



# **APPLICATION A1024 EQUIVALENCE OF PLANT STANOLS, STEROLS & THEIR FATTY ACID ESTERS ASSESSMENT REPORT**

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## **Executive Summary**

### **Purpose**

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 and New Zealand Food Standard 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 be permitted to be added to the four foods that currently are permitted in the Code to have specific forms of plant sterols added. 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 make the specific permissions for plant sterols more generic permissions.

The Applicant requested FSANZ to 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.

The current permissions for plant sterols set out in Standard 1.5.1 of the Code specify the specific compositional mixture and source permitted. Specific types of plant sterols may be added to each of the four allowable food vehicles; low-fat milk, 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. These specific permissions and specifications have been developed over time in response to previous FSANZ Applications that sought permissions for specific plant sterols to be added to specific foods.

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 – Novel Foods, 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 requires other consequential changes to the Code. There are no non-regulatory options available for this Application.

The Application is being assessed under the General Procedure.

## **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 allowable food vehicles.

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 evidence supports the safety of plant sterols at present levels of consumption irrespective of the proportion 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 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 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. Such a change in the market is unlikely to reduce the current price premium for these products or modify purchasing behaviour or product understanding. Therefore, existing estimates of dietary intake are not expected to change. 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 allowable 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 allowable 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.

## Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, 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 measure.
- 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.

### Preferred Approach

**To prepare 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 prepare 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 Approach

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 current specifications 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.

## Consultation

Public submissions are now invited on this Assessment Report. Comments are specifically requested on the scientific aspects of this Application, in particular, information relevant to the safety and nutritional assessment of equivalence of different forms of plant sterols, and the regulatory impact the proposed amendments would have on industry and enforcement agencies, if approved.

As this Application is being assessed as a General Procedure, there will be one round of public comment. Responses to this Assessment Report will be used to develop the Approval Report for the Application.

## Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au). There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 11 November 2009**

**SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED**

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand  
PO Box 7186  
Canberra BC ACT 2610  
AUSTRALIA  
Tel (02) 6271 2222**

**Food Standards Australia New Zealand  
PO Box 10559  
The Terrace WELLINGTON 6036  
NEW ZEALAND  
Tel (04) 473 9942**

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## **SUPPORTING DOCUMENTS**

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

<http://www.foodstandards.gov.au/standardsdevelopment/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 and New Zealand Food Standard 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 consequential effect 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
- amend the current permissions for the four foods permitted to contain plant sterols to reflect this generic specification
- express the units given for the compositional limits for addition to the four food vehicles as phytosterol equivalents (calculated by using the free phytosterol content (60%) of phytosterol esters<sup>2</sup>).

The Code (Standard 1.3.4 – Identity and Purity) was updated to reference the amended 2008 JECFA specifications as part of FSANZ Proposal P1008. 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.

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.

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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 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.

## 1. The Issue / Problem

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 allowable 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 JECFA specification in each of the allowable food vehicles needs to be established.

## 2. Current Standards and Phytosterol 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.

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 equivalent to 2.2 g of phytosterols. This is 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/serve	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>3</sup>.

The Applicant's suggested new permitted minimum and maximum levels calculated and expressed as free plant sterol equivalents are shown in Table 2. 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). 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) (see further explanation in section 6.5.3).

Section 2.2 and Figures 3 and 4 of SD1 discuss and show the chemical structures of some plant sterols and their esters.

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<sub>28</sub>H<sub>48</sub>O            MW 400.68  
 Campesteryl oleate:    C<sub>46</sub>H<sub>80</sub>O<sub>2</sub>            MW 665.14

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

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<sup>3</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.

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

**Table 2: Requested amended permissions, as plant sterol equivalents**

<b>Food matrix</b>	<b>Phytosterol esters (from vegetable oils)</b>	<b>Tall oil phytosterols</b>	<b>Suggested plant sterol equivalents</b>
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/serve	Not permitted	0.8-1.0 g/serve

## 2.2 Other Standards relevant to plant sterol permissions

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

The relevant references to plant sterols in the extracts of Standards below would need to be amended if this Application is successful 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.

#### *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	Sodium alginate	2 g/kg	
407	Carrageenan	2 g/kg	
412	Guar gum	2 g/kg	
471	Mono- and diglycerides of fatty acids	2 g/kg	
460	Microcrystalline cellulose	5 g/kg	

### 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, phytostanols and their esters' 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 the substance 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 Reduced-Fat Cheese is an Application from Kraft Foods which seeks to approve the exclusive use of tall oil phytosterol fatty acid esters in reduced 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 reduced fat cheese for a period of 15 months. The Application is at the Assessment 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>4</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, phytosterols 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 product users.

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 occur.

## **4. Questions to be answered**

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

1. Are plant sterols (conforming to the JECFA specifications) safe for human consumption at the levels of use currently specified in the Code?

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<sup>4</sup>[http://www.health.gov.au/internet/main/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/\\$File/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20Policy%20Guideline.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/2087CDEAEE7C703CCA256F190003AF4B/$File/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20Policy%20Guideline.pdf)

2. Are any nutritional safety concerns raised by consolidating the specifications in the Code into one generic specification?
3. Do the chemical properties of phytosterols, phytostanols and their esters (conforming to the JECFA specifications) make them technologically suitable for addition to all four approved foods?
4. Do plant sterols (conforming to the 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 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 Australian 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. Public comment on these two questions is specifically sought during the consultation period.

## **RISK ASSESSMENT**

### **5. Risk Assessment Summary**

The key findings from the risk assessment are summarised below under the questions they have addressed. The reference to plant sterols in the questions below means those plant sterols that meet the 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?**

Early evidence suggested that consumption of foods with added plant sterols reduced carotenoid uptake. However, 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.

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 meet the JECFA 2008 specifications are suitable for incorporation 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 uniform distribution but there is a range of technical solutions to this issue 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?**

FSANZ concludes that plant sterols that conform to the JECFA specifications do 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 and purchasing behaviour differ according to type of plant sterol?**

Broadening the specification and the associated permissions to include a wider variety of plant sterol preparations in already approved foods is predicted to not change dietary intake. 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, and a change 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. It is unlikely that this would lead to any substantial reduction in the price premium for plant sterol-fortified foods, or translate into increase purchasing or consumption of these products (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).



## **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, and seeks comment on, the preferred approach to these matters, the consequential proposed 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 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 JECFA specification would permit the addition of a broader range of plant sterol mixtures to be added to the current allowable 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>5</sup> which can be added to each of the four allowable 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.

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.

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<sup>5</sup> A maximum level only of phytosterols esters and tall oil phytosterols is set out for edible oil spreads in the Code.

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 will 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.

### **6.4 Policy Guideline**

As noted in Section 3 FSANZ is required to 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 foods 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 allowable 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 proposed drafting amendments to the Code are at Attachment 1. This section discusses issues relevant to the drafting amendments and seeks comment on the impact of these changes on affected parties.

### 6.5.1 Specification amendments

FSANZ proposes to remove 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 3 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>6</sup> in the Schedule to Standard 1.3.4 (see Table 3). Information provided to FSANZ from a company that manufactures products to these specifications indicated that its current formulation would not meet the solvent specification for plant sterols set by JECFA. It requested that FSANZ consider an upper limit of 1000 ppm for solvents for these plant sterol mixtures. The requested limit (1000 ppm) is tighter than the current solvent specification for tall oil phytosterols (5000 ppm). Therefore FSANZ considers it unlikely that the requested limit poses a health and safety risk. FSANZ has not amended the current solvent limit of 5000 ppm, for free phytosterol or phytostanol products (>95%) that is currently in the Code in the proposed draft amendments. We seek comment during the consultation period on whether this solvent limit is required, and for which type of plant sterol products, or if the limit can be reduced to 1000 ppm.

FSANZ needs 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 proposed drafting will refer to hexane, 1-propanol, ethanol, methanol, and methyl ethyl ketone<sup>7</sup>, either singly or in combination.

**Table 3: Comparison of Specifications**

<b>Phytosterol Content (%)</b>	<b>A1024 JECFA Monograph 5<sup>1</sup></b>	<b>Food Chemicals Codex 6<sup>th</sup> Edn (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		59 min		
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

<sup>6</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>7</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.

<b>Phytosterol Content (%)</b>	<b>A1024 JECFA Monograph 5<sup>1</sup></b>	<b>Food Chemicals Codex 6<sup>th</sup> Edn (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>
Brassicasterol		12 max	6 max	3
Stigmasterol			12-23	
$\Delta^5$ -Avensterol		6 max	4 max	
$\Delta^7$ -Stigmastenol			2 max	
$\Delta^7$ -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)	50 max			5000 max
Residue on ignition (%)	0.1 max			0.1 max
Acidity (g KOH/kg)		0.2 max		
<b>Heavy Metals (total, ppm)</b>				2 max
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 of the Code

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 proposes, 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) 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 has a concentration of no less than 950 g/kg of phytosterol and phytostanol concentration, 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.

### Questions for submitters

FSANZ requests interested stakeholders, in particular plant sterol manufacturers and suppliers to the food industry, to supply information and justifications to their answers to the questions below, particularly if the proposed drafting would detrimentally affect their products.

- Would removing the specifications for ‘tall oil phytosterols’ and ‘phytosterol esters derived from vegetable oils’ from the Schedule to Standard 1.3.4, and thereby requiring the use of the specifications in the alternate primary references, negatively impact on current plant sterol manufacturers and food manufacturers who add plant sterols to their products?
- Is the proposed permission for a solvent concentration of 5000 ppm in plant sterol mixtures ( $\geq 95\%$  unesterified phytosterols and phytostanols) required, or can this limit be reduced to 1000 ppm?
- Are the solvents as listed in the JECFA 2008 specification (hexane, 1-propanol, ethanol or methanol) and methyl ethyl ketone, either singly or in combination, sufficient to cover all types of plant sterol manufacture?

#### 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 suggested sentence to be added to Standard 1.1.1 is:

*A reference 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 allowable 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 1.

Plant sterol mixtures are a blend of individual compounds which have different molecular weights. Given the range of possible mixtures, it is extremely difficult to determine an exact ratio of the unesterified/esterified plant sterols which can be applied generically to all permissions. Therefore, a conversion factor of 60% has been applied to the original compositional limits to determine their plant sterol equivalence, as suggested in the Application, and discussed in section 2.1. The resulting figure has been rounded to a whole number since the conversion factor is an estimate<sup>8</sup>. The original and amended limits are found in Table 4.

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<sup>8</sup> Rounding to 0.1g/serve has been retained for yoghurts as the compositional limits are set out per serve (package) rather than per kg or per litre.

**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>9</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	16-19 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/serve	Not permitted	0.8-1.0 g/serve	0.8-1.0g/serve

Section 2.2 and Figures 3 and 4 of SD1 discusses and shows the chemical structures of some plant sterols and their esters.

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

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

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.

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 has been considered below.

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<sup>9</sup> Based on a 60% conversion factor.

#### 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 preventing misleading or deceptive conduct. It is therefore proposed to remove the specific requirement in Standard 1.5.1 relating to the declaration of the plant sterol mixture in the ingredient list. 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, we do not predict any significant impacts from this amendment.

#### 6.5.4.2 Mandatory Advisory Statements

The Table to clause 2 in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, 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 Assessment 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 2.1, 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 above 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, it is proposed to amend Standard 1.2.8 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 proposed drafting is contained in Attachment 1.

The stock-in-trade provisions (twelve months) in Standard 1.1.1 will apply with respect to any labelling changes resulting from this proposed amendment. FSANZ needs to know if this proposed requirement would necessitate labelling changes for current products on the market.

FSANZ welcomes comment on this proposed amendment, including any potential impacts for manufacturers of plant sterol products and for enforcement agencies.

## **6.6 Impact on current Applications**

As noted in Section 2.3 of this Report, Application A1019 seeks to use phytosterol esters sourced from tall oils in cheese (<9 g fat/100 g cheese). Application A1024 will not directly affect the progress of Application A1019. Should both Applications be approved, and after the exclusive use period has ended, a specific permission for the use of tall oil phytosterols esters in reduced fat cheese would sit alongside a generic permission for the use of plant sterols in the other permitted foods. An Application would be required to make the specific permission a generic one. This is since the current Application A1024 cannot make an assessment of the other various types of plant sterols and low fat cheese since the two Applications are progressing at the same time and FSANZ cannot know in advance if they may both be successful or whether there may be delays in progressing either. In future it may be straight forward to establish equivalence (of function and safety) of all plant sterols in low fat cheese based on the evaluation with low fat milk and yoghurts, but that may need to be further explored if the extension was requested.

## **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, phytostanol 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 allowable 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 is currently considering 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 JECFA 2008 specifications.

## 8. Impact Analysis

### 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 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) is 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 both 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

Consumers would not see any change if the *status quo* was retained. There would be no benefit. Consumers may be disadvantaged as they would not see any new competitive food products with alternative sources of plant sterols to those that are already permitted and commercially available.

### 8.2.1.3 Government

There are no added costs for enforcement agencies of this option. However, there is the lack of any added benefit to the broad community and therefore government if this option of the *status quo* is accepted. This is since the risk analysis concluded that other forms of plant sterol preparations are also efficacious at reducing LDL-cholesterol and so have a probable public health benefit. More products containing plant sterols potentially means 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 of this option for consumers. The option potentially could increase the choice and range of commercial products that contain plant sterols available in the market place. However, permissions still relate to the same food categories that currently exist in the Code, and the levels of plant sterols that are permitted have not been changed. Changes to the types of plant sterols that may be added should provide competition 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 2008 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 enriched products for other 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>10</sup>; SCF, 2002<sup>11</sup>). Therefore, there are no public health and safety concerns from increased exposure, availability or consumption of phytosterols.

### 8.2.2.3 Government

This option will have impacts on regulatory agencies that enforce the permissions in the Code, since there is likely to be more commercial products on the market that contain different forms of plant sterols. However, the methods of analysis required to analyse for these different forms are not believed to be any different to the current ones needed to analyse for the currently permitted forms of plant sterols in the Code. The 2008 JECFA specifications (as well as the Food Chemical Codex specification) for plant sterols contain quite detailed analytical methods appropriate for analysing and determining the compliance with the regulatory permissions of this option. Therefore, there are not expected to be significant costs or implementation issues associated with this option.

An added impact for Government agencies is the potential population health benefits 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*.

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<sup>10</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>11</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).

FSANZ invites comment on the impact analysis.

Are there any unexpected impacts on current plant sterol manufacturers or manufacturers of foods containing plant sterols that meet the current Code permissions if this Application is successful?

Are there likely to be impacts on a successful outcome of this Application on enforcement agencies?

## **COMMUNICATION AND CONSULTATION STRATEGY**

### **9. Communication**

FSANZ may undertake targeted consultation and communications with specific interested stakeholders who have views on the regulation of plant sterols permissions for the food supply. In particular FSANZ needs to consider whether any amendments made as part of the consideration of this Application have any 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.

### **10. Consultation**

#### **10.1 Public Consultation**

FSANZ is aware that this Application is of particular interest to the plant sterol industry and manufacturers of plant sterol products in Australia and New Zealand, and may be of interest to enforcement agencies and public health agencies. FSANZ is currently unaware of any interest expressed by consumers in relation to this Application.

FSANZ seeks further input from all affected parties to assist it in assessing the likely regulatory impact of this Application. It is particularly interested in receiving further information on the questions asked throughout this Report and in relation to the following issues:

- the proposed approach to ensure the technical suitability of the plant sterol mixtures added to allowable foods
- scientific aspects of the Application
- whether the proposed drafting amendments are suitable for use by industry and enforcement agencies
- whether there are any detrimental and unintended consequences of removing the two current plant sterol specifications in the Schedule to Standard 1.3.4
- views on the new solvent limit proposed for some types of plant sterols, to be added into the Schedule of Standard 1.3.4
- whether there are any concerns with removing the specific labelling statements in the Table to clause 2 of Standard 1.5.1 and the proposed changes to Standard 1.2.8.

FSANZ also welcomes comments from any other interested parties. Comments made by submitters during the consultation period will be reviewed and reported in the Approval Report.

## **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 will not be 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 Preferred Option**

#### **Preferred Approach**

**To prepare 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 prepare 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 Approach**

FSANZ recommends the preferred approach 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 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**

Following the consultation period for this document, an Approval Report will be completed and the draft variations will be considered for approval by the FSANZ Board. The FSANZ Board's decision will then 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**

1. Draft variations to the *Australia New Zealand Food Standards Code*

### Draft variations to the *Australia New Zealand Food Standards Code*

*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, phytosterols and their esters**

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

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

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