–	–	–
Sucralose	1	6	3	11	–	–	<0.5	11
Thaumatin	–	–	–	–	–	–	–	–

[a] Survey of population 12 years and above. Mean - exposure for respondents. P90 - 90th percentile exposure for consumers only.
[b] P150 Maximum Permitted Level of sweeteners used as the concentration in the dietary exposure assessment. 1995 National Nutrition Survey data of population 2 years and above. Mean – exposure for respondents. P95 – 95th percentile exposure consumers only.
**Indicates an exceedance of the ADI.*

Table A1.3. Estimated dietary exposures to cyclamates and steviol glycosides using Harvest and national nutrition survey data*

		Mean		90th percentile	
	Population group	mg/kg bw/day	% ADI	mg/kg bw/day	% ADI
Cyclamates at the MPL[a]	Australia 2 years and above	2.9	25	6.5	60
	New Zealand 5-14 years	5.2	45	10	90
	New Zealand 15+ years	1.9	15	4.1	40
Steviol glycosides refined assessment from A1149[10, b]	Australia 2 years and above	1.5	40	2.6	65
	New Zealand 5-14 years	1.9	45	3.8	95
	New Zealand 15+ years	1.5	35	2.3	60

[a] MPL -Maximum Permitted Levels, as specified in the Food Standards Code. New data, not previously published.
[b] Industry concentration data and market share data used in dietary exposure refinement.
** Australia 2 years and above based on 2 days of consumption data from the 2011-12 National Nutrition and Physical Activity Survey. New Zealand 5-14 years, 2002 New Zealand National Children's Nutrition Survey and New Zealand 15+ years, 2008 New Zealand Adult Nutrition Survey; one day of data only.*

Table A1.4 Intense sweetened products in the Australian and New Zealand marketplace*

Intense sweetener	Number of Products ᵡ (% of products identified)	
	Australia (n=205)	New Zealand (n=190)
Acesulphame potassium	58 (28)	16 (8)
Advantame	0 (0)	0 (0)
Alitame	0 (0)	0 (0)
Aspartame	22 (11)	4 (2)
Aspartame-acesulphame salt	0 (0)	0 (0)
Cyclamates	21 (10)	23 (12)
Neotame	3 (1)	0 (0)
Saccharin	0 (0)	31 (16)
Steviol glycosides	123 (60)	109 (57)
Sucralose	69 (34)	29 (15)
Thaumatin	4 (2)	2 (1)

**Products were identified for Australia through an online search of two major Australian supermarkets in 2017-2018, and for New Zealand through the Nutriweb database; a University of Auckland packaged food database collated in store via a smart phone application from major New Zealand supermarkets.*
Does not include monk fruit extract as this evaluation was conducted before it was approved for use.
ᵡ As some products contain more than one intense sweetener, the sum of the number of products containing each sweetener is greater than the total number of products included in the investigation.

Table A1.5 Consumers of intense sweetened foods as reported in the Australian and New Zealand National Nutrition Surveys*

Country	Age group (years)	Number of consumers	Consumer to respondent ratio (%)
Australia	**2+**	1803	23
	2-5	29	7
	6-12	84	12
	13-18	104	17
	19-69	1375	26
	70+	213	30
New Zealand	**5-14**	374	11
	15+	659	14

**Australia 2 years and above based on 2 days of consumption data from the 2011-12 National Nutrition and Physical Activity Survey. New Zealand 5-14 years, 2002 New Zealand National Children's Nutrition Survey and New Zealand 15+ years, 2008 New Zealand Adult Nutrition Survey; one day of data only*.

Appendix 2

Table A2.1 Food classifications and concentrations of steviol glycosides (as steviol equivalents) used in the dietary exposure assessment for the *Baseline* scenario

Food Standards Code food class code	Food Standards Code food class name	Number of samples	Harvest classification code	Harvest classification name	Concentration used in dietary exposure assessment scenario at *Baseline* (mg/kg steviol equivalents)
1.1.2	Liquid milk products and flavoured liquid milk	4	1.1.2	Liquid milk prod & flav liquid milk	NR
1.2.2	Fermented milk products and rennetted milk products	6	1.2.2	Ferm & renn milk prod, flavoured	34
3	Ice cream and edible ices	8	3	Ice cream & edible ices	67
4.3.2	Fruits and vegetables in vinegar, oil, brine or alcohol	0	4.3.2	Fruits & veges in vinegar/oil/brine/alcohol	160*
4.3.4.1	Low joule chutneys, low joule jams and low joule spreads	1	4.3.4.2	Low joule chutneys, jams & spreads	NR
4.3.6	Fruit and vegetable preparations including pulp	0	4.3.6	Fruit & vegetable preparations including pulp	210*
5.1	Chocolate and cocoa products	7	5.1	Chocolate & cocoa products	56
5.2	Sugar confectionery	2	5.2	Sugar confectionery	NR
6.3	Processed cereal and meal products	1	6.3	Processed cereal & meal products	NR
			20.2.2.3	Cereal products, bars	NR
7.1.1	Fancy breads	0	7.1.4	Fancy breads	160*
7.2	Biscuits, cakes and pastries	6	7.2	Biscuits, crackers, cakes, pastries & scones	120
11.4	Tabletop sweeteners	9	11.4	Tabletop sweeteners	28,000

Food Standards Code food class code	Food Standards Code food class name	Number of samples	Harvest classification code	Harvest classification name	Concentration used in dietary exposure assessment scenario at *Baseline* (mg/kg steviol equivalents)
13.3 13.4	Formulated meal replacements and formulated supplementary foods Formulated supplementary sports foods	28	13.3 13.4	Formula meal replacements & formulated supp foods Formulated supplementary sports foods	27- 65
14.1.2.1	Fruit and vegetable juices	8	14.1.2	Fruit & vege juices & fruit & vege juice products	29
14.1.2.2.1	Fruit Drink				
14.1.2.2.2	Low joule fruit and vegetable juice products				
14.1.2.2.3	Soy bean beverage (plain or flavoured)	0	14.1.7	Soy beverage	100*, 200*
14.1.3	Water based flavoured drinks	23	14.1.3	Water based flavoured drinks	21
14.1.4	Formulated Beverages	1	14.1.4	Formulated beverages	NR
14.1.5	Coffee, coffee substitutes, tea, herbal infusions and similar products	6	14.1.5	Coffee (or substitute), tea, herbal infusion & similar	15
			20.1.3.3.2	Beverages, non-alcoholic, beverages bases, ready to drink	NR
20.2.0.1	Custard mix, custard powder and blancmange powder	0	6.2.3	Flours, meals and starches, unspecified grain	80*
20.2.0.2	Jelly	4	20.2.1.4.1	Desserts, non-dairy, jelly	NR
20.2.0.3	Dairy and fat based desserts, dips and snacks (only dairy and fat based dessert products)	1	20.2.1.3	Desserts, dairy	NR
		0	20.2.1.4.7	Desserts, non-dairy, other	150*
20.2.0.4	Sauces and toppings (including mayonnaises and salad dressings)	8	20.2.6.1	Sauces & syrups, sweet	NR
			20.2.6.2	Gravy, sauces & condiments	51
			20.2.7	Mayonnaise & salad dressings	NR

** Maximum Permitted Level.*
NR – mean concentration used in the dietary exposure assessment but not reported in the table as <5 samples analysed.

Table A2.2 Estimated mean and 90th percentile dietary exposure to steviol glycosides, expressed as steviol equivalents, for Australia and New Zealand β

				Baseline scenario				*Refined* scenario				*Refined – Market Uptake* scenario ∩			
				Mean		P90		Mean		P90		Mean		P90	
Country	Age group (years)	Survey respondents (n)	Consumer to respondent ratio (%)	mg/kg bw/day	% of ADI	mg/kg bw/day	% of ADI	mg/kg bw/day	% of ADI	mg/kg bw/day	% of ADI	mg/kg bw/day	% of ADI	mg/kg bw/day	% of ADI
Australia	**2+** □	7735	99-100	0.5	10	0.9	20	0.4	10	0.7	20	0.1	3	0.2	6
New Zealand	**5-14** ψ	3275	99-100	0.9	20	1.7	40	0.7	15	1.4	35	0.2	5	0.4	10
	15+ *	4721	99-100	0.5	10	0.8	20	0.4	10	0.7	15	0.1	3	0.2	5

P90 – 90th percentile.
β Individual respondents' exposures are divided by their own body weight before deriving mean and P90 dietary exposures.
∩ Refined – Market Uptake dietary exposure scenario was derived assuming 30% market uptake.
□ Derived using the Australian 2011-12 NNPAS (2 day average exposure).
ψ Derived using the 2002 NZ CNS (Day 1 only).
** Derived using the 2008 NZ ANS (Day 1 only).*

Table A2.3 Foods contributing to total dietary exposure to steviol glycosides for the *Baseline* dietary exposure scenario

Note: These results should be interpreted with caution given the assumptions and limitations of the concentration data used for the assessment including the use of MPLs across some of the foods included. This mixture of MPLs and analytical concentrations within the one scenario may skew the foods contributing to the dietary exposure and may not truly reflect the contributors in reality.

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	11	1	1
1.2.2	Ferm & renn milk prod, flavoured	2	2	2
3	Ice cream & edible ices	4	7	2
4.3.2	Fruits & veges in vinegar/oil/brine/alcohol	1	1	1
4.3.4.2	Low joule chutneys, jams & spreads	<1	<1	<1
4.3.6	Fruit & vegetable preparations including pulp	3	6	3
5.1	Chocolate & cocoa products	1	2	1
5.2	Sugar confectionery	<1	1	<1
6.2.3	Flours, meals and starches, unspecified grain	<1	<1	<1
6.3	Processed cereal & meal products¥	2	3	2
7.1.4	Fancy breads	1	2	1
7.2	Biscuits, crackers, cakes, pastries & scones	12	17	12
11.4	Tabletop sweeteners	3	<1	4
13.3	Formula meal replacements & formulated supp foods	2	2	1
13.4	Formulated supplementary sports foods			
14.1.2	Fruit & vege juices & fruit & vege juice products	9	6	5
14.1.3	Water based flavoured drinks	15	17	12
14.1.4	Formulated beverages	<1	1	<1

14.1.5	Coffee (or substitute), tea, herbal infusion & similar	17	2	27
14.1.7	Soy beverage	3	7	6
20.2.1.3	Desserts, dairy	2	7	2
20.2.1.4.1	Desserts, non-dairy, jelly	1	1	<1
20.2.1.4.7	Desserts, non-dairy, other	<1	0	0
20.2.6.1	Sauces & syrups, sweet	2	2	2
20.2.6.2	Gravy, sauces & condiments	8	13	16
20.2.7	Mayonnaise & salad dressings	<1	<1	<1
Grand Total		100	100	100

[∞] *Derived using the Australian 2011-12 National Nutrition Physical Activity Survey (Day 1 only).*
[ψ] *Derived using the 2002 NZ CNS (Day 1 only).*
[*] *Derived using the 2008 NZ ANS (Day 1 only).*
[¥] *Includes cereal products, bars.*

All % contributions are expressed as a percentage of the total dietary exposure summed for all respondents for all food. Shading indicates that the food group is a major contributor (providing ≥5%) *to total steviol glycoside exposure.*

Table A2.4 Foods contributing to total dietary exposure to steviol glycosides for the *Refined* dietary exposure scenario

Note: These results should be interpreted with caution given the assumptions and limitations of the concentration data used for the assessment. This mixture of analytical concentrations and zero concentrations within one scenario may skew the foods contributing to the dietary exposure and may not truly reflect the contributors in reality.

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	13	3	2
1.2.2	Ferm & renn milk prod, flavoured	3	2	2
3	Ice cream & edible ices	1	3	<1
4.3.2	Fruits & veges in vinegar/oil/brine/alcohol	0	0	0
4.3.4.2	Low joule chutneys, jams & spreads	<1	<1	<1
4.3.6	Fruit & vegetable preparations including pulp	0	0	0
5.1	Chocolate & cocoa products	1	3	1
5.2	Sugar confectionery	<1	1	<1
6.2.3	Flours, meals and starches, unspecified grain	0	0	0
6.3	Processed cereal & meal products¥	<1	1	<1
7.1.4	Fancy breads	0	0	0
7.2	Biscuits, crackers, cakes, pastries & scones	8	11	7
11.4	Tabletop sweeteners	4	<1	5
13.3	Formula meal replacements & formulated supp foods	2	2	1
13.4	Formulated supplementary sports foods			
14.1.2	Fruit & vege juices & fruit & vege juice products	10	8	6
14.1.3	Water based flavoured drinks	19	24	15
14.1.3.1.2	Non-brewed soft drink, electrolyte drink/base	1	<1	<1

14.1.3.2	Brewed soft drink	<1	<1	<1
14.1.4	Formulated beverages	<1	2	<1
14.1.5	Coffee (or substitute), tea, herbal infusion & similar	19	2	31
14.1.7	Soy beverage	0	0	0
20.2.1.3	Desserts, dairy	5	20	7
20.2.1.4.1	Desserts, non-dairy, jelly	1	1	<1
20.2.1.4.7	Desserts, non-dairy, other	0	0	0
20.2.6.1	Sauces & syrups, sweet	2	1	2
20.2.6.2	Gravy, sauces & condiments	10	17	19
20.2.7	Mayonnaise & salad dressings	<1	<1	<1
Grand Total		100	100	100

^∞ *Derived using the Australian 2011-12 National Nutrition Physical Activity Survey (Day 1 only).*
^Ψ *Derived using the 2002 NZ CNS (Day 1 only).*
^* *Derived using the 2008 NZ ANS (Day 1 only).*
^¥ *Includes cereal products, bars.*

All % contributions are expressed as a percentage of the total dietary exposure summed for all respondents for all food. Shading indicates that the food group is a major contributor (providing ≥5%) *to total steviol glycoside exposure.*