

Sanitarium Health & Wellbeing

Application to amend the Australia New Zealand Food Standards Code

Inclusion of regulations specific to the addition of phytosterols to portion-controlled breakfast cereals in Schedule 25 – Permitted novel foods

22 June 2016

Contents

PART 1 GENERAL INFORMATION

1.1 Applicant Details.....	pg 3
1.2 Purpose of Application.....	pg 4
1.3 Justification for the Application.....	pg 5
1.3.1 Need for the proposed change.....	pg 5
a) Variable weight of similar volumes of breakfast cereals	
b) Variable serve sizes of breakfast cereals	
c) Low fortification levels of breakfast cereals compared to other food groups	
d) In support of single serve breakfast cereal as a phytosterol carrier	
1.3.2 Advantages of the proposed change.....	pg 9
a) Cholesterol-lowering benefit in a single serve of food	
b) Greater control over amount of phytosterol consumed	
c) Improved public health and safety & consumer choice	
d) Enabling innovation in the cereal category	
e) Efficacy	
f) Alignment with other standards	
1.3.3 Disadvantages of the proposed change.....	pg 13
1.3.4 Details of similar applications made in other countries by the applicant, if applicable	pg 13
1.3.5 Public health and safety issues related to the proposed change.....	pg 13
1.3.6 Consumer choice issues related to the proposed change.....	pg 13
1.3.7 Food industry interest/support of proposed change.....	pg 13
1.3.8 Regulatory Impact Information.....	pg 14
1.3.8.1 Costs and Benefits	
1.3.8.1.1 Consumers	
1.3.8.1.2 Industry	
1.3.8.1.3 Government	
1.3.8.2 Impact on International Trade	
1.4 Information to support the application.....	pg 18
1.5 Assessment procedure.....	pg 18
1.6 Confidential Commercial Information (CCI).....	pg 18
1.7 Other confidential information.....	pg 18
1.8 Exclusive Capturable Commercial Benefit (ECCB).....	pg 18
1.9 International and other National Standards.....	pg 18
1.9.1 International standards	
1.9.2 Other national standards or regulations	

PART 2 INFORMATION FOR APPLICATIONS FOR NEW FOODS – NOVEL FOODS

2.1 Exclusive use of novel foods.....	pg 19
2.2 Technical information on the novel food.....	pg 20
2.2.1 Information on the type of novel food.....	pg 20
2.2.2 Information on the purpose of adding novel food ingredient to food.....	pg 20
2.2.3 Information on the physical and chemical properties of the novel food or novel food ingredient.....	pg 20
2.2.4 Information on the impurity profile for a typical preparation.....	pg 20
2.2.5 Manufacturing process for a novel food ingredient.....	pg 21

2.2.6	Specification for identity and purity for a novel food ingredient.....	pg 21
2.2.7	Analytical method for detection of a novel food ingredient.....	pg 21
2.3	Information on the safety of the novel food – Single chemical entities and Dietary macro-components.....	pg 22
2.3.1	Information on the toxicokinetics and metabolism of the single chemical entity and, where appropriate, its degradation products and major metabolites.....	pg 22
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.....	pg 22
2.3.3	Safety assessment reports prepared by international agencies or other national government agencies.....	pg 23
2.4	Information on dietary exposure to the novel food.....	pg 23
2.4.1	List of the foods or food groups proposed to or which might contain the novel food ingredient or substance.....	pg 23
2.4.2	The proposed level of the novel food ingredient or substance for each food or food group.....	pg 23
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.....	pg 24
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.....	pg 24
2.4.5	For foods where consumption has changed in recent years, information on likely current food consumption.....	pg 24
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.....	pg 24
2.4.7	Information relating to the use of the novel food or novel food ingredient in other countries, if applicable.....	pg 25
2.5	Information on the nutritional and health impact of the novel food.....	pg 26
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.....	pg 26
2.5.2	Information to demonstrate that the addition of the novel food ingredient will not create a significant negative public health impact.....	pg 26
2.6	Information related to potential impact on consumer understanding and behavior.....	pg 28
2.6.1	Information to demonstrate the level of consumer awareness and understanding of the novel food or novel food ingredient.....	pg 28
2.6.2	Information on the actual and/or potential behaviour of consumers in response to the novel food or novel food ingredient.....	pg 28
2.6.3	Information to demonstrate that the food(s) containing the novel food ingredient will not adversely affect any population groups (e.g. particular age or cultural groups).....	pg 29
	Statutory Declaration.....	pg 31
	Checklists.....	pg 32
	REFERENCES.....	pg 34
	APPENDICES.....	pg 36

PART 1 GENERAL INFORMATION

[Section 3.1.1 of Application Handbook March 2016]

1.1 Applicant details

[Section 3.1.1 B of Application Handbook March 2016]

a) Applicant

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Nature of applicant's business	Food manufacturing
Other individuals, companies or organisations associated with the application	See below

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1.2 Purpose of the application

[Section 3.1.1 C of Application Handbook March 2016]

This Application seeks to amend Schedule 25 – Permitted novel foods specific to the addition of phytosterols to breakfast cereals. In particular, it seeks to add regulations specific to portion controlled breakfast cereals, where ‘portion controlled’ refers to either individually wrapped portions, or discreet portions that can be readily divided from a multi-serve container.

The specific proposed change includes an additional section 4. to the table S25-2 **Sale of novel foods**:

<i>Permitted novel food</i>	<i>Conditions of use</i>
*Phytosterols, phytostanols and their esters	<ol style="list-style-type: none"> The food must comply with requirements in Standard 1.2.1 insofar as they relate to section 1.2.3—2. May only be added to edible oil spreads: <ol style="list-style-type: none"> according to Standard 2.4.2; and where the total *saturated and *trans fatty acids present in the food are no more than 28% of the total fatty acid content of the food; and May only be added to breakfast cereals, not including breakfast cereal bars, if: <ol style="list-style-type: none"> the total fibre content of the breakfast cereal is no less than 3 g/50 g serve; and the breakfast cereal contains no more than 30g/100g of total sugars; and the *total plant sterol equivalents content is no less than 15 g/kg and no more than 19 g/kg. May only be added to portion controlled^ breakfast cereals, if – <ol style="list-style-type: none"> the total fibre content of the breakfast cereal is no less than 3 g/50 g serve; the breakfast cereal contains no more than 30g/100g of total sugars; and the total plant sterol equivalents content is no less than 0.8g and no more than 2g per serve. <p>(^Definition of “portion controlled breakfast cereals” = Breakfast cereals that are either delivered in individually wrapped, single-serve portions, or in discreet portions that can be readily divided from a multi-serve container.)</p> Foods to which phytosterols, phytostanols or their esters have been added must not be used as ingredients in other foods. May only be added to milk in accordance with Standard 2.5.1. May only be added to yoghurt in accordance with Standard 2.5.3

The primary purpose of the amendment is to improve public health & safety by increasing the accessibility of phytosterols through breakfast cereals, a food already approved for fortification with phytosterols. The amendment will allow for a more convenient and cost effective delivery of the efficacious dose of phytosterols in healthy breakfast cereals to consumers, allowing them to more easily monitor a daily intake of plant sterols, as well as improve access and choice in terms of the

form and amount of product consumers may purchase in order to obtain the health benefits associated with phytosterols within an inherently healthy food choice.

Further, this amendment will increase consistency in the manner in which the addition of phytosterol to foods is regulated across the various food groups (edible oil spreads, cheese, milk, yoghurt, breakfast cereals).

In the absence of the proposed change, the current regulation disadvantages breakfast cereals compared to the other food groups allowed to be fortified with phytosterols. For instance, a serve of flaked biscuits (two biscuits @ 30g serve) may currently contain only 0.57g phytosterols, compared to a single slice of cheese (~22g), which may contain up to 1.98g phytosterols. Thus, prohibitively large volumes of a phytosterol containing breakfast cereal need to be consumed in order to arrive at the efficacious dose of phytosterol per day (two to three grams), which has the direct consequence of encouraging overconsumption of energy, sodium and other nutrients, and discouraging innovation within this food category in the market. It is likely that no fortified breakfast cereals currently exist on the Australian and New Zealand market as a result of the current regulations.

Finally, this amendment will also provide greater consistency with international regulations, for example the EU 3g maximum in one serve or 1g maximum in three serves. Three serves of breakfast cereal is not a typical 'daily serve', nor should it be for energy intake reasons.

There are no safety concerns associated with the proposed change, as noted by FSANZ as recently as 2012 in their consideration of previous phytosterol submissions.

1.3 Justification for the application

[Section 3.1.1 D of Application Handbook March 2016]

1.3.1 Need for the proposed change

[Section 3.1.1 D (a) of Application Handbook March 2016]

In order to benefit from cholesterol-lowering effect of phytosterol enriched foods, consumers are required to consume 2 – 3 g per day. The National Heart Foundation Position Statement on Phytosterol/stanol enriched foods (updated in December 2009) advises that phytosterols are most effective if two to three grams are consumed per day (National Heart Foundation, 2009).

Currently the Code permits the addition of phytosterols to edible oil spreads, milk, yoghurt, cheese and breakfast cereals, latter being the only non-dairy, plant-based, grain option. Phytosterols (phytosterols, phytostanols and their esters) have been shown to be efficacious in breakfast cereals as a delivery format, comparable in efficacy to phytosterol-enriched yoghurt (Clifton et al. 2004).

However, the permitted levels of phytosterols in breakfast cereals are unreasonably low, particularly when compared with alternatives (edible oil spreads, milk, yoghurt and cheese), and consumers would be unlikely to benefit from phytosterol-enriched breakfast cereals. Reasons are outlined below. At the time this Application is submitted, no fortified cereal products are available on the Australian/New Zealand market.

a) Variable weight of similar volumes of breakfast cereals

Similar volumes of breakfast cereals, as opposed to edible oil spreads, milk, yoghurt and cheese, can have highly variable weights as a result of the diverse, often heterogeneous ingredients and

processing methods used in manufacture (e.g. rolling, flaking, extrusion). The same volume of one breakfast cereal may be much lighter or heavier than an equivalent volume of another breakfast cereal.

To demonstrate: The *Australian Guide to Healthy Eating* is a food selection guide which visually represents the proportion of the five food groups recommended for consumption each day. For ready-to-eat (RTE) breakfast cereals, the depicted serve sizes are a bowl of wheat flakes, an equally sized bowl of muesli, or 2 flaked biscuits (Australian Guide to Healthy Eating). A written explanation of what is a serve of cereal food provides examples of a serve, including half a cup (120g) cooked porridge, two thirds of a cup (30g) wheat cereal flakes, and a quarter cup (30g) muesli (Australian Dietary Guidelines, Serve sizes). The energy is maintained roughly constant by adjusting the volume of food used to define a serve, within a product range where weight per unit volume varies immensely. Within this scenario it is problematical that phytosterol addition is regulated on a g/kg basis rather than on a g/serve basis.

Under present regulations, where the quantity of phytosterols added is defined by the weight of the serving, a 30g flaked biscuit serve may only contain 0.57g phytosterol per serve, not even reaching the currently allowed minimum 0.8g phytosterol per serve fortification level (based on efficacy), and minimum required level to make the health claim “reduces blood cholesterol” (ANZFS, Schedule 4). In contrast, a loose breakfast cereal that claims a 45g serve could contain 0.855g phytosterols per serve. The 0.8g per serve level of fortification is also easily achieved in the other food categories.

Thus, regulations that permit fortification by weight of serving results in different fortification levels of comparable volumes of breakfast cereals, resulting in disadvantages *within* the breakfast cereal category depending on the type of breakfast cereal and what constitutes a serve size by weight.

b) Variable serve sizes of breakfast cereals

The differing weight of equivalent volumes of breakfast cereals of varying bulk density is not the only reason for variable serve sizes. Similar types of breakfast cereals (similar weight per cup) can have vastly different serving sizes declared on packaging. Any change to existing regulations needs to keep this in mind. We have attempted to do so while at the same time making the addition of phytosterols to breakfast cereals a more efficacious proposition.

Research conducted by the George Institute for Choice in 2011 revealed substantial inconsistencies in serving sizes declared in Nutrition Information Panels (NIP) amongst RTE breakfast cereals. Thus, among 33 plain adult cereal products surveyed, a five-fold range between the minimum 10g and maximum 55g serving sizes was observed. Similarly, of 110 muesli products, serving size varied from as high as 80g, to just 25g. (The George Institute, 2011)

Further to above, actual volumes of food consumed per serve do not always marry up with the recommended serve size declared on pack. Loose breakfast cereals that are not portion controlled are poured into breakfast bowls of varying sizes and serve sizes are estimated. Serve sizes of the same cereal may change for the same person from day to day, and from person to person. Surveys show that serve sizes often differ from on-pack recommendations and are often larger than on-pack recommendations. A 2014 Choice report states: *“In Australia as well, in some food categories such as cereal products, serving sizes are lower than the typical reported amounts consumed by adult Australians and those recommended in the Australian Guide to Healthy Eating. So it's not surprising that studies have found that people generally can't correctly estimate the number of servings in a package.”* (Choice, 2014)

Research has shown that the quantity of food consumed can also vary depending on the size of the bowl, and even by the size of the flake. People eat more breakfast cereal, by weight, when flake size is reduced (Rolls et al. 2014). This has important implications on controlling phytosterol intake when added to RTE breakfast cereals.

In contrast, the proposed changes provide certainty on controlling phytosterols in cereals through portions *that are either delivered in individually wrapped, single-serve portions, or in discreet portions that can be readily divided from a multi-serve container.*

c) Low fortification levels of breakfast cereals compared to other food groups

Under the present regulation, a serving of phytosterol enriched breakfast cereal would need to consist of 105g cereal or seven flaked biscuits (more than twice the present mean daily intake for men) to deliver two gram of phytosterols (Australian Health Survey 2011-12, Cereal and Cereal Products. Australian Bureau of Statistics. Table 6 Median amount of foods consumed).

In contrast, current regulations allow typical servings of other foods to contain two gram of phytosterols: one tablespoon of margarine, two 100g tubs yoghurt, one 22g slice cheese.

Consequently, under current regulation, to obtain an efficacious serve of phytosterols from breakfast cereals with 300ml skim milk requires an energy intake approximately >1.5 times that of edible oil spread consumed with 2 slices of wholemeal bread (1991kJ vs. 1173kJ, respectively); or 3 times that of low-fat cheese consumed with a slice of wholemeal bread (1991kJ vs. 701kJ, respectively).

Comparing the energy contributions of the foods without the accompanying milk or bread, energy intake is approximately >2.5 times that of edible oil spread, and 9 times that of low-fat cheese. [See Appendix 1: Nutrient comparisons current vs proposed regulations]

While healthy breakfast cereal consumption helps with intakes of fibre and wholegrain, which are associated with lower cardiovascular risk (National Heart Foundation, 2006; Grains and Legumes Nutrition Council, 2013), such high volumes of breakfast cereal do not support public health efforts in reducing consumption of energy, and possibly other nutrients such as sodium.

Further, these volumes are less manageable to eat, particularly for the intended target group of individuals aged 45 years and over, and could also come at a prohibitive financial cost burden to these consumers [Appendix 2: Cost burden based on volume]. This poses a commercial disadvantage to the manufacturer and, hence, discourages product innovation in an area of potential health benefit for the target group.

d) In support of single serve breakfast cereal as a phytosterol carrier

Breakfast cereals are typically eaten at a frequency of one serve per day (Rangan and Gill, 2002), for breakfast, particularly in the intended target group. According to the Australian Health Survey 2011-12, male consumers ate a median daily amount of 51 grams of ready to eat breakfast cereals, while females ate a median amount of 35 grams (Australian Health Survey 2011-12, Cereal and Cereal Products. Australian Bureau of Statistics. Table 6 Median amount of foods consumed).

Therefore, consumers who wish to derive phytosterols from breakfast cereals (e.g. those who would like to avoid dairy and margarines) would be looking to derive the recommended two gram from one serving. They would also be looking for a solution that does not require big volumes of food, and over-consumption of energy, sodium and other risk-associated nutrients should be avoided.

However, under the present regulation, a serving of phytosterol enriched breakfast cereal would require 105g cereal or seven flaked biscuits to deliver two gram phytosterols.

Further, current regulations require consumers to obtain two to three grams phytosterols from multiple serves of (perhaps various) foods per day to arrive at intakes of phytosterols at efficacious levels (two to three gram). This approach may increase complexity and actually reduce the likelihood of obtaining the two gram minimum efficacious dose across the day. Surveys have shown that consumers do not tend to use multiple phytosterol-enriched foods.

For example, from the 2008 EFSA Report *Consumption of Food and Beverages with Added Plant Sterols in the European Union*: *“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.”* For example, *“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)

Consequently consumers are unlikely to benefit from the cholesterol-lowering effect of phytosterols, contrary to the expectation raised by permitting a range of foods to be enriched with phytosterols. The same report states: *“Several of the authors raised the limitations of simulation studies to estimate plant sterol intake. Indeed, predictions were seen as hypothetical and representing worst-case scenarios. They were likely to be biased to the upper end when compared to actual consumption information on household level with the frequency of consumption appearing to be less than anticipated.”* And *“..real life observations indicate that many consumers do not reach exposure levels effective in reducing cholesterol blood levels even when using a mix of different products.”*

They conclude: *“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.”*

A single-dose approach is supported by the FSANZ Phytosterols Expert Advisory Group who, in September 2005, stated it *“would consider any future applications for products that offer a suitable quantity of phytosterols in a single serve of food”* due to the benefits such products would confer to the consumer. It can be argued that consumers have greater control over the amount of phytosterols consumed, if the two to three gram phytosterols were contained within a single serve. Such control would be particularly useful for the breakfast cereal category, an inherently healthy food category that is subject to highly variable serve sizes.

In summary:

There is a need to amend the current regulations pertaining to the addition of phytosterols to breakfast cereals that takes into consideration, improves and supports: consumer choice, control over consumption and public health efforts, whilst also addressing the current commercial disincentive for innovation.

In terms of phytosterol fortification of breakfast cereals, current regulations create disadvantages *within* the breakfast cereal category as well as *between* breakfast cereal and other food categories. Under current regulations, it is less likely that consumers will obtain the two gram minimum efficacious dose across the day, and thus benefit from phytosterol fortified foods.

1.3.2 Advantages of the proposed change

[Section 3.1.1 D (b) of Application Handbook March 2016]

a) Cholesterol-lowering benefit in a single serve of food

In countries outside of Australia products are marketed that contain two grams phytosterol in single-serve products [e.g. Benecol yoghurt drinks in Europe, including UK (Benecol UK, 2016)], however, current regulations in Australia and New Zealand do not allow this.

In response to the Ministerial Council request for a Second Review of Applications, Food Standards Australia New Zealand (FSANZ) formed a Phytosterols Expert Advisory Group, chaired by the Chief Medical Advisor Dr Bob Boyd, to broaden the technical input into safety and efficacy of phytosterols. Encouragingly, in September 2005, the Advisory Group reported: *“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 phytosterols. 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 phytosterols in one meal event. FSANZ would consider any future applications for products that offer a suitable quantity of phytosterols in a single serve of food.”* (FSANZ, 2006)

The proposed change to the Code would allow the addition of up to two grams per portion controlled serving of breakfast cereal, where ‘portion controlled’ refers to either individually wrapped portions, or discreet portions that can be readily divided from a multi-serve container.

This is particularly relevant to breakfast cereals, which are typically eaten at a frequency of one serve per day (Rangan and Gill, 2002), particularly in the intended target group. Breakfast cereals are currently also the only option for consumers who wish to avoid dairy and margarines.

b) Greater control over amount of phytosterols consumed

It has been previously discussed that similar volumes of breakfast cereals can have very different weights, and that serve sizes of breakfast cereals vary due to manufacturer declaration and consumer behavior. As a direct consequence, different breakfast cereals can contain different levels of phytosterols per serving, and intake of phytosterols from servings of breakfast cereals can vary widely.

A further consideration is that phytosterols added to loose, bulk cereals distribute unevenly in the packaging or settle at the bottom of the packaging. Thus, there is good reason to believe that actual amounts of phytosterols consumed per serve of loose cereal may be under- or overestimated, i.e. consumption of consistent amounts of phytosterols per serving is difficult if not impossible with “loose pack” cereal, i.e. cereals with non-discrete serves in multiple-serve containers.

In contrast, individually wrapped portions, or portions that can be readily divided from a multi-serve container, would provide a consistent amount of phytosterols per serve.

In 2012 packaging restrictions of phytosterol-enriched cheese was removed to allow individual cheese slices - previously individually wrapped – to be sold unwrapped in multi-serve containers, as the *“firmer, physical nature of the product does not require individual wrapping to maintain portion integrity.”* (FSANZ, 2012) No safety concerns were linked to this amendment as monitoring data in Europe by EFSA suggested that consumers are not meeting optimal intakes, and in any event on-pack advisory statements inform consumers on the appropriate use. Advantages listed were greater

access, reduced cost, greater choice and environmental benefits. A single 22g slice of cheese may be fortified by up to 1.98g phytosterol, the minimum optimal intake per day (the maximum optimal intake being three grams per day).

The same arguments can be applied by allowing fortification of flaked biscuit cereal portions that can be readily divided from a multi-serve container by nature of the maintained portion integrity. The proposed change would allow fortification levels up to two grams per serve, which consists of two flaked biscuits; i.e. approximately one gram per flaked biscuit. Due to the nature of this product, the added phytosterol is delivered within each biscuit and does not risk uneven distribution; ensuring that dosing of flaked biscuits is controlled.

Thus, the controlled dosing of flaked biscuit cereals and lack of ambiguity as to what constitutes a serving would allow the consumer complete control over the quantity of phytosterols consumed per serve.

For loose pack cereals, fortification of individually wrapped portions would serve to solve both the dosing issue, as well as variable serve size issue.

The proposed regulatory change would result in greater control of consumption of phytosterols from breakfast cereals due to the declared quantity per serve, controlled serve size, and elimination of the risk of uneven distribution of the phytosterols inside the product packaging.

c) Improved public health and safety & consumer choice

Following on from the previous two sections (a) Cholesterol-lowering benefit in a single serve of food, and b) Greater control over amount of phytosterols consumed), the improved ability to control the amount of phytosterols consumed per day, and ability to derive two gram phytosterols per serve, has direct benefits for public health and safety. Consumers are more likely to reach the minimum efficacious dose of two grams of phytosterols per day.

Further to greater control over phytosterol intake, breakfast cereals that meet the fibre and sugar requirements to qualify for phytosterol fortification (*the total fibre content of the breakfast cereal is no less than 3 g/50 g serve; the breakfast cereal contains no more than 30g/100g of total sugars*), represent an inherently nutritious food choice with added benefits of particular interest in the dietary management of cardiovascular disease (CVD). For instance, fibre and wholegrain consumption are associated with heart health benefits (National Heart Foundation, 2006; Grains and Legumes Nutrition Council, 2013). Also, eating breakfast is linked to health benefits, including weight management (Better Health Channel, 2016; Dietitians Association Australia, 2016), and should thus be encouraged in all people, especially those vulnerable to CVD risk.

Healthy breakfast cereal, consumed as recommended with low-fat milk or dairy milk alternatives, is relatively low in 'risk-associated' nutrients such as sodium, fat and energy [See Appendix 1: Nutrient comparisons current vs proposed regulations]. Recommendations are to limit intakes of sodium, saturated fat and energy to reduce CVD risk (World Heart Federation, 2016), whereas wholegrain and fibre intake should be encouraged. Thus, healthy breakfast cereals would be a particularly suitable carrier for phytosterols in this vulnerable target market of people at risk of developing heart disease and potentially other chronic diseases.

It should be repeated here that despite being a generally healthy option for breakfast, under current regulation consumers require intakes three and a half times the recommended serve size to achieve

intakes of two gram phytosterol from breakfast cereal. The proposed change to the Code would correct this. [See Appendix 1: Nutrient comparisons current vs proposed regulations].

The proposed change would limit fortification to carefully controlled products, rather than allowing higher levels of fortification in all breakfast cereals that meet fibre and sugar criteria. Avoiding fortification of large numbers of bulk cereals, further protects public health and safety.

The proposed change would also improve consumer choice. Breakfast cereal is the only non-dairy, plant-based, grain food product that may be fortified with phytosterols. Thus, consumers who wish to avoid dairy and margarines (e.g. due to intolerance, allergy, dislike or lifestyle choice), could choose phytosterol enriched breakfast cereal if available.

d) Enabling innovation in the cereal category

The food industry wants to meet the need for a phytosterol enriched breakfast cereal, however, current regulations discourage innovation for a number of reasons.

As previously discussed, current regulations create disadvantages *within* the breakfast cereal category as well as *between* breakfast cereal and other food categories. The current regulations would require a person to consume unrealistically large volumes of cereal to obtain the two gram of phytosterol. The sheer volume of food is prohibitive, particularly in the intended target market of people aged 45 years and over, as opposed to those younger and potentially more active. In contrast, the same amount of phytosterols can be obtained from relatively small volumes of other fortified foods. This puts the category of breakfast cereals at a competitive disadvantage, particularly flaked biscuit cereal. Thus, despite being an inherently healthy food choice in terms of fibre, wholegrain, sodium and sugar, the fortification of breakfast cereals under current regulations is unattractive to both industry and consumers.

The lack of presence of phytosterol-containing breakfast cereals on the Australian market may well be due to the commercial disadvantage that current regulations imposes on this category.

Further, there are indications that consumers are looking for manageable, convenient and affordable ways of consuming an efficacious quantity of phytosterols on a daily basis. For instance, in the UK, the food product enriched with phytosterols enjoying highest growth is the Benecol single-serve yoghurt shot/drink, which contains two grams of plant phytosterols per serve. Other enriched product formats are no longer in growth, demonstrating consumer demand for an easy way to access the two grams per serve rather than through multiple portions or foods. [Appendix 4: UK cholesterol lowering product market data]

e) Efficacy

The ANZFSC already accepts that breakfast cereals are a suitable choice for phytosterol fortification. Phytosterols have been consistently demonstrated to have cholesterol-lowering effects in a range of food formats. ANZFSC, Schedule 4 on Nutrition, Health and Related Claims, permits a cholesterol reduction claim (includes breakfast cereals containing phytosterols) provided the following requirements are met:

The food must:

1. meet the relevant conditions specified in the table in section S25—2;
2. contain a minimum of 0.8 g total plant sterol equivalents content per serving;

and the following context statements accompany the claim:

1. "Diet low in saturated fatty acids"; and
2. "Diet containing 2 g of phytosterols, phytostanols and their esters per day".

Phytosterols (phytosterols, phytostanols and their esters) have been shown to be efficacious in breakfast cereals as a delivery format. Existing research that has looked at the efficacy of phytosterols in breakfast cereals includes:

1. Clifton PM, Noakes M, Sullivan D, Erichsen N, Ross D, Annison G, Fassoulakis A, Cehun M, Nestel P. **Cholesterol-lowering effects of plant sterol esters differ in milk, yoghurt, bread and cereal.***Eur J Clin Nutr.* 2004;58:503–9. <http://www.ncbi.nlm.nih.gov/pubmed/14985690>
2. Nestel P, Cehun M, Pomeroy S, Abbey M, Weldon G. **Cholesterol lowering effects of plant sterol esters and non-esterified stanols in margarine, butter and low-fat foods.***Eur J Clin Nutr.* 2001;55:1084–90. <http://www.ncbi.nlm.nih.gov/pubmed/11781675>
3. Theuvsen E. and Mensink R.P. **Simultaneous Intake of b-Glucan and Plant Stanol Esters Affects Lipid Metabolism in Slightly Hypercholesterolemic Subjects.***J. Nutr.* 137: 583–588, 2007. <http://jn.nutrition.org/content/137/3/583.full.pdf+html>

Efficacy of phytosterols in breakfast cereal is comparable in efficacy to phytosterol-enriched yoghurt. In a 2004 study Clifton et al conclude that *"Neither of these two forms of PS-enriched food [cereal & bread] were significantly different in efficacy from PS-enriched yoghurt."* (Clifton et al. 2004)

Similar conclusions regarding the effect of fat content of the food format, and that it does not significantly affect the LDL-lowering capacity of the food, are made by other researchers such as Demonty et al (Demonty et al. 2009) and Nestel et al. (Nestel et al. 2006)

As previously discussed, intakes of phytosterols can be lower than the efficacious dose when derived from foods that require multiple consumption occasions across the day, with the consequence that achieving meaningful cholesterol reduction is unlikely in this proportion of users of these foods. For example, a *"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. (...) Based on reported levels and frequency of plant sterol enriched spread use, it is likely that a proportion of consumers will not receive enough phytosterols through their current consumption of enriched spreads on bread and toast."* (FSANZ, 2006)

And an EFSA report concludes: *"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."* (EFSA, 2008)

The proposed change would increase the ability of consumers looking to gain a real benefit from phytosterol enriched foods.

f) Alignment with other standards

The proposed regulatory change leads to greater international regulatory alignment in terms of fortification levels per serve and single-serve or portion controlled delivery of phytosterols.

In the EU, it is a requirement that products containing phytosterols must be presented in such a manner that they can be easily divided into portions, and thus allows product to be sold in multi-serve containers. *“In all events, the composition and labelling of products should be such as to allow users to easily restrict their consumption to maximum 3 g/day of phytosterols/phytosteranols through the use of either **one portion containing maximum 3 g, or three portions containing maximum 1 g.**”* (EU Commission Regulation, 2004)

Examples of relevant, current products in other markets that contain two grams phytosterol (plant stanol) per portion controlled serving (excluding mini drinks) include the following:

1. A cereal product (oat flakes) containing 2g plant stanol per 35g serve (individually wrapped) has been launched in Finland in 2011. The cereal retails as a 210g pack containing six serves/sachets.
2. A plant stanol containing rye bread was launched in Romania in February 2015 containing 2g plant stanols per 80g serve (not individually wrapped) contained in a 240g pack delivering three serves.

[Appendix 5: EU examples of 2g PS per portion controlled serve (excl mini drinks)]

1.3.3 Disadvantages of the proposed change

No disadvantages have been identified with the proposed regulatory change in regards to consumers or industry players.

1.3.4 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.

1.3.5 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

1.3.6 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.

1.3.7 Food industry interest/support of proposed change

There is no direct evidence that other breakfast cereal manufacturers have an interest in, or support, the proposed change to the Code, however, the following factors would be considered by food industry, indicating an attractive market opportunity.

- There is a high population of people in Australia and New Zealand who live with elevated cholesterol levels and who are actively seeking out solutions to lower them;
- There is an existing, healthy RTE Cereal market in Australia/ New Zealand, targeting people of the age of 45 and over;
- There may be export opportunities to other markets;
- Phytosterol-containing cereals overseas shows there is a market in overseas countries.

Further to above, the fact that there has been a previous successful application to add phytosterols to breakfast cereals indicates interest in this format for phytosterol fortification.

1.3.8 Regulatory Impact Information

[Section 3.1.1 D.1 of Application Handbook March 2016]

1.3.8.1 Costs and Benefits

[Section 3.1.1 D.1.1 of Application Handbook March 2016]

There are no cost/benefit impediments to this proposed change to allow fortification of up to two gram per portion controlled serve of breakfast cereals.

a) Consumers

There are no health and safety related costs for consumers from the proposed change. FSANZ has previously concluded that there are no public health and safety risks from consumption of approved plant sterol fortified products (FSANZ, 2010).

To the contrary, the proposed change is anticipated to increase public health and safety. Please refer to section 1.3.2 c) for a more detailed discussion.

The proposed change would result in:

1. Realistic amounts of phytosterol available in appropriate volumes of breakfast cereals that are in line with current consumption behaviour;

The recommendation of two flaked biscuits to deliver two grams of phytosterols is in-line with the target consumers' current consumption behaviour. The majority are eating two flaked biscuits per serve, making it an easy substitution behaviour for people to make for this health benefit. Surveys conducted for Sanitarium Health and Wellbeing indicate that the majority of people aged 45 years and over who eat Weet-Bix for breakfast, consume two flaked biscuits per serve. [Appendix 6: FF5 survey data_2015, slide 12].

Note, Sanitarium commissioned market research amongst the target population indicates that 76% of people complied with eating just two Weet-Bix per serve, after only one exposure to the product concept and the actual product itself. In other words, there was high compliance with dose even in the absence of final packaging materials, education, marketing activities, and the requirement to pay for the product. This compliance to consume two Weet-Bix per serve is expected to increase 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 2g of plant sterol - the daily requirement - being delivered in two Weet-Bix [Appendix 7: Mock packaging design]; 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.

Portion controlled healthy breakfast cereals containing two grams per serve will carry the mandatory advisory statements as well as other communication to target the intended consumer and to advise them on the appropriate use and amount to consume. [Appendix 7: Mock packaging design]

2. Greater control over amount of phytosterols consumed per serve breakfast cereal by nature of the discreet and/or portion-controlled serves of food;
3. Increased accessibility of phytosterol delivered in an inherently nutritious food format that offers positive nutrition such as fibre, which should be encouraged particularly in people at cardiovascular risk;
As discussed in the next section 1.3.2 d) *Enabling innovation in the cereal category*, current regulations present a barrier to innovation in this category. The proposed change to allow addition of up to two gram phytosterol per portion controlled serve would enable greater activity here, resulting in greater choice to the consumer.
4. A reduced need for multiple consumption moments across the day and/or from different food sources, and thus an increased likelihood of meaningful cholesterol reductions;
Real life observations in EU Member States where the range of phytosterol enriched products is wider and includes single-serve products containing two grams phytosterols per serve have shown that many consumers do not reach phytosterol intake levels required to gain a real benefit in terms of reducing cholesterol levels even when using a mix of products, and that there is little over-consumption. (EFSA, 2008)
5. Availability of an efficacious dose per serve, offering greater convenience and choice.
The FSA NZ Phytosterols Expert Advisory Group, in September 2005, stated it “would consider any future applications for products that offer a suitable quantity of phytosterols in a single serve of food” due to the benefits such products would confer to the consumer (FSANZ, 2006).
6. Financial cost benefits.
The proposed change results in the ability to provide an affordable phytosterol fortified option. [Appendix 2 & 3]. This is an important consideration given that sustained cholesterol-lowering benefits from phytosterols requires consistent, daily consumption. Nonetheless, a price premium 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 breakfast biscuit. 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.

Under current regulations, consumers would need to consume 7 flaked biscuits to achieve 2g phytosterol intake per day. This is 3.5 times the recommended serve (2 flaked biscuits) and would come at 3.5 times the cost per serve in addition to higher ingredient costs due to the phytosterols. [Appendix 2: Cost burden based on volume]

b) Industry

1. Multi-serve packs vs. individually wrapped flaked biscuits
The cost to the applicant of providing individually wrapped serves of flaked biscuits would be substantially higher due to the additional processes, labour and packaging material required [See Appendix 3: Cost single serve vs multi-pack]. Further, the price increase per serving to

include individually wrapped serves within a box of multiple serves would be seen as prohibitive and therefore, this approach would not be taken.

In contrast, multi-packs containing flaked biscuits (not individually wrapped) would enable the company to increase cost efficiency of sales and, as a flow on effect, the health benefit to consumers due to reduced cost of packaging and filling. There is a benefit to industry in the more efficient use of packaging for larger containers and for subsequent disposal costs. However, the applicant notes that other manufacturers who already sell individually wrapped serves of cereal may not experience the same cost barrier and able to avoid substantial flow on cost to the consumer per serve.

2. A significant investment in ingredient costs and manufacturing technology is required to achieve inclusion of phytosterol into the product.
3. International trade: The current restriction on pack size could be regarded as an anticompetitive regulatory impediment if anyone wishes to import a portion controlled breakfast cereal containing two grams per serve from countries having more lenient allowances for phytosterols in breakfast cereals. Conversely, approval of the proposed change would enable Australian based companies to invest in capability to include phytosterols in breakfast cereals, and thereby also help encourage export products to International markets.
4. Auditing/compliance costs
Additional auditing costs regarding discernment of the fortification levels of both breakfast cereals and portion controlled breakfast cereals are NOT expected as a result of the proposed change as phytosterols are already permitted to be added to breakfast cereals. Monitoring costs that ensure the correct dose is present in the portion or portionable quantity of cereal would need to be in place regardless of the specific level of permitted dose.
5. Costs or specific effects to segments of the market which would not currently be able to fortify their breakfast cereals to the new limit as their products do not fall under the new definition.
The applicant is not aware of any phytosterol-fortified breakfast cereal products currently in the market. Hence, there are no new limits or modifications required by this change for other manufacturers. Consequently, there are no anticipated costs arising from the proposed amendment for manufactures whose product are not in portion controlled serves.

c) Government

There are no perceived additional costs to government in making the proposed change. Rather, the proposed change is likely to encourage innovation in this category, and longer term benefits of the proposed change may include improved health expenditure due to lower blood cholesterol levels as a result of efficacious intakes of phytosterols amongst the target group.

1.3.8.2 Impact on International Trade

[Section 3.1.1 D.1.2 of Application Handbook March 2016]

This Application proposes to promote greater alignment with Europe, and potentially facilitates international trade in breakfast cereal products.

There are currently no phytosterol enriched cereals available in Australia or New Zealand, whether locally produced or imported.

The current restriction on pack size could be regarded as an anticompetitive regulatory impediment if anyone wishes to import a portion controlled breakfast cereal containing two grams per serve from overseas. Conversely, approval of the proposed change would enable Australian based companies to invest in capability to include phytosterols in breakfast cereals, and thereby also help encourage export products to International markets.

Conclusion to Justification for the application:

Section 18 of the FSANZ Act sets out FSANZ's objectives (in descending priority order) in developing food regulatory measures and variations of food regulatory measures as:

- (a) the protection of public health and safety; and*
- (b) the provision of adequate information relating to food to enable consumers to make informed choices; and*
- (c) the prevention of misleading or deceptive conduct.*

In developing food regulatory measures and variations of food regulatory measures, FSANZ must also have regard to the following:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;*
- (b) the promotion of consistency between domestic and international food standards;*
- (c) the desirability of an efficient and internationally competitive food industry;*
- (d) the promotion of fair trading in food; and*
- (e) any written policy guidelines formulated by the Ministerial Council (now known as the Forum).*

The primary purpose of the amendment as outlined in the preceding sections is (a) to protect public health by making phytosterols more accessible through an already approved food. The health and safety of phytosterols themselves has already been demonstrated repeatedly elsewhere and is not a focus in this application.

In regards to points *(b) provision of adequate information*, and *(c) the prevention of misleading or deceptive conduct*, this is already implicit in the on-pack statements required on products fortified with phytosterols.

In regard to the secondary matters above, we believe that this amendment also complies with these for various reasons set out above.

1.4 Information to support the application

[Section 3.1.1 E of Application Handbook March 2016]

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

1.5 Assessment procedure

[Section 3.1.1 F of Application Handbook March 2016]

The appropriate procedure to be adopted in assessing the application is considered General, Level 1, as the proposal pertains to extending the use of an already permitted and well established novel food (phytosterols) within a food type already permitted under Schedule 25 – Permitted novel foods (breakfast cereals).

1.6 Confidential Commercial Information (CCI)

[Section 3.1.1 G of Application Handbook March 2016]

Appendices 3, 6, 7 and 9 are CCI.

1.7 Other Confidential Information

[Section 3.1.1 H of Application Handbook March 2016]

1.8 Exclusive Capturable Commercial Benefit (ECCB)

[Section 3.1.1 I of Application Handbook March 2016]

The application does not confer an exclusive capturable commercial benefit.

1.9 International and other National Standards

[Section 3.1.1 J of Application Handbook March 2016]

1.9.1 International Standards

[Section 3.1.1 J.1 of Application Handbook March 2016]

The proposed regulatory change leads to greater international regulatory alignment in terms of fortification levels per serve and single-serve or portion controlled delivery of phytosterols.

In the EU, it is a requirement that products containing phytosterols must be presented in such a manner that they can be easily divided into portions, and thus allows product to be sold in multi-serve containers. *“In all events, the composition and labelling of products should be such as to allow users to easily restrict their consumption to maximum 3 g/day of phytosterols/phytosteranols through the use of either **one portion containing maximum 3 g, or three portions containing maximum 1 g.**”* (EU Commission Regulation, 2004)

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

1.9.2 Other national standards or regulations

[Section 3.1.1 J.2 of Application Handbook March 2016]

As explained above, the proposed change would lead to greater consistency within FSANZ regulations pertaining to the addition of phytosterols to different food groups, allowing similar fortification levels in breakfast cereals as those allowed in cheese, edible oil spreads and yoghurt.

PART 2 INFORMATION FOR APPLICATIONS FOR NEW FOODS – NOVEL FOODS

[Section 3.5.2 of Application Handbook March 2016]

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 breakfast cereals has been established previously and is already permitted in the Code.

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

The addition of phytosterols to breakfast cereals at the levels proposed is safe and consistent with that permitted in other foods.

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 breakfast cereals 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 are proposed.

2.1 Exclusive use of novel foods

[Section 3.5.2 A of Application Handbook March 2016]

If approved, the Applicant is seeking exclusive permission for 15 months from gazettal to add 2g/serve phytosterols to portion controlled breakfast cereal. The Applicant would include up to 2g/serve phytosterols in portion controlled Sanitarium & Weet-Bix branded breakfast cereal.

To date the applicant has invested significant financial resources in research, technical and regulatory arenas in support of this submission. In addition capital investment will be required to manufacture the product that delivers the 2gm/serve phytosterols to consumers.

2.2 Technical information on the novel food

[Section 3.5.2 B of Application Handbook March 2016]

2.2.1 Information on the type of novel food

[Section 3.5.2 B.1 of Application Handbook March 2016]

This application to amend the ANZFSC pertains to an extension of use of an already approved novel food, i.e. phytosterols, phytostanols and their esters, in an already approved food format, breakfast cereals. Thus, it is not relevant to the assessment to provide further information.

Refer to Schedule 3, S3-24 Specification for phytosterols, phytostanols and their esters for a brief description of the novel food.

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 2016]

Taken from the Position Statement by the National Heart Foundation on Dietary fats and dietary sterols for cardiovascular health (National Heart Foundation, 2009):

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, for people with high absolute risk of CVD, elevated LDL-C, familial hypercholesterolaemia or type 2 diabetes following recommendations to health care professionals are provided:

1. *“Consume 2–3 g of phytosterols per day from margarine, breakfast cereal, reduced fat yoghurt or reduced fat milk enriched with phytosterols”*
2. *“Include phytosterol enriched foods in addition to statin therapy.”*

This application to amend the ANZFSC pertains to an extension of use of an already approved novel food, i.e. phytosterols, phytostanols and their esters, in an already approved food format, breakfast cereals. Thus, it is not relevant to the assessment to provide further information.

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 2016]

This application to amend the ANZFSC pertains 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.

2.2.4 Information on the impurity profile for a typical preparation

[Section 3.5.2 B.4 of Application Handbook March 2016]

This application to amend the ANZFSC pertains 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 2016]

This application to amend the ANZFSFSC pertains to an extension of use of an already approved novel food, i.e. phytosterols, phytosteranols and their esters. Refer to Schedule 3, S3-24 Specification for phytosterols, phytosteranols 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 2016]

This application to amend the ANZFSFSC pertains to an extension of use of an already approved novel food, i.e. phytosterols, phytosteranols and their esters. Refer to Schedule 3, S3-24 Specification for phytosterols, phytosteranols 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 2016]

This application to amend the ANZFSFSC pertains to an extension of use of an already approved novel food, i.e. phytosterols, phytosteranols and their esters. Refer to Schedule 3, S3-24 Specification for phytosterols, phytosteranols and their esters.

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 2016]

In its assessment of Application A1019 for the exclusive use of phytosterol esters in lower-fat cheese products, in 2009 FSANZ compiled a risk assessment report which stated:

“FSANZ has previously concluded that consumption of plant sterol fortified foods raises no safety concerns and a reference health standard is not warranted. This conclusion was also reached by regulatory agencies in Europe and the USA. However in 2008, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an Acceptable Daily Intake (ADI) of 40 mg/kg bw, based on heart muscle degeneration in rats observed after 90 days of gavage administration. FSANZ has re-evaluated this toxicological evidence, together with other 90-day dietary feeding studies. Based on an analysis of all toxicological information, FSANZ finds no justification for establishing an ADI for plant sterols. The apparent treatment-related adverse effect is entirely explained by the background incidence of pathology reported in historical control data relevant for the strain of rats used in the experiments. Coupled with the absence of corroborating evidence from other studies in rats administered high doses of plant sterols, claims of an adverse effect due to plant sterols cannot be substantiated.” (FSANZ, 2010)

FSANZ updated its assessment in July 2012 for A1065 (FSANZ, 2012), an application amending packaging size limits for phytosterol enriched milk, and previous conclusions were maintained, that is, *“the consumption of phytosterol-enriched foods raises no safety concerns and a reference health standard is not warranted.”*

In December 2012 the Approval Report for Application A1070 (Packaging Size for Phytosterol-enriched Lower Fat Cheese) once again stated *“the conclusions of previous safety assessments remain valid, that is, the consumption of phytosterol-enriched foods raises no safety concerns and a health-based guidance value (i.e. acceptable daily intake, ADI) was not warranted. This conclusion was supported by available information from Europe and the USA on the use of phytosterol-enriched*

foods. FSANZ also concluded in an earlier safety assessment that a reduction in the absorption of beta-carotene with consumption of phytosterols is expected, however this was considered to have no significant nutritional impact.” (FSANZ, 2012)

A literature search was performed during June 2016, using the PubMed and TOXNET databases for animal toxicology studies with phytosterols published since the last FSANZ reviewer 2012. The search terms “phytosterols”, “phytostanols”, “plant sterols” and “plant stanols” AND “toxicity” were used. No relevant new studies were identified.

A literature search has been performed for phytosterol clinical trials published since 2012. The literature search strategy used were MEDLINE and-EMBASE databases which were searched for publications dating between January 2012 and December 2015 (FSANZ’ last statement regarding safety of consuming phytosterol enriched foods dated 6 December 2012). Articles were identified using the key words “phytosterols”, “phytostanols”, “plant sterols” and “plant stanols”. Further, the articles were then selected based on the peer reviewed type and clinical trials. 67 journals were generated and examined and 29 were selected for review. (Please refer to Appendix 8 for exclusion criteria.) None of the 29 reviewed studies reported any adverse health effects associated with the consumption of phytosterols. These findings are consistent with 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 et al., 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. In a recent review, Silbernagel et al. (2015) summarised and re-evaluated the four most important arguments against the use of plant sterol and stanol containing functional foods and concluded that there is no evidence that consumption of plant sterol and stanol containing functional foods may cause harm to consumers.

Refer to [Appendix 8: Safety_Plant Sterols Clinical Trials_Literature Search] for details of the literature search.]

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 2016]

This application to amend the ANZFSC pertains to an extension of use of an already approved novel food, i.e. phytosterols, phytostanols and their esters, in an already approved food format, breakfast cereals. There is no new data since the last FSANZ evaluation to support a review of the previous conclusions.

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 2016]

This application to amend the ANZFSC pertains to an extension of use of an already approved novel food, i.e. phytosterols, phytostanols and their esters, in an already approved food format, breakfast cereals. There is no new data since the last FSANZ evaluation to support a review of the previous conclusions.

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

[Section C.4.3 of Application Handbook March 2016]

This application to amend the ANZFSC pertains to an extension of use of an already approved novel food, i.e. phytosterols, phytostanols and their esters, in an already approved food format, breakfast cereals. There is no new data since the last FSANZ evaluation to support a review of the previous conclusions.

2.4 Information on dietary exposure to the novel food

[Section 3.5.2 D of Application Handbook March 2016]

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 2016]

The proposed change to the Code pertains to a higher level of phytosterol inclusion in a food already approved for fortification with phytosterols, i.e. breakfast cereals that have a total fibre content of no less than 3 g/50 g serve, and that contains no more than 30g/100g of total sugars.

Provided they meet above nutrient criteria, the type of products that could qualify for phytosterol fortification under this proposed Code change can include such products as listed in Appendix 9, i.e. single-serve oat sachets, single-serve boxed mueslis and other breakfast cereals, and flaked cereal biscuits.

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 2016]

The proposed change to the Code would be in addition to the current allowed fortification level (no less than 15 g/kg and no more than 19 g/kg), to allow the addition of total plant sterol equivalents content of no less than 0.8g and no more than 2g per serve to portion controlled breakfast cereals. "Portion controlled breakfast cereals" is defined as breakfast cereals that are either delivered in individually wrapped, single-serve portions, or in discreet portions that can be readily divided from a multi-serve container.

The permitted level would be in addition to the level of naturally occurring phytosterols in wholegrains, estimated at approximately 500 - 1000 µg/g (Chen et al. 2015).

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 2016]

Not applicable. Ready-to-Eat (RTE) breakfast cereals are listed in the most recent NNS. The Australian Health Survey 2011-2012 shows that the proportion of the target market (45-75 years) consuming RTE breakfast cereal is anywhere between 32%-50%. (Australian Health Survey 2011-12, Cereal and Cereal Products, Table 4 Proportion of persons consuming food).

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 2016]

It is not possible to predict the percentage of the market likely to use the novel food ingredient as this will be impacted not only by an individual's need (they have high cholesterol levels and are aware of it), but also their awareness of the products' availability, understanding of the products' benefit, accessibility of these products (both geographically as well as financially), and liking of the products. However, three sets of data may assist with estimations of defining percentage of the market likely to use the food:

- 1) Cereal consumption amongst target market: The Australian Health Survey 2011-2012 shows that the proportion of the target market (45-75 years) consuming RTE breakfast cereal is ranges from 32%-50%. (Australian Health Survey 2011-12, Cereal and Cereal Products, Table 4 Proportion of persons consuming food);
- 2) Prevalence of high cholesterol amongst target market: It is assumed that individuals with high total and high LDL-cholesterol would be interested in cholesterol-lowering foods.
 - a. According to the National Heart Foundation, prevalence of high cholesterol amongst 45 to 75 year olds ranges from 37.2% to 47.8% (National Heart Foundation, High cholesterol statistics);
 - b. According to the Australian Health Survey: Biomedical Results for Chronic Diseases, 2011-12 — Australia, abnormal LDL-cholesterol levels affect 43.6% of 45-54 year old individuals, 45.7% of 55-64 year old individuals and 35% of 65-74 year old individuals. Similarly, high total cholesterol levels affect 44.7% of 45-54 year old individuals, 47.8% of 55-64 year old individuals and 37.2% of 65-74 year old individuals. (Australian Health Survey: Biomedical Results for Chronic Diseases, 2011-12 — Australia, Table 1.3. Australian Bureau of Statistics.)
- 3) Per annum total volume of portion-controlled breakfast cereals currently eaten (flaked biscuit cereal & single serve cereal products), which amounts to 18.6% of the total breakfast cereal market. Please note, this data does not distinguish purchase by age group. Whilst the Applicant does not have specific data, phytosterol enriched foods are marketed to older Australians and carry a cost premium. It would be reasonable to conclude, therefore, that they will not be, as a rule, be consumed in households with young (under 5 years of age) children or fed to young children. [Appendix 9: Nielsen Retail Scan Track Sales Data to week ending November 2015]

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 2016]

The Australian Health Survey 2011-2012 shows that the proportion of the target market (45-75 years) consuming RTE breakfast cereal is anywhere between 32%-50%. Australian Health Survey 2011-12, Cereal and Cereal Products, Table 4 Proportion of persons consuming food)

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 2016]

It can be reasonably assumed that people interested in lowering their cholesterol levels with the help of phytosterol-containing breakfast cereal may replace their current breakfast cereal or other breakfast choice with the phytosterol-containing product.

In terms of consumption of other phytosterol fortified food products, in particular milk and yoghurt, Sanitarium commissioned market research highlighted the following regarding the core target market (45-74yrs, diagnosed high cholesterol, not using cholesterol medication, and regular flaked biscuit cereal eaters):

- 99% of people ate the flaked biscuit cereal with milk, 16% added yoghurt (some participants use either milk or yoghurt on different days). [Appendix 6: FF5 survey data_2015 [CONFIDENTIAL], page 13]
- This did not change over the course of the research.
- 27% of participants indicated that they consumed fortified foods for heart health. However, none of them used a plant sterol fortified milk or yoghurt product [Appendix 6: FF5 survey data_2015 [CONFIDENTIAL], page 14].

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 2016]

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, Edible oil spread, Skim milk, Juice
2. Porridge
3. Rye bread
4. Soy milk

North America:

1. Yoghurt drinks, Edible oil spread, Dairy-based shots, Dairy milk, Juice
2. Porridge
3. Soy milk
4. Oatmeal squares
5. Omega-3 real egg product
6. Wholegrain crackers
7. Cookies
8. Snack bars
9. Tortilla chips
10. Waffles

[Appendix 10: Mintel GNPD_ Phytosterol-containing foods launched over the last 10 years]

Other than yoghurt mini drinks, examples of relevant, current products in other markets that contain two grams phytosterol (plant stanol) per portion controlled serving (excluding mini drinks) include the following:

3. A cereal product (oat flakes) containing 2g plant stanol per 35g serve (individually wrapped) has been launched in Finland in 2011. The cereal retails as a 210g pack containing six serves/sachets.
4. A plant stanol containing rye bread was launched in Romania in February 2015 containing 2g plant stanols per 80g serve (not individually wrapped) contained in a 240g pack delivering three serves.

[Appendix 5: EU examples of 2g PS per portion controlled serve (excl mini drinks)]

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

[Section 3.5.2 E of Application Handbook March 2016]

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 2016]

In 2010 the FSANZ Approval Report for Application A1019 states: *“Consuming plant sterol fortified foods is associated with a reduction in serum levels of some carotenoids, particularly β -carotene, a precursor of vitamin A. However, after standardisation for reduced levels of LDL-cholesterol, only the change in serum levels of β -carotene is significant. Changes in other carotenoids are not significant. The evidence from numerous studies shows that carotenoid levels remain within a broad natural range considered to be typical of variable diets. In addition, clinical studies have demonstrated that increasing consumption of fruits and vegetables, particularly varieties rich in carotenoids, compensates for lower absorption of fat-soluble vitamins. Overall, consumption of plant sterols does not result in changes in vitamin levels that could be considered to raise any nutritional concerns.”* (FSANZ, 2010) In 2012, FSANZ again concluded *“that a reduction in the absorption of beta-carotene with consumption of phytosterols is expected, however this was considered to have no significant nutritional impact”* (FSANZ, 2012).

The latter conclusion is echoed by the National Heart Foundation who state that an additional serving of high-carotenoid fruit and vegetables is effective in maintaining blood carotenoid concentrations. (National Heart Foundation, 2009)

Sanitarium commissioned research data revealed that 31% of the target population (45 - 74 years) consume flaked biscuit cereals with fruit. It is reasonable to assume that this behaviour will be maintained when using the phytosterol enriched counterpart [Appendix 6: FF5 survey data_2015, slide 13]. On pack communication can also encourage fruit consumption [Appendix 7: Mock packaging design].

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 2016]

There is no evidence of adverse effects related to the consumption of phytosterol enriched foods by target or non-target consumers. The only exception is for consumers suffering a rare medical condition known as phytosterolaemia, which has been addressed in detail in the assessment of Application A1019.

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.

A Code change with subsequent launch of product would provide an opportunity to further educate consumers. As such, in addition to the mandatory labelling statements, other labelling and associated education strategies can be expected to address the following issues:

- The benefits/target of consuming up to 2g phytosterols per day;
- That portion controlled breakfast cereals provide an alternative to consumers who may wish to get their phytosterols from foods other than fat or dairy based products;
- That one portion (portion to be defined according to the relevant product) 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.*

* It should be noted that none of the participants included in Sanitarium commissioned market research was on any cholesterol-lowering medication. However, as is already done on other phytosterol containing products, on-pack and other type of communication can contain statements to ensure that no consumers will reject or reduce medication without medical oversight if they use this product. [Appendix 7: Mock packaging design]

Further to above, since phytosterol enriched cereals 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 flaked biscuit cereals and amongst a non-target consumer the premium price for such a product will be a barrier.

Note, Sanitarium commissioned market research amongst the target population indicates that 76% of people complied with eating just two Weet-Bix per serve, after only one exposure to the product concept and the actual product itself. In other words, there was high compliance with dose even in the absence of final packaging materials, education, marketing activities, and the requirement to pay for the product. This compliance to consume two Weet-Bix per serve is expected to increase 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 2g of plant sterol - the daily requirement - being delivered in two Weet-Bix [Appendix 7: Mock packaging design]; 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.

In relation to the most vulnerable groups of consumers, pregnant and lactating women and children under 5 years of age do not need to lower their cholesterol levels and so derive no benefit from consuming phytosterol-enriched foods. Safety data for pregnant women, lactating women, and children under 5 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 is no basis for postulating a risk to these population subgroups. Please refer to section 2.6.3 for further discussion.

2.6 Information related to potential impact on consumer understanding and behaviour

[Section 3.5.2 F of Application Handbook March 2016]

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 2016]

Independent Market Research conducted on behalf of Sanitarium on the target market indicated that a proportion of the target market is currently using phytosterol containing foods such as Flora Pro-activ and Logicol, which suggests there is at least some awareness of phytosterols and the benefits of their consumption. [Appendix 6: FF5 survey data_2015, slide 14].

However, there is confusion regarding portion size required for efficacy, and many are unaware that a minimum daily amount of two grams is required to benefit from a cholesterol lowering effect. This confirms previous findings that consumers may currently not be benefiting from a cholesterol-lowering effect of phytosterols due to consumption levels below two grams per day. The concept of a single-serve product as well as on-pack labelling would address these gaps.

A Code change with subsequent launch of product would provide an opportunity to further educate consumers. As such, labelling and associated education strategies can be expected to address the following issues:

- The benefits/target of consuming up to 2g phytosterols per day;
- That portion controlled breakfast cereals provide an alternative to consumers who may wish to get their phytosterols from foods other than fat or dairy based products;
- That one portion (portion to be defined according to the relevant product) 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.

Any labelling would occur in a manner which informs and does not mislead consumer regarding the nutritional quality of the food. Above communications would occur in addition to the mandatory labelling statements. Please refer to Section 2.6.3 regarding Mandatory advisory statements. As the proposed change to the Code does not change the delivery mode (via breakfast cereal), and proposed phytosterol concentrations would more closely resemble those permitted in other food formats no change to current mandatory labelling requirements are proposed.

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 2016]

It is expected that approval of the proposed change to the Code will lead to a greater number of phytosterol-containing breakfast cereals on the market (currently there are none). This may increase consumption of such products by target and possibly non-target populations. Based on data previously reviewed by FSANZ for other phytosterol 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).

Furthermore, since phytosterol enriched cereals 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 flaked biscuit cereals and amongst a non-target consumer the premium price for such a product will be a barrier.

This information suggests that the purchase of phytosterol-enriched breakfast cereals by younger households is for specific family members, and an alternative non-enriched breakfast cereal would be purchased for non-target members of the household. Therefore, any increased consumption by non-target groups such as children is likely to be low and there is no evidence to suggest this will have an adverse health effect (Discussed in Section 2.6.3).

Importantly, any increased consumption occurring in the target population is likely to be of additional benefit as there is evidence that at least some of this population may not be receiving the minimum effective amount of phytosterols shown to have a positive effect on lowering cholesterol levels (FSANZ, 2006 & EFSA, 2008).

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

[Section 3.5.2 F.3 of Application Handbook March 2016]

As discussed above there is no evidence to suggest that consumers who are not a part of the target group will regularly buy or consume phytosterol-enriched breakfast cereals. There is also no evidence of any adverse effects on the non-target population from the sale of pytosterol-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 portion control breakfast cereals.

The potential for consumption by people outside the target group, including children, is already addressed by mandatory advisory labelling for foods enriched with phytosterols (or their equivalents). No change to current labelling requirements are proposed as the proposed change to the Code does not change the delivery mode (via breakfast cereal), and proposed phytosterol concentrations more closely resemble those permitted in other food formats.

Schedule 9 (Mandatory advisory statements) requires that “foods containing added phytosterols, phytostanols or their esters” carry statements 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 5 years and pregnant or lactating women; and
- plant sterols do not provide additional benefits when consumed in excess of 3 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. However, as noted in the FSANZ approval report for A1070 *“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, 2012)

Within the same approval report and in response to the question raised by the Victorian Department of Health *“Why is it necessary for an advisory statement to the effect that consumption of phytosterols may not be suitable for children under 5 years and pregnant and lactating women? If deemed necessary, FSANZ should provide further information for consumers on why these products are not suitable for those population groups.”* (FSANZ, 2012; Table 1: Summary of issues raised in the Victorian Department of Health submission), FSANZ offered the following response: *“...based on knowledge of the mechanisms of action, the extensive experience in the general population and absence of effects in pregnant animals and their offspring there is no basis for postulating a risk to these population subgroups. As stated in previous assessment reports (e.g. the Second Review Report for A433, A434 and A508 at <https://www.foodstandards.gov.au/code/applications/documents/A508%20TOPs%20SRR%20FINAL.pdf>), 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. In this context, FSANZ does not consider that further explanation relevant to these population groups on food labels is warranted.”* (FSANZ, 2012)

Further, as with other phytosterol enriched foods, phytosterol enriched breakfast cereals will be characterised by distinctive packaging, that will targeted at the 45 – 75 year age group and distinguish them from non-enriched counterparts [Appendix 7: Mock packaging design]

The efficacy of phytosterols in relation to cholesterol lowering is not defined or limited by race or socioeconomic status. Therefore, above relates to the potential for adverse effects on populations, other than the target population (irrespective of race or socioeconomic status), specifically, 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 Application Handbook March 2016]

Statutory Declarations Act 1959:

[Redacted]

1 SANCTUARY DRIVE BERKELEY VALE 2261

TECHNICAL MANAGER

[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.

[Redacted]

[Signature of person making the declaration]

Declared at BERKELEY VALE 17th JUNE 2016
[place] on [day] of [month] [year]

[Redacted]

Before me,

[Signature of person before whom the declaration is made]

[Redacted]

17 Kilkenny Parade,

Berkeley Vale, NSW, 2261

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

Checklists

[Section 3.1.1 L of Application Handbook March 2016]

Checklist for General requirements (3.1.1)

Check	Page No.	Mandatory Requirements
✓	n/a	A Form of application <input type="checkbox"/> Application in English <input type="checkbox"/> Executive Summary (separated from main application electronically) <input type="checkbox"/> Relevant sections of Part 3 clearly identified <input type="checkbox"/> Pages sequentially numbered <input type="checkbox"/> Electronic copy (searchable) <input type="checkbox"/> All references provided
✓	Pg 3	B Applicant details
✓	Pg 4	C Purpose of the application
✓	Pg 5	D Justification for the application <input type="checkbox"/> Regulatory impact information <input type="checkbox"/> Impact on international trade
✓	Pg 18	E Information to support the application <input type="checkbox"/> Data requirements
✓	Pg 18	F Assessment procedure <input type="checkbox"/> General <input type="checkbox"/> Major <input type="checkbox"/> Minor <input type="checkbox"/> High level health claim variation
✓	Pg 18	G Confidential commercial information <input type="checkbox"/> CCI material separated from other application material <input type="checkbox"/> Formal request including reasons <input type="checkbox"/> Non-confidential summary provided
✓	Pg 18	H Other confidential information <input type="checkbox"/> Confidential material separated from other application material <input type="checkbox"/> Formal request including reasons
✓	Pg 18	I Exclusive Capturable Commercial Benefit <input type="checkbox"/> Justification provided
✓	Pg 18	J International and other national standards <input type="checkbox"/> International standards <input type="checkbox"/> Other national standards
✓	Pg 31	K Statutory Declaration
✓	Pg 32	L Checklist/s provided with application <input type="checkbox"/> 3.1.1 Checklist

		<input type="checkbox"/> All page number references from application included <input type="checkbox"/> Any other relevant checklists for Chapters 3.2–3.7
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Checklist for Novel Foods (3.5.2)

Check	Page No.	Mandatory Requirements
✓	Pg 19 Pg 20	<input type="checkbox"/> A. Exclusive use <input type="checkbox"/> B.1 Type of novel food <input type="checkbox"/> B.2 Information on potential beneficial outcomes <input type="checkbox"/> B.3 Chemical and physical properties <input type="checkbox"/> B.4 Impurity profile <input type="checkbox"/> B.5 Manufacturing process <input type="checkbox"/> B.6 Specification for identity and purity <input type="checkbox"/> B.7 Analytical detection method
✓	Pg 21 Pg 22 Pg 23	<i>C.4 Single chemical entities & dietary macrocomponents</i> <input type="checkbox"/> C.4.1 Toxicokinetics and metabolism <input type="checkbox"/> C.4.2 Toxicity studies <input type="checkbox"/> C.4.3 Safety assessments from other agencies

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APPENDICES

Appendix 1: Nutrient comparisons current vs proposed regulations
Appendix 2: Cost burden based on volume
Appendix 3: Cost single serve vs multi-pack [CONFIDENTIAL]
Appendix 4: UK cholesterol lowering product market data
Appendix 5: EU examples of 2g PS per portion controlled serve (excl mini drinks)
Appendix 6: FF5 survey data_2015 [CONFIDENTIAL]
Appendix 7: Mock packaging design [CONFIDENTIAL]
Appendix 8: Safety_Plant Sterols Clinical Trials_Literature Search
Appendix 9: Nielsen Retail Scan Track Sales Data to week ending November 2015 [CONFIDENTIAL]
Appendix 10: Mintel GNPD_ Phytosterol-containing foods launched over the last 10 years

** End of Application **