21 March 2019
[75-19]

Approval report – Application A1149

Addition of steviol glycosides to fruit drinks

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

On 9 October 2018, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 12 submissions.

FSANZ approved the draft variation on 6 March 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 21 March 2019.

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

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website:

SD1 Food technology, hazard and dietary exposure assessment

Executive summary

FSANZ has assessed an application from the Australian Beverage Council Limited (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 are an intense sweetener already permitted in a range of foods.

The food technology assessment concluded that the use of steviol glycosides as a food additive in fruit drinks as an intense sweetener is technologically justified in the quantity and form proposed. Steviol glycosides have international specifications established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and also accepted specifications in section S3—2(1)(a) of the Code.

The safety assessment concluded that toxicological and other relevant data published subsequent to FSANZ's previous assessments of steviol glycosides raised no safety concerns. It did not indicate a need to amend the acceptable daily intake (ADI) of 0-4 mg/kg bw for steviol glycosides, expressed as steviol. This was previously established by FSANZ and JECFA.

The dietary exposure assessment concluded that the ADI will not be exceeded by permitting the extension of use for steviol glycosides in fruit drinks at the MPL of 200 mg/kg steviol equivalents. Dietary exposures to steviol glycosides for Australian and New Zealand consumers were estimated based on industry use data in food categories where steviol glycosides are permitted. Estimated dietary exposures for high consumers (i.e. at the 90th percentile of exposure) were 95% of the ADI or less. This was for all the population groups assessed when the extension of use in fruit drinks was included. The impact of permitting steviol glycosides in fruit drinks on total dietary exposure was determined to be small (exposures increased on average by 5% of the ADI).

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

FSANZ has considered the potential impacts of approving a draft variation to the Code and concluded that the direct and indirect benefits that would arise from permitting steviol glycosides in fruit drinks most likely outweighs the associated costs.

FSANZ has therefore approved a draft variation to permit the use of steviol glycosides as a food additive in fruit drinks at a maximum permitted level of 200 mg/kg steviol equivalents.

1 Introduction

1.1 The applicant

The ABCL is the peak industry association for Australian non-alcoholic beverage manufacturers. The application is also supported by the New Zealand Beverage Council (NZBC)—the industry association for New Zealand non-alcoholic beverage manufacturers.

1.2 The application

The purpose of the application is to amend the Code to permit steviol glycosides as a food additive, with the technological purpose as an intense sweetener in fruit drinks, at a maximum permitted level of 200 mg/kg steviol equivalents[1].

1.3 The current Code requirements

The Code does not currently permit steviol glycosides to be added to fruit drinks. Australia and New Zealand food laws require that food for sale must comply with the Code requirements.

1.3.1 Food additive permissions

Paragraph 1.1.1—10(6)(a) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a food additive' unless that substance's use as a food additive is expressly permitted by the Code.

Section 1.3.1—3 details which substances are permitted to be used as a food additive for the purposes of the Code. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

Section 1.1.2—11 also provides that a substance is 'used as a food additive' if it is added to a food to perform one or more technological functions listed in Schedule 14 of the Code and is a substance identified in the table to section S15—5 as a permitted food additive.

Schedule 14 lists the permitted technological purposes of food additives. The table to section S14—2 provides that use as an intense sweetener is a permitted technological purpose.

Schedule 15 lists the specific food additive permissions for different classes of food products. Item 14.1.2.2.1 in the table to subsection S15—5 lists the permitted food additives for fruit drinks.

1.3.2 Labelling requirements

Paragraph 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Standard 1.2.4 of the Code requires most packaged food to be labelled with a statement of ingredients. Subsection 1.2.4—7(1) requires food additives to be declared in the statement of

[1] The concentration of steviol glycosides when added to foods is expressed as steviol equivalents. To calculate this, subsection 1.3.1—4(7) in the Code contains a formula and conversion factor to determine this.

ingredients by the relevant class name (if any) followed in brackets by the name or code number of the food additive.

Schedule 7 lists the food additive class names that can be used in the statement of ingredients.

Schedule 8 lists the names and code numbers of food additives that are to be used for labelling purposes. Schedule 8 refers to steviol glycosides (code number 960) which is currently permitted to be added to food as a food additive.

1.3.3 Identity and purity requirements

Food additives permitted by section 1.3.1 and Schedule 15 must also meet any relevant identity and purity specifications set out in Schedule 3. Section S3—2 of Schedule 3 provides a list of specifications contained in primary sources, including in the Code.

1.4 International and national requirements

1.4.1 International requirements

Codex's general standard for food additives (GSFA) contains permission for the use of steviol glycosides in a range of foods and maximum permitted limits (FAO/WHO 2018). The GSFA includes permission to add steviol glycosides (as steviol equivalents) to food category 14.1.4 water based flavoured drinks at a maximum permitted level of 200 mg/kg.

Product specifications for steviol glycosides are established by JECFA in the Combined Compendium of Food Additive Specifications. The most recent specifications are included in Monograph 20 (JECFA 2017). These are an accepted primary source of specifications in section S3—2(1)(b) of the Code.

1.4.2 European Union

Regulation EU 1131/2011 provides permission for the use of steviol glycosides (food additive number E960) as a sweetener in a range of foods. The regulation includes permission to add steviol glycosides as steviol equivalents to food categories 14.1.3 fruit and vegetable nectars and similar products and 14.1.4 flavoured drinks at 100 mg/kg and 80 mg/kg respectively (European Commission, 2011).

Product specifications for steviol glycosides are included in Regulation EU 2016/1814 (European Commission, 2016).

1.4.3 United States of America (USA)

Intense sweeteners, including steviol glycosides are generally recognized as safe ("GRAS") based on the United States Food and Drug Administration's (FDA's) review of information and data submitted by industry. The FDA has not questioned the GRAS status of certain high-purity steviol glycosides for use in food (FDA, 2018). There are numerous GRAS notifications to the FDA for steviol glycoside preparations used as intense sweeteners in a range of food categories.

The United States Pharmocopeial Convention Food Chemicals Codex (FCC) contains a product specification for steviol glycosides.

1.4.4 Canada

Health Canada permits the use of steviol glycosides as a food additive (sweetener) in a range of foods under the Food and Drugs Act and marketing authorisations for use of sweeteners (Health Canada 2018a). Steviol glycosides calculated as steviol equivalents are permitted in category S.1.2 (3) for unstandardized beverage concentrates, unstandardized beverages, unstandardized beverage mixes at a maximum permitted level of 0.02% in beverages as consumed (Health Canada, 2018b).

Health Canada follows JECFA product specifications for steviol glycosides and, as such, are consistent with Codex and also the USA's FCC (Health Canada, 2018c).

1.4.5 Other countries

Steviol glycosides are permitted in a range of foods in other countries including:

- Asia – Japan, India, South Korea, China, Malaysia, Indonesia, Singapore, Taiwan
- Central and South America – Brazil, Argentina, Paraguay, Uruguay, Mexico, Peru, Columbia
- Africa
- Israel
- Europe

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act;
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

The draft variation as proposed following assessment was approved without change.

The approved draft variation is at Attachment A. The variation takes effect on gazettal.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation between 9 October 2018 and 6 November 2018.

12 submissions were received, with 10 supporting the application. Those supporting the application were:

- Australian Beverage Council Limited (ABCL)

- Dietitians Association of Australia
- The Victorian Department of Health and Human Services and Victorian Department of Economic Development, Jobs, Transport and Resources
- Frucor Suntory
- Lencia Fruit Juices Pty Ltd
- Ministry for Primary Industries – New Zealand Food Safety
- New Zealand Beverage Council
- New Zealand Food and Grocery Council
- PepsiCo Australia and New Zealand
- International Stevia Council

The issues raised were from the Dietitians Association of Australia, New South Wales Food Authority and Queensland Health. These issues and FSANZ's responses are detailed in Table 1.

Table 1 Summary of issues raised in submissions

Issue	Raised by	FSANZ response
Recommend that FSANZ continue to review the evidence on long-term safety of artificial sweeteners to ensure consumption of these are not causing potential long-term harm to consumers.	Dietitians Association of Australia (DAA)	FSANZ's risk assessment concluded that there are no public health and safety concerns from the extension of use of steviol glycosides to fruit drinks at the proposed level. FSANZ continues to monitor research on the safety of intense sweeteners, including artificial sweeteners as referred to by DAA.
DAA are aware of a growing body of evidence that artificial sweeteners may have unwanted metabolic effects.	Dietitians Association of Australia (DAA)	FSANZ is aware that a number of research papers have reported on possible links between consumption of intense sweeteners and weight gain, some intense sweeteners are referred to as artificial sweeteners and others can be natural e.g. steviol glycosides. FSANZ recognises there is some uncertainty, but considers that the current weight of evidence does not support a causal relationship. Effects of intense sweeteners on weight gain appear neutral or beneficial in some studies.
DAA recommend ongoing public awareness and education on effects of sweeteners so consumers can make informed choices	Dietitians Association of Australia (DAA)	Information about sweeteners including steviol glycosides is available on the FSANZ website. When added to food, steviol glycosides must be included in the statement of ingredients on the food label to facilitate consumer choice.

Issue	Raised by	FSANZ response
Dietary exposure modelling at the higher end of exposure, using the refined approach is nearing the ADI limit of 4 mg/kg. Once this application is included, intakes for high end consumers are at 95% of the ADI or only 0.2 mg/kg below the ADI threshold.	New South Wales Food Authority and Queensland Health	The Dietary Exposure Assessment (DEA) results show estimated exposure to steviol glycosides for high end consumers (i.e. at the 90th percentile of exposure) are below the ADI. The DEA, which considers current permissions for steviol glycosides in the Code and the extension of use in fruit drinks, is highly protective of consumers as conservative assumptions were included in the dietary assessment model. For example, where industry data for actual use levels were not available the food class was assumed to contain steviol glycosides at the maximum permitted level. Where available, maximum and average industry use levels were used. In the DEA the maximum use levels provided by industry were used as a worst case scenario, and therefore are an over-estimate of likely exposures to steviol glycosides. It was assumed that all foods in all food categories contained steviol glycosides at the concentrations used. The highest dietary exposures estimated were based on a single day of consumption data, and high percentile exposures are lower when using multiple days of data which better reflects chronic dietary exposure.

Issue	Raised by	FSANZ response
Clarification from FSANZ needed on whether steviol glycosides from imported foods or goods listed on the Australian Register of Therapeutic Goods (ARTG) have been included in the refined modelling. It is not clear if these were included in the dietary exposure assessment.	New South Wales Food Authority and Queensland Health	Although the DEA used data specific to Australian and New Zealand products, imported foods must also comply with the Code requirements for use in food, including any limits for steviol glycosides. In addition food additives are used for a technological purpose and would be used in a similar quantity to provide the technological purpose. This means it is unlikely that levels in imported foods would differ substantially from Australian and New Zealand products, so are unlikely to change the DEA conclusions. The current DEA did not include goods listed on the ARTG. In the safety assessment undertaken by FSANZ an ADI was established for use in the risk assessment. The ADI represents the level of dietary exposure without appreciable risk to health over a lifetime. Therapeutic goods classified as registered medicines and prescription medicines are consumed under medical supervision with a medical benefit and therefore FSANZ considers that dietary exposure from this source is low in comparison to steviol glycosides in food sources and would not impact on dietary exposures over a lifetime and is therefore not relevant to this assessment. The DEA showed the ADI is not exceeded by permitting the extension of use in fruit drinks at levels of 200 mg/kg. The DEA took into account a range of consumers including those who may consume many products containing steviol glycosides. When added to food, steviol glycosides must be included in the statement of ingredients on the food label to facilitate consumer choice.

Issue	Raised by	FSANZ response
Concern that consumers may not have adequate information concerning total dietary intake of steviol glycosides to stay below the recommended daily intake thresholds. FSANZ to consider risk communication to consumers to enable informed purchase choices.	New South Wales Food Authority	FSANZ's scientific assessment demonstrated that intakes are below the recommended daily intake thresholds – i.e. the ADI. It should be noted that the ADI is the amount that can be ingested daily over a lifetime without appreciable health risk. Minor or occasional exceedances of the ADI would be not be expected to be of significant health concern. On this basis, FSANZ considers that additional information for consumers concerning total dietary intake of steviol glycosides is not required.
Focus on food reformulation in decreasing sugar content but retaining sweetness, may mean applications for steviol glycosides in the future.	New South Wales Food Authority	FSANZ would consider and assess any future applications for steviol glycosides to ensure the protection of public health and safety.
FSANZ to consider including foods permitted to contain steviol glycosides (incl levels) in the Australian Total Diet Survey (ATDS) to obtain accurate data for the Australian and New Zealand food supply.	New South Wales Food Authority	FSANZ can consider including these in future ATDS. Current surveillance activities include a FSANZ and MPI – New Zealand Food Safety led review on the use of intense sweeteners in foods and beverages, including steviol glycosides
Concern that the NZ Food (Supplemented Food) Standard may provide an avenue for manufactures to include concentrations levels higher than stipulated in the Food Standards Code permissions.	New South Wales Food Authority	Foods which meet the requirements to be considered under the NZ Supplemented Food Standard are required to meet requirements for food additives as set out in the Code. This is summarised in the New Zealand supplemented food standard user guide Section 6(2).
Permitting artificial sweeteners does not align with Food Regulation system priorities for 2017-2021 on reducing chronic disease related to overweight and obesity. It reinforces consumer preference for sweet foods, rather than positive behaviour change to less sweet foods.	Queensland Health	Permitting intense sweeteners can assist industry to reformulate or develop food (including beverages) that contain less sugar. This also gives consumers wishing to consume fruit drinks with reduced sugar greater choice as the use of steviol glycosides allow for a 30 to 50% reduction in sugar compared with standard fruit drinks as well as reduced energy intakes.

Issue	Raised by	FSANZ response
General comment not specifically related to application A1149– useful to include in call for submissions papers the adverse effects from exceeding the ADI for the substance under consideration. Noting this is already in the supporting document.	Queensland Health	FSANZ's risk assessments can be found in the supporting document (SD1) for an application, including the toxicological endpoint (adverse effect) used as the basis to establish the ADI. If the risk assessment indicated a potential for the ADI to be exceeded for a substance, this would be addressed in the risk characterisation.

2.2 Risk assessment

2.2.1 Food technology assessment 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.

2.2.2 Hazard and dietary exposure assessment conclusions

An acceptable daily intake (ADI) of 0-4 mg/kg bw for steviol glycosides, expressed as steviol, was established by FSANZ and JECFA (FSANZ 2008, JECFA 2009). Toxicological and other relevant data published subsequent to FSANZ's previous assessments of steviol glycosides raised no concerns about the safety of steviol glycosides and did not indicate a need to amend the ADI.

Dietary exposure as a proportion of the ADI for the *Refined baseline* (current food categories permitted to contain steviol glycoside with actual industry use levels) at the mean and 90th percentile ranged between 35–45% and 55–90%, respectively, across all of the Australian and New Zealand population groups assessed. For the *Refined extension of use* scenario (*Refined baseline* plus proposed permission for steviol glycosides in fruit drinks), 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 increased by up to 5% of the ADI between the *Refined baseline* and the extension of use in fruit drinks.

Based on the dietary exposure assessment, it was determined 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.

The hazard and dietary exposure assessment conclusion is that there are no public health and safety concerns from the extension of use of steviol glycosides to fruit drinks at the proposed levels.

2.3 Risk management decision

Based on the food technology, hazard and dietary exposure assessments, there are no

public health and safety concerns with using steviol glycosides as a food additive in the manner proposed in the application and that its use as an intense sweetener in fruit drinks is technologically justified.

Based on the risk assessment, the decision was made to approve a draft variation to the Code. Providing the permission for steviol glycosides as a food additive in fruit drinks requires an amendment to item 14.1.2.2.1 of the table to subsection S15-5. The approved draft variation will make this amendment.

2.3.1 Labelling requirements

Substances used as food additives are required to be declared in the statement of ingredients on the label of most packaged foods. These labelling requirements are outlined in section 1.3.2.

As steviol glycosides are already permitted for use as food additives, requirements for their declaration in the statement of ingredients on the label already exist in the Code, i.e. Schedule 8 – Food additive names and code numbers (for statement of ingredients) refers to 'steviol glycosides' with the appropriate code number '960'.

New, additional INS numbers have been developed by Codex Alimentarius for steviol glycosides that distinguish steviol glycosides obtained from the plant and from fermentation sources. These new INS numbers could be included in the Code for labelling purposes, however we have not amended the Code to use these new INS numbers as part of this application because the application relates to steviol glycosides in general. We will consider including new, relevant INS numbers in the Code for steviol glycosides in the future.

As no public health and safety concerns from the extension of use of steviol glycosides to fruit drinks at the proposed levels have been identified, the existing labelling requirements in the Code are considered sufficient and no additional labelling requirements are proposed.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards news.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards where steviol glycosides are already permitted in a range of foods, including fruit drinks. Amending the Code to permit steviol glycosides in fruit drinks is unlikely to have a significant effect on international trade. Therefore, a notification under Australia and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting food additives (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting food additives is machinery in nature and the use of the food additive is voluntary once the application has been approved. This standing exemption relates to the use of a food additive already permitted in other foods that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (S.29 (2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considers the addition of steviol glycosides in fruit drinks at a maximum permitted level of 200 mg/kg steviol equivalents. FSANZ is of the view that no other realistic food regulatory measures exist.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the addition of steviol glycosides in fruit drinks at a level of 200 mg/kg steviol equivalents.

Costs and benefits for the addition of steviol glycosides in fruit drinks at a maximum permitted level of 200 mg/kg steviol equivalents

Steviol glycosides are currently permitted in the Code for a range of beverages such as low joule fruit and vegetable juice products and water-based flavoured drinks. Approving the application will allow food manufacturers to develop fruit drinks with reduced sugar, provide a wider range of products and may encourage innovation in the sector. Due to the voluntary nature of the permission, industry will only use steviol glycosides in fruit drinks where they believe a net benefit exists.

Consumers wishing to consume fruit drinks with reduced sugar will have more options available to them, as the use of steviol glycosides typically allows a 30–50% reduction in sugar to standard fruit drinks.

Overseas markets currently permit steviol glycosides in a range of foods, including fruit drinks which may present a business opportunity for Australia New Zealand food manufacturers, although there may also be competing imports from these countries into the domestic market.

Permitting steviol glycosides in fruit drinks may result in a small cost to government in terms of adding it to the current range of additives that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting steviol glycosides in fruit drinks most likely outweigh the associated costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

The draft variation applies in Australia and New Zealand. There is no relevant New Zealand only standard.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ has completed a hazard and dietary exposure assessment (refer to SD1) which is summarised in section 2.2.2. The safety assessment concluded there are no public health and safety concerns in permitting steviol glycosides as a food additive (intense sweetener) in fruit drinks at a maximum permitted level of 200 mg/kg, expressed as steviol equivalents.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

As discussed in section 2.3.1, the existing labelling provisions for food additives will apply. These provisions ensure consumers are provided with information to enable them to make informed choices about foods containing steviol glycosides.

2.5.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with the application relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the food technology, hazard and dietary exposure assessment (SD1). The applicant submitted supporting information, including scientific studies, product information and relevant literature, as part of their application. FSANZ also considered other information relevant to the application (referenced in the document and reference list).

- **the promotion of consistency between domestic and international food standards**

Codex's GSFA contains permission for use of steviol glycosides in a range of foods, including for water-based flavoured drinks at a maximum permitted level of 200 mg/kg steviol equivalents. The USA, EU and Canada have similar permissions along with other countries.

- **the desirability of an efficient and internationally competitive food industry**

Permitting steviol glycosides in fruit drinks gives the applicant and other food manufacturers the opportunity to manufacture and sell reduced sugar beverages.

- **the promotion of fair trading in food**

FSANZ did not identify any relevant issues relating to this consideration.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline for Addition to Food of Substances other than Vitamins and Minerals[2] includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose, and
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ's has determined that permitting steviol glycosides in fruit drinks is consistent with the Ministerial Policy Guideline and the specific order principles for 'Technological Function' as a food additive.

3 References

European Commission (2016) Official Journal of the European Union. Commission Regulation (EU) 2016/1814 of 13 October 2016 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for steviol glycosides (E 960). Accessed 7 Sep 18

[2] http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

European Commission (2011) Official Journal of the European Union. Commission Regulation (EU) No 1131/2011 of 11 Nov 2011 , amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides. Accessed 7 Sep 18

FAO/WHO (2018) Codex Alimentaruis Commission. Codex general standard for food additives, codex STAN 192-1995. Accessed 7 Sep 18

JECFA (2017) Compendium of food additive specifications. Joint FAO/WHO Expert Committee on Food Additives. 84th meeting 2017, Monograph 20. Accessed 21 Aug 18

FAO/WHO (2009) Safety evaluation of certain food additives. Joint FAO/WHO Expert Committee on Food Additives. 69th meeting 2009, WHO Food Additives Series: 60. Accessed 28 Aug 2018

FSANZ (2008) Application A540 Steviol Glycosides as Intense Sweeteners. Food Standards Australia New Zealand.

Health Canada (2018a) Marketing authorisations that may be used as sweeteners. SOR/2012-210 Accessed 7 Sep 18

Health Canada (2018b) 9. Lists of permitted sweeteners (Lists of permitted food additives). Accessed 7 Sep 18

Health Canada (2018c) Labelling of steviol glycosides. Accessed 7 Sep 18United States Food and Drug Administration (2018). Has Stevia been approved by FDA to be used as a sweetener? Accessed 7 Sep 18

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1149 – Addition of Steviol Glycosides in Fruit Drinks) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

Insert Delegate's details]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Application A1149 – Addition of Steviol Glycosides in Fruit Drinks) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Schedule 15** is varied by inserting in item 14.1.2.2.1 of the table to subsection S15—5, after the entry for 'Dioctyl sodium sulphosuccinate'

960	Steviol glycosides	200

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted application A1149 which seeks to permit the use of steviol glycosides as a food additive – intense sweetener in fruit drinks. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation of a Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the Legislation Act 2003.

2. Purpose

The Authority has approved a draft variation to the Code to permit steviol glycosides as a food additive – intense sweetener at a maximum permitted level of 200 mg/kg steviol equivalents in fruit drinks.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1149 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 9 October 2012 for a four-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 15 is likely to have a minor impact on business and individuals and its use as a food additive is voluntary.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends Schedule 15 by inserting item 14.1.2.2.1 of the table to section S15—5 an entry for steviol glycosides with a maximum permitted level of 200 mg/kg steviol equivalents. The effect of this amendment will be to permit, for the purposes of Standards 1.1.1 and 1.3.1, the use in fruit drink of steviol glycosides subject to a maximum permitted level of 200 mg/kg steviol equivalents.