

23 March 2017
[08–17]

Approval report – Application A1134

Increased Concentration of Plant Sterols in Breakfast Cereals

Food Standards Australia New Zealand (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.

On 13 December 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received twelve submissions.

FSANZ approved the draft variation on 9 March 2017. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 22 March 2017.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	5
2 SUMMARY OF THE FINDINGS	5
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	5
2.2 RISK ASSESSMENT	14
2.3 RISK MANAGEMENT	15
2.4 DECISION	20
2.5 RISK COMMUNICATION.....	20
2.5.1 <i>Consultation</i>	20
2.6 FSANZ ACT ASSESSMENT REQUIREMENTS	21
2.6.1 <i>Section 29</i>	21
2.6.2 <i>Subsection 18(1)</i>	21
3 TRANSITIONAL ARRANGEMENTS	23
4 REFERENCE	23
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	24
ATTACHMENT B – EXPLANATORY STATEMENT	26

Supporting documents

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

- SD1 Risk assessment (at Approval)
- SD2 Assessment against the Forum Policy Guidelines

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

Executive summary

The Application sought to amend current novel food permissions for phytosterols, phytostanols and their esters (referred to as plant sterols in this report) added to breakfast cereals. Specifically the submission sought 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 requested exclusive use of the permission under the novel food provisions for a period of 15 months after gazettal.

Schedule 25 in the *Australia New Zealand Food Standards Code* (the Code) currently allows for the addition of *total plant sterol equivalents content*² of no less than 15 g per kg and no more than 19 g per kg to breakfast cereals (not including breakfast cereal bars). 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).

Plant sterols consumption at doses between 0.8 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. The clinical evidence indicates that consumption up to 9 g per day of total plant sterol equivalents is unlikely to pose a nutritional safety concern for children and adults. 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.

FSANZ considered a number of risk management issues in relation to this Application, and did 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. In light of these considerations, 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 is not affected by the serving size or density of the breakfast cereal. This approach provides better control of the amount of plant sterols that may be present in breakfast cereals and therefore better alignment with the efficacious amount compared to the gram per kg approach. The existing generic and specific labelling requirements for foods containing added plant sterols provide consumers with information to enable informed choice.

In conclusion, FSANZ has approved the new regulatory measure to allow increased concentrations of total plant sterols equivalent 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. Permissions 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. The exclusive use permission will 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.

²*Total plant sterol equivalents content* is defined in Standard 1.1.2 – Definitions used throughout the Code as the total amount of: phytosterols; and phytostanols; and phytosterols and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters.

1 Introduction

1.1 The Applicant

The Applicant is the food manufacturing company Sanitarium Health and Wellbeing³, Berkely Vale, New South Wales, Australia.

1.2 The Application

The Application sought 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 was 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 referred to 'portion-controlled' as either individually wrapped portions or portions that can be easily divided.

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

The Applicant stated that the primary purpose of the Application was to increase the accessibility of phytosterols⁴ through breakfast cereals. It was noted that the amendment would allow for a more convenient and cost effective delivery of the effective dose of plant sterols in breakfast cereals. The Application also noted that the proposed amendment would:

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

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*⁵ of no less than 15 g per kg and no more than 19 g per kg to breakfast cereals (not including breakfast cereal bars).

³ Information about the Applicant can be found [on the Sanitarium website](#).

⁴ term used in the Application

⁵ *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, certain breakfast cereals⁶, milk⁷ and yoghurt⁸. 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 added⁹. Tall oil phytosterol esters are permitted in cheese and processed cheese¹⁰ (subject to conditions on fat content)¹¹.

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. The novel food framework is currently being reviewed by FSANZ as Proposal P1024¹².

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.

⁶ [Application A433 – Phytosterol Esters derived from Vegetable Oils in Breakfast Cereals](#)

⁷ In accordance with Standard 2.5.1.

⁸ In accordance with Standard 2.5.3. See [Application A434 – Phytosterol Esters derived from Vegetable Oils in Low Fat Milk & Yoghurt](#)

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

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

¹⁰ In accordance with Standard 2.5.4.

¹¹ [Application A1019 – Exclusive Use of Phytosterol Esters in Lower Fat Cheese Products](#)

¹² <http://www.foodstandards.gov.au/Search/pages/results.aspx?k=P1024>

1.5 Procedure for assessment

The Application was assessed under the General Procedure of the FSANZ Act.

2 Summary of the findings

2.1 Summary of issues raised in submissions

There were 12 submissions in response to FSANZ's call for submissions. The issues raised in the submissions and FSANZ responses are provided in Table 1 below. One submission from a public health association opposed the draft variation while the other submissions either all supported the progression of the Application and draft variation or did not provide a definitive view. Of the twelve submissions, six were from industry associations or food companies, four were from government jurisdictions and two were from public health associations.

Four submissions were received supporting the further progression of the Application, but either raised no issues or provided comment only. The Table below provides a summary of the issues and comments provided by submissions.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
<p>FSANZ to develop a proposal to amend the Code to amend the permissions to add plant sterols to all current food categories, not just breakfast cereals, i.e. milk, cheese and processed cheese, yoghurt and edible oil spreads, at the higher levels proposed for this Application. That is up to 2.2 g of plant sterol equivalents per serve. The reason for this is to ensure consistent levels in the different food categories so providing benefits to consumers. A number of the current permissions for other food categories have maximum permissions per serve which are below those proposed for breakfast cereals, putting these industries at a disadvantage.</p>	<p>Australian Food & Grocery Council (AFGC) Lion Dairy & Drinks (Lion) Raisio Nutrition Limited (for yoghurt) Dairy Australia</p>	<p>Noted. However, extension of current permissions to add plant sterols to all current food categories is out of scope in terms of this Application. Industry groups or food companies can apply at any time to increase the maximum permitted levels for other food categories.</p>
<p>FSANZ should be more circumspect in future and restrict the use of ‘worst case’ scenarios for Dietary Exposure Assessments to the plausible but improbable, rather than the implausible and impossible.</p>	<p>AFGC</p>	<p>Noted. As described in section 2.2, FSANZ used two methods in the dietary exposure assessment. In the first approach it was assumed 2.2 g from a single serve of plant sterol-containing breakfast cereal was added to the plant sterol exposure estimated from food consumption data reported in 2011-13 Australian Health Survey (AHS). This was in line with the Application.</p> <p>The second approach was a more conservative one as estimated exposures from a broader permission to add plant sterols at the maximum amount proposed for all breakfast cereals that meet the specified nutrient criteria were added to current estimated dietary exposures.</p> <p>In line with a tiered approach to risk assessment, it was not considered necessary to further refine the dietary exposure estimate as there were no safety concerns identified using the conservative approach.</p>

Issue	Raised by	FSANZ response
<p>The ‘worst case’ scenario for the Dietary Exposure Assessment used is actually not a worst case, since it does not use the full range of food products currently permitted to add plant sterols to them. [Furthermore] this exposure is based on 2011-12 data from Australia and 2008 data from New Zealand; it is likely that additional products (spreads, milk, yoghurt, cheese) have come on the market since. With the combination of health claims and improving technologies for incorporating plant sterols into foods it is likely consumption will increase.</p> <p>Dietary exposure would be higher for an alternative worse case where a consumer actively sought to consume the full range of foods currently permitted to have plant sterols added to them, as well as breakfast cereals at the increased levels as proposed by the Application. It is acknowledged that such a scenario would be rare given the generally low product uptake and their higher costs but such a ‘worst case’ is worth considering.</p>	<p>Department of Health and Human Services Tasmania</p> <p>Department of Health Western Australia</p>	<p>Agreed the second scenario presented in the FSANZ report was technically not the ‘worst case’. However, as the submitter has noted, such a scenario would be very unlikely and unrealistic for the reasons cited. This conclusion is supported by market research which showed that users of plant sterol fortified products tend to use one product at a time, with only a small proportion of users consuming two or three plant sterol fortified products per day (EFSA, 2008). See SD1 – A1019¹³ page 53.</p> <p>As noted above, the second scenario was a more conservative approach than the first scenario since it estimated the potential effect on the population, assuming current use of plant sterol-containing foods (as reported in the 2011-13 AHS) in addition to a broader permission to add plant sterols to all breakfast cereals that meet the specified nutrient criteria. The report has been reworded to indicate this is a conservative approach rather than a ‘worst case scenario’.</p>

¹³ <http://www.foodstandards.gov.au/Search/pages/results.aspx?k=A1019>

Issue	Raised by	FSANZ response
<p>FSANZ should emphasise more strongly the potential public health and safety benefits as an outcome of the Application, since that is the primary justification for the addition of plant sterols to breakfast cereals. A comprehensive review of the scientific evidence has been undertaken of possible hazards and nutritional impacts of plant sterol consumption as detailed in SD1. But the benefit, being the strong association between plant sterol consumption and reduction in serum LDL-cholesterol levels and cardiovascular disease risk has been ignored.</p>	<p>AFGC</p>	<p>Noted. Section 4 (Nutrition assessment) of SD1¹⁴ addresses the health benefits of plant sterols with a detailed description of the association between dietary intake of plant sterols and a reduction in total and LDL cholesterol in the blood without an adverse effect on HDL cholesterol.</p>
<p>The PHAA opposes the addition of plant sterols to food as it has indicated in comments to other plant sterol applications. The reasons for this view are that such permissions are unnecessary, noting that following appropriate dietary advice is most effective in providing positive health outcomes for the general population. The PHAA also notes its opposition to ‘medicalisation’ of the food supply. Other concerns are:</p> <ul style="list-style-type: none"> • chance of overconsumption of such products by target and non-target populations • chance of incidental consumption by children, pregnant and lactating women, and people with low blood cholesterol • confusion in the general public about food and nutrition • burden on enforcement • diversion of government resources away from nutrition campaigns such as increased consumption of fruits and vegetables. 	<p>Public Health Association of Australia (PHAA)</p>	<p>The broader public health policy of how to effectively reduce cholesterol levels in humans and the subsequent costs and benefits of each individual measure (albeit by dietary intervention measures alone) cannot be decided by FSANZ in this Application. Consumption of plant sterol-containing foods is essentially just one measure whereby consumers can effectively reduce cholesterol.</p> <p>Considerations of overconsumption or consumption by non-target groups is addressed in the Risk Assessment – refer SD1. Mandatory advisory statements advise against consumption by children and pregnant and lactating women.</p> <p>FSANZ notes that a number of nutrition and public health associations support the consumption of food containing plant sterols to provide benefits to some targeted consumers.</p>

¹⁴ <http://www.foodstandards.gov.au/Search/pages/results.aspx?k=A1134>

Issue	Raised by	FSANZ response
		<p>These associations include the Heart Foundation which has produced two documents in 2009 (still current) being its position statement, and summary of evidence in relation phytosterol/stanol enriched foods, and the Dietitians Association of Australia which supports this Application.</p> <p>The cost benefit analysis identifies that extension of existing permission means relatively limited additional enforcement cost for regulators.</p>
<p>If the Application is approved as proposed, then the PHAA supports adding additional restrictions so the plant sterol addition would only apply to healthier breakfast cereals to prevent manufacturers achieving a ‘halo’ effect for their products. It recommends using the Nutrient Profiling Scoring Criteria (NPSC) though it notes differences to the criteria recommended for this Application. Therefore, further consideration should be made by FSANZ. Furthermore, permission should not apply to cereals marketed to children.</p> <p>The current draft variation retains the current nutrient profiling for breakfast cereals in the Code before they can contain added plant sterols. The NPSC was recently adopted for the addition of vitamin D to breakfast cereals. In the interests of ‘future-proofing’ and to promote consistency and reduce confusion the submitter suggests the NPSC should be considered rather than the current nutrient profiles. It does note that the vitamin D permission was dealt with under the Policy Guideline for fortification (for vitamins and minerals) and not novel foods.</p>	<p>PHAA New Zealand Ministry for Primary Industries (NZ MPI)</p>	<p>Noted. This is an increase in concentration of pre-existing permissions for addition of plant sterols in breakfast cereals, rather than a new permission, hence the qualifying nutrient criteria have been maintained.</p> <p>FSANZ notes that products containing plant sterols are likely to carry health claims. Therefore in addition to the existing criteria for fibre and sugar that apply to the addition of phytosterols, foods carrying a health claim about plant sterols must also meet the NPSC. Although applied for differing purposes, both sets of criteria provide safeguards on the nutritional profile of breakfast cereals that are either permitted to contain phytosterols or are able to make claims about them.</p> <p>The mandatory labelling requirements include advice that the product is not suitable for children (or lactating or pregnant women) and on this basis it is unlikely such products would be marketed to children.</p> <p>Public health associations or others can apply at any time to amend the qualifying nutrient criteria for breakfast cereals.</p>

Issue	Raised by	FSANZ response
<p>The submitter separately notes that for companies to be able to make health claims the food is required to meet the NPSC (section S4—6).</p>		
<p>Suggestion is made that the proposed draft variations could be made ‘cleaner’ so that the entire entry for ‘Phytosterols, phytostanols and their esters’ from clause 3 is replaced with clauses 3 to 8 numbered sequentially.</p>	<p>New Zealand Food & Grocery Council</p>	<p>Noted. Proposed conditions 3, 3A and 3B in effect provide an exclusive permission that operates for only 15 months. At the end of that period, conditions 3A and 3B will be removed from the Code and Condition 3 will be amended. In these circumstances, the numbering of the sections is considered appropriate.</p>
<p>The maximum level of 2.2 g per serve is supported but not the minimum level of 0.5 g per serve. The submission maintains that the minimum should be as requested by the Applicant, being 0.8 g per serve. The submitter believes it is unnecessary to retain the existing minimum as it is below the amount necessary to make a health claim (being 0.8 g/serve).</p>	<p>NZ MPI</p>	<p>Noted. This issue has been addressed in section 2.3.2.1. It was decided not to change the minimum level of 0.5 g per serve since that was currently in the Code as it was not thought appropriate to impact on any businesses who may be considering adding plant sterols to breakfast cereals at the lower level. It is understood companies may choose to add at least 0.8 g per serve (and meet all the other specified conditions in Standard 1.2.7) to make a health claim.</p>
<p>MPI notes that ‘Weetbix’ and comparable products are used as ingredients in recipes for certain baked products (made and consumed at home). It notes that in the FSANZ hazard assessment (section 3.1.1 in SD1) and in additional references the submitter provided, there is the potential for the formation of plant sterol oxidation products due to microwave heating or baking is identified. The submitter therefore asks if any additional further data is available from dietary intake studies on the use of breakfast cereals as ingredients in recipes and whether this poses any further concerns regarding the intake of plant sterol oxidation products.</p>	<p>NZ MPI</p>	<p>Noted. Condition 4 in the table to section S25—2 does not allow the use of food products to which plant sterols have been added to be used as ingredients in other foods.</p> <p>The estimates of plant sterol intakes did not take account of the potential use of plant sterol-containing ingredients in homemade foods, as this level of detail was not available from the 2011-13 AHS dataset.</p>

Issue	Raised by	FSANZ response
<p>In the nutrition assessment in SD1 the studies from Gylling et al. 2010 and Davidson et al. 2001 have been referenced incorrectly as both studies reported the intakes as plant sterol equivalents and not as plant sterol esters.</p>	<p>Raisio Nutrition Ltd</p>	<p>Noted. FSANZ considered that there was ambiguity in the description of the plant sterol forms mentioned in the study reports and therefore, for public health reasons, assumed that that the amounts stated referred to esterified plant sterols rather than free plant sterols.</p> <p>In response to the submission, FSANZ has contacted the authors directly and sought out confirmation on the chemical form of the plant sterols used. The authors have confirmed that the intakes refer to total plant sterol equivalents. SD1 has been amended to reflect this clarification, the assessment remains the same.</p>
<p>Also for the nutrition assessment in SD1 there is a third study that deals with high daily intake of plant sterols (as phytosterol esters). The reference is: Mensink RP, de Jong A, Lütjohann D, Haenen GRMM, Plat J (2010) Plant stanols dose-dependently decrease LDL-cholesterol concentrations, but not cholesterol-standardised fat-soluble antioxidant concentrations, at intakes up to 9 g/d. Am J Clin Nutr 92:24-33.</p>	<p>Raisio Nutrition Ltd</p>	<p>Noted. FSANZ has now commented on the study reported by Mensink et al (2010) in SD1. Because the studies reported by Gylling et al. (2010) and Davidson et al. (2001) were of longer duration and used similar amounts of plant sterols (as phytosterol esters) to that reported by Mensink et al (2010), FSANZ considered that the studies reported by Gylling and Davidson to be better suited to drawing conclusions about the long-term effects of plant sterols on fat-soluble vitamins and carotenoids.</p>
<p>An additional analytical method for the detection of plant sterols has been provided. US FDA researchers have published a validated method for the determination on plant sterols in different foods, which is very similar to the methods already listed in SD1. The reference is: Srigley CT, Haile EA (2015) Quantification of plant sterols in foods and dietary supplements containing added phytosterols. J Food Comp Anal 40:163-176.</p>	<p>Raisio Nutrition Ltd</p>	<p>Noted. Section 2.3 in SD1 has been updated to include this additional analytical method reference.</p>

Issue	Raised by	FSANZ response
<p>The same increase in plant sterols per portion (serve) should be made for yoghurts.</p>	<p>Raisio Nutrition Ltd</p>	<p>Noted. Extension of the increase in plant sterols per portion (serve) to yoghurts is considered out of scope</p> <p>Industry and others are free to apply at any time to amend the Code to provide such a permission for yoghurts. Any new application would need to comply with the data and other requirements of the Application Handbook and detail why such a change was justified and safe.</p>
<p>The submission noted that FSANZ's Code Revision P1025 agreed to remove tall oil phytosterol esters from the Code, but this has not occurred. It suggests that this change be made as part of this Application as it was agreed.</p>	<p>Raisio Nutrition Ltd</p>	<p>Noted. Removal of tall oil phytosterol esters permissions from the Code is considered out of scope.</p>
<p>The departments do not support the request for exclusivity to the Applicant. This is because the request is an extension of use of an already existing permission therefore they believe there has been limited investment in research and development by the Applicant to warrant such exclusivity. Such investments that would be required, ingredient costs and manufacturing technology and assets, are typical of commercial businesses and would be incorporated into new product development processes. They do not believe this demonstrates significant investment to justify exclusivity.</p> <p>The submission also notes the Higher Order Policy Principle on Novel Foods provides a regulatory environment that mentions 'encourages fair trade'. To do so the submission suggests the permissions should not be applied exclusively.</p>	<p>Victorian Departments of Economic Development, Jobs, Transport and Resources; and Health and Human Services (Vic Govt)</p>	<p>Noted. The Applicant requested exclusivity on the basis that it has invested resources in research and development to ensure higher levels of plant sterols can be uniformly incorporated into their brand of breakfast cereal without detrimental visual or flavour impacts.</p>

Issue	Raised by	FSANZ response
<p>The submission agrees with FSANZ’s observation that it is debatable whether plant sterols should be still considered novel. FSANZ should give consideration to how foods and substances can be transitioned from being considered novel to non-novel status.</p>	<p>Vic Govt</p>	<p>Noted. The comment is noted. This issue is being considered by Proposal P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods.</p>
<p>The submission supported the Application. It expressed an interest to view the evaluation and/or report after the 15 month exclusivity period prior to supporting a general permission after the exclusivity period expires.</p>	<p>Dietitians Association of Australia</p>	<p>Noted. There is no requirement to conduct a separate evaluation report after the completion of the 15-month exclusivity period is completed. The current assessment that has been performed, which is summarised in this report, deals with both the exclusivity period and the general permission.</p>
<p>The submissions support the continued use of the novel foods framework to consider future plant sterol applications, and in particular the whole of diet exposures. Continued monitoring and surveillance is warranted as more foods with added plant sterols become available as some consumers may choose to consume the full range of such products in their diet.</p> <p>The submissions support the current novel foods framework for future assessments of similar applications to facilitate ‘cautious expansion’ of foods containing added plant sterols.</p>	<p>Department of Health Western Australia</p> <p>Department of Health and Human Services Tasmania (DHHS)</p>	<p>Noted</p>
<p>The submission notes the specified nutrient criteria for this Application differ from the NPSC used for health claims. It is noted that the current specified nutrient criteria are those that currently exist in the Code and furthermore raises the issue of having multiple criteria in use for the same food category.</p>	<p>DHHS</p>	<p>Noted.</p>

2.2 Risk assessment

FSANZ performed a risk assessment on the Application (SD1); called for submissions; and has had regard to all submissions made. Amendments to SD1 reflect issues raised by submitters including consideration of a report by Mensink et al. (2010), and a clarification on the total plant sterols weight equivalents reported in the studies of Davidson et al. (2001) and Gylling et al. (2010).

Adding plant sterols at higher levels than currently permitted in breakfast cereals is concluded to be technologically feasible as methods are available to incorporate them into such foods. There are analytical methods available and specifications already in the Code for plant sterols. An additional analytical method provided in a submission has been added to the relevant section of SD1.

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).

Consuming total plant sterol equivalents 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 per day of plant sterols reduce LDL blood cholesterol concentrations by 9%. For daily doses above 3 g per 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. After adjusting for the change in total blood cholesterol concentration β -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/day of total plant sterol equivalents were tested in adults did not show statistically significant changes in fat-soluble vitamins. Clinical studies in which daily doses of up to 6 g of total plant sterol equivalents 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 total 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 9 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 per day and 3.0–5.1 g per 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 conservative estimate 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 for Australian consumers aged 2 years and above were 3.2 g/day and 6.4 g/day for the mean and P90 exposures, respectively, expressed as total plant sterol equivalents. Using this conservative approach it was predicted that about 2% of the population aged 2 years and up would be exposed to more than 9 g/day of added dietary total plant sterol equivalents, 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.

2.3 Risk management

FSANZ considered a number of risk management issues in relation to this Application, and did 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. After assessment, FSANZ has approved the new regulatory measure to allow increased concentrations of total plant sterols equivalent 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 are outlined in the following sections.

2.3.1 Basis for units for expressing concentration permitted (g/kg or g/serving)

The Risk Assessment (SD1) showed 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 identified 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 described dose-response models that reliably predicted that a daily amount 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 on a g per kg basis. This regulatory approach meant 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, no plant sterol fortified breakfast cereals have been identified 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 approved 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 Code¹⁵ 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.

2.3.2 Concentration of added plant sterols

2.3.2.1 Minimum

Based on a 30 g serving, which is at the lower end of serving sizes of breakfast cereals, FSANZ 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 accommodated the lower level of 0.5 g per serving of total plant sterol equivalents if added to breakfast cereals.

2.3.2.2 Maximum

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

The request for 2 g per serving arose from limitations of the existing permissions which allow (only) up to a maximum of 19 g per kg. This limit meant 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 2.3.4 below 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.

¹⁵ *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.

As typically only one serve of breakfast cereal is consumed per day, this situation provided little incentive for manufacturers to add plant sterols to breakfast cereals. This limitation placed 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 was 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 was 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 2.3.4). It would be difficult to achieve an average quantity of 2 g per serving if the maximum permitted amount was also set at 2 g per serving. Because there are no safety concerns relating to including an average 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, and avoids issues of potential non-compliance where the average quantity is less than the claimed amount of 2 g per serving, or exceeds the maximum permitted amount (in order to declare the efficacious amount of 2 g per serving). The risk assessment concluded that adding plant sterols to breakfast cereals at the maximum level of 2.2 g of total plant sterol equivalents per serving was safe and technologically feasible as methods are available to incorporate them.

2.3.3 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 available through this wider variety of breakfast cereals.

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

FSANZ also concluded that there were 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 2.3.4). 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 opt 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.

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 2.3.4 below).

In summary, FSANZ did not identify 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 recommended the increased concentration be permitted for all breakfast cereals (meeting existing specified nutrient criteria, excluding breakfast cereal bars).

2.3.4 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 presence of the advisory statements required on foods that contain added plant sterols as outlined in section 1.3 above will also alert consumers to the addition of phytosterols to a food to enable avoidance by non-target groups.

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 [Nutrition Profiling Scoring Criterion \(NPSC\)](#)¹⁶.

¹⁶ <http://www.foodstandards.gov.au/industry/labelling/Pages/Short-guide-for-industry-to-the-NPSC.aspx>

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’¹⁷. 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 plant sterols apply to breakfast cereals containing increased concentration of plant sterols.

2.3.5 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 to recognise the investment made in developing a novel food or ingredient and the need to achieve return on this investment, thereby supporting innovation. The Applicant had requested exclusivity on the basis they had invested significant financial resources in research, technical and regulatory arenas in support of their Application. Even though this was an expansion of a pre-existing permission the Applicant has advised that it has invested resources in research and development to ensure higher levels of plant sterols can be uniformly incorporated into their brand of breakfast cereal that do not have any detrimental visual or flavour impacts.

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.

The exclusive use permission reverts 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 the 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.

¹⁷ **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.

2.3.6 Risk management conclusion

FSANZ approved 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 plant 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 applies exclusively to the 'Sanitarium Health and Wellbeing' and 'Weet-Bix' brands during the fifteen month exclusive use period, as requested by the Applicant. The exclusive use permission reverts to a general permission after the exclusive use period expires, replacing the existing concentrations applying to breakfast cereals.

2.4 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

The related 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.

2.5 Risk communication

FSANZ developed a basic communication strategy for this Application.

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process. Public submissions were 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 are notified at each stage of the assessment.

The Board's 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.

Every submission on the Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.6 FSANZ Act assessment requirements

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

The direct and indirect benefits that are likely to arise from a food regulatory measure developed or varied as a result of the Application are likely to 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 with associated public health benefits such as improved blood lipid profiles. FSANZ has identified relatively limited additional cost to government given the minor expansion of an existing permission.

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

2.6.1.2 Other measures

There were 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.

2.6.1.3 Any relevant New Zealand standards

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

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

The Risk Assessment at SD1 concluded 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.

2.6.2.2 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 2.3.4 above. The existing labelling requirements in the Code are considered to be appropriate for breakfast cereals with increased levels of added plant sterols.

2.6.2.3 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 sought 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 serving in order to ensure 'trivial' amounts are not present.

The generic labelling requirements including for making voluntary nutrition and health claims (section 2.3.4 above) will apply to prevent consumers being misled or deceived.

2.6.3 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)¹⁸. 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 a maximum of 3 g per day of phytosterols/phytosteranols through the use of either one portion containing a maximum of 3 g, or three portions containing a maximum of 1 g¹⁹.

In the USA, the United States Food and Drug Administration 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.

¹⁸ 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.

¹⁹ <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0608>

- **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 facilitated alignment with Europe and USA as outlined above, and hence allowed for Australia and New Zealand suppliers to better compete in these markets.

This 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 draft variation is not considered to have an undue impact on fair trade. It will confer an exclusive permission on the applicant for only a relatively short period. This will recompense the Applicant for the cost of developing and implementing the technology to include higher concentrations of plant sterols. 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 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 will revert to a general permission for all nutrient qualifying breakfast cereals, thereby replacing the existing permission relating to breakfast cereals.

4 Reference

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. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved 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 – 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.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a 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 specified 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 included 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 variation 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] 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 the date of gazettal 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.