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

10-05
7 December 2005

INITIAL ASSESSMENT REPORT

APPLICATION A540

STEVIOL GLYCOSIDES AS INTENSE SWEETENERS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 1 February 2006
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

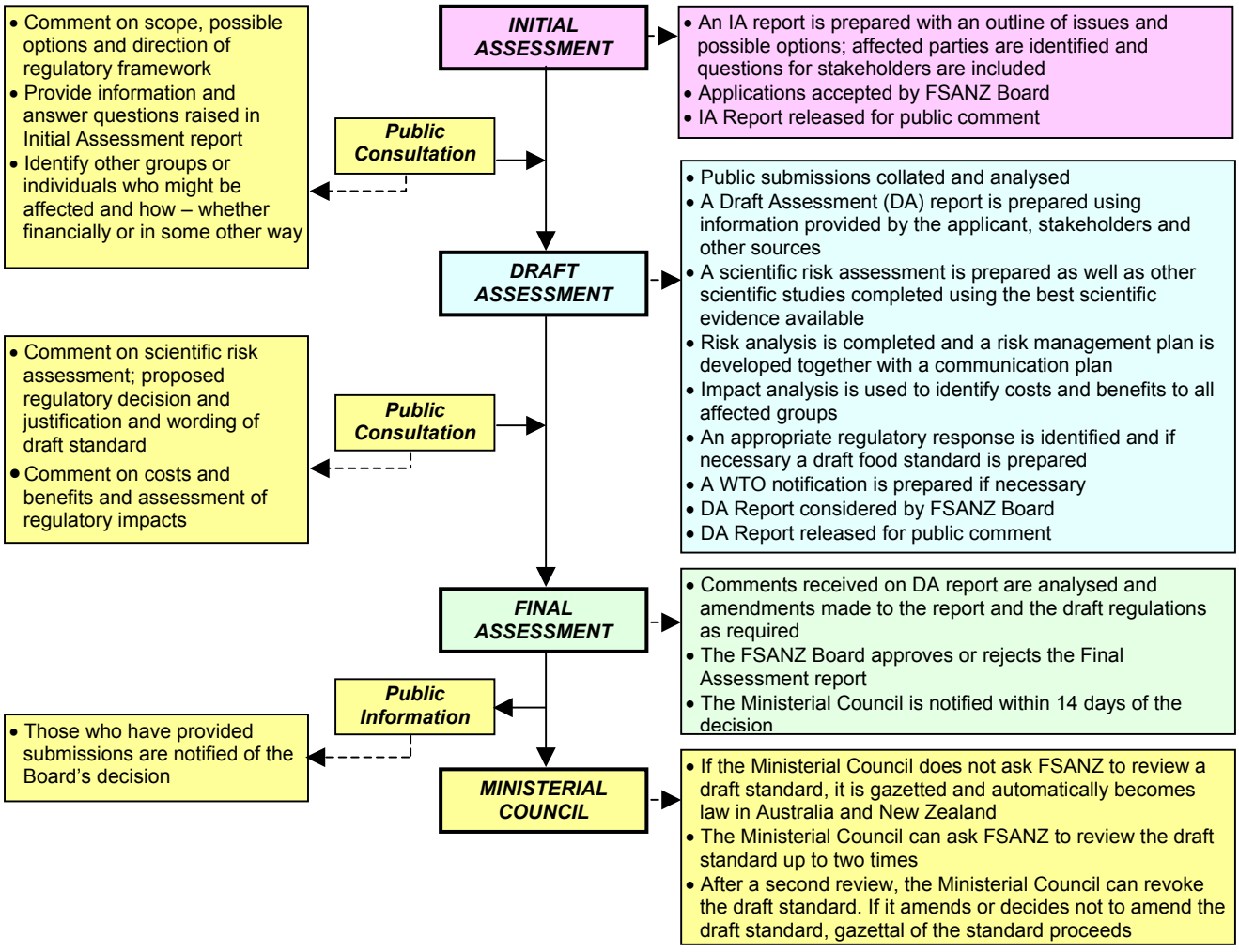
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report for Application A540, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 1 February 2006.

Submissions received after this date may not be considered, unless the Project Coordinator has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

Steviol glycosides are high intensity sweeteners, extracted from *Stevia rebaudiana*. They are 250-300 times sweeter than sucrose and have been used for several years in a number of countries as sweeteners for a range of food products.

FSANZ received an Application (A540) on 31 May 2004 from the Plant Sciences Group, Central Queensland University and Australian Stevia Mills Pty Ltd to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of steviol glycosides[1] (extracts of the herb *Stevia rebaudiana*) as an intense sweetener for a wide variety of foods. Approval is therefore specifically being sought to include steviol glycosides in Schedule 1 or 2 of Standard 1.3.1.

The Applicant notified FSANZ on 20 September 2005 that they were seeking the Application to be progressed under the cost-recovery arrangements of FSANZ, rather than waiting for commencement in the Second Quarter of 2006 under the current Work Plan. Consequently, Work on this Group 3 (cost-recovered) Application commenced on 30 September 2005 following receipt of the fee for Initial Assessment.

Food additives are required to undergo pre-market assessment before approval for use in Australia and New Zealand. The objective of this Initial Assessment Report is to determine whether it may be appropriate to amend the Code to permit the use of steviol glycosides as a food additive. This Initial Assessment Report is not a detailed assessment of the Application but rather an assessment of whether the Application should be accepted for further consideration. It also provides a summary of the information provided by the Applicant, outlining the relevant issues and questions, to assist in identifying affected parties necessary to complete the assessment.

The Applicant has submitted a thorough toxicological data package including details of the maximum levels in a range of foods to which steviol glycosides are proposed to be added. In addition, dietary exposure calculations of potential dietary intakes of steviol glycosides for Australian consumers based on 1995 National Nutrition Survey figures, were submitted by the Applicant. This Application will require a comprehensive risk assessment and consideration of risk management options.

Having regard to the criteria for Initial Assessments in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ recommends that the Application be accepted for the following reasons:

- The Application is to permit the use of steviol glycosides as an intense sweetener (food additive).

- The Application relates to a matter that may warrant a variation of a food regulatory measure in Standard 1.3.1, if further assessment supports such a variation.

- The Application is not so similar to a previous application that it ought not be accepted.

[1] The most common names used for steviol glycosides are stevia, stevioside and sometimes stevia extract and stevia sugar

- At this stage of the assessment, the Authority is not able to determine whether the costs that would arise from a variation to the Code to approve steviol glycosides as a food additive would outweigh the direct and indirect benefits to the community, Government or industry. The Authority will call for specific submissions on this issue and address the matter at Draft Assessment.

- There are no other measures (available to FSANZ or not) that would be available and more cost-effective than a variation to the Code as a result of this Application.

The Application has been accepted following Initial Assessment on this basis. FSANZ now seeks submissions to assist it to assess the Application at Draft Assessment.

1. Introduction

FSANZ received an Application on 31 May 2004 from the Plant Sciences Group, Central Queensland University and Australian Stevia Mills Pty Ltd to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of steviol glycosides (extracts of the herb *Stevia rebaudiana*) as intense sweeteners for a wide variety of foods.

Work on this Group 3 (cost-recovered) Application commenced on 30 September 2005.

1.1 Nature of Application

The Applicant requests that steviol glycosides be used as a food additive (sweetener and/or flavour enhancer) in the following foods:

- soft drinks and cordials,
- milk, soy and mineral drinks,
- canned fruit, jams and juices,
- ice creams, yoghurts and other dairy products,
- cakes, biscuits, pastries and desserts,
- toppings, sauces, chutneys, spreads etc; and
- cereals, muesli bars and confectionaries.

The Applicant provided data to estimate the maximum limits of steviol glycosides (expressed as steviol) likely to be used as a sugar replacement in a range of common food products.

2. Regulatory Problem

Standard 1.3.1 – Food Additives requires that food additives undergo a pre-market risk assessment through an application to FSANZ before being offered for sale in Australia and New Zealand.

Steviol glycosides are being requested as a new intense sweetener (food additive) for Australia and New Zealand. There is currently no permission within Standard 1.3.1 for using steviol glycosides as a food additive; therefore a pre-market assessment is required.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of steviol glycosides as a food additive for a wide variety of foods. The requirement for pre-approval is designed to ensure that steviol glycosides are safe for use and that there is a technological justification for its proposed use, prior to consumption in foods by members of the public.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;

- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.
- In developing and varying standards, FSANZ must also have regard to:
- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Background Information

Stevia rebaudiana is an herb belonging to the chrysanthemum family which grows wild as a small shrub in parts of Paraguay and Brazil. The leaves have traditionally been used as a sweetener. The leaves of *Stevia rebaudiana* contain 8 different steviol glycosides.

Steviol glycosides are considered high intensity sweeteners (250-300 times that of sucrose) and have been used for several years in a number of countries as a sweetener for a range of food products.

Steviol glycosides and rebaudioside A are the major components of Stevia. The Applicant claims that the ratio of these two components is the main determinant of taste 'quality'. Where steviol glycosides are more than 50% of the total glycosides the taste is 'common / traditional', with a 'metallic' or 'liquorice' after-taste. Where rebaudioside A makes up more than 50%, the taste is 'improved' with a reduced after-taste.

The common names used for the purified extract of the stevia plant have included stevia, stevioside and various other names. The extract is a mixture of one or more glycosides of steviol, the most predominant one usually being steviol glycosides. The Joint Expert Committee on Food Additives (JECFA) recently (2004) concluded that the most appropriate name to be used for this extract was "steviol glycosides".

In addition, previously the extract was expressed as a weight (usually mg) of steviol glycosides, although it was actually a mixture of very similar glycosides. As the molecular weights of the various glycosides are different, JECFA has determined that the concentrations/amounts of steviol glycosides should be expressed as steviol content, which is equivalent to approximately 40% of the steviol glycosides content.

4.2 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 4 (level of complexity) and placed in Group 3 on the FSANZ standards development Work Plan. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Food applications

Steviol glycosides are obtained by extracting leaves of *Stevia rebaudiana* Bertoni with hot water, followed by solvent extraction of the water-soluble extract. The composition of the extracts depends on the composition of the leaves, influenced by soil and climate conditions and on manufacturing process. Commercial products contain at least 95% steviol glycosides.

The Applicant has submitted the following information in regard to food applications of steviol glycosides:

- the main purpose of using steviol glycosides in foods is to enhance the taste and sweetness without needing to use high calorie sweeteners (sucrose, glucose, fructose, honey etc) or other artificial chemical sweeteners;

- steviol glycosides are generally considered to be 250 times sweeter than sucrose; with estimates of sweetness varying from as low as 200 times to over 300 times sweeter;

- the relative sweetness of the individual glycosides is different. Rebaudioside A is sweeter than steviol glycosides (300 times compared with 250 times sucrose) and also has a 'more palatable' taste profile, having less of the metallic/liquorice taste often associated with steviol glycosides;

- as can occur with other sweeteners, steviol glycosides have a synergistic effect on taste when used in conjunction with other sweeteners. Steviol glycosides also tend to produce a sweet taste less instantly than sucrose but it lasts for a longer period; and

- when used in association with other flavours, steviol glycosides act as a flavour enhancer producing a stronger flavour or enabling a smaller quantity of the flavour to be used, e.g. a lemon drink with some of its sugar replaced by steviol glycosides will enhance the lemon taste.

This information will be examined comprehensively at Draft Assessment.

5.2 Safety assessment

The Joint (FAO/WHO) Expert Technical Committee on Food Additives (JECFA) considered the toxicity data on steviol glycosides at its 51st meeting in 1999[2]. JECFA prepared an extensive report on the available safety data on steviol glycosides but was unable to recommend an acceptable daily intake (ADI) because of some deficiencies in the data.

[2] Safety evaluation of certain food additives. WHO Food Additive Series 42, pp 119-143 (1999)

Firstly, there was lack of human metabolism studies on steviol glycosides and the metabolite steviol and lack of information on the purity of steviol glycosides. Secondly, the potential mutagenicity of steviol had not been sufficiently tested, particularly *in vivo*.

At the June 2004 JECFA meeting[3], the Committee noted that data requested at the 51st meeting was now available, particularly studies on human metabolism of steviol glycosides, on *in vivo* genotoxicity and that specifications for purity were now developed. JECFA concluded that steviol glycosides and rebaudioside A were not genotoxic *in vitro* or *in vivo* and that the genotoxicity of steviol and some of its derivatives *in vitro* were not expressed *in vivo*. A temporary ADI of 2 mg/kg bw/day was established, expressed as steviol. The Committee required additional information to be submitted by 2007, on the pharmacological effects of steviol glycosides in humans and considered that these studies should also involve repeated exposure to dietary and therapeutic doses, in normotensive and hypertensive individuals and in insulin-dependent and insulin-independent diabetics.

A standard specification and other technical details for steviol glycosides were published by JECFA in the FAO Food and Nutrition Paper Series 52 addendum 12.

A comprehensive risk assessment and evaluation of the toxicological studies for this Application will be performed at Draft Assessment.

5.4 Dietary and nutrition considerations

A dietary exposure study was undertaken by the Nutrition Unit/Heart Foundation Research Centre, Griffith University to evaluate possible dietary implications for consumers of the introduction of steviol glycosides. This data was submitted with the Application. The study showed that the major dietary exposure contributors to exposure are likely to be soft drinks and dairy products.

During the draft assessment process this data will be examined and dietary modelling will be conducted by FSANZ to estimate the potential dietary intake of steviol glycosides in Australia and New Zealand that may result from permitting its use in the foods specified in the Application.

5.5 Relevant international or national regulatory standards

Steviol glycosides are approved for use in a number of countries. Japan has approved steviol glycosides for more than 30 years and other countries that allow the use of steviol glycosides are China, Russia, Korea, Brazil, Paraguay, Argentina, Indonesia and Israel. Steviol glycosides are not approved as an intense sweetener in the USA or EU.

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and Governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles at Draft Assessment.

[3] Safety evaluation of certain food additives. WHO Technical Report Series, pp 34-39 (2004)

There are no options other than a variation to the Code for this Application. Therefore the two regulatory options available for this Application are:

Option 1. **Not approve** the use of steviol glycosides as a food additive.

Option 2. **Approve** the use of steviol glycosides as a food additive.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

- consumer associations in Australia and NZ (including diabetic groups);
- manufacturers of intense sweeteners;
- State/Territory jurisdictions;
- Dietitians Association of Australia and the New Zealand Dietitians Association;
- importers of steviol glycosides-containing foods; and
- other regulatory agencies (e.g. the Therapeutic goods Administration) as steviol glycosides are approved as sweeteners in Over The Counter (OTC) supplements

7.2 Impact analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, and its health, economic and social impacts.

The regulatory impact of the proposed variation to the Code will be assessed at Draft Assessment.

8. Consultation

8.1 Public consultation

FSANZ is seeking public comment to assist in assessing this Application at Draft Assessment.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application during the second round of public consultation. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FSANZ will also be added to the mailing list for a further round of public consultation after the Draft Assessment.

Comments on, but not limited to, the following would be useful.

- Is there technological justification for the use of steviol glycosides as a food additive?
- Other scientific aspects of the Application, in particular any information relevant to the safety assessment and/or dietary exposure assessment. In addition, are there any dietary and nutritional implications of this Application?
- What are the likely costs and benefits to food manufacturers, consumers and government if steviol glycosides are approved? In particular, comment is sought from consumers with diabetes on the costs and benefits to those individuals of approval of steviol glycosides.
- In considering the potential costs or benefits of this application to you as a stakeholder, do the benefits outweigh the costs?
- What are the costs or benefits for government – administration, enforcement, public health and safety etc?

8.2 World Trade Organization (WTO)

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

Amending the Code to approve the use of steviol glycosides is unlikely to have a significant effect on trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion and Recommendation

Having regard to the criteria for Initial Assessments in section 13 of FSANZ Act, FSANZ recommends that the Application be accepted for the following reasons:

- The Application is to permit the use of steviol glycosides as a food additive.

- The Application relates to a matter that may warrant a variation of a food regulatory measure as a food additive in Standard 1.3.1, if further assessment supports such a variation.

- The Application is not so similar to a previous application that it ought not be accepted.

- At this stage of the assessment, the Authority is not able to determine whether the costs that would arise from a variation to the Code to approve steviol glycosides as a food additive would outweigh the direct and indirect benefits to the community, Government or industry. FSANZ will call for specific submissions on this issue and re-address the matter at Draft Assessment. There is nothing apparent at this stage of the assessment, however, to indicate that the costs arising from this variation will outweigh the benefits.

- There are no other measures (available to FSANZ or not) that would be available and more cost-effective than a variation to the Code as a result of this Application.

It is recommended that this Application now be progressed to Draft Assessment. Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.