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

5-05
3 August 2005

INITIAL ASSESSMENT REPORT

APPLICATION A560

PHYTOSTEROLS IN FRUIT JUICE & FRUIT JUICE DRINKS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time)
14 September 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

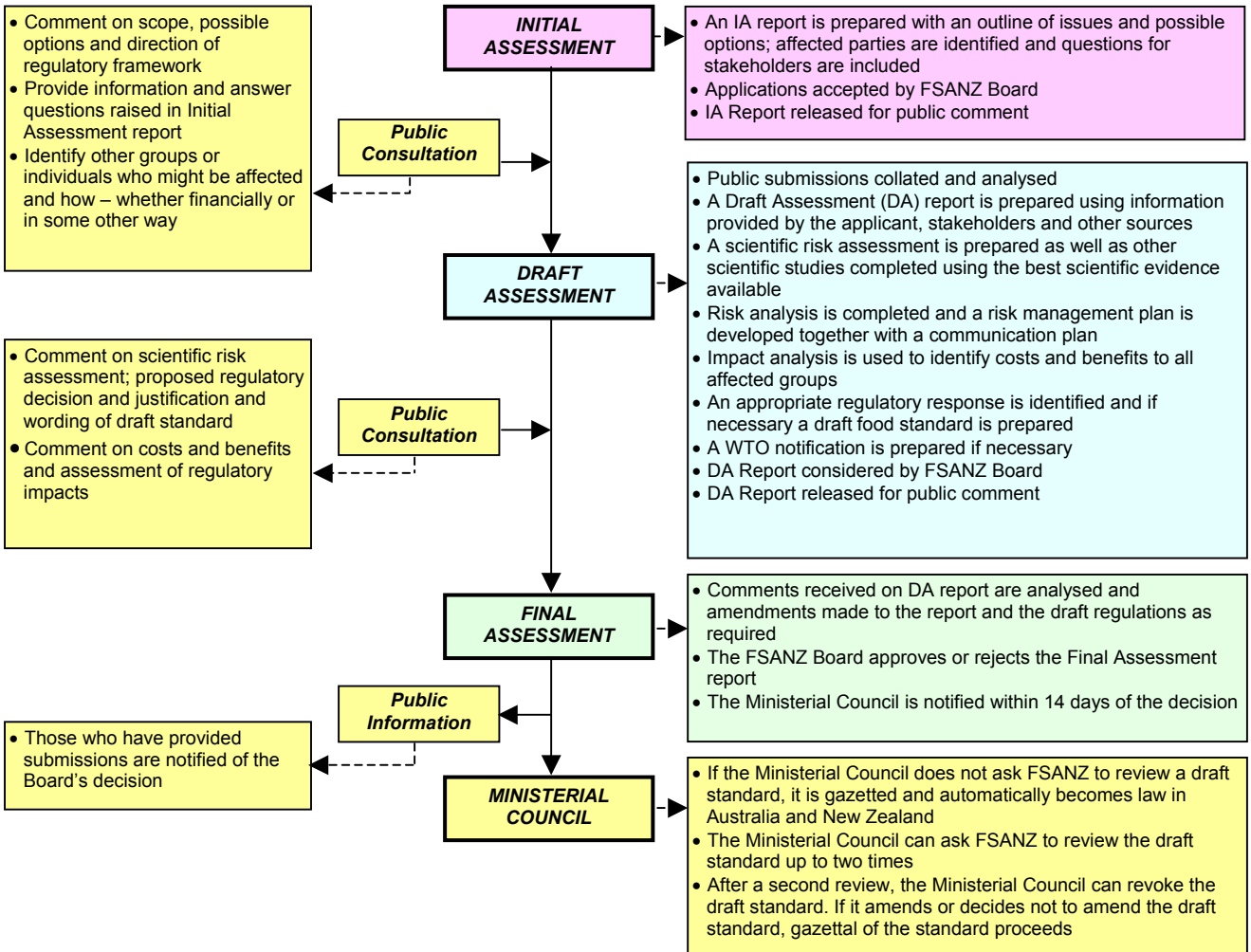
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Commonwealth; 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 Commonwealth, 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 Commonwealth, 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* (the 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 of Application A560, 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 references or by 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, 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) 14 September 2005.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

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

Coca-Cola South Pacific Pty Ltd has submitted an Application to FSANZ seeking approval for the use of phytosterols derived from vegetable oils as a novel food ingredient in fruit juice and fruit juice drinks (minimum 20% juice) under Standard 1.5.1 – Novel Foods in the *Australia New Zealand Food Standards Code* (the Code). Standard 1.5.1 requires that novel foods undergo a safety assessment before being permitted in the food supply. If approved, the novel food is listed in the Table to the Standard and must comply with any special conditions of use also listed in the Table. The products will be specifically marketed to the target population group i.e. consumers over the age of 40 with concerns about their blood cholesterol level.

Phytosterol esters (derived from vegetable oils) and non-esterified phytosterols (derived from a tall-oil source) have been permitted in edible oil spreads and margarines since 2000. In October 2004, FSANZ completed the assessments of three separate Applications seeking to broaden the use of phytosterols to low-fat milk and yoghurt and breakfast cereals (Applications A433, A434 and A508). However, approval of these Applications is pending a First Review called by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). In the Review, FSANZ is required to address both labelling and nutritional issues associated with phytosterol-enriched foods, including those that are already approved. The Ministerial Council's response to the outcome of this Review, which was completed on 21 July 2005, may impact on the progression of this Application.

In order to assess the merits of this Application, data on the efficacy and nutritional effects of phytosterols when added to a fruit juice matrix are required. The Applicant has supplied details of a clinical study and additional scientific information relevant to a safety assessment supporting the extended use of phytosterols in fruit juice and fruit juice drinks. The assessment will consider the potential dietary impact of a broader range of products containing phytosterols on target and non-target consumers.

This Initial Assessment report is not an assessment of the merits of this Application, but rather is an appraisal of whether the Application warrants further consideration according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). It is the conclusion of this assessment that, having regard to the requirements of section 13 of the FSANZ Act, this Application should be accepted.

This Report outlines the relevant issues necessary to proceed with assessment of the Application and also provides the general community with relevant information supplied by the Applicant to assist in identifying the issues and parties that may be affected by a decision.

Public submissions are invited on this Initial Assessment report. Comments are specifically sought on the public health and safety aspects of this application, and the costs and benefits to the food industry in general. Should any submissions be received, those will be considered as part of the assessment process.

1. Introduction

An Application was received from Coca-Cola South Pacific Pty Ltd on 13 April 2005 seeking approval to use phytosterols derived from vegetable oils as a novel food ingredient in fruit juices and fruit juice drinks under Standard 1.5.1 – Novel Foods and Standard 2.6.1 – Fruit Juice and Vegetable Juice of the Code. The Application is in Work Group 3 (cost-recovered).

The phytosterols intended for use are derived from edible vegetable oils, but are **not** esterified with long chain fatty acids. The Applicant seeks permission to use no more than 4.5 g phytosterols per one litre of fruit juice and fruit juice drinks containing a minimum of 20% fruit juice. Consumption of one serve of juice (250 ml) would therefore provide approximately 1 g phytosterols.

2. Regulatory Problem

Standard 1.5.1 requires that novel foods undergo a risk-based safety assessment before they are permitted in the food supply in Australia and New Zealand. Novel foods or novel food ingredients that have been assessed under the Standard, if fully approved, are listed in the Table to clause 2 of the Standard.

Permission to use phytosterol esters derived from vegetable oils as a novel food ingredient in edible oil spreads came into force on 14 June 2001. This permission was limited to edible oil spreads and margarines primarily because of a lack of information relating to the safety and efficacy of phytosterols in a broader range of foods.

There is no permission to add phytosterol esters to other foods, although applications (A433 and A434) to permit use in breakfast cereals, low-fat milk and low-fat yoghurt are currently being considered. Non-esterified phytosterols derived from a tall oil source are also permitted in edible oil spreads, and an Application (A508) to extend their use as ingredients in low-fat milk is also currently being considered. However, there is currently no permission in Australia and New Zealand to use non-esterified vegetable oil-derived phytosterols.

3. Objective

The objective of this Application is to establish if the food regulations should be changed to allow the use of phytosterols in fruit juice and fruit juice drinks. Before phytosterol-enriched fruit juice products can enter the food supply in Australia and New Zealand, FSANZ must undertake a safety assessment that specifically considers (a) the full potential health impact of dietary exposure to these and related plant sterol compounds on consumers in the target population group, and (b) the potential effects on non-target consumers. For approval, an amendment to the Code must be agreed by the FSANZ Board, and subsequently be notified to the Ministerial Council. An amendment to the Code may only be gazetted once the Ministerial Council process has been finalised.

In addressing the proposed variation to Standard 1.5.1 to approve the use of un-esterified vegetable oil phytosterols as novel food ingredients, 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

Phytosterols (plant sterols) are naturally present in many varieties of fruits, vegetables, nuts and cereals. The most common and major sterols in vegetable oils are sitosterol, campesterol and stigmasterol. Phytosterols can also be extracted from tall oil soap, which is a by-product of the pulping process used for coniferous trees in North America and Europe. Known as tall oil phytosterols (TOPs), these are predominantly a mixture of four phytosterols: sitosterol, sitostanol, campesterol and campestanol.

Free phytosterols are structurally related to cholesterol (found only in animals) and occur naturally at low levels (up to 0.9%) in common edible vegetable oils. Phytosterols can be esterified by reaction with fatty acid methyl esters or free fatty acids to produce phytosterol esters.

It is now well established that consumption of plant sterols, from either a vegetable oil or tall oil source, in amounts between 1-3 g per day can lead to reduced total and low-density lipoprotein (LDL) cholesterol levels in consumers. Phytosterols compete with cholesterol for uptake into the blood stream leading to less absorption of dietary cholesterol from the intestine.

As approvals for phytosterol-enriched foods are currently limited, the Applicant claims that incorporation of free phytosterols into fruit juice products will provide target consumers (i.e. those with concerns about their cholesterol level) with a wider choice of products providing similar benefits. The proposed fruit juice products would contain approximately 1 g phytosterols per 250 ml serve, and would be labelled to recommend consumption of two servings per day.

4.1 Previous phytosterol Applications

Both phytosterol esters and tall oil phytosterols have been approved for use in edible oil spreads since 2001. Subsequently, FSANZ received three Applications (Applications A433, A434 and A508) seeking to broaden these permissions to (i) phytosterol esters in high-fibre breakfast cereal, low-fat milk and yoghurt, and (ii) tall-oil phytosterols in low-fat milk.

The assessment of these applications involved consideration of both safety and efficacy data.

The consideration of the efficacy data was not an assessment of a health claim for phytosterols but rather an assessment of whether manufacturers' statements relating to the cholesterol lowering effects of phytosterol-enriched foods could be supported by appropriate scientific data, thereby ensuring truth in labelling.

4.2 Current regulatory status of phytosterol Applications

Due to significant similarities in terms of safety and the food categories under assessment, Applications A433, A434 and A508 were assessed in parallel. The Ministerial Council requested a First Review of FSANZ's approval of these Applications on the grounds that they (i) were not assessed in accordance with current Ministerial Council policy guidelines, (ii) do not protect public health and safety, and (iii) do not ensure adequate information to enable informed choice. FSANZ was required to complete the First Review of Applications A433, A434 and A508 by 12 August 2005.

4.3 Overseas approvals of phytosterols

Fruit juice and juice drinks containing phytosterols are permitted on the market in the United States. The name under which the products are being marketed is 'Minute Maid® Premium Heart Wise™'. The US FDA has approved an associated health claim[1] for these substances when consumed as part of a diet low in saturated fat and cholesterol.

The consumption of phytosterol containing fruit juices was recently considered by the Advisory Committee on Novel Foods and Processes (ACNFP) for the UK Food Standards Agency. This expert committee made an initial decision in February 2005 in favour of approving the application for phytosterols to be added to fruit juices, fruit nectars and tomato juice. This opinion has been forwarded by the European Commission to other Member States in the European Union for comment.

5. Relevant Issues

5.1 Safety assessment

The safety of phytosterols when consumed in fruit juices will be evaluated in relation to the following:

- the potential for adverse health effects in the target group of consumers through higher levels of consumption of phytosterols; and
- the potential health impacts on non-target consumers.

The assessment of this Application will entail consideration of the safety of phytosterols in the context of existing permissions for phytosterol-enriched table spreads and the applications seeking to use phytosterols in breakfast cereal and low-fat dairy products. The availability of a broader range of phytosterol-enriched foods necessarily involves consideration of the potential for increases in the levels of exposure to phytosterols through the diet.

[1] Federal Register 21 CFR Part 101, Food Labelling: Health Claims; Plant Sterols/Stanol Esters and Coronary Heart Disease; Interim Final Rule (2000).

In addition to the information supplied by the applicant, FSANZ will refer to other relevant information including from the published scientific literature, other regulatory agencies and the general community.

5.2 Efficacy of phytosterols in fruit juice

The Applicant has submitted a publication of a clinical study that investigated the efficacy of phytosterols in lowering serum cholesterol when incorporated into non-fat moieties such as orange juice. Evidence for the efficacy of phytosterols when present in fruit juice is required for this assessment to ensure that any labelling statements used by manufacturers would not be misleading or deceptive for consumers.

5.3 Marketing of products

The assessment of this Application will also consider the applicant's intended marketing strategy for these products, as well as risk management options that would apply to the whole range of phytosterol-enriched foods. The Applicant claims that fruit juice drinks with added phytosterols are premium products that will be clearly labelled and targeted at a very specific population sub-group. The label will include a recommendation for consuming two servings per day, and the phytosterol content will be prominently displayed in order to both inform the target group and provide justification for the increased unit price. The Applicant believes that, due to the specific and detailed labelling and the additional cost of purchase, the products will be used almost exclusively by the target group, and that consumption will not exceed the recommended amounts.

5.3.1 Consumption by children

As consumption of phytosterols is not considered appropriate for the whole population, the assessment will also consider whether fruit juice and fruit juice drinks are an appropriate food category for phytosterols given that these ingredients are primarily targeted to adults over 40 years of age who are seeking a lower cholesterol level.

The labelling, marketing and packaging of phytosterol-enriched fruit juices is intended to be openly and specifically aimed at adults. Because of this approach, the applicant considers that the products are unlikely to appeal to, or attract, younger consumers. The Applicant also supports the clear presentation of current mandatory advisory statements on packaging.

The juice drinks have been on the market in the US for only a short period, but initial information indicates that most purchasers choose them as a replacement for 100% juice.

5.4 Conditions of use of phytosterols

If approved, permission to use phytosterols in fruit juice and fruit juice drinks will be listed in the Table to clause 2 of the standard. Any special conditions of use, for example maximum permitted levels and reference to appropriate specifications, will also be listed in the Table in Column 2. The conditions of use may also include the requirement for distinctive labelling of products to provide information for consumers. The special conditions of use will be determined on completion of the comprehensive risk analysis.

5.4.1 Specifications for phytosterols

Currently, there are separate specifications for phytosterol esters (derived from vegetable oils) and non-esterified phytosterols derived from tall oils in Standard 1.3.4 – Identity and Purity. The specifications ensure that permitted substances meet internationally accepted standards for identity and purity. It should be noted that there is no entry for non-esterified phytosterols derived from vegetable oils in Standard 1.3.4, and therefore appropriate specifications would need to be considered for this Application.

6. Regulatory Options

6.1 Option 1 – do not approve the use of phytosterols in fruit juices and fruit juice drinks

This option maintains the status quo by not including these foods in the Table to clause 2 of Standard 1.5.1, thereby retaining the current limitations on use of phytosterols.

6.2 Option 2 – approve the use of phytosterols in fruit juices and fruit juice drinks

This option will result in an amendment to the Code to permit the sale of fruit juices and fruit juice drinks containing vegetable oil-derived phytosterols at specified levels.

7. Impact Analysis

7.1 Affected parties

- consumers, especially target groups such as adults over 40 years of age with health concerns about high serum cholesterol;
- dietitians and allied health professionals providing dietary advice to consumers;
- the manufacturing and retail sectors of the food industry; and
- Government generally, where a regulatory decision may impact on trade or WTO obligations, and State, Territory and New Zealand enforcement agencies.

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 in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, including the likely health, economic and social impacts.

The following Initial Assessment of the costs and benefits of the two regulatory options identified so far is based on a preliminary assessment of the information supplied by the applicant and knowledge of previous considerations relating to the use of phytosterols in the food supply.

7.2.1 Option 1

There is a potential cost to consumers with this option in terms of the lack of availability and choice of phytosterol-enriched food products. Similarly, there is an identifiable cost to the food industry in terms of a loss of product range and marketing opportunities. There would be no immediate impact on government.

7.2.2 Option 2

There are potential benefits to consumers associated with Option 2 in terms of access to a greater range of phytosterol-enriched food products and potential benefits to food manufacturers in terms of increased product range and greater market share. There are potential increasing marketing opportunities for food retailers. There would be no direct impact on Government as either of these options is unlikely to have any impact on monitoring resources.

To further develop the impact analysis in terms of the costs and benefits of the regulatory options proposed, FSANZ seeks comment on the following:

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

- What are 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 consumers in terms of public health and safety, consumer information and labelling?

- Do any identified health benefits for the targeted group of consumers outweigh any costs to non-target groups?

- What are the costs or benefits for business – increased market opportunities both domestically and overseas, production costs, marketing costs including providing advice to consumers, additional labelling requirements?

- What are the costs and benefits for government – administrative, public health and safety?

8. Consultation

This Initial Assessment Report is intended to seek early input from the general community on a range of issues associated with the availability of fruit juice products with added phytosterols in the food supply in Australia and New Zealand.

All individuals, groups or organisations who make a submission in relation to this Application will be included on a mailing list to receive further FSANZ documents pertaining to this Application. Readers are encouraged to bring this Initial Assessment Report to the attention of others with an interest in the Application. FSANZ will also add other interested parties to the mailing list for public consultation as they come to hand.

At this stage, FSANZ is seeking useful public comment to assist with the assessment of this Application. Such comments could cover:

- scientific aspects of the Application, in particular, any information relevant to the safety assessment;

- parties that might be affected by having this Application approved or rejected;

- potential costs and benefits to consumers, industry and government.

8.1 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.

There are not any relevant international standards and amending the Code to allow phytosterols in fruit juice and fruit juice drinks is unlikely to have a significant effect on international trade.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under 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

Section 13 of the FSANZ Act prescribes those matters that must be taken into account by FSANZ in making an Initial Assessment. FSANZ has taken those matters into account, and accepts the Application.

Accordingly, FSANZ now seeks public comment in order to proceed to the Draft Assessment of this application. If subsequently approved by FSANZ and agreed by the Ministerial Council, Standard 1.5.1 would allow the use of phytosterols derived from vegetable oils as ingredients in fruit juice and fruit juice drinks containing a minimum 20% fruit juice.