

# **APPLICATION A1024**

## **EQUIVALENCE OF PLANT STANOLS, STEROLS & THEIR FATTY ACID ESTERS**

### **EXPLANATORY STATEMENT**

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#### **Executive Summary**

##### **Purpose**

The purpose of the Application is to recognise the substantial equivalence of plant sterols as novel food ingredients to be added to different foods, and for this equivalence to be recognised in their regulation. In particular, this equivalence relates to their safety and their ability to reduce blood cholesterol when consumed in appropriate quantities.

An Application was received from Raisio Nutrition Ltd on 2 March 2009 which sought to replace the existing permissions and specifications for plant sterols (the term encompasses phytosterols, phytostanols and their fatty acid esters) in the *Australia New Zealand Food Standards Code* (the Code) with a single generic specification for phytosterols, phytostanols and their esters. The Applicant further requested that all forms of plant sterols that meet the generic specification (with some added conditions, developed after the original Application was received) be permitted to be added to the four foods that currently can be fortified with various forms of plant sterols in the Code. Currently, the Code permissions for addition of plant sterols to food are linked to a particular type (free or ester form), source (vegetable or tall oil) and specific specification of the preparation. Approval of this Application would amend the specific permissions for types of plant sterols generic permissions.

The Applicant requested that FSANZ recognise the substantial equivalence of all types of phytosterols, phytostanols and their fatty acid esters, no matter from which source, that are covered by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications of 2008 (Monograph 5). These specifications were adopted into the Code as part of FSANZ's Proposal P1008 – Code Maintenance VIII, after the Application was received. However, at that time, the specifications for the specific plant sterol permissions and approvals in the Code were not affected. During the assessment of the Application, FSANZ determined that two extra conditions to the JECFA specification were required to ensure only appropriate plant sterol preparations are approved (FSANZ refers to this in the Report as the modified JECFA specifications). The first requirement is that only plant sterols that have been assessed as being both safe and efficacious are permitted. This is met by permitting only those plant sterols preparations where the plant sterol equivalent component contains greater than 95% des-methyl sterols. Des-methyl sterols are the common forms of plant sterols that are contained in current commercial and well studied preparations. The second condition relates to solvents limits, which has been varied after consultation and a safety evaluation.

The current permissions for plant sterols set out in Standard 1.5.1 – Novel Foods detail the specific compositional mixture and source of the plant sterol preparation. Specific types of plant sterols may be added to each of the four approved food vehicles; low-fat milk, certain types of breakfast cereals, edible oil spreads and low-fat yoghurt. The specifications for these specific plant sterols are linked to the permissions and are listed in the Schedule to Standard 1.3.4 – Identity and Purity.

Two options were considered in relation to this Application; to reject this Application and so maintain the *status quo*, or to amend Standard 1.5.1 and consolidate the existing permissions into generic permissions for phytosterols, phytostanols and their esters for the specific food categories in the Code. The second option also required other consequential changes to the Code. There are no non-regulatory options available for this Application.

### **Risk Assessment**

In order to accept the Applicant's claim of the substantial equivalence of phytosterols, phytostanols and their esters, FSANZ undertook a risk assessment of the health and safety, efficacy and technical suitability of plant sterols having the broader specification in each of the approved food vehicles. The Risk Assessment Report (Supporting Document 1, **SD1**) contains the detail of FSANZ's risk assessment undertaken as part of the evaluation of this Application.

FSANZ has previously assessed the safety of phytosterols when approving the addition of phytosterols to the currently approved foods. As part of the current assessment, FSANZ considered whether there was any new evidence relating to safety. The weight of evidence supports the safety of plant sterols at present levels of consumption irrespective of the combination or proportion used of the individual phytosterol or phytostanol components used or their source. A further investigation of the effects of plant sterol consumption on serum sterol levels indicated no increased risk of cardiovascular disease other than in the rare group of individuals with sitosterolaemia, a severe disease of lipid metabolism. FSANZ concludes that phytosterols, phytostanols and their esters are bioequivalent in terms of their food safety properties.

All compositional variants of plant sterols that conform to the modified JECFA specifications are generally suitable for incorporation into the four foods approved in the Code. There are likely to be some technical issues around incorporating free forms of plant sterols into some foods to achieve uniform distribution but there is a range of technical solutions to this issue. Plant sterols that conform to the modified JECFA specifications can potentially lower blood cholesterol when added to the four approved foods and consumed in appropriate quantities.

It is possible that the wider availability and permission to use a wider range of plant sterol preparations could result in a greater number of brands entering the Australia and New Zealand market place. FSANZ's benefit cost analysis notes that there will be more market place competition but it cannot predict what impact this may have on price or dietary intake for populations or individuals.

### **Risk Management**

A key issue arising from the risk assessment was that while it is possible to add plant sterols to the approved foods, some mixtures, if added, may result in a physically unsuitable product. FSANZ considers that the existing compositional limits set out for these foods and commercial realities are sufficient to ensure the appropriate choice of plant sterol preparation for each product. Further regulatory measures to ensure technical suitability are therefore not required.

The proposed strategies associated with consolidated permissions for plant sterols are:

- maintain the current compositional limits for approved foods
- make consequential amendments to Standards 1.1.1, 1.2.3, 1.2.8, 1.3.1, 1.3.4, 2.4.2, 2.5.1 and 2.5.3 to clarify and ensure consistency in permissions given for phytosterols, phytostanols and their esters.

This change will most benefit those sectors of the food industry wishing to produce and market plant sterols and foods containing added plant sterols. As a consequence, these changes will likely benefit consumers in terms of increased product availability. This change is unlikely to impact on the costs for enforcement agencies.

The Application is being assessed under the General Procedure.

### **Assessing the Application**

In assessing the Application and the subsequent development of food regulatory measures, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether costs that would arise from amending Standard 1.5.1 and the consequential amendments required for Standards 1.1.1, 1.2.3, 1.2.8, 1.3.1, 1.3.4, 2.4.2, 2.5.1 and 2.5.3 outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measures.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.1, and the consequential amendments required for Standards 1.1.1, 1.2.3, 1.2.8, 1.3.1, 1.3.4, 2.4.2, 2.5.1 and 2.5.3 that could achieve the same end.
- There are no relevant New Zealand standards.
- There are no other relevant matters.

### **Decision**

**To approve draft variations to Standard 1.5.1 – Novel Foods so that specific source-based permissions for phytosterols esters and tall oil phytosterols are amended into a single generic permission for phytosterols, phytostanols and their esters, for the current four food vehicles to which plant sterols can be added.**

**To approve consequential draft amendments to Standards 1.1.1, 1.2.3, 1.2.8, 1.3.1, 1.3.4, 2.4.2, 2.5.1, and 2.5.3 to clarify and ensure consistency in the permissions given for phytosterols, phytostanols and their esters.**

### **Reasons for Preferred Decision**

FSANZ recommends amendments to the Code to reflect one set of generic permissions and specifications for phytosterols, phytostanols and their esters, based on the following reasons:

- All forms of plant sterols are equally safe for human consumption

- The amendments do not raise any additional nutritional safety concerns
- Any plant sterol that meets the specifications, including the extra conditions, is capable of lowering LDL-cholesterol
- Most plant sterol mixtures can be incorporated into currently approved foods
- Existing measures are likely to ensure that only suitable plant sterol mixtures are added to the foods
- The amendments are consistent with relevant Ministerial Council Policy Guidelines
- The amendments support industry innovation
- The amendments provide net benefits to affected parties
- No other measures would be more effective at achieving this outcome.

## Consultation

Public submissions on the Assessment Report for this Application were sought from 1 October 2009 to 11 November 2009. Twelve submissions were received. Eleven supported the Application being progressed, that is option 2, and one did not make a selection. A number of issues were raised in submissions which FSANZ was asked to address. The main issues discussed relate to labelling (ingredient, advisory statements and NIP), limits for residual solvents in the specification, some drafting amendments, a suitable analytical method to determine added plant sterols in food matrices and tightening the specifications so that only plant sterol equivalents that contain greater than 95% des-methyl sterols are permitted. How FSANZ has addressed these issues is detailed in section 10.1 of this Report. The summary of the submissions is contained in Attachment 2.

## Summary of changes from the Assessment Report to the Approval Report

The changes to the drafting are identified in Attachment 1B. Since the drafting changes are easily noted from the Attachment they will not be commented on further except to say some of the amendments also came from comments received in submissions. The following Table summarises the major changes between what was written in the Assessment Report to what is now stated in the Approval Report.

Issue	Changes made
Require an extra condition to the JECFA specifications to ensure only safe and efficacious plant sterols are permitted. This means only those where the plant sterol equivalents contain greater than 95% des-methyl sterols.	FSANZ accepted this suggestion and made amendments to the drafting to reflect tightening the JECFA specifications and therefore permissions so that only plant sterol preparations where the plant sterol equivalent component contains greater than 95% des-methyl sterols. This also required changing the term 'JECFA specifications' to 'modified JECFA specifications' throughout the report to refer to the two extra conditions imposed on the permissions; being the des-methyl sterol issue as well as the different solvent limits (see section 10.1.9)

<b>Issue</b>	<b>Changes made</b>
<p>Various responses to the solvent limits for plant sterol preparations, compared to those in the JECFA specification</p>	<p>In the Assessment Report the solvent limit was proposed to be 5000 ppm, while this has been reduced in the Approval Report to 2000 ppm.</p> <p>The list of approved solvents is varied from 1-propanol to iso-propanol (2-propanol) (see section 6.5.1). An added risk assessment within SD1 confirms the safety of the amended solvent limits (section 6.2.1 in SD1).</p>
<p>Define and use the term 'plant sterol equivalents' up front in the Code and use consistent terminology throughout the Report.</p>	<p>There have been changes to terminology in the drafting and throughout the Report, as well as a definition up front to the term 'plant sterol equivalents'.</p>
<p>Provide appropriate analytical methods to determine plant sterols in the food matrices as the information provided in the Assessment Report is only relevant to determining purity of the preparation.</p>	<p>Analytical methods are provided, in particular a reference from the Applicant, which details how to analyse the concentration of various plant sterols in different foods (see section 10.1.1, and subsequent changes to section 8.2.2.3).</p>
<p>Concerned that a new Application would be required, as flagged in the Assessment Report, when the exclusivity approval relevant to the concurrent cheese plant sterol Application A1019 lapses after 15 months and then becomes a general permission. FSANZ was asked to consider some alternative mechanism. If Application A1024 is accepted i.e. plant sterol equivalence, this should be carried over to the final permission so it is not source specific but also a generic plant sterol permission.</p>	<p>FSANZ has reworded the appropriate section (section 6.6) in the Approval Report, so it does not state that a new Application would be required. However, since it cannot be assumed that both Applications will be accepted and gazetted at the same time, how FSANZ will deal with this situation in the future is left more open. It cannot be categorically dealt with as part of this Application.</p>

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## **SUPPORTING DOCUMENT**

The following report was used in the preparation of this Approval Report and is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1024equi4316.cfm>

SD1: Risk Assessment Report - Application A1024, Equivalence of Plant Sterols, Stanols and Their Fatty Acid Esters

## **Introduction**

An Application was received from Raisio Nutrition Ltd on 2 March 2009 which sought to replace the existing permissions and specifications for plant sterols in the *Australia New Zealand Food Standards Code* (the Code) with one set of generic specifications for phytosterols, phytostanols and their esters, and subsequent generic permissions for the specific food categories.

The justification for this request is to be consistent with the recently published Joint FAO/WHO Expert Committee on Food Additives (JECFA) specification for 'Phytosterols, phytostanols and their esters'<sup>1</sup>. The Application contends that accepting the equivalence of any types of plant sterols that meet the JECFA specification brings the Code in line with the international regulatory position, and would simplify permissions for the addition of plant sterols to food.

As a consequence of accepting the Applicant's claim of 'substantial equivalence' of plant sterols, the Applicant also seeks to:

- replace the current source-specific specifications with the 2008 JECFA specifications for phytosterols, phytostanol and their esters (with added conditions, as agreed after the Application was submitted)
- amend the current permissions for the four foods permitted to contain plant sterols to reflect this generic specification
- express the units for the compositional limits that control the addition to food as plant sterol equivalents (calculated by using the free phytosterol content (60%) of phytosterol esters<sup>2</sup>).

Standard 1.3.4 – Identity and Purity was updated to reference the amended 2008 JECFA specifications (monograph 5) as part of Proposal P1008. However, the inclusion of these JECFA specifications did not change the compositional specifications for the current permitted forms of plant sterols in the Code. This amendment was gazetted in August 2009. Therefore, updating the JECFA specification reference is not required as part of the assessment of this Application. The current source-specific specifications remain in the Schedule within Standard 1.3.4 and will be considered in this Application.

During the assessment of the Application, FSANZ determined that two extra conditions to the JECFA specification were required to ensure only appropriate plant sterol preparations are approved (FSANZ refers to this in the Report as the 'modified JECFA specifications'). The first condition is that only plant sterols that have been assessed as being both safe and efficacious are permitted. This is met by permitting only those plant sterols preparations where the plant sterol equivalent component contains greater than 95% des-methyl sterols. Des-methyl sterols are the common forms of plant sterols that are contained in current commercial and well studied preparations.

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<sup>1</sup> Combined Compendium of Food Additive Specifications, Joint FAO/WHO Expert Committee on Food Additives (JECFA) Monograph 5 (2008) Phytosterols, phytostanols and their esters, Food and Agriculture Organisation of the United Nations, Rome  
<http://www.fao.org/ag/agn/jecfa-additives/specs/monograph5/additive-509-m5.pdf> Accessed on 4 September 2009.

<sup>2</sup> FSANZ will use the generic term 'plant sterol' rather than 'phytosterol' which the Applicant has used when either phytosterol or phytostanol (and their esters) is meant. The terminology is explained in the Table.



The second condition relates to solvents limits, which has been varied after consultation and a safety evaluation conducted. The Applicant agreed with the inclusion of these extra conditions.

The four food vehicles currently permitted to contain plant sterols are edible oil spreads, low-fat milk, low-fat yoghurt and certain breakfast cereals. The Application does not seek to alter the amounts of plant sterols permitted in these foods, but to amend the units in which the limits of addition are expressed to reflect plant sterol equivalents.

The following definitions are used in this Report:

Plant sterols	Collective term referring to all free (non-esterified) and esterified phytosterols and phytostanols, regardless of the biological source.
Phytosterols	Free (non-esterified) steroid alcohols occurring in plants e.g. $\beta$ -sitosterol, campesterol, stigmasterol.
Phytostanols	Any of the fully saturated phytosterols e.g. sitostanol, campestanol.
Phytosterol esters	Phytosterols esterified with fatty acids derived from vegetable oils.
Phytostanol esters	Phytostanols esterified with fatty acids derived from vegetable oils.
Plant sterol equivalents	The total free (non-esterified) phytosterol and phytostanol content of the product/preparation/commercial mixture.

## 1. The Issue

The current permissions for plant sterols set out in Standard 1.5.1 – Novel Foods specify the specific compositional mixture and source permitted to be added to each of the four approved food vehicles (low-fat milk, breakfast cereals, edible oil spreads, low-fat yoghurt). Therefore, other forms of plant sterols are not permitted and an amendment of this Standard is required to permit them.

In order to accept the Applicant's claim of the substantial equivalence of phytosterols, phytostanols and their esters, the health and safety, efficacy and technical suitability of plant sterols matching the modified JECFA specification (with added des-methyl sterol and solvent conditions<sup>3</sup>) in each of the approved food vehicles needs to be established.

## 2. Current Standards and Plant Sterol Applications

### 2.1 Standard 1.5.1 – Novel Foods

Plant sterols are considered novel foods in the Code. Novel foods are not permitted to be added to food for sale in Australia and New Zealand unless they are listed in Standard 1.5.1. 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. Approved novel foods are listed in the Table to clause 2 of Standard 1.5.1. Standard 1.5.1 also sets out conditions of use of approved novel foods, including risk management measures such as labelling.

<sup>3</sup> When referring to plant sterols that meet the modified JECFA specifications throughout the Report FSANZ also means the added condition that the plant sterol equivalent component contains greater than 95% des-methyl sterols (as discussed in section 10.1.9) to ensure only plant sterol preparations that have been assessed for their safety and efficacy are permitted. As well, the different solvent limits compared to the JECFA specification are another condition (as discussed in section 6.5.1 and 10.1.6).

The Table to clause 2 contains a number of specific permissions for phytosterol esters and tall oil phytosterols for specific food vehicles, as well as a number of conditions of use. These current permissions are summarised in Table 1. The different ranges of permitted levels for free phytosterols and phytosterol esters for the same food vehicles are to ensure equivalent levels of the active free phytosterol, taking into account the different molecular weights of the phytosterol esters and the free phytosterols. If consumers adhere to the recommended size and number of serves of plant sterol fortified foods, daily intake of plant sterols is estimated to be within the range shown to be optimal for a cholesterol-lowering effect.

**Table 1: Current permissions for plant sterols**

Food matrix	Phytosterol esters (from vegetable oils)	Tall oil phytosterols
Edible oil spreads	Max 137 g/kg	Max 80 g/kg
Breakfast cereals	26-32 g/kg	Not permitted
Milk	5.2-6.4 g/L	3.2-4.0 g/L
Yoghurt	1.3-1.6 g/package	Not permitted

The Applicant requests that the separate permissions for phytosterol esters and tall oil phytosterols be deleted and replaced with more generic plant sterol permissions in line with the JECFA specification. As a consequence of this request, the Applicant also seeks to amend the units in which the compositional limits are expressed to 'phytosterol equivalents'<sup>4</sup>.

## 2.2 Other Standards relevant to plant sterol permissions

There are also a number of other Standards that make reference to plant sterols and require amendment if this Application is successful.

The relevant references to plant sterols in the extracts of Standards below that need to be amended are underlined to highlight them. Drafting changes for these Standards are contained in Attachment 1.

### 2.2.1 Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations

The Table to clause 2 in Standard 1.2.3 requires that the label of foods containing added phytosterol esters and tall oil phytosterols include three advisory statements to the effect that:

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

### 2.2.2 Standard 1.3.1 – Food Additives

Schedule 1 of Standard 1.3.1 contains an entry of food additive permissions for liquid milk to which phytosterols or phytosterol esters have been added (food category 1.1.3). There are no other food additive permissions for plant sterols containing foods. The relevant extract from Schedule 1 is below.

<sup>4</sup> The Applicant explains that their term 'phytosterol equivalents' refers to the free phytosterol (60%) component of phytosterol esters. FSANZ is using the term 'plant sterol equivalents' for the same purpose.

### *Permitted uses of food additives by food type*

<b>INS Number</b>	<b>Additive Name</b>	<b>Max Permitted Level</b>	<b>Qualifications</b>
<b>1.1.3 Liquid milk to which <u>phytosterols or phytosterol esters</u> have been added</b>			
401	<i>Sodium alginate</i>	2	<i>g/kg</i>
407	<i>Carrageenan</i>	2	<i>g/kg</i>
412	<i>Guar gum</i>	2	<i>g/kg</i>
471	<i>Mono- and diglycerides of fatty acids</i>	2	<i>g/kg</i>
460	<i>Microcrystalline cellulose</i>	5	<i>g/kg</i>

#### **2.2.3 Standard 1.3.4 – Identity and Purity**

Standard 1.3.4 deals with the specifications of added nutrients, which includes plant sterols. Clause 2 of this Standard contains two primary sources (internationally recognised references) of specifications. As mentioned in the Introduction to this Report, the 2008 JECFA specifications for ‘phytosterols, phytosterols and their esters’, contained in Monograph 5, were included in the Code as part of FSANZ Proposal P1008 in August 2009.

The 6<sup>th</sup> Edition of the Food Chemicals Codex (2008) is the other primary source of specifications, referred to in subclause 2(b), which contains the source specific specification, ‘Vegetable oil phytosterol esters’.

If there is not a relevant specification monograph in either of these two primary sources of specifications that deal with the substance it needs to comply with any specification written in the Schedule to the Standard. In the case of plant sterols there are two such specifications, being for ‘phytosterol esters derived from vegetable oils’ and ‘tall oil phytosterols derived from tall oils’.

#### **2.2.4 Standard 2.4.2 – Edible Oil Spreads**

Clause 2 of Standard 2.4.2 (see below) sets out the conditions for the addition of phytosterol esters and tall oil phytosterols to edible oil spreads and margarine.

## **2 Composition of edible oil spreads and margarine**

(1) *Edible oil spreads and margarine may contain –*

- (a) *water; and*
- (b) *edible proteins; and*
- (c) *salt; and*
- (d) *lactic acid producing micro-organisms; and*
- (e) *flavour producing micro-organisms; and*
- (f) *milk products; and*
- (g) *no more than 137 g/kg of phytosterol esters; or*
- (h) *no more than 80 g/kg of tall oil phytosterols*

#### **2.2.5 Standard 2.5.1 – Milk**

Clause 5 of Standard 2.5.1 sets out the conditions for the addition of plant sterols to milk.

## **5 Tall oil phytosterols and added phytosterol esters**

Tall oil phytosterols or phytosterol esters may only be added to milk –

- (a) that contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the labelled volume of which is no more than 1 litre; and
- (c) where the total phytosterol ester added is no less than 5.2 g/litre of milk and no more than 6.4 g/litre of milk; and
- (d) where the total tall oil phytosterol added is no less than 3.2 g/litre of milk and no more than 4.0 g/litre of milk.

### **2.2.6 Standard 2.5.3 – Fermented Milk Products**

Clause 4 of Standard 2.5.3 sets out the conditions for the addition of phytosterol esters to yoghurt:

#### **4 Phytosterol esters**

Phytosterol esters may only be added to yoghurt –

- (a) such that the yoghurt contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the capacity of which is no more than 200 g; and
- (c) where the total phytosterol ester added is no less than 1.3 g and no more than 1.6 g.

### **2.3 Other current plant sterol Applications**

FSANZ is currently assessing one other Application (A1019) in relation to plant sterols.

Application A1019 - Exclusive Use of Phytosterol Esters in Lower-fat Cheese is an Application from Kraft Foods which seeks to approve the exclusive use of tall oil phytosterol fatty acid esters in lower-fat cheese at levels equivalent to 1.1 g of free phytosterols per 20 g serve. Under Standard 1.5.1, the Applicant seeks exclusive use of their particular form of tall oil phytosterol esters to be added to lower-fat cheese for a period of 15 months. The Application is at the Approval stage. The impact of the concurrent assessment of both plant sterol Applications is discussed in section 6.6.

## **3. Objectives**

In developing or varying a food standard, 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; and
- 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.

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has provided a Policy Guideline on *Addition to Food of Substances other than Vitamins and Minerals*<sup>5</sup> (Policy Guideline) which FSANZ considers relevant to this Application. In particular FSANZ has had regard to the Specific Order Policy Principles – Any Other Purpose set out in this guideline when assessing the merits of this Application. These principles are:

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

- a) the purpose for addition can be articulated clearly by the manufacturer (i.e. 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.*

### **3.1 Approach to Assessment**

For this Application the primary objective is the protection of public health and safety. To meet this objective, FSANZ undertook a risk assessment to ensure that adopting the generic permission for phytosterols, phytostanols and their esters in all currently approved foods does not pose a public health and safety risk. This assessment also considered whether adopting these generic permissions would have an effect on consumption patterns, and whether this in turn would have implications for the health of consumers of such products.

The safety assessments performed by FSANZ as part of previous plant sterol Applications have considered the effect plant sterol mixtures have on blood low density lipoprotein (LDL) cholesterol levels in hypercholesterolaemic individuals. The current safety assessment has updated these conclusions with assessment of more recent studies.

Accepting the Applicant's view and justifications would require a number of amendments to be made to the Code to give force to their request.

The effect of adopting new permissions on the existing permissions was addressed to ensure no unexpected consequences would occur.

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<sup>5</sup><http://www.foodstandards.gov.au/foodstandards/changingthecode/ministerialcouncilpolicyguidelines/policyguidelineonthe4132.cfm>

## 4. Questions to be answered

FSANZ addressed the following questions in the assessment of this Application.

1. Are plant sterols (conforming to the modified JECFA specifications) safe for human consumption at the levels of use currently specified in the Code?
2. Are plant sterols (conforming to the modified JECFA specifications) nutritionally safe?
3. Do the chemical properties of phytosterols, phytostanols and their esters (conforming to the modified JECFA specifications) make them technologically suitable for addition to all four approved foods?
4. Do plant sterols (conforming to the modified JECFA specifications) lower blood LDL-cholesterol when consumed in each of the four approved foods?
5. Does dietary intake, understanding of the product or purchasing behaviour differ according to the type and form of plant sterols?
6. Would a permission to add plant sterols (conforming to the modified JECFA specifications) to approved foods be likely to:
  - (a) increase the number of brands available in the market?
  - (b) result in flow-on changes in consumption patterns?
7. How would amending permissions impact on current manufacturers of plant sterols and foods containing plant sterols marketed in Australia and New Zealand, or enforcement agencies?
8. How would amending permissions affect current related plant sterol Applications?

The first six questions above are addressed in the Risk Assessment Report (**Supporting Document 1 (SD1)**) and summarised in the Risk Assessment section of this report. The following two questions are discussed briefly in the Risk Management (section 6.6), and in the benefit cost section (section 8.2) of this Report.

## **Risk Assessment**

### 5. Risk Assessment Summary

The key findings from the risk assessment are summarised below under the questions that have been addressed. The reference to plant sterols in the questions below means those plant sterols that meet the modified JECFA specifications.

#### 5.1 Are plant sterols safe?

The evidence supporting the safety of plant sterols discussed in Sections 4 and 5 of SD1 includes studies with variable preparations of phytosterols and phytostanols. No food safety concerns have been identified irrespective of the proportions of individual sterol or stanol compounds used, or their source. Based on consideration of all available evidence, phytosterols, phytostanols and their esters may be considered bioequivalent (see section 4 of SD1).

A comprehensive analysis of appropriately designed epidemiological studies to assess whether increased serum plant sterol concentrations contribute to the risk of cardiovascular disease (CVD) was conducted. The available evidence indicates that plant sterols do not have a role in CVD risk in the general population. This information confirms previous conclusions about the safety of consuming plant sterol-fortified foods (see section 5 of SD1).

## **5.2 Are there any nutritional safety concerns?**

Reduced carotenoid uptake associated with consumption of plant sterols is not a nutritional concern in adults as serum carotenoid levels fluctuate normally according to a number of dietary factors and environmental variables. A small reduction in the absorption of carotenes with intake of plant sterols is largely explained by the reductions in serum levels of carrier LDL-cholesterol attributed to plant sterols.

There have been no safety concerns identified should children, pregnant or lactating women consume plant sterols. However, children and pregnant or lactating women in general do not need to lower cholesterol levels and, in addition, are considered to have increased growth or physiological requirements compared with other adults and so consumption of cholesterol lowering products in these groups does not provide any benefit.

Clinical studies have shown that increasing intakes of fruits and vegetables, particularly varieties rich in  $\beta$ -carotene, while consuming plant sterol-fortified foods, partially compensates for lower absorption of carotenoids (see section 5 of SD1).

## **5.3 Are plant sterols suitable to be added to all four foods?**

Phytosterols, phytostanols and their esters that conform to the modified JECFA specifications are suitable for being incorporated into the four currently approved foods in the Code. There are likely to be some technical issues around incorporating some forms of plant sterols into some foods to achieve 100% uniform distribution but some of these difficulties can be overcome using technical solutions such as fine grinding of the particles or use of emulsifiers (see section 6 of SD1).

## **5.4 Are plant sterols capable of reducing blood cholesterol when added to all four foods?**

Plant sterols that conform to the modified JECFA specifications have been shown to lower LDL-cholesterol when consumed in the four currently approved food matrices, providing that they are suitably dispersed in the food matrix (see section 7 of SD1).

## **5.5 Does dietary intake understanding of the product or purchasing behaviour differ according to type and form of plant sterols?**

Broadening the specification and the associated permissions to include a wider variety of plant sterol preparations in already approved foods does not change existing estimates of dietary intake. The evidence suggests that consumers substitute between various plant sterol-fortified products. It is highly unlikely that the form of plant sterols added to an existing food vehicle could substantially change purchasing behaviour or product understanding (see section 8 of SD1).

## **5.6 Is there likely to be an increase in the number of brands, or flow on changes in consumption patterns?**

It is possible that the wider availability and permission to use a wider range of plant sterol preparations could result in a greater number of brands entering the Australia New Zealand market place (see section 8 of SD1). FSANZ's benefit cost analysis notes that there will be more market place competition but it cannot predict what impact this may have on price or dietary intake for populations or individuals (see section 8.2 of this Report).

## **Risk Management**

This section discusses matters of interest arising from the risk assessment and other matters relating to this Application. In addition, this section discusses the preferred approach to these matters, the consequential amendments to the Code and their implications for the plant sterol and the food industries in Australia and New Zealand and Government.

## **6. Issues considered**

### **6.1 Risk to public health and safety**

The risk assessment on the safety of plant sterols that meet the broader modified JECFA specifications, including assessment of the consequential impact broadening permissions would have on total plant sterol intakes and consumption patterns of plant sterol fortified foods, does not raise any public health and safety concerns. Therefore, no additional measures are needed to ensure food safety or the public health when consolidating the current permissions for plant sterols.

### **6.2 Technical suitability of plant sterols in approved foods**

Broadening the current specifications and permissions to include any form of phytosterol, phytostanol or their ester that meets the modified JECFA specification would permit the addition of a broader range of plant sterol mixtures to be added to the current approved foods in the Code. Each of these foods has different physical characteristics (e.g. fat content, polarity, viscosity, melting point) which may indicate certain plant sterol mixtures are more suitable to be added to these foods. Section 6 of SD1 provides more detail on the issues noted in this section.

The most common issue is settling or agglomeration of the plant sterol dispersion in the final product. This is most likely to occur with the use of free phytosterols or phytostanols in aqueous or non-homogenous media, as is the case for low-fat milk, low-fat yoghurt and breakfast cereals. The risk assessment indicates that technical solutions do exist to overcome these issues, such as cryogenic grinding, the use of emulsifiers or esterification of the plant sterol mixture.

The current permissions set out a range for the amount of plants sterols<sup>6</sup> which can be added to each of the four approved foods. Food manufacturers need to ensure that their products all comply with this range. Plant sterols in these products should be uniformly distributed for any individual serve or container, and the production and quality assurance procedures should ensure compliance of their products with the permissions. These existing limits and the technical challenges are likely to restrict the types of plant sterol mixtures which are suitable to be uniformly incorporated in the food.

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<sup>6</sup> A maximum level only of phytosterols esters and tall oil phytosterols is set out for edible oil spreads in the Code.



In addition, commercial realities are such that it is unlikely that a manufacturer will add an unsuitable plant sterol preparation to a food, which would lead to detrimental appearance, odour or flavour effects. Examples of commercially unacceptable problems are having lumps or aggregations of plant sterols form in the food, discolouration or odour problems of the food and phase separation between the food and the added plant sterol.

FSANZ considers that these two realities i.e. the requirement to produce a product which consistently meets the regulatory limits of plant sterol addition and one which is commercially acceptable, will ensure that only those plant sterol preparations which are suitable for addition will be added to permitted foods.

### **6.3 Efficacy of plant sterols in approved foods**

The totality of evidence suggests that phytosterols, phytostanols and their esters can deliver comparable cholesterol lowering effects in edible oil spreads, low-fat milk, low-fat yoghurt and breakfast cereal compared to the previously approved forms and foods (see section 7 in SD1).

The range of data available for phytosterols, phytostanols and their esters in the dairy food matrices shows similar LDL-cholesterol reductions to currently approved plant sterols.

The range of data available for free and esterified plant sterols shows similar LDL-cholesterol reductions to currently approved plant sterols for use in edible oil spreads, low-fat milk and low-fat yoghurt. There is some uncertainty (since there are fewer studies) around the efficacy of the free form of plant sterols in breakfast cereal to reduce LDL-cholesterol. However, noting the comments in section 6.2 there is no reason to believe different forms of plant sterols would not be as efficacious in breakfast cereals as the current permitted form. Breakfast cereal manufacturers will need to ensure the form of plant sterol preparation they use will be suitable to be added to their product.

As discussed further in section 10.1.9, it is important to note that the literature provided by the Applicant supporting their view that the various forms of plant sterols have comparable efficacy to reduce blood cholesterol are all based on the well studied des-methyl sterol compounds. These are also the studies that FSANZ has accessed in the Risk Assessment. FSANZ also identified that there are other studies on different plant sterol preparations (that do not comply with the 95% des-methyl sterol condition) available that show no or little blood LDL-cholesterol lowering effects.

### **6.4 Policy Guideline**

As noted in Section 3 FSANZ must have regard to the Specific Order Policy Principles on the Addition to Food of Substances other than Vitamins and Minerals.

With respect to Policy Principle a) which requires that the stated purpose is articulated, the purpose for adding plant sterols to food is clear (to reduce LDL-cholesterol) and does not require further discussion. With respect to Policy Principles b) – d), these matters have been addressed in the previous sections 6.1–6.3.

With respect to Policy Principle e), which requires that the presence of the substance does not mislead the consumer as to the nutritional quality of the food, the Applicant is not seeking to introduce plant sterols to a new food, nor increase the amounts currently permitted in approved foods. The amendments propose to relax the requirement for a specific descriptor to be used in the ingredient list; however, the risk assessment indicates that the consumer is unlikely to pay attention to any detailed information on the type of plant sterol provided on the label of these products.

Taking all these elements into consideration, FSANZ considers that the proposed amendments are unlikely to result in consumers being misled as to the products nutritional quality, and therefore the proposed amendments are consistent with policy principle e).

## 6.5 Proposed Drafting Amendments

The drafting amendments to the Code are at Attachment 1. This section discusses issues relevant to the drafting amendments.

### 6.5.1 Specification amendments

FSANZ has removed the current specifications for 'tall oil phytosterols' and 'phytosterol esters derived from vegetable oils' set out in the Schedule to Standard 1.3.4. With the exception of solvents, these source specific specifications are covered by the more generic 2008 JECFA specifications for plant sterols (see Table 2 below, and section 6.2 in SD1).

With respect to solvents, the JECFA specifications for plant sterols set a maximum limit of 50 ppm (hexane, 1-propanol, ethanol or methanol, either singly or in combination), which is tighter than that currently set for tall oil phytosterols (5000 ppm)<sup>7</sup> in the Schedule to Standard 1.3.4 (see Table 2). FSANZ sought comment from submitters to the Assessment Report as to whether plant sterol companies can comply with the JECFA solvent specification, and whether what was proposed in additional drafting was appropriate or needed to be amended.

The issue of drafting dealing with the solvent limit and submissions received on this topic are discussed in section 10.1.6 so will not be repeated here. The conclusions from FSANZ's evaluations of these submissions required some slight amendments to the drafting that was proposed in the Assessment Report.

A separate issue that arose from a submission to the Assessment Report also relates to specifications and subsequent extra drafting. The issue and FSANZ's response is detailed in section 10.1.9. The extra condition is that the plant sterol equivalent component of plant sterol preparations must contain greater than 95% des-methyl sterols.

The extra drafting to deal with the des-methyl sterol requirement is an added modification to the JECFA specifications. Table 2 contains a comparison of various plant sterol specifications and highlights the modification to the JECFA specifications.

FSANZ needed to ensure that there are no unintended consequences of removing the two current specifications on any of the plant sterol suppliers. FSANZ also wishes to follow the JECFA 2008 specification lead and specify which solvents the limits refer to and not leave it as generic, so the drafting refers to hexane, isopropanol (2-propanol)<sup>8</sup>, ethanol, methanol, and methyl ethyl ketone<sup>9</sup>, either singly or in combination.

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<sup>7</sup> A maximum limit for solvents is not specified in the current specifications for phytosterol esters derived from vegetable oil, contained in the Schedule for Standard 1.3.4.

<sup>8</sup> Two submitters stated that they used isopropanol and not 1-propanol, so the name has been changed from the drafting at Assessment.

<sup>9</sup> Correspondence with one plant sterol manufacturer indicated they use methyl ethyl ketone during their process, so this solvent has been listed along with those listed by JECFA.

**Table 2: Comparison of Specifications**

<b>Phytosterol Content (%)</b>	<b>Modified JECFA Monograph 5<sup>1</sup> modifications are in bold</b>	<b>Food Chemicals Codex 6<sup>th</sup> Ed (Vegetable oil phytosterol esters)</b>	<b>The Code (Vegetable oil phytosterol esters)<sup>6</sup></b>	<b>The Code (Tall oil phytosterols)<sup>6</sup></b>
Free phytosterol/stanols <sup>2</sup> + Phytosterol/stanols (from phytosterol/stanols esters after saponification) <sup>3</sup>	55-95			
Free phytosterol/stanols + Phytosterol/stanols esters		95 min	94 min	
Free phytosterol/stanol (for non-esterified products) <sup>4</sup>	95 min			97 min
Phytosterol esters		86 min		
Phytosterol/stanols after saponification of the esters <sup>5</sup>	55 min			
Des-methyl-sterols	<b>95 min<sup>7</sup></b>	59 min <sup>5</sup>		
Free phytosterols		9 max	10 max	
Steradienes			0.3 max	
Acyl-glycerides		5 max		
<b>Sterol profile (%)</b>				
Campesterol		10 – 40	20-29	4-25
Campestanol			0-6	0-14
β-sitosterol		30 – 65	42-55	36-79
β-sitostanol			0-2	6-34
Brassicasterol		12 max	6 max	3
Stigmasterol			12-23	
Δ <sup>5</sup> -Avenasterol		6 max	4 max	
Δ <sup>7</sup> -Stigmastenol			2 max	
Δ <sup>7</sup> -Avenasterol		7 max	2 max	
Other sterols			6 max	
Cholesterol			2 max	
<i>Trans</i> fatty acids (%)			1.0 max	
Fatty acid methylester (%)			0.5 max	
Moisture (%) loss on drying	4 max	0.1 max	0.1 max	4 max
Solvents (ppm)	<b>2000 max<sup>8</sup></b>			5000 max
Residue on ignition (%)	0.1 max			0.1 max
Acidity (g KOH/kg)		0.2 max		
<b>Heavy Metals (total, ppm)</b>				
Iron			1.0 max	
Copper			0.5 max	
Arsenic	3 max			0.1 max
Lead	1 max	0.1 max		0.1 max
Cadmium				0.1 max
Mercury				0.1 max
<b>Microbiological</b>				
Total aerobic count (CFU/g)				10,000 max
Moulds and yeasts (CFU/g)				100 max
Coliforms				Negative
E. coli				Negative
Salmonella				Negative

<sup>1</sup> A combined specification of phytosterols, phytostanols and their esters.

<sup>2</sup> Free phytosterols/stanols refer to non-esterified phytosterols/stanols.

<sup>3</sup> For products that are mixture of free and esterified phytosterols/stanols –content of phytosterols/stanols measured as free phytosterols/phytostanols in a native and saponified sample.

<sup>4</sup> For products containing only free phytosterols – on a total free phytosterol basis.

<sup>5</sup> For products containing only esterified phytosterols – measured as phytosterols/phytostanols on a saponified sample.

<sup>6</sup> Taken from Schedule to Standard 1.3.4

<sup>7</sup> See sections 6.5.1 and 10.1.9 of the Report

<sup>8</sup> See section 6.5.1 and 10.1.6 of the Report. The solvents are hexane, iso-propanol, ethanol, methanol or methyl ethyl ketone, either singly or in combination.

The 2008 JECFA specifications specify that for non-esterified mixtures, the total phytosterol and phytostanol concentration must be no less than 95% (this is for preparations of 'free' phytosterols and phytostanols that contain no or little ester forms of the sterols or stanols). FSANZ understands that the production of phytosterol and phytostanol preparations may require higher solvent specifications due to their production processes. FSANZ therefore wrote new drafting, in addition to removing the specifications for tall oil phytosterols and phytosterol esters derived from vegetable oil, to include the following clause in Standard 1.3.4:

#### **Specification for phytosterols, phytostanols and their esters**

- (1) Subject to subclauses (2) and (3) phytosterols, phytostanols and their esters must comply with a monograph specification in clause 2 or 3 of this Standard.
- (2) However, for a mixture which contains no less than 950 g/kg of phytosterol and phytostanol concentration, the concentration of hexane, isopropanol, ethanol, methanol or methyl ethyl ketone either singly or in combination must be no more than 2 g/kg.
- (3) The total plant sterol equivalents content must contain no less than 95% des-methyl sterols.

#### *6.5.2 Reference to phytosterol, phytostanol and their esters*

The proposed drafting includes a reference to *phytosterols, phytostanols and their esters* in Standard 1.1.1. This is to clarify their meaning and subsequent application in the Code, and would apply horizontally to all Standards.

The new drafting added to Standard 1.1.1 is:

*A reference in this Code to phytosterols, phytostanols and their esters is a reference to a substance which meets a specification for phytosterols, phytostanols and their esters in Standard 1.3.4.*

#### *6.5.3 Amendments to compositional limits*

To help facilitate a broader range of plant sterol mixtures to be added to approved foods, FSANZ proposes that the limits of addition (i.e. maxima and minima) set out in the Code be expressed as the (unesterified) phytosterol and phytostanol component of the plant sterol mixture (that is as plant sterol equivalents). This is reflected in the drafting at Attachment 1A.

The Applicant's suggested new permitted minimum and maximum levels calculated and expressed as plant sterol equivalents are shown in Table 3. The Applicant has used the simple calculation that the plant sterol equivalent is 60% of the plant sterol fatty acid ester (by a calculation of the different molecular weights, see example calculation below). Section 2.2 and Figures 3 and 4 of SD1 discuss and show the chemical structures of some plant sterols and their esters. The ranges have been determined by multiplying the 2<sup>nd</sup> column numbers by 60% (and also ensuring they are still consistent with the 3<sup>rd</sup> column of permissions).

As an example of the calculations performed we use the molecular structures of a common phytosterol, campesterol and a fatty acid ester of the sterol, being the oleic acid ester of campesterol, campesteryl oleate.

The plant sterol equivalent conversion factor for campesterol from the ester campesteryl oleate can be calculated as the ratio of the molecular weights (MW).

Campesterol:  $C_{28}H_{48}O$  MW 400.68  
 Campesteryl oleate:  $C_{46}H_{80}O_2$  MW 665.14

$$400.68/665.14 = 0.60 \text{ (60\%)}$$

All the other plant sterols will have slightly different ratios depending on their molecular weights.

**Table 3: Requested amended permissions, as plant sterol equivalents**

Food matrix	Phytosterol esters (from vegetable oils)	Tall oil phytosterols	Suggested plant sterol equivalents
Edible oil spreads	Max 137 g/kg	Max 80 g/kg	Max 82.2 g/kg
Breakfast cereals	26-32 g/kg	Not permitted	15.6-19.2 g/kg
Milk	5.2-6.4 g/L	3.2-4.0 g/L	3.1-4.0 g/L
Yoghurt	1.3-1.6 g/package	Not permitted	0.8-1.0 g/package

The resulting figure has been rounded to a whole number since the conversion factor is an estimate<sup>10</sup>. The original and amended limits are found in Table 4. For breakfast cereals the range of limits has been slightly increased since rounding both limits to whole numbers narrows the range. That is 15.6 would be rounded up to 16 and 19.2 is rounded down to 19, giving a range of only 3 units. For this reason it has been decided to reduce the lower limit slightly to 15 g/kg rather than 16 g/kg, so providing a compliance range of 4 g/kg.

**Table 4: Current and proposed limits of addition for plant sterols in permitted foods**

Food	Current Phytosterol esters (from vegetable oils)	Current Tall oil phytosterols	Plant sterol equivalents <sup>11</sup>	Proposed limits
Edible oil spreads	Max 137 g/kg	Max 80 g/kg	Max 82.2 g/kg	Max 82 g/kg
Breakfast cereals	26-32 g/kg	Not permitted	15.6-19.2 g/kg	15-19 g/kg
Milk	5.2-6.4 g/L	3.2-4.0 g/L	3.1-3.8 g/L	3-4 g/L
Yoghurt	1.3-1.6 g/package	Not permitted	0.8-1.0 g/package	0.8-1.0 g/package

FSANZ defined a new term in Standard 1.1.1 which is total plant sterol equivalents content, which is then used to provide permissions for the addition of plant sterols to food, as a defined range:

In this Code, **total plant sterol equivalents content** means the sum of:

- (a) phytosterols; and
- (b) phytosterols; and
- (c) phytosterols and phytosterols following hydrolysis of any phytosterol esters and phytosterol esters.

<sup>10</sup> Rounding to 0.1g/serve has been retained for yoghurts as the compositional limits are set out per package (serve) rather than per kg or per litre.

<sup>11</sup> Based on a 60% conversion factor.

Hydrolysis of phytosterol esters and phytostanol esters produces phytosterols and phytostanols respectively, which are the active ingredients that have the LDL-cholesterol reducing effect. Thus 'plant sterol equivalents' refer to the active phytosterol or phytostanol component of the preparations.

#### 6.5.4 Labelling

The labelling requirements that apply to plant sterols are:

- Declaration of plant sterols in the Ingredient list - Table to clause 2 in Standard 1.5.1 and clause 4 in Standard 1.2.4.
- Mandatory Advisory Statements – Table to clause 2 in Standard 1.2.3.
- Declaration of plant sterols in the nutrition information panel – Clause 5 in Standard 1.2.8.

Each of these is considered below.

##### 6.5.4.1 Declaration of Plant Sterols in the Ingredient List

The Table to clause 2 in Standard 1.5.1 requires that the specific name of the plant sterol mixture be listed in the ingredient list of the product. Where phytosterol esters are added to a food, the names 'phytosterol esters' or 'plant sterol esters' must be used and where tall oil phytosterols are added to a food, the names 'tall oil phytosterols' or 'plant sterols' must be used.

Under Standard 1.2.4 – Labelling of Ingredients, ingredients must be listed in the statement of ingredients using the common name of the ingredient, a name that describes the true nature of the ingredient or where applicable, a generic name as set out in the Standard. These general requirements also apply to plant sterols and FSANZ considers that these are sufficient in terms of providing consumers with adequate information about the ingredients in the product and to prevent misleading or deceptive conduct. Therefore, the specific requirements in Standard 1.5.1 relating to the declaration of the plant sterol mixture in the ingredient list have been removed. This is reflected in the drafting amendments at Attachment 1.

The current requirements in Standard 1.5.1 do not differ in effect from those in Standard 1.2.4 therefore, there are not expected to be any significant impacts from this amendment.

##### 6.5.4.2 Mandatory Advisory Statements

The Table to clause 2 in Standard 1.2.3 requires that the label of 'foods containing added tall oil phytosterols or added phytosterol esters' include three advisory statements to the effect that:

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

The intent of the latter statement is to ensure that target consumers are informed about the optimum amount of plant sterols that should be consumed to achieve a cholesterol-lowering effect (i.e. 2-3 g plant sterol equivalents per day), as well as ensuring cost-effective use of the products.

This Application does not have any impact on the intent of these advisory statements and therefore no amendments to the statements have been proposed. However, a drafting amendment has been made in column 1 in the Table to clause 2 in Standard 1.2.3 so that the advisory statements will now apply to 'foods containing added phytosterols, phytosterols and their esters'.

#### 6.5.4.3 Declaration of Plant Sterols in the Nutrition Information Panel

Under clause 5 in Standard 1.2.8 - Nutrition Information Requirements in the Code, the amount of plant sterols per serving and per 100g of the food must be declared in the nutrition information panel (NIP) if a nutrition claim is made about plant sterols. This also allows consumers to monitor their consumption of plant sterols.

This Report introduces the concept of 'plant sterol equivalents' to rationalise and simplify the various forms of plant sterols that would be permitted by this Application. As discussed in section 6.5.3, a 'plant sterol equivalent' represents 60% of the plant sterol fatty acid ester. A potential issue raised by this Application is that currently the requirements in Standard 1.2.8 do not specify the form of plant sterols to be declared in the NIP and therefore whether the amount to be declared should reflect the 'free' form or the esterified form. As the advisory statement discussed in the above section relates to the consumption of 2-3 g plant sterol equivalents (that is in the 'free' form), a declaration in the NIP that represents the esterified form has the potential to mislead consumers in terms of consuming an advised amount.

To address this issue, Standard 1.2.8 has been amended such that where declaration of plant sterols is required in the NIP the amount that is declared reflects the 'plant sterol equivalent'. It is intended however that the more familiar term 'plant sterols' continue to be used to facilitate consumer understanding and provide consistency with the advisory statement in the Table to clause 2 in Standard 1.2.3 (though use of this term is not mandated). This amendment also provides greater clarity from an enforcement perspective. Another important point is to ensure consistency between the term used for the NIP declaration and the mandatory advisory statement to ensure appropriate consumer information is provided. The drafting is contained in Attachment 1.

To deal with any potential labelling changes that may be required due to these changes FSANZ has provided a labelling transition period of two years. There were no submissions on the potential impact or labelling changes on this new drafting, so it is assumed that there will be no or minimal changes required. One submitter did request that the terms used in the NIP and advisory statement be mandated in the Code, but FSANZ has not agreed to this request (see section 10.1.5 for the discussion of the reasons).

## **6.6 Impact on current Applications**

As noted in Section 2.3 of this Report, Application A1019 seeks exclusive permission to use phytosterol esters sourced from tall oils in lower-fat cheese (<12 g fat/100 g cheese). Application A1024 will not directly affect the progress of Application A1019. Under the FSANZ Act, FSANZ must consider both Applications separately and not assume that one or other or both of the Applications would be successful and therefore may have an impact on the other Application. Any draft variations to the Code approved by FSANZ need to be considered by the Ministerial Council.

Therefore, FSANZ cannot at this stage, confirm the final form of drafting for Application A1019 once the 15-month exclusivity period is completed and by what mechanism it would be amended. FSANZ is aware of the various options that may be available and will deal with them at that time.

Should both Applications be approved, and after the exclusive use period has expired, a specific permission for the use of tall oil phytosterols esters in lower-fat cheese will sit alongside a generic permission for the use of plant sterols in the other permitted foods. The acceptance of Application A1024 would indicate that there is agreement about the equivalence of different types of plant sterols. It might be straight forward to establish equivalence (of efficacy and safety) of all plant sterols in lower-fat cheese based on the evaluation with low-fat milk and yoghurts already conducted as part of the assessment performed for this Application.

If Application A1019 is successful, the exclusive drafting is valid only for 15 months. This exclusive permission is limited to only the Applicant's brand of cheese products. After the 15 months have expired, the exclusive permission listed in the Table to clause 3 would be removed and the permission reverts to a more general permission in the Table to clause 2. As a minimum, the new general permission would mean that other cheese manufacturers could use the permission and produce their own products that meet the conditions of use. The extra question to be considered at that time is whether the plant sterol form should be the specific form of Application A1019 (i.e. 'phytosterol esters derived from tall oils'), or the more generic term 'phytosterols, phytosterols and their esters'. That question needs to be considered in the future and cannot be decided as part of this Application. FSANZ notes the support of some submitters that the generic permission is the one that should be given once the exclusivity period expires (see section 10.1.3 and Attachment 2).

Should FSANZ agree to proceed, it will need to determine how to amend the Code to convert the specific exclusivity permission for cheese into a general permission for all plant sterols and not just for phytosterol esters from tall oils after the 15-month exclusivity period expires.

## **6.7 Risk Management Strategy**

FSANZ considers that there are no issues with regard to the health and safety and efficacy associated with consolidating the current permissions for plant sterol mixtures into one set of generic permissions which encompass phytosterols, phytosterols and their esters (see SD1 and the summary sections in section 5).

In relation to ensuring the technical suitability of any such mixture in permitted foods, FSANZ considers this issue can be sufficiently managed through the existing conditions of use and the commercial realities involved with producing these foods. Plant sterols in these products should be uniformly distributed for any individual serve or container, and the production and quality assurance procedures should ensure compliance of their products with the permissions. Commercial considerations will ensure plant sterol mixtures that cause appearance, flavour and odour problems will not be used. On this basis, FSANZ does not propose to set out any further regulatory conditions in addition to those currently in the Code.

The proposed strategies associated with consolidating permissions for plant sterols are:

- maintain the current compositional limits for approved foods, but expressed as plant sterol equivalents



- make consequential amendments to Standards 1.1.1, 1.2.3, 1.2.8, 1.3.1, 1.3.4, 2.4.2, 2.5.1 and 2.5.3 to clarify and ensure consistency in permissions given for phytosterols, phytostanols and their esters.

## 7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand.

There are no non-regulatory options available for this Application.

FSANZ has considered two regulatory options:

### **Option 1: Reject the Application, thus maintaining the *status quo***

Maintain the *status quo* by rejecting the Application.

### **Option 2: Amend references and permissions in the Code to reflect equivalence of plant sterols**

Amend the permissions in Standard 1.5.1, and make consequential amendments to other relevant Standards in the Code to reflect the equivalence of plant sterol mixtures that meet the modified JECFA 2008 specifications.

## 8. Impact Analysis (RIS ID: 10643)

### 8.1 Affected Parties

The likely parties affected by the regulatory options outlined above are:

1. those sectors of the **food industry** currently marketing, and in the future wishing to market, plant sterols and foods containing added plant sterols;
2. **consumers**, in particular those who purchase and consume foods that contain added plant sterols; and
3. **Government**; Commonwealth, State, Territory and New Zealand health and enforcement agencies.

### 8.2 Benefit Cost Analysis

In developing food regulatory measures 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 relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts.

The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party.

FSANZ has liaised with the Office of Best Practice Regulation (OBPR), which has subsequently approved a preliminary assessment of the regulatory impact of this Application.

This concluded that there were no business compliance costs involved and/or minimal impact and consequently a detailed Regulation Impact Statement (RIS) was not required.

### 8.2.1 **Option 1: Reject the Application**

#### 8.2.1.1 Industry

Under this option there are no changes to the types of plant sterol preparations that can be added to the specific food vehicles than the restrictive permissions that exist in the Code.

These permissions are linked to very tight and 'company specific' specifications which currently exist in the Schedule to Standard 1.3.4. These tight specifications were originally required as there were no specific specifications within the primary sources of specifications in clause 2 of this Standard for these products.

Since these 'company specific' specifications were approved some more generic specifications have been developed and written into the primary sources of specifications for plant sterols. These are for 'Vegetable oil phytosterol esters' in the Food Chemicals Codex, and 'Phytosterols, phytostanols and their esters' in the Combined Compendium of Food Additives Specifications, Monograph 5, JECFA (2008). These specifications are broader and do not have the very tight specific percentage range of individual sterols that the current two specifications have in the Schedule. Using these more general specifications allows more options for manufacturers of plant sterol preparations and for the food manufacturers who are trying to source supplies of plant sterols.

Not allowing a broadening of supply of plant sterols imposes a tight limitation on plant sterol manufacturers especially if their raw material or their manufacturing process changes, and also food manufacturers who wish to add plant sterols to their food product.

In summary there is a cost to the food industry under this option, because of the continuation of the very tight and restrictive permissions of the Code. However producers of existing products that contain plant sterols would benefit because they would not face extra market competition.

#### 8.2.1.2 Consumers

If the *status quo* was retained, consumers would not see any change. Consequently, consumers may be disadvantaged as the commercially available product range would be limited.

#### 8.2.1.3 Government

There are no added costs for enforcement agencies of retaining the *status quo*. However, there is the opportunity cost arising from the loss of possible additional health benefit to the broad community and flowing onto healthcare costs. This may be postulated from the risk analysis conclusion that other forms of plant sterol preparations are also efficacious at reducing LDL-cholesterol and so may have a probable public health benefit. More products containing plant sterols potentially mean an increased chance that consumers will purchase and consume an efficacious level of plant sterols to reduce their LDL-cholesterol level. Accepting this option denies this public health benefit.

## 8.2.2 **Option 2:** Amend references and permissions in the Code to reflect equivalence of plant sterols

### 8.2.2.1 Food Industry

This option will be a benefit to the food industry, in particular those that supply plant sterols to food manufacturers and those food manufacturers who source plant sterols to add to their food products.

This option allows a broader range of plant sterol preparations that a food manufacturer can add to the four food categories (that currently are permitted in the Code to have specific types of plant sterols added to them). This provides greater flexibility to the food industry and individual food companies, and could potentially provide more competition among plant sterol suppliers. Increased competition could reduce the costs of plant sterol preparations and food containing plant sterols but FSANZ cannot predict whether this will actually occur.

The increase in the options of supply of plant sterols under this option brings the Australian and New Zealand regulatory approaches to plant sterols more into line with the regulation of plant sterols in other countries, in particular in Europe, where there are many more types of plant sterol preparations that can be added to food. This option would allow more products containing added plant sterols in the Australia and New Zealand market. It would therefore require the Australia and New Zealand market to become more competitive and more linked to the international plant sterol industry.

### 8.2.2.2 Consumers

There may be benefits arising from this option for consumers. While existing product permissions have not been changed, changes to the types of plant sterols that may be added may provide competition and increased product range in the market place. Plant sterol fortified products are currently priced at a premium to those that do not contain added plant sterols.

There are no risks to consumers of this option since the assessment of the Application has concluded that the different forms of plant sterols that meet the modified JECFA specifications do not pose any public health and safety risks. They are equivalent to the current forms of plant sterols permitted in food products in the Code in terms of food safety and are all efficacious in reducing LDL-cholesterol. Moreover research in markets where additional plant sterol enriched products have been available for some time (The Netherlands, the United Kingdom, France, Germany, and Belgium), shows increased product availability is not linked to increased or excess consumption of plant sterols by individual consumers. Most users consume one or two products, and substitute plant sterol enriched products for other different types of plant sterol enriched food products. Most of the evidence collected in Member States in the European Union indicates that current intakes of free plant sterols are below the optimal intake of 3 g/day recommended for cholesterol reduction (EFSA, 2008<sup>12</sup>; SCF, 2002<sup>13</sup>). Therefore, there are no public health and safety concerns from increased exposure, availability or consumption of phytosterols.

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<sup>12</sup> EFSA (2008) Consumption of food and beverages with added plant sterols in the European Union. A Report from the Data Collection and Exposure Unit in Response to a Request from the European Commission. *The EFSA Journal*, 133, 1-21.

<sup>13</sup> European Commission, Scientific Committee on Food. Opinion of the Scientific Committee on Food on a report on Post Launch Monitoring of "yellow fat spreads with added phytosterol esters". SCF/CS/NF/DOS/21 ADD 2 Final (4 October 2002).

### 8.2.2.3 Government

This option is expected to have impacts on regulatory agencies that enforce the permissions in the Code, since there are likely to be more commercial products on the market that contain different forms of plant sterols. The methods of analysis required to analyse for these different forms are believed to be comparable to the existing methods needed to analyse for the currently permitted forms of plant sterols in the Code. As explained in more detail in section 10.1.1 of this Report there are a number of analytical methods available in the literature, in particular that of Laakso 2005<sup>14</sup>, which is believed to be suitable for analysing plant sterols in various different food matrices that can be used for analytical purposes if required. This reference is an analytical method referred to in the plant sterol literature and developed by the Applicant, Raisio, and also provided in their Application. Therefore, there are not expected to be significant costs or implementation issues associated with this option.

A further potential impact for Government agencies is the possible population health benefit of reducing LDL-cholesterol of more of the population if more consumers purchase plant sterol fortified products than currently. However, it is not clear if there is likely to be any major change in consumption patterns by the population or individuals (section 8 of SD1).

## **8.2 Comparison of Options**

Analysis of the costs and benefits of each option indicates that Option 2 provides net benefits to consumers and industry. Permitting flexibility in plant sterol mixtures will enable opportunities for growth within the plant sterol market, which will likely benefit consumers in terms of increased product choice. These products are considered safe for consumers at the estimated levels of intake. While there is a potential for slight costs to enforcement agencies in terms of enforcement of these products, the associated costs, if any, are likely to be small and not considered to outweigh the benefits to community and industry.

Therefore, Option 2 is preferred as it delivers net benefits to the community over and above the *status quo*.

## **Communication and Consultation Strategy**

### **9. Communication**

FSANZ undertook targeted consultation and communications with specific interested stakeholders who have views on the regulation of plant sterols permissions for the food supply. FSANZ considered and consulted on the amendments made to the Assessment Report and from considering submissions. In particular FSANZ sought assurances that there were no detrimental unintended consequences to the plant sterol manufacturers and suppliers and the food industry that currently produce food containing plant sterols under the current permissions in the Code. As well FSANZ conducted consultations with those jurisdictions that provided a submission to the Assessment Report to ensure we understood and dealt with their specific issues.

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<sup>14</sup> Laakso, P., 2005. Analysis of sterols from various food matrices. Eur. J. Lipid Sci. Technol. 107, 402-410.

## 10. Consultation

### 10.1 Issues raised in Public Consultation

Public comment on the Assessment Report for this Application was sought between 1 October 2009 and 11 November 2009. Twelve submissions were received of which eleven supported progression of the Application, while one stated an intent to review its position at the next stage of consideration. The submissions were split between eight from industry or industry groups, two from government jurisdictions and two public health associations. The summary of the submissions is contained in Supporting Document 2.

The issues raised in these submissions and FSANZ's responses to these issues are provided in the sections below.

#### 10.1.1 *Analytical method for plant sterols in food*

One submission raised the issue about ensuring that there is an appropriate analytical method to determine the amount of plant sterols in the various food matrices. That is, there needs to be a robust analytical method available that enforcement agencies can use to check for compliance with the limits provided for maximum and minimum content of plant sterols in the different food matrices in the draft variations of this Application. The submission noted that FSANZ needed to take account of this issue as part of the compliance costs of this Application for jurisdictions. They noted that the analytical methods detailed in the JECFA and Food Chemicals Codex plant sterol specifications (as discussed in the Assessment Report) are specific for analysing and ensuring purity of the specific plant sterol preparations, not necessarily for determining the amount of the plant sterol actually in the food matrix, or to ensure compliance.

##### 10.1.1.1 FSANZ response

FSANZ has not evaluated the various analytical methods it notes below for suitability and applicability. However, it provides this information, from that which was provided in the Application and from further assessment of the scientific literature, as assistance to enforcement agencies.

The Application provided information related to both analytical methods for determining the purity of the plant sterol preparations and for analysing for plant sterol content in the food. The Application states that in most cases, quantitative analysis of plant sterols occurs as their trimethylsilyl (TMS) derivatives in the presence of an internal standard by capillary gas chromatography (GC) with a flame ionisation detector (FID). To date there are no official international reference methods developed for the analysis of plant sterols added to food. There are some international reference analytical methods available for determining the natural occurrence of plant sterols as minor food components but these levels are much lower than that found in plant sterol fortified foods.

The Applicant, Raisio, has developed an in-house analytical method for determining the total plant sterol content (total of both free and the free form derived from the esters due to saponification) in the fortified food. This method was modified from ISO 6799, 1991 and IUPAC 2.401 and IUPAC 2.403 standard methods. The Raisio method has been validated in-house and published in the literature by Laakso (2005)<sup>15</sup>.

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<sup>15</sup> Laakso, P., 2005. Analysis of sterols from various food matrices. Eur. J. Lipid Sci. Technol. 107, 402-410.

The method is based on saponification of the food in the presence of an internal standard with 2M potassium hydroxide in ethanol at 60°C for 1 hour to break the ester bonds of any phytosterol and phytostanol esters in the food. The unsaponifiable material containing the free phytosterols and phytostanols is extracted with an organic solvent, such as heptane and evaporated to dryness. The free phytosterols and phytostanols are derivatised to their TMS derivatives and analysed by GC-FID. Laakso states that this method is suitable to determine plant sterols contained in spreads, milk and yoghurt. It is stated that some food matrices, such as pasta (and may be breakfast cereals) require acid hydrolysis in order to release matrix bound plant sterols before the saponification step.

The JECFA Chemical and Technical Assessment Report for 'Phytosterols, Phytostanols and their Esters'<sup>16</sup> also has a section on analytical methods. Three references relevant to analyse plant sterols in foods are provided in this report and are noted to be relevant for any jurisdiction or analytical laboratory aiming to develop a method for determining compliance of levels of plant sterols in food within the permissions in the Code. A GC-FID method commonly used is based on the AOAC Official Method 994.10 for 'Cholesterol in Food'<sup>17</sup>. Most analytical methods are based on an ISO method<sup>18</sup>.

Plant sterols have been permitted to be added to food in the Code since June 2001, with the first permission being for the addition of phytosterol esters to be added to edible oil spreads. Since this time the permissions for addition of various plant sterols has been expanded to include permissions for addition of phytosterol esters also to breakfast cereals, low-fat milk and low-fat yoghurt. As well, tall oil phytosterols have been permitted to be added to edible oil spreads and low-fat milk. Therefore, analytical methods would have already been required to be developed to ensure compliance for these permissions and it is likely that these already developed methods can be used or modified to ensure complete analytical capability to meet any new requirements that may arise from this Application.

#### *10.1.2 Consideration of plant sterols as novel foods*

One submitter wondered when can plant sterols be no longer considered novel since they have been added to the Australia and New Zealand food supply since phytosterol esters from vegetable oil were first permitted to be added to edible oils spreads in 2001. Can the various forms of plant sterols now be considered 'traditional' and so no longer novel, and if not now then when would this be the case?

##### 10.1.2.1 FSANZ response

The question of when a currently permitted 'novel food' would no longer be defined as a novel food since there has been a history of consumption of the food in Australia and New Zealand is believed to be outside the scope of the issues directly relevant for the assessment of this Application. This question has been raised before but it is not appropriate to consider the issue as part of this specific Application. It would be more appropriate to consider it as part of a more complete review of the whole Novel Food Standard.

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<sup>16</sup> Joint FAO/WHO Expert Committee on Food Additives (JECFA), 2008. Phytosterols, phytostanols and their esters. Chemical and Technical Assessment 1-13. Available at [http://www.fao.org/ag/agn/agns/jecfa/cta/69/Phytosterols\\_CTA\\_69.pdf](http://www.fao.org/ag/agn/agns/jecfa/cta/69/Phytosterols_CTA_69.pdf) Assessed on 22 December 2009

<sup>17</sup> AOAC Official Method 994.10 for "Cholesterol in Foods" AOAC International, Gaithersberg (USA)

<sup>18</sup> ISO 12228:1999. Animal and vegetable fats and oils – Determination of individual and total sterols contents – gas chromatographic method. International Organisation for Standardization, Geneva, Switzerland.

It should be noted that in the current Editorial note in Standard 1.5.1, FSANZ is required to review clause 3 (exclusivity) after 3 years and before 5 years from the date of gazettal..

#### *10.1.3 Linkage between Application A1024 and Application A1019 (plant sterol permission in lower-fat cheese products)*

Some submitters noted that FSANZ was concurrently assessing two plant sterol Applications, being this Application, A1024 and Application A1019 (exclusive use of phytosterol esters in lower-fat cheese products). In Application A1019 exclusive permission is being sought for a certain type of plant sterol added to specific brands of the Applicant's products. The exclusive period of the permission is 15 months if the Application is successful, and the permission is provided in the Table to clause 3 of Standard 1.5.1. Once the 15 months exclusivity period is completed, the brand specific permission becomes a general novel food permission in the Table to clause 2 of the Standard.

The issue some submitters have raised is how this general permission should be written. The submitters argue that accepting the conclusions of Application A1024, that various forms of plant sterols are equivalent in terms of their safety and efficacy has implications for how the final permissions for Application A1019 should be written. That is, the permission for plant sterols that can be added to lower-fat cheese products should be the generic term of plant sterols, that is 'phytosterols, phytostanols and their esters' and not the specific type of plant sterols that A1019 relates to, being 'tall oil phytosterol esters'.

##### 10.1.3.1 FSANZ response

Section 6.6 deals with the assessment of the two concurrent plant sterol Applications, which addresses the issues raised by the submitters. To address the submissions, this section has been amended.

#### *10.1.4 Maintain use of mandated terms in ingredient labels*

One submission did not support FSANZ's recommendation in section 6.5.4.1 of the Assessment Report (section 6.5.4.1 in this Report), to remove the requirement to use specific terms in the ingredient list for the different types of plant sterols. The submitter is of the view that the current explicit ingredient labelling requirements for plant sterols that are prescribed in the Table to clause 2 of Standard 1.5.1 should be retained to provide consumers with adequate information about these ingredients. They do not agree that the general requirements in Standard 1.2.4 are explicit enough, especially if this Application is successful and permissions will apply to plant sterol mixtures. The submitter suggests that without prescribed labelling terms to describe the different types of plant sterols, there is potential for inconsistent interpretation of the intended legal requirements. The submission further states that the JECFA 2008 specification is not of assistance in this matter as there are a variety of terms used in this document as 'synonyms'.

##### 10.1.4.1 FSANZ response

FSANZ maintains the view that the general requirements for ingredient labelling within Standard 1.2.4 are both sufficient and appropriate for the labelling of plant sterols in the ingredient list. Standard 1.2.4 requires that ingredients be listed by their common name, a name that describes the true nature of the ingredient or a generic name, where applicable. Under these requirements it is incumbent on the supplier to ensure that the names of ingredients are accurate and sufficiently detailed so as not to be false, misleading or deceptive. Therefore, mandating specific terms to be used in the ingredient list may be considered as unduly prescriptive and potentially inconsistent with the Council of Australian Governments (COAG) principle of minimum effective regulation.

A further issue to consider is whether more prescriptive ingredient labelling requirements for plant sterols would provide additional benefits to the consumer in terms of facilitating informed choice. Under the approach suggested by the submitter, specific terms would need to be defined in the Code to cover all potential sources and blends of plant sterols that meet the generic specification, for the purposes of ingredient labelling. It is unclear how mandating the use of specific terms to be used in the ingredient list would provide additional information to assist consumers in making purchasing choices.

In conclusion, FSANZ proposes to retain the proposal in the Assessment Report (and explained in section 6.5.4.1) to remove the specific ingredient labelling requirement for plant sterols in the Table to clause 2 in Standard 1.5.1 and to rely on the general ingredient labelling requirements of clause 4 of Standard 1.2.4.

#### *10.1.5 Mandate term 'plant sterols' in nutrition information panel and advisory statement*

One submission requested that the specific term 'plant sterols' should be prescribed for both the Nutrition Information Panel (NIP) declaration and the mandatory advisory statement. The submitter suggests that if the term is not mandated, different food manufacturers could use different terms on the labels of their products (e.g. 'plant sterols' or 'phytosterol equivalents') and that this inconsistency could be misleading and confusing to consumers. The submitter agrees that the declaration in the NIP should be meaningful to consumers and so should relate to plant sterol equivalents; however, it considers that the term 'plant sterol equivalent' should be defined in the Code.

##### 10.1.5.1 FSANZ response

As discussed in section 6.5.4.3, FSANZ considers that the declaration of plant sterols in the NIP should be consistent with the mandatory advisory statement and that the amount declared in the NIP should relate to the 'plant sterol equivalent'. This ensures that consumers receive appropriate information to readily calculate their daily consumption of plant sterol equivalents. FSANZ does not consider that sufficient justification has been provided by the submitter to warrant prescribing the term 'plant sterols' in the NIP and advisory statement. FSANZ also notes that for those products currently on the market, the term 'plant sterols' is used in the NIP, consistent with the term used in the advisory statement. Consideration may be given to mandating these terms in future, should evidence of significant market variation leading to consumer confusion or uncertainty become apparent.

The issue of defining 'plant sterol equivalents' is discussed in Section 6.5.3 with a definition also provided in the Table in the Introduction section. The former equivalent term 'total phytosterol content' was used in the drafting for the Assessment Report.

#### *10.1.6 Solvent limits in specification*

In section 6.5.1 of the Assessment Report, FSANZ proposed changes to the drafting for Standard 1.3.4 to deal with solvent limits for preparations of plant sterols that are at least 95% of phytosterol and phytostanol (i.e. not phytosterol or phytostanol esters). This new drafting relates to the solvent limits within the JECFA 2008 specifications. FSANZ sought specific comments from submitters on this issue. In particular, comment was requested on whether the solvent limit of 5000 ppm in current specifications could be reduced. As well, comment was sought about whether the lists of solvents proposed (hexane, 1-propanol, ethanol, methanol and methyl ethyl ketone) was correct to cover the manufacture of all types of plant sterols.

There were a number of submissions received on this issue, as summarised below.



There were no submissions that directly supported the 5000 ppm limit. Two submissions agreed with lowering the limit to 1000 ppm, while one requested the limit to be 2000 ppm. One submission expressed concern about the high solvent level and proposed that the limit should be 50 ppm (as the JECFA specification). This same submitter provided the recently updated European Solvent Directive (Directive 2009/32/EC) and requested that in the interests of public health and safety that the solvent limit should be harmonised with this Directive [this does not have a specific solvent limit for plant sterol preparations but the individual limits for different extraction solvents are very low, being below 50 ppm for all use of solvents, with some being limited to GMP]. One submission requested that FSANZ provide an intake calculation (or alternative justification) to show why a higher limit is appropriate.

Two submitters also requested that isopropanol (2-propanol, propan-2-ol) also be listed as a solvent since some plant sterol manufacturers use it. One plant sterol manufacturer indicated that they use isopropanol, methyl ethyl ketone and methanol as solvents and no longer use hexane and acetone.

#### 10.1.6.1 FSANZ response

The process of steam stripping unreacted free fatty acids from the esterified product mixtures effectively removes all residual extraction solvents. However, formulations of unesterified plant sterols, where steam is not used, will contain low levels of particular extraction solvents. The current specifications for tall oil-derived phytosterols listed in the Code specify a maximum level of residual extraction solvents of 5000 ppm, equivalent to 0.5% (see Table 2 in section 6.5.1). This level corresponds to the maximum limit for organic volatile impurities in the Certificate of Analysis for FCP-3P1, tall-oil derived phytosterols, used in a 90 day toxicity study in rats (Forbes Medi-Tech Study Number: 115-003). This study formed part of the safety information submitted to FSANZ in 2001, underpinning the current approvals for the use of tall oil-derived phytosterols<sup>19</sup>. The maximum level of 5000 ppm for solvents also accords with the US FDA specifications for Phytrol™ under GRAS notification number GRN 000039.

Based on updated information obtained from major manufacturers of plant sterols used in the food industry, FSANZ has determined that manufacturers are consistently able to meet a maximum level of 2000 ppm (0.2%) for residual solvents. In revising the current specifications, FSANZ is therefore proposing to lower the maximum level of solvents to 2000 ppm in accordance with the principles of Good Manufacturing Practice (GMP).

Solvent residues in plant sterol preparations typically include hexane, 1-propanol, ethanol or methanol, which may be present either singly or in combination. FSANZ is advised by some manufacturers that preparations of plant sterols may contain residual levels of isopropanol and/or methyl ethyl ketone as a result of using contemporary extraction methods. While the Code currently does not specify the solvents to which the maximum level applies, FSANZ proposes to include a list of solvents in revised specifications. Residues of any of these particular solvents (hexane, isopropanol, ethanol, methanol and methyl ethyl ketone) up to a maximum level of 2000 ppm raise no food safety concerns and should be readily achievable by any manufacturer of plant sterols.

A solvent limit of 5000 ppm for plant sterol preparations is considered safe. This limit of 5000 ppm is currently in the Code for a specific type of plant sterol preparation as well as other international specifications (mentioned above). However, FSANZ now understands that all plant sterol manufacturers are now able to achieve a lower limit of 2000 ppm.

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<sup>19</sup> FSANZ previously completed the assessment of tall oil phytosterols under Application A417.

Requiring a solvent limit lower than 2000 ppm will mean added costs for manufacturers and no real improvement in safety. Therefore, a solvent limit of 2000 ppm has been chosen consistent with the principle of minimum effective regulation.

#### *10.1.7 Explanation around how costs for enforcement determined*

A submission requested that FSANZ provide more information about how FSANZ determined the level of impacts on regulatory agencies that enforce the permissions in the Code for option 2, including analytical costs and how these costs were determined.

In the Assessment Report FSANZ indicated that option 2 (permitting the Application) 'will have impacts on regulatory agencies that enforce the permissions in the Code, since there are likely to be more commercial products on the market that contain different forms of plant sterols'. The submission highlighted the word 'more' in this extract.

##### 10.1.7.1 FSANZ response

FSANZ does not have, nor has it determined or calculated what potential increase in costs there may be for enforcement agencies, including for the submitter, for approving the Application, i.e. option 2. FSANZ made the reasonable assumption that if this Application is successful this could open up the market for plant sterols added to the current food matrices so concluding there could be more commercial products on the market. By implication FSANZ was assuming this would require allocation of resources from enforcement agencies to check for compliance of labelling and to analyse compliance with the compositional limits proposed for the foods. This is dependent on enforcement agencies determining that compliance with these new permissions is important and worthy of committing resources. The issue of analytical method development has already been discussed in section 10.1.1.

A question that arises is whether enforcement agencies already perform analyses for the current permissions for plant sterols in the four food matrices, and whether the likelihood of doing this will change if this Application is successful. This is not a question that FSANZ can answer. Interpreting and enforcing the requirements of the Code are the responsibilities of the jurisdictions. How the various agencies do this will depend on a variety of internal and external drivers, including whether there are issues of public health and safety or consumer deception that may warrant putting resources to investigating plant sterol fortified foods.

Due to the matters stated above FSANZ is reliant on the various jurisdictions to provide comments and information, including suggested costs on the impacts to them. FSANZ sought comments from enforcement agencies on this matter in the Assessment Report but beside the questions received in the submission there were no other comments or information received. FSANZ's risk benefit analysis can therefore only be qualitative not quantitative.

#### *10.1.8 Legibility issue with advisory statements*

A similar submission was received on both this Application and Application A1019. The issue from both submissions relate to lack of prominence of the mandatory advisory statements that are on plant sterol fortified products currently on the market. The submitter provided examples of this labelling in their submission to Application A1019.

The submission noted that currently these statements may be located in the least prominent position on the package, displayed in capitals which people find hard to read or buried and so lost in a block of text.

The submission requests that FSANZ review this matter and consider whether more stringent requirements need to be associated with the mandatory advisory statements required for plant sterol fortified products.

#### 10.1.8.1 FSANZ response

The issue of legibility of advisory statements was raised during the public consultation process for the three previous Applications that sought permission to add plant sterols to a broader range of foods (Applications A433, A434 and A508). Comments were raised in relation to the lack of prominence of these advisory statements and the location of these statements on the packages.

Standard 1.2.9 - Legibility Requirements sets out the legibility requirements for the labelling of packaged and unpackaged foods. The Standard requires that any word, statement, expression or design that is prescribed to be contained, written or set out in a label must be legible and prominent such as to afford a distinct contrast to the background and in the English language. The editorial note to clause 2 in Standard 1.2.9 states that the Standard will be reviewed within 24 months of the Gazettal of the Editorial note. This review was due to commence by 9 November 2008 and was specifically prompted by the three previous plant sterol Applications.

In July 2009, members of the Implementation Sub-Committee (ISC) were asked to provide advice on whether the previous concerns raised by jurisdictions in relation to the legibility of advisory statements on plant sterol-fortified products were still current or whether the Standard was difficult to enforce. ISC members did not raise any new issues with respect to the legibility of advisory statements or enforcement of the Standard. FSANZ has therefore deferred the review of Standard 1.2.9 until after the Ministerial Council review of labelling policy and law has been completed, and within the context of a broader review of labelling standards.

Due to the limited risk of consumption of plant sterol enriched products FSANZ concludes that there is insufficient reason to review these current advisory statements. Therefore, FSANZ would lack an evidence base to prescribe in the Code more stringent legibility provisions.

#### *10.1.9 Added conditions to the JECFA 2008 specifications*

One submission expressed concern that the JECFA 2008 specification for 'phytosterols, phytostanols and their esters' (monograph 5) which is directly linked to permissions and justifications for this Application, does not specifically limit the plant sterol preparations to the major phytosterols and phytostanols and their esters that have been included in the FSANZ review of commercial preparations of phytosterols, phytostanols and their esters. The submission proposes that FSANZ consider extra conditions to clarify the intent of the JECFA specification and to ensure approval is given for only those major forms of plant sterols which have been scientifically substantiated to reduce cholesterol. This would include those plant sterol preparations that have been assessed as part of FSANZ's review of the literature performed for this Application (i.e. within the Risk Assessment Report, SD1).

To that extent the submitter requested that FSANZ consider adding the following conditions:

1. The esters of phytosterols and phytostanols are only fatty acid esters; and
2. Specify that the sterol profile for plant sterol preparations must have >95% des-methyl sterols (on the sterol basis, related to the plant sterol equivalents of the preparation).

### 10.1.9.1 FSANZ response

FSANZ considers that the JECFA specification currently limits plant sterol esters to fatty acid esters as per the following extract:

Esters are also produced by reacting the sterols/stanols with fatty acids derived from food grade vegetable oils.

Thus the first proposed condition is implicit in the JECFA specification and no additional condition is required.

In relation to the second proposed condition, FSANZ is supportive of the proposal to clarify the intention of the JECFA specifications to ensure that only appropriate forms of plant sterols are permitted to be added to approved foods. The six major plant sterols noted in the JECFA specification are all des-methyl sterols ( $\beta$ -sitosterol, sitostanol, campesterol, campestanol, stigmasterol and brassicasterol), however the specification does not explicitly state this plant sterol group is the only group permitted. The addition of an extra condition in the drafting will limit the permissions to plant sterol preparations with >95% des-methyl sterols<sup>20</sup> content to ensure the permissions align with the efficacy evidence base. This will exclude 4,4'-dimethyl sterols and/or pent acyclic triterpene alcohols (found at higher levels in plant sterol preparations derived from shea nut oil and rice bran oil), as these have been shown to be not effective in lowering LDL cholesterol in humans (Weststrate & Meijer, 1998<sup>21</sup>; Sierksma et al., 1999<sup>22</sup>; Vissers et al., 2000<sup>23</sup> Trautwein et al., 2002<sup>24</sup>; and Meijer et al., 2003<sup>25</sup>).

This condition will not affect commercial plant sterol preparations used currently as ingredients to fortify food around the world as des-methyl sterols are the main components of plant sterols extracted from vegetable oil and tall oil. This condition also aligns with previous specifications listed in the Code, the Food Chemicals Codex 6<sup>th</sup> edition for 'vegetable oil phytosterol esters' and European specifications for plant sterols. Preparations that do not meet this condition would require an Application and supporting data to confirm safety and efficacy before they would be permitted to be added to food. The Applicant was also supportive of this proposed extra condition, of ensuring that only plant sterol preparations that have proven safety and efficacy to reduce blood cholesterol levels should be permitted to be added to food. The other plant sterol manufacturers and suppliers who submitted comments to the Assessment report were also consulted by FSANZ and they were also supportive of this extra condition.

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<sup>20</sup> Des-methyl sterols (also called 4-desmethyl sterols) are discussed in sections 2.2.1 and 6.2 of SD1. This class of plant sterols includes the six major plant sterols ( $\beta$ -sitosterol, sitostanol, campesterol, campestanol, stigmasterol and brassicasterol) which are currently used in commercial plant sterol preparations added to foods.

<sup>21</sup> Weststrate, J.A. and Meijer, G.W. (1998) Plant sterol-enriched margarines and reduction of plasma total- and LDL-cholesterol concentrations in normocholesterolaemic and mildly hypercholesterolaemic subjects. *Eur. J. Clin. Nutr.* **52**: 334-343

<sup>22</sup> Sierksma, A., Weststrate, J.A. and Meijer, G.W. (1999) Spreads enriched with plant sterols, either esterified 4,4-dimethylsterols or free 4-desmethylsterols, and plasma total- and LDL-cholesterol concentrations. *Brit. J. Nutr.* **82**, 273–282.

<sup>23</sup> Vissers, M.N., Zock, P.L., Meijer, G.W. and Katan, M.B. (2000) Effect of plant sterols from rice bran oil and triterpene alcohols from sheanut oil on lipoprotein concentrations in humans. *Am. J. Clin. Nutr.* **72**: 1510-1515.

<sup>24</sup> Trautwein, E.A., Schulz, C., Rieckhoff, D., Kunath-Rau, A., Erbersdobler, H.F., de Groot, W.A. and Meijer, G.W. (2002) Effect of esterified 4-desmethylsterols and -stanols or 4,4'-dimethylsterols on cholesterol and bile acid metabolism in hamsters. *Brit. J. Nutr.*, **87**: 227-237

<sup>25</sup> Meijer, G.W., Bressers, M.A.J.J., de Groot, W.A. and Rudrum, M. (2003) Effect of structure and form on the ability of plant sterols to inhibit cholesterol absorption in hamsters. *Lipids*. **38**(7) 713-721.

The Applicant also suggested an alternative condition, which further specified the source of the plant sterol as being 'only plant sterols sourced from vegetable oil and so-called tall oil can be used'. Regardless of their source, commercial plant sterol mixtures consist predominantly of the compounds  $\beta$ -sitosterol, sitostanol, campesterol and campestanol. Depending on the plant source, commercial plant sterols also contain varying amounts of minor components, such as stigmasterol and brassicasterol. Thus FSANZ does not consider there is a need for any extra condition as the des-methyl sterol condition deals with ensuring only appropriate plant sterol preparations which have good evidence of safety and efficacy are permitted.

The extra condition (minimum des-methyl sterol content) is not expected to change the current enforcement requirements or raise any new or extra analytical issues since the determination of the known and measured des-methyl compounds is the same as already analysed using the analytical methods discussed in section 10.1.1 above. As well the Food Chemicals Codex 6<sup>th</sup> edition specification for 'vegetable oil phytosterol esters' contains analytical methods for the determination of des-methyl sterols.

The extra condition requiring a minimum content of >95% des-methyl sterols in plant sterol preparations requires new drafting. This extra drafting is added to the earlier entry relating to specifications for phytosterols, phytostanols and their esters in Standard 1.3.4 that was proposed in the Assessment Report (see Attachment 1).

#### *10.1.10 Drafting amendments*

A number of submissions related to errors, inconsistencies or suggested amendments noted in the proposed drafting in the Assessment Report. As well there are amendments to drafting from the consideration of other issues raised in submissions as discussed in the earlier sections. These relate to issues of solvent limits in the specifications and other suggested conditions added to the JECFA specifications to relate to permissions to add plant sterols to food.

The individual drafting amendments and FSANZ's response is provided in the section below.

##### 10.1.10.1 FSANZ response

#### ***Amendment to subclause 15(1) of Standard 1.1.1***

A submission noted that the phrase 'their esters' was missing from the definition of 'Phytosterols, phytostanols and their esters'. The submission noted that the complete definition should be:

- (1) A reference in this Code to phytosterols, phytostanols and their esters is a reference to a substance which meets a specification for phytosterols, phytostanols and their esters in Standard 1.3.4.

FSANZ notes this error and this has been corrected in the drafting at Attachment 1A.

#### ***Replace the term 'total phytosterol content' in Standard 1.1.1 with 'total plant sterol equivalents content' and throughout the rest of the Code***

One submission commented about inconsistent use of terminology in the Report, and more particularly in the drafting. It requested that the clearer and more useful term 'plant sterol equivalents' be used in the drafting rather than 'total phytosterol content'.

Another submission requested that the term 'plant sterol equivalents' be defined in the Code so that the correct active components are used in calculations to ensure consistency between the advisory statement and the NIP. Other submitters also expressed their support for the general approach of using plant sterol equivalents to determine permissions.

FSANZ notes the comments in the submissions and is aware of ensuring consistent terminology is used throughout the Report and the importance of defining and explaining the concept of plant sterol equivalents. The terms 'plant sterol equivalents' and 'total phytosterol content' are equivalent to each other. FSANZ recognises that using different terms when referring to the same concept, in the Report and then separately in the drafting, does provide an added amount of complexity which is not required.

A slightly different term, mirroring the use of 'plant sterol equivalents', is therefore proposed in amended drafting, to try and address the aim for consistent terminology. Because of how the term is required to be used in drafting to provide limits of minimum and maximum amounts of plant sterols FSANZ believes it is more appropriate to use this new term, which has also been proposed in the submission. The new term is 'total plant sterol equivalents content', which replaces the original term 'total phytosterol content' in the new drafting. This term is defined in subclause 15(2) of Standard 1.1.1 and then used as required in other sections of the Code.

#### ***Amendment to the Table of provisions to Standard 1.2.8***

A submission noted that the Table of provisions for Standard 1.2.8 needs to be updated to reflect the title change of clause 6.

FSANZ notes this oversight and this has been corrected in the drafting at Attachment 1A.

#### ***Amendment requested to the food category 1.1.3 in Schedule 1 of Standard 1.3.1***

One submitter believed that FSANZ had incorrectly referred to the current food category of 1.1.3 as 'Liquid milk to which phytosterols or phytosterol esters have been added' in Schedule 1 of Standard 1.3.1, when the current entry should be 'Liquid milk to which phytosterol esters have been added'.

This observation was superseded by the recent gazettal of Amendment 111 (of 13 August 2009) that made an amendment to this food category resulting from Proposal P1008. So that which was stated in the Assessment Report is correct and no change is required.

#### ***Amendment to plant sterol limits in the Table to clause 2 in Standard 1.5.1***

A submission noted that the incorrect plant sterol limits are provided in point 3 for the permissions to plant sterols to breakfast cereals. These limits are listed in Table 3 in this Report. That is, the minimum limit of 16 g/kg should be amended to 15.6 and the maximum limit should be amended from 19 g/kg to 19.2.

FSANZ notes this point but re-affirms that it is not appropriate to list the limits to such accuracy, that is to three significant figures, when the multiplying factor of 60% is only an approximation. However, it notes that staying with the original rounded whole numbers does reduce the compliance range, i.e. 15.6 is rounded up to 16 and 19.2 is rounded down to 19. To take account of this FSANZ has decided to reduce the lower limit from 16 to 15 g/kg, and the drafting has been amended to reflect this. This is explained in section 6.5.3.

### ***Amendment to the new entry for paragraph 2(1)(g) in Standard 2.4.2***

A submission noted that the new words for paragraph 2(1)(g) do not flow with the wording at the top of the subclause.

The new entry reads:

(g) Edible oil spreads and margarine may contain the total phytosterol content is no more than 82 g/kg.

FSANZ accepts that the two parts of the entry do not readily link to each other so has amended the drafting in Attachment 1A (picking up the change in the term as noted above) to read:

(g) Edible oil spreads and margarine may contain no more than 82 g/kg of total plant sterol equivalents content.

### ***Amendment to the new subclause 4(c) in Standard 2.5.3***

Two submissions noted subclause 4(c) had not been amended to reflect the changes proposed in the Report. The term 'total phytosterol ester' should be replaced by 'total phytosterol content' (now changed to 'total plant sterol equivalents content', to reflect the above discussion).

FSANZ notes these comments and has amended the subclause in Attachment 1A.

The new subclause is:

(c) where the total plant sterol equivalents content is no less than 0.8 g and no more than 1.0 g per package.

A suggestion to also amend the wording in subclause 4(a) has been accepted. This is to amend the words 'such that the yoghurt contains no more than 1.5 g total fat per 100 g' to 'that contains no more than 1.5 g total fat per 100 g'.

## **10.2 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 no relevant international standards and amending the Code to consolidate plant sterol permissions to reflect the JECFA 2008 specifications is unlikely to have a significant effect on international trade. The amendments are consistent with internationally recognised specifications being developed by JECFA, and the proposed amendments would bring the Code further in line with the existing permissions set out for the trading partners of Australia and New Zealand. Therefore, notification was not made to the agencies responsible in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements.

## **Conclusion**

### **11. Conclusion and Decision**

#### **Decision**

**To approve draft variations to Standard 1.5.1 – Novel Foods so that specific source based permissions for phytosterols esters and tall oil phytosterols are amended into a single generic permission for phytosterols, phytostanols and their esters, for the current four food vehicles to which plant sterols can be added.**

**To approve consequential draft amendments to Standards 1.1.1, 1.2.3, 1.2.8, 1.3.1, 1.3.4, 2.4.2, 2.5.1, and 2.5.3 to clarify and ensure consistency in the permissions given for phytosterols, phytostanols and their esters.**

#### **11.1 Reasons for Preferred Decision**

FSANZ recommends the preferred decision to recognise the equivalence of phytosterols, phytostanols and their esters and consolidate the existing phytosterol permissions as:

- All forms of plant sterols are equally safe for human consumption
- The amendments do not raise any additional nutritional safety concerns
- Any plant sterol that meets current specifications, including the extra conditions, in the Code is capable of lowering LDL-cholesterol
- Most plant sterol mixtures can be incorporated into currently approved foods
- Existing measures are likely to ensure that only suitable plant sterol mixtures are added to the foods
- The amendments are consistent with relevant Ministerial Council Policy Guidelines
- The amendments support industry innovation
- The amendments provide net benefits to affected parties
- No other measures would be more effective at achieving this outcome.

### **12. Implementation and Review**

The FSANZ Board's decision of this Approval Report will be notified to the Ministerial Council. Following notification, the proposed draft variations to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.



## **ATTACHMENTS**

- 1A Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)
- 1B Draft variations to the *Australia New Zealand Food Standards Code* (indicating changes from drafting at Assessment)
- 1C Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)
- 2 Summary of Submissions

## Draft variations to the Australia New Zealand Food Standards Code (at Approval)

*Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting*

**To commence: on gazettal, except for Item [3.2] which commences 2 years from the date of gazettal.**

[1] **Standard 1.1.1** of the Australia New Zealand Food Standards Code is varied by –

[1.1] *omitting the headings for Division 1 – Interpretation and Application and Division 2 – General Prohibitions.*

[1.2] *inserting after clause 14 –*

### **15 Phytosterols, phytostanols and their esters**

(1) A reference in this Code to phytosterols, phytostanols and their esters is a reference to a substance which meets a specification for phytosterols, phytostanols and their esters in Standard 1.3.4.

(2) In this Code, **total plant sterol equivalents content** means the sum of:

- (a) phytosterols; and
- (b) phytostanols; and
- (c) phytosterols and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters.

[1.3] *updating the Table of Provisions to reflect these variations.*

[2] **Standard 1.2.3** of the Australia New Zealand Food Standards Code is varied by *omitting from Column 1 of the Table to clause 2 –*

Foods containing added tall oil phytosterols or added phytosterol esters

*substituting –*

Foods containing added phytosterols, phytostanols or their esters

[3] **Standard 1.2.8** of the Australia New Zealand Food Standards Code is varied by –

[3.1] *omitting the heading to clause 6, substituting –*

### **6 Expression of particular matters in the nutrition information panel**

[3.2] *inserting after subclause 6(4) –*

(5) If a nutrition claim is made about phytosterols, phytostanols or their esters, then the nutrition information panel must include declarations of –

- (a) the substances using the same name as used in the mandatory advisory statement required by clause 2 of Standard 1.2.3; and
- (b) the amount of the substances calculated as total plant sterol equivalents content.

(6) Subclause 1(2) of Standard 1.1.1 does not apply to subclause (5).

[3.3] *updating the Table of Provisions to reflect these variations.*

**[4]** **Standard 1.3.1** of the Australia New Zealand Food Standards Code is varied by omitting from Schedule 1 –

**1.1.3 Liquid milk to which phytosterols or phytosterol esters have been added**

*substituting –*

**1.1.3 Liquid milk to which phytosterols, phytostanols or their esters have been added**

**[5]** **Standard 1.3.4** of the Australia New Zealand Food Standards Code is varied by –

[5.1] *omitting from the Schedule the following specifications –*

Specification for phytosterol esters derived from vegetable oils

Specification for tall oil phytosterols derived from tall oils

[5.2] *inserting in Schedule the following specification –*

#### **Specification for phytosterols, phytostanols and their esters**

(1) Subject to subclauses (2) and (3), phytosterols, phytostanols and their esters must comply with a monograph specification in clause 2 or 3 of this Standard.

(2) However, for a mixture which contains no less than 950 g/kg of phytosterol and phytostanols, the concentration of hexane, isopropanol, ethanol, methanol or methyl ethyl ketone either singly or in combination must be no more than 2 g/kg.

(3) The total plant sterol equivalents content must contain no less than 95% des-methyl sterols.

**[6]** **Standard 1.5.1** of the Australia New Zealand Food Standards Code is varied by –

[6.1] *omitting from the Table to clause 2 the entries for Phytosterol esters and Tall oil phytosterols*

[6.2] *inserting in the Table to clause 2 –*

Phytosterols, phytostanols and their esters	<p>The food must comply with requirements in clause 2 of Standard 1.2.3.</p> <p>May only be added to edible oil spreads –</p> <p>(1) according to Standard 2.4.2; and</p> <p>(2) where the total saturated and trans fatty acids present in the food are no more than 28% of the total fatty acid content of the food.</p> <p>May only be added to breakfast cereals, not including breakfast cereal bars, if –</p> <p>(1) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve;</p> <p>(2) the breakfast cereal contains no more than 30g/100g of total sugars; and</p> <p>(3) the total plant sterol equivalents content is no less than 15 g/kg and no more than 19 g/kg.</p> <p>Foods to which phytosterols, phytostanols or their esters have been added must not be used as ingredients in other foods.</p> <p>May only be added to milk in accordance with Standard 2.5.1.</p> <p>May only be added to yoghurt in accordance with Standard 2.5.3.</p>
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[7] **Standard 2.4.2** of the Australia New Zealand Food Standards Code is varied by omitting paragraphs 2(1)(g) and (h), substituting –

(g) no more than 82 g/kg of total plant sterol equivalents content.

[8] **Standard 2.5.1** of the Australia New Zealand Food Standards Code is varied by –

[8.1] omitting clause 5, substituting –

## 5 Phytosterols, phytostanols and their esters

Phytosterols, phytostanols and their esters may only be added to milk –

- (a) that contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the labelled volume of which is no more than 1 litre; and
- (c) where the total plant sterol equivalents content is no less than 3 g/L of milk and no more than 4 g/L of milk.

[8.2] updating the Table of Provisions to reflect these variations.

[9] **Standard 2.5.3** of the Australia New Zealand Food Standards Code is varied by –

[9.1] omitting clause 4, substituting –

#### **4 Phytosterols, phytosterols and their esters**

Phytosterol, phytosterols and their esters may only be added to yoghurt –

- (a) that contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the capacity of which is no more than 200 g;  
and
- (c) where the total plant sterol equivalents content added is no less than 0.8 g  
and no more than 1.0 g per package.

[9.2] *updating the Table of Provisions to reflect these variations.*

**Draft variations to the *Australia New Zealand Food Standards Code*  
(indicating changes from drafting at Assessment)**

**1. Item [1.2]**

1.1 *At Assessment*

[1.2] *inserting after clause 14 –*

**15 Phytosterols, phytostanols and their esters**

(1) A reference in this Code to phytosterols, phytostanols and their esters is a reference to a substance which meets a specification for phytosterols, phytostanols and in Standard 1.3.4.

(2) In this Code, **total phytosterol content** means the sum of:

- (a) phytosterols; and
- (b) phytostanols; and
- (c) phytosterols and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters.

1.2 *At Approval*

[1.2] *inserting after clause 14 –*

**15 Phytosterols, phytostanols and their esters**

(1) A reference in this Code to phytosterols, phytostanols and their esters is a reference to a substance which meets a specification for phytosterols, phytostanols and their esters in Standard 1.3.4.

(2) In this Code, **total plant sterol equivalents content** means the sum of:

- (a) phytosterols; and
- (b) phytostanols; and
- (c) phytosterols and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters.

**2. Item [3.2]**

2.1 *At Assessment*

[3.2] *inserting after subclause 6(4) –*

(5) If a nutrition claim is made about phytosterols, phytostanols or their esters, then the nutrition information panel must include declarations of –

- (a) the substances using the same name as used in the mandatory advisory statement required by clause 2 of Standard 1.2.3; and
- (b) the amount of the substances calculated as total phytosterol content.

## 2.1 *At Approval*

[3.2] *inserting after subclause 6(4) –*

(5) If a nutrition claim is made about phytosterols, phytostanols or their esters, then the nutrition information panel must include declarations of –

- (a) the substances using the same name as used in the mandatory advisory statement required by clause 2 of Standard 1.2.3; and
- (b) the amount of the substances calculated as total plant sterol equivalents content.

(6) Subclause 1(2) of Standard 1.1.1 does not apply to subclause (5).

## 3. **Item [3.3]**

### 3.1 *At Assessment*

No amendment proposed.

### 3.2 *At Approval*

[3.3] *updating the Table of Provisions to reflect these variations*

## 4. **Item [5.2]**

### 4.1 **At Assessment**

[5.2] *inserting in the Schedule the following specification –*

#### **Specification for phytosterols, phytostanols and their esters**

(1) Phytosterols, phytostanols and their esters must comply with a monograph specification in clause 2 or 3 of this Standard.

(2) However, for a mixture which contains no less than 950 g/kg of phytosterol and phytostanols, the concentration of hexane, 1-propanol, ethanol, methanol or methyl ethyl ketone either singly or in combination must be no more than 5000 mg/kg.

### 4.2 *At Approval*

[5.2] *inserting in the Schedule the following specification –*

#### **Specification for phytosterols, phytostanols and their esters**

(1) Subject to subclauses (2) and (3), phytosterols, phytostanols and their esters must comply with a monograph specification in clause 2 or 3 of this Standard.

(2) However, for a mixture which contains no less than 950 g/kg of phytosterol and phytostanols, the concentration of hexane, isopropanol, ethanol, methanol or methyl ethyl ketone either singly or in combination must be no more than 2 g/kg.

(3) The total plant sterol equivalents content must contain no less than 95% des-methyl sterols.

**5. Item [6.2]**

5.1 *At Assessment*

[6.2] *inserting in the Table to clause 2 –*

Phytosterols, phytostanols and their esters	<p>The requirements in clause 2 of Standard 1.2.3.</p> <p>May only be added to edible oil spreads –</p> <p>(1) according to Standard 2.4.2; and</p> <p>(2) where the total saturated and trans fatty acids present in the food are no more than 28% of the total fatty acid content of the food.</p> <p>May only be added to breakfast cereals, not including breakfast cereal bars, if –</p> <p>(1) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve;</p> <p>(2) the breakfast cereal contains no more than 30g/100g of total sugars; and</p> <p>(3) the total phytosterol content is no less than 16 g/kg and no more than 19 g/kg.</p> <p>Foods to which phytosterols, phytostanols or their esters have been added must not be used as ingredients in other foods.</p> <p>May only be added to milk in accordance with Standard 2.5.1.</p> <p>May only be added to yoghurt in accordance with Standard 2.5.3.</p>
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4.5 *At Approval*

[6.2] *inserting in the Table to clause 2 –*



Phytosterols, phytostanols and their esters	<p>The food must comply with requirements in clause 2 of Standard 1.2.3.</p> <p>May only be added to edible oil spreads –</p> <p>(1) according to Standard 2.4.2; and</p> <p>(2) where the total saturated and trans fatty acids present in the food are no more than 28% of the total fatty acid content of the food.</p> <p>May only be added to breakfast cereals, not including breakfast cereal bars, if –</p> <p>(1) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve;</p> <p>(2) the breakfast cereal contains no more than 30 g/100 g of total sugars; and</p> <p>(3) the total plant sterol equivalents content is no less than 15 g/kg and no more than 19 g/kg.</p> <p>Foods to which phytosterols, phytostanols or their esters have been added must not be used as ingredients in other foods.</p> <p>May only be added to milk in accordance with Standard 2.5.1.</p> <p>May only be added to yoghurt in accordance with Standard 2.5.3.</p>
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## 6. Item [7]

### 6.1 At Assessment

[7] **Standard 2.4.2** of the Australia New Zealand Food Standards Code is varied by omitting paragraphs 2(1)(g) and (h), substituting –

- (g) the total phytosterol content is no more than 82 g/kg.

### 6.2 At Approval

[7] **Standard 2.4.2** of the Australia New Zealand Food Standards Code is varied by omitting paragraphs 2(1)(g) and (h), substituting –

- (g) no more than 82 g/kg of total plant sterol equivalents content.

## 7. Item [9.1]

### 7.1 At Assessment

[9.1] omitting clause 4, substituting –

#### **4 Phytosterols, phytostanols and their esters**

Phytosterol, phytostanols and their esters may only be added to yoghurt –

- (a) such that the yoghurt contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the capacity of which is no more than 200 g; and
- (c) where the total phytosterol ester added is no less than 0.8 g and no more than 1.0 g per package.

7.2 *At Approval*

[9.1] *omitting clause 4, substituting –*

#### **4 Phytosterols, phytostanols and their esters**

Phytosterol, phytostanols and their esters may only be added to yoghurt –

- (a) that contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the capacity of which is no more than 200 g; and
- (c) where the total plant sterol equivalents content added is no less than 0.8 g and no more than 1.0 g per package.

### **8. Commencement**

8.1 *At Assessment*

To commence: on gazettal.

8.2 *At Approval*

To commence: on gazettal, except for Item [3.2] which commences 2 years from the date of gazettal.

**Draft variations to the *Australia New Zealand Food Standards Code*  
(at Assessment)**

*Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting*

[1] **Standard 1.1.1** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *omitting the headings for Division 1 – Interpretation and Application and Division 2 – General Prohibitions.*

[1.2] *inserting after clause 14 –*

**15 Phytosterols, phytostanols and their esters**

(1) A reference in this Code to phytosterols, phytostanols and their esters is a reference to a substance which meets a specification for phytosterols, phytostanols and in Standard 1.3.4.

(2) In this Code, **total phytosterol content** means the sum of:

- (a) phytosterols; and
- (b) phytostanols; and
- (c) phytosterols and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters.

[1.2] *updating the Table of Provisions to reflect these variations.*

[2] **Standard 1.2.3** of the *Australia New Zealand Food Standards Code* is varied by *omitting from Column 1 of the Table to clause 2 –*

Foods containing added tall oil phytosterols or added phytosterol esters

*substituting –*

Foods containing added phytosterols, phytostanols or their esters

[3] **Standard 1.2.8** of the *Australia New Zealand Food Standards Code* is varied by –

[3.1] *omitting the heading to clause 6, substituting –*

**6 Expression of particular matters in the nutrition information panel**

[3.2] *inserting after subclause 6(4) –*

(5) If a nutrition claim is made about phytosterols, phytostanols or their esters, then the nutrition information panel must include declarations of –

- (a) the substances using the same name as used in the mandatory advisory statement required by clause 2 of Standard 1.2.3; and
- (b) the amount of the substances calculated as total phytosterol content.

[4] **Standard 1.3.1** of the Australia New Zealand Food Standards Code is varied by omitting from Schedule 1 –

1.1.3 **Liquid milk to which phytosterols or phytosterol esters have been added**

*substituting –*

1.1.3 **Liquid milk to which phytosterols, phytostanols or their esters have been added**

[5] **Standard 1.3.4** of the Australia New Zealand Food Standards Code is varied by –

[5.1] *omitting from the Schedule the following specifications –*

Specification for phytosterol esters derived from vegetable oils

Specification for tall oil phytosterols derived from tall oils

[5.2] *inserting in Schedule the following specification –*

**Specification for phytosterols, phytostanols and their esters**

(1) Phytosterols, phytostanols and their esters must comply with a monograph specification in clause 2 or 3 of this Standard.

(2) However, for a mixture which contains no less than 950 g/kg of phytosterol and phytostanols, the concentration of hexane, 1-propanol, ethanol, methanol or methyl ethyl ketone either singly or in combination must be no more than 5000 mg/kg.

[6] **Standard 1.5.1** of the Australia New Zealand Food Standards Code is varied by –

[6.1] *omitting from the Table to clause 2 the entries for Phytosterol esters and Tall oil phytosterols*

[6.2] *inserting in the Table to clause 2 –*

Phytosterols, phytostanols and their esters	<p>The requirements in clause 2 of Standard 1.2.3.</p> <p>May only be added to edible oil spreads –</p> <p>(1) according to Standard 2.4.2; and</p> <p>(2) where the total saturated and trans fatty acids present in the food are no more than 28% of the total fatty acid content of the food.</p> <p>May only be added to breakfast cereals, not including breakfast cereal bars, if –</p> <p>(1) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve;</p> <p>(2) the breakfast cereal contains no more than 30g/100g of total sugars; and</p> <p>(3) the total phytosterol content is no less than 16 g/kg and no more than 19 g/kg.</p> <p>Foods to which phytosterols, phytostanols or their esters have been added must not be used as ingredients in other foods.</p> <p>May only be added to milk in accordance with Standard 2.5.1.</p> <p>May only be added to yoghurt in accordance with Standard 2.5.3.</p>
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[7] **Standard 2.4.2** of the Australia New Zealand Food Standards Code is varied by omitting paragraphs 2(1)(g) and (h), substituting –

(g) the total phytosterol content is no more than 82 g/kg.

[8] **Standard 2.5.1** of the Australia New Zealand Food Standards Code is varied by –

[8.1] *omitting clause 5, substituting –*

## 5 **Phytosterols, phytostanols and their esters**

Phytosterols, phytostanols and their esters may only be added to milk –

- (a) that contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the labelled volume of which is no more than 1 litre; and
- (c) where the total phytosterol content is no less than 3 g/L of milk and no more than 4 g/L of milk.

[8.2] *updating the Table of Provisions to reflect these variations.*

[9] **Standard 2.5.3** of the Australia New Zealand Food Standards Code is varied by –

[9.1] *omitting clause 4, substituting –*

#### **4 Phytosterols, phytosterols and their esters**

Phytosterol, phytosterols and their esters may only be added to yoghurt –

- (a) such that the yoghurt contains no more than 1.5 g total fat per 100 g; and
- (b) that is supplied in a package, the capacity of which is no more than 200 g;  
and
- (c) where the total phytosterol ester added is no less than 0.8 g and no more than 1.0 g per package.

[9.2] *updating the Table of Provisions to reflect these variations.*

### Summary of Submissions

Submitter	Comment
Food Technology Association of Australia	<p>Agreed with Option 2 – to amend references and permissions in the Code to reflect equivalence of plant sterols.</p> <p>Are plant sterols still regarded as novel foods or non-traditional foods since they have been part of the Australia/New Zealand diet since first permitted in the Code in June 2001?</p>
FoodLegal for Arboris LLC	<p>Arboris LLC claims to be the largest plant sterol producer in the world, manufacturing primarily ‘tall oil phytosterols’.</p> <p>Supports option 2, the equivalence of plant sterols and stanols and their fatty acid esters.</p> <p>Supports the bioequivalence of ‘phytosterols’ and ‘tall oil phytosterols’ which is consistent with the international situation, as indicated by the JECFA specification for ‘phytosterols, phytostanols and their esters’.</p> <p>Notes that the Code has to date been highly prejudicial against suppliers of ‘tall oil phytosterols’ and for food manufacturers who wish to use ‘tall oil phytosterols’ in their products. It is pleased that this situation will be changed as a result of the Application. That is ‘phytosterols’ and ‘tall oil phytosterols’ (as well as plant stanols) are treated equally in terms of safety and efficacy, regardless of their source.</p> <p>Supports FSANZ’s position on equivalence on the following grounds:</p> <ul style="list-style-type: none"> <li>• It promotes consistency with international food standards.</li> <li>• It will contribute to an efficient and internationally competitive food industry, by allowing more food products containing plant sterols in the Australian and New Zealand market. It will also allow greater choice of plant sterol preparations to food manufacturers.</li> <li>• It will promote fair trade in food by removing the current tight limitations and so opening up the preparation of plant sterols to a wider group of suppliers.</li> </ul>
Kraft Foods Ltd	<p>Supports the Application</p> <p>Supports the work carried out by JECFA and its conclusion of substantial equivalence of all types of phytosterols, phytostanols and their fatty acid esters, no matter from which source. It, therefore, supports the use of the term sterol equivalents and the suggested amendments to the Standards.</p> <p>Supports the more flexible approach of the Application to allow food manufacturers to be able to change their source of plant sterols.</p> <p>Agrees with the Report that the food type will dictate which type of plant sterol is suitable to be added.</p> <p>Applications for approvals of any extra food additives that may be required to assist incorporating some forms of plant sterols in foods should still continue to be considered on a case by case basis.</p>

Submitter	Comment
	<p>Supports the proposed drafting changes in Standard 1.2.8 in relation to the Nutrition Information Panel. The current wording is not clear and therefore is open to misinterpretation. The changes will assist manufacturers, jurisdictions and consumers by ensuring consistency of expression.</p> <p>Pointed out a drafting error on page 30 of the Report relating to Standard 2.5.3 where subclause 4(c) should read 'total phytosterol <u>content</u>' instead of 'total phytosterol <u>ester</u>'.</p>
<p>New Zealand Food Safety Authority</p>	<p>Supports the Application.</p> <p>Comfortable with adding in the JECFA generic specifications for plant sterols in Standard 1.3.4. However, would like to know why the JECFA specification for solvent limits has a maximum of 50 ppm and asks that FSANZ provide an intake calculation to show why a higher limit (as proposed in the drafting) is safe.</p> <p>Does not agree with FSANZ's proposed removal of specific names for plant sterols to be used in the ingredient lists of food from the conditions of use column in the Table to clause 2 of Standard 1.5.1. Believes the current requirements are explicit while what is being proposed does not give this certainty and there could be inconsistent interpretations over names of the plant sterols added.</p> <p>Agrees that the current mandatory advisory statements should be maintained.</p> <p>Suggests that the term 'plant sterol equivalents' be defined in the Code so that the correct active components are used in calculations (i.e. consistency between the advisory statement and NIP) but the term 'plant sterols' is prescribed to be used on the labels for the advisory statement and NIP.</p> <p>More information is required on analytical methods as a cost to enforcement agencies as the method referred in the report to the JECFA 2008 specifications is not necessarily suitable for analysing for plant sterols in various foods.</p> <p>A number of suggested amendments to the drafting are proposed for Standards 1.1.1, 1.2.8, 1.3.1, 2.4.2 and 2.5.3.</p>
<p>Australian Food and Grocery Council</p>	<p>Supports the Application.</p> <p>Contains a recently sourced reference providing more evidence that reduced cholesterol levels have a positive health benefit. This research article relates to decreased risk of men having prostate cancer linked to their lower levels of cholesterol.</p> <p>Believes there is an overwhelming public health benefit for adults, particularly older age groups, in being able to access a greater variety of food products containing added plant sterols in order to reduce their cholesterol absorption.</p>



Submitter	Comment
Cognis Australia Pty Ltd	<p>Supportive of the Application.</p> <p>Does not support the proposed limits for solvents of 1000 ppm, which it states is extraordinarily high. Believes, in the interests of public health and safety, that the solvent limit should be harmonised with the European Solvent Directive (Directive 2009/32/EC, link provided to this Directive in the submission), or at least to a maximum of 50 ppm. [The limit proposed in the Assessment Report for some types of plant sterols is actually 5000 ppm].</p> <p>Supportive of the idea of 'phytosterol equivalents', which will help consumers calculate an effective daily dose from all sources.</p>
Raisio Nutrition Ltd (the Applicant)	<p>Supports the preferred approach of FSANZ, with the provisos as summarised below.</p> <p>Concern about inconsistent use of terminology in the Report, in particular refers to use of the term 'plant sterol equivalents' and 'total phytosterol content'. Suggests using the clearer and more useful term 'plant sterol equivalents' rather than 'total phytosterol content'.</p> <p>Seeks clarity over what terms can be used to specify the plant sterol type for labelling and other consumer communication. Suggests adopting the terminology as written in the Table on page 5 of the Risk Assessment Report (it is assumed for this purpose).</p> <p>Supports the solvent limit of 50 ppm as in the JECFA specification. However, is aware that some plant sterol products currently on the market are unable to comply with this limit but believes these products can comply with 1000 ppm, so it endorses FSANZ's suggestion to set the limit at 1000 ppm.</p> <p>Endorses the suggestion that the manufacturing source of the plant sterol is not helpful to the consumer so should not need be declared in ingredient lists.</p> <p>Agrees that plant sterol equivalents should be used for determining the amounts listed in the NIP as that is the relevant information consumers will look for to work out their daily intake of plant sterols. The ingredient listing can contain the precise information on the type of plant sterol used.</p> <p>Is deeply concerned about the implication of section 6.6 in the Report dealing with the impact of assessing two concurrent plant sterol Applications (A1019 and this Application). Wishes FSANZ to reconsider the statement that a new Application is required to extend the plant sterol category for A1019 (reduced fat cheese) to the general category of phytosterols, phytostanols and their esters once the period of exclusivity expires, if the permission is granted. This is behind the current Application; to establish equivalence of function and safety of all forms of plant sterols. The submission urges FSANZ to have some proviso or internal process so that after the exclusive period expires the permission would automatically be updated to ensure generic permission is granted to this food category.</p> <p>A number of proposed drafting changes:</p> <ul style="list-style-type: none"> <li>• Replace the term 'total phytosterol content' with 'total plant sterol equivalent content' within the new drafting.</li> </ul>

Submitter	Comment
	<ul style="list-style-type: none"> <li>• Standard 1.3.4; for the solvent limit, replace 5000 ppm with 1000 ppm.</li> <li>• Standard 1.5.1, entry (3) replaced with (3) the total plant sterol equivalent content is not less than 15.6 g/kg and no more than 19.2 g/kg.</li> </ul>
Unilever Australasia	<p>Supports the Application</p> <p>Supports the review and comparison of the plant sterol specifications.</p> <p>Supports the removal of the current specifications for phytosterols derived from vegetable oils and tall oil phytosterol esters.</p> <p>The proposed limit for solvent concentration in plant sterol mixtures (<math>\geq 95\%</math> unesterified phytosterols and phytostanols) can be reduced to 1000 ppm.</p> <p>Requests that isopropanol be added as a solvent to this list as it is currently used during the manufacture of plant sterols by suppliers.</p> <p>However, expresses some concern about the ramifications of adopting the JECFA 2008 specifications for 'phytosterols, phytostanols and their esters' (monograph 5). In particular is concerned that the specification is very broad and is not limited to only the major phytosterols and phytostanols.</p> <p>To that end proposes that FSANZ institute further conditions to clarify the intent of the JECFA specifications so that only plant sterols that have a scientifically substantiated cholesterol lowering effect be permitted.</p> <p>The extra conditions proposed are:</p> <ol style="list-style-type: none"> <li>1. Sterol [or stanol] esters are only fatty acid esters; and</li> <li>2. Specify the allowed sterol profile for sterol mixes be <math>&gt;95\%</math> des-methyl sterols (on sterol basis).</li> </ol>
Population Health Queensland	<p>Neither accepts nor rejects the Application, but intends to review its position at the next stage of consideration.</p> <p>Notes FSANZ's risk assessment summary that 'all forms of plant sterols are equally safe for human consumption' and 'that amendments do not raise any additional nutritional safety concerns'.</p> <p>Requests FSANZ to review the legibility and position of the required advisory statements on products containing added plant sterols (similar to submission to Application A1019).</p> <p>Seeks more useful analytical methods for determining the concentration of plant sterols in food matrices. Notes that the discussion provided in the Assessment Report (being analytical methods available in the JECFA and Food Chemicals Codex specifications) are for assaying the purity of the plant sterol preparations themselves, which may not be suitable for accurately analysing for them when incorporated in foods.</p> <p>Requires more information as to what costs were determined to be increased for enforcement agencies from approving this Application and how these costs were determined.</p>

<b>Submitter</b>	<b>Comment</b>
Dietitians Association of Australia	<p>Supports the Application</p> <p>Supportive of FSANZ's preferred approach.</p> <p>Provided an internet reference link (National Heart Foundation of Australia: Summary of evidence on phytosterol/stanol enriched foods. May 2009) to the Heart Foundation's findings that indicate that efficacy, safety, technical usage of the stanols and sterols appeared to be equivalent.</p> <p>Notes FSANZ is concurrently assessing another plant sterol Application, A1019. Requests FSANZ consider widening the food category usage (approval of generic group of plant sterols) and so carry through the generic thinking of A1024, into A1019 (once the exclusivity period finishes). Does not support FSANZ's statement in the Report that a new Application would be required as that defeats the overall purpose and apparent scientific assessment of the equivalence of plant sterols.</p>
National Heart Foundation of Australia	<p>Supports the Application</p> <p>Has reviewed the evidence and concludes that the findings from the scientific literature indicate that efficacy, safety, technical usage of the stanols and sterols appeared to be equivalent. Supplied two of its documents supporting this conclusion: 'Position statement on phytosterol/stanol enriched foods' and 'Summary of evidence on phytosterol/stanol enriched foods (January 2007)'.</p> <p>The summary of the conclusions and the level of evidence provided are supportive of FSANZ's conclusions.</p> <p>A similar response to that of the Dietitians Association of Australia in relation to considering broadening the plant sterol permissions for reduced fat cheese products (A1019) once the exclusivity period finishes. Also believes that a new Application would not need to be submitted as stated in the Report. States that not considering broadening the plant sterol permissions would defeat the overall purpose and scientific assessment of the equivalence of the various forms of plant sterols.</p> <p>Provided an internet reference link to their document (National Heart Foundation of Australia: Summary of evidence on phytosterol/stanol enriched foods. May 2009).</p>
Forbes Medi-Tech Inc	<p>Supports the Application</p> <p>Supportive of having a generic specification.</p> <p>Requests FSANZ consider a maximum level of 2000 ppm for solvents as a lower figure would not allow the manufacture or approval of their phytosterols derived from tall oils.</p> <p>Like the request from Unilever also requests isopropanol (2-propanol) be approved as a solvent. Uses isopropanol, methyl ethyl ketone and methanol as solvents during manufacture of their phytosterols derived from tall oil (hexane and acetone are no longer used).</p> <p>Plant sterol ester manufacturers use steam stripping to remove free fatty acids during their production which removes all solvents for their products so such producers can meet the 50 ppm solvent limit.</p>

<b>Submitter</b>	<b>Comment</b>
	<p data-bbox="528 232 1430 320">Approving the Application would be advantageous as it would allow phytosterols derived from tall oils to be added to breakfast cereals and low-fat yoghurt. This could provide a greater choice of products to consumers.</p> <p data-bbox="528 353 1417 441">Believes that it is most unlikely that the dietary intake of plant sterols for populations or individuals would be significantly changed as a result of this Application.</p> <p data-bbox="528 474 1398 562">Acceptance of the Application would bring Australia and New Zealand regulatory approaches to plant sterols more in line with their regulation in other countries, particularly in Europe.</p> <p data-bbox="528 595 1385 683">Most plant sterol mixtures can be incorporated into currently approved foods and that existing measures are likely to ensure only suitable plant sterols are added to food.</p>