4 November 2022
[219-22]

Approval report – Application A1249

Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Sanitarium Health Food Company seeking to amend the Australia New Zealand Food Standards Code (the Code) to extend the current permissions for plant sterols to also allow the addition of phytosterols, phytostanols or their esters as a novel food to plant-based milk alternatives.

On 1 July 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 26 October 2022. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 4 November 2022.

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

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website:

SD1 Risk Assessment

Executive summary

Sanitarium Health Food Company (Sanitarium) applied to Food Standards Australia New Zealand (FSANZ) to amend Schedule 25 of the Australia New Zealand Food Standards Code (the Code) to permit the addition of phytosterols, phytostanols or their esters as a novel food to beverages derived from legumes, cereals, nuts, seeds or a combination of those ingredients. These beverages are also referred to as 'plant-based milk alternatives' in the application and in this report.

Phytosterols, phytostanols or their esters, collectively referred to as plant sterols in this report, are currently permitted to be added as a novel food to certain foods. This application is therefore an extension of a current permission to a new food matrix. Exclusive use of the permission for a period of 15 months from gazettal was requested by Sanitarium.

The purpose of the requested amendment is to provide an alternative source of plant sterols in the food supply for consumers seeking to lower their blood cholesterol.

FSANZ has undertaken an assessment to determine the feasibility of adding plant sterols to plant-based milk alternatives, the risk to public health and safety and the benefit to consumers seeking to lower their blood cholesterol, as a result of the proposed addition.

FSANZ concluded that plant sterols can be uniformly incorporated into, and are stable in, plant-based milk alternatives.

Overall, the available data for plant sterols are considered to provide a high level of confidence in the safety of plant sterol-enriched plant-based milk alternatives up to the proposed maximum concentration, for the general population.

The scientific literature provided evidence that consuming soy-based drinks with plant sterols added at levels similar to the proposed maximum concentration is likely to lower the total and LDL-cholesterol of adults with untreated hypercholesterolaemia or hyperlipidaemia. Based on the comparable nutrition composition and food matrix, FSANZ considers the efficacy of plant sterols in soy-based milk alternatives would also apply to the broader category of plant-based milk alternatives.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation on 1 July 2022 for a six-week consultation period. FSANZ received two submissions, both from government agencies, supporting the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the Code to permit the addition of plant sterols as novel food to plant-based milk alternatives. The approved draft variation amends Schedule 25 of the Code by listing new conditions of use for plant sterols, including the permitted addition to plant-based milk alternatives.

The new permission will be subject to the following compositional limits (after addition of the plant sterols):

a) the calcium content of the plant-based milk alternative is no less than 100 mg per 100 mL
b) the plant-based milk alternative contains no more than 0.75 g per 100 mL saturated fatty acids
c) the total plant sterol equivalents content of the plant-based milk alternative is no less than 0.8 g per 250 mL and no more than 2.2 g per 250 mL.

The compositional limit applying to calcium is intend to provide consumers with a comparable calcium content to cow's milk and ensure the consumption of these products will not cause an imbalance of calcium intake. Ensuring these products are also low in saturated fatty acids is of high importance to the target consumers who are seeking to lower cholesterol and understand the relationship between saturated fat intake to blood cholesterol.

The new permission will apply exclusively to plant-based milk alternatives sold under the Sanitarium Health Food Company brand for a period of 15 months commencing on the date of gazettal of the variation.

The approved draft variation will permit the proposed addition of plant sterols as novel food to plant-based milk alternatives in accordance with the Code, including existing conditions of use in the table to section S25—2 for the addition of plant sterols to food.

1 Introduction

1.1 The applicant

The applicant is Sanitarium Health Food Company (Sanitarium), a food manufacturing company.

1.2 The application

The applicant sought to amend Schedule 25 of the Australia New Zealand Food Standards Code (the Code) to permit the addition of phytosterols, phytostanols or their esters[2] (plant sterols) as a novel food to beverages derived from legumes, cereals, nuts, seeds or a combination of those ingredients. These beverages are referred to as 'plant-based milk alternatives' in the application and in this report.

The primary purpose of the requested amendment, as described in the application, is to safely improve public health by increasing the accessibility of efficacious and recommended amounts of plant sterols for consumers seeking to lower their cholesterol, a modifiable risk factor for cardiovascular disease.

The applicant sought permission for a concentration of up to 2.2 g of 'total plant sterol equivalents content' (see Section 1.3 of this report below) per 250 mL of plant-based milk alternatives, to enable 2 g per 250 mL serving to be declared without exceeding the maximum permitted limit. A lower limit of no less than 0.8 g of total plant sterol equivalents content per 250 mL serving was also proposed by the applicant, however they also stated that FSANZ may determine a lower amount for regulatory purposes.

The applicant proposed that only plant-based milk alternatives with at least 100 mg of added calcium per 100 mL and that are low in saturated fat (no more than 0.75 g of saturated fat per 100 mL) are permitted to contain added plant sterols.

The applicant did not request permission to add 'tall oil phytosterol esters' to plant-based milk alternatives.

Exclusive use of the permission for a period of 15 months from gazettal was requested by Sanitarium.

[2] Phytosterols, phytostanols or their esters are referred to as 'plant sterols' where appropriate in this report.

1.3 The current Standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted addition of plant sterols

'Novel food' is defined in section 1.1.2—8 of Standard 1.1.2.

'Novel food' means a *non-traditional food* that requires an assessment of the public health and safety considerations having regard to any of the following (see subsection 1.1.2—8(1)):

- the potential for adverse effects in humans
- the composition or structure of the food
- the process by which the food has been prepared
- the source from which it is derived
- patterns and levels of consumption of the food
- any other relevant matters.

'Non-traditional food' is defined as any of the following (see also subsection 1.1.2—8(1)):

- a food that does not have a history of human consumption in Australia or New Zealand, or
- a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food, or
- any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

For the purposes of the definition of 'novel food', neither of the following constitutes a history of human consumption in Australia or New Zealand (see subsection 1.1.2—8(2)):

- the presence of a food in a food for special medical purposes
- the use of a food as a food for special medical purposes.

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).

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 that table.

Schedule 25 currently allows for the addition of plant sterols to edible oil spreads[3], breakfast cereals[4], milk[5] and yoghurt[6], subject to meeting specific conditions of use. There are limits on the content of plant sterols that can be added to the food, expressed as 'total plant sterol

[3] In accordance with Standard 2.4.2.
[4] Not including breakfast cereal bars.
[5] In accordance with Standard 2.5.1.
[6] In accordance with Standard 2.5.3.

equivalents content'. Total plant sterol equivalents content means the total amount of:

(a) phytosterols; and
(b) phytostanols; and
(c) phytosterols and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters (subsection 1.1.2—2(3)).

All foods to which plant sterols have been added must:

- not be used as ingredients in other foods; and
- comply with labelling requirements in Standard 1.2.1 relating to the provision of advisory statements (see Section 1.3.2 of this report below).

Phytosterols, phytostanols and their esters are defined in section 1.1.2—2(3) as a substance which meets a specification for phytosterols, phytostanols and their esters in section S3—24 of Schedule 3. Subject to conditions in that specification, plant sterols added to foods for retail sale in Australia and New Zealand must comply with a monograph specification in section S3—2 or section S3—3 of Schedule 3 (further detail is provided in SD1). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has a specification titled 'Phytosterols, Phytostanols and their Esters' in its Combined Compendium of Food Additive Specifications (FAO and WHO 2008), which is a monograph specification in paragraph S3—2(1)(b).

FSANZ's approach to regulation of plant sterols as novel foods was stated in A1134 i.e. that the primary aim of assessment of plant sterols within the novel foods framework is to protect public health and safety, to enable dietary exposure to be assessed and considered, and to facilitate the careful expansion of the use of these ingredients in the food supply.

1.3.2 Labelling

The table to section S25—2 requires a food offered for retail sale which either consists of, or has as an ingredient, a plant sterol, to comply with requirements in Standard 1.2.1 insofar as they relate to section 1.2.3—2.

Advisory statements are required on foods for retail sale and foods for catering purposes that contain added plant sterols (see subsection 1.2.3—2(1) and the table to section S9—2). 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 concerned is sold from a vending machine, the advisory statements must either accompany the food; or be displayed in connection with the display of the food (subsections 1.2.1—9(2) and (3)).

If the food concerned is not sold from a vending machine and does not otherwise have to bear a label, the advisory statements must either be displayed in connection with the display of the food; or provided to the purchaser on request (subsections 1.2.1—9(6) and (7)).

Where a plant sterol is added to food as an ingredient, the plant sterol must be declared in the statement of ingredients for the food concerned in accordance with Standard 1.2.4, for example, by the name of which the plant sterol is commonly known or by a name that describes the true nature of the plant sterol (see section 1.2.4—4).

Nutrition content and health claims related to the presence of plant sterols in a food must be made in accordance with Standard 1.2.7 and Schedule 4, which set out conditions for making nutrition content and health claims in relation to food.

A nutrition content claim to the effect that the food 'contains' or 'does not contain' plant sterols, or contains a specified amount of plant sterols, may be made (see section 1.2.7—13), but the use of descriptors, such as 'high', 'low', 'reduced', are not permitted[7].

A health claim about plant sterols and reduced blood cholesterol is permitted in accordance with Standard 1.2.7 (see the tables to sections S4—4 and S4—5). In order to make such a claim about a food, the food must (among other things) meet the requirements in section S25—2 and contain a minimum of 0.8 g total plant sterol equivalents content per serving (see the tables to sections S4—4 and S4—5). The claim must include dietary context statements referring to (among other things) a diet low in saturated fatty acids and containing 2 g of phytosterols, phytostanols and their esters per day (see section 1.2.7—20). Foods carrying a health claim about plant sterols must also meet the nutrient profiling scoring criterion (NPSC)[8] (paragraph 1.2.7—18(1)(a)).

Packaged food to which plant sterols have been added would also have to comply with requirements related to nutrition information panels in Standard 1.2.8. In particular, if a nutrition content or health claim is made about plant sterols in food which is packaged food, the nutrition information panel for that food must include declarations of the amount of the substances, calculated as 'total plant sterol equivalents content'[9] (subsection 1.2.8—6(10)).

1.4 Overseas regulations and international standards

In Europe, plant sterols are specifically permitted in a wide variety of foods including rice drinks and soya drink (Regulation (EU) 2017/2470)[10]. Foods containing added plant sterols must be presented so they can be easily divided into portions that contain either a maximum of 3 g (for one portion per day) or 1 g (for three portions per day) of added plant sterols. The amount of plant sterols added to a container of beverages must not exceed 3 g.

In the USA, the United States Food and Drug Administration has raised no objection to a number of foods (including plant-based milk alternatives) that may contain plant sterols, on the basis of GRAS (generally recognized as safe) notifications. The notifications for plant-based milk alternatives are for amounts of added plant sterols ranging from approximately 0.5–1 g per serving.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of *the Food Standards Australia New Zealand 1991* (the FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

[7] A nutrition content claim that a food does nor does not contain plant sterols must not use a descriptor listed in Column 3 of the table to section S4—3; or any other descriptor (see subsection 1.2.7—13(2)).
[8] In accordance with Schedule 5 - Nutrient profiling scoring method.
[9] Refer to Section 1.3.1 above for the meaning of 'total plant sterol equivalents content'.
[10] Available at L_2017351EN.01007201.xml (europa.eu). Foods authorised to contain plant sterols under Regulation (EU) 2017/2470 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.

1.6 Procedure for assessment

The application was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

For the reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to permit the addition of plant sterols as novel food to plant-based milk alternatives.

The draft variation as proposed following assessment was approved without change. The variation takes effect on 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 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ sought public comments on the draft variation included in the call for submissions report between 1 July and 12 August 2022.

FSANZ received two submissions, both from government agencies. New Zealand Food Safety supported the draft variation and raised no issues. The submission from the Victorian Departments of Health and of Jobs, Precincts and Regions and Dairy Food Safety Victoria was also supportive of the draft variation but raised issues for consideration, as discussed in Table 1 below.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Question whether proposed drafting will adequately prevent the addition of plant sterols to unintended products such as sweetened and flavoured plant milk. Note FSANZ decided not to set a composition limit for sugar because products are expected to carry a health claim, and therefore are also expected to limit sugar content in order to meet the Nutrient Profiling Scoring Criterion (NPSC). However, under the NPSC, a protein enriched plant milk could contain up to 9 g of sugar, which would not be consistent with dietary guidelines or the objectives of plant sterol permissions. Suggest compositional sugar limits be reconsidered to prevent misleading promotion of 'cholesterol lowering' products where the composition is not consistent with health advice.	Victorian Departments of Health and of Jobs, Precincts and Regions and Dairy Food Safety Victoria	FSANZ considers the proposed permission to be appropriate and consistent with other plant sterol permissions in the Code. Current permissions for the addition of plant sterols to milk and yoghurt do not have compositional limits for sugar content. The compositional limits for saturated fatty acids and calcium directly align with the recommendations of the dietary guidelines (NHMRC, 2013; MoH 2020). The limit for saturated fatty acids also aligns with the intent of cholesterol lowering products. The nutrition assessment concluded that consumption of plant sterols at 2 g per day reduces LDL cholesterol concentrations. As this level is consistent with the permission (2.2 g per 250 mL) FSANZ does not consider the proposed drafting to portray misleading promotion of 'cholesterol lowering' products. As noted by the submitter, a plant-based milk alternative could contain up to 9 g per 100 ml of sugar under the NPSC, subject to the content of other nutrients such as protein and also the energy content. The total energy content of the food would be directly affected by increased sugar content. The NPSC takes into account the overall nutrient profile of a food. FSANZ has not identified a robust reason to single out sugar content in relation to permissions to add plant sterols to plant-based milk alternatives, over and above relying on the current application of the NPSC to plant-based milk alternatives making health claims.
Note the proposed permission introduces regulatory inconsistency which may create unequal barriers to innovation among industry sectors. The proposed maximum permitted level of added plant sterols in plant milk (2.2 g per 250 ml) is four times permissions in dairy milk (4 g per L, equivalent to 1 g per 250 mL). As they are consumed in a similar manner, the difference appears unjustified.	Victorian Departments of Health and of Jobs, Precincts and Regions and Dairy Food Safety Victoria	The permission to add total plant sterols equivalents of no less than 3 g per L and no more than 4 g per L to low fat milk was based on an application by Dairy Farmers (Application A343). It was noted in the application that the requested amount was shown to be sufficient to provide a benefit when the products (including spreads, yoghurt, breakfast bars and yoghurt) are consumed as directed, being to consume 2-3 servings per day. FSANZ's Social Science assessment (Section 6 of SD1) concluded that on average individuals are only consuming one serve (approximately 250 mL)

The Policy Guideline on the addition of substances other than vitamins and minerals states it may be necessary to review existing standards, noting the need to consider the cumulative impact of the addition of substances to multiple foods. Ongoing applications to amend plant sterol permissions and these consistency issues indicate a need to review broader plant sterol permissions. The departments would support FSANZ raising a proposal to address this matter.		of plant-based milk alternatives per day. This conclusion was further supported by the dietary exposure assessment (Section 5 of SD1). These conclusions demonstrate that plant sterol fortified foods are not consumed in a similar fashion to dairy milks. In terms of the policy guideline mentioned by the Victoria Departments, FSANZ considers that the reference to reviewing existing standards is in relation to achieving optimal public health outcomes in the context of the 'cumulative impact' of the addition of substances to multiple foods. FSANZ took this into account when considering the permission to add plant sterols to plant-based milk alternatives (see Section 2.5.3). FSANZ does not consider the risk of 'unequal barriers to industry innovation' or the point identified above from the policy guideline sufficient at this stage to justify the preparation of a proposal by FSANZ under the FSANZ Act to review broader plant sterol permissions. Anyone can however, apply to FSANZ to amend the Code to allow for industry innovation, in the same way that the applicant for this application did.

2.2 Risk assessment

The risk assessment of the addition of plant sterols to plant-based milk alternatives includes an assessment of its feasibility, potential for adverse effects, effects on blood cholesterol and other health outcomes, change in dietary exposure and consumer behaviour.

2.2.1 Technical assessment

FSANZ has reviewed information and evidence about the incorporation of plant sterols into plant-based milk alternatives and their stability in these products, particularly in relation to heating. That information and evidence indicates that plant sterols can be uniformly incorporated into, and are stable in, plant-based milk alternatives.

Based on studies of the stability of plant sterols in liquid non-fat milk products during storage and the availability of plant-based milk alternatives currently in the market overseas, FSANZ concludes that plant sterols are stable in plant-based milk alternatives over their shelf life.

2.2.2 Risk assessment

FSANZ previously concluded there are no toxicological concerns regarding consumption of plant sterol-fortified foods by the general population, and that there is no justification for establishing an acceptable daily intake (ADI) for plant sterols. A review of newly available information does not indicate a need to amend this conclusion.

As noted in previous FSANZ assessments, safety data for pregnant women, lactating women, and children under five years of age is relatively limited compared to the extensive data available for the target population. However, based on knowledge of the mechanisms of phytosterol action, the now extensive experience of use of phytosterol-enriched foods in the general population and the absence of effects in pregnant animals and their offspring, there was no basis for postulating a risk to these population sub-groups. No new data were identified that would change this conclusion. However, appropriate risk management measures may be required for individuals with phytosterolaemia[11] to enable them to identify foods containing plant sterols.

A review of the recent literature has not identified convincing evidence that the addition of plant sterols to soy-based drinks is associated with nutrition-related adverse effects in the general adult population. FSANZ did not identify evidence investigating the effects on children and other sub-groups such as pregnant or lactating women, and, therefore, the effects on these populations are unknown.

Efficacy studies demonstrate that consumption of soy-based drinks with added plant sterols is associated with lowered total and low density lipoprotein (LDL) blood cholesterol concentrations in adults with untreated hypercholesterolaemia[12] or hyperlipidaemia[13], but not in normocholesterolaemic[14] adults. The intake of plant sterols in these studies ranged from 1.6 to 2.7 g/day. The effect of plant sterols added to plant-based milk alternatives other than soy drinks was unable to be assessed due to a lack of evidence.

[11] Phytosterolaemia, also referred to as sitosterolaemia, is an extremely rare inherited metabolic disease. People with this condition absorb high levels of plant sterols which can lead to premature atherosclerosis and heart disease. People with phytosterolaemia should avoid foods with added plant sterols. Cases of phytosterolaemia are managed strictly under medical supervision.
[12] High levels of cholesterol, such as low-density lipoprotein (LDL) and total cholesterol, in the blood.
[13] High levels of lipids (fats such as cholesterol and/or triglycerides) in the blood.
[14] Normal levels of cholesterol in the blood.

Plant sterol dietary exposures for Australia and New Zealand populations were estimated, assuming the addition of plant sterols to plant-based milk alternatives at the maximum concentration of 2.2 g per 250 mL serving. Existing permissions were also considered. The resulting change in total dietary exposures to added plant sterols from baseline was an increase of 0.3 g/day or less at the mean and 90th percentile, expressed as plant sterol equivalents. For plant-based milk alternatives only, based on a concentration of 2.2 g per 250 mL serve and typical consumption patterns, mean dietary exposures for consumers would be around 2 grams on any given day and around double that for high consumers.

FSANZ has identified no substantial risks associated with potential changes to consumer behaviour as a result of the addition of plant sterols to plant-based milk alternatives on the basis of research that examined consumer understanding and use of a range of phytosterol-enriched products, including milk. Although it is possible that consumers may use multiple plant sterol-enriched products, which could lead to consumption of plant sterols beyond an adequate level of intake for cholesterol reducing effects, this does not raise public health and safety concerns. The availability of additional and diverse plant sterol-enriched products would benefit consumers by increasing the range of choice available, as well as increasing the likelihood of consumers reaching an adequate intake of plant sterols recommended for cholesterol reduction.

Overall, the available data provide a high level of confidence in the safety of plant sterol-enriched plant-based milk alternatives up to the proposed maximum concentration, for the general population. The current literature provides evidence that consuming soy-based drinks with plant sterols added at levels similar to the proposed maximum concentration is likely to lower the total and LDL-cholesterol of adults with untreated hypercholesterolaemia or hyperlipidaemia.

For further details, refer to SD1 – Risk Assessment.

2.3 Risk management

The risk management options available to FSANZ after assessment were to either:

- approve the draft variation that was set out in the earlier call for submissions
- amend and then approve that draft variation
- reject that draft variation.

For the reasons set out in this report, and having regard to all submissions received, FSANZ decided to approve the draft variation without amendment (Attachment A).

The specific risk management considerations that were relevant to this decision are discussed below.

2.3.1 Concentration of added plant sterols

2.3.1.1 Minimum

The applicant sought permission to add a minimum of 0.8 g of plant sterol equivalents content per 250 mL of plant-based milk alternative. This minimum level is similar to other minimum levels for permissions to add plant sterols within the Code, such as the addition to yoghurt which has a minimum of 0.8 g per package (<200 g). This minimum is also reflective of a requirement related to the pre-approved health claims in Schedule 4 of the Code that the food must contain a minimum of 0.8 g ‘plant sterol equivalents content’ per serve.

2.3.1.2 Maximum

The applicant sought permission to add a maximum of 2.2 g plant sterol equivalents content per 250 mL of plant-based milk alternative, in order to be able to declare an average quantity of 2 g per 250 mL serving in the nutrition information panel[15]. This maximum is consistent with the conclusions of the risk assessment (Section 4 of SD1) and FSANZ (2014) Systematic Review of the Evidence for a Relationship between Phytosterols and Blood Cholesterol which note intakes of approximately 2 g per day reduces LDL cholesterol concentrations. Permitting 2.2 g plant sterols per 250 mL of plant-based milk alternative would allow consumption of the efficacious daily amount of plant sterols to be more readily achieved through a single serve of plant-based milk alternatives, as per dietary guideline recommendations.

As noted above in Section 2.2.2, FSANZ assessed the efficacy of plant sterols in soy-based milk alternatives only, due to a lack of data for other plant-based milk alternatives. Based on the comparable nutrition composition and food matrix, FSANZ considered the efficacy of plant sterols in soy-based milk alternatives would also apply to the broader category of plant-based milk alternatives.

The risk assessment concluded that there are no public health or safety concerns with the addition of plant sterols to plant-based milk alternatives at the maximum level of 2.2 g per 250 mL. As noted above, the applicant sought to declare an average quantity of 2 g plant sterols per 250 mL of plant-based milk alternatives. It would be difficult to achieve an average quantity of 2 g per 250 mL if the maximum permitted amount is also set at 2 g per 250 mL. Given there are no safety concerns related to including a slight overage amount, the approved draft variation allows for a maximum permitted amount of 2.2 g of total plant sterol equivalents per 250 mL rather than 2 g. The overage also allows declaration of the efficacious amount as an average quantity. It further 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 daily amount of approximately 2 g on a per 250 mL serving basis.

This maximum also aligns with FSANZ's most recent permission for plant sterol addition to breakfast cereals (Application A1134 – Plant sterols in breakfast cereals) which allows a maximum of 2.2 g per serving.

Enabling dietary exposure at an efficacious amount of approximately 2 g total plant sterol equivalents content from one serve of plant-based milk alternatives 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).

Plant sterols are currently permitted to be added to breakfast cereal, yoghurt, milk, edible oil spread including margarine and processed cheese. The basis for each permission differs depending on the specific food class, for example, the total plant sterol equivalents content permitted to be added to milk is on a per litre basis (3 – 4 g per L of milk) whereas for breakfast cereals, the permission is on a per serving basis (0.5 – 2.2 g per serving). For plant-based milk alternatives the approved draft variation will permit the addition of plant sterols on a per 250 mL basis. This is the typical serving size of plant-based milk alternatives recommended by manufacturers as shown by Zhang (2020) and as recommended by dietary guidelines (NHMRC, 2013; MoH 2020). The 250 mL basis provides control of the

[15] The dietary context statement for a health claim must refer to (among other things) the diet containing 2 g of phytosterols, phytostanols and their esters per day (see Section 1.3.2 above).

concentration of plant sterols that may be present in the plant-based milk alternatives irrespective of the serving size. As the serving size of plant-based milk alternatives is however, not as variable as it is for products such as breakfast cereals, FSANZ considered the basis of 250 mL (rather than a per serving basis) will still allow consumers to achieve the efficacious amount of approximately 2 g per day from one serving.

The findings of the Social Science assessment (section 6 of SD1) align with the above approach. The Social Science assessment concluded that consumers are most likely to consume a plant sterol enriched plant-based milk alternative via a single 250 mL serve if this was the consumers' original habit regarding plant-based milk alternatives. This is further supported by the dietary exposure assessment (section 5 of SD1) which concluded that the mean exposure to plant sterols from plant-based milk alternatives would range between 1.2 – 2.0 g/day for Australians aged two years and above and New Zealand adults aged 15 years and above. Consumption data presented in the dietary exposure assessment indicates that on any single consumption day, individuals are only consuming one serve (approximately 250 mL) of plant-based milk alternatives per day (a mean of between 217 and 242 g/day for the Australian and New Zealand population groups assessed).

Based on the risk assessment, a substantial proportion of users of plant-based milk alternatives also have the potential to consume plant-based milk alternatives in the serving size that the applicant recommends, therefore reaching the efficacious intake level in one serve. The applicant noted that plant sterol enriched plant-based milk alternatives are likely to be offered at a price premium. A higher price point associated with the plant sterol enriched version of plant-based milk alternatives is likely to discourage non-target consumers, excessive consumption and equivalent use in contexts where plant-based milk alternatives are the predominant ingredient. These factors also lessen the possibility of use within a household by non-target consumers and beyond the amounts recommended. Other permissions within the Code that permit the addition of plant sterols on a per kg or per L basis are based on the assumption that individuals consume up to 2-3 serves per day. However, due to the increased price point and discrete group of individuals who consume plant-based milk alternatives, the consumption of two to three 250 mL serves per day of plant sterol enriched plant-based milk alternatives is not expected.

Based on the above rationale, FSANZ considered it most appropriate to permit the addition of plant sterols up to 2.2 g per 250 mL of plant-based milk alternative.

2.3.2 Food matrix and nutrient criteria

The applicant sought an extension of the existing permissions to add plant sterols to certain foods, to permit the addition of plant sterols to plant-based milk alternatives. The approved draft variation uses the wording 'beverages derived from legumes, cereals, nuts or seeds or a combination of those ingredients'. This is consistent with the food matrix suggested by the applicant and with the wording currently used in the Code for the permissions allowing fortification of plant-based milk alternatives with vitamins and minerals (the table to S17—4).

The application also noted that the regulatory change is to allow the addition of plant sterols to plant-based milk alternatives in alignment with dietary guidelines (NHMRC, 2013; MoH 2020).

Australian and New Zealand dietary guidelines recommend consumption of plant-based milk alternatives that are appropriately enriched with calcium and the Australian dietary guidelines note that plain milks are preferable (NHMRC, 2013; MoH 2020). FSANZ therefore considered limiting the permission to unflavoured or plain plant-based milk alternatives. In the interests of minimal effective regulation, FSANZ considered that to limit increased fortification permissions to 'unflavoured' plant-based milk alternatives only would be

unnecessary and could be difficult to interpret and apply to particular products. Flavourings are typically added to ‘plain’ plant-based milk alternatives to aid the flavour profile and make acceptable to the consumer across a variety of uses. Excluding products based on added flavours could also exclude ‘plain’ plant-based milk alternatives and in turn limit the number of products available to target consumers.

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 plant-based milk alternatives will be a niche product and marketed accordingly to the relevant population groups. A mandatory advisory statement (refer to Section 1.3.2 above) will, for example, indicate the product is not targeted to children under five 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 purchasing by consumers other than those for whom there will be a benefit. As noted above (Section 2.3.1.2) it is unlikely that these products will be consumed more broadly within households due to a higher price point.

The approved draft variation requires that plant sterol enriched plant-based milk alternatives are subject to specific compositional criteria. These include limits on calcium and saturated fatty acids content in alignment with dietary guidelines. Dietary guidelines recommend consuming calcium-enriched varieties of plant-based milk alternatives that are not sweetened and limiting the intake of foods high in saturated fat and added sugars (NHMRC, 2013; MoH 2020).

The calcium content of the plant-based milk alternatives must be no less than 100 mg calcium per 100 mL and the saturated fatty acids content must be no more than 0.75 g per 100 mL. These limits are consistent with the limits requested by the applicant except that the applicant suggested a minimum of 100 mg of ‘added’ calcium. FSANZ has required a total content of calcium rather than just the added amount to avoid the need to determine what was added and what was naturally present, for ease of implementation and enforcement. The calcium content would provide consumers with a comparable calcium content to cow’s milk and ensure the consumption of these products will not cause an imbalance of calcium intake. FSANZ noted it is common practice for key nutrients such as calcium to be declared in the nutrition information panel on plant-based milk alternatives.

Ensuring these products are also low in saturated fat is of high importance to the target consumers as they will be invested in lowering cholesterol and understanding the relationship between saturated fat intake to blood cholesterol. No more than 0.75 g saturated fatty acids per 100 mL is consistent with the conditions for a ‘low saturated fatty acid’ claim (see the table to section 4-3 of Schedule 4). It is also consistent with the requirement for a dietary context statement to the effect of a ‘diet low in saturated fat’ to be included with a health claim about plant sterols and blood cholesterol (as required by Schedule 4, see Section 1.3.2 above). It will also be mandatory for saturated fatty acids levels to be stated on the nutrition information panel of the product (see Section 2.3.3 of the report below).

FSANZ also considered a limit on the sugar content. Given the costs associated with adding plant sterols to products it seems highly likely they will carry a health claim and in turn will need to meet the NPSC which already takes into account sugar content. 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. Only products that meet the NPSC would be eligible to make health claims regarding plant sterols. Further detail about why a limit on sugar content was not imposed is included in Table 1 in Section 2.1 above.

In summary, FSANZ considered the food matrix and nutrient criteria specified above to be appropriate for plant-based milk alternatives containing added plants sterols.

2.3.3 Labelling relating to foods containing added plant sterols

The existing requirements in the Code for the labelling and advertising of foods containing added plants sterols (refer Section 1.3) will apply to plant-based milk alternatives containing added plant sterols.

Declarations of plant sterols in the statement of ingredients and nutrition information panel would enable consumers, including those with the rare inherited disorder phytosterolaemia (sitosterolaemia) (see Section 3.1 of SD1), to identify and monitor their consumption of plant sterols.

With regard to consumers' ability to identify recommended intakes of plant sterols, FSANZ considers adequate information would be provided through the declaration of plant sterols in the nutrition information panel. While this declaration is only required if a nutrition content or health claim about plant sterols is made (see subsection 1.2.8—6(10)), it would seem unlikely for a manufacturer to add them to a plant-based milk alternative without then wishing to declare their presence.

2.3.4 Exclusivity

An applicant may request that permission applies exclusively to the applicant for a specified period of time. In this application, the applicant requested exclusive use of the permission to add plant sterols to plant-based milk alternatives for a period of 15 months from the date of gazettal (subject to endorsement by the Food Ministers' Meeting of the approved draft variation). The applicant identified their financial and resource investment in research and development to qualify product feasibility as well as regulatory investment to submit the application as reasons for granting exclusivity.

The approved draft variation provides that the permission to add plant sterols to plant-based milk alternatives applies exclusively to the Sanitarium Health Food Company brand for a period of 15 months commencing on the date of gazettal of the variation, as requested by Sanitarium. This recognises the financial investment made by the applicant in research and development related to the application, as identified by the applicant. Existing regulations will apply to all other brands of plant-based milk alternatives until the end of this exclusive use period.

The exclusive use permission will revert to a general permission after the exclusive use period expires.

An exclusive use permission in the Code 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 same use of the same novel food by other food companies, providing the application process is undertaken. The approved draft variation will not change this.

2.3.5 Conclusion

The approved draft variation to the Code will permit the addition of plant sterols as a novel food to plant-based milk alternatives (Attachment A) subject to the following compositional limits:

(a) the calcium content of the plant-based milk alternative is no less than 100 mg per 100 mL
(b) the plant-based milk alternative contains no more than 0.75 g per 100 mL of saturated fatty acids
(c) the total plant sterol equivalents content of the plant-based milk alternative is no less than 0.8 g per 250 mL and no more than 2.2 g per 250 mL.

The new permission could only be exercised in accordance with the Code, including existing conditions of use in the table to S25—2 for the addition of plant sterols to food.

The new permission will apply exclusively to plant-based milk alternatives sold under the Sanitarium Health Food Company brand for a period of 15 months commencing on the date of gazettal of the variation, as requested by the applicant.

Plant sterols have been associated with lowered total and LDL blood cholesterol concentrations in adults. Approving the application will provide an alternative source of plant sterols in the food supply for those consumers interested in lowering their cholesterol through plant sterol consumption, especially those consumers who are seeking plant-based products.

2.4 Risk communication

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this application (OBPR correspondence dated 19 April 2022, OBPR ID:22-02151). This exemption was provided as the OBPR assessed the proposed change is deregulatory and the likely impacts to only have a minor effect on consumers, businesses and government. FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29 (2)(a)).

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). The analysis considered amending Schedule 25 to permit the addition of plant sterols as novel food to plant-based milk alternatives.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the

assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the addition of plant sterols as a novel food, to plant-based milk alternatives.

Costs and benefits of permitting the addition of plant sterols as novel food to plant-based milk alternatives

Sterol-enriched plant-based milk alternatives up to the proposed maximum concentration, are safe for the general population. These products are likely to lower the total and LDL-cholesterol of adults with untreated hypercholesterolaemia or hyperlipidaemia. Consumers interested in the cholesterol lowering benefit of plant sterols will be able to access them in an alternative form that may better meet their needs.

Due to the voluntary nature of the permission, manufacturers will only use it where they believe a net benefit exists for them. That is, if they believe there is sufficient demand for products with these attributes and it is possible to make a profit supplying them. The change also has the potential to facilitate international trade.

Beyond making compliance officers aware of the new permission, there are no additional costs to government in making the change, beyond the normal costs of enforcing compliance with the Code.

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the addition of plant sterols to plant-based milk alternatives most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than the approved draft variation.

2.5.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ undertook a risk assessment (SD1 and as summarised in Section 2.2 of this report) and concluded that the available data for plant sterols provide a high level of confidence in the safety of plant sterol-enriched plant-based milk alternatives up to the approved maximum concentration, for the general population.

2.5.2.2 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 Sections 1.3.2 and 2.3.3 of this report above. The existing labelling requirements in the Code will apply to plant-based milk alternatives with added plant sterols to assist consumers to make informed choices.

2.5.2.3 The prevention of misleading or deceptive conduct

The existing labelling requirements applying to foods containing added plant sterols will apply to plant-based milk alternatives containing added plant sterols (Section 1.3.2 above), as well as existing requirements for voluntary nutrition content and health claims if these claims are made about plant sterols. Additionally, under the approved draft variation, if plant sterols are added to plant-based milk alternatives, a 250 mL serving must contain at least 0.8 g of total plant sterol equivalents content. These conditions all apply to prevent misleading or deceptive conduct.

2.5.3 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 applicant submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was used in assessing the application.

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

There are no international food standards directly relevant to this application. Plant sterols added to foods for retail sale in Australia and New Zealand must meet the internationally recognised international specification, the JECFA specification titled Phytosterols, Phytostanols and their Esters (refer Section 1.3.1 above).

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

Permission to add plant sterols to plant-based milk alternatives would facilitate alignment with Europe and USA as outlined in Section 1.4 above. As identified by the applicant, there are some plant-based milk alternatives currently on the market in Europe.

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

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

The exclusive use provision would recompense the applicant for the cost of research and development to qualify product feasibility as well as regulatory investment to submit the application. This advantage however, will cease at the end of the exclusive use period to then enable all manufacturers of plant-based milk alternatives that meet the specified nutrient criteria to add plant sterols to those products in accordance with the Code.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

FSANZ must have regard to any written policy guidelines formulated by the Australia and New Zealand Ministerial Forum on Food Regulation[16] (the Forum[17]). There are two policies relevant to this application:

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

FSANZ has had regard to these two policy guidelines as detailed in the following sections. In addition, the high order principles in both guidelines reflect FSANZ's statutory objectives in subsections 18(1) and 18(2) in the FSANZ Act. FSANZ's assessment in relation to these objectives is described in Sections 2.5.1, 2.5.2 and 2.5.3 above.

Policy Guideline on Novel Foods

The 'Ministerial Council Policy Guidelines on Novel Foods' also includes the high order principle *'be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion'*. With respect to that principle, FSANZ considers the addition of plant sterols to plant-based milk alternatives is consistent with national nutrition policies in Australia and New Zealand that recommend consumption of calcium enriched plant-based milk alternatives and diets that limit saturated fat intake (NHMRC, 2013; MoH 2020). Increased availability of plant sterols through the food supply would provide interested consumers with greater choices for increasing dietary exposures to plant sterols.

The Specific Principles in this guideline are:

- To ensure that public and industry confidence in the food system is maintained.
- To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.
- To ensure consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.

Following assessment as outlined in this report and SD1, FSANZ has determined that permitting the addition of plant sterols as novel food to plant-based milk alternatives is consistent with the above Specific Principles.

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

The 'Policy Guideline Addition to Food of Substances other than Vitamins and Minerals'[18] includes Specific Order Policy Principles for substances added for a technological function as well as for any other purpose. This application falls under 'any other purpose' and therefore regard has been given to these policy principles in the assessment of this application. These specific order policy principles state that the addition of substances other than vitamins and minerals to food should be permitted where:

a) the purpose for adding the substance can be articulated clearly by the manufacturer (i.e. the 'stated purpose')
b) the addition of the substance to food is safe for human consumption
c) the substance is added in a quantity and a form which is consistent with delivering the

[16] Available at Food Regulation - Food policies (accessed 27 April 2022).
[17] Now known as the Food Ministers' Meeting.
[18] Available on the Food regulation website (accessed 11 April 2022).

stated purpose
d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population
e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.

Following assessment as outlined in this report and SD1, FSANZ has determined that permitting the addition of plant sterols as novel food to plant-based milk alternatives is consistent with the above principles. In particular, principle (a) and (e) are addressed within Section 1.3.2 of this report and principles (b), (c), (d) in Section 2.1 of this report, or in more detail within SD1.

This policy guideline also includes a section on implementation. The points under that section are covered as outlined above and in the table 1 in Section 2.1 of this report.

3 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

FSANZ (2014) Systematic Review of the Evidence for a Relationship between Phytosterols and Blood Cholesterol. Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/publications/Documents/EU%20health%20claims%20reviews/Systematic%20review%20phytosterols%20and%20cholesterol.pdf

MOH (2020) Eating and Activity Guidelines for New Zealand Adults: Updated 2020. Wellington: Ministry of Health.

NHMRC (2013) Australian Dietary Guidelines. Canberra: National Health and Medical Research Council. Canberra, Australia.

Zhang YY, Hughes J, Grafenauer S (2020) The Emerging Role of Australian Plant-Based Milk Alternatives as A Cow's Milk Substitute. 2020, 12, 1254; doi:10.3390/nu12051254

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 A1249 – Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives) Variation

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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 Delegate]

[Delegate's name and position]
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 A1249 – Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives*) *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

Schedule 25—Permitted novel foods

[1] Section S25—2 (table item dealing with 'Phytosterols, phytostanols and their esters', column 2)

Add:

7. May only be added to a beverage derived from legumes, cereals, nuts, seeds, or a combination of those ingredients if, after that addition, each of the following compositional limits are met:
   (a) the calcium content of the beverage is no less than 100 mg per 100 mL; and
   (b) the beverage contains no more than 0.75 g saturated fatty acids per 100 mL; and
   (c) the total plant sterol equivalents content of the beverage is no less than 0.8 g and no more than 2.2 g per 250 mL of the beverage.
8. During the exclusive use period, a beverage to which phytosterols, phytostanols and/or their esters have been added in accordance with condition 7 above may only be sold under the brand SANITARIUM HEALTH FOOD COMPANY.
9. For the purposes of condition 8 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1249 – Addition of phytosterols, phytostanols or their esters to plant-based milk alternatives) 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.

The Authority accepted Application A1249 which seeks approval for the addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved the draft variation amending Schedule 25 of the Code to permit the addition of phytosterols, phytostanols or their esters as a novel food to plant-based milk alternatives, subject to certain conditions.

4. Documents incorporated by reference

The approved draft variation itself does not incorporate any documents by reference.

However, section 1.1.1—15 of the Code requires certain substances (such as a novel food) to comply with any relevant identity and purity specifications listed in Schedule 3. Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2019).

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1249 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 1 July 2022 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this application (OBPR correspondence dated 19 April 2022, OBPR ID:22-02151). This exemption was provided as the OBPR assessed that the proposed change would be deregulatory and the likely impacts to only have a minor effect on consumers, businesses and government.

6. 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 44 of the *Legislation Act 2003*.

7. Variation

Item [1] of the Schedule to the approved draft variation amends Schedule 25 by adding three new conditions of use for phytosterols, phytostanols and their esters into the table to section S25-2.

The table to section S25-2 sets out permitted novel foods and their conditions for use.

Specifically, the new conditions of use (numbered 7 to 9) are included, in numerical order, in column 2 for the table item dealing with phytosterols, phytostanols and their esters.

New condition 7 permits the addition of phytosterols, phytostanols and their esters to a beverage derived from legumes, cereals, nuts, seeds, or a combination of those ingredients only if, after the addition, the following compositional limits are met:

- the calcium content of the beverage is no less than 100 mg per 100 mL; and
- the beverage contains no more than 0.75 g saturated fatty acids per 100 mL; and
- the total plant sterol equivalents content of the beverage is no less than 0.8 g and no more than 2.2 g per 250 mL of the beverage.

New condition 8 provides that a beverage to which phytosterols, phytostanols and/or their esters have been added in accordance with new condition 7 may only be sold under the brand SANITARIUM HEALTH FOOD COMPANY during the exclusive use period.

New condition 9 defines 'exclusive use period' for the purposes of new condition 8 as meaning:

> "the period commencing on the date of gazettal of the *Food Standards (Application A1249 – Addition of phytosterols, phytostanols or their esters to plant-based milk alternatives) Variation* and ending 15 months after that date."

The effects of the approved draft variation are that:

- phytosterols, phytostanols and their esters may be added, as novel food, to beverages derived from legumes, cereals, nuts, seeds, or a combination of those ingredients, subject to compositional limits;
- the new permission can only be exercised in accordance with the Code, including existing conditions of use in the table to S25—2 for the addition of plant sterols to food;
- beverages to which phytosterols, phytostanols and their esters have been added in accordance with new condition 7 may only be sold under the SANITARIUM HEALTH FOOD COMPANY brand for a 15-month period commencing on the date of gazettal of the approved draft variation.

Existing regulations will apply to all other brands of plant-based milk alternatives until the end of the exclusive use period.

Once the exclusive use period ends, the exclusive use permission will revert to a general permission. This means that the new permission for the addition of phytosterols, phytostanols and their esters as novel food to beverages derived from legumes, cereals, nuts, seeds, or a combination of those ingredients, will then apply to *all* brands of those beverages that meet the specified compositional limits.