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412–26

Call for submissions – Application A1326

Addition of phytosterols, phytostanols and their esters as a novel food to bread

Food Standards Australia New Zealand (FSANZ) has assessed an application made by George Weston Food Limited, trading as Tip Top Bakeries, to amend the Australia New Zealand Food Standards Code to permit the addition of phytosterols, phytostanols and their esters as a novel food to bread.

On the basis of this assessment, FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the [Consultation Hub](#).

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [Making a submission](#). For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 27 October 2026

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

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Supporting document

The following document which informed the assessment of this application are available on the [A1326 page](#) on the FSANZ website:

SD Risk and technical assessment

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by George Weston Food Limited, trading as Tip Top Bakeries, to amend the Australia New Zealand Food Standards Code (the Code) to permit the addition of phytosterols, phytostanols and their esters (collectively referred to as plant sterols) as a novel food to bread, at levels up to 2.2 g per serving. The proposed amendment would provide an additional source of plant sterols for consumers seeking to lower their blood cholesterol. During the assessment, the applicant agreed that 'bread' captures the scope of the permission requested. Accordingly, the risk and technical assessment, and this report, relate to the addition of plant sterols to bread.

Plant sterols are 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 - bread offered for retail sale.

FSANZ has undertaken an assessment to determine the feasibility of adding plant sterols to bread, the risk to public health and safety and the effect on consumers seeking to lower their blood cholesterol.

The food technology assessment concluded plant sterols can effectively be incorporated into bread and remain stable. Plant sterols as a novel food must comply with relevant identity and purity specifications in the Code when added to food offered for retail sale in accordance with the Code or sold for use in such food.

The risk assessment concluded plant sterols can be safely added to bread at the proposed levels and that bread is an effective vehicle for delivering plant sterols to assist in lowering blood cholesterol concentrations.

Following assessment, for the reasons set out in this report, FSANZ has prepared a draft variation to permit plant sterols to be added as a novel food to bread offered for retail sale at levels up to 2.2 g per serving (or sold for such use). If approved, the draft variation would amend the Code by:

- including a new condition in the entry for 'Phytosterols, phytostanols and their esters' in the table to section S25—2, providing that phytosterols, phytostanols and their esters only be added to bread in accordance with Standard 2.1.1, and
- including a new provision in Standard 2.1.1 stating that plant sterols may be added to bread only if all of the following conditions are met:
 - the bread contains no less than 2 g dietary fibre per serving
 - the bread contains no more 380 mg sodium per 100 g
 - the total plant sterol equivalents content (as defined in subsection 1.1.2—2(3)) is no less than 0.8 g per serving and no more than 2.2 g per serving.

The table to section S25—2 also sets out conditions of use that apply to plant sterols as a novel food and, consequently, if the draft variation is approved—would also apply to plant sterols when added to bread offered for retail sale.

If approved, the effect of the draft variation would permit the addition of plant sterols as a novel food to bread offered for retail sale (or sold for such use) in accordance with the Code (including, but not limited to, the conditions listed above).

FSANZ now seeks submissions on the draft variation of the Code.

1 Introduction

1.1 The applicant

The applicant is George Weston Foods Limited, trading as Tip Top Bakeries (Tip Top), a food manufacturing company.

1.2 The application

Tip Top has applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the addition of phytosterols, phytostanols and their esters (collectively referred to as plant sterols) as a novel food to bread at levels up to 2.2 g per serving¹. During the assessment, the applicant agreed that 'bread' captures the scope of the permission requested. Accordingly, the risk and technical assessment, and this report, relate to the addition of plant sterols to bread.

According to the application, the purpose of the amendment is to improve public health by providing an additional source of plant sterols in the food supply for consumers seeking to lower their blood cholesterol, a modifiable risk factor for cardiovascular disease.

The concentration proposed to be added was up to 2.2 g of 'total plant sterol equivalents' per serving of bread, with a lower limit of no less than 0.8 g of total plant sterol equivalents per serving.

Tip Top also proposed only bread containing at least 2 g of dietary fibre per serving and no more than 380 mg of sodium per 100 g be permitted to contain added plant sterols.

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 as novel food

Novel food

'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,

¹ One serving of bread is equivalent to two slices of bread, one bread roll or one English muffin.

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, and
- does not include a cell-cultured food (as defined in subsection 1.1.2—2(3)).

For the purposes of the definition of ‘novel food’, the following do not constitute 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 presence of a food in a special medical purpose product for infants,
- the use of a food as a food for special medical purposes,
- the use of a food as a special medical purpose product for infants.

Current novel food permissions for plant sterols

Paragraphs 1.1.1—10(5)(b) and (6)(f) of the Code provide that food for retail sale must not be, or have as an ingredient or a component, novel food unless expressly permitted by the Code.

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.

The table to section S25—2 in Schedule 25 lists certain foods offered for retail sale to which plant sterols are permitted to be added subject to meeting specific conditions of use.

Bread is not included in that table. For most food offered for retail sale listed in the table to section S25—2 to which plant sterols are permitted to be added, there are limits on the content of plant sterols that can be added to the food, expressed as ‘total plant sterol equivalents content’. Total plant sterol equivalents content means the total amount of all of the following:

- (a) phytosterols;
- (b) phytostanols;
- (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 mandatory advisory statements (see section 1.3.2 of this report).

‘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.

FSANZ’s approach to regulation of plant sterols as novel foods was included in the assessment for Application A1134. This is, 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.

Regulation of bread

Subsection 1.1.2—3(2) defines 'bread' as meaning:

- a food that is made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water, or
- such a food with other foods added.

Division 2 of Standard 2.1.1 contains requirements specifically for bread and bread products.

Section 2.1.1—3 requires a food that is sold as 'bread' to be bread.

Sections 2.1.1—5 and 2.1.1—6 contain compositional requirements specifically for bread and wheat flour that is sold as suitable for making bread. However, according to section 2.1.1—4, those requirements do not apply to:

- bread that is represented as organic,
- other food listed in paragraph 2.1.1—4(a), for example, pizza bases, breadcrumbs, pastries and biscuits,
- wheat flour used to make the food listed in paragraph 2.1.1—4(a).

If a food (including bread) sold as, or as being made from, 'wholemeal' or 'wholegrain'—section 2.1.1—7 requires that food to consist of, or have as an ingredient, wholemeal or wholegrain as appropriate.

1.3.2 Identity and purity requirements

Section 1.1.1—15 of the Code requires that, when added to a food in accordance with the Code, or sold for use in a food, a substance that is a novel food must comply with any relevant identity and purity specification set out in Schedule 3 of the Code.

There is a specification for phytosterols, phytostanols and their esters in section S3—24, with which plant sterols must comply when added to food offered for retail sale in accordance with the Code, or sold for use in such food. Subsection S3—24(1) requires plant sterols to comply with a monograph specification from either a primary source (section S3—2) or, if there is no relevant specification from a primary source under section S3—2, a specification from a secondary source (section S3—3). That requirement is subject to the following conditions:

- for a mixture which contains no less than 950 g/kg of phytosterol and phytostanols—the concentration of hexane, isopropanol, ethanol, methanol or methyl ethyl ketone either singly or in combination must be no more than 2 g/kg (subsection S3—24(2)), and
- the total plant sterol equivalents² content must contain no less than 95% des methyl sterols (subsection S3—24(3)).

There are 2 relevant primary source specifications listed in section S3—2 of Schedule 3 – the Joint Food and Agriculture Organization (FAO)/World Health Organisation (WHO) Expert Committee on Food Additives (JECFA) in its Combined Compendium of Food Additive

² **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)).

Specifications (FAO JECFA Monograph 5 for Phytosterols, Phytostanols and their Esters (FAO/WHO 2008)), and the Food Chemicals Codex (FCC) specification for Vegetable Oil Phytosterol Esters (USP 2024).

Schedule 3 of the Code also includes specifications for arsenic, lead, cadmium and mercury (section S3—4) if they are not already detailed within specifications in sections S3—2 or S3—3. The FAO JECFA specification for Phytosterols, Phytosterols and their Esters has specifications for arsenic and lead, and the FCC specification has specifications for lead.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements in the Code for that food.

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 (mandatory advisory statements).

Advisory statements made in accordance with subsection 1.2.3—2(1) are required for foods for retail sale and foods sold to a caterer that contain added plant sterols (see subsection 1.2.3—2(1) and the table to section S9—2). The advisory statements must indicate all of the following:

- a) when consuming the product, it should be consumed as part of a healthy diet;
- b) the product may not be suitable for children under 5 years and pregnant or lactating women;
- 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 (subsection 1.2.1—9(2) and paragraph 1.2.1—9(3)(d)).

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 for retail sale 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, or a combination of the previous two claims, may be made (see subsection 1.2.7—13(1)), but the use of descriptors such as ‘high’, ‘low’ and ‘reduced’ are not permitted³.

³ 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, except a descriptor that indicates that the food does not contain the property of food (see subsection 1.2.7—13(2)).

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). 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, phytosterols 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)⁴ (paragraph 1.2.7—18(1)(a)).

Packaged food offered for retail sale to which plant sterols have been added would also have to comply with requirements related to nutrition information panels in Standard 1.2.8. If a nutrition content or health claim is made about plant sterols in such food, the nutrition information panel for that food must include (among other things) declarations of the amount of the substances, calculated as ‘total plant sterol equivalents content’⁵ (subsection 1.2.8—6(10)).

1.4 International and overseas requirements

1.4.1 International

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). There is no Codex Standard for novel foods, including for plant sterols and their addition to foods.

1.4.2 Overseas requirements

There are relevant overseas requirements for the addition of plant sterols to bread in Europe and USA. In Europe, plant sterols are permitted in a wide variety of foods including for rye bread, along with compositional requirements for rye, wheat, sugar and fat content (EU 2017/2470). 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 3 portions per day) of added plant sterols.

In the USA, the United States Food and Drug Administration has raised no objection to a number of foods, including bread and baked goods including bread rolls, pastries, pies, cookies and cake that may contain added plant sterols in the form of phytosterols esters and diglycerides, on the basis of GRAS (generally recognized as safe) notifications (US FDA GRN 206). The notifications for bread baked goods and baking mixes are for amounts of added plant sterols ranging from approximately 0.65g reference amounts consumed per eating occasion (RACC), and for baked goods a 1.3% plant sterol use level.

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 Act 1991* (the FSANZ Act).
- it related to a matter that warranted the variation of a food regulatory measure.

⁴ In accordance with Schedule 5 - Nutrient profiling scoring method

⁵ Refer to footnote 5 for the meaning of ‘total plant sterol equivalents content’.

1.6 Procedure for assessment

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

2 Summary of the assessment

During the assessment, the applicant agreed that 'bread' captures the scope of the permission requested. Therefore, the risk and technical assessments were confined to 'bread'

2.1 Food technology assessment

FSANZ completed a food technology assessment to confirm identity and purity, methods of analysis, the feasibility of incorporating plant sterols into bread, and their stability.

There is an identity and purity specification for phytosterols, phytostanols and their esters provided in section S3—24 of the Code. If the draft variation at Attachment A is approved, plant sterols being added to bread and offered for retail sale, or sold for use in such food, would need to comply with that section, and the relevant primary sources specifications listed in subsection S3—2 i.e. the FAO JECFA specification for sterols, phytostanols and their esters (FAO/WHO 2008) and the FCC specification for vegetable oil phytosterol esters (USP 2024).

Suitable analytical methods are available to identify and quantify added plant sterols in food matrices, including bread.

Esterification of plant sterols facilitates their incorporation into various foods, including bread. The food technology assessment indicates that plant sterols can be effectively incorporated and uniformly distributed in bread using commercially available preparations.

Based on previous FSANZ assessments on plant sterol use in other foods, their availability domestically and in overseas markets, and information reviewed for this assessment, FSANZ concludes plant sterols are expected to be stable in bread.

2.2 Risk assessment

The risk assessment identified no new evidence to alter FSANZ's previous conclusions that the addition of plant sterols to certain foods raises no safety concerns for the general population. Absorption of plant sterols from the diet is very low.

Consumption of plant sterols is associated with reductions in circulating concentrations of some fat-soluble vitamins and carotenoids, however, concentrations remain within normal reference ranges. Previous assessment by FSANZ (see section 3.2 and 3.3 of the SD) concluded that consumption of up to approximately 9 g/day of total plant sterol equivalents based on the highest amount assessed in the available evidence is unlikely to pose a safety concern for children or adults.

The toxicological assessment concluded that the available evidence did not justify establishing an ADI for plant sterols.

The dietary exposure assessment indicates the addition of plant sterols to bread will increase exposure among consumers. An increase in mean and P90 dietary exposures from the baseline were estimated to be 2.6 g/day or less, and 4.9 g/day or less, respectively. Estimated dietary exposures to plant sterol equivalents including the extension of use ranged between 4.1 and 5.2 g/day at the mean and 7.4 to 9.6 g/day for high exposures for all

population groups assessed. Estimated dietary exposures are consistent with levels associated with cholesterol-lowering effects and when considered with the available toxicological data and evidence for nutritional effects, do not raise safety concerns. Evidence from a randomised controlled trial and a recent meta-analysis found that plant sterols delivered in bread are associated with reductions in total cholesterol and low-density lipoprotein cholesterol concentrations (LDL-C), consistent with previous FSANZ assessments in other food matrices.

FSANZ concludes that plant sterols can be safely added to bread at the proposed levels and that bread is an effective vehicle for delivering plant sterols to assist in lowering blood cholesterol concentration.

2.3 Risk management

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

- reject the application, or
- prepare a draft variation of the Code.

For the reasons set out in this report, FSANZ decided to prepare a draft variation to the Code (Attachment A) to permit the addition of plant sterols as a novel food to bread. If approved, the proposed permission would be subject to compliance with certain conditions when added as a novel food to bread offered for retail sale under the Code (or sold for use in such food).

Further details on the proposed permission and associated proposed conditions are provided below.

2.3.1 Food matrix

The applicant requested permission for the use of plant sterols in bread and bread products. The definition for 'bread' in section 1.1.2—3 of the Code means:

- a food that is made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water; or
- such a food with other foods added.

'Bread products' are not defined in the Code.

During the assessment, the applicant agreed that 'bread' as defined in the Code captures the food they are seeking permission for. The proposed draft variation therefore refers only to 'bread', not bread products.

2.3.2 Concentration of added plant sterols

2.3.2.1 Minimum concentration

The applicant has applied to amend the Code to permit a minimum concentration of 0.8 g of plant sterol equivalents content per serving of bread. The requested minimum level reflects other permissions for plant sterols in the Code and the pre-approved health claims requirement in Schedule 4 of the Code, which specifies that a food must contain a minimum of 0.8 g of total plant sterol equivalents content per serving for certain health claims to be made.

Based on the above rationale, FSANZ considers it appropriate to require the addition of a minimum concentration of 0.8 g of total plant sterol equivalents content per serving when plant sterols are added to bread.

2.3.2.2 Maximum concentration

The applicant has applied to amend the Code to permit a maximum concentration of 2.2 g of total plant sterol equivalents content per serving of bread. The requested maximum level would enable a declaration of an average quantity of 2 g of plant sterol equivalents per serving in the nutrition information panel⁶, which aligns with the dietary intake associated with cholesterol-lowering effects. It could be difficult to achieve an average quantity of 2 g per serving if the maximum permitted amount is also set at 2 g per serving. The overage of 0.2 g per serving would assist in avoiding issues of non-compliance of either misleading declarations (if the average quantity present is less than that declared) or exceeding the maximum permitted amount to declare the efficacious daily amount of approximately 2 g per serving.

FSANZ's risk assessment concluded the addition of plant sterols to bread at 2.2 g per serving does not pose public health or safety concerns and would allow consumers to achieve a daily intake of plant sterols associated with significant reductions in total cholesterol and LDL-C concentrations through a single serving (see section 4 of the SD). The proposed maximum level is consistent with existing permissions in the Code for the addition of plant sterols to plant-based milk alternatives⁷ and breakfast cereals⁸.

Based on the above rationale, FSANZ considers it appropriate to permit the addition of plant sterols up to and including 2.2 g of total plant sterol equivalents content per serving of bread.

2.3.3 Nutrient criteria

The addition of plant sterols is likely to be accompanied by a health claim, given the cost of ingredient incorporation and the nature of the proposed permission. Foods carrying health claims must meet the NPSC, which helps ensure products containing plant sterols have an appropriate nutritional profile. This requirement supports the use of plant sterols in foods that align with broader public health objectives and healthy dietary patterns.

The applicant proposed that plant sterol-enriched bread is subject to specific compositional criteria. These include a minimum fibre content and a limit on sodium content in alignment with dietary guidelines (NHMRC, 2013; MoH, 2020).

- The fibre content of the bread must be no less than 2 g per serving. Ensuring bread with added plant sterols contain adequate amounts of fibre is of importance to the target consumers as a diet high in fibre can help lower cholesterol levels and reduce the risk of cardiovascular disease (NHMRC, 2013). This amount is consistent with the conditions for a 'source of fibre' content claim in the Code (see the table to section 4-3 of Schedule 4).
- The sodium content of the bread must be no more than 380 mg per 100 g. Bread with added plant sterols that is not high in sodium contributes to lowering blood pressure, which when combined with cholesterol management, provides greater protection against cardiovascular disease (NHMRC, 2013). This amount is consistent with the reformulation target for leavened breads in the Healthy Food Partnership Reformulation Program⁹.

⁶ 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.

⁷ Approved under application A1249 – Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives.

⁸ Approved under application A1134 – Increased concentration of plant sterols in breakfast cereals.

⁹ The Healthy Food Partnership Reformulation Program involved the Australian Government working with food companies to gradually reduce sugar, sodium and saturated fat in some processed and manufactured foods and drinks. The program is voluntary for food companies.

Based on the reasons set out above, FSANZ considers the nutrient criteria specified above to be appropriate for bread containing added plant sterols.

2.3.4 Effects of total plant sterol consumption

FSANZ considered the estimated dietary exposure across all food categories with permitted use, including the additional exposure arising from the expansion of permissions for plant sterols in the Code. Bread is a commonly consumed food and dietary guidelines in Australia and New Zealand recommend that adults (the population group likely to consume bread containing added plant sterols) consume between 3 and 6 serves of grain (cereal) foods per day (NHMRC, 2013; MoH, 2020).

While the addition of plant sterols to bread is expected to increase the dietary exposure for Australian and New Zealand consumers of plant sterol containing products, the consumption of more than one serving of bread containing plant sterols, or consumption in combination with other foods containing plant sterols, does not pose a public health and safety risk.

Dietary exposures for high consumers of plant sterol equivalents were estimated to be 7.4 g/day for Australian adults, 9.1 for New Zealand children and 9.6 g/day for New Zealand adults in the extension of use scenario (see section 3.3.3.1 of the SD). The dietary exposure assessment is based on conservative assumptions that all bread contains added plant sterols at the proposed maximum level (2.2 g per 76 g serve), and that all other foods currently permitted to contain added plant sterols under the Code (breakfast cereals, yoghurt, cheese and plant-based milk alternatives) contain plant sterols at their maximum permitted levels. FSANZ's risk assessment concluded that while consumption of plant sterols is associated with reductions in circulating concentrations of some fat-soluble vitamins and carotenoids, these changes do not reflect adverse effects on nutrient status. The risk assessment found that at intakes of up to 9 g/day of added plant sterols, although reduced circulating carotenoid concentrations are observed, there is no measurable effect on Vitamin A status (see section 3.2.2 and 3.2.3 of the SD). The effects of intake levels above 9 g/day have not been assessed in the currently available studies. However, the risk assessment concluded that there is no justification for an ADI due to the low systemic absorption of plant sterols and their efficient elimination from the body (see section 3.1.3 of the SD).

The risk of excess consumption of plant sterols is also mitigated through the advisory statement required on foods that contain added plant sterols, indicating that plant sterols do not provide additional benefits when consumed in excess of 3 g/day (see section 1.3.3 of this report). In addition, the applicant noted that plant sterol enriched bread is likely to be offered at a price premium. This is likely to discourage non-target consumers and excessive consumption.

2.3.5 Labelling

The existing requirements in the Code for the labelling and advertising of foods containing added plant sterols (see section 1.3) would apply to bread 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 the SD), to identify and monitor their consumption of plant sterols.

In addition, mandatory advisory statements made in accordance with subsection 1.2.3—2(1) would inform consumers about the need to consume the plant-sterol enriched bread as part of a healthy diet; the bread may not be suitable for children under 5 years and pregnant or

lactating women; and plant sterols do not provide additional benefits when consumed in excess of 3 grams per day.

Regarding consumers' ability to identify recommended intakes of plant sterols, FSANZ considers adequate information would be provided through the declaration of specified information related to 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)), FSANZ considers that manufacturers adding plant sterols to bread would be highly likely to declare their presence through a nutrition content or health claim, therefore triggering the declaration requirement.

2.3.6 Conclusion

FSANZ is proposing to permit the addition of plant sterols as a novel food to bread subject to all of the following compositional limits:

- (a) the bread contains no less than 2 g dietary fibre per serving,
- (b) the bread contains no more than 380 mg sodium per 100 g,
- (c) the total plant sterol equivalents content of the bread is no less than 0.8 g per serving and no more than 2.2 g per serving.

The compositional requirements and amount of plant sterols per serving align with what the applicant has proposed. The amount of plant sterols per serving allows for variability in serving size within the product category so manufacturers can comply with the compositional requirements and permission for the amount of total plant sterols.

If approved, the proposed 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 as a novel food to food offered for retail sale; and existing labelling provisions.

If approved, the permitted addition of plant sterols in bread would provide an alternative source of plant sterols in the food supply for those consumers seeking to lower their cholesterol through plant sterol consumption.

2.4 Risk communication

2.4.1 Consultation

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

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, FSANZ's digital channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

2.4.2 World Trade Organization

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

As stated in section 1.4.1, there are no relevant international standards and amending the Code to permit the addition of plant sterols to bread is unlikely to have a significant effect on international trade as their addition would be voluntary and an extension of existing permissions to add plant sterols to certain foods to a new food - bread.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

FSANZ has assessed that a Regulation Impact Statement is not required for this application. This is because the proposed permission to add plant sterols, as a novel food, to bread is determined to be safe and considered to be minor in impact or deregulatory in nature, as their use will be voluntary if the draft variation is approved.

FSANZ, however, had 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 consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the extension of a current permission to a new food - bread offered for retail sale

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

Costs and benefits of permitting the addition of plant sterols, as a novel food, to bread as proposed

Consumers interested in the cholesterol lowering benefit of plant sterols will be able to access them in an alternative form that may better suit their needs.

Due to the voluntary nature of the permission, manufacturers will only use it where they believe a net benefit exists for them.

Permitting the proposed extension of plant sterols might result in a small, inconsequential cost to government in terms of an addition to the current range of novel foods that are already monitored for compliance.

Conclusion of costs and benefits

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the addition of plant sterols, as a novel food, to bread as proposed are likely to outweigh the

associated costs.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only 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 3 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 (SD and summarised in section 2.2 of this report) and concludes the available data for plant sterols provide a high level of confidence in the safety of plant sterols added to bread up to the proposed 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 1.3.3 and 2.4.5 of this report. The existing labelling requirements in the Code would apply to bread 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 bread containing added plant sterols (sections 1.3.3 and 2.4.5 of this report), as well as existing requirements for voluntary nutrition content and health claims if these claims are made about plant sterols.

Under the proposed draft variation, if plant sterols are added to bread, a serving must contain certain levels of dietary fibre and sodium and 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 (SD) which formed the basis of the risk analysis. The applicant submitted scientific studies as part of the application. This, together with 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 specifications, the FAO JECFA specification, Phytosterols, Phytosteranols and their Esters and FCC specification (section 1.3.1).

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

If approved, the proposed permission to add plant sterols to bread would facilitate alignment with Europe and USA as outlined in section 1.4 above. As identified by the applicant, bread containing added sterols is currently on the market in Europe and USA. The recommended approach would also allow for innovation in plant sterol enriched foods and increased market opportunities.

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

If approved, the addition of plant sterols in bread would enable all manufacturers of bread 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 Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation¹⁰). There are 2 policies relevant to this application:

- Policy Guidelines on Novel Foods¹¹
- Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals¹²

FSANZ has had regard to these policy guidelines as detailed below. In addition, the high order principles in both guidelines reflect FSANZ's statutory objectives in subsections 18(1) and 18(2) of 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 bread as proposed is consistent with national nutrition policies in Australia and New Zealand. 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.

¹⁰ [Ministerial policy guidelines | Food Regulation](#)

¹¹ [Policy guideline on novel foods | Food Regulation](#)

¹² [Policy guideline for the fortification of foods with vitamins and minerals | Food Regulation](#)

- 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 the SD, FSANZ has determined that permitting the proposed addition of plant sterols as novel food to bread would be consistent with the above 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' 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 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 SD, FSANZ has determined that permitting the addition of plant sterols as novel food to bread, as proposed, would be consistent with the above specific order policy principles. In particular, principle (a) and (e) are addressed within sections 1.3.3 and 2.3.5 of this report, and principles (b), (c) and (d) are addressed in sections 2.1 and 2.2 of this report, and in more detail in the SD.

3 Draft variation

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

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

Attachments

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

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



Food Standards (Application A1326 – Addition of phytosterols, phytostanols and their esters as a novel food to bread) 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 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 A1326 – Addition of phytosterols, phytostanols and their esters as a novel food to bread) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 2.1.1—Cereal and cereal products

[1] At the end of Division 2

Add:

2.1.1—6A Compositional requirement for phytosterols, phytostanols and their esters in bread

*Phytosterols, phytostanols and their esters may be added to bread only if:

- (a) the bread contains no less than 2 g dietary fibre per serving; and
- (b) the bread contains no more than 380 mg sodium per 100 g; and
- (c) the *total plant sterol equivalents content is no less than 0.8 g per serving and no more than 2.2 g per serving.

Schedule 25—Permitted novel foods

[2] Section S25—2 (table, item dealing with **Phytosterols, phytostanols and their esters*, column headed *Conditions of use*)

Add:

- 10. May only be added to bread in accordance with Standard 2.1.1.

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1326 – Addition of phytosterols, phytostanols and their esters as a novel food to bread) Variation

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 A1326 which seeks to permit the addition of phytosterols, phytostanols and their esters as a novel food to bread and bread products. During assessment, the applicant confirmed that ‘bread’ as defined in the Code captures the food matrix they are seeking permission for. FSANZ has therefore proposed permission to add plant sterols to ‘bread’ but not bread products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1326 – Addition of phytosterols, phytostanols and their esters as a novel food to bread) Variation* (the draft variation).

2. Variation will be a legislative instrument

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

If approved, this instrument would not be subject to the disallowance or sunset 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 sunset 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 sunset 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 Food Ministers Meeting (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 prepared the draft variation amending Standard 2.1.1 and Schedule 25 of the Code to permit the addition of phytosterols, phytosteranols and their esters as novel food to bread offered for retail sale, subject to certain conditions and in accordance with the Code.

4. Documents incorporated by reference

The draft variation 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 and the United States Pharmacopeial Convention (2024) Food chemicals codex, 14th ed.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1326 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a 6-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A regulation impact statement (RIS) has not been prepared. FSANZ's assessment is that a RIS is not required for this application. This is on the basis that the application is minor and deregulatory in nature. Also, the application seeks to permit the use of a novel food currently used in other foods and found to be safe and, if the draft variation concerned is approved, that use will be voluntary.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to 'variation' in this section are references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1326 – Addition of phytosterols, phytosteranols and their esters as a novel food to bread) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of

the instrument.

Schedule to the variation

Item [1] of the Schedule to the variation would amend Standard 2.1.1 of the Code.

Standard 2.1.1 is a Standard for cereal and cereal products. This Standard contains requirements, including compositional requirements, specifically for bread and bread products (Division 2) and food sold as wholemeal or wholegrain product (Division 3).

Item [1] would add new section 6A at the end of Division 2 of this Standard. New section 6A sets out compositional requirements for phytosterols, phytostanols and their esters in bread and provides that phytosterols, phytostanols and their esters may be added to bread *only if* all of the following conditions are met:

- (a) the bread contains no less than 2 g dietary fibre per serving;
- (b) the bread contains no more than 380 mg sodium per 100 g;
- (c) the total plant sterol equivalents content is no less than 0.8 g per serving and no more than 2.2 g per serving.

‘Phytosterols, phytostanols and their esters’ and ‘total plant sterol equivalents content’ are defined in section 1.1.2—2 of the Code.

Item [2] of the Schedule to the variation would amend Schedule 25 of the Code.

Paragraphs 1.1.1—10(5)(b) and (6)(f) of the Code provide that food for retail sale must not be, or have as an ingredient or a component, novel food unless expressly permitted by the Code.

‘Novel food’ is defined in section 1.1.2—8 of the Code.

Subsection 1.5.1—3(1) of the Code provides that despite paragraphs 1.1.1—10(5)(b) and (6)(f), a food offered for retail sale (other than an infant formula product) may consist of, or have as an ingredient, a novel food if:

- (a) the novel food is listed in the table to section S25—2; and
- (b) any conditions of use specified in the corresponding row of that table are complied with.

The table to section S25—2 lists permitted novel food and their associated conditions of use for the purposes of section 1.5.1—3 of the Code.

Item [2] would amend the entry for phytosterols, phytostanols and their esters in that table by adding a new condition of use for that entry.

The new condition of use would be numbered ‘10’ and would state ‘May only be added to bread in accordance with Standard 2.1.1.’.

As stated above, new section 2.1.1—6A in Standard 2.1.1 sets out compositional requirements for phytosterols, phytostanols and their esters in bread (see **item [1]** above)

If the draft variation is approved—the effect of **item [2]** would be that phytosterols, phytostanols and their esters may be added, as novel food, to bread offered for retail sale *only if* the conditions listed in proposed new section 2.1.1—6A are met.

However, if the draft variation is approved—existing requirements in the Code, which would be relevant to bread offered for retail sale to which phytosterols, phytostanols and their esters have been added, would also apply to that bread. For example, according to the table

to section S25—2, *all foods* offered for retail sale to which phytosterols, phytostanols and their esters have been added must:

- not be used as ingredients in other foods; and
- comply with labelling requirements in Standard 1.2.1 of the Code (Requirements to have labels or otherwise provide information) relating to the provision of mandatory advisory statements in accordance with Standard 1.2.3 of the Code (Information requirements – warning statements, advisory statements and declarations).

Concluding comments

If approved, the effect of the draft variation would be that phytosterols, phytostanols and their esters may be added, as novel food, to bread offered for retail sale in accordance with the Code.