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

17 December 2008
[20-08]

INITIAL ASSESSMENT REPORT

APPLICATION A604

PHYTOSTEROLS IN FRUIT JUICE & FRUIT JUICE DRINKS

DEADLINE FOR PUBLIC SUBMISSIONS: **6pm (Canberra time) 11 February 2009**
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Coca-Cola South Pacific Pty Ltd has made 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 with a minimum 20% juice. In the *Australia New Zealand Food Standards Code* (the Code) Standard 1.5.1 – Novel foods, 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 adult consumers, generally over the age of 40, with concerns about their blood cholesterol level (the 'target consumers').

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 2001. In November 2006, permission was given for the addition of phytosterol esters to breakfast cereals, low-fat milk and low-fat yoghurt. Non-esterified phytosterols derived from a tall oil source are also permitted in low-fat milk. However, there is currently no permission in Australia and New Zealand to use non-esterified vegetable oil-derived phytosterols.

In assessing this Application, FSANZ will have regard to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) policy guideline on *Addition to Food of Substances other than Vitamins and Minerals* (the Guideline). This provides general guidance to assist FSANZ determine the appropriate circumstances under which substances should be permitted for addition to foods.

In order to assess the merits of this Application, data on the cholesterol lowering effects, nutritional effects and safety of phytosterols when added to fruit juice and fruit juice drinks will be taken into consideration. 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. FSANZ will consider the studies submitted by the Applicant as well as a wide range of other evidence, including published studies. FSANZ will consider the Acceptable Daily Intake (ADI) recently established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the potential dietary impact of a broader range of products containing phytosterols on target and non-target consumers.

At Initial Assessment, FSANZ has identified a number of issues that will need to be considered at Draft Assessment. These include:

- The possibility for cumulative intakes of phytosterols (including current permissions for tall oil phytosterols and phytosterol esters) to exceed the ADI, especially among children, once they are permitted in a broader range of foods.

- The potential for increased juice and juice drink consumption by the target consumers, and concerns around increased energy intakes related to this.

- That in the future, food manufacturers may wish to make health claims on products containing phytosterols.

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).

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.

Purpose

The purpose of this Application is to seek permission for the addition of phytosterols to fruit juice and fruit juice drinks (minimum 20% juice), at a maximum level of 4.5 g/L.

Reasons for Assessment

After considering the requirements for Initial Assessment, as prescribed in section 13 of the FSANZ Act (as was in force prior to 1 July 2007), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for the addition of phytosterols to fruit juice and fruit juice drinks. Such an approval, if accepted, would warrant a variation to Standard 1.5.1 – Novel Foods, Standard 2.6.1 – Fruit Juice and Vegetable Juice, and Standard 1.3.4 – Identity and Purity.

- There is currently no applicable permission in the Code.

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

- There are no other measures that would be more cost-effective and that could achieve the same end.

- At this stage, no other relevant matters are apparent.

Proposed Approach to Assessment

When developing and varying food standards, FSANZ must have regard to any written policy guidelines formulated by the Ministerial Council. In May 2008, the Ministerial Council endorsed a *Policy Guideline* on *Addition to Food of Substances other than Vitamins and Minerals*. The Guideline covers substances not intended to be consumed as foods in their own right which are added intentionally to foods, for a technological or other purpose.

This provides general guidance to assist FSANZ determine the appropriate circumstances under which substances should be permitted for addition to foods. FSANZ will have regard to the Guideline and proposes that the assessment of this Application will consider the following:

- The cholesterol lowering effects of phytosterols when added to fruit juice and fruit juice drinks. This assessment is required since the policy guidance advises that substances should only be permitted to be added to foods if they are added in a quantity and form which is consistent with delivering the stated purpose.

- The safety of phytosterols when added to fruit juice and fruit juice drinks. This will include a consideration of current levels of intake, potential for increased intakes in the target and non-target populations, and the safety of these levels of intake.

- The nutritional impact of the addition of phytosterols to fruit juice and fruit juice drinks. These two beverage categories have different nutritional properties, so will be considered separately in relation to their potential nutritional impact.

- Consumer behaviour and the effectiveness of current risk management measures (namely advisory statements).

Consultation

Public submissions are now invited on this Initial Assessment Report. Comments may be made on any aspect of the Application. Information relating to the public health and safety aspects of this Application and potential benefits and costs would be of particular interest.

Responses to the Initial Assessment Report will assist FSANZ in preparing a Draft Assessment of this Application.

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INVITATION FOR PUBLIC SUBMISSIONS

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 of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 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, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 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. 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. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

Submissions need to be received by FSANZ by 6pm (Canberra time) 11 February 2009.

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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
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INTRODUCTION

An Application was received from Coca-Cola South Pacific Pty Ltd on 30 March 2007 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. The Application is unpaid.

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 litre of fruit juice and fruit juice drinks containing a minimum of 20% fruit juice[1]. The Applicant states that the consumption of 250 mL would therefore provide approximately 1 g phytosterols. The Applicant suggests that target consumers should consume two servings of 250 mL daily to achieve optimal intake of phytosterols.

There is currently no permission in the Code to use non-esterified vegetable oil-derived phytosterols.

The purpose of this Initial Assessment Report is to:

- clearly articulate the regulatory problem sought to be addressed;
- identify the objectives of any regulatory action;
- identify any relevant issues associated with the addition of phytosterols to the specified foods (including considering matters in the Ministerial Council Policy Guideline on Addition to Food of Substances other than Vitamins and Minerals);
- detail the potential impacts on all affected parties; and
- seek the views of stakeholders and any further available evidence on all of the above issues.

1. 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.

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.

[1] Throughout this report, the term 'fruit juice drinks' refers to those fruit juice drinks containing a minimum of 20% fruit juice.

It is now well established that consumption of plant sterols, from either a vegetable oil or tall oil source, in amounts between 2-3 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 bloodstream 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 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 Applicant requests that 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.

1.1 Terminology

For the purpose of this Report:

Phytosterols: refer to vegetable oil-derived, non-esterified phytosterols, as requested to be permitted in this Application.

Fruit juice: refers to products meeting the definition of 'fruit juice' in the Code. Standard 2.6.1 – Fruit Juice and Vegetable Juice, defines fruit juice as the liquid portion, with or without pulp, obtained from –

(a) fruit; and
(b) in the case of citrus fruit, other than lime, the endocarp only of the fruit;

and includes products that have been concentrated and later reconstituted with water to a concentration consistent with that of the undiluted juice from which it was made.

This includes fruit juice blends.

Fruit juice drink: refers to fruit juice drink containing at least 20% fruit juice. This is what the Applicant has specifically sought permission for.

This definition is distinct from the Standard 2.6.2 – Non-alcoholic Beverages definition, which defines *fruit drink* as containing no less than 50 mL/L of fruit (except in the case of passionfruit drink which must contain no less than 35 mL/L of passionfruit) prepared from any of the following sources:

(a) fruit juice; and
(b) fruit purée; and
(c) concentrated fruit juice; and
(d) concentrated fruit puree; and
(e) comminuted fruit; and
(f) orange peel extract; and

This is also different from the permission in Standard 1.3.2 for the addition of certain vitamins and minerals to fruit and/ vegetable drinks containing at least 25% juice.

Target consumers: The population group at which this product is specifically aimed i.e. adult consumers, generally aged over 40 years, with concerns about their cholesterol.

Non-target consumers: Consumers other than *target consumers*, including children, teenagers, pregnant and lactating women.

1.2 Standard 1.5.1 - Novel Foods Standard

Under Standard 1.5.1, novel foods are required to undergo a pre-market safety assessment. The purpose of this Standard is to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale in Australia or New Zealand.

Novel Food is defined in clause 1 of Standard 1.5.1 as:

> *a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account;*
>
> *(a) the composition or structure of the product;*
> *(b) levels of undesirable substances in the product;*
> *(c) the potential for adverse effects in humans;*
> *(d) traditional preparation and cooking methods; or*
> *(e) patterns and levels of consumption of the product.*

Non-traditional food *means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand*.

In 1999, it was agreed among Senior Food Officers in each of the Australian States and Territories and New Zealand and the then Australia New Zealand Food Authority (ANZFA) that phytosterol esters ought to be regarded as novel food ingredients because of the lack of a history of significant consumption by the broad community at the proposed levels of dietary intake (See section 2). Since then, tall oil phytosterols have also been considered novel foods.

1.3 Current permissions for the addition of phytosterols

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 effectiveness of phytosterols in lowering cholesterol when present in a broader range of foods. In November 2006, permission was given for the addition of phytosterol esters to 'healthy' breakfast cereals (low sugar and high fibre), low-fat milk and low-fat yoghurt. Non-esterified phytosterols derived from a tall oil source are also permitted in edible oil spreads and low-fat milk.

These phytosterol-enriched foods are required to contain a minimum of 0.8 g and a maximum of 1.0 g per quantity (average serving size) of food. The minimum level ensures that intake of phytosterol-enriched foods (of any type) is more likely to reach the optimal amounts for a cholesterol-lowering effect. The maximum level is intended to assist consumers avoid higher intakes that provide no additional cholesterol-lowering benefits.

All plant sterols, whether derived from a vegetable oil or tall oil source, are permitted within the same range, to avoid consumer confusion between the two types of phytosterols permitted in the Code.

All currently permitted phytosterol-enriched food are required to be labelled with statements to the effect that:

- when consuming the product, it should be consumed as part of a healthy diet[2];
- the product may not be suitable for children under the age of five years and pregnant or lactating women[3]; and
- plant sterols do not provide additional benefits when consumed in excess of three grams per day[4].

These statements are intended to provide information to consumers at the time of purchase.

An Acceptable Daily Intake for phytosterols was not established when these permissions were given, however the proposed intake levels were considered to be consistent with the safety recommendations, which found phytosterols were well tolerated, efficacious in the foods under consideration (over and above a background low-fat diet) and raised no safety concerns in adults or children. High levels of consumption (up to 10 g per day) had been shown in clinical studies to be safe, providing a margin of exposure when compared to the expected level of consumption of 2-3 g per day. Phytosterol-enriched foods had been available in the food supply for more than 10 years in other jurisdictions without raising safety concerns. Limitations on the level of consumption are recommended primarily because increasing intake beyond 3 g per day produces little additional reduction in LDL-cholesterol.

A number of Standards relate to the above phytosterol permissions. These are:

- 1.2.3 – Mandatory Warning and Advisory Statements and Declarations
- 1.2.4 – Labelling of Ingredients
- 1.5.1 – Novel Foods
- 2.4.2 – Edible Oils Spreads

[2] Plant sterols are permitted only in foods that are compatible with a healthy diet (e.g. low-fat milk, low-fat yoghurt and breakfast cereal that is not marketed to children). The 'healthy diet' message is consistent with other public health messages in relation to diet and chronic disease.

[3] While studies in pregnant women were not available, the effects of phytosterols in children with familial hypercholesterolaemia were well studied. While consumption by children with hypercholesterolaemia was without adverse physiological effects, it was generally agreed that children do not derive a benefit to the same extent as adults from a reduction in their cholesterol levels, nor do children generally need to reduce their cholesterol levels.

[4] The optimal cholesterol lowering benefits are achieved when consumption of plant sterols is around 2-3 g per day. Furthermore, there is no significant improvement in cholesterol reduction above approximately 3 g per day, and therefore higher levels of consumption are unnecessary. This statement is intended to allow consumers to use the products cost-effectively.

1.4 Other related FSANZ projects

In addition to the current permissions, FSANZ has also completed the Initial Assessment of an Application for the addition of phytosterol esters to low-fat yoghurt mini-drinks (A596 – Vegetable Oil Phytosterol Esters in Low-Fat Yogurt Mini-Drinks).

A health claim was not part of the assessment of any previous phytosterol application, nor is it part of Application A604. Nevertheless, it is pertinent to note that, as part of Proposal P293 – Nutrition, Health & Related Claims, FSANZ is proposing that specific conditions must be met before a general level health claim can be made in relation to biologically active substances (including phytosterols)[5].

1.5 Policy Guidance on Addition to food of substances other than vitamins and minerals

When developing and varying food standards, FSANZ must have regard to any written policy guidelines formulated by the Ministerial Council. In May 2008, the Ministerial Council adopted a *Policy Guideline* on *Addition to Food of Substances other than Vitamins and Minerals*. The Guideline covers substances not intended to be consumed as foods in their own right which are added intentionally to foods, and includes those substances added to achieve a technological purpose or for other reasons.

This provides general guidance to assist FSANZ determine the appropriate circumstances under which substances should be permitted for addition to foods. In addition to 'High Order' policy principles, specific order policy principles relevant to the addition of phytosterols have been set out as follows:

The addition of substances other than vitamins and minerals to food where the purpose of the addition is for other than to achieve a solely technological function should be permitted where:

a) the purpose for adding the substance can be articulated clearly by the manufacturer (ie the 'stated purpose'); and

b) the addition of the substance to food is safe for human consumption; and

c) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and.

d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population; and

e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.

1.6 Application A560 – Phytosterols in Fruit Juice and Fruit Juice Drinks

In April 2005, Coca-Cola South Pacific Pty Ltd submitted an Application (Application A560 – Phytosterols in Fruit Juice & Fruit Juice Drinks) for the addition of phytosterols to fruit juice and fruit juice drinks.

[5] Proposal P293 has not been finalised yet. It is currently under review as per a request by the Ministerial Council .http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm

This was a cost-recovered Application and work commenced immediately with FSANZ preparing an Initial Assessment Report which was publicly consulted upon from August to September 2005.

At that time three other phytosterol Applications (A433, A434 and A508) were under consideration by FSANZ. The Ministerial Council had requested a First Review of all three of these Applications on the grounds that they (i) were not assessed in accordance with current Ministerial Council policy guidelines[6], (ii) do not protect public health and safety, and (iii) do not ensure adequate information to enable informed choice.

FSANZ prepared a First Review Report addressing both labelling and nutritional issues associated with phytosterol-enriched foods. The Ministerial Council considered this Report and a Second Review was requested (on the basis that the Applications did not protect public health and safety and did not provide adequate information to enable informed choice by consumers). As the Ministerial Council's response to the Second Review Report could have affected the progression of Application A560, Coca-Cola chose to withdraw Application A560 until these three Applications had been finalised.

The three Applications, A433, A434 and A508, were approved by Ministerial Council and the subsequent changes to the Code gazetted in November 2006.

This Application, is a re-submitted version of Application A560.

1.7 International regulations

1.7.1 Codex Alimentarius Commission

There are no Codex standards in relation to phytosterols.

1.7.2 Joint FAO/WHO Expert Committee on Food Additives

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered phytosterols, phytostanols and their esters at its 69th Meeting, in June 2008. An Acceptable Daily Intake[7] (ADI) was established at 40 mg/kg body weight. This is a group ADI for phytosterols, phytostanols and their esters which meet the specification set by JECFA at the same meeting. Prior to this, an ADI had not been set by Australia, New Zealand or any other country.

1.7.3 Approvals in other countries

United States of America

According to the Applicant, fruit juice and juice drinks containing phytosterols are permitted on the market in the United States.

[6] At that time policy guidelines had been set by the Council in relation to novel foods, health claims and fortification. The policy guideline on the Addition to Food of Substances other than Vitamins and Minerals was being developed.

[7] The Acceptable Daily Intake is an estimate of the amount of a substance in food or drinking water, expressed on a body mass basis (usually mg/kg body weight), which can be ingested daily over a lifetime without appreciable health risk.

The name under which the products are being marketed is 'Minute Maid® Premium Heart Wise™'. The US FDA has approved an associated health claim[8] for plant sterol and stanol esters when consumed as part of a diet low in saturated fat and cholesterol.

A large range of other phytosterol-containing products (esters or tall oils) permitted on the market in the USA have self-confirmed Generally Recognized as Safe (GRAS) status[9].

European Union

The consumption of phytosterol containing fruit juices and nectars was 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 allowing phytosterols to be added to fruit juices and nectars. This opinion was forwarded by the European Commission to other Member States in the European Union. The Member States expressed different views on the issue. Several Member States opposed the placing on the market of the product for comment due to concerns that additional foods containing phytosterols could lead to their over-consumption. In view of the divergent views, the European Commission sought the opinion of the European Food Safety Authority (EFSA).

EFSA expressed an opinion in February 2007 that providing no greater than 3 g of phytosterols were consumed per day, the addition of phytosterols to fruit juice and nectars could be accepted. However, EFSA was unable to determine whether the addition of phytosterols to fruit juices and nectars might lead to this level of consumption, and so stated that quantitative intake data of phytosterols added to food in the European Union is needed for an adequate assessment and conclusion with respect to the potential risk of over-consumption.

More generally, in Europe, plant *sterols* in their various forms are permitted in yellow fat spreads[10], milk-type products (and fermented milk- and yoghurt-type products), cheese-type products, milk-based fruit drinks, soy drinks, spicy sauces and salad dressings and certain rye breads.

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

[9] **GRAS GRN 000206 (December 2006**): for use as an ingredient in baked goods and baking mixes; fats and oils; frozen dairy desserts and mixes; gelatins, puddings, and fillings; grain products and pastas; gravies and sauces; hard candy; milk; milk products; soft candy; soups and soup mixes; and snack foods at a level of 0.65 gram (g) phytosterol esters per reference amount customarily consumed.
GRAS GRN 000181 (March 2006): for use as an ingredient in egg products, including egg whites and egg substitutes, at levels up to 20 milligrams (mg) plant sterol per gram (g) of egg product, providing 1100 mg phytosterol per serving.
GRAS GRN 000112 – (February 2003): for use as an ingredient in margarine and vegetable-based spreads (margarine-like); yogurt and yogurt-like products; milk-based juice beverages; ice cream and non-standardized ice cream products; cream cheese and cream cheese-like products; snack bars (health bars); salad dressing, mayonnaise, French dressing, and dressings for salads; and white breads, white rolls and buns, and comparable non-standardized white bread products.
GRAS GRN 000053 (December 2000): for use as an ingredient in vegetable oil, at a level up to 13.3 per cent by weight, for home use applications such as baking, frying, and salad dressings.
GRAS GRN 000048 (November 2000): for use as an ingredient in vegetable oil spreads, dressings for salads, bars, and yogurt.
GRAS GRN 00039 (April 2000): for use as an ingredient in vegetable oil spread at a level up to 12% free phytosterols.

[10] Excluding cooking and frying fats and spreads based on butter or other animal fat

Plant *stanols* are permitted on the market in the EU, without being subject to review, because they were marketed in a member State before the Novel Foods Regulation came into force. Initially, the products were edible oil spreads (margarines), but this has broadened to other foods such as fresh cheese, snack bars, salad dressing and yoghurt. Given the similarities in composition of the plant sterols (sterols, stanols and their conjugated esters), and similar conclusions regarding safe levels of consumption, the EC has moved to common labelling requirements and specifications for all phytosterol products, irrespective of their plant source. Generally, there is a requirement that a portion of the food will not contain more than 3 g (in the case of one portion per day) or more than 1 g (in the case of 3 portions per days) of added phytosterols/phytostanols.

2. The Regulatory Problem

There is currently no permission in the Code to allow the addition of phytosterols to fruit juices or fruit juice drinks.

Phytosterols are considered to be novel foods. Standard 1.5.1, requires that novel foods, which have features or characteristics that may raise safety concerns, undergo a risk-based safety assessment before they are offered for retail sale 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.

Therefore FSANZ will consider if Standard 1.5.1 ought to be amended to allow the use of phytosterols (non-esterified) in fruit juice and fruit juice drinks.

3. Objectives

In addressing the proposed variation to Standard 1.5.1 to approve the use of phytosterols as novel food ingredients in fruit juice and fruit juice drinks, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 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. Approach to the Assessment

FSANZ has previously evaluated the safety and cholesterol lowering effects of vegetable oil phytosterol esters in spreads, breakfast cereals, low-fat milk and low-fat yoghurts, and tall oil phytosterols in edible oil spreads and low-fat milk. Therefore, this Application will be assessed by examining the overall cholesterol-lowering effect, safety concerns, other nutrition effects and the nutritional impact that could result from permission to add phytosterols to fruit juice and fruit juice drinks.

FSANZ must have regard to Ministerial policy guidance as discussed in Section 1.3 and proposes that the assessment of this Application will consider the following:

- The potential for these forms of phytosterols when added to fruit juice and fruit juice drinks to lower cholesterol levels.

- The safety of phytosterols when added to fruit juice and fruit juice drinks. This will include a consideration of current levels of intake, potential for increased intakes in the target and non-target populations, and the safety of these levels of intake. This will include an evaluation of the Acceptable Daily Intake (ADI) recently established by JECFA and dietary modelling of the levels of intake in Australia and New Zealand.

- The nutritional impact of the addition of phytosterols to fruit juice and fruit juice drinks. Because fruit juice and fruit juice drinks have different nutritional properties, they will be considered separately in relation to nutritional impact.

- Consumer behaviour and the effectiveness of current risk management measures (namely advisory statements).

5. Health Benefits of Phytosterols

It is well established in the literature that consuming phytosterols in amounts up to 3 g per day can lead to reduced total and low-density lipoprotein (LDL) cholesterol levels[11]. Although FSANZ previously assessed phytosterols predominantly on their safety, the beneficial cholesterol lowering properties of phytosterols in spreads, breakfast cereals, and low-fat yoghurt and milk was also considered. Assessment of other phytosterol Applications (A433, A434 and A508) concluded the evidence demonstrated reduced cholesterol absorption in subjects, resulting in lower plasma cholesterol levels following ingestion of 2-3 g/day of phytosterol esters. As part of this Application, FSANZ will consider if phytosterols in juice and juice drinks have the same effect.

6. Key Assessment Questions

As part of the evaluation of the Application, FSANZ will consider the following questions:

[11] Katan et al. (2003) Efficacy and Safety of Plant Stanols and Sterols in the Management of Blood Cholesterol Levels. *Mayo Clin Proc*. 2003;78:965-978.

6.1 Potential Health Benefit

1. Do phytosterols added in this form to fruit juice and fruit juice drinks have the potential to deliver the intended health benefit (i.e. are they functionally equivalent to currently permitted phytosterol esters and tall oil phytosterols)?

6.2 Food Technology

2. Would phytosterols added to fruit juice and fruit juice drinks remain stable over the shelf-life of the product, so as to provide the stated benefit to consumers?

6.3 Safety

3. What are the safety issues identified recently that resulted in the establishment of a reference health standard (Acceptable Daily Intake, ADI) for phytosterols?

4. Has any new and relevant information relating to the safety of phytosterols in either target or non-target population groups become available since the previous assessment?

6.4 Intake

5. What is the current estimated phytosterol intake in target and non-target consumers from currently permitted forms of phytosterols (phytosterol esters and tall-oil phytosterols)?

6. Would permission for the addition of phytosterols to fruit juice and fruit juice drinks increase the total intake of phytosterols (including phytosterol esters and tall-oil phytosterols) by target and/or non-target consumers?

7. How does the estimated intake of phytosterols from fruit juice and fruit juice drinks in addition to intakes from currently permitted phytosterol-enriched foods compare with the ADI?

8. Do consumers understand the purpose of consuming phytosterols containing products and the appropriate levels of consumption for both target and non-target groups?

6.5 Nutritional impact

9. Could the addition of phytosterols in fruit juice and fruit juice drinks confer a negative public health impact to the target or non-target population (fruit juice and fruit juice drinks will be considered as separate food categories for assessment of their nutritional impact)?

6.6 Risk management

10. How effective have the existing mandatory advisory statements been in: informing consumers; limiting consumption to targeted groups; ensuring adequate consumption; and limiting over-consumption?

RISK ASSESSMENT

7. Risk Assessment

7.1 Safety Assessment

The safety of phytosterols in the context of existing permissions for phytosterol-enriched table spreads, breakfast cereal and low-fat milk and yoghurt products has been adequately demonstrated. Clinical studies using patients with mildly elevated blood cholesterol levels have shown no adverse effects at levels of consumption up to 10.2 g phytosterols per day over a period of 12 weeks. On the basis of these and other published findings, consumption of approximately 3 g phytosterols per day (consistent with three servings of phytosterol-enriched foods) is considered to be optimal for achieving a cholesterol-lowering effect and is well within the levels of consumption previously shown to be safe.

Since the current range of products was approved however, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has reviewed the available toxicological evidence at their meeting in June 2008[12]. At this meeting, the focus of discussion was on newly submitted data and other information relevant to the safety of phytosterols, phytostanols and their esterified forms. Based on similar chemistry and effects on cholesterol levels in humans, the Committee decided that these compounds and mixtures could be considered as one group. The Committee established a group Acceptable Daily Intake[13] (ADI) of 0-40 mg/kg body weight for phytosterols, phytostanols and their esters, expressed as the sum of sterols and stanols in the free form. This reference health standard was supported by the combined evidence from several 90-day toxicity studies.

The FSANZ assessment of the safety of phytosterols when present in fruit juice drinks will consider the basis for establishing the ADI, recently set by JECFA, in the context of the whole diet. This will include consideration of the potential for adverse health effects in the target population group as well as any potential health impacts on non-target consumers.

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.

7.2 Nutrition Assessment

7.2.1 Potential adverse nutritional effects from phytosterols

Phytosterols have previously been shown to lower LDL-cholesterol levels. Given that vegetable oil-derived phytosterols have not previously been assessed by FSANZ, consideration will be given to whether their consumption has potential for adverse nutritional effects. In relation to previous Applications, a 20-25% decrease in serum β-carotene levels resulting from consumption of phytosterol-enriched foods was not considered to represent a nutritional risk.

[12] 69th Meeting of the Joint FAO/WHO Expert Committee on Food Additives, Rome (June 2008).
[13] The reference health standard *Acceptable Daily Intake* (ADI) is an estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk.

This is because the levels of β-carotene in serum are known to fluctuate widely as a consequence of many dietary and environmental factors and a decrease of this magnitude falls within a broad natural variation. Additionally, the evidence consistently shows no change in vitamin A levels in consumers of phytosterol-enriched products. However, FSANZ will evaluate any new evidence, and any evidence specifically relating to the consumption of vegetable oil-derived phytosterols and β-carotene levels.

FSANZ will also consider whether increased consumption of phytosterols and phytosterol esters, arising from a broader range of enriched-products, may have adverse nutritional effects in target and non-target consumers.

7.2.2 Potential health benefits of phytosterols in fruit juice and fruit juice drinks

The evidence for the cholesterol lowering potential of phytosterols when added to fruit juice and fruit juice drinks will be assessed. The Applicant has submitted a published clinical study that investigated the efficacy of phytosterols in lowering serum cholesterol when incorporated into orange juice (a non-fat beverage). This study, in combination with other relevant published scientific literature, will be used to assess the effectiveness of these substances when present in low fat beverages such as fruit juice.

7.2.3 Potential public health nutrition impact from the use of juice and juice drinks as a food vehicle for phytosterols

As phytosterols lower LDL-cholesterol levels, it is appropriate that they be permitted in foods that are consistent with a healthy diet. Similarly, the products should not promote consumption patterns that are inconsistent with dietary advice to reduce cholesterol.

The Australian National Health and Medical Research Council (NHMRC) Dietary Guidelines for Australian Adults[14] suggest that as fruit juice is low in fibre and energy dense, one serve a day is acceptable. The Australian Guide to Healthy Eating (Commonwealth Department of Health and Ageing, 1998[15]) suggests that half a cup (125 mL) of fruit juice is equivalent to one serve of fruit. The New Zealand Food and Nutrition Guidelines for Healthy Adults (Ministry of Health, 2003[16]) suggest one cup (250 mL) of fruit juice can be consumed as a serve of fruit in a day. This Application proposes the consumption of 500 mL of juice or juice drink per day. The public health impact, both positive and negative, of the potential high juice consumption recommended in the Application will be considered at Draft Assessment. As it has different nutritional properties, fruit juice will be considered separately from fruit juice drink.

7.3 Consumer Behaviour Assessment

There is limited research around how consumers respond to the current range of phytosterol-enriched products available in Australia and New Zealand. In terms of the key consumer research findings of interest, data generally show that:

[14] Available at http://www.nhmrc.gov.au/publications/synopses/dietsyn.htm (Accessed 22 July2008)
[15] Available at http://www.nhmrc.gov.au/publications/synopses/_files/n31.pdf (Accessed 22 July 2008)
[16] Available at http://www.moh.govt.nz/moh.nsf/ae8bff4c2724ed6f4c256669006aed56/fe468ceed06b0771cc256cd600709490?OpenDocument (Accessed 22 July 2008)

- In Australia and New Zealand[17], phytosterol-enriched spread users have mixed understandings of the role of phytosterol-enriched products and labelling information, e.g. issues such as the suitability for children, and serving size information. This was reflected also in UK FSA data[18] (relating to phytosterol-enriched products such as spreads, yoghurt pots and yoghurt drinks), which indicated that consumption guidelines have not been successfully communicated to the majority of consumers. These data also show a level of confusion amongst product users over the distinction of cholesterol-lowering yoghurts and yoghurts designed to maintain a healthy digestive system.

- Self-reported consumption data across Australia and New Zealand show that there has been very little overconsumption of phytosterols, consistent with the recommendations of labels to consume 3 g per day for optimal cholesterol reduction[19]. From international data, an estimated 0.5-3% of people in the UK, 2.3% of people in Germany, and a larger proportion of 23% of people in Ireland were found to be exceeding the recommended intake of 3 g per day[20].

- In terms of consumption and potential changes in lifestyle behaviours, Australian and New Zealand phytosterol-enriched spread consumers do not see phytosterols as a "magic bullet" and still recognise that they need to pay attention to their diet and exercise in addition to consuming the spread.

- Australian and New Zealand data show that phytosterol-enriched spread users are generally older adults who do not have children in the household. UK data shows some consumption of phytosterol products by children (1 in 200 under five year olds).

At Draft Assessment, FSANZ will consider the available information on consumer awareness and understanding of phytosterols and phytosterol-enriched products (including understanding and effectiveness of advisory statements on phytosterol-enriched products); actual and/or potential behaviour of consumers in response to phytosterol-enriched foods (including consumption of phytosterol-enriched products, and any trade-off behaviours or changes in lifestyle behaviours); and if there are disparate understanding / behavioural effects on any population groups (e.g. particular age or cultural groups). Where possible, this information will be used to inform the nutrition assessment, dietary intake assessment and risk management strategies.

Information gathered already by FSANZ relating to these issues is summarised below.

[17] FSANZ. (2006). Exploring consumer perceptions and use of phytosterol enriched spreads. Prepared by TNS Social Research for Food Standards Australia New Zealand: Canberra.
[18] UKFSA (2006). Consumer research on the consumption of phytosterols. Prepared by TNS Global for COI and the Food Standards Agency: London.
[19] Currently on labels
[20] European Food Safety Authority. (2008). Consumption of food and beverages with added plant sterols in the European Union. *The Efsa Journal, 133*, 1-21.

7.3.1 Impacts on consumption behaviour

7.3.1.1 Profile of consumers of phytosterol-enriched products and consumption motivations

Data collected in Australia and New Zealand, and the United Kingdom provide information on who consumes phytosterol-enriched products, and reasons / motivations for consumption. This data will be used for dietary modelling purposes to determine which subgroups of the population are consuming phytosterol-enriched products.

Australian and New Zealand data show that enriched spread users were more likely to be aged over 35 years, and score moderate to high on the scale of health consciousness. Main reasons for consumption of phytosterol enriched spreads included lowering cholesterol levels (30%) preventing high cholesterol (20%), and to improve health in general[21].

Data from the United Kingdom show that of the sample of adults surveyed[22], 27% of males, and 30% of females had consumed phytosterol-enriched products in the past 6 months. Breakdowns by age group showed that 35% of 16-24 year olds, 31% of 55-64 year olds and 29% of 45-54 year olds had consumed these products in the past 6 months. Of people who consumed phytosterol-enriched products in the past 6 months, 21% of males, and 29% of females consumed them regularly[23]. By age group, findings showed that 29% of those aged between 16-44 years, 25% of 55-64 year olds, 20% of 45-54 year olds, and 17% of those aged 65 and over had consumed these products regularly in the past 6 months[24].

The most common reasons for consumption among consumers of phytosterol enriched products in the UK were 'to lower my/my partner's cholesterol' (27%) (59% of whom have been diagnosed with high cholesterol), and 'because it's healthy / good for you' (27%). When examined by age group, lowering cholesterol was listed as a main reason for consuming these products by those aged 45 to 65 years and over. The main reason for product consumption by 16-44 year olds was 'it's good for you' / healthy[25].

7.3.1.2 Self-reported consumption levels

FSANZ will explore self-reported consumption levels of phytosterol-enriched products in Australia and New Zealand where possible, and this data will be used for dietary modelling purposes to ascertain levels of exposure of phytosterols across the population (where possible). This data may also reveal population subgroups consuming products for whom the product is not necessary; i.e. unintended (non-target) consumption across any subgroups of the population.

Mechanisms of how enriched product users consume these products will also be investigated where possible, e.g. *substitution* versus *additive* consumption of like products.

[21] FSANZ. (2006). Exploring consumer perceptions and use of phytosterol enriched spreads. Prepared by TNS Social Research for Food Standards Australia New Zealand: Canberra.
[22] This survey utilised the TNS Family Food Panel data, a diary-based continuous monitor of food and drink consumption of a representative sample of people in Great Britain. The data relates to that collected in 2005.
[23] Regularly = Weekly, but not daily
[24] UKFSA (2006). Consumer research on the consumption of phytosterols. Prepared by TNS Global for COI and the Food Standards Agency: London.
[25] UKFSA (2006). Consumer research on the consumption of phytosterols. Prepared by TNS Global for COI and the Food Standards Agency: London.

Data from Australia and New Zealand show that users of phytosterol-enriched spreads use these in addition to other non-enriched spreads. Assumptions about *substitution* versus *additive* consumption behaviours may also be used to inform dietary modelling scenarios.

7.3.2 Changes in lifestyle behaviours

FSANZ investigated the likelihood of phytosterol-enriched spread users in Australia and New Zealand to 'trade-off' healthy dietary behaviours or exercise regimes for consumption of the enriched spread. Australian and New Zealand data[26] shows that users of phytosterol-enriched spreads do not have different levels of physical activity or fruit and vegetable consumption to users of non-enriched spreads. FSANZ concludes that consumers of these products do not appear to be adopting any trade-off dietary or lifestyle behaviours, e.g. exercising less or eating less nutritiously.

7.3.3 Consumer awareness and understanding of advisory statements

Data from Australia and New Zealand[27] show that between half and two thirds of enriched spread consumers were aware that the product reduces cholesterol; and between a fifth and a third of consumers were not sure of the benefits. Around 10% believed the product to generally improve health. Only a quarter of respondents agreed with the statement that plant sterols are not suitable for children.

Results were similar in the UK where consumption guidelines have not been successfully communicated to the majority of consumers[28]. Findings show low levels of knowledge of the product and guidelines and low levels of label readership[29]. In terms of product knowledge, 60% correctly agreed a benefit of the product is that it can lower cholesterol. Half of respondents held the common misconception that the products help maintain a healthy digestive system, a quarter believed the products can lower blood pressure, and a fifth thought that consuming the product was more effective than other changes to lifestyle behaviours (e.g. exercising) in lowering cholesterol. Ten per cent of consumers also believed the products were suitable for children under 5 years of age. Only 10-13% were aware of maximum and minimum consumption guidelines.

Of consumers in Germany, only 4% were aware of the recommended upper limit of phytosterol intake of 3 g per day, and only around 10% of consumers correctly answered that children are not a target group for consumption of phytosterol-enriched products[30].

Regarding label readership, half of users indicated they could recall seeing 'lowers cholesterol level' on product labels, but only around 10% could remember seeing the maximum amount, and 10% the minimum amount you should eat each day to be of benefit. Four per cent reported seeing the products were not suitable for certain groups, as advised on the label.

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[26] FSANZ. (2006). Exploring consumer perceptions and use of phytosterol enriched spreads. Prepared by TNS Social Research for Food Standards Australia New Zealand: Canberra.
[27] FSANZ. (2006). Exploring consumer perceptions and use of phytosterol enriched spreads. Prepared by TNS Social Research for Food Standards Australia New Zealand: Canberra.
[28] Products with added phytosterols at time of survey include spreads, yoghurt drinks and yoghurt pots.
[29] UKFSA (2006). Consumer research on the consumption of phytosterols. Prepared by TNS Global for COI and the Food Standards Agency: London.
[30] European Food Safety Authority. (2008). Consumption of food and beverages with added plant sterols in the European Union. *The Efsa Journal, 133*, 1-21.

Overall, data indicates that enriched spread users have mixed understandings of the role of phytosterol-enriched products and current mandatory labelling information.

To further understand current use and understanding by consumers of phytosterol containing products, FSANZ seeks any additional information on the following:

Consumption Behaviour

- Who consumes phytosterol-enriched products, and why?
- Are there any subgroups of the population consuming phytosterol enriched products who are not intended to do so?
- What is the likely consumption behaviour of phytosterol enriched fruit juice/fruit juice drink e.g. addition, substitution and/or avoidance?

Impact on lifestyle behaviours

- What is the impact on 'trade-off' or lifestyle factors of allowing phytosterol enriched fruit juice/fruit juice drink, e.g. diet and exercise regimes?

Awareness, understanding and effectiveness of advisory statements

- What is the level of awareness in Australia and New Zealand of cholesterol-lowering measures and the role of phytosterols?
- Do phytosterol consumers understand the purpose of consuming phytosterols?
- How effective has the existing mandatory advisory statements been in informing consumers, limiting consumption to targeted groups, ensuring adequate consumption, and limiting over-consumption?
- Do phytosterol consumers understand the effective level of consumption required, and that no additional benefit is gained from consuming greater than 3 g /day?
- Are purchasers of phytosterols products aware that children, pregnant and lactating mothers are advised not to consume phytosterol enriched products?

7.4 Dietary Intake Assessment

The availability of a broader range of phytosterol-enriched foods necessarily involves consideration of the potential for increases in the levels of intake of phytosterols through the diet. The dietary intake assessment will therefore consider total intake of phytosterol esters and tall oil phytosterols currently permitted in foods as well as the proposed use of phytosterols in fruit juice and fruit juice drinks. Available information on consumer behaviour will also be taken into consideration, including the understanding and effectiveness of the current advisory statements.

The dietary intake assessment will be presented in the Draft Assessment Report.

7.4.1 Previous dietary intake assessments conducted by FSANZ

FSANZ previously produced dietary intake estimates for phytosterols as part of Applications A433, A434 and A508. Although an ADI had not been established at this time, modelling was done in order to compare potential intakes with the levels of phytosterols that had been used in the clinical studies assessed in the safety assessment.

Modelling was conducted assuming that consumers do not change the amounts and general types of foods they eat, simply substituting phytosterol-containing foods for their non-phytosterol counterparts. It was further assumed that all edible oil spreads, 'healthy' (i.e. high-fibre, low-sugar) breakfast cereals, and low fat milks and low fat yoghurt contained added phytosterols. Assessments were conducted for the general Australian and New Zealand populations (2 years and above and 15 years and above, respectively), for two target populations (those aged 40-64 years, and those aged 65 years and above) and for two non-target populations - women of childbearing age (16-44 years) and children (2-12 years, Australia only). Food consumption data were derived from the 1995 Australian National Nutrition Survey (NNS) and the 1997 New Zealand NNS.

Modeling for intakes of phytosterol esters derived from vegetable oils in edible oil spreads, breakfast cereals (A433) and in low fat milk and low fat yoghurt (A434) indicated estimated mean dietary intake from these foods, expressed as free phytosterols, did not exceed 1.9 g per day in any population group assessed. At the 95th percentile of intake, no population group exceeded 4.7 g free phytosterols per day. The major source of dietary intake to added phytosterols was edible oil spreads for all population groups assessed.

An assessment was also conducted of potential intake of tall oil phytosterols in edible oil spreads and low fat milks (A508). Estimated mean dietary intake (expressed as free phytosterols) did not exceed 1.9 g per day in any population group assessed. At the 95th percentile of intake, no population group assessed exceeded 4.8 g free phytosterols per day. The analysis showed that, for the target population group in particular, edible oil spreads contribute more to dietary intake of added free phytosterols (78-84% of intake) than low fat milks, according to the available data on food consumption patterns.

It should be noted that the modelling approach in the above cases assumed all requested foods contained phytosterols at the maximum concentration, and therefore dietary intake is overestimated.

7.5 Food Technology Assessment

Phytosterols derived from edible vegetable oils are comprised of varying ratios of the same four primary phytosterol substances sitosterol, sitostanol, campesterol and campestanol, with varying amounts of minor components such as stigmasterol and brassicasterol.

At Draft Assessment FSANZ will prepare a Food Technology Report, which will consider the physical properties (solubility, uniformity and stability in the food) of phytosterols in juice and juice drinks. The use of food additives in the phytosterol preparation will also be considered.

RISK MANAGEMENT

8. Risk Management

8.1 Marketing of products

The assessment of this Application will 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.

The Applicant states that 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. This will be evaluated as part of the consumer behaviour assessment discussed at Section 7.3, and will inform FSANZ's risk management approach.

8.2 Advisory statements

A key part of the risk management strategy for currently available phytosterol-enriched products is the use of mandatory advisory statements informing consumers about the food. All phytosterol-enriched products currently on the market are required to be labelled with statements to the effect that the food should be consumed as part of a healthy diet, may not be suitable for children under the age of five years and pregnant or lactating women, and that plant sterols do not provide additional benefits when consumed in excess of 3 g per day.

The labelling of products with these statements is intended to limit consumption to three grams per day, and thus prevent over-consumption, as well as limiting consumption by non-target populations.

The consumer behaviour assessment, discussed at Section 7.3 will help FSANZ ascertain how consumers understand and use the current advisory statements and if these are not sufficient to prevent over consumption by any group and the consumption by non-target populations. If necessary, other risk management strategies will be considered.

8.2.1 Unintended consumption of phytosterol-enriched products

As consumption of phytosterols is not considered appropriate for the whole population, the assessment will also consider the potential for consumption by children, and other subgroups of the population (e.g. pregnant and lactating mothers), and whether fruit juice and fruit juice drinks are appropriate foods for the addition of phytosterols.

The current mandatory advisory statement advising that the product may not be suitable for these groups will be evaluated, to determine if this risk management approach is sufficient or if further strategies are required.

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. FSANZ will assess this at Draft Assessment.

8.3 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 Standard 1.5.1. Any special conditions of use, including maximum permitted levels and reference to appropriate specifications, will also be listed in the Table in Column 2. The conditions of use are likely to 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.

8.4 Specifications for phytosterols

Standard 1.3.4 contains specification for 'tall oil phytosterols derived from tall oils' and 'phytosterol esters derived from vegetable oils'. JECFA recently published new specifications on 'phytosterols, phytostanols and their esters' (June 2008). As the JECFA specifications will be taken up into Standard 1.3.4 as a primary source, there is no longer a need to maintain individual specifications, and these can be deleted either as part of this or other applications, or through an omnibus amendment.

Standard 1.5.1 lists 'tall oil phytosterols' and 'phytosterol esters' as approved novel foods, and lists what foods they can be added to. As the new JECFA ADI applies broadly to all phytosterol preparations meeting its specification (phytosterols, phytostanols and their esters) it is reasonable for FSANZ to consider altering the permissions in Standard 1.5.1 to include the products that meet the specification for phytosterols, phytostanols and their esters as considered by JECFA. This would be considered a consequential amendment and accomplished as part of this Application.

9. Options at Initial Assessment

9.1 Option 1 – Reject the Application

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.

9.2 Option 2 – Accept the Application

This option allows FSANZ to conduct a full consideration of the potential impacts of the addition of phytosterols to fruit juice and fruit juice drinks.

At Draft Assessment, FSANZ will consider the levels and food vehicles requested by the Applicant, and assess if these are acceptable, or if they should be revised. For example, FSANZ will consider if the serve size should be changed, or if the addition should be limited to certain sub-categories of the food groups identified.

10. Impact Analysis

10.1 Affected Parties

1. Consumers – especially target groups such as adults over 40 years of age with health concerns about high serum cholesterol

2. Government generally, where a regulatory decision may impact on trade or WTO obligations, and State, Territory and New Zealand enforcement agencies

3. Dietitians and allied health professionals providing dietary advice to consumers

4. The manufacturing and retail sectors of the food industry.

10.2 Benefit / Cost 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.

10.2.1 Option 1

This option continues the *status quo*.

10.2.2 Option 2

This option allows FSANZ to conduct a full consideration of the potential impacts of the addition of phytosterols to fruit juice and fruit juice drinks. If the Application is agreed, there are potential benefits to consumers in terms of potential access to a greater range of phytosterol-enriched food products and ensuing health benefits. For example, consumers who avoid dairy products or high fat products such as spreads would have greater access to phytosterol-enriched products. There are potential benefits to food manufacturers in terms of increased product range and greater market share. There are potential increased marketing opportunities for food retailers. There would be no direct impact on Government as either of these options is unlikely to have any significant 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:

- 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?

COMMUNICATION AND CONSULTATION STRATEGY

11. Communication

FSANZ has applied a basic communication strategy to this Application. This will involve advertising the availability of assessment reports for public comment in the national press and making reports available on the FSANZ website.

The Applicant and individuals and organisations who make submissions on this Application will be notified at each stage of the assessment of the Application. If approval is recommended, once the FSANZ Board has approved the Final Assessment Report, FSANZ will notify the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the website.

FSANZ provides an advisory service to the jurisdictions on changes to the Code.

12. 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.

12.1 Consultation on previous Application A560

Public consultation was invited on the Initial Assessment Report for Application A560 – Phytosterols in Fruit Juices and Fruit Juice Drinks (see Section 1.2), between 3 August 2005 and 14 September 2005.

Twenty-one submissions were received; nine opposed and six supported the Application, while another six expressed no preferred option at IAR. The key issues raised in previous submissions have been addressed below as far as possible. Further consideration of the issues specific to this application will occur at Draft Assessment.

12.1.1 Consistency of Application with current dietary guidelines

A number of submitters expressed concern over whether it is appropriate to encourage the consumption of up to 500 mL fruit juice or fruit juice drink per day (the suggested daily intake; two 250 mL serves), when current dietary guidelines recommend limiting the consumption of fruit juice and fruit juice drinks and encouraging consumption of water. The potential role of fruit juice and fruit juice drinks (and other sweet beverages) in overweight and obesity was of concern and it was suggested that the loss of excess body weight can contribute to managing cholesterol levels.

12.1.1.1 FSANZ response

The appropriateness of addition of phytosterols to fruit juice and fruit juice drinks will be considered as part of the nutrition assessment at Draft Assessment. One of the conditions of the Ministerial Council policy guidance is that the addition of the substance must not be likely to create a significant negative public health impact to the general population or sub population. Negative public health impact may occur through increased consumption of a particular food, or decreased consumption of other foods which might be displaced by the new food product. FSANZ will consider the potential for the addition of phytosterols to influence consumption patterns in a way which could lead to negative public health impacts, and if it is likely for this to occur, will develop a strategy to manage this in the regulatory context.

12.1.2 Safety concerns that the addition of phytosterols to a broad range of foods could lead to overconsumption

Several submitters expressed concern that more and more foods are having phytosterols added and that this may lead to over-consumption by both the target group and by non-target consumers (e.g. children and teenagers).

12.1.2.1 FSANZ response

FSANZ will have regard to the cumulative impact of phytosterols being added to multiple food products. This matter will be fully considered at Draft Assessment.

Consumer research presented as part of the Second Review Report for Applications A433, A434 and A508, concluded that under-consumption of plant sterol-enriched products in the target audience is a greater issue than over-consumption.

Those foods that are currently permitted to contain added phytosterols have mandatory labelling requirements, informing consumers about the appropriate number of servings to consume per day. If this application were approved, similar labelling requirements are likely to be imposed. However, it is important to note that limitations on the level of consumption are recommended primarily because increasing intake beyond 3 g per day produces no additional benefit to consumers (i.e. reduction in LDL-cholesterol).

Standard 1.2.3 provides that permitted products are also required to include the following advisory statement: *This product may not be suitable for children under the age of five years and pregnant or lactating women*.

The purpose of this statement is to limit consumption of phytosterol-enriched foods by non-target groups, as these groups will generally not benefit from the consumption of such foods, rather than because these foods pose a risk. If this Application is approved, similar labelling requirements are likely to be imposed. As part of Draft Assessment, FSANZ will aim to determine if consumers understand and use the information provided on the labels of phytosterol-enriched foods.

12.1.3 Standardisation of specifications for phytosterols/international harmonisation

Standard 1.3.4 – Identity and Purity, contains specifications for phytosterol esters and for tall oil phytosterols. This application will require a separate specification for non-esterified phytosterols. One submitter suggested that FSANZ should consider broadening the specification within a safe and efficacious range so that it covers the array of phytosterol products that might be added to foods. This could allow Australia and New Zealand to harmonise our specification with those used internationally.

12.1.3.1 FSANZ response

FSANZ agrees that this approach would be more streamlined than the current approach, and is considering how simplification and harmonisation could occur without altering the intent of the current regulations. The more generic JECFA specification for 'phytosterols, phytostanols and their esters' will be included in Standard 1.3.4, and other parts of the Code that refer to tall oil phytosterols or phytosterol esters could be amended to reflect this broader specification. This will be considered at Draft Assessment.

12.1.4 Labelling of phytosterol-enriched products

A number of submitters commented that there should be labelling requirements for fruit juice and fruit juice drinks with added phytosterols, for example, clear labelling stating for whom the product is or is not suitable and the appropriate serving size and number of serves.

FSANZ response

Currently permitted phytosterol-enriched foods have specific mandatory labelling requirements. These include a statement to the effect that the product may not be suitable for children under five years and pregnant or lactating women, and provides no additional benefit over 3 g/day of phytosterols. It is likely that similar requirements would apply to fruit juices and fruit juice drinks if this application is approved. Consideration will be given to the labelling requirements at Draft Assessment.

12.2 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.

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 Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (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.

CONCLUSION

13. Conclusion

This Initial Assessment Report is based mainly on information provided by the Applicant and discusses relevant issues in relation to approving the addition of phytosterols as a novel food ingredient in fruit juice and fruit juice drinks. After having regard to the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act (as was in force prior to 1 July 2007), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for the addition of phytosterols to fruit juice and fruit juice drinks. Such an approval, if accepted, would warrant a variation to Standard 1.5.1 – Novel Foods, Standard 2.6.1 – Fruit Juice and Vegetable Juice and Standard 1.3.4 – Identity and Purity.

- There is currently no applicable permission in the Code.

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

- There are no other measures that would be more cost-effective and that could achieve the same end.

- At this stage no other relevant matters are apparent.

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.