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Te Mana Kounga Kai - Ahitereiria me Aotearoa

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Supporting document

Risk and technical assessment – Application A1326

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

Executive summary

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

The risk and technical assessment considered the feasibility of incorporating plant sterols into bread, their stability, potential safety and nutrition implications, estimated dietary exposure, and their effect on blood cholesterol levels. The food technology assessment concluded that plant sterols can be effectively added to bread and are expected to remain stable during storage. Plant sterols added as a novel food must comply with relevant identity and purity specifications in the Code and applicable primary sources.

The risk assessment identified no new evidence to alter FSANZ's previous conclusions that the addition of plant sterols to foods raises no safety concerns for the general population. Absorption of plant sterols from the diet is very low. Consumption of plant sterols is associated with reductions in circulating concentrations of some fat-soluble vitamins and carotenoids, however, concentrations remain within normal reference ranges. Previous assessment by FSANZ concluded that consumption of up to approximately 9 g/day of total plant sterol equivalents based on the highest amount assessed in the available evidence is unlikely to pose a safety concern for children or adults. The toxicological assessment concluded that the available evidence did not justify establishing an ADI for plant sterols.

The dietary exposure assessment indicates the addition of plant sterols to bread will increase exposure among consumers. An increase in mean and P90 dietary exposures from the baseline were estimated to be 2.6 g/day or less, and 4.9 g/day or less, respectively. Estimated dietary exposures to plant sterol equivalents including the extension of use ranged between 4.1 and 5.2 g/day at the mean and 7.4 to 9.6 g/day for high exposures. Estimated dietary exposures are consistent with levels associated with cholesterol-lowering effects, and when considered with the available toxicological data and evidence for nutritional effects, do not raise safety concerns. Evidence from a randomised controlled trial and a recent meta-

analysis found that plant sterols delivered in bread are associated with reductions in total cholesterol and low-density lipoprotein cholesterol concentrations, consistent with previous FSANZ assessments in other food matrices.

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

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1 Introduction

The applicant, George Weston Foods Limited, trading as Tip Top Bakeries (Tip Top), is seeking permission to amend the Australia New Zealand Food Standards Code (the Code) to permit the addition of phytosterols, phytostanols and their esters (collectively referred to as plant sterols) as a novel food to bread. During the assessment, the applicant agreed that 'bread' captures the scope of the permission requested. Accordingly, the risk and technical assessment, and this report, relate to the addition of plant sterols to bread.

The applicant requested permission to add plant sterols at concentrations of 0.8 to 2.2 g total plant sterol equivalents content[1] per serving. The requested conditions of use for bread containing added plant sterols include a minimum of 2 g dietary fibre per serving and a maximum of 380 mg sodium per 100 g. The term 'total plant sterol equivalents content' includes phytosterols and phytostanols in free form, as well as the hydrolysis products of their esters.

Plant sterols have been assessed by FSANZ in earlier applications (FSANZ 2010a and b; FSANZ 2017; FSANZ 2022). Plant sterols are currently permitted in a range of foods under the Code. The purpose of the requested amendment to bread is to provide an additional source of plant sterols for consumers seeking to lower their blood cholesterol.

2 Food technology assessment

2.1 Scope of the assessment

The objectives of the food technology assessment were to confirm whether there is a relevant and current specification in the Code for plant sterols. Additionally, the methods of analysis, feasibility of incorporating plant sterols into bread and their stability have been assessed.

2.2 Characterisation of plant sterols

The chemical and physical properties of plant sterols are provided in section 2 of the supporting document for Application A1024 – Equivalence of plant sterols, stanols and their fatty acid esters (FSANZ 2010a) and summarised in the supporting document for Application A1134 – Increased concentration of plant sterols in breakfast cereals (FSANZ 2017). A definition and the chemical names and structural formulae of major free phytosterols and phytostanols are also provided in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) specification for Phytosterols, phytostanols and their esters (FAO/WHO 2008). That information is not repeated here, however a summary relevant to this application is provided below.

Plant sterols are a group of steroid alcohols and esters that occur naturally in plants. Synonyms are plant sterols/stanols, plant sterol/stanol esters, and phytosterol/phytostanol esters. Commercially, phytosterols and phytostanols are isolated from vegetable oils such as soybean oil, rapeseed oil, sunflower oil or corn oil or from tall oil (a by-product of the manufacture of pine wood pulp) (FAO/WHO, 2008).

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[1] ***total plant sterol equivalents content*** means the total amount of:
(a) phytosterols; and
(b) phytostanols; and
(c) phytosterols and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters (subsection 1.1.2—2(3)).

There are many different types of plant sterols with over 100 chemically distinct plant sterols reported. The most common free phytosterols and phytostanols and their corresponding CAS (Chemical Abstracts Service) identification numbers are shown in Table 1.

Table 1 *Common free phytosterols and phytostanols*

Compound	CAS number
Sitosterol (β-sitosterol)	83-46-5
Sitostanol (β-sitostanol)	83-45-4
Campesterol	474-62-4
Campestanol	474-60-2
Stigmasterol	83-48-7
Brassicasterol	474-67-9

Phytosterols and phytostanols can be esterified by reacting with vegetable oil long chain fatty acids to form plant sterol esters, for example, sitostanyl oleate and campesteryl oleate. Esterification converts solid sterols, which have a high melting point, into liquid/semi-liquid sterol esters, materials with comparable chemical and physical properties to edible fats. This improves solubility in fat and oil matrices, enabling incorporation into the target foods.

Commercial products may be mixtures of phytosterols, phytostanols and their esters. They do not serve a technical function in food (FAO/WHO 2008).

2.3 Specifications

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

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

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

There are 2 relevant specifications in the primary sources listed in section S3—2 of the Code - the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in its Combined Compendium of Food Additive Specifications (FAO JECFA Monograph 5 for Phytosterols, Phytosterols and their Esters (FAO/WHO 2008)), and in the Food Chemicals Codex (FCC) specification for Vegetable Oil Phytosterol Esters (USP 2024).

Schedule 3 of the Code also includes specifications for arsenic, lead, cadmium and mercury (section S3—4) if they are not already detailed within specifications in sections S3—2 or

[2] ***total plant sterol equivalents content*** means the total amount of:
(a) phytosterols; and
(b) phytostanols; and
(c) phytosterols and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters (subsection 1.1.2—2(3))

S3—3. The FAO JECFA specification for Phytosterols, Phytosterols and their Esters has specifications for arsenic and lead, and the FCC specification has specifications for lead.

2.4 Method of Analysis

The analysis of the presence of, and the amounts of, added plant sterols in different food matrices has been well established and published in the scientific literature (Laakso 2005, Guadalupe et al. 2021).

The applicant has provided the method of identification for phytosterols by gas chromatography, the AOCS Official Method Ce 12-16 —*Sterols and stanols in foods and dietary supplements containing added phytosterols* (reapproved in 2024). This method can determine total free sterols/stanols and total steryl/stanol esters and quantify each of the five major phytosterols that are the subject of the United States Food and Drug Administration's (FDA's) health claim for phytosterols and the reduced risk of coronary heart disease.

In addition, there is an ISO standard*, ISO 23349:2020(en) Animal and vegetable fats and oils — Determination of sterols and stanols in foods and dietary supplements containing added phytosterols* which provides a reference method for the determination of free sterols/stanols and steryl/stanol esters in foods containing added plant sterols and plant stanols and in plant sterols and plant stanols food additive concentrates.

2.5 Incorporating plant sterols in bread

The applicant intends to add plant sterols to bread as defined in Standard 1.1.2. of the Code.

The applicant intends to use a commercially available phytosterol product that has been demonstrated to be soluble and uniformly distributed in bread. Research papers on the incorporation of plant sterols to bread were obtained from literature searches[3].

A paper from Ferguson et al. (2019) includes an example of a commercially available plant sterol product comprising a mixture of plant sterol fatty acid esters spray dried into a water dispersible powder, with the carrier containing sodium caseinate, glucose syrup and antioxidants to effectively deliver plant sterols as a food ingredient in bread to assist in lowering blood cholesterol (see Section 4.3 for further detail on the cholesterol lowering effects reported in this paper).

Bread with added plant sterols is permitted and available in Europe and the USA. Examples were provided by the applicant as confidential commercial information (CCI). The availability of these products indicate that plant sterols can be effectively incorporated into bread using commercially available plant sterol preparations. The applicant and food manufacturers would be responsible for ensuring the plant sterols are uniformly incorporated and comply with the provisions in the Code.

European food regulations, EU 2017/2470 permit the addition of plant sterols to rye bread containing at least 50% rye flour, not more than 30% wheat flour, no more than 4% added sugar and no added fat. In a study of rye bread meeting the composition requirements and enriched with plant sterols, Makran et al. (2023) investigated whether wholemeal rye bread (WRB) bread is a suitable food matrix for plant sterol enrichment. Plant sterols were added to the dough during the initial mixing stage. Based on the analysis of rheological properties, composition and simulated digestion, the authors concluded that WRB is a suitable food

[3] Search terms included combinations of 'phytosterol' 'phytostanol' 'phytosterol ester' 'plant sterol' 'plant sterols' 'bread' 'bread products' 'and' 'added to'.

matrix for plant sterol enrichment.

2.6 Stability of plant sterols in bread

The stability of plant sterols generally, and their addition to plant-based milks and breakfast cereals, has been assessed in previous applications.

Plant sterol degradation due to oxidation may occur due to heating time and temperature, heating method and the food matrix they are being added to; the manufacturing process controls and ingredients in plant-sterol preparations helps the stability of plant sterol enriched products throughout the products shelf-life (FSANZ 2017; FSANZ 2022). Similarly for bread enriched with phytosterols, the plant sterol preparations containing antioxidants and other ingredients assist in stability (Ferguson et al. 2019). A study on the stability of plant sterols from different sources in different ingredient preparations (e.g. with the addition of dextrin, inulin, preservatives, citric acid, antioxidants, antimicrobial agents in the plant sterol preparation) in liquid, powder and paste forms found the plant sterols in these preparations remained stable following heating to 150C for 2 hours (Gonzalez-Larena M et al. 2011).

A study by Soupas et al. (2003) on the stability of phytosterols in bread found the phytosterol oxide products in baked bread, bread crusts and toasted bread did not lead to substantial phytosterol oxidation reactions. Further research findings from Soupas (2006) found phytosterol ingredient preparations were stable during spray drying and ultra-high temperature (UHT) heating and on long-term storage. Only pan-frying resulted in more substantial phytosterol oxidation. Further details on phytosterol oxidation products are discussed in Section 3.1.4.3.

Bread with added plant sterols is commercially available in the EU and USA and remains stable over the intended shelf-life (information provided by the applicant as CCI).

2.7 Conclusions of the food technology assessment

Plant sterols are well characterised substances for which suitable identity and purity specifications are available in the Code.

There is an identity and purity specification for phytosterols, phytostanols and their esters provided in section S3—24 of the Code. Relevant primary-source specifications listed in subsection S3—2 include the FAO JECFA specification for sterols, phytostanols and their esters (FAO/WHO 2008) and the FCC specification for vegetable oil phytosterol esters (USP 2024).

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

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

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

3 Safety assessment

3.1 Toxicology assessment

3.1.1 Scope of the assessment

The objectives of the toxicology assessment were to consider whether there is any new evidence that would indicate a need to revise FSANZ's previous conclusions regarding the safety of foods containing added plant sterols.

3.1.2 Previous FSANZ assessment of plant sterols

FSANZ has previously conducted several assessments of plant sterols and concluded that addition of plant sterols to foods raises no safety concerns for the general population, including young children and pregnant and lactating women, although there is a risk to individuals with sitosterolaemia (phytosterolaemia) (FSANZ 2010b; FSANZ 2017; FSANZ 2022). This is a rare inherited disease affecting lipid metabolism and is discussed in further detail in section 3.1.4.4.

3.1.3 Kinetics and metabolism

Previous safety assessments by FSANZ have concluded that systemic absorption of phytosterols and phytostanols is low. No new data were found to alter this conclusion.

Absorption is of the order of 0.5–2% for phytosterols and 0.04–0.2% for phytostanols. Excretion into the bile is efficient, with the result that circulating levels are low, varying from 7 to 24 mmol/L for sterols and from 0.05 to 0.3 mmol/L for phytostanols (Ruscica et al 2025). Esterification increases absorption of phytosterols approximately five-fold (Zhang et al. 2025).

3.1.4 Toxicity studies

3.1.4.1 Animal or human studies

No animal studies or human tolerance studies of the safety of plant sterols that postdate FSANZ's previous safety assessment (Application A1249 – Addition of plant sterols as a novel food to plant-based milk alternatives; FSANZ 2022) were located in literature searches[4].

Rat studies summarised in Application A1019 – Exclusive use of phytosterol esters in lower-fat cheese products (FSANZ 2010b), which include ninety-day studies and 2-generation reproductive/developmental studies, indicate that plant sterols are of low toxicity and do not have adverse effects on reproductive parameters. One ninety-day study suggested that high levels of consumption of plant sterols was associated with cardiopathy in male rats, but this effect was not observed in other studies of similar or longer duration. FSANZ considers this finding to be a background lesion characteristic of the strain of rat used (see section 3.1.5).

FSANZ previously reviewed a range of clinical studies investigating the impact of dietary phytosterol supplementation up to 2 g/day on blood lipids in adults, which showed that the intervention was generally well tolerated and no serious treatment-related adverse events

[4] Search terms included 'phytosterol' AND 'safety', 'phytosterol' AND 'toxic', phytostanol' AND 'safety', phytostanol' AND 'toxic', 'phytosterol ester' AND 'safety', 'phytosterol ester' AND 'toxic', 'phytostanol ester' AND 'safety', and 'phytostanol ester' AND 'toxic'

were reported. FSANZ concludes 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.

Consumption of plant sterols is associated with reductions in circulating concentrations of some fat-soluble vitamins and carotenoids; however concentrations remain within normal ranges. Previous assessment by FSANZ concluded that consumption of up to approximately 9 g/day of total plant sterol equivalents based on the highest amount assessed in the available evidence is unlikely to pose a safety concern for children or adults. The effects of plant sterol consumption on absorption of fat-soluble vitamins is further discussed in Section 3.2.

3.1.4.2 Potential for allergenicity

No new information was submitted or located to suggest that plant sterols are associated with significant risk of allergic reactions.

3.1.4.3 Phytosterol oxidation products

Concerns have been raised by some authors that phytosterol oxidation products may be atherogenic. FSANZ has previously reviewed the peer-reviewed scientific literature concerning phytosterol oxidation products in response to a submission concerning A1134 and concluded there is no robust evidence to support concerns that the oxidation products of dietary plant sterols pose a risk to consumers (FSANZ 2017). At that time, FSANZ noted the cholesterol-lowering benefits of dietary plant sterol consumption. As part of the current hazard assessment, advanced literature searches[5] of PubMed were conducted. No publications were found that would warrant any change to FSANZ's existing conclusion on phytosterol oxidation products.

3.1.4.4 Sitosterolaemia

Sitosterolaemia is inherited as an autosomal recessive disease and is characterised by greatly increased intestinal absorption of phytosterols. People with this condition are at elevated risk of early-onset atherosclerotic cardiovascular disease, as well as other lesions including tendon xanthomata, thrombocytopenia, haemolytic anaemia, and splenomegaly. The prevalence of sitosterolaemia in the general population is very low, with around 1 in 200,000 people being homozygous for the condition. Management of the disease includes a diet low in plant sterols, avoidance of phytosterol supplementations, and ongoing treatment with ezetimibe and bile acid sequestrants (Ruscica et al. 2025).

Sitosterolaemia is an active field of research, with numerous papers published in the peer-reviewed literature since FSANZ's previous safety assessment of phytosterols (A1249; FSANZ 2022). This is a condition that needs to be managed with a medical professional.

3.1.5 Assessments by other agencies

No safety assessments postdating the most recent safety assessment by FSANZ (A1249; FSANZ 2022) have been published.

In 2008, JECFA established an Acceptable Daily Intake (ADI) of 40 mg/kg bw for phytosterols, phytostanols and their esters, based on heart muscle degeneration in a 90-day oral toxicity study in rats. FSANZ re-evaluated this study as part of A1019 and concluded that it did not support establishing an ADI for plant sterols. The incidence of heart muscle

[5] Search terms 'phytosterol oxidation product' AND 'risk'; 'phytosterol oxidation product' AND 'toxic'; and 'phytosterol oxidation product' AND 'hazard'

changes was within the range of historical control data relevant for the strain of rats used in the study, and similar changes were not seen in other 90-day rat studies of phytosterols in the diet, so it was not considered to be treatment-related (FSANZ 2010b).

3.1.6 Conclusions of the toxicology assessment

Absorption of dietary plant sterols is very low, and they are not associated with adverse effects in animal studies or human studies even when consumed at high doses. No new evidence has been found to alter FSANZ's previous conclusions that fortification of foods with plant sterols raises no safety concerns for the general population, including young children and pregnant and lactating women, although there is a risk for individuals with sitosterolaemia (phytosterolaemia).

3.2 Nutrition assessment

3.2.1 Scope of assessment

The objectives of the nutrition assessment were to:

- determine whether the addition of plant sterols affects the absorption and status of other nutrients, particularly fat-soluble vitamins and carotenoids
- identify any nutritional concerns associated with the consumption of bread containing added plant sterols at the proposed levels of use.

FSANZ has previously identified interactions between plant sterols and the absorption and status of fat-soluble vitamins and carotenoids as a potential nutritional risk, most recently assessed in A1134 (FSANZ 2017). Accordingly, the current assessment focused on these nutrients as a primary area of interest.

In addition, to identify any other potential nutritional concerns associated with the proposed addition of plant sterols to bread, a broader literature search was undertaken to capture evidence relating to the nutritional, dietary or health effects of plant sterol consumption in this food vehicle.

3.2.2 Previous FSANZ assessment of plant sterols

The reduction in plasma concentrations of some fat-soluble vitamins and carotenoids associated with the consumption of plant sterol-fortified foods has been evaluated in previous FSANZ assessments (FSANZ 2005; FSANZ 2006; FSANZ 2010b; FSANZ 2017), including studies investigating foods containing added plant sterols at intakes up to approximately 9 g/day (Davidson et al., 2001; Gylling et al., 2010; Mensink et al., 2010).

These assessments concluded that:

- Studies showed decreases in vitamin K, vitamin D and tocopherol concentrations; however, these decreases were not statistically significant after adjustment for changes in blood cholesterol concentrations, reflecting their transport in circulation by lipoproteins (e.g. low-density lipoprotein cholesterol (LDL-C)).
- Consumption of plant sterols is associated with reductions in serum carotenoid concentrations (α- and β-carotenes and lycopene).
- Serum carotenoid concentrations are highly variable due to dietary and environmental factors and observed reductions fall within this range of variation.
- Reductions in carotenoid concentrations do not have implications for nutrition, as concentrations remain within normal reference ranges and there is no measurable effect on serum retinol levels (vitamin A).

- Increased consumption of carotenoid-rich fruits and vegetables may offset reductions in serum carotenoids associated with plant sterol intake.

Overall, these findings indicate that reductions in serum carotenoid concentrations associated with plant sterol consumption do not pose a nutritional risk.

3.2.3 Current assessment

3.2.3.1 Absorption of fat-soluble vitamins

The potential for plant sterols to affect the absorption and status of fat-soluble vitamins has been previously assessed by FSANZ, most recently in A1134 (FSANZ 2017).

A literature search[6] was conducted in PubMed on 26 June 2026 to identify additional studies published since 2016 that were relevant to the nutrition assessment. The search retrieved 95 records, of which one study was considered relevant (Baumgartner et al. 2017). Studies were not considered for inclusion in the assessment if the effect of plant sterols on the absorption or status of fat-soluble vitamins was not quantified.

A meta-analysis of randomised controlled trials conducted by Baumgartner et al. (2017) assessed the effects of plant sterol and stanol consumption on plasma fat-soluble vitamin and carotenoid concentrations across 41 studies involving a total of 3,306 participants. Consumption of plant sterols and stanols (mean 2.5 g/day) was associated with reductions in circulating carotenoid concentrations, including β-carotene (-16.3%), α-carotene (-14.4%) and lycopene (-12.3%). These reductions remained statistically significant after standardisation to total cholesterol, although the magnitude of change was smaller (-6.3% to -10.1%) compared with non-standardised changes. Reductions were also reported for oxygenated carotenoids, although these were attenuated (zeaxanthin and β-cryptoxanthin) or no longer present (lutein) after standardisation to total cholesterol. Reductions in tocopherol concentrations were also observed; however, no changes were present after standardisation to total cholesterol. No effects were reported for concentrations of retinol and vitamin D. Overall, reductions in circulating carotenoid concentrations, although observed, were attenuated following standardisation to total cholesterol and remained within normal ranges, indicating no nutritional concern.

3.2.3.2 Other nutritional impacts of plant sterols in bread

An additional literature search[7] was undertaken in PubMed on 3 June 2026 to identify any potential nutritional, dietary or health effects of plant sterol consumption in bread. No studies relevant to the nutrition assessment were identified.

3.2.4 Conclusions of the nutrition assessment

Consumption of plant sterols is associated with reductions in circulating concentrations of some fat-soluble vitamins and carotenoids. These changes are largely attributable to reductions in circulating lipoproteins and do not reflect adverse effects on nutrient status. Although reductions in circulating carotenoid concentrations have been observed,

[6] Search terms: Human AND (plant sterol* OR plant sterol* OR plant stanol* OR phytosterol* OR phytostanol* OR sitosterol* OR sitostanol* OR campesterol* OR campestanol* OR stigmasterol* OR brassicasterol*) AND (absorbed OR absorption OR inhibi* OR interference*) AND (vitamin* OR carotene OR carotenoid). Filters: from 2016 – 2026.

[7] Bread* AND (plant sterol* OR plant sterol* OR plant stanol* OR phytosterol* OR phytostanol* OR sitosterol* OR sitostanol* OR campesterol* OR campestanol* OR stigmasterol* OR brassicasterol*) AND (nutriti* OR diet* OR health*) AND human.

concentrations remain within normal reference ranges and there is no measurable effect on vitamin A status, including at intakes up to 9 g/day of added plant sterols. Accordingly, these changes do not present a nutritional risk. No additional nutritional concerns associated with the proposed use of plant sterols in bread were identified.

3.3 Dietary exposure assessment

FSANZ has previously conducted assessments for the estimated dietary exposure to plant sterols[8] if added to edible oil spreads, breakfast cereals, low fat milk, low fat yoghurt, reduced fat cheese and plant-based milk alternatives. The most recent of these (A1249; FSANZ 2022) has been used as the basis of this assessment. This application seeks permission to add plant sterols to bread at levels of up to 2.2 g per serving.

3.3.1 Objectives of the dietary exposure assessment

The objectives of this dietary exposure assessment were to:

- estimate the total plant sterol exposure from foods which may contain added plant sterols at baseline
- estimate any potential increase in plant sterol exposure from the addition of plant sterols to bread
- determine whether normal consumption patterns of bread would result in dietary exposure to plant sterols of 2.2 g per serving.

3.3.2 Dietary exposure methodology

Dietary exposure assessments require data on the concentration of the chemical of interest in the foods requested, and consumption data for the foods that have been collected through a national nutrition survey.

Baseline dietary exposure was estimated using (1) the consumption of foods containing added plant sterols, and other foods as reported in the Australian and New Zealand national nutrition surveys for which there are current permissions for the addition of plant sterols; and (2) maximum permitted levels (MPL) for added plant sterols in the Code. The application requests permission to add plant sterols to bread at up to 2.2 g per serving. Therefore, dietary exposures of added plant sterols from bread were calculated using 2.2 g per serving in a conservative approach.

The dietary exposure assessment was undertaken using FSANZ's dietary modelling computer program Harvest. A summary of the general FSANZ approach to conducting dietary exposure assessments for applications is on the FSANZ website. A detailed discussion of the FSANZ methodology and approach to conducting dietary exposure assessments is set out in Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2024).

3.3.2.1 Food consumption data used

The permissions contained in the Code apply to foods sold in both Australia and New Zealand, therefore dietary exposure assessments were undertaken for both countries.

The food consumption data used for the dietary exposure assessment were:

[8] The term plant sterols has been used in the dietary exposure assessment to include the total amount of phytosterols, phytostanols and phytosterols, and phytostanols following hydrolysis of any phytosterol esters and phytostanol esters, as defined as 'total plant sterol equivalents content' in section 1.1.2—2 in the Code.

- 2002 New Zealand National Children's Nutrition Survey (2002 NZNNS), one 24-hour recall covering 3,275 New Zealand children aged 5-14 years (Ministry of Health 2005).
- 2008/09 New Zealand Adult Nutrition Survey (2008 NZANS), one 24-hour recall covering 4,721 New Zealanders aged 15 years and above (University of Otago and Ministry of Health 2011a, b).
- 2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS), one 24-hour food recall survey of 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% of respondents (n=7,735) (ABS 2015).

For Australia, 2 days of consumption data were averaged to represent longer term exposures, whereas the assessments for New Zealand were based on a single day of data. All results were weighted to make them representative of the respective populations[9]. The design of these nutrition surveys varies and the key attributes of each, including survey limitations is included in the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2024).

FSANZ acknowledges that the nutrition survey data for Australia and New Zealand used for this assessment are several years old. These data are the best nationally representative data currently available. Conducting dietary exposure assessments based on these food consumption data provides the best estimate currently available of actual consumption of a food and the resulting estimated exposure to a food chemical. It should be noted that while the nutrition surveys may not include information regarding specific food products that are now available in the market, for staple foods such as breads, cereals and milk etc the data derived from the nutrition surveys available are still adequate for representing the range of consumption amounts for foods.

Whilst data from the Australian 2023 National Nutrition and Physical Activity Survey (2023 NNPAS) have been released by the Australian Bureau of Statistics, only summary consumption statistics at the food group level have been published to date (ABS 2023). At the time of this assessment the raw data from the survey that allows extraction of consumption for specific foods was not available in Harvest. Therefore, although the 2023 NNPAS data could not be used for this assessment, summary consumption data have been included in the discussion.

In addition to the specific assumptions made and limitations identified in relation to this dietary exposure assessment, there are several limitations associated with the nutrition surveys per se. A discussion of these limitations is included in the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2024).

3.3.2.2 Population groups assessed

The hazard assessment did not identify any population sub-groups or at-risk groups for which there were specific safety considerations or where separate dietary exposure estimates were needed. Therefore, the whole survey population from each of the nutrition surveys were used for the dietary exposure assessment.

3.3.2.3 Scenarios

Two scenarios were used to estimate added plant sterol exposures:

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[9] Survey sample weighting factors are used to adjust the results of surveys to better reflect the results that would have been obtained if a truly representative sample from the population had been able to be obtained, and to make population-based estimations of results.

- *'Baseline'* included plant sterol exposure from foods in which the addition of plant sterols is currently permitted in the Code (see Table 2). For this application, the *baseline* scenario was derived from the A1249 'baseline plus plant-milk' scenario.
- *'Baseline plus bread'* includes plant sterol exposure from baseline plus the addition of plant sterols from bread based on the requested maximum permitted level of 2.2 g plant sterols per serving.

3.3.2.4 Food categories and plant sterol concentrations

Table 2 *Foods currently permitted to contain added plant sterols in Australia and New Zealand*

Food	Standard	Prescribed form	Maximum Permitted Level	Conditions for plant sterol addition
Breakfast cereals	Schedule 25	Total plant sterol equivalents	2.2 g/serving	The total fibre content is no less than 3 g/50 g and contains no more than 30 g/100 g of total sugars
Yoghurt	2.5.3–5	Total plant sterol equivalents	1.0 g/package (capacity no more than 200 g)	Contains no more than 1.5 g total fat/100 g
Milk	2.5.1–6	Total plant sterol equivalents	4 g/L	Contains no more than 1.5 g total fat/100 g
Edible oil spread (including margarine)	2.4.2–2	Total plant sterol equivalents	82 g/kg	
Cheese and processed cheese	2.5.4–4	Tall oil phytosterol esters	90 g/kg	Contains no more than 12 g total fat/100 g
Plant-based milk alternatives	Schedule 25	Total plant sterol equivalents	2.2 g/250 mL	(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

The food classifications and concentrations used in this dietary exposure assessment are in Appendix 1.

3.3.2.5 Branded Food Database

The Branded Food Database (BFD) contains product information for over 32,000 unique branded products available in the Australian retail market. The data used in this analysis were sourced directly from brand owners and through in-store collections conducted by FSANZ across Coles, Woolworths, Aldi and Metcash stores in the ACT between 2023 – 2025.

Serve size information from product labels available in the BFD was used to estimate the average serving size of bread for use in the dietary exposure assessment. The estimate was derived from the subset of products remaining after excluding those that did not meet the specified sodium and fibre criteria. Breadcrumbs, pizza bases and bread mixes were excluded from the estimation of serving size as they may be consumed differently to other breads. An estimate of the serve size was required to convert the addition of 2.2 g plant sterols per serve to an amount per kilogram of the food to use in the Harvest dietary modelling program for the *'Baseline plus bread' scenario*.

The data in the BFD provides a comprehensive snapshot of products sold in the Australian retail market at a point in time. It does not capture data from all retailers and therefore will not capture data for all products available to Australian consumers. Data currency and accuracy is also dependent on the accurate provision and entry of data. Annual audits are undertaken to ensure the data are as accurate and reflective of the current food supply as possible.

3.3.2.6 Assumptions and limitations

The aim of the dietary exposure assessment was to make the most realistic estimation of dietary exposure of plant sterols as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the estimated dietary exposure was not an underestimate of exposure.

Assumptions made in the dietary exposure assessment include those used in the dietary exposure assessment for A1249 in addition to the assumptions listed below:

- Naturally occurring plant sterols were not included in the assessment.
- Where a food or food classification was not included in the dietary exposure assessment, it was assumed to contain a zero concentration of plant sterols.
- 1 serving of bread (from the BFD) = 76 g.
- All bread contains plant sterols.

In addition to the specific assumptions made in relation to this dietary exposure assessment, there are several limitations associated with the nutrition surveys from which the food consumption data used for the assessment are based. A discussion of these limitations is included in Section 4 of the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2024).

3.3.3 Dietary exposure results

3.3.3.1 Estimated dietary exposure to added plant sterols

The estimated mean and 90th percentile (P90) exposures to added plant sterols for the scenarios assessed for Australian and New Zealand consumers, assuming added plant sterols at the MPL, for all plant sterol containing foods reported as being consumed in the national nutrition surveys (milk and edible oil spreads), all other foods for which there is permission to contain added plant sterols in the Code (breakfast cereals, yoghurt and cheese, plant based milk alternatives) in addition to bread are shown in Table 3.

For Australian consumers (aged 2+ years), the estimated mean and P90 exposures to added plant sterols at *Baseline* are 2.2 g/day and 4.6 g/day respectively, expressed as plant sterol equivalents. For the *Baseline plus bread* scenario, estimated mean and P90 exposures are 4.1 g/day and 7.4 g/day respectively, expressed as plant sterol equivalents.

For New Zealand children (aged 5-14 years), the estimated mean and P90 exposures for consumers at *Baseline* are 2.4 g/day and 4.2 g/day respectively, expressed as plant sterol equivalents. For the *Baseline plus bread* scenario, estimated mean and P90 exposures are 5.0 g/day and 9.1 g/day respectively, expressed as plant sterol equivalents.

For New Zealand adults (15 years and over), the estimated mean and P90 exposures for consumers at *Baseline* are 2.7 g/day and 5.3 g/day respectively, expressed as plant sterol equivalents. For the *Baseline plus bread* scenario, estimated mean and P90 exposures are

5.2 g/day and 9.6 g/day respectively, expressed as plant sterol equivalents.

Table 3 *Estimated dietary exposure to added plant sterols for baseline and the extension of use to bread assuming plant sterols added at the proposed Maximum Permitted Level*

Country	Age group	Scenario	Proportion of plant sterol consumers (%)	Estimated dietary exposure, consumers only (g/day)*	
				Mean	P90
Australia	2 years and above	Baseline	59.5	2.2	4.6
		Baseline plus bread	97.6	4.1	7.4
New Zealand	5-14 years	Baseline	42.3	2.4	4.2
		Baseline plus bread	94.1	5.0	9.1
	15 years and above	Baseline	46.2	2.7	5.3
		Baseline plus bread	91.0	5.2	9.6

* Expressed as plant sterol equivalents. Two-day average for Australia; day 1 only data for New Zealand.

3.3.4 Conclusions of the dietary exposure assessment

Plant sterol dietary exposures from foods which may contain added plant sterols were estimated using a conservative approach, whereby all foods reported in the national nutrition surveys to contain plant sterols and all other foods for which there is permission to contain added plant sterols in the Code were included in the assessment, in addition to bread.

Baseline dietary exposures to plant sterols (as plant sterol equivalents) from current permitted uses are around 2 to 3 g/day at the mean and around 5 g/day for high consumers in Australia and New Zealand. By including bread, the proportion of consumers in Australia and New Zealand increased from less than 60% to approximately 91 to 98%. Therefore, the overall addition of plant sterols to bread is predicted to increase the estimated exposures for Australian and New Zealand consumers of plant sterol containing products in the context of the whole diet. Expressed as plant sterol equivalents, the increase in mean and P90 dietary exposures were estimated to be 2.6 g/day or less, and 4.9 g/day or less respectively.

For the extension of use scenario, estimated mean dietary exposures to plant sterol equivalents ranged between 4.1 and 5.2 g/day across all population groups assessed. Dietary exposures for high consumers of plant sterol equivalents were estimated to be 7.4 g/day for Australians, 9.1 g/day for New Zealand children and 9.6 g/day for New Zealand adults. The estimates of dietary exposure for high consumers in New Zealand are in the vicinity of the highest amount assessed in studies of 9 g/day, and whilst some reductions in circulating carotenoid concentrations were observed in studies including up to this level, concentrations remain within normal reference ranges and there is no measurable effect on vitamin A status identified. All estimates of mean dietary exposure, including for the extension of use were below 9 g/day. The dietary exposure assessment is based on conservative assumptions that all bread contains added plant sterols at the proposed maximum level (2.2 g per 76 g serving), and that all other foods currently permitted to contain added plant sterols under the Code (breakfast cereals, yoghurt, cheese and plant-based milk alternatives) contain plant sterols at their maximum permitted levels. Given these and that the toxicological assessment concluded that the available evidence did not justify establishing an ADI for plant sterols, the estimates of dietary exposure are not of a public health and safety concern.

In the 2023 NNPAS, the median daily consumption of *'Regular breads, and bread rolls (plain, unfilled and untopped varieties)'* for all consumers is 72 g/day (ABS, 2023). This is similar to the serving size of bread derived from the BFD used in the dietary exposure assessment (76 g/day). Therefore, for bread only, based on a concentration of plant sterols of 2.2 g per serving and typical consumption patterns, median dietary exposure to plant sterols for consumers would be around 2 grams a day.

4 Effect on blood cholesterol

4.1 Scope of assessment

The objective of this assessment was to determine whether there are beneficial effects on blood cholesterol from consuming bread with added plant sterols.

4.2 Previous FSANZ assessment of plant sterols

FSANZ assessed whether consumption of foods containing added plant sterols affects blood cholesterol concentrations in a systematic review (FSANZ 2014). Subsequent assessments considered the applicability of this effect to specific food matrices, including breakfast cereals (A1134; FSANZ 2017) and plant-based milk alternatives (A1249; FSANZ 2022).

FSANZ's 2014 systematic review concluded, with a high degree of certainty, that consumption of foods containing added plant sterols reduces total cholesterol and LDL-C concentrations. This conclusion was based on 125 randomised controlled trials (>9,000 participants), with meta-analyses indicating that intakes of approximately 1.6 to 2.2 g/day reduce LDL-C by approximately 0.33 mmol/L (equivalent to approximately 8.5%) and total cholesterol by approximately 0.36 mmol/L (equivalent to approximately 5.9%). The effect was consistently observed across studies, including in adults with normal baseline total cholesterol and LDL-C concentrations, and across a range of food matrices.

4.3 Current assessment

FSANZ conducted a literature review of the evidence published since the 2014 systematic review. The literature search[10] was conducted in PubMed on 25 May 2026 to identify additional studies relevant to the assessment. The eligibility criteria previously used by FSANZ (FSANZ 2014; FSANZ 2022) were applied, with an amendment to specify the food format as bread (see Table 4). The search retrieved 7 records, of which 2 studies met the eligibility criteria[11] for inclusion in the assessment (Ferguson et al. 2019, Fontané et al. 2023).

Table 4 *PICOTS criteria for study selection*

Population	Humans
Intervention	Phytosterols, phytostanols or their esters in bread
Comparator	Placebo required in control arm
Outcomes	Total, LDL and or HDL cholesterol
Time	Minimum 2 weeks
Study type	Randomised control trial

A double-blind, randomised, placebo-controlled trial by Ferguson et al. (2019) investigated

[10] Search terms: Bread* AND (cholesterol[MeSH Terms] OR Hyperlipidemias[MeSH Terms] OR cholesterol*) AND (plant sterol* OR plant sterol* OR plant stanol* OR phytosterol* OR phytostanol* OR sitosterol* OR sitostanol* OR campesterol* OR campestanol* OR stigmasterol* OR brassicasterol*). Filters: from 2014 – 2026.

[11] For the systematic review and meta-analysis by Fontané et al. (2023), no minimum intervention duration was specified in the eligibility criteria, with duration treated as an analytical variable. The study was included as it was otherwise consistent with the PICOTS criteria.

the effects of phytosterol-enriched bread, with or without curcumin, on lipid profiles in hypercholesterolaemic adults (*n* = 75) in Australia. Participants (mean age 56 years) consumed 2 slices of bread daily for 4 weeks, providing: 2.3 g/day phytosterols; 228 mg/day curcumin; both interventions; or placebo. Curcumin did not significantly affect blood lipid concentrations. Therefore, treatment groups were pooled for analysis (phytosterol-containing versus non-phytosterol groups). Compared with control, the consumption of phytosterol-enriched bread significantly reduced total cholesterol (-0.52 mmol/L; -7.6%; $p < 0.001$) and LDL-C (-0.49 mmol/L; -10.6%: $p < 0.001$). Within the treatment group, these corresponded to reductions of 6.1% for total cholesterol and 8.8% for LDL-C from baseline. No significant effects on high-density lipoprotein cholesterol (HDL-C) or triglyceride concentrations were observed.

A systematic review and meta-analysis conducted by Fontané et al. (2023) assessed the effects of phytosterol-fortified foods (including plant sterols and plant stanols) on LDL-C concentrations across 125 randomised controlled trials. The mean phytosterol dose was approximately 2.1 g/day. On average, phytosterol consumption reduced LDL-C concentrations by 0.35 mmol/L (95% CI 0.32 to 0.38). The magnitude of LDL-C reduction increased with phytosterol dose, consistent with a dose-response relationship. Subgroup analyses indicated that food format influenced the magnitude of effect, with smaller reductions in LDL-C observed for cereal-based products (bread, biscuits and cereals) compared with the reference group (butter, margarine and spreads). This was supported by multivariate meta-regression, which showed a 0.16 mmol/L smaller reduction in LDL-C for cereal-based products relative to the reference group (95% CI -0.26 to -0.06; $p=0.001$). This difference may reflect the lower average phytosterol dose in these products (approximately 1.8 g/day), as well as potential differences attributable to the food matrix.

The findings of these 2 studies indicate that plant sterols delivered in bread are effective in reducing LDL-C, particularly when consumed at doses consistent with established intake levels (approximately 2 g/day).

4.4 Conclusion of the effect on blood cholesterol

The available evidence is consistent with previous FSANZ conclusions that consumption of foods containing approximately 2 g/day of added plant sterols reduces total cholesterol and LDL-C concentrations. Evidence from a randomised controlled trial showed that consumption of bread containing 2.3 g/day of plant sterols resulted in reductions in total cholesterol and LDL-C concentrations comparable to those previously reported by FSANZ. A recent meta-analysis on the effects of phytosterol-fortified foods on LDL-C reported a smaller magnitude of effect for cereal-based products (including bread), compared with butter, margarine and spreads. However, this difference may be attributable to the lower phytosterol dose in the cereal-based products. Overall, the evidence supports the efficacy of plant sterols in reducing total cholesterol and LDL-C concentrations when consumed in a bread matrix.

5 Consumer research

No specific research on consumer responses to plant sterols in bread was identified in a search of bibliographic databases. Plant sterol-enriched foods have been available on the market for the last 2 decades. Consumer understanding and behaviour of plant sterols have been comprehensively assessed by FSANZ in earlier applications including most recently A1249 (FSANZ 2022). In line with previous assessments and a lack of any further research, it is not anticipated that any substantial risks would arise from changes in consumer behaviour associated with the addition of phytosterols to bread.

6 Conclusions of the risk and technical assessment

Plant sterols can be incorporated into bread and are likely to remain stable over their shelf-life, provided they comply with relevant specifications in the Code and applicable primary sources. The risk and technical assessment identified no new safety concerns, supporting FSANZ's previous conclusions that the addition of plant sterols to foods does not raise safety risks for the general population. Estimated dietary exposures to plant sterols increase with the addition to bread but remain consistent with levels associated with cholesterol-lowering effects.

Evidence indicates that plant sterols delivered in bread are associated with reductions in total cholesterol and LDL-C concentrations. Overall, plant sterols can be safely added at the proposed levels, and bread is an effective delivery vehicle.

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Appendix 1 - Concentration data and classification systems used in the dietary exposure assessment

Table A1.1 *Classification names and codes and concentrations used in the dietary exposure assessment*

Food and use details				
Existing Permissions – Food Standards Code				
Food category	**Standard**	**MPL^**	**Harvest classification name**	**Harvest classification code**
Yoghurt	Section 2.5.3–5	1.0 g/200 g package (5 g/kg)	Ferm & renn milk, unflav, low/skim	1.2.1.4
			Ferm & renn milk prod, flavoured, low/skim	1.2.2.4
Milk	Section 2.5.1–6	4 g/L	Liquid milk, phytosterol esters (PSE)	1.1.2.5
			Liquid milk products and flavoured liquid milk, reduced fat, unflavoured, phytosterols	1.1.2.3.1.1
Edible oil spread (including margarine)	Section 2.4.2–2	82 g/kg	Edible oil spread, standard fat (60-80%), regular salt, phytosterols	2.2.2.1.1.4.1
			Edible oil spread, standard fat (60-80%), reduced salt, phytosterols	2.2.2.1.1.5.1
			Edible oil spread, reduced fat (<60%), reduced salt, phytosterols	2.2.2.1.2.5.1
Cheese	Section 2.5.4–4	90 g/kg*	Unripened cheese, red fat	1.6.1.2
			Unripened cheese, low fat (<=3%)	1.6.1.3
			Ripened cheese, red/low fat (<15%)	1.6.2.2
			Processed cheese, whole fat (=>15%), PSE added	1.6.3.1.2
			Processed cheese, red/low fat (<15%)	1.6.3.2
Breakfast cereals	n/a	61 g/kg	Breakfast biscuits	6.3.5
			Breakfast cereals, ready to eat, biscuit type	20.2.2.5.1.4
		44 g/kg	Breakfast flakes	6.3.6
			Breakfast cereals, ready to eat, flaky type	20.2.2.5.1.3
		49 g/kg	Oats, raw	6.1.1.1
			Breakfast cereals, porridge, dry mix	20.2.2.6.1
		7 g/kg	Oats, cooked	6.1.1.2
			Breakfast cereals, porridge	20.2.2.6
Plant-based milk alternatives	Schedule 25	2.2 g/250 ml serving (9 g/kg)	Nut- or seed-based beverages	14.1.9
			Cereal beverages	14.1.8
			Soy beverage	14.1.7
Requested use as included in the application				
Bread	MPL proposed in this application	2.2 g/76 g serving (29 g/kg)	Bread & related prod	7.1

Abbreviations: PSE = phytosterols esters, ferm = fermented, renn = rennetted, prod= products, unflav = unflavoured, red=reduced, MPL= maximum permitted level (value in brackets refers to the concentration used in the dietary exposure assessment estimation if converted from a per serve to a per kg basis); na = not applicable.
^ Refer to Risk and Technical Assessment for Application A1249 for serving sizes.
* The concentration of 90 g/kg is the MPL expressed as tall oil phytosterol esters, and is the concentration used in the dietary exposure assessment. This would correspond to 54 g/kg of total phytosterol equivalents so therefore what is used in the assessment is a worst-case scenario.