



APPLICATION

January 2025

TO:

Food Standards Australia New Zealand

IN RELATION TO:

Application to amend *Schedule 25 – Permitted Novel Foods* of the Australia New Zealand Food Standards Code

Extension of use to permit up to 2.2g per serve of plant sterols in bread & bread products.

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ADMINISTRATIVE INFORMATION

(As per section 3.1.1 B of the Application Handbook as at 1 July 2024)

Applicant Details

(As per section 3.1.1 B of the Application Handbook as at 1 July 2024)

Applicant	██████████ Sustainability & Nutrition Manager
Organisation	George Weston Foods Limited trading as Tip Top Bakeries® (Tip Top)
Address: office & postal	Office & Postal Level 2, Building A, 11 Talavera Road, North Ryde NSW 2113
Telephone	██████████
Email address	████████████████████
Primary contact	██████████ ████████████████████ ██████████

Nature of Business

(As per section 3.1.1 B of the Application Handbook as at 1 July 2024)

Tip Top® is a division of George Weston Foods Limited (GWF).

GWF is one of Australia and New Zealand's largest food manufacturers employing more than 6,000 people across 43 manufacturing sites, including a significant presence in regional areas. Additionally, we have a broad supply chain of businesses that we partner with to deliver our products.

Our products are diverse and include leading brands such as Tip Top, Abbott's Bakery, Burgen, Golden, Big Ben, Dad's Pies, DON Smallgoods, Yumi's. Through our MAURI business, we are one of Australia's leading suppliers of flour, bakery ingredients and animal foods. We support parts of the local operations for other brands on behalf of our parent company.

GWF is a wholly owned subsidiary of Associated British Foods Plc (ABF), a diversified international food, ingredients, and retail group with operations in 52 countries across Europe, Southern Africa, the Americas, and Asia Pacific.

This application relates to the products marketed by Tip Top under the Tip Top 9 Grain, Tip Top English Muffins, Abbott's Bakery and Burgen brands.

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Details of other parties associated with the Application

(As per section 3.1.1 B of the Application Handbook as at 1 July 2024)

The following Scientific and Regulatory Consultant is involved in the preparation, submission, and stewardship of this application:

[REDACTED]

1. Application Information

Terminology

For the purpose of this application document phytosterols, phytostanols and their esters, will be referred to collectively as plant sterols.

Status of Similar Applications

(As per Section 3.1.1 D of the Application Handbook as at 1 July 2024)

Tip Top is not aware of any similar current applications.

Assessment Procedure

(As per section 3.1.1 F of the Application Handbook as at 1 July 2024)

Tip Top seeks to proceed with an **unpaid** for consideration as a General Procedure, Level 2 (maximum total variable hours: 290 hours).

Confidential commercial information [CCI]

(As per section 3.1.1 G of the Application Handbook as at 1 July 2024)

Tip Top is providing information to support this application which it considers to be confidential commercial information (CCI).

This information is provided separately and clearly labelled as CCI.

Other confidential information

(As per section 3.1.1 H of the Application Handbook as at 1 July 2024)

This application does include any other confidential information, aside from the confidential commercial information noted above. This information is provided separately with the CCI information.

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Exclusive capturable commercial benefit [ECCB]

(As per section 3.1.1 I of the Application Handbook as at 1 July 2024)

This application will **not** confer an exclusive capturable commercial benefit (ECCB) for Tip Top or any other individual company.

The permission to voluntarily add plant sterols to bread and bread products would be available to all manufacturers.

Although the manufacturers of plant sterols may derive some economic benefit from approval of the application, other food manufacturers who use plant sterols may also derive some economic benefit.

In addition, there are several different manufacturers of plant sterols and therefore the economic benefit would be spread and not be exclusive.

Statutory declaration

(As per section 3.1.1 K of the Application Handbook as at 1 July 2024)

A statutory declaration has been provided with this application.

Checklist

(As per section 3.1.1 L of the Application Handbook as at 1 July 2024)

Completed checklists for sections 3.1.1 (General requirements), 3.2.1 (General Information to support the proposed labelling change) and 3.5.2 (Novel Foods) and of the Application Handbook are provided with this application.

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2. Purpose of the Application

(As per section 3.1.1 C of the Application Handbook as at 1 July 2024)

Tip Top is making this application to request an amendment to the *Australia New Zealand Food Standards Code* (hereafter, the Code) to extend the permitted use of plant sterols to bread and bread products to deliver an average 2g of total plant sterol equivalents per serving. The total maximum requested is 2.2g per serve.

This application is an extension of a current permission to a new food matrix.

The proposed amendment will provide 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.

Bread has the meaning defined in the Code - [Standard 1.1.2-3](#):

bread means:

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

The application is **not** requesting the ability to add 'tall oil phytosterol esters' to bread and bread products.

The following is provided as an example of the changes that would achieve the purpose of this Application.

S25 – 2 Sale of novel foods	
Permitted Novel Food	Conditions of use
*Phytosterols, phytosteranols and their esters	May only be added to bread and bread products as defined in Standard 2.1.1 – Cereal and cereal products if: (a) the dietary fibre content is no less than 2g/serve (contains); and (b) the sodium content is no more than 380mg/100g; and (c) the *total plant sterol equivalents content is no less than 0.8g per serving and no more than 2.2g per serving.

*Note: * as defined in Standard 1.1.2 – Definitions used throughout the Code*

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3. Justification for the Application

(As per section 3.1.1 D of the Application Handbook as at 1 July 2024)

3.1 Need for the Proposed Change

(As per section 3.1.1 D(a) of the Application Handbook as at 1 July 2024)

The requested amendment will increase the accessibility to efficacious and recommended amounts of plant sterols for consumers seeking to lower their cholesterol, a modifiable risk factor for cardiovascular disease (CVD).

CVD remains a leading cause of morbidity, mortality, and health care expenditure in Australia and with 6.7% of the populations suffering CVD (AIHW, 2024; Blakey et al, 2019). In 2021 CVD cost the Australian health system approximately 14.3 billion dollars (AIHW 2024) and a recent study estimated that by 2029 this could exceed 61.8 billion dollars (Marquina et al, 2022).

In New Zealand, 180,000 people are currently living with heart disease.¹

Elevated blood cholesterol is recognised as a modifiable risk factor for CVD (NVDPA, 2012; NHF AU, 2024; NHF NZ, 2024). Based on blood tests taken as part of Australia's most recent national health survey, 32.8% or 5.6 million Australians had abnormal or high total cholesterol levels (ABS, 2013).

Approximately one in four New Zealand adults need to manage their cholesterol levels for their heart health.²

A recent review noted the typical Western diet provides only ~300mg of plant sterols and that, for patients not requiring pharmaceutical interventions, clinicians ought to recommend consumption of foods fortified with plant sterols for the cholesterol lowering benefits (Barkas et al, 2023).

The proposed change will provide Australian and New Zealand consumers who are interested in cholesterol lowering the choice of accessing the proven cholesterol lowering effects of plant sterols in a daily staple – bread and bread products.

¹ <https://www.heartfoundation.org.nz/statistics#1>, accessed 10/01/2025.

² <https://www.hri.org.nz/health/learn/risk-factors/risk-factors-for-cardiovascular-disease>, accessed 10/01/2025

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3.2 Advantages of the Proposed Change

(As per section 3.1.1 D(b) of the Application Handbook as at 1 July 2024)

3.2.1 Bread and bread products as the delivery vehicle

Bread and bread products are an appropriate vehicle for delivering plant sterols to consumers for the following reasons:

- a) Grain (cereal) foods are recommended by the *Australian Dietary Guidelines*³ and the *Eating and Activity Guidelines for New Zealand Adults*⁴
- b) Nutrition profile of bread and bread products proposed to contain sterols will deliver dietary fibre and meet a sodium target of 380mg/100g, and
- c) Plant sterol enriched bread and flour products are an effective vehicle for plant sterols.

Dietary Guidelines

The *Australian Dietary Guidelines* aim to promote the benefits of healthy eating, not only to reduce the risk of diet-related disease, but also to improve community health and wellbeing (NHMRC, 2013).

The *Australian Dietary Guidelines* and the *Australian Guide to Healthy Eating* (AGHE)⁵ provide up-to-date advice about the amounts and kinds of foods that are needed for health and wellbeing. The recommendations are based on scientific evidence, developed after looking at good quality research.

Guideline 2 of the *Australian Dietary Guidelines* recommends enjoying a wide variety of nutritious foods from five food groups every day.

Grain (cereal) foods, mostly wholegrain and/or high cereal fibre varieties, such as breads, cereals, rice, pasta, noodles, polenta, couscous, oats, quinoa, and barley are listed as one of the five food groups.

The *Eating and Activity Guidelines for New Zealand Adults* Eating Statement 1 recommends:

Enjoy a variety of nutritious foods every day including grain foods, mostly whole grain, and those naturally high in fibre and includes the following statement:



grain foods, mostly whole grain and those naturally high in fibre

Whole grains provide dietary fibre, vitamins and minerals. Eating whole grains is linked with a lower risk of heart disease, type 2 diabetes, weight gain and bowel cancer.

- Examples of healthy grain foods include whole grain bread, whole grain cereals like oats (porridge), brown rice, wholemeal pasta and noodles, and whole grain couscous.

³ [The Australian Dietary Guidelines | Australian Government Department of Health and Aged Care](#)

⁴ [Eating and activity guidelines – Health New Zealand | Te Whatu Ora](#)

⁵ [Australian guide to healthy eating | Eat For Health](#)

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Nutrition profile

The bread and bread products that the applicant proposes to contain plant sterols will meet the following criteria:

- (a) the dietary fibre content of the bread or bread product no less than 2g/serve (contains), and
- (b) the sodium content of the bread or bread product no more than 380mg/100g.

The bread and flour products containing plant sterols will contain whole grains.

100% of Tip Top Bakeries bread product display a Health Star Rating (HSR) on pack.

Bread Consumption

Bread and bread products are widely consumed, providing plant sterols in an 'everyday staple' product.

Within the bakery category, packaged bread over-indexes on a frequency consumption of 4-6 times per week, meaning that it is an integral part of consumers diets.

Bread is most commonly consumed at lunch (50%) of people who eat lunch include bread in their meal. It is also commonly consumed at breakfast (36%) giving consumers ample opportunity throughout the day to consume.

25% of people expect to be eating more specialty health bread in the next 12 months. (Foster et al, 2020)

Effective vehicle for plant sterols

Plant sterol's cholesterol lowering effects occur in a wide range of food and liquid formats/matrices (Ras, 2014; Trautwein, 2018).

Plant sterols have demonstrated their cholesterol lowering effects when delivered via bread and cereal products (Clifton et al, 2004, Makran et al, 2022). A clinical trial showed that bread and cereal products fortified with plant sterols resulted in a change to the participant's plasma phytosterols and up to 6.5% reduction in serum LDL-C (Clifton et al, 2004).

3.2.2 Consumer Choice

Current regulations limit the choice for consumers interested in the cholesterol lowering benefits of plant sterols.

Currently available plant sterol enriched products in Australian and New Zealand include margarines, breakfast cereal, reduced fat dairy milk and most recently, plant-based milk alternatives.

An audit of the websites of the two major grocery retailers in Australia (Woolworths and Coles) and New Zealand (Woolworths and New World) conducted by the Applicant in December 2024 found that plant sterol enriched product choices are more limited than what is possible under the Code.

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The full details of the audit are set out in Appendix 1 - Plant sterol enriched products available in Australian and New Zealand Audit – December 2024.

Key findings:

- There is one plant sterol enriched ready to eat cereal product available with 2g phytosterols in one serve.
- Plant sterol enriched margarine:
 - three brands of in Australia - one brand had multiple pack sizes, and flavour variants, each with 0.8g phytosterols per serve.
 - two brands were identified in New Zealand, also with 0.8 grams phytosterols per serve.
- Two dairy milk products were identified - containing 0.8g phytosterol per 250ml serve.
- No plant sterol enriched cheese or plant sterol enriched yoghurt products were identified.
- A plant-based beverage from oat milk was available containing 1.0g/250mL serve.

The proposed change would support further diversification of plant sterol enriched product choices available to consumers and provide a cost effective and convenient way to achieve recommended daily amounts of plant sterols in one serve of a bread or bread product.

The expectation that consumers purchase and consume multiple serves of plant sterol enriched products daily (or a combination of serves of multiple products) is likely to be unrealistic. Indeed, surveys have shown this including the *2008 EFSA Report Consumption of Food and Beverages with Added Plant Sterols in the European Union* which stated:

“It is clear that only a small proportion of consumers eat two or more products with added plant sterols during the same day even with an expanding range of products available on the market”.

and as an example, they stated,

“During the German survey products from five different food categories were available on the market, yet only 1- 2% consumed three products or more during the same day.” (EFSA, 2008).

The same report concluded:

“In general, there seems so far to be little over-consumption of food products with added plant sterols, rather some consumers don’t eat enough of the products to gain a real benefit.”

These findings were re-iterated in 2015 via a monitoring survey on consumer purchase behaviour of foods with added plant sterols in UK, Germany, France, Netherlands, Belgium, and Greece, which gathered data from 80,825 households. The median plant sterol intakes ranged from 0.11 to 0.30 g/d for all purchasers, from 0.26 to 0.37 g/d for occasional purchasers (purchased less than monthly) from 0.91 to 1.44 g/d for regular purchasers (purchased at least once a month) and are hence well below recommended intakes (Ras, 2017). This survey also demonstrated consumption above recommended 3 grams per day was rare, only occurring in 2.5% of purchasing households in the UK and Belgium.

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Previously FSANZ has concluded:

“There is no evidence that consumers of plant sterol enriched products consume too much – the reverse appears to be true” (FSANZ, 2006):

The FSANZ survey found that adults who used plant sterol enriched spreads used them differently to those who did not use sterol enriched spreads. They tended to use less spread on bread and toast. This is consistent with a health-based motivation that may be linked to reduction in fat intake more generally. Based on reported levels and frequency of plant sterol enriched spread use, it is likely that a proportion of consumers will not receive enough plant sterols through their current consumption of enriched spreads on bread and toast.

These results indicate current intakes of plant sterols from enriched spreads are below the optimal intake recommended for cholesterol reduction. As this could be due to the nature of the food vehicle itself, the availability of additional plant sterol-enriched products will increase the range of choice for consumers. Several post-market monitoring reports from European countries indicate however that increased product availability is not linked to excess consumption of plant sterols. Recent data collected in the UK across the major phytosterol-enriched products provide additional evidence that products are more likely to be under-consumed.

In 2017 FSANZ noted:

The proposal for enabling dietary exposure to an efficacious amount of 2g total plant sterol equivalents from one serve of food was further supported by Australian and New Zealand national nutrition survey consumption data that reflect relatively low levels of consumption of other plant sterol fortified foods (refer SD1, section 5). (FSANZ, 2017, A1134)

In the Approval Report for A1249, 2022 FSANZ stated:

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.

The proposed change to enable bread and bread products to deliver up to 2.2 grams of plant sterols in a serve, will provide users of these products the convenience and assurance they can meet daily recommended amounts of plant sterols and benefit more optimally from their cholesterol lowering properties.

A serve bread or bread products is feasible to consume at one meal occasion or across multiple meal occasions over the day as part of a healthy diet.

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The applicant considers the current inability to add plant sterols to bread and bread products due to the absence of permission in the Code is a barrier to innovation. Specialty bread is one of the sub-categories within the bakery category with increasing consumer demand - 25% of consumers expect to be eating more specialty health bread in the future. Extending the use of plant sterols to bread and bread products will enhance consumer choice.

3.2.3 Convenience

The requested amendment to enable bread and bread products to deliver up to 2.2g of plant sterols per serve, will provide consumers of these products the convenience and assurance that they can meet daily recommended amounts of plant sterols in one single serve daily and benefit more optimally from their cholesterol lowering properties.

One serve is feasible to consume at one meal occasion or across multiple meal occasions over the day as part of a healthy diet.

Table 1 provides a summary of the serving sizes for the bread and bread products covered by this application.

Table 1: Tip Top Bakeries Bread and Bread Product Serving Sizes⁶

Bread or Bread Product	Serving Size	Serving Size (g) Range
Bread	2 slices	74g – 84g (2 slices)
Bread roll	1 roll	55g – 87g (1 roll)
English muffin	1 muffin	67g (1 muffin)

Overall, bread products are an appropriate format and category to deliver and/or contribute towards the recommended 2g of plant sterols daily to lower cholesterol as part of a healthy diet. A sterol enriched bread with up to 2.2g per serve of plant sterols would provide a feasible and convenient option for consumers to achieve the required 2g each day.

3.2.4 Recommended amount of plant sterols

2 – 3 g of plant sterols daily is recommended

The Heart Foundation of Australia recommends adult Australians with high absolute risk of CVD, benefit from the cholesterol-lowering effect of consuming phytosterols naturally occurring in plant foods and from phytosterol enriched foods. Therefore, the Heart Foundation recommends they do the following:

1. Consume 2–3 g of phytosterols per day from margarine, breakfast cereal, reduced fat yoghurt or reduced fat milk enriched with phytosterols.
2. Consume phytosterols within a health balanced diet low in saturated and trans-fat and high in oily fish, wholegrains, fruits, and vegetables (NHF AU, 2017).

⁶ Tip Top Bakeries website (<https://www.tiptop.com.au/our-range/>)

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The New Zealand Heart Foundation note the following:

Eating foods that contain plant sterols as part of a balanced diet can help to reduce 'bad' cholesterol. Eating 2 grams of plant sterols everyday can help to lower cholesterol by around 9%. If you've been prescribed medication to lower your cholesterol, like a statin, it's important that you continue to take your medication alongside taking plant sterols.

Eating foods with plant sterols added, or taking a supplement is only effective if you do it regularly.

Plant sterols may be best for people trying to lower their cholesterol. They should be taken as part of a heart-healthy diet with healthy fats, whole grains, vegetables, fruit, legumes, nuts, and seeds.⁷

Schedule 4 – Nutrition, health and related claims of the Code permit the high-level health claim that:

**Phytosterols, phytostanols and their esters reduces blood cholesterol*

in the context of a “diet low in saturated fatty acids containing 2 g of *Phytosterols, phytostanols and their esters per day”.

ANZ Food Regulation

Schedule 9 - Mandatory advisory statements of the Code requires the following:

“A food that contains added phytosterols, phytostanols or their esters must also state ...(c)plant sterols do not provide additional benefits when consumed in excess of 3 grams per day.” (ANZFSC, S-4)

Up to 2.2g of plant sterols in a single serve of bread is consistent with previous FSANZ guidance.

The outcome from the two most recent phytosterol related Application - [A1134](#) - *Increased Concentration of Plant Sterols in Breakfast Cereals (2017)* and [A1249](#) – *Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives (2022)* - have resulted in changes to the Code that allows for these products to deliver 2g per serve, based on serve sizes of available breakfast cereals and plant-based milk alternatives.

These outcomes are consistent with the FSANZ commentary published in 2006 that recognized the benefits to the consumer of single serve products with required amounts to lower cholesterol (FSANZ, 2006):

Some phytosterol-enriched products available in Europe contain the target amounts required for a cholesterol-lowering benefit in a single serve of food. For example, a single shot of drinking yoghurt can contain two grams of plant sterols. Such products diversify the phytosterol-enriched foods market in general and, for some consumers, undoubtedly offer a simpler choice for obtaining the target amount of plant sterols in one meal event. FSANZ would consider any future applications for products that offer a suitable quantity of plant sterols in a single serve of food.

⁷ [Dietary Supplements and Heart Health - Heart Foundation NZ](#), accessed 14 August 2024

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3.2.5 The promotion of consistency between domestic and international food standards

Currently the Code permits the addition of plant sterols at varying levels to edible oil spreads, reduced fat milk, yoghurt, reduced fat cheese, breakfast cereals and plant-based milks.

The proposed change would be consistent with the outcomes of the two most recent Applications to FSANZ regarding phytosterol addition to food, which effectively permit the inclusion of 2g of phytosterols in one serve of some breakfast cereals (A1134) and 2.2g per 250ml of plant-based milks (A1249).

Bread products containing plant sterols are permitted and available internationally, including in Europe and the USA. Examples of bread and bread products available in these markets are set out in Appendix 1A [CCI].

Mintel search details:

Search for products where **date published** is between Jun 1996 and Aug 2024.

and **Ingredient Search** matches one or more of *[Phytosterols and all child ingredients; Phytosterols]* as the *Ingredients* and **Category** matches *Bakery*

51 results found.

3.3 Disadvantages of the Proposed Change

(As per section 3.1.1 D(b) of the Application Handbook as at 1 July 2024)

The Applicant has not identified any disadvantages of the proposed change.

3.4 Public Health and safety issues

(As per section 3.1.1 D of the Application Handbook as at 1 July 2024)

The Applicant has not identified any public health and safety issues in relation to the proposed change.

The Code currently permits the additional of plant sterols as set out in Table 4.

Refer **Sections 7.2** and **7.3** for information about the safety of plant sterols.

3.5 Consumer choice

(As per section 3.1.1 D of the Application Handbook as at 1 July 2024)

The Applicant has not identified any consumer choice issues in relation to the proposed change.

Under existing labelling requirements in the Code (unless the food is exempt from the requirement for a statement of ingredients) plant sterols are required to be declared in the statement of ingredients.

Consumers will be able to identify products that contain plant sterols and make an informed choice to purchase these products.

3.6 Support for the proposed change

(As per section 3.1.1 D of the Application Handbook as at 1 July 2024)

The Applicant is not aware of any direct evidence that other bread manufacturers have an interest in, or support, the amendment requested. However, given the clear need for the amendment requested, the advantages described above demonstrate there is a market opportunity, and the Applicant anticipates other manufacturers will be supportive of the proposed changes which facilitates innovation in the category.

The requested amendment is voluntary so manufacturers will be able to choose whether they take up the opportunity to provide plant sterol enriched bread products for their consumers.

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4 Regulatory Impact Information

(As per section 3.1.1 D.1 of the Application Handbook as at 1 July 2024)

4.1 Costs and Benefits of the Application

(As per section 3.1.1 D.1.1 of the Application Handbook as at 1 July 2024)

4.1.1 Costs and Benefits – Consumer

Consumers interested in the cholesterol lowering benefit of plant sterols will be able to make an informed choice to purchase and include plant sterol enriched bread and bread products in their diets. 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. These products are expected to be marketed at a price point in the premium price tier/specialty health space, and higher than standard products that do not contain plant sterols.

Affordability is an important consideration given that sustained cholesterol-lowering benefits from plant sterols requires consistent daily consumption of the recommended levels.

Nonetheless, a price premium over most non-enriched bread is anticipated to act as a natural barrier to excessive intakes in the target population, or intakes in non-target populations. Thus, there is a direct cost to the consumer as the price of the plant sterol containing products will be higher than a standard bread. However, this is a cost that consumers can choose to incur in the context of making an informed decision about the product, it is not imposed upon them.

The benefits for consumers are further outlined in Section 3.2.

4.1.2 Costs and Benefits - Industry and Business

The requested amendment is a voluntary permission to add plant sterols to bread and bread products. Manufacturers can make a choice as to whether they take up the opportunity to offer consumers plant sterol enriched bread and bread products.

The costs for manufacturers who choose to develop and market plant sterol enriched products include investment in ingredient costs and manufacturing process to achieve inclusion of plant sterol into the product, as well as monitoring to ensure the amount claimed reflects composition and permitted amounts. Due to the voluntary nature of the permission, industry will only use the food additive where they believe a net benefit exists.

The benefit to industry is the opportunity to offer consumers plant sterols via bread and bread products which are widely consumed.

4.1.3 Costs and Benefits – Government

The requested amendment places no additional regulatory costs to Government beyond:

- the initial regulatory cost of approval
- educating compliance officers of the new permission, and
- normal costs of enforcing compliance with the Code.

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In the Approval Report for A1249, 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.

4.2 Impact on International Trade

(As per section 3.1.1 D.1.2 of the Application Handbook as at 1 July 2024)

The Applicant notes that, in developing food standards, FSANZ must have regard to its WTO obligations; the promotion of consistency between domestic and international food standards; and the promotion of fair trading in food. These matters encompass consideration of international standards and trade issues.

Approval of the requested amendment may promote greater alignment with other jurisdictions.

Approval may also provide additional markets for plant sterols manufactured in markets outside of Australia and New Zealand by increasing the range of product categories permitted to contain plant sterols in the ANZ market.

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5 Information to Support the Application

(As per section 3.1.1 E of the Application Handbook as at 1 July 2024)

5.1 Data Requirements

(As per section 3.1.1 E.1 of the Application Handbook as at 1 July 2024)

The data and information provided to support the application fulfils the requirements for data as set out in the FSANZ Application Handbook (2024):

- the source, author and year of evidence is identified
- it has been obtained using validated methods
- it represents Australian and New Zealand populations where possible, and
- it has been compiled from studies conducted under good laboratory practice (GLP).

Refer to **Section 7** for information about the novel food – plant sterols.

5.2 FSANZ Act Objectives

Information is provided in this Application to address the objectives specified in Section 18 of the FSANZ Act 1991 as follows:

Protection of public health and safety (1a)

This is addressed in Sections 7.2 and 7.3 of this application document.

For [A1249](#) (2022), FSANZ undertook a risk assessment 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.

The provision of adequate information relating to food to enable consumers to make informed choices (1b)

The existing labelling requirements in the Code will apply to bread and bread products with added plant sterols to assist consumers to make informed choices.

The prevention of misleading or deceptive conduct (1c)

The existing labelling requirements applying to foods containing added plant sterols will apply to bread and bread products as well as existing requirements for voluntary nutrition content and health claims if these claims are made about plant sterols.

Additionally, under the requested draft variation, if plant sterols are added to bread and bread products, a serving must contain at least 0.8 g of total plant sterol equivalents content. These conditions all apply to prevent misleading or deceptive conduct.

The need for standards to be based on risk analysis using the best available scientific evidence (2a)

This is addressed in Sections 7.2 and 7.3 of this application documents.

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The promotion of consistency between domestic and international food standards (2b)

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, Phytosteranols and their Esters](#).

The desirability of an efficient and internationally competitive food industry (2c)

Permission to add plant sterols to bread and bread products would facilitate alignment with Europe and USA as outlined.

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

The promotion of fair trading in food (2d)

As above – 2c.

Any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority 2(e)

Refer to Table 2.

5.3 Policy Guidelines

(As per section 3.3.2 of the Application Handbook as at 1 July 2024)

5.3.1 Addition to Food of Substances other than Vitamins and Minerals

The Policy Guideline '[Addition of Substances other than Vitamins and Minerals](#)' includes specific order policy principles for substances added to achieve a solely technological function and for any other purpose.

These specific order policy principles state that permission should be granted as per the principles set out in Table 2.

Table 2: Specific Order Policy Principles

Specific Order Policy Principles – Any Other Purpose	Section of Application
a) the purpose for adding the substance can be articulated clearly by the manufacturer (i.e., the 'stated purpose'); and	Sections 2 and 7.1
b) the addition of the substance to food is safe for human consumption; and	Sections 7.2 and 7.3. The addition of plant sterols to bread at the levels proposed is safe.
c) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and	Section 7.1. The form of the plant sterols is consistent with the stated purpose and already permitted in the Code.
d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population; and	Section 7.2 and 7.3 There are no adverse health effects associated with the addition of plant sterols to bread as proposed.

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Specific Order Policy Principles – Any Other Purpose	Section of Application
e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.	Section 7.5 Products containing added phytosterols are already to be labelled in a manner which informs and does not mislead consumer regarding the nutritional quality of the food. No change to current labelling requirements is proposed.

5.3.2 Policy Guidelines on Novel Foods

Phytosterols are currently regulated as novel foods in Schedule 25, rather than substances “used as a nutritive substance” therefore the [Ministerial Council Policy Guidelines on Novel Foods](#) applies to this Application.

The high order and specific principles of this Ministerial Policy Guideline are set out in Table 3.

Table 3: Policy Principles – Novel Foods

High Order Policy Principles – Novel Foods	Section of Application
To ensure that priority is given to the protection and improvement of public health and safety in relation to food matters.	Sections 2 and 3
To ensure that consumers have access to sufficient information to enable informed and healthy food choices.	Section 7.5
Be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion.	Section 3
To draw on the best elements of international regulatory systems (i.e., protocols, standards, guidelines, assessment processes) and be responsive to future trends and developments (i.e., CODEX, WHO/FAO).	Section 6
To provide a regulatory environment that is timely, cost effective, transparent, and consistent with minimum effective regulation, and which encourages fair trade, industry growth, innovation, and international trade.	Section 2, 3 and 6
Specific Order Policy Principles – Novel Foods	Section of Application
To ensure that public and industry confidence in the food system is maintained.	Sections 7.4 and 8
To provide an assessment process that aims to protect commercially sensitive information and recognise industry’s intellectual property to the maximum extent possible.	FSANZ responsibility
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.	Sections 7.4 and 8

5.4 Exclusive use of novel foods

The Applicant is **NOT** requesting an exclusive use permission to manufacture and sell bread products containing plant sterols.

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6 International and Other National Standards

(As per section 3.1.1 J of the Application Handbook as at 1 July 2024)

6.1 International Standards

(As per section 3.1.1 J.1 of the Application Handbook as at 1 July 2024)

6.1.1 Codex

There are no Codex Alimentarius Commission (Codex) Standards relevant to this application.

6.1.2 JECFA

There is a 2008 JECFA Monograph published for [‘Phytosterols, Phytostanols and their Esters’](#).

6.2 Other National Standards or Regulations

(As per section 3.1.1 J.2 of the Application Handbook as at 1 July 2024)

6.2.1 Australia/New Zealand

Table 4 sets out the current permissions in the Code for plant sterols in food products and the proposed level for bread products.

Regulations related to breakfast cereals (Schedule 25) and cheese (Standard 2.5.4) effectively allow for the addition of 2.2 grams of phytosterols to be delivered in one serving, this is consistent with the proposed amount to be added to bread and bread products.

Table 4: Current plant sterol permissions in the Code

Food	Standard	Prescribed form	Permitted level	Conditions for PS addition
Breakfast cereals	Schedule 25	Total PS equiv	Min: 0.5 g per serving Max: 2.2 g per serving.	(a) the total fibre content of the breakfast cereal is no less than 3 g/50 g; and (b) the breakfast cereal contains no more than 30 g/100 g of total sugars; and (c) the *total plant sterol equivalents content is no less than 0.5 g per serving and no more than 2.2 g per serving.
Yoghurt	Section 2.5.3-5	Total PS equiv	1.0g/package	(a) the yoghurt contains no more than 1.5 g total fat/100 g; and (b) the yoghurt is supplied in a package, the capacity of which is no more than 200 g; and (c) the *total plant sterol equivalents content added

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Food	Standard	Prescribed form	Permitted level	Conditions for PS addition
				is no less than 0.8 g and no more than 1.0 g/package.
Milk	Section 2.5.1-6	Total PS equiv	Min: 3g/L Max: 4g/L	(a) the milk contains no more than 1.5 g total fat/100 g; and (b) the *total plant sterol equivalents content is no less than 3 g/L of milk and no more than 4 g/L of milk.
Edible oil spread (including margarine)	Section 2.4.2-2	Total PS equiv	Max: 82g/kg	(a) according to Standard 2.4.2; and (b) where the total *saturated and *trans fatty acids present in the food are no more than 28% of the total fatty acid content of the food.
Cheese and processed cheese spread	Section 2.5.4-4	Tall oil phytosterol esters	Min: 70g/kg Max: 90g/kg	Tall oil phytosterol esters may only be added to cheese or to processed cheese if: (a) the cheese or processed cheese contains no more than 12 g total fat/100 g; and (b) the tall oil phytosterol ester is added at no less than 70 g/kg and no more than 90 g/kg.
Beverage derived from legumes, cereals, nuts, seeds, or a combination of those ingredients	Schedule 25	Total PS equiv	Min: 0.8 g Max: 2.2 g per 250 mL of the beverage.	(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.

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Food	Standard	Prescribed form	Permitted level	Conditions for PS addition
PROPOSED: Bread and bread products	Schedule 25	Total PS equiv	Min: 0.8 g Max: 2.2 g Per serving	(a) the dietary fibre content is no less than 2g/serve (contains); and (b) the sodium content is no more than 380mg/100g; and (c) the *total plant sterol equivalents content is no less than 0.8g per serving and no more than 2.2g per serving.

[Schedule S9-2](#) – Mandatory advisory statements require the following mandatory advisory statement:

A food that contains added phytosterols, phytostanols or their esters.

- (a) when consuming this 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.

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6.2.2 Other Jurisdictions

Table 5 sets out the global regulatory approvals and conditions for plant sterols.

European Union (EU)

In Europe, plant sterols are specifically permitted in a wide variety of foods including rice drinks and soya drink (Regulation (EU) 2017/2470)⁸. Foods containing added plant sterols must be presented so they can be easily divided into portions that contain either a maximum of 3g (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 3g.

United States of America (USA)

The applicant acknowledges that GRAS is not a regulation however, consideration of the GRAS history of plant sterols has been included in this section of the application for completeness.

In the USA, the United States Food and Drug Administration has raised no objection to several foods that may contain plant sterols, based on GRAS (generally recognized as safe) notifications.

Canada

In 2010, Health Canada published a safety assessment of certain foods containing added phytosterols (Health Canada, 2010)⁹. Historically, isolated phytosterols had a history of sale and use in Canada as drugs and as natural health products to treat hypercholesterolemia. More recently, foods containing phytosterols were classified and regulated as foods.

The safety of phytosterols was assessed by the Food Directorate according to the Guidelines for the Safety Assessment of Novel Foods. The Food Directorate concluded that intakes of 3 g/day for adults, and 1 g/day for children could be used as reference safe intakes. Through modeling studies, Health Canada determined that the addition of phytosterols at up to 1 g (free phytosterols) per serving and per reference amount to unstandardized spreads, mayonnaise, margarine, calorie reduced margarine, salad dressing and unstandardized salad dressings, yogurt and yogurt drinks, and vegetable and fruit juices would not result in exposure exceeding the reference safe intakes in the general population.

Plant sterols can be added to spreads, mayonnaise, margarine, calorie-reduced margarine, salad dressing, yogurt and yogurt drinks, and vegetable and fruit juices.

A limited number of foods will be allowed to contain up to 1 g of plant sterols per serving.

Health Canada research determined the levels and ranges of foods to which plant sterols could be added without exceeding the upper intake limit of 3 g of plant sterols per day in adults and 1 g plant sterols per day in children.

⁸ Available at [L_2017351EN.01007201.xml \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R2470). 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.

⁹ [Health Canada](#)

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Health Canada assesses the safety of all novel foods proposed for sale or advertising in Canada.

Manufacturers are required to submit detailed scientific data for review by Health Canada before such foods can be authorized for sale.

Health Canada also maintains a complete [list of assessed novel foods](#) (including novel GM foods).

A search of the list of assessed novel foods for ‘plant sterols’, ‘phytosterols’, ‘stanols’ yielded 12 completed novel food safety assessments as shown in Table 5.

Table 5: Summary of Global Regulatory Approvals

Food category(s)	Prescribed form & Permitted level	Conditions for PS addition
European Union Regulation (EU) 2017/2470		
Spreadable fats Milk based products. Yoghurt Cheese Soya drinks Salad dressings, mayonnaise, and spice sauces	Oil enriched with phytosterols/phytostanols	In accordance with Annex III.5 to Regulation (EU) No 1169/2011
Rice drinks Rye bread with flour containing $\geq 50\%$ rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and $\leq 30\%$ wheat; and with $\leq 4\%$ added sugar but no fat added. Salad dressings, mayonnaise, and spicy sauces. Soya drink Milk type products, such as semi-skimmed and skimmed milk type products, possibly with the addition of fruits and/or cereals, where possibly the milk fat has been reduced, or where milk fat and/or protein has been partly or fully replaced by vegetable fat and/or protein. Products based on fermented milk such as yoghurt and cheese type products (fat content $< 12\%$ per 100 g), where possibly the milk fat has been reduced, or where milk fat and/or protein has been partly or	Phytosterols/phytostanols They shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3 g (in case of 1 portion/day) or a maximum of 1 g (in case of 3 portions/day) of added phytosterols/phytostanols. The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g. Salad dressings, mayonnaise and spicy sauces shall be packed as single portions.	In accordance with Annex III.5 to Regulation (EU) No 1169/2011

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Food category(s)	Prescribed form & Permitted level	Conditions for PS addition
fully replaced by vegetable fat and/or protein. Spreadable fats as defined in Annex VII, Part VII, Appendix II points B and C, of Regulation (EU) No 1308/2007, and excluding cooking and frying fats and spreads based on butter or other animal fat.		
United States of America The applicant acknowledges that GRAS is not a regulation however it has been included in this section of the application for completeness. GRAS (generally recognized as safe) notifications		
981; 492; 398; 387; 335; 265; 250; 206; 181; 177; 176; 112; 61; 53; 48; 39 Period: 2000 - 2022	Phytosterols; phytosterol esters Tall oil phytosterols; Plant stanol esters.	
Canada		
Food and Drug Regulations Division 28, Novel Foods		
Products covered: unstandardized spreads, mayonnaise, margarine, calorie-reduced margarine, salad dressing and unstandardized salad dressings, yogurt and yogurt drinks, and vegetable and fruit juices. LINK	Maximum level of 1g (free phytosterols) per serving and per reference amount.	

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7 Novel foods

(As per section 3.5.2 of the Application Handbook as at 1 July 2024)

7.1 Technical Information on the novel food

(As per section 3.5.2 B of the Application Handbook as at 1 July 2024)

7.1.1 Information on the type of novel food

(As per section 3.5.2 B.1 of the Application Handbook as at 1 July 2024)

A FAO JECFA Monograph for phytosterols, phytostanols and their esters was prepared at the 69th JECFA (2002) and published in [FAO JECFA Monographs 5 \(2008\)](#).

An ADI of 0-40 mg/kg bw, expressed as the sum of phytosterols and phytostanols in their free form, was established at the 69th JECFA ([2008](#)).

The requirements for Identity and purity for phytosterols, phytostanols and their esters is set out in [Schedule 3](#) of the Code - S3-24 Specification for phytosterols, phytostanols and their esters.

The Applicant's plant sterol will comply with the JECFA Monograph which satisfies the requirements of Schedule 3 of the Code.

7.1.2 Information on the purpose of adding a novel food ingredient to food

(As per section 3.5.2 B.2 of the Application Handbook as at 1 July 2024)

As set out in Sections 2 and 3, the purpose for adding plant sterols to bread and bread products relates to the potential for users to benefit from their cholesterol lowering properties when consumed at recommended and efficacious amounts daily.

This application is an extension of a current permission to a new food matrix.

Plant sterol's cholesterol lowering effects occur in a wide range of food and liquid formats/ matrices as discussed in this application.

The target consumers for the intended plant sterol enriched bread and bread products include consumers interested in lowering their cholesterol.

The National Heart Foundation's (NHF) Position Statement on '*Dietary fats and dietary sterols for cardiovascular health*' recommends that health care professionals encourage patients with CVD to include foods enriched with plant sterols as part of a healthy, balanced diet. In the summary of evidence, the NHF state the following: (NHF 2017):

- *"Phytosterols lower LDL-C in normocholesterolaemic, hypercholesterolaemic and diabetic individuals."*
- *"A daily intake of 2–3 g phytosterols have been shown to lower blood cholesterol levels by up to 10% depending on the age and individual metabolism of the person."*
- *"A daily intake of approximately 2.5 g phytosterols from enriched low fat breakfast cereal, yoghurt, milk, or bread reduces LDL-C levels by approximately 5–15%"*

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- “Consuming more than 3 g per day phytosterols provides no additional benefits.”
- “Daily consumption frequency does not influence the cholesterol-lowering efficacy of phytosterol/stanols.”

Further, recommendations to health care professionals are provided:

1. Encourage adult Australians with evidence of CVD, familial hypercholesterolaemia or diabetes to include Plant sterol enriched foods as part of a healthy balanced diet as described above.
2. Advise adult Australians on statin therapy about the benefits of consuming Plant sterol enriched foods.

7.1.3 Information on the chemical and physical properties of the novel food or novel food ingredient

(As per section 3.5.2 B.3 of the Application Handbook as at 1 July 2024)

This application to amend the Code relates to an extension of use of an already approved novel food - phytosterols, phytostanols and their esters. For detailed information on the physical and chemical properties of phytosterols, phytostanols and their esters refer to [Schedule 3, S3-24](#) Specification for phytosterols, phytostanols and their esters as well as the respective food additive specifications, FAO JECFA monograph ([FAO, 2008](#)).

The applicant intends to use a commercially available phytosterol product that has been demonstrated to be soluble and uniformly distributed in bread products.

7.1.4 Information on the impurity profile for a typical preparation

(As per section 3.5.2 B.4 of the Application Handbook as at 1 July 2024)

This application to amend the Code relates to an extension of use of an already approved novel food, i.e., phytosterols, phytostanols and their esters. Refer to [Schedule 3, S3-24](#) Specification for phytosterols, phytostanols and their esters.

7.1.5 Manufacturing Process for a novel food ingredient

(As per section 3.5.2 B.5 of the Application Handbook as at 1 July 2024)

This application to amend the Code relates to an extension of use of an already approved novel food, i.e., phytosterols, phytostanols and their esters. Refer to [Schedule 3, S3-24](#) Specification for phytosterols, phytostanols and their esters.

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7.1.6 Specification for identity and purity for a novel food ingredient

(As per section 3.5.2 B.6 of the Application Handbook as at 1 July 2024)

This application to amend the Code relates to an extension of use of an already approved novel food, i.e., phytosterols, phytostanols and their esters. Refer to [Schedule 3, S3-24](#) Specification for phytosterols, phytostanols and their esters.

7.1.7 Analytical method for detection of a novel food ingredient

(As per section 3.5.2 B.7 of the Application Handbook as at 1 July 2024)

The method of identification for phytosterols is by gas chromatography, specifically AOCS Official Method Ce 12-16 - *Sterols and stanols in foods and dietary supplements containing added phytosterols*.

Method Ce 12-16 can determine total free sterols/stanols and total steryl/sterol esters, as well as quantify each of the five major phytosterols that are the subject of the FDA's health claim. Ce 12-16 provides three protocols for extracting phytosterols from different matrices (sterol/sterol concentrates, steryl/sterol ester concentrates, foods, and dietary supplements). Each protocol derivatizes the phytosterols to trimethylsilyl (TMS) ethers so that they may be separated on a capillary GC column, detected by a flame ionization detector (FID), and identified by their retention times.

The [method](#) was reapproved in 2024.

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7.2 Information on the safety of the novel food - single chemical entities and dietary macro-components

(As per section 3.5.2 C.4 of the Application Handbook as at 1 July 2024)

In the [Approval Report for Application A1249 \(November 2022\)](#), FSANZ stated:

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.

7.2.1 Update on studies investigating toxicity or safety of orally consumed phytosterols

FSANZ has conducted several assessments of plant sterols in the past, these assessments have evaluated information on the toxicokinetics and metabolism of the plant sterols. The outcome of each previous safety assessment has been that the available data for plant sterols has been considered to provide a high level of confidence in the safety and suitability for use in specific plant sterol enriched products.

FSANZ most recent comprehensive assessment in 2022, as part of [A1249 – Addition of phytosterols, phytostanols or their esters as novel food to plant-based milk alternatives](#) reported the following regarding the safety of phytosterols ([FSANZ 2022](#)):

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 did 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 phytosterolaemia¹⁰ to enable them to identify foods containing plant sterols.

FSANZ further acknowledged that 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

¹⁰ 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.

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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.

Previous FSANZ evaluations and regulatory outcomes are supportive for plant sterols safety and suitability for amounts of 2g in one serving of plant sterol enriched foods.

FSANZ have advised that for an application to extend the use of a currently permitted novel food, this section need only include the reports of studies conducted since the last safety evaluation by FSANZ which was undertaken in 2022.

To evaluate if there are any studies in the literature investigating toxicity or safety of orally consumed phytosterols since 2022, literature searches were performed using the search terms set out in Appendix 2. The following databases and sources were searched:

- Google Scholar
- PubMed
- Cochrane

The outcome from the above literature searches with abstracts is set out in Appendix 2.

In summary, the literature review identified several relevant articles on that have been published in the period 2022 – 2024. The key points from each review article are set out in Table 6. Further details of each of the reviews is provided in Appendix 2.

Zio et al (2025) noted:

Indeed, sterols can have adverse effects on health when established standards are not respected. As a result, the health benefits of sterols (cholesterol and phytosterols) require particular attention, given their contribution to the public health problems facing our countries.

The Applicant notes the amendment requested for plant sterols in bread and bread products is in line with current permitted levels in other food categories and the mandatory advisory statements ([Schedule 9](#)) required for foods that contain added phytosterols, phytostanols or their esters to also provide guidance on appropriate use to ensure no nutrition imbalances are caused.

The Applicant acknowledges that further evaluation of the safety of the proposed changes in the Australian and New Zealand context will be undertaken by FSANZ.

Table 6: Key Points from recent studies on Plant Sterols

Title	Authors	Key points
Plant Sterols and Plant Stanols in Cholesterol Management and Cardiovascular Prevention Nutrients 2023	Barkas et al.	Noted current guidelines recommend plant sterols and plant stanols in the amount of approximately 2 g/day with the goal of reducing LDL-C by approximately 10% in combination with dietary changes. Both physicians and consumers should keep in mind that this recommendation might be

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Title	Authors	Key points
		applied to individuals with hypercholesterolaemia who are expected to have a cardiovascular benefit, but also that the daily intake must not exceed the recommended dose. Finally, plant sterols/stanols should not be viewed as a substitute for much more effective and evidence-based cholesterol-lowering therapies, especially in individuals at high CVD risk.
Health outcomes associated with phytosterols: An umbrella review of systematic reviews and meta-analyses of randomized controlled trials. Phytomedicine, Volume 122, 2024	Liu et al	We conducted an umbrella review, which incorporated verification spanning a number of meta-analyses and systematic reviews to clarify the link that existed between PS consuming and health outcomes. This umbrella review summarized a range of beneficial functions of PS to humans, highlighting the promising potential for the development of PS into functional foods.
Health interest of cholesterol and phytosterols and their contribution to one health approach: Review. Heliyon, Volume 10, Issue 21 e40132, November 15, 2025	Zio et al	Sterols, and in particular phytosterols, play a number of roles in the pharmaceutical field (therapeutic steroids), nutrition (anti-cholesterol, anti-cancer properties). Indeed, sterols can have adverse effects on health when established standards are not respected. As a result, the health benefits of sterols (cholesterol and phytosterols) require particular attention, given their contribution to the public health problems facing our countries.
Effects of phytosterols on cardiovascular risk factors: A systematic review and meta-analysis of randomized controlled trials Phytotherapy Research. Nov 2024	Yang et al	Short-term clinical trials have demonstrated phytosterols' cholesterol-lowering potential, but their effects on cardiovascular risk factors remain controversial, and relevant meta-analyses are limited and incomplete. Our results suggest that phytosterols may be beneficial in reducing the levels of TC, LDL-C, TG, CRP, SBP, and DBP, but have no significant effect on GLU, HbA1c, TNF-α, IL-6, OXLDL-C, BMI, WC, and Weight.
Phytosterols and the Digestive System: A Review Study from Insights into Their Potential Health Benefits and Safety.	Miszcuk et al	This article provides consolidated knowledge on a new potential use of phytosterols, namely the treatment or prevention of gastrointestinal diseases.

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Title	Authors	Key points
Pharmaceuticals 2024		Noted in the context of their safe use, however, the issue of the negative effect of phytosterols on the absorption of certain vitamins and provitamins, especially vitamin D and beta-carotene is relevant.
Phytosterols and phytostanols and the hallmarks of cancer in model organisms: A systematic review and meta-analysis. Critical Reviews in Food Science and Nutrition, Nov 2022	Cioccoloni et al	Phytosterols and phytostanols are already clinically recommended for cardiovascular disease risk reduction and represent promising anti-cancer agents that could be delivered in clinic and to the general population at low cost, with a well understood safety profile, and now with a robust understanding of mechanism-of-action. Given the well understood toxicity profile of PSS, combined with their now >20-year use in clinic to reduce cardio-vascular disease risk, and the plethora of preclinical in vivo evidence we have summarized here, it is timely to consider PSS as adjuncts to cancer therapies.
Phytosterol and phytostanol-mediated epigenetic changes in cancer and other non-communicable diseases: a systematic review. Br J Nutr. 2024	Jefrei et al	The aim of this systematic review was to identify all publications that have evaluated changes to epigenetic mechanisms (post-translation modification of histones, DNA methylation and miRNA expression) in response to phytosterols/phytostanols.

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7.2.2 Information on the toxicokinetics and metabolism of the single chemical entity and, where appropriate, its degradation products and major metabolites

(As per section 3.5.2 C.4.1 of the Application Handbook as at 1 July 2024)

This application to amend the Code relates to an extension of use of an already approved novel food, i.e., phytosterols, phytostanols and their esters.

Overall, the recent studies have demonstrated that plant sterols are not toxic.

There is no basis to conclude that the proposed use of plant sterols in bread products poses any risk to any segment of the general population.

7.2.3 Information from studies in animals or humans that is relevant to the toxicity of the single chemical entity and, where appropriate, its degradation products and major metabolites

(As per section 3.5.2 C.4.2 of the Application Handbook as at 1 July 2024)

As for 7.2.2 above.

7.2.4 Safety assessment reports prepared by international agencies or other national government agencies

(As per section 3.5.2 C.4.3 of the Application Handbook as at 1 July 2024)

The Applicant has not identified any safety assessments prepared by international agencies or other national government agencies since the report published by an overseas agency noted by FSANZ in the Approval Report for A1249 (November 2022).

In 2020, the European Food Safety Authority (EFSA) Panel on Nutrition, Novel Foods, and Food Allergens (NDA) published an opinion on the safety of an extension of use of the novel food 'plant sterol esters' when added to vegetable fat spreads and to liquid vegetable fat-based emulsions for cooking and baking purposes (EFSA 2020). The Panel concluded that the safety of the intended extension of use of plant sterol esters under the proposed conditions of use has not been established.

The conclusions of this report are not considered relevant to the current application given the differences in proposed use conditions. FSANZ is not aware of any proposed changes to current European regulations which permit the addition of plant sterols to plant-based milk alternatives (soy drinks and rice drinks specifically) and other foods.

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7.3 Information related to the dietary exposure to the novel food

(As per section 3.5.2 D of the Application Handbook as at 1 July 2024)

7.3.1 A list of the foods or food groups proposed to or which might contain the novel food ingredient or substance

(As per section 3.5.2 D.1 of the Application Handbook as at 1 July 2024)

The proposed change would permit bread to contain up to 2.2g of plant sterols per serve.

As FSANZ has pointed out in previous plant sterol related applications, products containing plant sterols are likely to carry health claims and so would need to meet the Nutrient Profiling Scoring Criterion (NPSC).

The Applicant is proposing:

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

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

Some examples of the Tip Top Bakeries bread products which might contain plant sterols are set out in Table 6.

Table 7: Tip Top Bakeries bread products which might contain plant sterols^{11,12,13}

Product	Serving Size	HSR
Burgen Soy Lin	83g (2 slices)	4.5
Burgen Whole Grain & Oats	83g (2 slices)	5
Tip Top 9 Grain Classic	74g (2 slices)	4.5
Tip Top 9 Grain Wholemeal	79g (2 slices)	4.5
Abbott's Bakery Wholemeal	84g (2 slices)	4
Abbott's Bakery Light Rye	76g (2 slices)	4
Tip Top English Muffins (Original)	67g (1 muffin)	4
Tip Top English Muffins (Multigrain)	67g (1 muffin)	4
Tip Top Thins (Mixed Grain)	40g (1 Thin)	4.5
Tip Top The One Gluten Free Smooth Wholegrain	93g (2 slices)	4

¹¹ Tip Top brands, <https://www.tiptop.com.au/our-range/>, accessed 10/01/25.

¹² Abbott's Bakery, <https://www.abbottsbakery.com.au/>, accessed 10/01/25.

¹³ Burgen, <https://www.burgen.com.au/>, accessed 10/01/2025.

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7.3.2 The proposed level of the novel food ingredient or substance for each food or food group

(As per section 3.5.2 D.2 of the Application Handbook as at 1 July 2024)

The requested amendment to the Code is for bread products to contain total plant sterol equivalents of no less than 0.8g per serving and no more than 2.2g per serving.

The applicant is not aware of and could not locate any data on the naturally occurring levels of plant sterol equivalents in bread products. The dietary plant sterol exposure on a typical Western-type diet (i.e., derived from non-enriched foods) has been reported to be between 150 to 360 mg per day (Chan, 2006).

Minimum

The applicant is seeking permission to add a minimum of 0.8g of plant sterol equivalents per serve. This minimum level is like other minimum levels for permissions to add plant sterols within the Code as set out in Table 6. 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.

Maximum

The applicant is seeking permission to add a maximum of 2.2g plant sterol equivalents per serve to declare an average quantity of 2g per serving in the nutrition information panel¹⁴. It would be difficult to achieve an average quantity of 2g per serve if the maximum permitted amount is also set at 2g per serve.

FSANZ have previously approved an overage for plant sterols in beverage derived from legumes, cereals, nuts, seeds, or a combination of those ingredients in the assessment of [A1249](#).

Following is an excerpt from the [Approval Report for A1249](#) [Nov, 2022) to support the Applicant's request.

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 2.2g per 250mL. Given there are no safety concerns related to including a slight overage amount, the approved draft variation allows for a maximum permitted amount of 2.2g of total plant sterol equivalents per 250mL rather than 2g. 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 to declare the efficacious daily amount of approximately 2g on a per 250mL 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 2.2g per serving.

¹⁴ The dietary context statement for a health claim must refer to (among other things) the diet containing 2g of phytosterols, phytostanols and their esters per day.

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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 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.

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.

7.3.3 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

(As per section 3.5.2 D.3 of the Application Handbook as at 1 July 2024)

The Australian National Nutrition and Physical Activity Survey (NNPAS) (2011-12)¹⁵ included Cereals and Cereal Products food group which included grains, flours, bread and bread rolls, breakfast cereals, plain pasta, noodles, and rice.

Bread types included those shown in Figure 1 which are similar to the bread and bread products which the applicant is proposing to add plant sterols to.

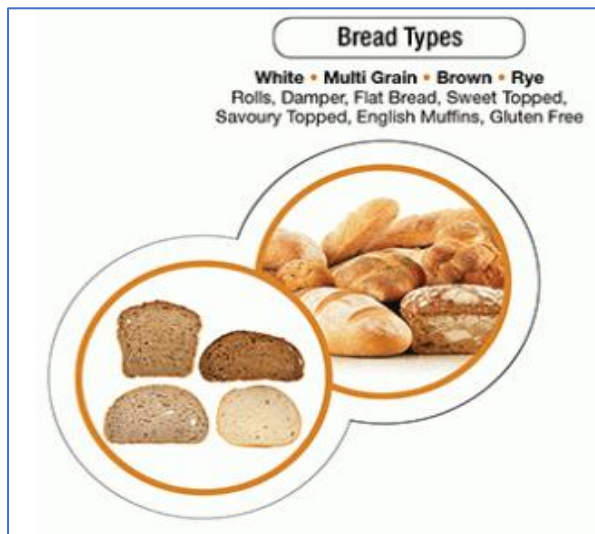
¹⁵ <https://www.abs.gov.au/statistics/health/health-conditions-and-risks/australian-health-survey-nutrition-first-results-foods-and-nutrients/latest-release>, accessed 03/09/2024.

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Figure 1: Cereals and cereal products¹⁶



¹⁶ <https://www.abs.gov.au/statistics/health/health-conditions-and-risks/australian-health-survey-nutrition-first-results-foods-and-nutrients/latest-release#foods-consumed>, accessed 03/09/2024.

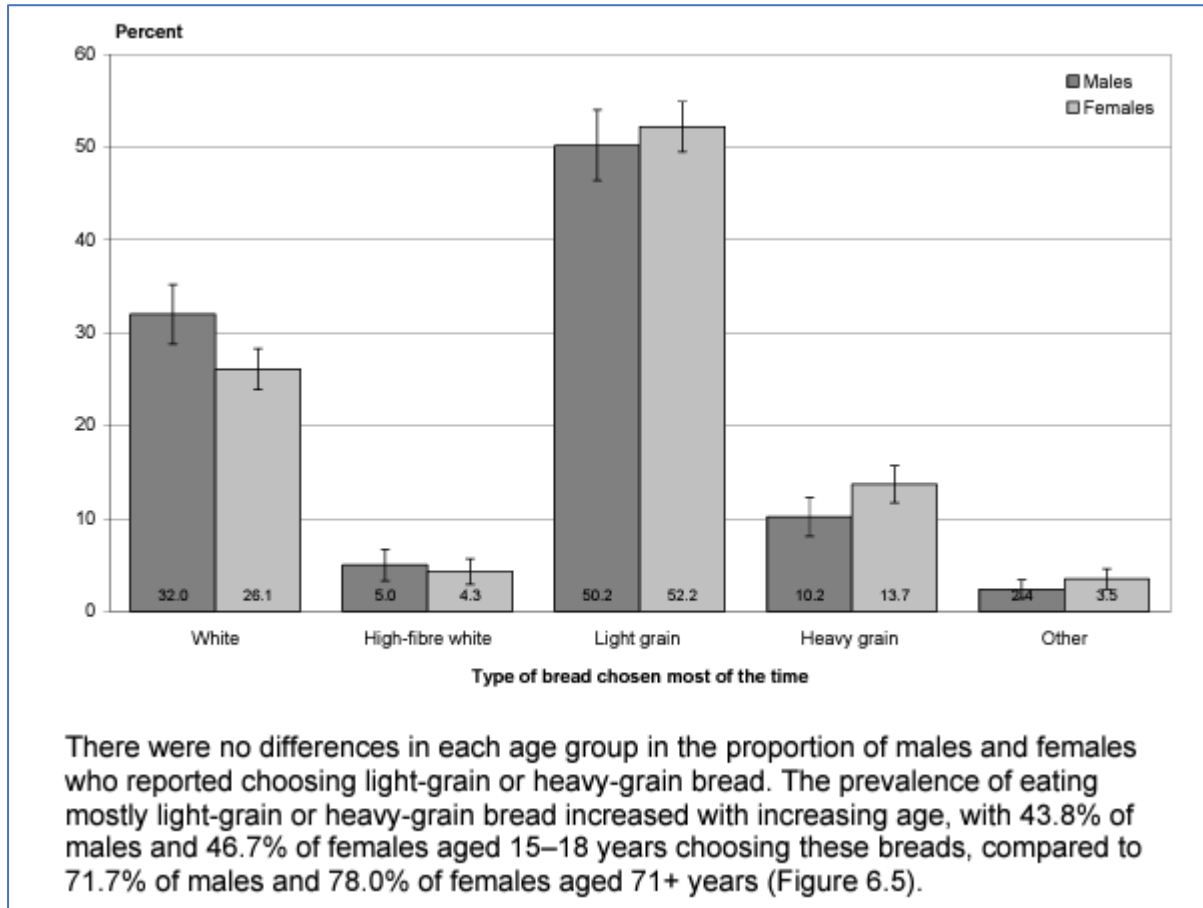
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The 2008/09 NZ Adult Nutrition Survey identified the type of bread/rolls/toast eaten most of the time across white, high fibre white, light grain bread, heavy grain bread and other as shown in Figure 2 below.

Figure 2: Type of bread chosen most of the time by sex¹⁷



¹⁷ Figure 6.4 from the 2008/09 NZ Adult Nutrition Survey Findings, Chapter 6.
<https://www.health.govt.nz/publications/a-focus-on-nutrition-key-findings-from-the-200809-nz-adult-nutrition-survey>

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7.3.4 The percentage of the food group in which the novel food ingredient is proposed to be used or the percentage of the market likely to use the novel food ingredient

(As per section 3.5.2 D.4 of the Application Handbook as at 1 July 2024)

Tip Top Bakeries estimates that approximately 1% of the categories set out in Table 6 would contain plant sterols.

Information on TTB market share data is provided as confidential commercial information.

This information is based on the Circana Scan Sales report up to July 2024

7.3.5 For foods where consumption has changed in recent years, information on likely current food consumption

(As per section 3.5.2 D.5 of the Application Handbook as at 1 July 2024)

While the units sold for sliced bread have been softly declining over the years, there are other categories on the rise: buns and rolls (except dinner rolls), sandwich alternatives, and flatbread.

The applicant has a confidential bread audit report conducted by Grains & Legumes Nutrition Council (GLNC) in November/December 2023 – ‘GLNC Bread Audit George Weston Foods FY 23/24’, which provides a category overview and changes since 2021.

This report is provided as confidential commercial information.

Consumers are currently in a state of flux regarding use of Bread. Traditional Sliced Loaves have been seeing trended decline with a rise in SW ALT & Rolls¹⁸ – categories that are more experimental in terms of offerings. Low Carb & High Protein mixed bread (SW ALT format) has become more accessible as consumers become more health conscious.

Sales information for different bread categories is provided as confidential commercial information.

¹⁸ SW ALT = Sandwich Alternatives

7.3.6 Data to show whether the food, or the food in which the novel food ingredient is used, is likely to replace another food from the diet, if applicable

(As per section 3.5.2 D.6 of the Application Handbook as at 1 July 2024)

The Applicant has identified the target consumers for plant sterol enriched bread and bread products to be those who are aware of the plant sterol claim in margarine and find that appealing – they want a bread with extra health benefits that is also a satisfying eat.

While the Applicant does not have data on how future users would adopt this product in their diets, it is anticipated that existing bread consumers would likely replace their existing bread variety over occasions which they already use bread. Consumers who are not interested in cholesterol lowering benefits of plant sterols are not expected to be interested in an alternative bread.

In July 2022 the Applicant conducted consumer research testing and one of the concepts tested was plant sterols in bread. Following is a compilation of words participants had written about their thoughts on plant sterols in bread. There was a total of 600 participants who answered the survey for this particular concept.

The assumption of taste plus a very clear and compelling claim drives interest.

- *It sounds tasty and has added benefit of reducing cholesterol.*
- *I would love to try this bread loaf as there aren't too many healthy bread options out there that taste good.*
- *The claim* stands out and is believable that it is healthy and helps lower cholesterol which is great because everyone eats bread every day so to have that option is very innovative.*
- *How it lowers cholesterol by 10% is extremely appealing and makes me think that it makes a considerable difference towards improving my heart health.*

The claim* referred to above was:

Heart Smart with plant sterols in every serve to help lower your cholesterol by up to 10%.

The relevant section of the Consumer Research report (August 2022) is provided as confidential commercial information.

7.3.7 Information relating to the use of the novel food or novel food ingredient in other countries, if applicable

(As per section 3.5.2 D.7 of the Application Handbook as at 1 July 2024)

Phytosterols are added to different foods and food groups overseas, and at varying levels per serve.

Phytosterol-containing foods launched over the last 10 years are summarised in Table 7.

Table 8: Phytosterol-containing foods launched over the last 10 years.

Country/Region	Products containing plant sterols
Europe	1. Yoghurt drinks, Yoghurt, Cheese, 2. Edible oil spread, 3. Skim milk, 4. Juice 5. Porridge 6. Rye bread 7. Soy milk 8. Rice drink
North America	1. Yoghurt drinks, 2. Edible oil spread, 3. Dairy-based shots, 4. Dairy milk, 5. Juice 6. Enriched waters 7. Porridge 8. Soy milk 9. Oatmeal squares 10. Omega-3 real egg product 11. Wholegrain crackers 12. Cookies 13. Snack bars 14. Tortilla chips 15. Waffles
Australia & New Zealand	1. Cereal 2. Margarine 3. Yoghurt 4. Milk 5. Cheese 6. Plant-based milk alternatives

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7.4 Information on the nutritional and health impact of the novel food

(As per section 3.5.2 E of the Application Handbook as at 1 July 2024)

7.4.1 Information to demonstrate that the use of the novel food or novel food ingredient will not cause a nutritional imbalance in the diet

(As per section 3.5.2 E.1 of the Application Handbook as at 1 July 2024)

As bread and plant sterol enriched products are already available to consumers, the Applicant considers the choice to consume a plant sterol enriched bread will not contribute to an imbalance in dietary choices.

Likely consumers

Consumers most likely to be interested in a plant sterol enriched bread are those very interested in cholesterol-lowering benefits who are existing bread consumers.

Dietary context

A product that contains 2g of plant sterols per serve would clearly communicate that the cholesterol lowering benefit occurs in the context of a diet containing 2g of plant sterols per day that is low in saturated fat (context claim statements in schedule 4), and so appropriate use would be one serve a day.

Further, the mandatory advisory statements ([Schedule 9](#)) require foods that contain added phytosterols, phytostanols or their esters to also provide guidance on appropriate use to ensure no nutrition imbalances are caused as follows:

- (a) when consuming this 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.*

The addition of plant sterol to bread and bread products which are a source of dietary fibre, low in saturated fat with an appropriate level of sodium will not cause a nutrition imbalance.

The proposed regulatory change to permit 2.2g of plant sterols per serve of bread has the advantage of allowing consumers to include in their diets and achieve recommended plant sterols requirements with minimal overall nutritional changes regardless of how the product is adopted, compared with a product that requires multiple serves daily to achieve the 2g of plant sterols.

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7.4.2 Information to demonstrate that the addition of the novel food ingredient will not create a significant negative public health impact

(As per section 3.5.2 E.2 of the Application Handbook as at 1 July 2024)

There is no evidence of adverse effects related to the consumption of plant sterol enriched foods by target or non-target consumers in the general population.

In relation to vulnerable groups, including pregnant and lactating women and children under 5 years of age, FSANZ evaluation as part of A1249 stated:

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.

If this requested amendment is approved the launch of a range of bread products with 2g of total plant sterol equivalents per serve would provide an opportunity to further educate consumers on the benefits of plant sterols for heart health alongside the benefits of bread consumption.

In addition to the mandatory labelling statements, other labelling, and associated education strategies could be expected to communicate:

- the benefits/target of consuming up to 2g phytosterols per day
- that plant sterol enriched breads provide an alternative food option for consumers to get their daily recommended phytosterols from foods
- that one serve of bread (2 slices) is a simple way of getting your daily requirement of plant sterols
- there is no benefit in consuming more than 3g phytosterols per day, and
- That individuals using cholesterol lowering medication should follow their doctor's advice while using the product.

Mandatory advisory statements must be provided on the labels of phytosterol-enriched foods to the effect that:

- when consuming this product, it should be consumed as part of a healthy diet
- this product may not be suitable for children under the age of five years and pregnant and lactating women, and
- plant sterols do not provide additional benefits when consumed in excess of 3g per day.

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This advice directed at children and pregnant and lactating women originally was based on the absence of a benefit and relatively limited amount of safety data compared to the extensive data available for the target population. Further as *stated in previous FSANZ assessment reports (e.g., the [Second Review Report for A433, A434, A508](#) (FSANZ, 2006) and [A1249](#) (FSANZ, 2022))* the purpose of this statement is largely educational, to assist consumers to use the products appropriately and cost effectively. The statement is therefore intended to reduce the possibility of use by consumers who would gain no benefit from the foods.

Data previously reviewed by FSANZ for other plant sterol enriched foods ([A1065](#), [A1070](#)), senior couples and independent singles are the main life stage groups of purchasers of phytosterol-enriched food products, and the primary shopper tends to be aged 55+ years. In younger households where phytosterol-enriched products are bought, the non-enriched counterpart is bought more frequently (FSANZ, 2012).

Further to above, since plant sterol enriched breads are likely to be offered at a price premium, it is unlikely that they will be purchased or consumed regularly by non-target consumers. It can be reasonably assumed that there is price sensitivity for bread and amongst a non-target consumer the premium price for such a product will be a barrier.

This compliance to consume one serve is expected to be enhanced based on:

- the requirement to pay the price premium for the product on an ongoing basis
- appropriate communication via packaging artwork design with emphasis on plant sterol content delivered in one 250ml serve for example, where a product contains the recommended two grams per day, then communication on pack and advertising would suggest one serve per day as the appropriate use by the target consumer, and
- appropriate communication and education via channels other than packaging design, such as marketing and advertising support, as well as via recommendations from health care bodies.

The Applicant proposes that products with added phytosterols, phytostanols or their esters should contain no less than 0.8 g of total plant sterol equivalents per serve. The rationale for the prescribed amount of total plant sterol equivalents to be no less than 0.8 g per serve, is that for a product to be eligible to use the pre-approved high level health claim, Schedule 4 of the Code requires the food to contain a minimum of 0.8 g plant sterol equivalents per serve.

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7.5 Information related to potential impact on consumer understanding and behaviour

(As per section 3.5.2 F of the Application Handbook as at 1 July 2024)

7.5.1 Information to demonstrate the level of consumer awareness and understanding of the novel food or novel food ingredient

(As per section 3.5.2 F.1 of the Application Handbook as at 1 July 2024)

There are phytosterol products available to consumers in Australia and New Zealand at present and consumers of these products have a level of awareness around phytosterols and their cholesterol lowering benefits, which can be communicated via the permitted high level health claim (Schedule 4).

Trends suggest plant sterol is very niche and not many consumers are talking about it. This shows a need to educate consumers on the benefits of plant sterols and why they should consume them. The following figures provide information on these trends.

Tastewise Database Summary

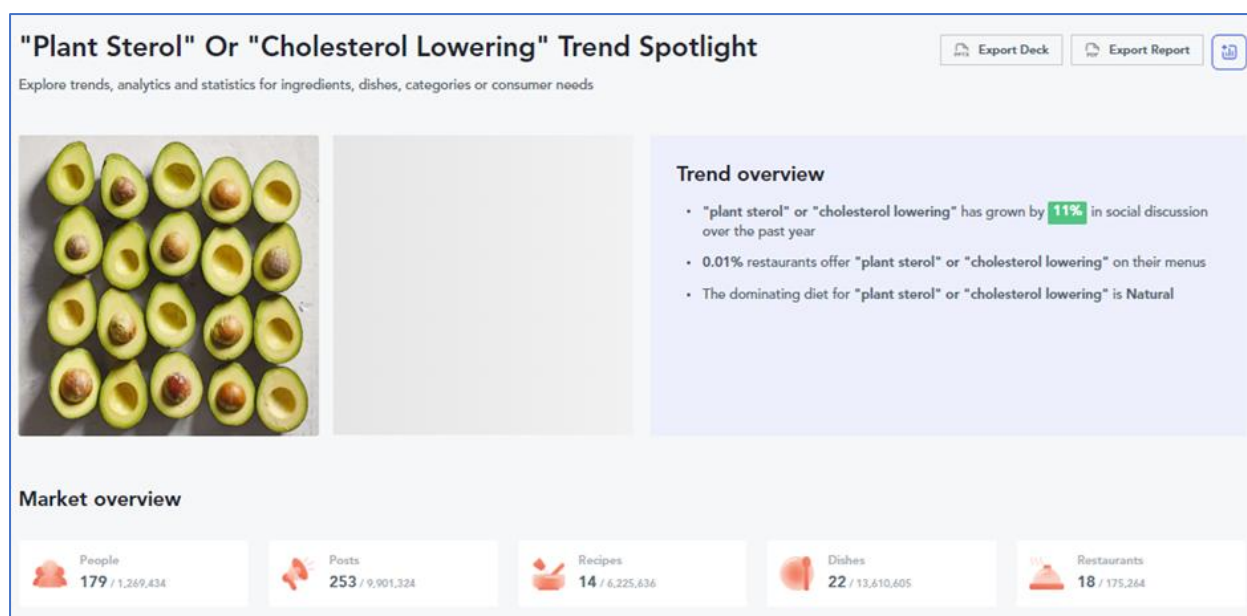
Location: Australia

Date Range: July 2023 – July 2024

Source: Mainly Instagram, small portion from TikTok

Demographics: All demographics on Instagram

Figure 3: Plant Sterol / Cholesterol lowering Market Overview



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Figure 3 shows that “plant sterols” has increased by 11% in terms of social mentions in the last 12 months, however it has almost 0% menu offerings in Australia. In total, there are 14 recipes (Out of 6 million recipes) and 179 people (Out of 1.2 million people) are talking about it. This demonstrates that plant sterol is extremely niche and in its very early life cycle.

Figure 4: Plant Sterols as Share of Menu



Figure 4 demonstrates that between July 2023 – July 2024, plant sterols / cholesterol lowering made up for less than 0.02% of the menu mentions in Australia. There is limited growth in the last 7 months (December 2023 to July 2024).

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Figure 5: Plant Sterols as Share of Voice (Social)



Figure 5 shows that plant sterols / Cholesterol lowering are still very much in their infancy in terms of social media. There is little-to-no consumer awareness to what plant sterol is on this platform.

Figure 6: Plant Sterols / Cholesterol lowering Recipes



Figure 6 demonstrates that this ingredient is very niche and little to no consumers are using it in everyday recipes in Australia.

Previous international surveys show that consumers of plant sterol enriched products may currently not be benefiting from a cholesterol-lowering effect of phytosterols due to consumption levels below 2g per day ([EFSA, 2008](#); Ras, 2017).

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Potential consumers will be informed and educated through on pack as well as off pack communications including mandatory advisory statements. Any labelling would be compliant and not misleading consumers regarding the nutritional quality of the food.

7.5.2 Information on the actual or potential behaviour of consumers in response to the novel food or novel food ingredient

(As per section 3.5.2 F.2 of the Application Handbook as at 1 July 2024)

It is expected that approval of the requested amendment to the Code will lead to availability of a range of plant sterol enriched bread and bread products with an average of 2g of phytosterols per serve.

The target consumer for a plant sterol enriched bread is a health-conscious consumer seeking additional nutritional benefits from their bread/bakery products.

These products are expected to be marketed at a price point in the premium price tier/specialty health space, and higher than standard products that do not contain plant sterols.

Consumers interested in the cholesterol lowering benefit of plant sterols will be able to make an informed choice to purchase and include plant sterol enriched bread and bread products in their diets.

Affordability is an important consideration given that sustained cholesterol-lowering benefits from plant sterols requires consistent daily consumption of the recommended levels.

Nonetheless, a price premium over most non-enriched bread is anticipated to act as a natural barrier to excessive intakes in the target population, or intakes in non-target populations. Thus, there is a direct cost to the consumer as the price of the plant sterol containing products will be higher than a standard bread. However, this is a cost that consumers can choose to incur in the context of making an informed decision about the product, and it is not imposed upon them.

The Applicant considers the pricing for a plant sterol enriched bread and bread products would not exceed the maximum price range in market of that category at the time of launch.

Importantly, any consumption occurring in the target population is likely to be of added benefit as there is evidence that many of those consuming plant sterol enriched products may not be receiving the minimum effective amount of phytosterols shown to have a positive effect on lowering cholesterol levels (FSANZ, 2006; EFSA, 2008; Ras, 2017).

7.5.3 Information to demonstrate that the food(s) containing the novel food ingredient will not adversely affect any population groups (e.g. particular age or cultural groups)

(As per section 3.5.2 F.3 of the Application Handbook as at 1 July 2024)

There is also no evidence of any adverse effects in the target as well as non-target populations from the sale of phytosterol-enriched foods currently in the market. Consequently, there is no basis to anticipate any adverse effects for the non-target population from phytosterol enrichment of bread.

It is very unlikely that consumers who are not adults interested in heart health and specifically cholesterol lowering will buy or consume a phytosterol-enriched bread. Previously data reviewed by FSANZ for other plant sterol enriched foods (A1065, A1070), found that senior couples and independent singles are the main life stage groups of purchasers of phytosterol enriched food products, and the primary shopper tends to be aged 55+ years. In younger households where phytosterol-enriched products are bought, the non-enriched counterpart is bought more frequently (FSANZ, 2012). The Applicant has not identified a more recent analysis.

The potential for consumption by people outside the target group, including children, is already addressed by mandatory advisory labelling for foods enriched with phytosterols (or their equivalents). No change to current labelling requirements is proposed and the proposed plant sterol concentrations per serve are already permitted in other food categories.

The efficacy of phytosterols in relation to cholesterol lowering is not defined or limited by race or socioeconomic status. Plant sterol intake is safe and not associated with adverse events irrespective of race or socioeconomic status or those non-target population groups already identified through existing phytosterol risk communication labelling in the Code (i.e., children and pregnant and lactating women).

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8 General food labelling

(As per section 3.2.1 of the Application Handbook as at 1 July 2024)

8.1 General Information to support the proposed labelling change

(As per section 3.2.1 A of the Application Handbook as at 1 July 2024)

The Applicant is **not** proposing a change to food labelling however, the following comments are provided in relation to labelling of plant sterols in a food product for the sake of completeness.

The existing requirements in the Code for the labelling and advertising of foods containing added plant sterols will apply to breads and bread products containing added plant sterols.

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

The Applicant understands 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.

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 permitted¹⁹.

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 0.8g 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 2g 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)²⁰ (paragraph 1.2.7—18(1)(a)).

¹⁹ 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)).

²⁰ [In accordance with Schedule 5 - Nutrient profiling scoring method.](#)

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In relation to A1247, FSANZ made the following comment:

Regarding 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.

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Appendix 1: Plant sterol enriched products available in ANZ

An audit of the websites of the two major grocery retailers in Australia (Woolworths and Coles) and New Zealand (Countdown and New World) conducted by the Applicant in August 2024

Product Category	Brand	Product Description	Phytosterols (per serve or specified amount)
Edible oil spreads [S15-2.2.1.3] <i>Margarine and similar products</i> [S25 & 2.4.2]	Coles	Coles Cholesterol Lowering Spread 500g (currently unavailable)	0.8g/serve (not specified) 8.00g/100g
	Tablelands	Heart Smart Reduced Cholesterol spread 500g	2g/serve Serve = 25g
	Flora	Proactiv Cholesterol Lowering Margarine Spread Light 500g	0.8g/serve Serve = 10g 25g provides 2g plant sterols
	Flora	Proactiv Cholesterol Lowering Margarine Spread Original 250g	0.8g/serve Serve = 10g 25g provides 2g plant sterols
	Flora	Flora ProActiv Buttery 500g	25g provides 2g plant sterols
	Olivani (NZ)	Cholesterol Lowering Buttery Spread 500g.	2 tablespoons provides 2 g plant sterols
	Olivani (NZ)	Cholesterol Lowering Original Spread 500g.	2 tablespoons provides 2 g plant sterols
Breakfast cereals [S15-6.3] [S25]	Sanitarium	Weet-Bix Cholesterol Lowering Cereal 440g	2g/serve Serve = 36g
Liquid milk [S15 – 1.1.1.1] [S25 & 2.5.1]	Australia's Own	Cholesterol Lowering Milk, 1L https://www.coles.com.au/product/australia's-own-cholesterol-lowering-milk-1l-6506589	0.8g/250mL
	Dairy Farmers	Heart Active Milk, 1L 99% fat free	0.8g/serve Serve = 250mL
Yoghurt [S15 – 1.2.1] [S25 & 2.5.3]		No products	
Cheese [S15-1.6]		No products	
Beverages from plants [S25]	Sanitarium Plantwell	Cholesterol lowering Oat milk	1.0g/serve Serve = 250mL

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Reference:

[Coles](#) online searched 29 August 2024, updated 11 January 2025

[Woolworths](#) online searched 29 August 2024, updated 11 January 2025

[New World \(NZ\)](#) online searched 29 August 2024, updated 11 January 2025

[Woolworths NZ](#) online searched 29 August 2024, updated 11 January 2025

Appendix 1A: Plant sterol enriched products available in other countries [CCI]

Mintel Search details:

Search for products

where **Date Published** is between *Jun 1996* and *Aug 2024*

and **Ingredient Search** matches one or more of *[Phytosterols and all child ingredients; Phytosterols]* as the *Ingredients*

and **Category** matches *Bakery*

51 results found.

The search result is provided as **Appendix 1A [CI]**.

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Appendix 2: Literature search results on studies investigating plant sterols – safety assessments.

Sources: Google Scholar, PubMed, and Cochrane

Timeline: 2022 to December 2024 inclusive

Search terms:

(phytosterols OR phytosterol OR phytostanol OR phytostanols OR “plant sterol” OR “plant sterols” OR “plant stanol” OR “plant stanols” OR “sterol esters” OR “sterol ester” OR “stanol esters” OR “stanol ester”) AND (“systematic review” OR meta-analysis) AND (human OR rat OR mouse)

(phytosterols OR phytostanols OR "plant sterols" OR "plant stanols") AND human

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Search results

1. Barkas, F.; Bathrellou, E.; Nomikos, T.; Panagiotakos, D.; Liberopoulos, E.; Kontogianni, M.D. *Plant Sterols and Plant Stanols in Cholesterol Management and Cardiovascular Prevention*. *Nutrients* 2023, 15, 2845. <https://doi.org/10.3390/nu15132845>

Abstract

Atherosclerotic cardiovascular disease (ASCVD) remains the major mortality cause in developed countries with hypercholesterolaemia being one of the primary modifiable causes. Lifestyle intervention constitutes the first step in cholesterol management and includes dietary modifications along with the use of functional foods and supplements. Functional foods enriched with plant sterols/stanols have become the most widely used nonprescription cholesterol-lowering approach, despite the lack of randomized trials investigating their long-term safety and cardiovascular efficacy. The cholesterol-lowering effect of plant-sterol supplementation is well-established and a potential beneficial impact on other lipoproteins and glucose homeostasis has been described. Nevertheless, experimental, and human observational studies investigating the association of phytosterol supplementation or circulating plant sterols with various markers of atherosclerosis and ASCVD events have demonstrated controversial results. Compelling evidence from recent genetic studies have also linked elevated plasma concentrations of circulating plant sterols with ASCVD presence, thus raising concerns about the safety of phytosterol supplementation.

Thus, the aim of this review is to provide up-to-date data on the effect of plant sterols/stanols on lipid-modification and cardiovascular outcomes, as well as to discuss any safety issues and practical concerns.

Conclusions

Current guidelines recommend plant sterols and plant stanols in the amount of approximately 2 g/day with the goal of reducing LDL-C by approximately 10% in combination with dietary changes. Despite their undoubtable cholesterol-lowering effect, past experimental and human studies have demonstrated controversial results regarding the effect of phytosterol consumption on various markers of atherosclerosis. Compelling evidence from recent genetic studies have linked elevated plasma concentrations of circulating plant sterols with CVD presence, thus raising concerns about the safety of phytosterol supplementation.

Considering the lack of, and the inability to design, randomized clinical trials addressing cardiovascular efficacy and safety, future studies could clarify whether the relatively small increase in the plasma concentration of circulating phytosterols induced by phytosterol-enriched food attenuates atherosclerosis and increases CVD risk. In the meantime, both physicians and consumers should keep in mind that this recommendation might be applied to individuals with hypercholesterolaemia who are expected to have a cardiovascular benefit, but also that the daily intake must not exceed the recommended dose. Finally, plant sterols/stanols should not be viewed as a substitute for much more effective and evidence-based cholesterol-lowering therapies, especially in individuals at high CVD risk.

<https://www.mdpi.com/2072-6643/15/13/2845>

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2. Bing Liu, Ke Chen, Xi Chen, Jian Wang, Guangjie Shu, Zhiguang Ping, Shenshen Zhang, *Health outcomes associated with phytosterols: An umbrella review of systematic reviews and meta-analyses of randomized controlled trials*, *Phytomedicine*, Volume 122, 2024, 155151, ISSN 0944-7113,

Abstract

Background

[Phytosterols](#) (PS), as a kind of plant active ingredients, have many benefits to human health. However, there is currently no comprehensive overview of the clinical evidence and an assessment of the evidence quality.

Purpose

We conducted an umbrella review, which incorporated verification spanning a number of meta-analyses and [systematic reviews](#) to clarify the link that existed between PS consuming and health outcomes.

Methods

The databases [PubMed](#), [Embase](#), Web of Science and The [Cochrane Library](#) were searched for appropriate research and ultimately included 23 articles involving 79 results. Methodological quality and the validity of evidence received designation in the included meta-analyses leveraging the Assessment of Multiple Systematic Reviews (AMSTAR-2) and the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE).

Results

The consumption of PS makes a contribution to the alleviation of metabolic conditions such as [hypercholesterolemia](#), diabetes, obesity, and hypertension. Its most essential function is to decrease cholesterol absorption, leading to dramatically reductions in [total cholesterol](#) and [low density lipoprotein cholesterol](#). Furthermore, utilizing PS products can have a favorable impact on managing [apolipoprotein](#) levels along with decreasing the probability of obtaining [atherosclerotic cardiovascular disease](#).

Conclusion

This umbrella review summarized a range of beneficial functions of PS to humans, highlighting the promising potential for the development of PS into functional foods.

<https://doi.org/10.1016/j.phymed.2023.155151>.

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3. Souleymane Zio, Bakary Tarnagda, François Tapsoba, Cheikna Zongo, Aly Savadogo. (2024) *Health interest of cholesterol and phytosterols and their contribution to one health approach: Review*. Heliyon, Volume 10, Issue 21 e40132, November 15, 2025

Abstract

Plants and animals are potential sources of food, particularly lipids. They are sources of nutrients for humans and are used in various applications in food industries. Foods whose lipids consumed, have benefits for animal and human health. Sterols are among the compounds essential to the well-being of living beings. Phytosterols are derived from plants and algae, and zoosterols from animals dominated by cholesterol. Cholesterol is found in small quantities in some plant lipids. Also, cholesterol is produced by herbivorous insects by metabolizing phytosterols. Oilseeds and vegetable oils contain sterols and are the richest natural sources of phytosterols. Vegetables and fruit also contain small quantities. These compounds play an undeniable role in our diet. Foods, particularly vegetable oils, when produced, preserved, and used according to established prescriptions, help to ensure consumer health, and prevent certain pathologies. Sterols, and in particular phytosterols, play a number of roles in the pharmaceutical field (therapeutic steroids), nutrition (anti-cholesterol, anti-cancer properties). These natural molecules with their nutritional and therapeutic properties have a positive impact on human and animal health, and possibly on vegetative growth (development cycle of plants). The same is true for cholesterol, which has multiple functions in humans and animals. Also, a diet based on plants or their by-products with positive effects on human and animal health is closely in line with the objectives of the 'One health approach'. Indeed, sterols can have adverse effects on health when established standards are not respected. As a result, the health benefits of sterols (cholesterol and phytosterols) require particular attention, given their contribution to the public health problems facing our countries. The aim of the present research is to highlight the health benefits of cholesterol and phytosterols for living organisms, particularly humans, and their contribution to the One Health approach.

[https://www.cell.com/heliyon/fulltext/S2405-8440\(24\)16163-4](https://www.cell.com/heliyon/fulltext/S2405-8440(24)16163-4)

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4. Yanhong Yang, Jiayue Xia, Tingqing Yu, Shiyun Wan, Yajie Zhou, Guiju Sun. (2024). *Effects of phytosterols on cardiovascular risk factors: A systematic review and meta-analysis of randomized controlled trials*. Phytotherapy Research.

Abstract

Cardiovascular diseases are the major cause of death globally. The primary risk factors are high blood lipid levels, hypertension, diabetes, and obesity. Phytosterols are naturally occurring plant bioactive substances. Short-term clinical trials have demonstrated phytosterols' cholesterol-lowering potential, but their effects on cardiovascular risk factors remain controversial, and relevant meta-analyses are limited and incomplete. We conducted a systematic and comprehensive search of PubMed, Web of Science, Embase and Cochrane Library up to December 22, 2023. A total of 109 randomized controlled trials (RCTs) of phytosterols (PS) intervention on cardiovascular risk factor outcomes were included in a preliminary screening of the retrieved literature by Endnote 20. We assessed the quality of all included randomized controlled trials using the Cochrane Collaboration's Risk of Bias tool. Cochrane data conversion tool was used for data conversion, and finally Stata was used for meta-analysis, egger test and sensitivity analysis of the included studies. The results indicated that dietary phytosterols intake could significantly decrease total cholesterol (TC) level (mean difference = -13.41; 95% confidence interval [CI]: -15.19, -11.63, $p < 0.001$), low density lipoprotein cholesterol (LDL-C) level (mean difference = -12.57; 95% CI: -13.87, -11.26, $p < 0.001$), triglycerides (TG) level (mean difference = -6.34; 95% CI: -9.43, -3.25, $p < 0.001$), C-reactive protein (CRP) level (mean difference = -0.05; 95% CI: -0.08, -0.01, $p = 0.671$), systolic blood pressure (SBP) level (mean difference = -2.10; 95% CI: -3.27, -0.9, $p < 0.001$), diastolic blood pressure (DBP) level (mean difference = -0.83; 95% CI: -0.58, -0.07, $p = 0.032$), increased high-density lipoprotein cholesterol (HDL-C) level (mean difference = 0.46; 95% CI: 0.13, 0.78, $p = 0.005$), but did not alter the levels of blood glucose (GLU) (mean difference = -0.44; 95% CI: -1.64, 0.76, $p = 0.471$), glycosylated hemoglobin, Type A1C (HbA1c) (mean difference = -0.28; 95% CI: -0.75, 0.20, $p = 0.251$), interleukin-6 (IL-6) (mean difference = 0.00; 95% CI: -0.02, 0.02, $p = 0.980$), tumor necrosis factor (TNF- α) (mean difference = 0.08; 95% CI: -0.08, 0.24, $p = 0.335$), oxidized low-density lipoprotein cholesterol (OXLDL-C) (standard mean difference = 0.16; 95% CI: -0.38, 0.06, $p = 0.154$), body mass index (BMI) (mean difference = 0.01; 95% CI: -0.07, 0.09, $p = 0.886$), waist circumference (WC) (mean difference = -0.10; 95% CI: -0.50, 0.30, $p = 0.625$) and body weight (mean difference = 0.03; 95% CI: -0.18, 0.24, $p = 0.787$). Our results suggest that phytosterols may be beneficial in reducing the levels of TC, LDL-C, TG, CRP, SBP, and DBP, but have no significant effect on GLU, HbA1c, TNF- α , IL-6, OXLDL-C, BMI, WC, and Weight. However, there were a small number of RCTs included in this study and their small population size may have reduced the quality of the study. And most of the included studies were short-term intervention trials. Therefore, higher quality studies need to be designed in future studies to establish more accurate conclusions.

<https://doi.org/10.1002/ptr.8308>

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5. Miszczuk, E.; Bajguz, A.; Kiraga, Ł.; Crowley, K.; Chłopecka, M. *Phytosterols and the Digestive System: A Review Study from Insights into Their Potential Health Benefits and Safety*. *Pharmaceuticals* 2024, 17, 557. <https://doi.org/10.3390/ph17050557>

Abstract

Phytosterols are a large group of substances belonging to sterols—compounds naturally occurring in the tissues of plants, animals, and humans. The most well-known animal sterol is cholesterol. Among phytosterols, the most significant compounds are β -sitosterol, stigmasterol, and campesterol. At present, they are mainly employed in functional food products designed to counteract cardiovascular disorders by lowering levels of ‘bad’ cholesterol, which stands as their most extensively studied purpose. It is currently understood that phytosterols may also alleviate conditions associated with the gastrointestinal system. Their beneficial pharmacological properties in relation to gastrointestinal tract include anti-inflammatory and hepatoprotective activity. Also, the anti-cancer properties as well as the impact on the gut microbiome could be a very interesting area of research, which might potentially lead to the discovery of their new application. This article provides consolidated knowledge on a new potential use of phytosterols, namely the treatment or prevention of gastrointestinal diseases. The cited studies indicate high therapeutic efficacy in conditions such as peptic ulcer disease, IBD or liver failure caused by hepatotoxic xenobiotics, however, these are mainly in vitro or in vivo studies. Nevertheless, studies to date indicate their therapeutic potential as adjunctive treatments to conventional therapies, which often exhibit unsatisfactory efficacy or serious side effects. Unfortunately, at this point there is a lack of significant clinical study data to use phytosterols in clinical practice in this area.

<https://www.mdpi.com/1424-8247/17/5/557>

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6. Giorgia Cioccoloni, Chrysa Soteriou, Alex Websdale, Lewis Wallis, Michael A. Zulyniak & James L. Thorne (2022) *Phytosterols and phytostanols and the hallmarks of cancer in model organisms: A systematic review and meta-analysis*, *Critical Reviews in Food Science and Nutrition*, 62:5, 1145–1165, DOI: 10.1080/10408398.2020.1835820

Abstract

Phytosterols and phytostanols are natural products present in vegetable oils, nuts, and seeds, or added to consumer food products whose intake is inversely associated with incidence and prognosis of several cancers. Randomized cancer prevention trials in humans are unfeasible due to time and cost yet the cellular processes and signaling cascades that underpin anti-cancer effects of these phytochemicals have been explored extensively in vitro and in preclinical in vivo models. Here we have performed an original systematic review, meta-analysis, and qualitative interpretation of literature published up to June 2020. MEDLINE, Scopus, and hand-searching identified 408 unique records that were screened leading to 32 original articles that had investigated the effects of phytosterols or phytostanols on cancer biology in preclinical models. Data was extracted from 22 publications for meta-analysis. Phytosterols were most commonly studied and found to reduce primary and metastatic tumor burden in all cancer sites evaluated. Expression of pAKT, and markers of metastasis (alkaline phosphatase, matrix metalloproteases, epithelial to mesenchymal transcription factors, lung and brain colonization), angiogenesis (vascular endothelial growth factor, CD31), and proliferation (Ki67, proliferating cell nuclear antigen) were consistently reduced by phytosterol treatment in breast and colorectal cancer. Very high dose treatment (equivalent to 0.2–1 g/kg body weight not easily achievable through diet or supplementation in humans) was associated with adverse events including poor gut health and intestinal adenoma development.

Phytosterols and phytostanols are already clinically recommended for cardiovascular disease risk reduction and represent promising anti-cancer agents that could be delivered in clinic and to the general population at low cost, with a well understood safety profile, and now with a robust understanding of mechanism-of-action.

<https://www.tandfonline.com/doi/full/10.1080/10408398.2020.1835820#abstract>

To: Food Standards Australia New Zealand

In relation to: Schedule 25 amendment to extend the permitted use of plant sterols to bread & bread products.

Date: January 2025

7. Jefrei E, Xu M, Moore JB, Thorne JL. *Phytosterol and phytostanol-mediated epigenetic changes in cancer and other non-communicable diseases: a systematic review*. Br J Nutr. 2024 Mar 28;131(6):935-943. doi: 10.1017/S0007114523002532. Epub 2023 Nov 13. PMID: 37955052; PMCID: PMC10876456.

Abstract

Phytosterols/phytosteranols are bioactive compounds found in vegetable oils, nuts and seeds and added to a range of commercial food products. Consumption of phytosterols/phytosteranols reduces levels of circulating LDL-cholesterol, a causative biomarker of CVD, and is linked to a reduced risk of some cancers. Individuals who consume phytosterols/phytosteranols in their diet may do so for many years as part of a non-pharmacological route to lower cholesterol or as part of a healthy diet. However, the impact of long term or high intakes of dietary phytosterols/phytosteranols has not been on whole-body epigenetic changes before. The aim of this systematic review was to identify all publications that have evaluated changes to epigenetic mechanisms (post-translation modification of histones, DNA methylation and miRNA expression) in response to phytosterols/phytosteranols. A systematic search was performed that returned 226 records, of which eleven were eligible for full-text analysis. Multiple phytosterols were found to inhibit expression of histone deacetylase (HDAC) enzymes and were also predicted to directly bind and impair HDAC activity. Phytosterols were found to inhibit the expression and activity of DNA methyl transferase enzyme 1 and reverse cancer-associated gene silencing. Finally, phytosterols have been shown to regulate over 200 miRNA, although only five of these were reported in multiple publications. Five tissue types (breast, prostate, macrophage, aortic epithelia and lung) were represented across the studies, and although phytosterols/phytosteranols alter the molecular mechanisms of epigenetic inheritance in these mammalian cells, studies exploring meiotic or transgenerational inheritance were not found.

<https://pubmed.ncbi.nlm.nih.gov/37955052/>

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