

**13 December 2016**  
**[31–16]**

## **Call for submissions – Application A1134**

### **Increased Concentration of Plant Sterols in Breakfast Cereals**

---

FSANZ has assessed an Application made by Sanitarium Health and Wellbeing Australia to seek approval for the exclusive use for 15 months of an increased concentration of plant sterols to be added to breakfast cereals under the novel food provisions and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly 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 via the link on [documents for public comment](#). You can also email your submission directly to [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 via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 24 January 2017**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand  
PO Box 5423  
KINGSTON ACT 2604  
AUSTRALIA  
Tel +61 2 6271 2222

Food Standards Australia New Zealand  
PO Box 10559  
The Terrace WELLINGTON 6143  
NEW ZEALAND  
Tel +64 4 978 5630

## Table of contents

<b>EXECUTIVE SUMMARY</b> .....	<b>2</b>
<b>1 INTRODUCTION</b> .....	<b>4</b>
1.1 THE APPLICANT .....	4
1.2 THE APPLICATION .....	4
1.3 THE CURRENT STANDARD .....	4
1.4 REASONS FOR ACCEPTING APPLICATION .....	5
1.5 PROCEDURE FOR ASSESSMENT .....	5
<b>2 SUMMARY OF THE ASSESSMENT</b> .....	<b>6</b>
2.1 RISK ASSESSMENT .....	6
2.2 RISK MANAGEMENT .....	7
2.2.1 <i>Basis for units for expressing concentration permitted (g/kg or g/serving)</i> .....	7
2.2.2 <i>Concentration of added plant sterols</i> .....	8
2.2.3 <i>Food vehicle – breakfast cereals</i> .....	9
2.2.4 <i>Labelling relating to foods containing added plant sterols</i> .....	10
2.2.5 <i>Exclusivity</i> .....	11
2.2.6 <i>Risk management conclusion</i> .....	12
2.3 RISK COMMUNICATION.....	12
2.3.1 <i>Consultation</i> .....	12
2.3.2 <i>World Trade Organization (WTO)</i> .....	13
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS .....	13
2.4.1 <i>Section 29</i> .....	13
2.4.2 <i>Subsection 18(1)</i> .....	13
2.4.3 <i>Subsection 18(2) considerations</i> .....	14
<b>3 DRAFT VARIATION</b> .....	<b>15</b>
3.1 TRANSITIONAL ARRANGEMENTS .....	15
<b>4 REFERENCES</b> .....	<b>16</b>
ATTACHMENT A – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	17
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT .....	19

### Supporting documents

The [following documents](#)<sup>1</sup>, which informed the assessment of this Application, are available on the FSANZ website:

- SD1 Risk assessment
- SD2 Assessment against the Forum Policy Guidelines

---

<sup>1</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1134.aspx>

## Executive summary

FSANZ has assessed an application from Sanitarium Health and Wellbeing Australia that seeks to amend current novel food permissions to allow increased concentrations of plant sterols in 'portion-controlled' breakfast cereals, where 'portion-controlled' refers to either individually wrapped portions or portions that can be easily divided. The Applicant states that the requested amendment would allow for a more convenient and cost effective delivery of the efficacious dose of phytosterols in breakfast cereals. The Applicant has requested exclusive use of the permission for a period of 15 months after gazettal.

Phytosterols, phytostanols and their esters, are collectively termed plant sterols for the purpose of this report, while the term total plant sterol equivalents specifically encompasses phytosterols and phytostanols (i.e. free form) as well as the hydrolysis products of their esters. These naturally occurring steroidal compounds are structurally similar to cholesterol. The usual dietary sources of plant sterols include vegetable oils, nuts, and certain vegetables. Commercial plant sterol mixtures consist predominantly of the compounds:  $\beta$ -sitosterol, sitostanol, campesterol and campestanol. Plant sterols are currently permitted to be added to specified foods as a novel food in the *Australia New Zealand Food Standards Code* (the Code), including to breakfast cereals (meeting specified nutrient criteria, and excluding breakfast cereal bars) where if added, they must be at a minimum of 15 g/kg and a maximum of 19 g/kg.

FSANZ has no toxicological concerns regarding the addition of plant sterols to breakfast cereals up to the concentrations proposed in the Application, for consumption by the general population. A review of the recent literature has not identified evidence to alter the conclusion reached previously by FSANZ, that a specified ADI is not justified for plant sterols for the general population. Patients with the rare inherited disorder of phytosterolaemia (sitosterolaemia), have increased absorption and decreased excretion of plant sterols however, the specific risk to this small congenitally susceptible subpopulation can be addressed by appropriate risk management measures. People with this condition are advised to avoid foods containing plant sterols. Plant sterols are required to be declared in the ingredient list, thereby enabling their identification.

Consumption of total plant sterol equivalents between 0.8 g and 2 g per day has been shown to reduce total and low density lipoprotein (LDL) blood cholesterol concentrations without adversely affecting high density lipoprotein (HDL) cholesterol concentration. Dose-response models reliably predicted that a daily dietary exposure to 2 g of total plant sterol equivalents per day reduces LDL blood cholesterol concentrations by 9%, with a maximum effect of 12.7% reached by 3 g per day. Some dietary intervention studies using plant sterols show a reduction in blood concentration of provitamin A carotenoids, which is not unexpected. However, it is noted the blood concentrations of carotenoids of subjects consuming plant sterols remain within the broad natural range of variation and vitamin A concentrations are not affected. The clinical evidence indicates that consumption of 5.4-6 g per day of total plant sterol equivalents is unlikely to pose a nutritional safety concern for children and adults.

After assessing the Application, FSANZ has prepared a draft variation to the Code which permits the addition of plant sterols to breakfast cereals at no less than 0.5 g and no more than 2.2 g total plant sterol equivalents per serving of breakfast cereal. FSANZ has not identified sufficient reason to limit the scope of breakfast cereals permitted to be fortified at the higher concentration to 'portion-controlled' breakfast cereals only, and recommends that the higher concentration is permitted for all breakfast cereals meeting existing nutrient criteria.

This permission would apply exclusively to the 'Sanitarium Health and Wellbeing' and 'Weet-Bix' brands only, for an exclusive use period of 15 months commencing on the date of gazettal of the variation, as requested by the Applicant. The exclusive use permission would revert to a general permission after the exclusive use period expires, replacing the existing concentrations applying to breakfast cereals. However, Standard 1.5.1 does not and cannot prevent approval of second or subsequent applications within that exclusive use period for the use of the same novel food (or containing the approved ingredient) by other food companies, providing the application process is undertaken. This variation does not change this.

# 1 Introduction

## 1.1 The Applicant

The Applicant is the food manufacturing company Sanitarium Health and Wellbeing<sup>2</sup>, Berkely Vale, New South Wales, Australia.

## 1.2 The Application

The Application seeks to amend current novel food permissions for phytosterols, phytostanols and their esters (referred to as plant sterols in this report) added to breakfast cereals. This is to add a new regulatory measure to allow increased concentrations of plant sterols of a minimum of 0.8 g and a maximum of 2 g per serving, in portion-controlled breakfast cereals only. The Applicant refers to 'portion-controlled' as either individually wrapped portions or portions that can be easily divided.

The Applicant has requested exclusive use of the permission for a period of 15 months after gazettal.

The Applicant states that the primary purpose of the Application is to increase the accessibility of phytosterols<sup>3</sup> through breakfast cereals. It is noted that the amendment would allow for a more convenient and cost effective delivery of the effective dose of phytosterols in breakfast cereals. The Application also notes that the proposed amendment would:

- allow consumers to more easily monitor a daily intake of phytosterols
- improve access and provide more choices for consumers on the type and amount of product they purchase to obtain the health benefits associated with phytosterols.

## 1.3 The current Standard

Plant sterols are currently permitted to be added to specified foods as a novel food in the *Australia New Zealand Food Standards Code* (the Code).

Novel foods are prohibited from being sold as a food offered for retail sale or as an ingredient or component in a food offered for retail sale unless expressly permitted by the Code (section 1.1.1—10 of Standard 1.1.1 – Structure of the Code and general provisions).

However, section 1.5.1—3 of Standard 1.5.1 – Novel foods, permits a food offered for retail sale to consist of, or have as an ingredient, a novel food that:

- is listed in the table to section S25—2 of Schedule 25 – Permitted novel foods; and
- complies with any conditions of use specified in the corresponding row of the table.

Permitted novel foods are listed in the table to section S25—2 of Schedule 25. Schedule 25 currently allows for the addition of *total plant sterol equivalents content*<sup>4</sup> of no less than 15 g per kg and no more than 19 g per kg to breakfast cereals (not including breakfast cereal bars).

---

<sup>2</sup> Information about the Applicant can be found on their website at [www.sanitarium.com.au](http://www.sanitarium.com.au)

<sup>3</sup> term used in the Application

<sup>4</sup> *Total plant sterol equivalents content* is defined in Standard 1.1.2 – Definitions used throughout the Code as the total amount of:

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

The breakfast cereal must contain no less than 3 g of fibre per 50 g and no more than 30 g of total sugars per 100 g (specified nutrient criteria). Foods to which plant sterols have been added must not be used as ingredients in other foods.

In addition, under section S25—2, the permitted novel food must comply with requirements in Standard 1.2.1 insofar as they relate to section 1.2.3—2 of Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations. Advisory statements are required on foods for retail sale and foods for catering purposes that contain added plant sterols (section 1.2.3—2 and Schedule 9 – Mandatory advisory statements). The advisory statements must indicate that:

- (a) when consuming the product, it should be consumed as part of a healthy diet; and
- (b) the product may not be suitable for children under 5 years and pregnant or lactating women; and
- (c) plant sterols do not provide additional benefits when consumed in excess of 3 grams per day.

If the food for retail sale is exempt from the requirement to bear a label, this information must be displayed in connection with the display of the food or provided to the purchaser upon request.

Permission to use phytosterol esters derived from vegetable oils as a novel food ingredient in Australia and New Zealand first came into effect on 14 June 2001. This permission was limited to edible oil spreads. Plant sterols are now permitted to be added to certain edible oil spreads, and certain breakfast cereals<sup>5</sup>, milk<sup>6</sup> and yoghurt<sup>7</sup>. Specific source-based permissions for phytosterol esters and tall oil phytosterols were amended in 2008 into a single generic permission for phytosterols, phytostanols and their esters, for the four food vehicles to which specified plant sterols could then be added<sup>8</sup>. Tall oil phytosterol esters are permitted in cheese and processed cheese<sup>9</sup> (subject to conditions on fat content)<sup>10</sup>.

FSANZ notes that although the continuing novelty of plant sterols is debatable, assessment of plant sterols within the novel foods framework is protective of public health and safety. By taking a case-by-case approach, FSANZ can consider dietary exposures and facilitate a cautious expansion of the use of these ingredients in the food supply.

## 1.4 Reasons for accepting Application

The Application was accepted for assessment because it:

- complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- related to a matter that warranted the variation of a food regulatory measure.

## 1.5 Procedure for assessment

The Application is being assessed under the General Procedure of the FSANZ Act.

---

<sup>5</sup> [Application A433 – Phytosterol Esters derived from Vegetable Oils in Breakfast Cereals](#)

<sup>6</sup> In accordance with Standard 2.5.1.

<sup>7</sup> In accordance with Standard 2.5.3. See [Application A434 – Phytosterol Esters derived from Vegetable Oils in Low Fat Milk & Yoghurt](#)

<sup>8</sup> [Application A508 – Phytosterols derived from Tall Oils as Ingredients in Low-fat Milk](#)

<sup>9</sup> [Application A1024 - Equivalence of Plant Stanols, Sterols & their Fatty Acids Esters](#)

<sup>9</sup> In accordance with Standard 2.5.4.

<sup>10</sup> [Application A1019 – Exclusive Use of Phytosterol Esters in Lower Fat Cheese Products](#)

## 2 Summary of the assessment

### 2.1 Risk assessment

Plant sterols are a group of naturally occurring steroid compounds that are structurally related to cholesterol. Phytosterols, phytostanols and their esters, are collectively termed plant sterols for the purpose of this report, while the total plant sterol equivalents specifically encompass phytosterols and phytostanols (i.e. free form) as well as the hydrolysis products of their esters. These naturally occurring steroidal compounds are structurally similar to cholesterol. The usual dietary sources of plant sterols include vegetable oils, nuts, and certain vegetables. Commercial plant sterol mixtures consist predominantly of the compounds:  $\beta$ -sitosterol, sitostanol, campesterol and campestanol. Increased plant sterol dietary exposure has been shown to reduce blood total and LDL cholesterol levels.

Adding plant sterols at higher levels than currently permitted in breakfast cereals is concluded to be technologically justified as methods are available to incorporate them into such foods. There are analytical methods available and specifications already in the *Australia New Zealand Food Standards Code* for plant sterols.

A review of the recent literature has not identified evidence to alter the conclusion reached previously by FSANZ, that a specified ADI is not justified for plant sterols for the general population. FSANZ has no toxicological concerns regarding the addition of plant sterols to breakfast cereals up to the concentrations proposed in the Application, for consumption by the general population. However, appropriate risk management measures are required for individuals with phytosterolaemia (sitosterolaemia).

Plant sterols consumption at doses between 0.8 and 2 g/day has been shown to reduce total and low density lipoprotein (LDL) blood cholesterol concentrations without adversely affecting high density lipoprotein (HDL) cholesterol concentration. Dose-response models reliably predicted that a daily dose of 2 g/day of plant sterols reduce LDL blood cholesterol concentrations by 9%. For daily doses above 3 g/day, the models predict that the reduction in blood LDL concentration will approach an asymptotic value of 12.7%. Pregnant and lactating women and children under 5 years of age do not need to lower their cholesterol levels because growing children and developing embryos have an increased need for cholesterol and, therefore, may not benefit from consuming plant sterol-enriched foods.

There is currently no robust evidence to support concerns that consuming plant sterols will increase the risk of cardiovascular disease or that the oxidation products of dietary plant sterols pose a risk to consumers. Some dietary intervention studies using plant sterols show a reduction in blood concentration of provitamin A carotenoids. These lipid-soluble phytochemicals are transported in blood by low density lipoprotein cholesterol, which is reduced by dietary exposure to plant sterols. Consequently, the decrease in circulating amounts of carotenoids is not unexpected. Furthermore, after adjusting for the change in total blood cholesterol concentration  $\beta$ -carotene is the only carotenoid whose concentration remains significantly different from the control group value.

However, it should be noted that the blood concentrations of carotenoids of subjects consuming plant sterols remain within the broad natural range of variation. Clinical studies in which up to 9 g of phytosterol esters per day (5.4 g of total plant sterols equivalent based on molecular weight conversion) were tested in adult subjects did not show statistically significant changes in fat-soluble vitamins. Clinical studies in which up to daily doses of 6 g of free plant sterols were consumed by children (2–17 years of age) for up to six months demonstrate that total and LDL cholesterol concentrations are significantly decreased without affecting HDL concentrations and show no evidence of a nutritional safety risk.

Similarly, consumption of 0.7 g and 0.8 g of plant sterol equivalents during pregnancy and one-month post-partum, respectively, did not show evidence of a nutritional safety concern for both the women and their infants and did not significantly decrease maternal total or LDL cholesterol concentrations.

The clinical evidence indicates that consumption of 5.4-6 g/day of total plant sterol equivalents is unlikely to pose a nutritional safety concern for children and adults.

The dietary exposure assessment (DEA) used two approaches to estimate plant sterol exposure from breakfast cereals containing added plant sterols. The first approach estimated total dietary exposure based on consumption of foods with existing permissions to add plant sterols (i.e. the baseline exposure, estimated from the consumption of plant sterol-containing foods as reported in recent National Nutrition Surveys for Australian and New Zealand populations) and consumption of a serving of breakfast cereal per day containing 2.2 g of plant sterols per serving. The total estimated dietary exposures to plant sterols (expressed as plant sterol equivalents) by this approach, across all surveys and age groups assessed for Australian (aged 2 years and over) and New Zealand (aged 15 years and over) populations, were 2.7–4.0 g/day and 3.0–5.1 g/day for the mean and P90 exposures, respectively.

The second approach used a scenario model to estimate chronic plant sterol exposure based on baseline exposure and exposure from breakfast cereal consumption. The scenario assumed all breakfast cereals contained plant sterols at the proposed maximum amount of 2.2 g/serve. This exposure estimate represented a 'worst-case' scenario since it assumed that persons who reported consuming breakfast cereal in the survey would consume the same amount of cereal if it contained added plant sterols at the proposed maximum amount. The total estimated dietary exposures to plant sterols (expressed as plant sterol equivalents) for Australian consumers aged 2 years and above were 3.2 g/day and 6.5 g/day for the mean and P90 exposures, respectively. By using this second approach, it was also predicted that less than 10% of the population would be exposed to more than 5.4 g/day of added dietary total plant sterol equivalents (9 g phytosterol esters/day), an amount that has been shown in humans to cause no adverse health effects. Occasional ingestion of plant sterols at these levels is unlikely to pose any safety concerns.

Overall, the available data for plant sterols are considered to provide a high level of confidence in the safety and suitability of plant sterol fortified breakfast cereal products at the proposed maximum concentration, for all population groups.

## **2.2 Risk management**

FSANZ has considered a number of risk management issues in relation to this Application, and has done so within the context of plant sterol containing foods currently on the market and the current estimated dietary exposure to plant sterols from such foods. On assessment, FSANZ recommends the new regulatory measure allow increased concentrations of plant sterols of a minimum of 0.5 g and a maximum of 2.2 g per serving, in all breakfast cereals meeting existing specified nutrient criteria. The details supporting this recommendation are outlined in the following sections.

### **2.2.1 Basis for units for expressing concentration permitted (g/kg or g/serving)**

The Risk Assessment (SD1) shows that there are no safety concerns with the addition of plant sterols to breakfast cereals at the levels requested by the Applicant (0.8–2.0 g per serving).



The Risk Assessment identifies that plant sterol consumption at 2 g per day has been shown to reduce total and low density lipoprotein (LDL) blood cholesterol concentrations without adversely affecting high density lipoprotein (HDL) cholesterol concentration, and describes dose-response models that reliably predicted that a daily dose of 2 g per day of plant sterols reduce LDL blood cholesterol concentrations by 9%.

Plant sterols are currently permitted to be added to breakfast cereals in the Code on a g per kg basis. This regulatory approach means that the actual amount of plant sterols in a serving of breakfast cereal could vary depending on the weight of the serving. In particular, a more dense (heavy) breakfast cereal may contain more plant sterols per serving than a lighter/less dense breakfast cereal. Currently, there are no plant sterol fortified breakfast cereals on the market in Australia and New Zealand. FSANZ understands this is largely because of the limitations in providing an efficacious amount of plant sterols in a single serving. Some overseas markets have provisions that allow 2 g plant sterols per serve. Finland provides an example where a breakfast cereal is available as single serve sachets of porridge (oats) containing 2 g plant stanols.

The draft variation does not specify the actual serving size, but specifies the permitted range of plant sterols per serving. This means the permitted amount per serving remains the same irrespective of the serving size or density of the breakfast cereal, e.g. maximum of 2 g per 30 g serving and per 60 g serving. This approach therefore provides better control of the amount of plant sterols that may be present in breakfast cereals and therefore better alignment with the efficacious amount of 2–3 g per day, compared to the g per kg approach.

FSANZ notes that this regulatory approach differs from permissions for adding plant sterols to most other foods in the Code. It is however, similar to the regulation of the addition of plant sterols to yoghurt in the Code where the permission is on a g per package basis.

'Serving' is defined in Standard 1.1.2 – Definitions used throughout the Code<sup>11</sup> and the serving size of a food must be declared in the nutrition information panel (Standard 1.2.8 – Nutrition information requirements). It is therefore expected that the serving specified in the panel would be the basis for determining compliance with the minimum and maximum permitted amounts of added plant sterols.

## **2.2.2 Concentration of added plant sterols**

### **2.2.2.1 Minimum**

Based on a 30 g serving, which is at the lower end of serving sizes of breakfast cereals, FSANZ has calculated the existing minimum permitted amount of 15 g of total plant sterol equivalents per kg of breakfast cereal to be 0.5 g of total plant sterol equivalents per serving of breakfast cereal.

A requirement to include at least 0.5 g of total plant sterol equivalents per serving is similar to the current minimum required in the Code. Although this is lower than the amount requested by the Applicant (of 0.8 g per serving), this level would reduce the impact on suppliers who add (none known), or are planning to add, plant sterols to breakfast cereals at levels less than 0.8 g per serving. The draft variation therefore accommodates the lower level of 0.5 g per serving of total plant sterol equivalents if added to breakfast cereals.

---

<sup>11</sup> *Serving* means an amount of the food which constitutes one normal serving when prepared according to manufacturer's directions or when the food requires no further preparation before consumption, and in the case of a formulated meal replacement is equivalent to one meal.

### **2.2.2.2 Maximum**

The Application seeks a maximum of 2 g of plant sterols per serving and also indicates that labelling and associated education activities will refer to a serving of breakfast cereal containing 2 g.

The request for 2 g per serving has arisen from limitations of the existing permissions which allow (only) up to a maximum of 19 g per kg. This limit means only breakfast cereals with serving sizes greater than 45 g per serving can achieve the minimum amount required to make a health claim (refer section 2.2.4 of this assessment summary and Schedule 4 – Nutrition, health and related claims). Moreover, three or more ‘normal servings’ of plant sterol enriched breakfast cereal would be required to gain an efficacious daily amount of plant sterols. As typically only one serve of breakfast cereal is consumed per day, this situation provides little incentive for manufacturers to add plant sterols to breakfast cereals and as such, there are currently none in the Australia or New Zealand food supplies. This limitation places the breakfast cereal sector at a disadvantage compared with other food categories with plant sterol fortification permissions, such as edible oil spreads, cheese, yoghurt and milk, where 2 g of plant sterols per day can be more readily achieved, either as a single serve, or because such foods are routinely consumed through more than one serving a day.

The proposal for enabling dietary exposure to an efficacious amount of 2 g total plant sterol equivalents from one serve of food, is further supported by Australian and New Zealand national nutrition survey consumption data that reflect relatively low levels of consumption of other plant sterol fortified foods (refer SD1, section 5). There is also evidence from Europe that many consumers do not reach efficacious dietary exposures to plant sterols even when using a mix of products (EFSA 2008).

As a further consideration to the above, the Code requires that an ‘average quantity’ must be declared in the nutrition information panel (refer to section 2.2.4). It would be difficult to achieve an average quantity of 2 g per serving if the maximum permitted amount is also set at 2 g per serving. Because there are no safety concerns of including a slight overage amount, the draft variation allows a maximum permitted amount of 2.2 g of total plant sterol equivalents per serving rather than 2 g. This allows declaration of the efficacious amount as an average quantity. It avoids issues of non-compliance of either misleading declarations (if the average quantity is less than that declared) or exceeding the maximum permitted amount in order to declare the efficacious amount of 2 g per serving. The risk assessment concludes that adding plant sterols to breakfast cereals at the maximum level of 2.2 g of total plant sterol equivalents per serving is safe and technologically feasible as methods are available to incorporate them.

### **2.2.3 Food vehicle – breakfast cereals**

The Application sought to increase the concentration of plant sterols permitted to be added to portion-controlled breakfast cereals only. The application defined ‘portion-controlled’ as ‘breakfast cereals that are either delivered in individually wrapped portions, single-serve portions, or in discreet portions that can be readily divided from a multi-serve container’. This approach was proposed as a reliable means for manufacturers to deliver a consistent amount of plant sterols per serving with confidence, and as a practical way for consumers to reliably identify and consume the recommended serving to achieve the intended/efficacious amount of plant sterols.

However existing permissions in the Code allow plant sterol addition to both portion controlled and non-portion controlled breakfast cereals that meet the requisite nutrient criteria (no less than 3 g of fibre per 50 g and no more than 30 g of total sugars per 100 g).

Maintaining this approach allows for increased fortification of 'portion-controlled' breakfast cereals as requested by the Applicant, and also for non-portion controlled breakfast cereals. FSANZ's risk assessment and consideration of dietary exposures to plant sterols indicates consumers are not at risk of unsafe dietary exposures to plant sterols, were they to be potentially available through this wider variety of breakfast cereals.

In the interest of minimal effective regulation, FSANZ considers that to limit increased fortification permissions to 'portion-controlled' breakfast cereals only would be unnecessarily restrictive because it may limit innovation, the availability of fortified breakfast cereals and consumer choice.

FSANZ is also of the view there are a number of technological and market forces at play that will limit the number of breakfast cereals to which plant sterols will be added. In order to avoid false or misleading representations manufacturers must be able to ensure sufficiently reliable distribution of added plant sterols throughout the food, and specifically within a readily identifiable 'serve', such that a serving contains the amount of plant sterols claimed (see section 2.2.4). Similarly, there are commercial imperatives to ensure that the plant sterol addition does not cause any appearance, odour or flavour defects in the final product (refer SD1). Manufacturers may therefore choose to limit fortification to certain breakfast cereals only.

Plant sterols are of little benefit to consumers other than those with elevated serum cholesterol levels, and of no benefit to pregnant and lactating women and children under five years of age. FSANZ understands plant sterol enriched breakfast cereals will be a niche product and marketed accordingly to the relevant population groups. A mandatory advisory statement (refer to section 1.3 in this assessment summary) will, for example, indicate the product is not targeted to children under 5 years and pregnant or lactating women. Similarly, assuming such products will have a nutrition or health claim about plant sterols, these claims are unlikely to trigger purchase by consumers, other than those for whom there will be a benefit.

With regard to consumers' ability to identify and consume recommended intakes of plant sterols, FSANZ considers adequate information is provided to consumers to manage plant sterol intakes by virtue of the average quantity of plant sterols per serve size being declared in the nutrition information panel. While this declaration is only required if a nutrition content or health claim about plant sterols is made, given the costs involved in adding plant sterols it would seem highly unlikely a manufacturer would add them without wishing to declare their presence. Consumers can determine the appropriate amount of breakfast cereal and plant sterols they wish to consume based on labelling information if provided (see section 2.2.4 below).

In summary, FSANZ has not identified sufficient reason to limit the scope of breakfast cereals permitted to be fortified at the higher concentration to 'portion-controlled' breakfast cereals only. FSANZ therefore recommends the increased concentration is permitted for all breakfast cereals (meeting existing specified nutrient criteria, and excludes breakfast cereal bars).

#### **2.2.4 Labelling relating to foods containing added plant sterols**

Added plant sterols must be declared in the statement of ingredients on foods (Standard 1.2.4 – Information requirements – statement of ingredients) by the name of which the ingredient is commonly known or by a name that describes the true nature of the ingredient. This enables consumers, including those with the rare inherited disorder phytosterolaemia, to identify these added ingredients.

The advisory statements required on foods that contain added plant sterols are outlined in section 1.3 above.

Standard 1.2.7 sets out conditions for nutrition content and health claims in labelling and advertising of foods. This standard permits nutrition content claims to the effect that the food ‘contains’ plant sterols but descriptors such as ‘high’ are not permitted.

A health claim about phytosterols, phytostanols and their esters and reduced blood cholesterol is permitted in accordance with Standard 1.2.7. In order to make such a claim about a food, the food must meet the requirements in section S25—2 and in accordance with Schedule 4, contain a minimum of 0.8 g total plant sterol equivalents content per serving. The claim must include dietary context statements referring to a diet low in saturated fatty acids and containing 2 g of phytosterols, phytostanols and their esters per day. Foods carrying a health claim about plant sterols must also meet the nutrient profiling scoring criterion (NPSC)<sup>12</sup>. The NPSC is a nutrient profiling system used in Australia and New Zealand to determine whether a food is suitable to make a health claim, based on its nutrient profile.

If a nutrition content or health claim is made about a food, the average quantity of the claimed property of food must be declared in the nutrition information panel on the label of the food on a per serving and per 100 g (solid and semi solid foods) or 100 mL (liquid foods) basis (Standard 1.2.8). Section 1.1.1—6 outlines how the average quantity is to be calculated and section 1.1.2—2 defines the term ‘average quantity’<sup>13</sup>. The serving size of the food must also be declared in the panel.

Any additional labelling or advertising provided in association with a food would need to meet the relevant requirements in the Code as outlined above, as well as consumer protection legislation.

In summary, it is appropriate that the existing requirements for the labelling and advertising in the Code for foods containing added plants sterols apply to breakfast cereals containing increased concentration of plant sterols.

## 2.2.5 Exclusivity

An applicant, in relation to a novel food permission, may request that the permission applies exclusively to the applicant for a period of time as a recognition of the investment made in developing a novel food or ingredient and the need to achieve return on this investment, thereby supporting innovation. The Applicant has requested exclusivity on the basis they have invested significant financial resources in research, technical and regulatory arenas in support of their Application.

The draft variation specifies that the total plant sterol equivalents content of 0.5–2.2 g per serving permitted to be added to breakfast cereals would apply exclusively to the ‘Sanitarium Health and Wellbeing’ and the ‘Weet-Bix’ brands only, for an exclusive use period of 15 months commencing on the date of gazettal of the variation, as requested by the Applicant. Existing regulations will apply to all other brands of breakfast cereal until the end of this period.

---

<sup>12</sup> <http://www.foodstandards.gov.au/industry/labelling/Pages/Short-guide-for-industry-to-the-NPSC.aspx>

<sup>13</sup> **average quantity**, of a substance in a food, means the average, for such foods from that producer or manufacturer, of:

(a) where a serving or reference amount is specified—the amount of the substance that such a serving or reference amount contains; or

(b) otherwise—the proportion of that substance in the food, expressed as a percentage.

During the exclusive use period, any other business would require the agreement of Sanitarium Health and Wellbeing in order to benefit financially from the amendment to the Code (if approved).

The exclusive use permission would revert to a general permission after the exclusive use period expires, replacing the existing permission relating to breakfast cereals. This means that the permission for the addition of the increased amount of plant sterols in breakfast cereals will then apply to *all* brands of breakfast cereals that meet specified nutrient criteria.

However, Standard 1.5.1 does not and cannot prevent approval of second or subsequent applications within that exclusive use period or during the progression of this application for the use of the same novel food (or containing the approved ingredient) by other food companies, providing the application process is undertaken. This variation does not change this.

### **2.2.6 Risk management conclusion**

FSANZ recommends an increase in the concentration of plant sterols permitted to be added to breakfast cereals that meet existing specified criteria for sugar and fibre. The draft variation permits a total plant sterol equivalents content of 0.5–2.2 g per serving of breakfast cereal.

The existing labelling requirements for foods containing added plants sterols will apply to breakfast cereals containing an increased concentration of plant sterols compared to current permissions. This includes declaration of added plant sterols in the ingredient list to enable identification by consumers, including those with the rare inherited disorder of phytosterolaemia who are advised to avoid consuming plant sterols.

The range of 0.5–2.2 g of total plant sterol equivalents content per serving of breakfast cereal would apply exclusively to the ‘Sanitarium Health and Wellbeing’ and ‘Weet-Bix’ brands during the exclusive use period, as requested by the Applicant. The exclusive use permission would revert to a general permission after the exclusive use period expires, replacing the existing concentrations applying to breakfast cereals.

## **2.3 Risk communication**

FSANZ has developed a basic communication strategy for this Application.

### **2.3.1 Consultation**

Consultation is a key part of FSANZ’s standards development process. Public submissions are called for to obtain the views of interested parties on the Application and the impacts of the regulatory options. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ’s social media tools and Food Standards News. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

Following consultation, the FSANZ Board will consider the proposed variation having regard to all submissions. If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation (Forum). If the decision is not subject to a request for a review, the Applicant and stakeholders including the public will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

## **2.3.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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 increase the concentration of plant sterols permitted to be added to breakfast cereals is unlikely to have a significant effect on international trade as the proposed measure just extends an existing permission. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.4 FSANZ Act assessment requirements**

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

### **2.4.1 Section 29**

#### **2.4.1.1 Consideration of costs and benefits**

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the application outweigh the costs to the community, government or industry. This is because it is a voluntary provision that manufacturers may implement based on potential positive business outcomes, and consumers will buy products if they feel the benefits outweigh any additional cost.

The proposed increase to the permitted concentration of plant sterols in breakfast cereals is deregulatory. Consumers wishing to consume plant sterols will have a greater range of products available to them, and enhanced access to a single-serve of plant sterols in breakfast cereals that is efficacious.

A Regulation Impact Statement is not required for this Application because the proposed variation to the Code is minor in nature and unlikely to have a regulatory impact on business, community organisations, government, or individuals (OBPR ID 21244).

#### **2.4.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

#### **2.4.1.3 Any relevant New Zealand standards**

The draft variation amends a joint Australia and New Zealand standard.

#### **2.4.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **2.4.2 Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

#### **2.4.2.1 Protection of public health and safety**

The Risk Assessment at SD1 and as summarised in section 2.1 of this report outlines that adding plant sterols to breakfast cereal up to a level of 2.2 g per serving is safe.

Plant sterols are already permitted to be added to breakfast cereals that meet specified nutrient criteria. Increasing the concentration of plant sterols permitted per serving of such breakfast cereals may result in increased uptake of these permissions. Because consumers will be able to obtain the efficacious amount of 2 g plant sterols per serving of breakfast cereal there may be some public health benefits associated with improved blood cholesterol levels.

#### **2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The labelling requirements for foods containing added plant sterols are discussed in section 2.2.4 above. The existing labelling requirements in the Code are considered to be appropriate for breakfast cereals with increased levels of added plant sterols.

#### **2.4.2.3 The prevention of misleading or deceptive conduct**

There is an existing permission for the addition of plant sterols to breakfast cereals in the Code. This application seeks to increase the maximum amount permitted. Under the draft variation, if plant sterols are added to breakfast cereals, a serving must contain at least 0.5 g of total plant sterol equivalents per day in order to ensure 'trivial' amounts are not present. The generic labelling requirements including for making voluntary nutrition and health claims (section 2.2.4 above) will apply to prevent consumers being misled or deceived.

#### **2.4.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk assessment (SD1) which formed the basis of the risk analysis.

- **the promotion of consistency between domestic and international food standards**

In Europe, phytosterols and their esters are specifically permitted in a wide variety of foods (Regulation (EC) 258/97)<sup>14</sup>. Plant stanols and their esters are permitted for use without requiring pre-market assessment, as they were for sale in a Member State before the Regulation came into effect. The European Commission recommends that the composition and labelling of products containing plant sterols should be such as to allow users to easily restrict their consumption to maximum 3 g per day of phytosterols/phytostanols through the use of either one portion containing maximum 3 g, or three portions containing maximum 1 g<sup>15</sup>.

---

<sup>14</sup> Foods authorised to contain plant sterols under Regulation (EC) 258/97 include yellow fat spreads, milk-type products, yoghurt-type products, milk-based fruit drinks, soy drinks, rice drinks, spicy sauces, salad dressings and certain rye breads.

<sup>15</sup> COMMISSION REGULATION (EC) No 608/2004 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:097:0044:0045:EN:PDF>

In the USA, the United States Food and Drug Administration (USFDA) has raised no objection to a number of foods (including breakfast cereals) that may contain plant sterols, on the basis of GRAS (generally recognized as safe) notifications. The notifications for breakfast cereals are for amounts of added plant sterols ranging from approximately 0.4–2 g per serving.

The draft variation therefore facilitates greater alignment with Europe and the USA with respect to the addition of plant sterols to foods.

- **the desirability of an efficient and internationally competitive food industry**

FSANZ is not aware of any breakfast cereals that contain added plant sterols available in Australia or New Zealand. Permission to increase the concentration of plant sterols in breakfast cereals facilitates alignment with Europe and USA as outlined above, and hence allows for Australia and New Zealand suppliers to better compete in these markets.

The recommended approach will also allow for more innovation in the area of plant sterol enriched breakfast cereals and increased market opportunities generally.

- **the promotion of fair trading in food**

The exclusive use provision recompenses the applicant for the cost of developing and implementing the technology to include higher concentrations of plant sterols. But this advantage ceases at the end of the exclusive use period to then enable all manufacturers of breakfast cereals that meet specified nutrient criteria to use the higher amounts.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There are two policy guidelines relevant to A1134:

- Policy Guideline on Novel Foods
- Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals.

FSANZ has had regard to these Policy Guidelines and the assessment is summarised in SD2.

## **3 Draft variation**

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

### **3.1 Transitional arrangements**

The exclusive use period referred to above is transitional.

The range of 0.5–2.2 g of total plant sterol equivalents content per serving permitted to be added to breakfast cereals that meet specified nutrient criteria would apply exclusively to the ‘Sanitarium Health and Wellbeing’ and the ‘Weet-Bix’ brand only, for an exclusive use period of 15 months, as requested by the Applicant. The existing permission of 15 g/kg to 19 g/kg would remain for other breakfast cereals during this time.



However, after the exclusive use period expires, the exclusive use permission would revert to a general permission for all nutrient qualifying breakfast cereals - thereby replacing the existing permission relating to breakfast cereals.

## **4 References**

European Food Safety Authority (EFSA) (2008). Consumption of Food and Beverages with Added Plant Sterols in the European Union. The EFSA Journal 133, 1-21. Parma

### **Attachments**

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1134 – Increased Concentration of Plant Sterols in Breakfast Cereals) Variation

---

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer  
Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Application A1134 – Increased Concentration of Plant Sterols in Breakfast Cereals) Variation*.

## 2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a standard in the *Australia New Zealand Food Standards Code*.

## 3 Commencement

The variation commences on the date of gazettal.

### Schedule

[1] **Schedule 25** is varied by omitting from the entry for ‘\*Phytosterols, phytostanols and their esters’ in the table to section S25—2

3. May only be added to breakfast cereals, not including breakfast cereal bars, if:
  - (a) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve; and
  - (b) the breakfast cereal contains no more than 30 g/100 g of total sugars; and
  - (c) the \*total plant sterol equivalents content is no less than 15 g/kg and no more than 19 g/kg.

substituting,

3. May only be added to breakfast cereals, not including breakfast cereal bars, if:
  - (a) the total fibre content of the breakfast cereal is no less than 3 g/50 g; and
  - (b) the breakfast cereal contains no more than 30 g/100 g of total sugars; and
  - (c) the \*total plant sterol equivalents content is the prescribed amount.
- 3A. For the purposes of condition 3(c) above,
  - (a) the prescribed amount during the exclusive use period is:
    - (i) for breakfast cereals sold under the brands *Sanitarium Health and Wellbeing* or *Weet-Bix* – an amount that is no less than 0.5 g per serving and no more than 2.2 g per serving; and
    - (ii) for all other breakfast cereals - an amount that is no less than 15 g/kg and no more than 19 g/kg; and
  - (b) the prescribed amount after the end of the exclusive use period is an amount that is no less than 0.5 g per serving and no more than 2.2 g per serving.
- 3B. For the purposes of condition 3A above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1134 – Increased Concentration of Plant Sterols in Breakfast Cereals) Variation* and ending 15 months after that date.

## **Attachment B – Draft Explanatory Statement**

### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1134 – Increased Concentration of Plant Sterols in Breakfast Cereals, which seeks to amend current novel food permissions for plant sterols added to breakfast cereals to allow increased concentrations. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

### **2. Purpose**

The purpose of this variation to the Code is to permit an increased amount of phytosterols, phytostanols and their esters (referred to collectively as ‘plant sterols’) to be added to specified breakfast cereals that meet prescribed nutrient criteria.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority’s consideration of Application A1134 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

A Regulation Impact Statement was not required because the proposed variations to Schedule 25 are unlikely to have a regulatory impact on business, community organisations, government, or individuals.

### **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

### **6. Variation**

Item [1] of the variation amends the table to section S25—2 by omitting existing condition 3 under the entry for ‘Phytosterols, phytostanols and their esters’ in the table; and substituting new conditions 3, 3A and 3B.

Condition 3 states that phytosterols, phytostanols and their esters may only be added to breakfast cereals, not including breakfast cereal bars, if:

- (a) the total fibre content of the breakfast cereal is no less than 3 g/50 g; and

- (b) the breakfast cereal contains no more than 30 g/100 g of total sugars; and
- (c) the total plant sterol equivalents content is the prescribed amount.

Condition 3A relates to paragraph (c) in Condition 3 and states the meaning of 'prescribed amount' as follows:

- (a) the prescribed amount during the exclusive use period is:
  - (i) for breakfast cereals sold under the brands *Sanitarium Health and Wellbeing* or *Weet-Bix* – an amount that is no less than 0.5 g per serving and no more than 2.2 g per serving; and
  - (ii) for all other breakfast cereals – an amount that is no less than 15 g/kg and no more than 19 g/kg; and
- (b) the prescribed amount after the end of the exclusive use period is an amount that is no less than 0.5 g per serving and no more than 2.2 g per serving.

Condition 3B defines 'exclusive use period' to be the period commencing on gazettal date of the variation and ending 15 months after that date. This means that the new permission will apply exclusively to breakfast cereals sold under the brands *Sanitarium Health and Wellbeing* or *Weet-Bix* during an exclusive use period of 15 months commencing on the date of gazettal of the variation (exclusive use permission).

Once this period ends, the exclusive use permission would revert to a general permission, replacing the existing permission relating to the addition of plant sterols in breakfast cereals. This means that the permission for the addition of the increased amount of plant sterols in breakfast cereals will then apply to *all* brands of breakfast cereals that meet specified nutrient criteria.