Sanitarium Health Food Company

Application to amend the Australia New Zealand Food Standards Code

Extension of the use to permit 2 grams per serve of plant sterols in plant-based milk alternatives in Schedule 25 – Permitted novel foods

21 December 2021

Executive Summary

Plant sterol enriched foods have a long history of use in the Australian and New Zealand, being available to consumers for the past two decades via enriched edible oil spreads, and permitted in other foods including reduced fat milks, reduced fat cheese, yoghurt and breakfast cereals.

This Application seeks to amend Schedule 25 (Permitted novel foods) to extend the use of phytosterols, phytostanols and their esters to plant-based milk alternatives which are products recommended by Australian Dietary Guidelines as well as Eating Guidelines for New Zealand Adults. Specifically, the proposed change will permit the addition of phytosterols, phytostanols and their esters so that plant-based milk alternatives can contain 2g of total plant sterol equivalents per 250ml serve.

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

The Australian National Heart Foundation recommends 2–3 g of plant sterol equivalents per day from products enriched with phytosterols within a healthy balanced diet for people to benefit from the cholesterol-lowering effects. The LDL-cholesterol (LDL-C) lowering effect of plant sterols/stanols has been demonstrated in several systematic reviews and meta-analyses of randomized controlled trials in humans and shows a dose-response relationship with intakes of up to 3 g/day lowering LDL cholesterol. Plant sterols lower cholesterol when delivered across a wide range of food and liquid formats/ matrices and occasions, and studies have demonstrated their cholesterol lowering effects when delivered via plant sterol enriched plant-based milk alternatives.

Sales of plant-based milk alternatives as a category, and each major segment of soy, almond and oat, has been growing steadily over the past decade in Australia and New Zealand driven by an increase in users of these products. The proposed change will, for the first time provide Australian and New Zealand consumers who are interested in lowering their cholesterol the choice of accessing effective amounts of plant sterols via one serve of plant sterol enriched plant-based milk alternative as part of their diet.

The proposed extension of use, to allow the addition of 2 grams of plant sterol equivalents in a single serve of plant-based milk alternatives is consistent with the outcomes from the two most recent plant sterol related applications (A1019 plant sterols addition to reduced fat cheese, and A1134 plant sterol addition to breakfast cereals). The benefits to the consumer of single serve products with 2 grams of plant sterols was also recognised by the FSANZ Phytosterols Expert Advisory Group in September 2005 when it stated *"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."*

Plant sterol enriched plant-based milk alternatives will carry mandatory advisory statements and other communication to target the intended consumer and packaging will be distinctive to differentiate it from non-fortified counterparts. A price premium is also expected to be a purchase signal to non-target groups. There are no cost/benefit impediments to the proposed change, other

than the additional cost of the plant sterol itself, which will be passed to the consumer via a price premium for the product.

There are no new health and safety concerns associated with the proposed change, which is consistent with FSANZ's previous assessment that there are no public health and safety risks from consumption of approved plant sterol fortified products.

In addition to widening consumer choice, the proposed regulatory change is consistent with other categories where 2 grams plant sterols are permitted in one serve of other foods and internationally where the use of plant sterols in plant-based milk alternatives is currently permitted.

To align with dietary guidelines we propose eligible products are plant-based milk alternatives with at least 100mg of added calcium per 100ml and low in saturated fat. The below drafting is provided as an example of proposed changes that would achieve the outcome being sought:

S25—2 Sale of novel foods

Permitted novel food	***Conditions of use***
*Phytosterols, phytostanols and their esters	7. May only be added to plant-based milk alternative (beverages derived from legumes, cereals, nuts, seeds, or a combination of those ingredients); and, if: (a) the beverage has at least 100mg of added calcium per 100ml; and (b) the beverage has no more than 0.75g of saturated fat per 100ml; and (c) the *total plant sterol equivalents content is the prescribed amount. 7A. For the purposes of condition 7(c) above: (a) the prescribed amount during the exclusive use period is: (i) for beverages sold under a brand from Sanitarium Health Food Company – an amount that is no less than 0.8 g per 250ml and no more than 2.2 g per 250ml; and (ii) for all other plant-based milk alternative – no phytosterols, phytostanols and their esters are to be added. (b) the prescribed amount after the end of the exclusive use period is an amount that is no less than 0.8 g per 250ml and no more than 2.2 g per 250ml.

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1 PART 1 GENERAL INFORMATION

[Section 3.1.1 of Application Handbook March 2019]

1.1 Applicant details

[Section 3.1.1 B of Application Handbook March 2019]

a) Applicant

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
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1.2 Purpose of the application

[Section 3.1.1 C of Application Handbook March 2019]

This Application seeks to amend Schedule 25 (Permitted novel foods) to extend the use of phytosterols, phytostanols and their esters to plant-based milk alternatives which are food products recommended by Australian Dietary Guidelines as well as Eating Guidelines for New Zealand Adults (NHMRC, 2013; MoH 2020). Specifically, the proposed change will permit the addition of phytosterols, phytostanols and their esters so that plant-based milk alternatives can contain 2g of total plant sterol equivalents per 250ml serve.

Plant sterol enriched foods have a long history of use in the Australian and New Zealand food supply, being available to consumers for the past two decades via enriched edible oil spreads, and permitted in other foods including reduced fat milks, reduced fat cheese, yoghurt, and breakfast cereals.

The primary purpose of the requested amendment is to safely improve public health by increasing the accessibility of efficacious and recommended amounts of plant sterols for consumers seeking to lower their cholesterol. Cardiovascular disease (CVD) remains a leading cause of morbidity, mortality, and health care expenditure in Australia & New Zealand (AIHW, 2020; MoH, 2018; Blakey et al, 2019). Elevated blood cholesterol is recognised as a modifiable risk factor for CVD (NVDPA, 2012; NHF AU, 2021; NHF NZ, 2021). 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) and in 2020 over 400,000 New Zealanders were estimated to have diagnosed high cholesterol and taking medication (MoH, 2021).

The Australian and New Zealand plant-based milk alternatives category, and each segment, is growing in Australia and New Zealand (refer to Appendix 1. Nielsen Non-Dairy Milks_Aust and NZ **[CONFIDENTIAL]**). The proposed change will, for the first time provide Australian and New Zealand consumers who are interested in cholesterol lowering the choice of accessing the proven cholesterol lowering effects of plant sterols by including a plant sterol enriched plant-based milk alternative as part of their diet.

The requested change is intended to allow the addition of phytosterols, phytosterols or their esters to plant-based milk alternatives to deliver a total 2g of total plant sterols equivalents. We are not requesting the ability to add 'tall oil phytosterol esters' to plant-based milk alternatives. The below drafting is provided as an example of changes that would achieve the outcome being sought.

S25—2 Sale of novel foods

Permitted novel food	***Conditions of use***
*Phytosterols, phytostanols and their esters	7. May only be added to plant-based milk alternative (beverages derived from legumes, cereals, nuts, seeds, or a combination of those ingredients); and, if: (a) the beverage has at least 100mg of added calcium per 100ml; and (b) the beverage has no more than 0.75g of saturated fat per 100ml; and (c) the *total plant sterol equivalents content is the prescribed amount. 7A. For the purposes of condition 7(c) above: (a) the prescribed amount during the exclusive use period is: (i) for beverages sold under a brand from Sanitarium Health Food Company – an amount that is no less than 0.8 g per 250ml and no more than 2.2 g per 250ml; and (ii) for all other plant-based milk alternative – no phytosterols, phytostanols and their esters are to be added. (b) the prescribed amount after the end of the exclusive use period is an amount that is no less than 0.8 g per 250ml and no more than 2.2 g per 250ml.

1.3 Justification for the application

[Section 3.1.1 D of Application Handbook March 2019]

1.3.1 The need for the proposed change and the advantages for the proposed change over the status quo

[Section 3.1.1 D (a) and (b) of Application Handbook March 2019]

Improved public health & safety

The proposed change will enable current users of plant-based milk alternatives, as well as those wishing to include these products in their diet, to consume the recommended and efficacious two grams plant sterols per day. It is expected that individuals who choose to use a plant sterol enriched plant-based milk alternative will directly benefit from plant sterol's ability to reduce their cholesterol levels, a recognized risk factor for CVD (NVDPA, 2012; NHF AU, 2021; NHF NZ, 2021). At the population level a product that helps to lower cholesterol levels has the potential to favorably impact public health outcomes related to CVD risk in the community.

Non-dairy plant-based milk alternatives are recommended as appropriate choices by Australian and New Zealand dietary guidelines. Such products will contribute towards a person's dietary adequacy, whilst being relatively lower in risk associated nutrients including saturated fat, sodium, and total sugars.

Plant sterols have a long history and track record of safety. Previous FSANZ evaluations are supportive for plant sterols safety and suitability, including their addition to reduced fat dairy milk and the use of up to 2 grams in one single serving is already possible to deliver in reduced fat cheese and breakfast cereals (FSANZ, 2006; FSANZ, 2010; FSANZ 2017 A1134).

Further justification of the need for, and advantages of, the proposed change includes:

i. <u>Justification and advantages of the format and category of plant-based milk alternatives</u>

Use of plant-based milk alternatives is aligned with 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 recognize "*soy, rice or other cereal drink with at least 100mg of added calcium per 100ml*" at a standard serve size of *1 cup (250ml) as contributing to* recommended daily serves of 'milk, yoghurt, cheese and/or alternatives' food group. It is acknowledged that "*some people choose to follow a dairy-free or milk-free diet because of allergies, intolerances to lactose*". Similarly, the Eating and Activity Guidelines for New Zealand Adults state one standard serve of plant-based milk alternative as being "1 cup (250 ml) calcium-fortified plant-based milk alternatives (e.g., soy, rice, almond, oat milk) (with at least 100 g of added calcium per 100 ml)" and contribute to recommended serves of 'milk and milk products' (MoH, 2020).

The standard serve size of 250ml from dietary guidelines is consistent with serving sizes reported in the nutrition information for plant-based milk alternatives available in the Australian and New Zealand market (Zhang, 2020). The most recent Australian National Nutrition Survey reported median intakes for "Dairy milk substitutes, unflavoured" were 200, 154.5, 164.1, 193.1 grams respectively for 19 to 30 years, 31-50 years, 51-70 years, and 71 and over (ABS, 2014). Median intakes indicate that daily usage of ~250ml is a feasible amount to expect adult plant-based milk alternative users to consume daily, and the proposed change would support the delivery of up to 2 grams of phytosterols in one single 250ml serve. To our knowledge there is no other recent median intake data from Australia, and the 2008/09 New Zealand Adult Nutrition Survey data tables

published in 2012 is the most recent national data for New Zealand on milk intake, however median intake of users of plant-based milk alternatives was not reported (MoH, 2012).

Overall, plant-based milk alternatives are an appropriate format and category to deliver and/or contribute towards the recommended 2 grams of plant sterols daily to lower cholesterol as part of a healthy diet. A plant sterol enriched plant-based milk alternative with 2 grams per serve (250ml) would provide a feasible and convenient option for plant milks users to consume the required 2 grams each day.

Plant sterol enriched plant-based milk alternatives are an effective vehicle for phytosterols to lower cholesterol

The LDL-cholesterol (LDL-C) lowering effect of plant sterols/stanols has been demonstrated in several systematic reviews and meta-analyses of randomized controlled trials in humans and shows a dose-response relationship with intakes of up to 3 g/day lowering LDL cholesterol (Demonty, 2009; Ras, 2014; FSANZ 2014).

Plant sterol's cholesterol lowering effects occur in a wide range of food and liquid formats/ matrices (Ras, 2014; Trautwein, 2018), and plant sterols have demonstrated their cholesterol lowering effects when delivered via enriched plant-based milk alternatives including soy milks (Weidner, 2008; Chau, 2020; Rideout, 2009; Dong, 2016; Hallikainen, 2013; Kriengsinyos, 2011) as well as a mixed intervention with an oat beverage (Gylling, 2010).

Enhances consumer choice

Currently available plant sterol enriched products in Australian and New Zealand include margarines, breakfast cereals and a reduced fat dairy milk (only in Australia). While also permitted in yoghurt and cheese, the are no products available today in Australian or New Zealand.

National scan sales data from Australia and New Zealand from the past 5 to 10 years demonstrates the category of plant-based milk alternatives has grown steadily, and each major segment (soy, oat, almond) has contributed to this growth in both value and volume (Nielsen, 2021 ; Refer to Appendix 1. Nielsen Non-Dairy Milks_Aust and NZ **[CONFIDENTIAL]**)] .

In addition to the growing popularity of plant-based milk alternatives, a recent nationally representative online survey of Australians (n= 558, conducted in July 2021) conducted by an independent market research agency on behalf of Sanitarium also demonstrated strong appeal of a plant sterol enriched plant-based milk alternative in people very interested in cholesterol lowering benefit who were current users of plant-based milk alternatives (Appendix 2. Consumer Research on a Plant sterol enriched plant-based milk alternative Sept 2021 CONFIDENTIAL COMMERCIAL INFORMATION (CCI))

The inability to add plant sterols to plant-based milk alternatives is a barrier to innovation in a growing category of products with increasing consumer demand. Current regulations limit the choice for consumers interested in the cholesterol lowering benefits of plant sterols in a plant-based milk alternative.

Extending the use of plant sterols to plant-based milk alternatives will enhance consumer choice within the growing category of plant-based milk alternatives.

ii. Justification and advantages of the proposed change to permit up to 2 grams of phytosterols per 250ml in eligible plant-based milk alternatives includes:

2 – 3 g of phytosterols daily is recommended

The Australian National Heart Foundation recommends 2–3 g of phytosterols per day from products enriched with phytosterols within a healthy balanced diet for people to benefit from the cholesterol-lowering effects (NHF AU, 2017).

The Australia New Zealand Food Standards Code Schedule 4 permit the health claim that phytosterols, phytostanols and their esters reduces blood cholesterol, in the context of "diet low in saturated fatty acids and diet containing 2 g of *Phytosterols, phytostanols and their esters per day" and the Code's Schedule 9 Mandatory advisory statements whereby, "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, Sch4)

Up to 2 grams in a single serve of plant-based milk alternatives is consistent with previous FSANZ guidance as well as the outcomes from the two most recent phytosterol related applications

The outcome from the two most recent phytosterol related Applications to FSANZ A1019 (reduced fat cheese - Standard 2.5.4) and A1134 (breakfast cereals – schedule 25) have resulted in changes to the Code that allow for these products to deliver 2g per serve, based on serve sizes of available breakfast cereals and cheeses. 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.*

Greater control, convenience, and assurance for consumers to achieve recommended daily amounts of phytosterols

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 2021 found that plant sterol enriched product choices are more limited than what is possible under the Code (Refer to Appendix 3. Plant sterol enriched products available in Australian and New Zealand PS content Audit August 2021). Key findings:

- There are two plant sterol enriched ready to eat cereal products available in Australia and two available in New Zealand each with 2g phytosterols in one serve
- There are four brands of plant sterol enriched margarine 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.
- Only one reduced fat dairy milk product was identified in Australia and it contained 0.8g phytosterol per 250ml serve.
- No Plant sterol enriched cheese or Plant sterol enriched yoghurt products were identified.

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 plant-based milk alternative.

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.

Previously FSANZ has concluded *"Australian and New Zealand national nutrition survey consumption data that reflect relatively low levels of consumption of other plant sterol fortified foods"* (A1134 refer SD1, section 5) and *"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 (ACNFP 2006; Bradford 2006, unpublished data).*

The proposed change to enable plant-based milk alternatives to deliver up to 2 grams of plant sterol in a single 250ml serve, will provide users 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 250ml serve of plant-based milk alternative is feasible to consume at one meal occasion or across multiple meal occasions over the day as part of a healthy diet.

Proposed change provides an affordable option for consumers

The proposed change is anticipated to support the launch of a plant-based milk alternative product containing 2g of phytosterols per 250ml. This product will provide consumers with an affordable option for them to achieve the recommended 2 grams of plant sterols daily compared to the currently available plant sterol enriched products.

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 plant-based milk alternatives 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 fortified product will be higher than a standard plant-based dairy milk alternative. 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.

Branded plant milks currently range in price from AUD$1.70 up to AUD$6.50 (search of Woolworths online shopping, 6 September 2021). Indicative pricing for a plant sterol enriched plant-based milk alternative is within this range.

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, and breakfast cereals.

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 and reduced fat cheese (A1019 - reduced fat cheese; A1134 - breakfast cereals).

Plant enriched plant-based milk alternatives are permitted and available internationally, including in Europe and in the USA. Examples of plant-based milk products in these markets including soy, rice and oat-based beverages are illustrated in Appendix 4 - Plant sterol enriched plant-based beverages launched in Europe and North America. Source – Mintel [CONFIDENTIAL]. A number of these products launched in European markets contain 2 grams or plant sterols or plant stanol per serve.

1.3.2 Disadvantages of the proposed change

No disadvantages have been identified with the proposed regulatory change regarding consumers or industry players.

1.3.3 Details of similar applications made in other countries by the applicant, if applicable

No applications of this nature have been made by the applicant in other countries.

1.3.4 Public health and safety issues related to the proposed change

No public health and safety issues are anticipated related to the proposed change - Refer Part 2 C

1.3.5 Consumer choice issues related to the proposed change

There are no perceived impediments of consumer choice related to the proposed change, rather, the proposed change will increase consumer choice and access to enriched phytosterol foods to lower their cholesterol.

1.3.6 Food industry interest/support of proposed change

The Applicant is not aware of any direct evidence that other plant-based milk manufacturers have an interest in, or support, the proposed change to the Code. However, given the clear need for the proposed changes and the advantages for the proposed change described above demonstrate there is a market opportunity, and so we anticipate that food industry generally and other manufacturers will be supportive of the proposed changes which facilitate innovation in the rapidly growing plant-based milk alternatives category.

1.4 Regulatory Impact Information

[Section 3.1.1 D.1 of Application Handbook March 2019]

1.4.1 Costs and Benefits

There are no cost/benefit impediments to this proposed change.

a) Consumers

There are no costs to consumers in general arising from this application. Consumers interested in the cholesterol lowering benefit of plant sterols will be able to make an informed choice to purchase and include plant sterols enriched plant-based milk alternatives in their diets.

Benefits to consumers from the inclusion plant sterol enriched plant-based milk alternatives are outlined in sections 1.3.1 and 2.2.

b) Industry

Given no plant-based milk alternatives are currently permitted to contain plant sterols, there are no costs to industry for this application in terms of impact on current products or practices.

If the proposed changes occur, there is potential for food manufacturers to benefit commercially from the sale of plant sterol enriched plant-based milk alternatives. The costs for manufacturers of plant-based milk alternatives 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 quality control to ensure the amount claimed reflects composition and permitted amounts. It is anticipated these costs would be typical for new product development and marketing of a new product.

c) Government

There are no perceived additional costs to government in making the proposed change, beyond the normal costs of enforcing compliance with food laws. The proposed change is likely to encourage innovation in this category and increase consumers access to plant sterols which lower cholesterol, a modifiable risk factor for CVD. Given the burden of CVD on total health expenditure, the proposed change has the potential benefits for government via improvement in public health and as a result health expenditure related to cholesterol.

1.4.2 Impact on International Trade

[Section 3.1.1 D.1.2 of Application Handbook March 2019]

This Application proposes to promote greater alignment with other international jurisdictions including but not limited to Europe and the United States where a variety of plant sterol enriched plant-based milk alternatives are permitted to contain added plant sterols, and plant-based milk alternatives are available in these markets (Appendix 4. Plant sterol enriched plant-based beverages launched in Europe and North America (EU Commission, 2017; US FDA, 2021). Source – Mintel [CONFIDENTIAL]). European regulations also permit the inclusion of 2 grams of plant sterols per 250ml serve.

Approval of the proposed change has the potential to facilitate international trade. Australian based companies would be able to invest in capability to produce plant sterols in plant-based milk alternatives for sale domestically, the business case to warrant this investment may be more attractive if these products were also exported for sale in other markets.

Further, food businesses that operate internationally, including those already producing plant sterol enriched plant-based milk alternatives for other markets may choose to expand their business, or

partner with local businesses, to import and sell plant sterol enriched plant-based milk alternatives in Australia and New Zealand.

1.5 Information to support the application

[Section 3.1.1 E of Application Handbook March 2019]

Please refer to Part 2: Information for applications for new foods – Novel Foods

1.6 Assessment procedure

[Section 3.1.1 F of Application Handbook March 2019]

The appropriate procedure to be adopted in assessing the application is considered General, Level 2, as the proposal relates to extending the use of the well-established novel food (plant sterols) already permitted under Schedule 25 – Permitted novel foods at a level per serve that is already permitted to be delivered in one serve in other categories of food (i.e., breakfast cereals and cheese).

1.7 Confidential Commercial Information (CCI)

[Section 3.1.1 G of Application Handbook March 2019]

CCI information includes Appendices 2 and 5 which are all labelled as CCI. A non-confidential summary of the CCI information is provided where each of these CCI Appendices are referenced.

CCI Material	**Reasons this material is CCI**
Appendix 2. Consumer Research on a Plant sterol enriched plant-based milk alternative Sept 2021 **[CONFIDENTIAL COMMERCIAL INFORMATION (CCI)]**	Contains details of innovative new product and marketing strategies that has commercial value that would be destroyed or diminished if the information were disclosed.
Appendix 5. Usage & Attitudes Data Online Nat Rep Australian & New Zealand Surveys 2021 **[CONFIDENTIAL COMMERCIAL INFORMATION (CCI)]**	Contains information relating to a food product and marketing strategies that has commercial value that would be destroyed or diminished if the information were disclosed.
Appendix 9. Plant sterol enriched plant based milk food technological information **[CONFIDENTIAL COMMERCIAL INFORMATION (CCI)]**	Contains trade secret regarding a product innovation
Appendix 10. Plant sterol product Info sheet **[CONFIDENTIAL COMMERCIAL INFORMATION (CCI)]**	Contains trade secret regarding a product innovation

1.7.1 Other Confidential Information

[Section 3.1.1 H of Application Handbook March 2019]

The following appendices are non-CCI, but the applicant requests FSANZ treat this information as confidential.

Request to treat as confidential	**Reasons this material is confidential**
Appendix 1. Nielsen Non-Dairy Milks_Aust and NZ **[CONFIDENTIAL]**	

Appendix 4. Plant sterol enriched plant-based beverages launched in Europe and North America. Source – Mintel **[CONFIDENTIAL]**	The aggregated information is not publicly available and obtained by the applicant by a paid subscription.
Appendix 7. Plant sterol enriched products launched in EU, North America, Aust, NZ globally past 10 years **[CONFIDENTIAL]**	

1.8 Exclusive Capturable Commercial Benefit (ECCB)

[Section 3.1.1 I of Application Handbook March 2019]

The application does confer an exclusive capturable commercial benefit, and the Applicant is seeking the full 15 months exclusive use period.

Sanitarium Health Food Company has invested time and resources into research and development for the new product and in developing this application. Sanitarium Health Food Company would seek to launch a plant sterol enriched plant-based milk alternative once permitted and would benefit from sales of this product.

1.9 International and other National Standards

[Section 3.1.1 J of Application Handbook March 2019]

1.9.1 International Standards

[Section 3.1.1 J.1 of Application Handbook March 2019]

There are no Codex Alimentarius Commission (Codex) Standards relevant to this application. The proposed regulatory change leads to greater international regulatory alignment including alignment with Europe and the United States where a variety of plant-based milk alterative may contain plant sterols (EU Commission, 2017; US FDA, 2021). Refer to Appendix 4 for product examples from Europe and United States **[CONFIDENTIAL]**.

1.9.2 Other national standards or regulations

[Section 3.1.1 J.2 of Application Handbook March 2019]

The proposed change would lead to greater consistency within FSANZ regulations relating to the addition of plant sterols to other food groups. Reduced fat dairy milks are already permitted to contain phytosterols, however plant-based milk alternatives are not permitted.

Regulations related to breakfast cereals (schedule 25) and cheese (Standard 2.5.4) effectively allow for the addition of 2 grams of phytosterols to be delivered in one serving, this is consistent with the proposed amount to be added to plant-based milk alternatives.

2 PART 2 INFORMATION FOR APPLICATIONS FOR NEW FOODS – NOVEL FOODS

[Section 3.5.2 of Application Handbook March 2019]

Relevant Policy Guidelines

Ministerial policy guidelines on the addition of substances other than vitamins and minerals to food.

Phytosterols are currently regulated as novel foods in Schedule 25, rather than substances "used as a nutritive substance". However, to avoid uncertainty, the ministerial guidelines - Specific Order Policy Principles – Any Other Purpose are specifically addressed below and in greater detail in Part 2.
The addition of substances other than vitamins and minerals to food where the purpose of the addition is for other than to achieve a solely technological function should be permitted where:

a) The purpose for adding the substance can be articulated clearly by the manufacturer (i.e. the 'stated purpose'); and

The purpose for adding phytosterols to plant-based milk alternatives has been established in sections 1.2 and 1.3.

b) The addition of the substance to food is safe for human consumption; and

The addition of phytosterols to plant-based milk alternatives 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.

The form of the phytosterols is consistent with the stated purpose and is 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

There are no adverse health effects associated with the addition of phytosterols to plant sterols as proposed.

e) The presence of the substance does not mislead the consumer as to the nutritional quality of the food.

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.

2.1 Exclusive use of novel foods

[Section 3.5.2 A of Application Handbook March 2019]

If approved, the Applicant is seeking exclusive permission for 15 months from gazettal to bring to market an eligible phytosterols enriched plant-based milk alternative product manufactured by Sanitarium Health Food Company, under the Sanitarium Health Food Company brand or a sub-brand.

To date the applicant has invested financial resources in research and development to qualify product feasibility, as well as regulatory investment to develop and submit this Application.

2.2 Technical information on the novel food

[Section 3.5.2 B of Application Handbook March 2019]

2.2.1 Information on the type of novel food

[Section 3.5.2 B.1 of Application Handbook March 2019]

Information on the type of novel food is provided in Schedule 3 (S3-24 Specification for phytosterols, phytostanols and their esters).

Plant sterols are naturally present at low levels in some fruits, vegetables, nuts, cereals and common vegetable oils. As plant sterols are extracted from plant source, they fall within 'plant or animal extracts' category of the FSANZ's guidelines for novel food.

In the year 2001, FSANZ approved phytosterols (including free phytosterols), phytostanols and their esters as a novel food ingredient according to definitions in Standard 1.5.1 – Novel Foods for use in edible oil spreads. Since then, its use has been extended to breakfast cereals, low fat yogurt and low-fat milk and low-fat cheese.

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

[Section 3.5.2 B.2 of Application Handbook March 2019]

As stated in section 1.2., the purpose for adding plant sterols to plant-based milk alternatives relates to the potential for users to benefit from their cholesterol lowering properties when consumed at recommended and efficacious amounts daily.

Plant sterol's cholesterol lowering effects occur in a wide range of food and liquid formats/ matrices (Ras, 2014; Trautwein, 2018). Plant sterol's cholesterol lowering effects have been demonstrated in plant based milk alternatives (Refer to Appendix 8 Plant sterol enriched plant based milk alternative human randomised controlled trials for summary of the following trials including Weidner, 2008; Chau, 2020; Rideout, 2009; Dong, 2016; Hallikainen, 2013; Kriengsinyos, 2011; Gylling, 2010).

The target consumers for the intended plant sterol enriched plant-based milk alternatives include aged 40 years and above, and specifically those interested in lowering cholesterol who are using plant-based milk alternatives.

Taken from the Position Statement by the National Heart Foundation on Dietary fats and dietary sterols for cardiovascular health (National Heart Foundation, Updated 2017):

1. *"Phytosterols lower LDL-C in normocholesterolaemic, hypercholesterolaemic and diabetic individuals."* (Level I evidence)
2. *"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."*
3. *"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%"* (Level II evidence)
4. *"Consuming more than 3 g per day phytosterols provides no additional benefits."*
5. *"Daily consumption frequency does not influence the cholesterol-lowering efficacy of phytosterol/stanols"* (Level II evidence)

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.

As further information, the table below outlines the nutritional composition of currently available plant-based milk alternatives in the Australian/New Zealand market which are not enriched with plant sterols.

Table 1. Nutritional composition examples of currently available plant-based milk alternatives in the Australian/New Zealand market

	Per 100ml serve		
	Non plant sterols enriched manufactured by Sanitarium Health Food Company		
	So Good Oat No Added Sugar	**So Good Almond Unsweetened**	**So Good Soy Regular**
Energy (kJ)	181	69	273
Protein (g)	0.8	0.6	3.2
Fat, total (g)	1.5	1.4	3.5
- Saturated fat (g)	0.2	0.1	0.4
- Polyunsat'd (g)	0.6	0.4	1.7
Monounsat'd (g)	0.6	0.9	1.4
Cholesterol (mg)	0	0	0
Carbohydrate, total (g)	6.4	0.3	5.1
- Sugars (g)	2.3	0.1	2.0
- Lactose (g)	0	0	0
Dietary Fibre (g)	0.5	0.3	0.3
Sodium (mg)	43	36	40
Potassium (mg)	245	19	145
Vitamin A (µg)	40	-	40
Riboflavin (mg)	0.17	0.17	0.17
Vitamin B12 (µg)	0.4	0.4	0.4
Vitamin D (µg)	0.5	-	2.0
Vitamin E	-	0.6	-
Calcium (mg)	120	120	160
Phosphorus (mg)	100	75	100

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

[Section 3.5.2 B.3 of Application Handbook March 2019]

This application to amend the ANZFSC relates to an extension of use of an already approved novel food, i.e., 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).

Current international regulations permit the addition of plant sterols to plant-based milk alternatives (EU Commission, 2017; FDA, 2020). Long shelf-life, single serve and multi-serve, plant-based milk alternative products in the market (Appendices 4 & 7) demonstrate that plant sterols can be successfully added to shelf-stable plant milks for the duration of their shelf-life. Furthermore, plant

sterols have also been shown to be effective in plant milk matrices in reducing LDL-cholesterol as evidenced by a number of clinical trials (Appendix 8. Plant sterol enriched plant-based milk alternative human randomised controlled trials).

Plant sterol enriched plant-based milk alternatives will undergo similar processing and procedures as both conventional extended shelf-life plant-based milk alternatives such as those identified in table 1 (section 2.2.2) and corresponding dairy equivalents. Production will involve ultra-high temperature (UHT) treatment. Food technological information regarding the inclusion of phytosterol and their esters in milks, including long shelf-life milk products which undergo UHT, can be found in the relevant FSANZ application (FSANZ A434, 2004). Standard food manufacturing processes ensure the ingredients are present and intact throughout shelf-life.

The applicant intends to use a commercially available phytosterols product that has been demonstrated to be soluble and uniformly distributed in beverages similar to the intended finished product. For more information regarding the type of plant sterol and processing used, please refer to Appendices 9 & 10.

2.2.4 Information on the impurity profile for a typical preparation

[Section 3.5.2 B.4 of Application Handbook March 2019]

This application to amend the ANZFSC 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.

2.2.5 Manufacturing process for a novel food ingredient

[Section 3.5.2 B.5 of Application Handbook March 2019]

This application to amend the ANZFSC 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.

2.2.6 Specification for identity and purity for a novel food ingredient

[Section 3.5.2 B.6 of Application Handbook March 2019]

This application to amend the ANZFSC 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.

2.2.7 Analytical method for detection of a novel food ingredient

[Section 3.5.2 B.7 of Application Handbook March 2019]

The method of identification for phytosterols is by gas chromatography, specifically AOCS Official Method Ce 12-16 (AOCS, 2017).

2.3 Information on the safety of the novel food – Single chemical entities and Dietary macro-components

[Section 3.5.2 C & C.4 of Application Handbook March 2019]

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 have 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 was in 2016, as part of A1134 – Increased Concentration of Plant Sterols in Breakfast Cereals. In 2016, FSANZ hazard assessment in Supporting document 1 Risk assessment – Application A1134 Increased Concentration of Plant Sterols in Breakfast Cereals reported the following regarding he safety of phytosterols (FSANZ 2016):

> *An ADI of 0-40 mg/kg of body weight, expressed as the sum of phytosterols and phytostanols in their free form, was established at the 69th JECFA (JECFA 2008). FSANZ concluded in 2010 that there is no justification for an ADI for plant sterols, because the apparent treatment-related adverse effect is entirely explained by the background incidence of pathology found in historical control data for the strain of rats used in the studies on which JECFA based the ADI.*
>
> *There is currently no robust evidence to support the concerns that the consumption of plant sterols will increase the risk of cardiovascular disease or that the oxidation products of dietary plant sterols pose a risk to consumers. Some dietary intervention studies using plant sterols show a reduction in blood concentration of provitamin A carotenoids. These lipid-soluble phytochemicals are transported in blood by low density lipoprotein cholesterol, which is reduced by the intake of plant sterols. Consequently, the decrease in circulating amounts of carotenoids is not unexpected. Furthermore, after adjusting for the change in total blood cholesterol concentration β-carotene is the only carotenoid whose concentration remains significantly different from the control group value. However, it should be noted that the blood concentrations of carotenoids of subjects consuming plant sterols remain within the broad natural range of variation.*
>
> *Clinical studies in which up to 9 g phytosterol esters per day (5.4 g of total plant sterols equivalent based on molecular weight conversion) were tested in adult subjects did not show statistically significant changes in fat-soluble vitamins. Clinical studies in which up to daily doses of 6 g of free plant sterols were consumed by children (2-17 years of age) for up to six months demonstrate that total and LDL cholesterol concentrations are significantly decreased without affecting HDL concentrations and show no evidence of a nutritional safety risk. Similarly, consumption of 0.7 g and 0.8 g of plant sterol equivalents during pregnancy and one-month post-partum, respectively, did not show evidence of a nutritional safety concern for both the women and their infants and did not significantly decrease maternal total or LDL cholesterol concentrations. The clinical evidence indicates that consumption of 5.4-6 g/day of total plant sterol equivalents is unlikely to pose a nutritional safety concern for children and adults.*

FSANZ last statement regarding safety of consuming Plant sterol enriched foods Dec 2016 A1134. To evaluate if there are any studies in the literature investigating toxicity or safety of orally consumed phytosterols since 2016, the following literature searches were performed:

<u>Human studies published since 2016 (inclusive)</u>

On the 2nd June 2021, a search via PubMed using the search terms ((tox [subset]) AND (phytosterols[Title] OR phytostanols[Title] OR "plant sterols"[Title] OR "plant stanols"[Title])) since 2016 (inclusive) and in “humans”. On the 2nd June 2021, a further search via PubMed was conducted

using the search terms (phytosterols[Title/Abstract] OR phytostanols[Title/Abstract] OR "plant sterols"[Title/Abstract] OR "plant stanols"[Title/Abstract]) since 2016 (inclusive) using filter "humans" and "clinical trial". After excluding duplicates, studies where the exposure was a mixed intervention only or intravenous /parenteral exposure to plant sterols only (not relevant to this application which is related to orally consumed food), 25 relevant new studies in humans were identified. The studies identified are summarized in Appendix 6 – Literature search results: Studies investigating plant sterols . None of the 25 recent human studies reported any adverse health effects associated with the consumption of phytosterols in humans.

Three review articles were also identified from a search of references (Ghaedi, 2020; Fardet, 2017; Trautwein, 2018). Ghaedi et al undertook a systematic review of human trials on plant sterols and blood pressure and they stated *"Based on extensive safety evaluation studies, phytosterols are considered safe",* and they also recognised the nutrition concern which FSANZ evaluated in 2016 regarding the potential for orally consumed plant sterols to reduce the serum levels of fat-soluble vitamins and their precursors including tocopherols and b-carotene (Ghaedi, 2020). Fardet et al undertook an update of the evidence regarding the impact of plant sterols on plasma fat-soluble vitamins and carotenoid levels of all data up to December 2014, and so whilst this has been published since 2016 the evidence presented was available at the time of FSANZ last review in 2016 which is referenced above (FSANZ 2016). Trautwein et al collated the relative LDL-C lowering of plant sterols evidence from published meta-analyses, however did not report on adverse outcomes.

Human Studies delivery plant sterol via plant based milk alternatives

To evaluate if there are any human studies which have investigated the effect of plant sterols delivered via plant-based milk alternative beverages a literature search was conducted. The following search were performed on 30th June 2021 via Cochrane central database – search terms (soy or soya or soymilk or oat or almon or "non-dairy" or nondairy or "plant based")[in record title] AND ("plant sterol" or plant stanol" [in Title, Abstract, keyword], time was unrestricted. This search yielded 35 results, and of these six relevant publications where identified which described a total of 7 studies. One further study was identified as relevant (Gylling, 2010) from a hand search of included studies of the most recent meta-analysis on the effect of plant sterols (Ras, 2014). The relevant studies identified from the above searches are summarised in Appendix 8 – Plant sterol enriched plant-based milk alternative human randomised controlled trials. One study reported non-serious adverse gastrointestinal events in the ~5% of subjects in the treatment arm, and none occurring control (Chau, 2020). All remaining studies did not report any adverse events associated with plant sterols delivered via plant-based milk intervention.

Animal Studies published since 2016 (inclusive).

A further literature search was performed on 15 Dec 2021, using Search: (tox [subset]) AND (phytosterols[Title] OR phytosterols[Title] OR "plant sterols"[Title] OR "plant stanols"[Title]) Filters: from 2016/6/1 - 2021/12/31. Four experimental animal studies were identified and are summarised in Appendix 6.

Three of the four studies reported favorable outcomes and no adverse effects with plant sterol treatment (Akinloye, 2020; Zhao, 2019; Qasimi, 2017). Nunes et al investigated the metabolism of phytosterols in hypercholesterolemic mice knockouts (KO) for low density lipoprotein receptor (LDLR) and apolipoprotein E (apoE) mice compared to wild-type mice (controls), and concluded the apoE-KO mice have a marked defect in the elimination of both phytosterols from the body – which they noted bears some analogy with the increased phytosterol concentrations in the plasma and tissues of the rare human genetic condition of sitosterolemia. The relevance of this finding beyond those with the rare human genetic condition of Phytosterolaemia (sitosterolaemia) is unclear. With

regards to Phytosterolaemia (sitosterolaemia), in 2016 FSANZ concluded (Supporting document 1 A1134):

> *Overall, there is a lack of convincing evidence that the premature atherosclerosis observed in congenital phytosterolaemia is relevant to an assessment of the likelihood that plants sterols are atherogenic in the general population.*
> *The specific risk to this susceptible subpopulation can be addressed by appropriate risk management measures.*

The findings from the above literature searches are consistent with FSANZ assessment in 2016 (FSANZ 2016 A1134) and previous international bodies evaluations including a 2014 report by a European Atherosclerosis panel, published in the journal Atherosclerosis, which found that no harm is to be anticipated by the intake of plant sterol and stanol containing foods (Gylling, 2014). The panel further concluded that concerns raised by some researchers about the consumption of plant sterols and stanols were not supported by conclusive evidence.

We acknowledge that further evaluation of the safety of the proposed changes in the Australian and New Zealand context will be undertaken by FSANZ. Previous FSANZ evaluations and regulatory outcomes are supportive for plant sterols safety and suitability for amounts of 2 grams in one serving of plant sterol enriched foods.

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

[Section C.4.1 of Application Handbook March 2019]

This application to amend the ANZFSC relates to an extension of use of an already approved novel food, i.e. phytosterols, phytostanols and their esters. Literature searches described in section 2.4 identified studies published since FSANZ last review in 2016 (summarised in section 2.4 and Appendix 6. Literature search results studies investigating plant sterols 2016 inclusive to June 2021). Overall there is limited new data since the last FSANZ evaluation.

2.3.2 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

[Section C.4.2 of Application Handbook March 2019]

This application to amend the ANZFSC relates to an extension of use of an already approved novel food, i.e. phytosterols, phytostanols and their esters. Literature searches described in section 2.4 identified studies published since FSANZ last review in 2016 (summarised in section 2.4 and Appendix 6. Literature search results - studies investigating plant sterols 2016 inclusive to June 2021). Overall there is limited new data since the last FSANZ evaluation.

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

[Section C.4.3 of Application Handbook March 2019]

One report prepared by international agencies was identified since 2016 (EFSA, 2020). Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) delivered 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. 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 conclusion of this report is not relevant to this application as the intended food of this application is plant-based milk alternatives, and not vegetable fat spreads or liquid vegetable fat-based emulsions for cooking and baking. The conclusion from this report has not impacted the current European regulations which permit the addition of plant sterols to plant-based milk alternatives (soy drinks and rice drinks specifically), and no changes have been proposed as a result of the report for food which can currently add plant sterols (EU Commission, 2017).

2.4 Information on dietary exposure to the novel food

[Section 3.5.2 D of Application Handbook March 2019]

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

[Section 3.5.2 D.1 of Application Handbook March 2019]

The proposed change would allow plant milks derived from legumes, nuts, seeds, cereals, or combinations of these to contain 2 grams of plant sterols (meaning total plant sterol equivalents) per 250ml.

As FSANZ has pointed out in previous plant sterols related applications (e.g. FSANZ 2017, Breakfast cereals approval report), products containing plant sterols are likely to carry health claims and so would need to meet the Nutrient Profiling Scoring Criterion (NPSC).

The Australian Dietary Guidelines and the Eating and Activity Guidelines for New Zealand Adults recommend plant-based milk alternatives with at least 100mg of added calcium per 100ml. As outlined in section 2.5.1 many adults have inadequate intake of calcium, therefore limiting the addition of plant sterols to plant-based milk alternatives with a minimum calcium fortification levels (100mg/100ml) would be consistent with these guidelines.

Ensuring eligible products are also low in saturated fat (0.75g per 100ml) is also warranted given target consumers will have a clear interest in lowering cholesterol and the relationship between saturated fat intake to blood cholesterol (FSANZ, 2016 ; Schedule 4 permitted claims for saturated fat). This criterion is also consistent with the claim context for the plant sterols and blood cholesterol health claim, that requires the health claims to be made in the context of diets low in saturated fatty acids (Schedule 4).

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

[Section 3.5.2 D.2 of Application Handbook March 2019]

The proposed change to the Code would allow eligible plant-based milk alternatives to declare 2 grams of total plant sterols equivalents per 250ml serve. As per the approach with cereals, a maximum level of slightly above 2 grams per 250ml serve (e.g. 2.2 g total plant sterol equivalents per serve) would be appropriate for an average quantity of 2 g per serving to be declared without needing to exceed the maximum permitted amount of 2 g per serving.

The proposed change would allow phytosterol enriched plant-based milk alternative to contribute 2 grams of total plant sterol equivalents per 250ml serve.

The applicant is not aware of and could not locate any data on the naturally occurring levels of plant sterol equivalents in plant-based milk alternatives that are not enriched with plant sterols. 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).

As outlined in section 1.2 we proposed that products that add phytosterols, phytostanols or their esters should contain no less than 0.8 g of total plant sterol equivalents per 250ml 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 in Schedule 4 of the Code requires the food to contain a minimum of 0.8 g "plant sterol equivalents" per serve. We acknowledge FSANZ may determine a lower amount is a more appropriate regulatory measure and this will not impact the "purpose of the application" stated in section 1.2.

2.4.3 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

[Section 3.5.2 D.3 of Application Handbook March 2019]

The intended products to be eligible are plant-based milk alternatives listed in the most recent National Nutrition Survey, within "Dairy milk substitutes, unflavoured" AHS classification:

201	**Dairy milk substitutes, unflavoured**
20101	Soy-based beverage, plain
20102	Soy-based beverage, plain, fortified
20103	Soy-based beverage, plain, reduced fat
20104	Soy-based beverage, plain, reduced fat, fortified
20105	Soy-based beverage, plain, skim, fortified
20106	Cereal- or nut-based milk substitute
20107	Dairy milk substitute, unspecified

The applicant is not aware of New Zealand national nutrition survey data that reports plant-based milk alternative median levels of consumption.

Please refer to section 2.4.5 for more information on likely current food consumption

2.4.4 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

[Section 3.5.2 D.4 of Application Handbook March 2019]

Appendix 3 shows Plant sterol enriched products available in Australia and New Zealand based on an audit of two major Australian and New Zealand online shopping conducted in August 2021. In each category there are very few products with added plant sterols i.e. margarines and spread (4 brands were identified in Australia some with multiple pack sizes and flavour variants, and 2 brands in New Zealand), milk (1 product identified in Australia only) and cereals (2 products identified in Australian and 2 in New Zealand). It is expected that, like the milks, spreads and cereals category - a very small proportion products within the plant-based milk alternatives category would be likely to add plant sterols.

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

[Section 3.5.2 D.5 of Application Handbook March 2019]

The plant-based milk alternatives category has grown in recent years. The category growth appears to be driven by new households and users of these products, rather than increased consumption by existing users.

Nielsen data on sales scan data from Australia and New Zealand from the past 5 to 10 years demonstrates the plant-based milk alternatives category as a whole and each segment has grown steadily in both value and volume [Appendix 1. Nielsen Non-Dairy Milks_Aust and NZ **[CONFIDENTIAL]**

Two separate online surveys conducted in August 2021 by an independent market research agency on behalf of Sanitarium (one conducted in Australians n=3,033 nationally representative and the other in New Zealanders n= 1,543 nationally representative) provides complementary data suggesting most people who have ever tried plant-based based milk alternatives have done so in the past five years (Refer to Appendix 5. Usage & Attitudes Data Online Nat Rep Australian & New Zealand Surveys 2021 **[CONFIDENTIAL COMMERCIAL INFORMATION (CCI)]**).

The available household penetration data and the trend of most users first trying plant-based milks in the past five years demonstrates growth in the number of users of plant-based milk alternatives since the most recent 2011-12 Australian National Nutrition Survey and the 2008/09 New Zealand Adult Nutrition Survey.

In 2011-12 Australian National Nutrition Survey reported that the proportion of the persons consuming “Dairy milk substitutes, unflavoured” was between 3.9%, 3.2%, 4.4%, 3.8% and 3.3% for 19 to 30 years, 31-50 years, 51-70 years, 71 and over, and 2 years and over respectively (ABS, 2014). Median intakes for “Dairy milk substitutes, unflavoured” were 200, 154.5, 164.1, 193.1, and 193.1 grams for 19 to 30 years, 31-50 years, 51-70 years, 71 and over, and 2 years and over respectively.

The 2008/09 New Zealand Adult Nutrition Survey reported an unadjusted frequency (% users in the population) of soy milk for age groups 31-50, 51-70, 71+ respectively for men was 0.8, 2.1, 1.4 and women was 2.6, 4.7, 0.9 and for other (not defined) intakes for age groups 31-50, 51-70, 71+ respectively were men 1.7, 0, 0.9 and for women were 2.3, 0.6 and 1 (MoH, 2012). No median intakes were reported in this data.

To our knowledge there is not more recent data on the mean or median intake of plant-based milk alternatives consumers (excluding non-users) from Australian or New Zealand survey’s. The data provided above is evidence of a growing number of households and users of plant-based milk alternatives in recent years.

2.4.6 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

[Section 3.5.2 D.6 of Application Handbook March 2019]

The target consumers for a plant sterol enriched plant-based milk alternative are adults interested in cholesterol lowering who currently use plant-based milk alternatives.

A recent nationally representative online survey of Australians (n= 558, 18 – 75 years, interested in heart health and non-rejectors of plant-based milk alternatives) was conducted on behalf of Sanitarium by an independent market research agency [Appendix 2. Consumer Research on a Plant sterol enriched plant-based milk alternative August 2021 [**CONFIDENTIAL COMMERCIAL INFORMATION (CCI)**]. This survey estimates the size of the target segment of Australian population "very interested in cholesterol" AND "have bought / consumed plant-based milk alternatives in the past 12 months” (existing users).

While we do not have data on how future users would adopt this product in their diets, we anticipate that existing users of plant-based milk alternatives are likely replace one serve of their existing plant-based milk alternative product, over occasions which they already use plant-based milk alternatives. Two separate online surveys conducted in August 2021 by an independent market research agency on behalf of Sanitarium (one conducted in Australians n=3,033 nationally representative and the other in New Zealanders n= 1,543 nationally representative) provides data on typical 'in home' usage of plant-based milk alternatives and includes uses such as on its own; with coffee; other hot drinks; cold drinks (e.g. Smoothies, milkshakes); Protein shake or weight loss shakes; with cereals **(CONFIDENTIAL COMMERCIAL INFORMATION (CCI)** - Refer to Appendix 5. Usage & Attitudes Data Online Nat Rep Australian & New Zealand Surveys 2021).

People who are not interested in cholesterol lowering benefit or are not open to using plant-based milk alternatives daily are not expected to be interested in a plant sterol enriched plant-based milk alternative.

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

[Section 3.5.2 D.7 of Application Handbook March 2019]

Phytosterols are added to many different foods and food groups overseas, and at varying per serve levels.
Phytosterol-containing foods launched over the last 10 years include, but are not limited to:

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

Refer to Appendix 7 – Plant sterol enriched products launched in EU, North America, Aust, NZ globally past 10 years **[CONFIDENTIAL]**

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

[Section 3.5.2 E of Application Handbook March 2019]

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

[Section 3.5.2 E.1 of Application Handbook March 2019]

As plant-based milk alternative products and the novel food of plant sterols are already widely available to consumers, the choice to consume a plant sterol enriched plant-based milk alternative will not contribute to imbalance in dietary choices.

Likely Users

Consumers most likely to be interested in a plant sterol enriched plant-based milk alternative product is outlined in section 2.4.6, namely those very interested in cholesterol-lowering benefits who are existing users of plant-based milk alternatives [Appendix 2. Consumer Research on a Plant sterol enriched plant-based milk alternative Sept 2021 [**CONFIDENTIAL COMMERCIAL INFORMATION (CCI)**]. They represent a specific segment of the total adult population and exclude children.

Dietary Context:

A product that contains 2 grams of plant sterols per serve would clearly communicate that the cholesterol lowering benefit occurs in the context of a diet containing 2 g of plant sterols per day that is low in statured 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.

(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.

Calcium:

A high proportion of Australian and New Zealand adults of all ages, and the majority of all women and men over 50 years had inadequate intakes of calcium (ABS, 2014; NZ ANS, 2008–09). As proposed in section 2.4.1. eligible plant-based milk alternatives should contain at least 100mg of calcium per 100ml, this would ensure the proposed change will not cause an imbalance of calcium intake.

Protein:

The 2011-12 Australian Health Survey as well as the 2008-09 New Zealand Adults Nutrition Survey found average protein intakes across all age groups exceeded requirements, and most adults had adequate protein intakes (ABS, 2014; NZ ANS, 2008–09). As most Australian and New Zealand adults consume adequate protein, the lower protein content for plant-based milk alternatives derived from cereals, nuts and seeds is unlikely to adversely affect protein adequacy for the target consumers.

Saturated Fat:

As proposed in section 2.4.1., limiting the addition of plant sterols to low in saturated fat plant-based milk alternatives is consistent with the dietary context for permitted health claims for plant sterols, is relevant to the target consumers given the relationship between reducing saturated fat intake and reduced blood cholesterol (FSANZ, Schedule 4; FSANZ , 2016).

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 2021 found the majority of plant-based milk alternatives were lower in saturated fats with 88% (158/176 of all plant-based milks were) being low in saturated fat containing no more than 0.75g per 100ml of saturated fat, of the 18 products that had greater than 0.75g per 100ml saturated fat 15 were plant-based milk alternatives derived from coconut. While most products were low in saturated fat, only 29.5% (52/176) were low in total fat, which demonstrates that most products derived their fat content from unsaturated fats rather than saturated fats.

Replacement of saturated fatty acids with polyunsaturated and/or monounsaturated fatty acids decrease blood total cholesterol and LDL cholesterol concentrations (FSANZ, 2016). Given the relatively higher unsaturated fat content of regular fat or reduced fat plant-based milk alternatives, an unfavorable fat intake imbalance would not occur were eligible plant-based milk alternatives were low in saturated fats.

Carotenoid’s bioavailability:

In past plant sterols related applications, the impact of plant sterols on circulating levels of carotenoids has been evaluated by FSANZ. In 2016, after evaluating the specific concern of whether ‘plant sterols supplementation may result in decreased circulating levels of carotenoids, which might in turn lead to a higher incidence of certain cancers and or macular degeneration’ FSANZ concluded “there is no evidence that plant sterol supplementation leads to adverse outcomes through the mechanism of decreasing circulating amounts of carotenoids” (Supporting document 1 for Application A1134).

Studies identified via literature searches summarized in section 2.3 did not identify other adverse nutritional risks since FSANZ last review related to plant sterols consumption (Appendix 6), including pant sterol enriched plant-based milk alternative consumption (soy studies and an oat study summarized in Appendix 8).

In conclusion, the use of the plant sterol enriched plant-based milk alternative in products low in saturated fat and appropriately fortified with calcium will not cause a nutritional imbalance. The proposed regulatory change to permit 2 grams of plant sterols per 250ml serve of plant-based milk alternative also 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 2 grams of plant sterols.

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

[Section 3.5.2 E.2 of Application Handbook March 2019]

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.

Studies identified via literature searches summarised in section 2.3 did not identify evidence for adverse events related to plant sterols consumption (Appendix 6), including pant sterol enriched plant-based milk alternative consumption (soy studies and an oat study summarized in Appendix 8).

In relation to vulnerable groups, including pregnant and lactating women and children under 5 years of age, FSANZ evaluation as part of A1134 stated:

> *Pregnant and lactating women and children under 5 years of age do not need to lower their cholesterol levels because growing children and developing embryos have an increased need for cholesterol and, therefore, may not benefit from consuming plant sterol-enriched foods.*
>
> *FSANZ has previously stated that 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 subgroups (FSANZ 2012a). No new data was identified that would change this conclusion.*
>
> *Occasional consumption of plant sterol-enriched breakfast cereal by young children or pregnant or lactating women is therefore not considered to be of toxicological concern.*

With specific regard to patients with the rare condition phytosterolaemia (sitosterolaemia), in 2016 FSANZ re-evaluated the risks and concluded (Supporting document 1 A1134):

> *Overall, there is a lack of convincing evidence that the premature atherosclerosis observed in congenital phytosterolaemia is relevant to an assessment of the likelihood that plants sterols are atherogenic in the general population.*
> *The specific risk to this susceptible subpopulation can be addressed by appropriate risk management measures.*

A Code change with subsequent launch of product with 2g of total plant sterol equivalents would provide an opportunity to further educate consumers. In addition to the mandatory labelling statements, other labelling and associated education strategies can be expected to communicate:

- The benefits/target of consuming up to 2g phytosterols per day;
- That plant-based milk alternatives provide an alternative food option for consumers to get their daily recommended phytosterols from foods;
- That one 250ml serve is a simple way of getting your daily requirements;
- That there is no benefit in consuming more than 3g phytosterols per day.
- 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
- plant sterols do not provide additional benefits when consumed in excess of three grams per day.

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. FSANZ recent evaluation regarding these vulnerable group has been covered in section 2.5.2. Further as *stated in previous FSANZ assessment reports (e.g., the Second Review Report for A433, A434 and A508* (FSANZ, 2006), 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.

As with other plant sterol enriched foods, plant sterol enriched plant-based milk alternatives will be characterised by distinctive packaging within the category and will target the 40 years and above age group to distinguish them from products that are not plant sterol enriched products. 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 plant-based milk alternatives 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 plant-based milk alternatives 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:

a) the requirement to pay the price premium for the product on an ongoing basis;
b) 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
c) 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.

As outlined in section 1.2 we proposed that products that add phytosterols, phytostanols or their esters should contain no less than 0.8 g of total plant sterol equivalents per 250ml 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 in Schedule 4 of the Code requires the food to contain a minimum of 0.8 g “plant sterol equivalents” per serve. We acknowledge FSANZ may determine a lower amount is a more appropriate regulatory measure and this will not impact the “purpose of the application” stated in section 1.2.

2.6 Information related to potential impact on consumer understanding and behaviour

[Section 3.5.2 F of Application Handbook March 2019]

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

[Section 3.5.2 F.1 of Application Handbook March 2019]

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

FSANZ 2016 Risk assessment for Application A1134 (Supporting document 1) dietary exposure assessments provide information on plant sterol use, albeit some of this data is dated.

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 two grams per day (EFSA, 2008; Ras, 2017).

Potential consumers will be informed and educated through on pack as well as off pack communications such as those outlined in section 2.5.2 including mandatory advisory statements. Any labelling would be compliant and not misleading consumers regarding the nutritional quality of the food.

2.6.2 Information on the actual and/or potential behaviour of consumers in response to the novel food or novel food ingredient

[Section 3.5.2 F.2 of Application Handbook March 2019]

It is expected that approval of the proposed change to the Code will lead to availability of at least one plant sterol enriched plant-based milk alternative with up to 2 grams of phytosterols per 250ml serve.

The target consumer for a plant sterol enriched plant-based milk alterative is middle aged to older adults very interested in cholesterol lowering and a current user of plant-based milk alternatives [Appendix 2. Consumer Research on a Plant sterol enriched plant-based milk alternative Sept 2021 **CONFIDENTIAL COMMERCIAL INFORMATION (CCI)**].

Since plant sterol enriched plant milks would be offered at a price premium, it is unlikely that they will be purchased or consumed regularly by non-target consumers nor excessive consumption by the target audience. It can be reasonably assumed that there is price sensitivity for plant milks and amongst a non-target consumer the premium price for such a product will be a barrier. 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 – discussed in section 1.3.1).

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

[Section 3.5.2 F.3 of Application Handbook March 2019]

To our knowledge 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 plant-based milk alternative.

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 plant-based milk alternatives. 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). We have 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) (refer to section 2.5.2). 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, and as outline in section 2.3 plant sterols intake are 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).

Statutory Declaration

[Section 3.1.1.K of handbook]

Statutory Declarations Act 1959[1]

I, John Montgomery

1 Sanitarium Drive, Berkeley Vale NSW 2261 , Executive General Manager Strategy /ANU

[Name, address and occupation of person making the declaration]

make the following declaration under the Statutory Declarations Act 1959:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.

DocuSigned by:
John Montgomery
FB45B3EB9169440...

[Signature of person making the declaration]

Sydney NSW on 21 December 2021

[Declared at [place] on [day] of [month] [year]

Before me,

DocuSigned by:
Aimee Barclay
F191F17913BE408...

[Signature of person before whom the declaration is made][2]

Aimee Barclay, Solicitor of NSW, of 1 Sanitarium Drive, NSW

[Full name, qualification and address of person before whom the declaration is made (in printed letters)]

[1] http://www.comlaw.gov.au/Series/C1959A00052

[2] A statutory declaration must be made before a prescribed person under the Statutory Declarations Act 1959.
The list of prescribed persons is available in the Statutory Declarations Regulations 1993 at http://www.comlaw.gov.au/Series/F1996B00198

Checklists

[Section 3.1.1 L of Application Handbook March 2019]

Checklist for General requirements (3.1.1)

Check	Page No.	Mandatory Requirements
√	n/a	A Form of application □ Application in English □ Executive Summary (separated from main application electronically) □ Relevant sections of Part 3 clearly identified □ Pages sequentially numbered □ Electronic copy (searchable) □ All references provided
√		B Applicant details
√		C Purpose of the application
√		D Justification for the application □ Regulatory impact information □ Impact on international trade
√		E Information to support the application □ Data requirements
√		F Assessment procedure □ General □ Major □ Minor □ High level health claim variation
√		G Confidential commercial information □ CCI material separated from other application material □ Formal request including reasons □ Non-confidential summary provided
√		H Other confidential information □ Confidential material separated from other application material □ Formal request including reasons
√		I Exclusive Capturable Commercial Benefit □ Justification provided
√		J International and other national standards □ International standards □ Other national standards
√		K Statutory Declaration
√		L Checklist/s provided with application □ 3.1.1 Checklist

		□ All page number references from application included □ Any other relevant checklists for Chapters 3.2–3.7

Checklist for Novel Foods (3.5.2)

Check	Page No.	Mandatory Requirements
√		□ A. Exclusive use □ B.1 Type of novel food □ B.2 Information on potential beneficial outcomes □ B.3 Chemical and physical properties □ B.4 Impurity profile □ B.5 Manufacturing process □ B.6 Specification for identity and purity □ B.7 Analytical detection method
√		***C.4 Single chemical entities & dietary macrocomponents*** □ C.4.1 Toxicokinetics and metabolism □ C.4.2 Toxicity studies □ C.4.3 Safety assessments from other agencies

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APPENDICES

- Appendix 1. Nielsen Non-Dairy Milks_Aust and NZ _Aug 21 **[CONFIDENTIAL]**
- Appendix 2. Consumer Research on a Plant sterol enriched plant-based milk alternative Sept 2021 **[CCI]**
- Appendix 3. Plant sterol enriched products available in Australian and New Zealand_Audit August 2021
- Appendix 4. Plant sterol enriched plant-based beverages launched in Europe and North America. Source – Mintel **[CONFIDENTIAL]**
- Appendix 5. Usage & Attitudes Data Online Nat Rep Australian & New Zealand Surveys 2021 **[CCI]**
- Appendix 6. Literature search results: Studies investigating plant sterols
- Appendix 7. Plant sterol enriched products launched in EU, North America, Aust, NZ globally past 10 years **[CONFIDENTIAL]**
- Appendix 8. Plant sterol enriched plant based milk alternative human randomised controlled trials
- Appendix 9. Plant sterol enriched plant based milk food technological information **[CCI]**
- Appendix 10. Plant sterol product Info sheet **[CCI]**

** End of Application **

DocuSign

Certificate Of Completion

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Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	21-Dec-2021 | 10:57
Certified Delivered	Security Checked	21-Dec-2021 | 11:30
Signing Complete	Security Checked	21-Dec-2021 | 11:34

Envelope Summary Events	Status	Timestamps
Completed	Security Checked	21-Dec-2021 | 12:26

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure