FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

7-06
4 October 2006

SECOND REVIEW REPORT

APPLICATION A433
PHYTOSTEROL ESTERS DERIVED FROM VEGETABLE OILS IN BREAKFAST CEREALS

APPLICATION A434
PHYTOSTEROL ESTERS DERIVED FROM VEGETABLE OILS IN LOW-FAT MILK & YOGHURT

APPLICATION A508
PHYTOSTEROLS DERIVED FROM TALL OILS AS INGREDIENTS IN LOW-FAT MILK

For Information on matters relating to this Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

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Decision

FSANZ re-affirms its approval of Applications A433, A434 and A508, subject to drafting amendments specified in this Second Review, and supported by appropriate risk management measures because:

1. **The recently established Phytosterols Expert Advisory Group evaluated safety concerns raised by jurisdictions in relation to nutritional effects, possible interactions with cholesterol-lowering medications and long-term usage of phytosterol-enriched foods and concluded that there was no basis for health concerns;**

2. **A change to permit a minimum and maximum amount of plant sterols in a product will assist consumers to:**

   (i) more easily monitor a daily intake of plant sterols;
   (ii) consume an efficacious amount; and
   (iii) use the products cost effectively;

3. **Revised mandatory advisory statements will provide information to consumers at the time of purchase that is consistent with the safety evidence for different population groups;**

4. **A survey of New Zealand and Australian consumers found that users of phytosterol-enriched margarines are in the target group, use the products in moderation and for the appropriate health reasons. Recent post-market monitoring in Europe, where a broader range of phytosterol-enriched foods has been available for some time, shows that consumers welcome choice of products, and over-consumption does not occur;**

5. **A review of Standard 1.2.9 Legibility Requirements will go ahead, but the insertion of an Editorial note is a practical, interim measure to clarify the legibility requirements of the Code for mandatory advisory statements;**

6. **FSANZ and the National Heart Foundation of Australia will collaborate in broadly based education activities that will significantly increase the visibility of information on plant sterols in the context of heart-healthy nutrition and dietary advice;**

7. **FSANZ will also prepare its own educational material on phytosterol-enriched foods suitable for wide distribution to professional organisations and the general public, linking to other sources of information on plant sterols;**

8. **Approval of the current applications is a conservative extension of use of plant sterols into foods types that are compatible with a healthy diet message; and**

9. **The development of policy guidance on the addition to food of non-vitamins and minerals and a new Standard for Health, Nutrition and Related Claims should not halt the progression of Applications A433, A434 and A508.**

Summary Table

Issues addressed in the Second Review of Applications A433, A434 and A508 seeking to broaden the use of phytosterol esters and tall-oil phytosterols.

MINISTERIAL COUNCIL ISSUE	FSANZ RESPONSE
1. Protection of public health and safety.	• Officials of jurisdictions contacted to seek clarification on concerns. • Formation of the Phytosterols Expert Advisory Group to consider safety issues holistically. • Further assessment of nutritional issues in the context of Australian data on beta-carotene levels. • Further assessment of effects of plant sterols used in conjunction with cholesterol-lowering medication. • Assessment of recently published literature on plant sterol-enriched foods and effects in children. • Further explanation of the potential benefits to consumers from a wider choice of phytosterol-enriched foods and clarification on the restrictions to breakfast cereals. • Consideration of several, recent post-market monitoring reports on phytosterol-enriched foods in Europe. • Revision of specifications for the tall oil phytosterols.
2. Provision of adequate information to enable informed choice.	• TNS social research commissioned to conduct a survey of consumers in New Zealand and Australia of phytosterol-enriched spreads to ascertain behaviour patterns and motivation. • Revision of the mandatory labelling statements for packaging of all phytosterol-enriched foods. • Established professional links with the National Heart Foundation of Australia to assist with the development and implementation of community education initiatives providing information relevant to the appropriate use of plant sterols, and dietary/nutritional advice in relation to heart disease.
3. Policy issues.	• Provided further explanation regarding the impact of the proposed health claims standard and the development of policy guidance for the addition to food of non-vitamins and minerals.

Key changes as a result of the Second Review

PREVIOUS ASSESSMENT	ASSESSMENT AT SECOND REVIEW
No more than 0.8 g plant sterols (as free sterols) or no more than 0.9 g tall oil plant sterols in one serve of food.	**A range is proposed as follows:** ***a minimum of 0.8 g and a maximum of 1.0 g plant sterols (either vegetable oil or tall oil) per serve of food*** • The minimum amount is based on efficacy and the maximum amount is based on avoidance of consumer deception. • All plant sterols, whether derived from a vegetable oil or tall oil source, will be permitted within the same range, to avoid consumer confusion between the two types of phytosterols permitted in the FSC. • Dietary exposure estimates, including the use of phytosterol-ester enriched table spreads, show that mean daily consumption would be within 1-3 g.
Existing mandatory advisory statements: 1. *the product should be consumed in moderation as part of a diet low in saturated fats and high in fruits and vegetables.*	**Revised statement to the effect that:** ***when consuming this product, it should be consumed as part of a healthy diet*** • Plant sterols permitted only in foods that are compatible with a healthy diet i.e. low-fat milk, low-fat yoghurt and breakfast cereal with a compositional profile that is not attractive to children. • Advice to consume carotenoid-rich fruit and vegetables is not justified on the grounds that the reduction in serum beta-carotene is not indicative of any nutritional deficiency and is within natural variation. • Healthy diet message compatible with other public health messages in relation to diet and chronic disease.
Existing mandatory advisory statements: 2. *the product is not recommended for infants, children and pregnant or lactating women unless under medical supervision.*	**Revised statement to the effect that:** ***the product may not be suitable for children under the age of five years and pregnant or lactating women.*** • Many studies in hypercholesterolaemic children show the efficacy and safety of plant sterol-enriched foods. However, young children do not need to consume specific foods to achieve a cholesterol reduction. • Similarly, pregnant and lactating women do not need to lower serum cholesterol levels.
Existing mandatory advisory statements: 3. *consumers on cholesterol-lowering medication should seek medical advice on the use of this product in conjunction with their medication.*	**Deleted this advisory statement.** • Clinical studies show that consumption of plant sterol-enriched foods can lead to a modest reduction in cholesterol levels, even in individuals on cholesterol-lowering medication, and is not a health concern. • There is no scientific evidence of adverse interactions of plant sterols in conjunction with cholesterol-lowering medication, particularly the statins, as they work by different physiological mechanisms. • Plant sterol-enriched foods may provide a more cost-effective means of reducing cholesterol in those who cannot achieve a reduction using prescribed medication alone.

PREVIOUS ASSESSMENT	ASSESSMENT AT SECOND REVIEW
Proposed mandatory advisory statement: *Foods containing added plant sterols do not provide additional benefits when consumed in excess of three serves per day.*	**Revised statement to the effect that:** ***plant sterols do not provide additional benefits when consumed in excess of three grams per day.*** • Consumers can more easily monitor their daily intake in grams of plant sterols across a range of foods. • Advises consumers that more than 3 g per day plant sterols do not provide any additional cholesterol-lowering benefit, thereby encouraging cost-effective use of the products. • There are no standardised serve sizes for these products, although manufacturers often indicate a recommended serving size on packaging.
Existing conditions of use: The name 'phytosterol-esters', 'tall oil phytosterols' or 'plant sterols' must be used when declaring the ingredient in the ingredient list , as prescribed in Standard 1.2.4	**No change to this requirement.** • Manufacturers of phytosterol-enriched table spreads currently use the more generic term 'plant sterols'. • Consumers can readily monitor daily intake in grams of plant sterols by reference to the ingredient list.
Proposed condition of use: Foods to which tall oil phytosterols or phytosterol esters have been added may not be used as ingredients in other foods.	**No change to this requirement.** • Manufacturers will not be permitted to use phytosterol-enriched foods in the preparation of other mixed foods.
Current specifications for the tall oil phytosterols are listed in the Schedule to Standard 1.3.4 Identity and Purity.	**Revised specifications for the tall oil phytosterols** • New specifications for the tall oil phytosterols incorporate a minimum 97% level of purity, with a maximum of 3% minor sterols. The revised specifications also incorporate a reduction in the 'total heavy metals' component from a maximum of 10 ppm down to 2 ppm.
Proposed editorial note in Standard 1.2.9 Legibility Requirements (inserted at First Review)	**Revised wording of editorial note to read as follows:** ***The requirements of this Standard will not be met where prescribed information is placed other than on the outside of a package where it is readily accessible by a consumer prior to purchase, or during the life of the product, and not obscured by an outer covering. The requirements of this Standard will also not be met where prescribed information is printed in a small font so the statement cannot be read easily.*** • Intended only as an interim measure to reinforce the principles underpinning Standard 1.2.9, pending a systematic review of the effectiveness of the Standard.

All drafting changes for Applications A433, A434 and A508 are at **Attachment 1**.

1. Introduction

In September 2005, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a Second Review of Applications A433, A434 and A508. These applications seek to broaden the range of foods to which phytosterols (plant sterols) may be added as follows:

Application A433	Addition of phytosterol esters* derived from vegetable oils to breakfast cereals
Application A434	Addition of phytosterol esters* derived from vegetable oils to low-fat milk and yoghurt
Application A508	Addition of phytosterols derived from tall oils** to low-fat milk

***Phytosterol esters** are plant sterols derived from edible vegetable oils which have been esterified with long-chain fatty acids from vegetable oil sources.
****Tall oil phytosterols** (non-esterified) are a by-product of the pulping process from coniferous trees.

Approval of all three applications involves variations to Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, Standard 1.5.1 – Novel Foods, Standard 2.5.1 – Milk, and Standard 2.5.3 Fermented Milk Products of the *Australia New Zealand Food Standards Code* (the Code).

The purpose of the Second Review is to respond to the issues raised by the Ministerial Council, as outlined in Section 3. FSANZ has addressed these issues by seeking additional information from key stakeholders, undertaking further research and engaging external expertise. An extension of time was granted until 27 July 2006 to complete the review.

2. Objectives of review

The objective of the Second Review is to reconsider the draft variations notified to the Ministerial Council by FSANZ in July 2005 following completion of the First Review.

3. Grounds for the review

A Second Review was requested on the grounds that approval of the draft variations:

- does not protect public health and safety; and
- does not provide adequate information to enable informed choice.

The Ministerial Council provided additional comments concerning the grounds on which the Second Review is based. These comments have been broadly categorised in the following groups:

- Long term safety of phytosterols;
- Possible interactions with cholesterol-lowering medication;
- Nutritional effects;
- The effectiveness of labelling and advisory statements; and
- Consumer education and the role of health professionals.

Specific advice was also requested on the sterol composition of the tall oil phytosterols (TOPS) on the basis of changes to the specifications in the European Union.

4. Background

Currently, under Standard 1.5.1 - Novel Foods, phytosterol esters and tall oil phytosterols (plant sterols) are permitted for use only in edible oil spreads. As separate novel food ingredients, they are listed individually in the Table to clause 2 and are subject to specified conditions of use. Plant sterols must be declared in the ingredient list, and three advisory statements must be presented on packaging to advise consumers on how to use the products appropriately[1].

Consumption of plant sterols reduces absorption of dietary cholesterol leading to lower serum LDL-cholesterol levels. Foods containing added plant sterols are therefore targeted primarily to adult consumers with concerns about their cholesterol levels. Manufacturers seek to expand the range of phytosterol-enriched products primarily to broaden consumer choice.

In October 2004, the FSANZ Board approved the Final Assessment of Applications A433, A434 and A508. The FSANZ assessment focused on (i) the safety of phytosterol esters and tall oil phytosterols at proposed levels of use when used in breakfast cereal, low-fat milk and yoghurt, (ii) their efficacy in the relevant food matrices to ensure truth in labelling, and (iii) the suitability of the products to target consumers.

The optimal cholesterol-lowering effect is achieved when consumption is between 2-3 g plant sterols per day, irrespective of the type of sterols consumed. To ensure that target consumers were informed about this, an additional advisory statement was proposed to the effect that:

foods containing added plant sterols do not provide additional benefits when consumed in excess of three serves per day.

As an additional risk management measure, the conditions of use were also extended to the effect that:

foods containing added plant sterols must not be used as ingredients in other foods.

In December 2004, the Ministerial Council requested a First Review of the Applications on the grounds that there were remaining standards and policy issues. After consideration of these issues, in July 2005, the Board reaffirmed its approval of the draft variations recommended to the Ministerial Council.

4.1 Phytosterol-enriched foods in other countries

A variety of phytosterol-enriched foods are approved in Europe and the USA in the following categories:

[1] It should be noted that although the permission for tall oil phytosterols exists in the Code, there are no tall oil products on the market. The two currently available brands of phytosterol-enriched table spreads (Logicol® and ProActive®) both contain phytosterol esters from vegetable oils.

(1) Fats and oils
(2) Dairy products
(3) Beverages
(4) Bakery products

Because of the complexity of the approval process for individual products in the European Union, FSANZ sought information from the food industry on the regulatory status and availability of phytosterol-enriched products in Europe. The information received is at **Attachment 2**. Milk and fermented milk products have been approved under the Novel Foods Regulation (EC No. 258/97) since 2004. Recently in 2006, the range of approved products was extended to rye bread.

4.2 Other applications

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

5. Issues in the Second Review

Formation of Expert Advisory Group

FSANZ formed a Phytosterols Expert Advisory Group, chaired by the Chief Medical Advisor Dr Bob Boyd, to broaden the technical input into the Second Review. The Group is comprised of invited members with identified expertise and knowledge on phytosterols from a variety of professional backgrounds. As well as researchers, academics and a clinician, representatives from organisations such as the Dietitians Association of Australia, the New Zealand Dietetics Association and the National Heart Foundation of Australia (NHF) were invited into the Group2.

The Group's purpose and function is to provide advice to FSANZ on the interpretation and evaluation of available scientific evidence relevant to consideration of the efficacy, safety and nutritional effects of phytosterol-enriched foods. Through representatives from health professional organisations, the Group also provided advice in relation to a number of consumer-related issues.

At a meeting in May 2006, the Phytosterol Expert Advisory Group discussed specific technical issues identified in the comments received from the Ministerial Council at Second Review. Through a consensus approach, the meeting was able to address a number of key concerns using the most recent scientific information and progressive thinking on the role of phytosterol-enriched foods in the context of a healthy diet.

[2] **Phytosterol Expert Advisory Group**: Dr Alex Chisholm, University of Otago (Dunedin, NZ); Dr Peter Clifton, CSIRO Human Nutrition; Ms Barbara Eden, National Heart Foundation of Australia; Ms Linda Hodge, Dietitians Association of Australia; Professor Paul Nestel, Baker Medical Research Institute; Dr Manny Noakes, CSIRO Human Nutrition; Professor Brian Priestly, Director, Australian Centre for Human Health Risk Assessment (Department of Epidemiology and Preventive Medicine, Monash University, Melbourne).

Wherever relevant, the deliberations and conclusions of the meeting have been used in addressing the following issues.

5.1 Protection of public health and safety

5.1.1 Long term safety of phytosterols at high levels of consumption

The Expert Advisory Group was not aware of more recent long term studies (greater than twelve months) on phytosterols, however considered that extrapolation from the results of the large number of published studies showing no safety concerns was appropriate.

Additional toxicological studies in animals were published between 2001-2004, and these had confirmed the absence of any adverse effects. Phytosterols are only poorly absorbed, and a number of potential toxicological effects had been examined and ruled out as a concern.

There are many studies examining safety in humans, and the effects on uptake of fat-soluble nutrients was the most significant finding, although these were variable in different studies. Low amounts of dietary phytosterols are currently being explored as anti-cancer agents, particularly for hormone-dependent cancers.

Studies on the effects of dietary phytosterols are available for both normocholesterolaemic and hypercholesterolaemic people. Previously, FSANZ has focused on studies using subjects with normal or mildly elevated cholesterol levels. Consideration of the studies using hypercholesterolaemic subjects, usually those in whom high cholesterol levels occur in families, broadens the available evidence as these tend to be longer term studies.

A 2004 Norwegian study examined the long-term compliance and changes in plasma lipids, plant sterols and carotenoids in children and parents with familial hypercholesterolaemia (FH) consuming phytosterol ester-enriched spread. The duration of the study was 6 months. A total of 37 children (7-13 y) and 20 parents (32-51 y) diagnosed with heterozygous FH were required to consume 20 g per day of phytosterol-enriched spread as part of their lipid lowering diet. The mean daily intake of phytosterols corresponded to 1.2 g in the children and 1.5 g in the parents. Most parents, but no children, used statins in addition to the dietary intervention. There was a reduction of approximately 11% in LDL cholesterol levels in both groups. The authors reported that lipid-adjusted serum alpha- and beta- carotene decreased by 17% and 11% respectively in the children at the end of the controlled phytosterol period. However, levels of both nutrients increased again during the follow-up period. Of note, serum alpha- and beta-carotene concentrations were unchanged in the parents. There were no adverse effects reported and the study concluded that long-term compliance of phytosterol consumption was associated with sustained efficacy in cholesterol reduction (Amundsen et al., 2004).

With respect to tall oil phytosterols (Application A508 only), FSANZ acknowledges that there have been no long term studies at higher levels of consumption, with studies limited to 28 days (3.6 g/day) or 8 weeks (1.8 g/day). However, given the higher proportion of stanols in the tall oil preparations, large studies examining the safety of plant stanol-enriched foods are relevant.

The Stresa Workshop3 whose findings were published in the Mayo Clinic Proceedings (Katan et al. 2003), is one of the most comprehensive reviews on the efficacy and safety of plant stanols and sterols. This review concluded that consuming 2 g per day of stanols and sterols lowers LDL cholesterol levels by 10%, and based on epidemiological data and trials with cholesterol-lowering drugs, long-term use likely will lower coronary heart disease risk by between 12% to 20% in the first 5 years, and by 20% over a lifetime. The Workshop further concluded:

> *Safety testing of [plant] sterols and stanols has exceeded that of ordinary foodstuffs that are eaten widely and generally recognised as safe; and*
> *Adverse health outcomes due to observed decreases in beta carotene levels in plasma are speculative and are of no major concern.*

With respect to the potential oestrogen-disrupting effects of phytosterols in foods, studies on tall oil phytosterols previously evaluated by FSANZ under Application A417[4], found no evidence of *in vitro* or *in vivo* oestrogenic activity in rats or humans. In addition, the former EU Scientific Committee on Food (SCF) Final Report (3 October 2002) stated that newly submitted studies provided sufficient reassurance of the absence of endocrine effects via the oral route (SCF, 2002). In addition, the Stresa Workshop report references several studies, including long-term and in vitro and in vivo studies, in reaching a conclusion that plant sterols do not bind to the oestrogen receptor and that there is no evidence of oestrogenic activity of stanols.

Based on the large number of safety/efficacy studies in humans and toxicological studies in animals, FSANZ concluded that there is no evidence to suggest that adverse effects would result from longer term consumption of phytosterols, from either tall oil or vegetable oil sources. On the contrary, phytosterols were well tolerated, efficacious in the food matrices under consideration (over and above a background low-fat diet) and raised no safety concerns in adults or children. High levels of consumption (up to 10 g per day) have been shown in clinical studies to be safe, providing a safe margin of exposure when compared to the expected level of consumption of 2-3 g per day.

5.1.1.1 Conclusion

Phytosterol-enriched foods are well studied in both adults and children and in situations of varying cholesterol status and there are no indications of adverse long-term effects. They have been available in the food supply for more than 10 years without raising safety concerns. Limitations on the level of consumption are recommended primarily because increasing intake beyond 3 g per day produces little additional reduction in LDL-cholesterol.

5.1.2 Beta carotene and diabetes

The Expert Group agreed that no causative link between lower serum beta-carotene levels and type 2 diabetes has been established. On the basis of current information, the biological meaning of the observations reported by Ford *et al* (2003) was not resolved.

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[3] The Stresa Workshop facilitated the combined deliberations of 32 scientific experts on the safety of sterols and stanols.

[4] Application A417 – An application assessed in 2000/2001 seeking permission to use non-esterified phytosterols from a tall oil source as a Novel Food ingredient in edible oil spreads.

The papers by Ford *et al* are analyses of the US Third National Health and Nutrition Examination Survey (NHANES). The NHANES are cross-sectional surveys conducted at regular intervals in the US and are similar to the 1995 Australian and 1997 New Zealand National Nutrition Surveys and the 1999-2000 Australian Diabetes, Obesity and Lifestyle (AusDiab) Study (Dunstan, Cameron). Serum carotenoids were measured in the Queensland participants of the AusDiab study and, like the results reported by Ford *et al*, analysis shows that those with diabetes have lower mean serum beta-carotene levels than those without diabetes (Coyne 2005).

In a cross-sectional survey, all factors are measured at the same time – i.e. diabetes presence and level of serum beta-carotene were measured in the same sample of blood – therefore it is not possible to know whether the diabetes led to the low serum beta-carotene levels or the low serum beta-carotene levels led to the diabetes. Either is theoretically possible: diabetes may increase the level of oxidants which might "use up" anti-oxidants leading to lower serum levels or alternatively, low serum beta-carotene levels may create an oxidative environment that may predispose to diabetes development. In a 10 year follow-up study, Wang *et al* found no prospective association between baseline plasma carotenoids and the risk of type 2 diabetes in middle-aged and older women (Wang *et al*, 2006).

The strongest way to examine these questions is to conduct a randomised controlled trial in which participants without diabetes are given beta-carotene or placebo and followed over time to determine whether the incidence of diabetes differs between the groups. Liu *et al* (1999) randomised 22,071 healthy US male doctors aged 40-84 years to 50 mg beta-carotene or placebo on alternate days. Over the next 12 years, the incidence of type 2 diabetes was the same in both groups (RR=0.98, 95%CI: 0.85-1.12).
Therefore it must be concluded that, in the studies of Ford and Coyne, serum beta-carotene levels act as a marker for some other factor that could be related to diabetes, but is not itself shown to be the causal agent.

Furthermore, a reduction in serum beta-carotene in the order of 20% should be put into perspective. In the Queensland AusDiab participants, mean serum beta-carotene levels ranged from 0.46 umol/L in men aged 25-43 years to 0.79 umol/L in men aged 75 years and older (i.e. young men have levels 42% lower than older men), and from 0.59 umol/L in women aged 25-34 years to 1.25 umol/L in women aged 75 years and older (i.e. young women have levels 53% lower than older women) (Coyne 2002). In other words, the age and sex-related range of mean serum beta-carotene levels across the Queensland population is much larger than the reduction seen in studies on plant sterols.

The Stresa Workshop (Katan *et al* 2003) also reports a similar conclusion with respect to other chronic diseases such as coronary heart disease and cancers. The Workshop concluded that a decrease in serum beta-carotene levels caused by plant sterols should be viewed in the context of other dietary factors that influence circulating levels. As well as dietary and seasonal factors, some lipid-lowering drugs cause decreases in serum beta-carotene levels beyond the expected decrease from the lower LDL-cholesterol levels. Several long-term trials (such as the Lipid Research Clinics Coronary Primary Prevention Trial) in which the health of subjects on certain cholesterol-lowering medication was followed for up to 10 years, found that significantly reduced beta-carotene levels were not associated with an increased incidence of coronary events or cancers.

5.1.2.1 Conclusion

A 25% reduction in serum beta-carotene levels is not considered significant in the context of fluctuations that occur naturally due to environmental factors. Furthermore, current reports of diabetes and low carotenoids do not constitute evidence that a reduction in serum beta-carotene in the order of 25% is causal with respect to disease outcomes. Rather, the available evidence indicates that a reduction of this magnitude in serum beta-carotene levels has no effect on vitamin A levels and cannot be directly associated with an adverse impact on nutritional status.

5.1.3 Possible interactions with cholesterol-lowering medications

There are several groups of drugs used to lower serum cholesterol levels, acting on different aspects of cholesterol metabolism. Sites of action, modes of action and side-effect profiles differ, however there are no reports in the literature of adverse interactions between phytosterol-enriched foods and cholesterol-lowering medications.

Two groups of drugs, the anion-exchange resins and the more recently introduced ezetimibe act, like the phytosterols, within the gut to inhibit the absorption of cholesterol. There is no evidence of hazard from combining these non-absorbed agents. Gastro-intestinal side-effects limit the use of the resins and these may possibly be increased if drugs are used in combination. The fibrate group act mainly by reducing serum triglycerides. Although there are precautionary statements about combining fibrates and statins, there are no recognised hazards from combining fibrates with drugs acting within the gut. The same would apply to phytosterols.

Statins (HMG Co-A reductase inhibitors) are overwhelmingly the most prescribed cholesterol lowering drugs. They act predominantly in the liver by blocking cholesterol synthesis. There is increasing evidence that "aggressive" cholesterol lowering treatment, such as combining optimum doses of statins with a drug working at another site, such as ezetimide, produces additional clinical benefits. There is no evidence that this combination treatment with statins increases side-effects or risks. Phytosterols and ezetimibe have similar actions, both blocking cholesterol absorption in the gut. Therefore it can be concluded that a phytosterol/statin combination is likely to be safe and effective.

Prolonged statin therapy is reported to cause increases in the levels of all plant sterols in the blood (cholesterol-adjusted), and small but significant increases in serum campesterol levels (unadjusted) (Tikkanen, 2005). However, the levels of plant sterols remain much lower than those observed in patients with sitosterolaemia (a rare metabolic disorder in which all naturally occurring plant sterols in the diet are hyperabsorbed). To put this into perspective, mean serum levels of plant sterols from consumption of phytosterol-enriched margarine represent only 5%-15% of the concentrations of plant sterols in the serum of patients with sitosterolaemia. A mechanism has been proposed to explain the increased absorption of plant sterols with concomitant statin use: a medication-induced reduction in biliary cholesterol leads to a diminished cholesterol pool in the intestine, which allows more plant sterols to become incorporated in mixed micelles, which in turn facilitates their uptake in enterocytes.

Overall, the evidence indicates an additive cholesterol-lowering effect of plant sterols combined with statin therapy.

A trial conducted on patients using statins found an additional reduction of 10% in LDL levels with incorporation of stanol ester-enriched spread into the diet (Blair *et al*, 2000). The additional efficacy is reported to be greater than the effects usually achieved by doubling the statin dose (which normally provides an extra reduction in LDL-cholesterol levels in the order of 5%-7%).

5.1.3.1 Conclusion

Plant sterols can have an additional small cholesterol-lowering effect in people who are using cholesterol-lowering medications such as the statins. There are no reports in the literature of adverse effects from the consumption of phytosterol-enriched foods. Cholesterol-lowering medications are available on prescription only, and there are no reports of adverse interactions between plant sterols and cholesterol-lowering drugs. On the contrary, for those patients who have failed to respond adequately to medication, consumption of plant sterols may be a suitable (and more cost-effective) dietary intervention for further improving their cholesterol levels.

5.1.4 Specifications for tall oil phytosterols

The initial EU application for permission of tall oils was rejected because the purity of the nominated tall oil was 95%, with the remaining 5% of the sterols unknown. A later application reduced the levels of unknown sterol compounds to less than 1%.

The Applicant has provided FSANZ with revised specifications for tall oil phytosterols, incorporating a minimum purity level of 97%, with a maximum of 3% minor sterols. The revised specifications also incorporate a reduction in the 'total heavy metals' component from a maximum of 10 ppm to 2 ppm. These amendments have been included in revised drafting in the Schedule to Standard 1.3.4 Identity and Purity, at **Attachment 1**.

5.1.4.1 Conclusion

As there are no products containing tall oil phytosterols currently on the market in Australia and New Zealand, the revised specifications will not impact on any Australian or New Zealand manufacturers. Any tall oil products that enter the food supply in the future must comply with the new specifications.

5.1.5 Elevated serum cholesterol levels should be managed medically

Many studies have shown that the optimal cholesterol lowering effect from plant sterols is achieved when consumption is between 2-3 g per day. In approving a broader range of phytosterol-enriched foods, FSANZ has confined the permission to foods with a healthy compositional profile. Foods such as low-fat milk, low-fat yoghurt and high-fibre breakfast cereal are compatible with healthy eating patterns.

People with hypercholesterolaemia would be expected to be under medical supervision, however the preferred means of lowering a mildly elevated cholesterol level is through changes to the diet. Phytosterol-enriched foods are part of a package of dietary and lifestyle advice to help people self-manage their cholesterol levels. In addition, the food vehicle choices in these Applications are broadly compatible with current public health guidelines.

Some consumers with a slightly elevated cholesterol level may already be eating a 'healthy' diet. For these people, consumption of phytosterol-enriched foods involves a conservative dietary change that can assist them with achieving individual health-related goals or dietary preferences. The results of the consumer survey (see Section 5.3) indicate that consumers who are current users of phytosterol-enriched spreads are motivated by concern about their health, particularly cholesterol levels.

In terms of prescribed medications, patient compliance has always been an issue for clinicians. The availability of a broader range of phytosterol-enriched foods could not reasonably be considered to impact directly on this issue, given that people disregard medical advice for a variety of reasons. In addition, there would be a negligible cost benefit in choosing phytosterol-enriched foods over prescribed cholesterol-lowering medication.

5.1.5.1 Conclusion

Consumption of phytosterol-enriched low-fat milk, yoghurt and breakfast cereal has been shown to give small reductions in serum cholesterol levels irrespective of the background diet. Approval of these Applications therefore provides consumers with an additional range of appropriate dietary choices, over and above low saturated fat products, for addressing concerns about cholesterol levels.

5.1.6 Consumption of phytosterol-enriched products by non-target groups

FSANZ acknowledges that regular consumption of phytosterol-enriched foods is not generally appropriate for children, and pregnant or lactating women since there may be no necessity to lower blood cholesterol levels in these groups. Notwithstanding the absence of a health benefit, the modest reduction in cholesterol that may result from an increased intake of phytosterols by non-target groups is not likely to be physiologically or nutritionally significant.

Based on the findings of the consumer research undertaken by FSANZ (Section 5.3), and similar findings in the United Kingdom from a post-market consumer survey (ACNFP, 2006), FSANZ considers that the approval of a limited range of phytosterol-enriched foods would not be expected to significantly increase the likelihood of consumption by non-target groups for a number of reasons:

(i) Phytosterol-enriched foods are specialised, niche products, marketed to a limited consumer sector (adults with cholesterol concerns);
(ii) The evidence indicates that current users of phytosterol-enriched margarines choose the product for a health (cholesterol-lowering) benefit;
(iii) Post-market surveys in Europe, where additional phytosterol-enriched products are available, found they are used in moderation by the target group of consumers;
(iv) Lifestyle and dietary advice, including the use of phytosterol-enriched foods, is already available from dietitians, General Practitioners, and public health organisations such as the NHF;
(v) The food industry also provide advice on the suitability of products to consumer groups (via product information lines, promotional material and advertising);
(vi) Mandatory labelling on packaging advises against consumption by children and pregnant or lactating women; and

(vii) FSANZ is committed to preparing additional educational material that will be available for consumers on the website and distributed to health professionals.

5.1.6.1 Conclusion

Occasional consumption of phytosterol-enriched foods by non-target groups would not be a cause for concern. Consumer education strategies combined with appropriate risk management measures and consumer-specific marketing should ensure that the public has sufficient knowledge about phytosterol-enriched products to be able to make well-informed decisions on foods that are appropriate to their health needs.

5.1.7 Reduced beta carotene levels in individuals with a low fruit and vegetable intake.

A lower beta-carotene level would be of greater nutritional concern if consumption of phytosterols affected retinol (vitamin A) levels. However, a reduction in retinol has never been reported in studies on phytosterols, even with consumption up to 10 g per day.

People who have a high fruit and vegetable intake could have low serum beta-carotene if the fruit and vegetables they choose are apples, bananas, pears, nashi pears, cucumber, potatoes, inside leaves of iceberg lettuce, eggplant, corn, blueberries, dark grapes, strawberries or parsnip. Some of these foods have quite high levels of anthocyanins and other plant nutrients that are also antioxidants. Conversely, a low fruit and vegetable diet consisting of one carrot per day could result in a moderately high beta-carotene level.

5.1.7.1 Conclusion

Fruits and vegetables in the diet contribute a complexity of vitamins and other nutrients. Public health educators continue to promote the daily consumption of minimum quantities of fruits and vegetables as part of a healthy diet. Consumption of plant sterols is generally expected to lead to a reduction in LDL-cholesterol levels in the range of 5%-15%, a reduction which the National Health and Medical Research Council (NHMRC) equates to a significant reduction in cardiovascular disease risk. In this context, a moderate reduction in serum beta-carotene is not a health concern.

5.2 Labelling and consumer information

5.2.1 Advisory versus warning statements

FSANZ's labelling risk management framework for decision-making was developed during the review of the former Australian *Food Standards Code* and is outlined below:

High risk
Where the risk to public safety is potentially life threatening and it can reasonably be assumed that the general population or the specific target group is unaware of the potential safety risk, a prescribed labelling statement is needed to alert consumers of the risk. Warning Statements are required where the risk to public health and safety is high and awareness of the potential risk is low.

Medium risk
Advisory statements are provided where the general population or a sub group of the population are largely unaware of a potential, but non life threatening risk to public health and safety and need advice about that risk.

Low risk
Where a risk to public health and safety is determined to be low because the likelihood of an adverse event occurring is rare and the consequences minor, it should be sufficient to rely on general labelling provisions and existing food law to manage the risk. An education initiative could be used to raise awareness of and promote the use of general labelling information (FSANZ, 2002).

FSANZ has assessed the potential risk to public health and safety as low with respect to the consumption of phytosterol enriched products by non-target groups, and therefore a warning statement would be inappropriate.

Labelling is only one means of providing advice to consumers, recognising that its effectiveness as a source of information varies with the consumer and the nature of the food product. Despite these variables, advisory statements on phytosterol-enriched products provide the appropriate *level* of risk management advice in relation to the low risk to public health and safety posed by these foods.

5.2.1.1 Conclusion

A warning statement on phytosterol-enriched foods would be inconsistent with the existing framework and is not justified on public health and safety grounds.

5.2.2 Revision of advisory statements

Currently, the labelling of phytosterol-enriched table spreads must include three advisory statements. A fourth statement was proposed with the approval of these Applications. However, the Second Review triggered a re-evaluation of the purpose and effectiveness of the advisory statements as risk management tools. As a result of the review, FSANZ now proposes three new mandatory advisory statements for all phytosterol-enriched foods including the table spreads.

(i) Fruit and vegetable consumption

One of the current advisory statements required on phytosterol-enriched spreads requires words to the effect that *the product should be consumed in moderation as part of a diet low in saturated fats and high in fruit and vegetables*.

The Expert Advisory Group considered the effectiveness of this statement in correcting for the small reduction in beta-carotene observed with consumption of phytosterol-enriched foods. Given that there is no specific reference to *carotenoid* rich varieties, the wording of the statement could mislead consumers on the potential benefits of any additional fruits and vegetables when consuming plant sterols. Moreover, as *carotenoid* is not in common use as a term to describe particular nutrients, additional words to this effect would be likely to lead to some degree of consumer confusion.

FSANZ also considered that adding a list of carotenoid-rich fruits and vegetables to the labelling requirements would not meaningfully assist consumers to raise blood levels of beta-carotene because of a number of variables including seasonal variations, cooking and bioavailability. In addition, while a diet low in saturated fat is regarded as a healthy alternative, phytosterols have been studied in both a normal and low-fat background diet and are similarly effective in lowering cholesterol absorption.

Given the complexity of the additional message concerning consumption of carotenoid-rich fruit and vegetables necessary with phytosterol-enriched foods, FSANZ considers that consumer education on this issue could be undertaken more effectively through other types of educational approaches. FSANZ notes that a healthy diet message encouraging the consumption of fruits and vegetables is currently part of wider public health initiatives to lower the incidence of obesity and certain diseases in the population. In addition, organisations such as the NHF produce material for use by health professionals such as General Practitioners, cardiologists, clinical dietitians and nutritionists. FSANZ can also contribute to the education process by producing a fact sheet for the website and for public distribution, and provide links to information available on other websites.

To strengthen the capability of a consumer education initiative, FSANZ and the NHF have recently agreed to collaborate on the preparation of material providing information on (i) plant sterols in general, and (ii) the potential role of phytosterol-enriched foods in the diet for the purpose of lowering LDL-cholesterol levels, for both health professionals and the general public. As well as publications, the NHF supplements its educational role with other activities that directly link the distribution of information to its target audiences.

Providing information on phytosterol-enriched foods in addition to that provided on food labels should ensure that more consumers are able to access sufficient factual information to enable informed choice in the management of their diet.

5.2.2.1 Conclusion

While it is broadly consistent with public health messages, on the basis of more recent scientific evidence, the current statement on fruits and vegetables is superfluous and potentially misleading for consumers of phytosterol-enriched foods. A revised mandatory statement to the effect that ***when consuming plant sterol enriched foods, these should be consumed as part of a varied and healthy diet*** is considered to be more appropriate in the context of general dietary advice.

(ii) Non-target consumer groups

One of the current advisory statements required on phytosterol-enriched spreads requires words to the effect that *the product is not recommended for infants, children and pregnant or lactating women unless under medical supervision.*

The Expert Advisory Group noted that while studies in pregnant women were not available, the effects of phytosterols in children with familial hypercholesterolaemia were well studied. While consumption by children with hypercholesterolaemia was without adverse physiological effects, it was generally agreed that children do not derive a benefit to the same extent as adults from a reduction in their cholesterol levels.

For this reason, it was therefore considered appropriate to compare the use of advisory statements currently required on packaging of foods such as low-fat milk and beverages made from soy or rice for the purpose of informing consumers that these foods are unsuitable for children under the age of two years.

5.2.2.2 Conclusion

On the basis of available safety data, a revised mandatory statement to the effect that ***the product may not be suitable for children under the age of five years, and pregnant or lactating women*** is proposed for all phytosterol-enriched foods.

(iii) Efficacy of plant sterols

The Ministerial Council noted that the nature of the food vehicle appears to be a factor in the overall cholesterol-lowering effect of plant sterols. Milks are particularly effective (up to 15% reduction), while some studies show that yoghurts and breakfast cereal generally lead to reductions of 5%-8%. The Expert Group agreed that many other factors could also affect efficacy and there would be no advantage for consumers by making this information a mandatory labelling requirement for phytosterol-enriched foods.

There are insufficient data to show that different food matrices consistently produce a similar degree of efficacy. For example, the data for yoghurt vary considerably, with the literature reporting differing results (some papers show 5% reduction, while others report a 10% reduction), even when the same amounts of plant sterols are used. Other studies show phytosterols are effective in orange juice while some show no significant cholesterol-lowering effect. Phytosterols are generally more effective in a meal that contains fat. In addition, small variations in efficacy can arise due to the way in which the plant sterols are incorporated into the product (there are 5 patented processes), and even with batch-to-batch variation. This situation is not unique to phytosterol-enriched products and applies to any other nutrient or food component, where the benefits that are transferred to an individual may vary due to a combination of factors.

In general, the data do not support providing consumers with information to this level of detail for the following reasons:

- some variability between studies means that an unqualified statement could be misleading;
- this type of information is not provided for other foods (or drugs);
- there are variations between individuals due to metabolic profiles and lifestyle factors; and
- the NHF dietary advice is simply to eat a variety of (recommended) foods.

Rather than focus consumer attention on the food matrix, the Expert Advisory Group concluded that information on the minimum amount of plant sterols required to achieve a cholesterol-lowering effect would be more useful to consumers for allowing them to make informed choices. Based on a large number of published studies, the optimal cholesterol lowering benefits are achieved when consumption of plant sterols is around 2-3 g per day. Furthermore, there is no significant improvement in cholesterol reduction above approximately 3 g per day, and therefore higher levels of consumption are unnecessary.

In previous assessments, FSANZ used number of serves as a means to communicate to consumers on appropriate consumption levels. However, FSANZ acknowledges that determining the food serving sizes could be an issue for some consumers. There are no international standards for typical food portion sizes that are useful, on an allocation basis, for a strategy for phytosterol enrichment. To some extent, the Applicants are using self-appointed portion sizes which may not correlate closely with consumer behaviour.

Revised drafting is therefore proposed which provides for **a minimum of 0.8 g and a maximum of 1.0 g per quantity (average serving size) of food**. The minimum level ensures that intake of phytosterol-enriched foods (of any type) is more likely to reach the optimal amounts for a cholesterol-lowering effect. On the other hand, the maximum level should assist consumers to avoid higher intakes that provide no additional cholesterol-lowering benefits. This range is also in good compliance with the safety recommendations on the entire intake of phytosterols from multiple sources (see additional dietary exposure estimates at **Attachment 4**).

A mandatory labelling statement to the effect that ***plant sterols do not provide additional benefits when consumed in excess of 3 grams per day*** is also proposed. Expressing amounts in grams of plant sterols rather than serves of food should make individual monitoring of consumption easier on a daily basis.

5.2.2.3 Conclusion

Changes to the drafted permissions for plant sterols in low-fat milk, yoghurt and breakfast cereal should ensure that consumers have sufficient labelling information to allow them to use the products cost-effectively.

5.2.3 Labelling statements on efficacy of plant sterols

A health claim was not part of the assessment of these Applications. Nevertheless, it is pertinent to note that, as part of Proposal P293 – Nutrition, Health and Related Claims, FSANZ is proposing that specific conditions must be met before a general level health claim can be made in relation to biologically active substances (including phytosterols). Currently, these conditions are:

- only 'contains'/'source' type descriptors are permitted;
- manufacturers will be required to substantiate the daily amount of the substance that will achieve the specific health effect;
- a serve of the food must contain at least 10% of the amount that must be consumed per day to achieve the specific health effect; and
- the claim must state the amount of the substance that is required to be consumed per day to achieve the health effect, in the context of a healthy diet including a variety of foods.

This Proposal is at Draft Assessment and subject to change.

5.2.3.1 Conclusion

Current labelling statements on table spreads are not regarded as health claims.

Any future application under a standard for nutrition, health and related claims would be required to meet the defined criteria and conditions for making a claim. Any high level claim will require pre-approval from FSANZ (see section 5.4.1 below).

5.2.4 Presentation and legibility of mandatory advisory statements

The size and legibility requirements of advisory statements on packaging are not explicitly defined in the Code. FSANZ acknowledges that the legibility of labelling statements can vary with products and is therefore open to interpretation. An Editorial Note to Standard 1.2.9 Legibility Requirements which clarifies for manufacturers what is expected in terms of placement and legibility of prescribed information is not legally binding.

FSANZ has previously agreed to review Standard 1.2.9 and a new Proposal is currently at the scoping stage. The purpose of the review will be to evaluate the effectiveness of the Standard for general labelling information requirements. However, the insertion of an Editorial Note is seen as an appropriate interim measure until the review of Standard 1.2.9 is completed.

FSANZ has noted that industry is conscious of this issue and has made efforts to improve the presentation and legibility of labelling information on existing phytosterol-enriched products. For example, mandatory advisory statements are no longer being presented on a removable outer cardboard sleeve, thereby improving consumer access to the information.

5.2.4.1 Conclusion

An Editorial Note is regarded as a practical, short term measure to reinforce the principles underpinning the Standard, pending a more comprehensive review.

5.3 Consumer knowledge and behaviour

FSANZ has previously claimed that consumers have some knowledge of phytosterol-enriched foods through the market availability of two brands of table spreads since 2001. From advertising and other marketing strategies as well as information on various websites, health professionals are also aware of the products, although it is unclear to what extent their awareness is translated to consumers.

A number of key consumer issues were raised in the Second Review request. These include:

- ***Target audience:*** including the possibility that those outside the target group of consumers will be primary consumers, such as children or pregnant or lactating women;

- ***Consumption levels:*** including frequency and quantity of enriched product and the potential for consumption in excess of recommended amounts;

- ***Understanding and comprehension:*** including the interpretation of serving sizes and label information; and

- ***Dietary and lifestyle behaviours:*** including possible changes to diet and exercise, such as an increased consumption of cholesterol/saturated fats or a reduction in the level of exercise.

There is a lack of data concerning the responses of consumers to plant sterol-enriched products in Australia and New Zealand. However there are a number of international studies that show consistent results with respect to key issues of concern. FSANZ is confident that conclusions can be drawn about how Australian and New Zealand consumers are likely to react to these products. In addition to the existing literature FSANZ commissioned a survey of Australian and New Zealand consumers of plant sterol-enriched spreads.

This section provides a summary of the findings relevant to the four key issues identified above. A detailed discussion of the findings is at **Attachment 3**.

5.3.1 Target audience

5.3.1.1 Plant sterol enriched products appear to occupy a small niche market.

Plant sterol enriched products are likely to be a niche product in Australia and New Zealand appealing to a small, but highly differentiable market segment. Existing Australian market data confirm that plant sterol enriched spreads are a small proportion of the overall spread market accounting for 3.7% by volume of the total Australian spread market (data supplied by industry).

5.3.1.2 Most users of plant sterol enriched products are older adults.

There are no Australian data that provide a measure of the number of individuals who use plant sterol enriched spreads. International studies carried out in the European Union and United States confirm that plant sterol enriched spreads are used by a minority of adults, less than 5% (Anttolainen *et al.* 2001; Simojoki *et al.* 2005; 2004 Gallop Study of Cholesterol Lowering Options provided by Goodman Fielder). Those who used the products were older, with 75 to 95% of purchasers being over 45 years old (SCF 2002).

5.3.1.3 Most purchasers of plant sterol enriched products do not have children in the household.

Plant sterol enriched products are generally recommended for use by adults and the potential that children may incidentally consume these products was raised in the second review. European research found that 79%-91% of households that had purchased plant sterol enriched spreads had no children (SCF 2002).

5.3.1.4 Purchasers are motivated by concern about their health, particularly cholesterol.

The FSANZ survey found health related concerns were the primary motivation for the largest group of enriched spread users followed by convenience. Of these the majority highlighted cholesterol as the major issue. Seven percent of enriched spread users reported their primary motivation for using enriched spread as ‘someone else in my household prefers it so I use it too’.

From a large nation-wide study in Finland on the use of plant stanol enriched spread the researchers concluded:

Users of plant stanol ester margarines are a self-selected group of persons who have taken an active interest in their health. They use plant stanol ester margarines as part of a generally healthy life-style and diet. Nevertheless, they commonly have a history of cardiovascular disease or are at risk to have it. Thus plant stanol ester margarine seems to be used by persons for whom it was designed and in a way it was meant: as part of efforts for cardiovascular disease risk reduction (Simojoki et al. 2005).

5.3.2 Consumption levels

5.3.2.1 There is no evidence that consumers of plant sterol enriched products consume too much – the reverse appears to be true.

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

These results indicate current intakes of plant sterols from enriched spreads are below the optimal intake recommended for cholesterol reduction. As this could be due to the nature of the food vehicle itself, the availability of additional plant sterol-enriched products will increase the range of choice for consumers. Several post-market monitoring reports from European countries indicate however that increased product availability is not linked to excess consumption of plant sterols. Recent data collected in the UK across the major phytosterol-enriched products provide additional evidence that products are more likely to be under-consumed (ACNFP 2006; Bradford 2006, unpublished data).

5.3.3 Understanding and comprehension

5.3.1.1 Consumers have mixed understandings of the role of these products and labelling information.

Concerns about consumers' understanding of target audience, purpose and recommended serving size have been raised. The FSANZ survey suggested that consumers were mixed in their levels of understanding and comprehension with respect to these issues. They indicate some areas of limited understanding, particularly with regards to the suitability of plant sterol enriched products for children and consumers considered they had insufficient serve size information.

5.3.4 Dietary and lifestyle behaviours

A key concern raised in the second review request is the extent to which the consumption of plant sterol enriched products will lead to changes in dietary or lifestyle behaviours that are contrary to the National Dietary Guidelines or recommended exercise regimens. The contention is that consumers of plant sterol enriched products may gain a benefit from consumption of these products and consequently be less concerned about their health and accordingly be less inclined to adopt appropriate diet and lifestyle behaviours. For example consumers may eat more saturated fats as they believe their consumption of plant sterol enriched products will counteract their indulgence.

As there was no evidence to support or refute this contention the FSANZ survey specifically sought to collect data in order to better understand the motivations and likely behaviours of people in response to plant sterol enriched foods.

5.3.4.1 Consumers do not see plant sterol enriched spreads as a 'silver bullet' that will absolve them of further responsibility for health conscious behaviour.

The FSANZ survey found no significant differences between users and non-users of plant sterol enriched spreads in the level of exercise they carried out. In terms of diet there was a demographic distinction with younger users of enriched spreads having a 'better diet' than those who didn't use enriched spreads. There was no significant differences in diet between enriched-spread users and non-users in consumers of age 35 years and older. There was a minority of enriched spread users who reported that their diet and exercise had improved since using plant sterol enriched spreads. Overall, consumption of plant sterol enriched spread was not linked to either better or worse diet and exercise measures, although a minority of consumers considered they had improved diet and exercise levels.

The diet and the exercise findings highlight that those who consume plant sterol enriched spreads do not have significantly worse diets and exercise levels than those who do not use plant sterol spreads. This evidence does not support the contention that use of plant sterol enriched spreads are associated with less healthy diet and lifestyle choices. While the evidence does not suggest that those who consume plant sterol enriched spreads make healthier diet and lifestyle choices than those who do not consume these spreads, self-assessments of enriched spread users suggest there have been some improvements in diet and exercise for some individuals.

5.4 Policy considerations

FSANZ has previously stated that there are no provisions in the FSANZ Act for deferral of the assessment of an application on the grounds that it intersects with policy issues under consideration by FRSC, or pending finalisation of a new standard. Assessment of the current Applications has therefore progressed under the existing policy for Novel Foods, which calls for a pre-market safety assessment.

5.4.1 Health claims

Approval of these Applications to add phytosterols to breakfast cereal, low-fat milk and yoghurt **does not** constitute approval for a health claim in relation to these products. Assessment of a health claim would require examining data and information on phytosterols from a different perspective. Any future requests by manufacturers for assessment of a health claim would need to be submitted under the health claims standard, which is yet to be completed.

Proposal P293 Nutrition, Health and Related Claims is currently at the Preliminary Final Assessment stage but is not expected to be finalised until 2007. Claims which reference a biomarker or serious disease will be regulated as a high level claim and will be required to undergo pre-approval by FSANZ. However, general level claims which do not reference a serious disease or condition will be generally permitted provided they can be substantiated and provided they comply with any criteria or conditions specified in the Standard.

As serum cholesterol is proposed as a biomarker for serious disease, under the proposed regime, any claim that references serum cholesterol would be regulated as a high level claim. However, a claim that references dietary cholesterol, which is not a biomarker for a serious disease, would be regulated as a general level claim.

Until the new Standard is finalised, manufacturers must comply with the current requirements in the Transitional Standard for Health Claims, Standard 1.1A.2 in the Code. This Standard sets out the following restrictions on the use of health claims in food labels or in advertising:

- The label on or attached to a package containing, or an advertisement for, food shall not contain a claim or statement that the food is a slimming food nor has intrinsic weight reducing properties.

- Any label on or attached to a package containing, or any advertisement for, food shall not include a claim for therapeutic or prophylactic action or a claim described by words of similar import.

- Any label on or attached to a package containing or an advertisement for a food shall not include the word 'health' or any word or words of similar import as a part of or in conjunction with the name of the food.

- Any label on or attached to a package containing or any advertisement for food shall not contain any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person.

- The label on or attached to a package containing or any advertisement for food shall not contain the name of or a reference to any disease or physiological condition.

A failure to comply with these requirements when making any voluntary statement about a food constitutes a breach of the Code.

5.4.2 Other policy issues

The Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals is currently being developed by the FRSC. The scope of the policy is yet to be agreed but the initial scope included all substances that can potentially be added to food for a technological purpose, with the exception of vitamins and minerals. Therefore, foods or food ingredients such as phytosterols that have already been considered by FSANZ as novel foods may be included. There is a clear interface of this process with a review of the Novel Foods Standard.

Nevertheless, there is currently a clear mechanism for dealing with novel food applications under Standard 1.5.1 – Novel Foods. FSANZ considers that progression of Applications A433, A434 and A508 is consistent with the existing policy for novel foods and the transitional health claims standard and should not depend on the outcome of any review process that is not yet completed.

5.5 Nutrient criteria

Given that plant sterols lower LDL-cholesterol levels, it is appropriate that they be permitted in foods that are consistent with a healthy diet. Similarly, the products should not promote consumption patterns that are inconsistent with dietary advice to reduce cholesterol.
The nutrient criteria proposed for breakfast cereal was based on an existing range of products targeted specifically to adult consumers.

The primary purpose of imposing specific nutrient criteria on the phytosterol-enriched breakfast cereals[5] was to focus on those properties of the food that are considered to have a greater impact on the target consumer group, and at the same time be less attractive to children. The fibre and maximum sugar requirements proposed were modelled on a muesli-style product containing added fruit that was considered to be more compatible with adult preferences. On the basis of evidence gathered at that time, these requirements could not be met by breakfast cereal products that are typically marketed to children.

A small survey of the available range of breakfast cereals conducted by FSANZ showed a clear demarcation between 'high sugar' breakfast cereals and those of a more moderate type when assessed on the basis of the content of *added sugar*. Those breakfast cereals that have a total sugars content above 30g/100g use added sugar only (i.e. primarily sucrose) to achieve this level. For cereals with a range between 10-30g/100g of total sugars, the main contributor to total sugars is through the addition of fruit (as found in muesli style cereals), not refined sugar. As such, breakfast cereals typically contain either 0-10g/100g or 30+ g/100g of added sugars.

Sugar content across the range of breakfast cereals

Breakfast cereal category	Total sugars content (g/100 g)	Estimated added sugar content (% total sugar content)
Low/moderate in added sugar	1.5-11	0-11
Muesli style or those with added fruit	15-30	0-10
High in added sugar	31-53	31-53

Thus, the selected criteria were not specifically intended to classify a breakfast cereal into a 'healthy' category in terms of general nutrition advice. Moreover, regulating the use of phytosterols according to dietary ideals for sugar, fat and salt intake would introduce an inappropriate level of control that could not be justified on the basis of the safety evidence and the proposed levels of use.

8. Review Options

Three options were considered in this Review:

1. re-affirm the draft variations to Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, Standard 1.2.9 – Legibility Requirements, Standard 1.3.1 – Food Additives, Standard 1.3.4 – Identity and Purity, Standard 1.5.1 – Novel Foods, Standard 2.5.1 – Milk, and Standard 2.5.3 – Fermented Milk Products of the Code approved at Final Assessment and First Review; or

[5] Application A433 only

2. re-affirm approval of the draft variations to the Code as listed above, subject to specified amendments as a result of the Second Review; or

3. withdraw approval of the previous draft variations to the Code as listed above.

Summary of specified amendments under Option 2:

1. A minimum of 0.8 g and a maximum of 1.0 g phytosterols per serve (one serve taken to be 250 ml low-fat milk, one punnet of yoghurt up to 200 g, 45 g cereal);

2. Three mandatory advisory statements:

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

3. Deleted the following advisory statement: consumers on cholesterol-lowering medication should seek medical advice on the use of this product in conjunction with their medication.

4. Existing specifications for the tall oil phytosterols replaced with new specifications relating to the purity of the sterol components and reduced levels of heavy metals.

5. Additional wording in the Editorial note inserted at First Review to Standard 1.2.9 – Legibility Requirements, to read (in part):

   The requirements of this standard will not be met where prescribed information is placed other than on the outside of a package where it is readily accessible by a consumer prior to purchase, and during the life of the product, and not obscured by an outer covering.

9. Conclusion and recommendation

The Second Review concludes that the preferred review option is Option 2. This re-affirms the approval for the addition of phytosterol esters in breakfast cereal, low-fat milk and low-fat yoghurt and tall oil phytosterols in low-fat milk according to the draft variation to Standards 1.2.3, 1.2.9, 1.3.1, 1.3.4, 1.5.1, 2.5.1 and 2.5.3 of the Code, as detailed in **Attachment 1**.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*.
2. Approvals of phytosterol-enriched food products in Europe.
3. Social research on use of phytosterol-enriched spreads in New Zealand and Australia.
4. Report on additional dietary exposure estimates.
5. References

ATTACHMENT 1

Draft Variations to the *Australia New Zealand Food Standards Code*

APPLICATION A433

To commence: On gazettal

[1] ***Standard 1.2.3*** *of the Australia New Zealand Food Standards Code is varied by omitting from the* Table to clause 2 –

Food regulated in Standard 2.4.2 containing phytosterol esters	Statements to the effect that – 1. the product should be consumed in moderation as part of a diet low in saturated fats and high in fruit and vegetables; 2. the product is not recommended for infants, children and pregnant or lactating women unless under medical supervision; and 3. consumers on cholesterol-lowering medication should seek medical advice on the use of this product in conjunction with their medication.

substituting –

Foods containing added phytosterol esters	Statements to the effect that - 1. when consuming this product, it should be consumed as part of a healthy diet; 2. this product may not be suitable for children under the age of five years and pregnant or lactating women; and 3. plant sterols do not provide additional benefits when consumed in excess of three grams per day.

[2] ***Standard 1.2.9*** *of the Australia New Zealand Food Standards Code is varied by inserting after subclause 2(1) –*

Editorial note:
The requirements of this Standard will not be met where prescribed information is placed other than on the outside of a package where it is readily accessible by a consumer prior to purchase, and during the life of the product, and not obscured by an outer covering. The requirements of this Standard will also not be met where prescribed information is printed in a small font so the statement cannot be read easily.

Within 24 months of the gazettal of this editorial note, Standard 1.2.9 Legibility Requirements will be reviewed.

[3] ***Standard 1.5.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[3.1] *omitting from the* Table to clause 2 –

Phytosterol esters	The requirements in clause 2 of Standard 1.2.3. The name 'phytosterol esters' or 'plant sterol esters' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4. May only be added to food – (1) according to Standards 1.3.4 and 2.4.2; and (2) where the total saturated and trans fatty acids present in the food is no more than 28% of the total fatty acid content of the food.

substituting –

Phytosterol esters	The requirements in clause 2 of Standard 1.2.3. The name 'phytosterol esters' or 'plant sterol esters' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4. May only be added to edible oil spreads – (1) according to Standard 2.4.2; and (2) 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. May only be added to breakfast cereals, not including breakfast cereal bars, if – (1) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve; (2) the breakfast cereal contains no more than 30g/100g of total sugars; and (3) the total phytosterol ester added is no less than 26g/kg and no more than 32g/kg. Foods to which phytosterol esters have been added may not be used as ingredients in other foods.

[3.2] *omittin*g from the Editorial note *after the* Table to clause 2 –

The Table to Clause 2 contains conditions relating to novel foods. Nothing contained in this Code permits the mixing of phytosterol esters and tall oil phytosterols. .

APPLICATION A434

To commence: On gazettal

[1] ***Standard 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by inserting in* Schedule 1*, after* item 1.1.2 –

1.1.3 Liquid milk to which phytosterol esters have been added

401	Sodium alginate	2	g/kg
407	Carrageenan	2	g/kg
412	Guar gum	2	g/kg
471	Mono- and diglycerides of fatty acids	2	g/kg

[2] ***Standard 1.5.1*** *of the Australia New Zealand Food Standards Code is varied by inserting in* Column 2 *of the* Table to clause 2 *corresponding to the entry for Phytosterol esters –*

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.

[3] ***Standard 2.5.1*** *of the Australia New Zealand Food Standards Code is varied by inserting after the* Editorial note *to clause 4 –*

5 Phytosterol Esters

Phytosterol esters may only be added to milk –

(a) such that the milk contains no more than 1.5 g total fat per 100 g; and
(b) that is supplied in a package, the labelled volume of which is no more than 1 litre; and
(c) where the total phytosterol ester added is no less than 5.2 g/litre of milk and no more than 6.4g/litre of milk.

[4] ***Standard 2.5.3*** *of the Australia New Zealand Food Standards Code is varied by inserting after the* Editorial note *to clause 3 –*

4 Phytosterol Esters

Phytosterol esters may only be added to yoghurt –

(a) such that the yoghurt contains no more than 1.5 g total fat per 100 g; and
(b) that is supplied in a package, the capacity of which is no more than 200 g; and
(c) where the total phytosterol ester added is no less than 1.3 g and no more than 1.6g.

APPLICATION A508

To commence: On gazettal

[1] ***Standard 1.2.3*** *of the Australia New Zealand Food Standards Code is varied by omitting from the* Table to clause 2 –

Food regulated in Standard 2.4.2 containing tall oil phytosterols	Statements to the effect that – 1. the product should be consumed in moderation as part of a diet low in saturated fats and high in fruit and vegetables; 2. the product is not recommended for infants, children and pregnant or lactating women unless under medical supervision; and 3. consumers on cholesterol-lowering medication should seek medical advice on the use of this product in conjunction with their medication.

substituting –

Foods containing added tall oil phytosterols	Statements to the effect that - 1. when consuming this product, it should be consumed as part of a healthy diet; 2. this product may not be suitable for children under 5 years and pregnant or lactating women; and 3. plant sterols do not provide additional benefits when consumed in excess of three grams per day.

[2] ***Standard 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by inserting in* Schedule 1 *after* item 1.1.2 –

1.1.4 Liquid milk to which tall oil phytosterols have been added

460	Microcrystalline cellulose	5	g/kg

[3] ***Standard 1.5.1*** *of the Australia New Zealand Food Standards Code is varied by omitting from the* Table to clause 2 –

Tall oil phytosterols	The requirements in clause 2 of Standard 1.2.3. The name 'tall oil phytosterols' or 'plant sterols' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4. May only be added to food - (1) according to Standards 1.3.4 and 2.4.2; and (2) where the total saturated and trans fatty acids present in the food is no more than 28% of the total fatty acid content of the food.

substituting –

Tall oil phytosterols	The requirements in clause 2 of Standard 1.2.3. The name 'tall oil phytosterols' or 'plant sterols' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4. May only be added to edible oil spreads – (1) according to Standard 2.4.2; and (2) where the total saturated and trans fatty acids present in the food is no more than 28% of the total fatty acid content of the food. May only be added to milk in accordance with Standard 2.5.1. Foods to which tall oil phytosterols have been added may not be used as ingredients in other foods.

[4] ***Standard 2.5.1*** *of the Australia New Zealand Food Standards Code is varied by inserting after the* Editorial note *to clause 4 –*

6 Tall oil phytosterols

Tall oil phytosterols may only be added to milk –

(a) such that the milk contains no more than 1.5 g total fat per 100 g; and
(b) that is supplied in a package, the labelled volume of which is no more than 1 litre; and
(c) where the total tall oil phytosterol added is no less than 3.2 g/litre of milk and no more than 4.0 g/litre of milk.

[5] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by omitting from the* Schedule –

Specification for tall oil phytosterols derived from tall oils

Tall oil phytosterols (non-esterified) are derived from tall oil soap, a by-product of the pulping process and then purified.

Total Phytosterol/phytostanol content (%)	min. 95
Loss on drying (water (%))	max. 5.0
Solvents (%)	max. 0.5
Residue on ignition (%)	max. 0.1
Total Heavy metals (ppm)	max. 10
Cadmium (ppm)	max. 1.0
Mercury (ppm)	max. 1.0
Arsenic (ppm)	max. 2.0
Lead (ppm)	max. 0.25
Total aerobic count (CFU/g)	max. 10,000

Combined moulds and yeasts (CFU/g)	max. 100
Coliforms	Negative to test
E. coli	Negative to test
Salmonella	Negative to test

Major Sterol profile (%) as below –

Campesterol	min. 4.0	max. 25.0
Campestanol	min. 0.0	max. 14.0
β-Sitosterol	min. 36.0	max. 79.0
β-Sitostanol	min. 6.0	max. 34

substituting –

Specification for tall oil phytosterols derived from tall oils

Tall oil phytosterols (non-esterified) are derived from tall oil soap, a by-product of the pulping process and then purified.

Total Phytosterol/phytostanol content (%)	min. 97
Loss on drying (water (%))	max. 4.0
Solvents (%)	max. 0.5
Residue on ignition (%)	max. 0.1
Total Heavy metals (ppm)	max. 2
Cadmium (ppm)	max. 0.1
Mercury (ppm)	max. 0.1
Arsenic (ppm)	max. 0.1
Lead (ppm)	max. 0.1
Total aerobic count (CFU/g)	max. 10,000
Combined moulds and yeasts (CFU/g)	max. 100
Coliforms	Negative to test
E. coli	Negative to test
Salmonella	Negative to test

Major Sterol profile (%) as below –

Campesterol	min. 4.0	max. 25.0
Campestanol	min. 0.0	max. 14.0
β-Sitosterol	min. 36.0	max. 79.0
β-Sitostanol	min. 6.0	max. 34

Minor sterols (%)	max. 3.0

ATTACHMENT 2

European Union (EU) Regulation and the marketing of phytosterol/phytostanol containing food products in the EU[6]

In the European Union (comprised of 25 countries[7]) the use of phytosterols in foods is regulated under Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 May 1997. Regulation EC No. 258/97 lays out detailed rules for the authorisation of novel foods and novel food ingredients[8].

Before a novel food or food ingredient can be placed on the market, it must go through an applicant specific authorisation procedure. This involves a safety assessment. Decisions about authorisation prior to marketing are made by the European Commission (EC) and experts in the 25 Member States. Additional scientific input is provided, if requested, by the European Food Safety Authority[9].

To date the EC has granted eight applicant specific approvals (see Table 1):

Table 1: EC Approvals

Commission Decision	Applicant	Approved Food Formats
2000/500/EC	Unilever	yellow fat spreads
2004/333/EC	Archer Daniels Midland Company (ADM)	yellow fat spreads, salad dressing, milk type products, fermented milk type products, soya drinks, cheese type products
2004/334/EC	Pharmaconsult Oy Ltd.	yellow fat spreads, milk type products, yoghurt type products, spicy sauces
2004/335/EC	Unilever	milk type products, yoghurt type products
2004/336/EC:	Teriaka Ltd.	yellow fat spreads, milk based fruit drinks, yoghurt type products and cheese type products
2004/845/EC	Novartis (now Forbes Medi-Tech Inc.)	milk based beverages
2006/58/EC	Pharmaconsult Oy Ltd.	rye bread
2006/59/EC	Karl Fazer Ltd.	rye bread

NOTE: Approvals have been granted for phytosterols and phytostanols that are extracted from plants (vegetable and tall oil) and may be presented as free sterols and stanols or esterified with food grade fatty acids.

[6] Author: Tiina Mutru, Regulatory Affairs Manager, Unilever, United Kingdom. Date: June 2006

[7] Austria, Belgium, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, the Netherlands, UK.

[8] Note that plant stanols are not covered by this Regulation as yellow fat spreads containing stanol esters were launched in Finland prior to 15 May 1997. The European Commission (EC) decided that neither the spread nor the ingredient was covered by Regulation EC No. 258/97.

[9] European Union scientific body charged with providing independent and objective advice on food safety issues associated with the food chain.

The approved food formats, with added phytosterols, can be marketed in any of the 25 European Union countries.

Novel foods or novel food ingredients may follow a simplified procedure, only requiring a notification from the company, when they are considered by a national food assessment body as "substantially equivalent" to existing foods or food ingredients (as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein). Table 2 provides a summary of all the notifications that applicant companies (includes ingredient suppliers and food manufacturers) have submitted to the EC for the marketing of phytosterol ingredients that are considered to meet the criteria set out above.

Table 2: Notifications under Article 5 of the Novel Foods Regulation (EC) No. 258/97 specific to phytosterol ingredients[10]

Notifier	Food Format	Date of Notification
Corporacion Alimentaria Peffasanta SA (Spain)	milk type and fermented milk type products	7 June 2004
Teriaka Ltd. (Finland)	milk type products, soya drinks	1 July 2004
Novandie (France)	yoghurt type products	22 July 2004
Cognis (Germany)	milk type products, yoghurt type products, yellow fats spreads	23 July 2004
Danone (France)	yoghurt	29 July 2004
Dairygold (Ireland)	yellow fat spreads	30 August 2004
Lactogal Produtos Alimentares S.A. (Portugal)	milk and yoghurt type products	30 September 2004
Teriaka Lts. (Finland)	fermented milk type products	4 October 2004
Cargill (USA)	yellow fat spreads	24 October
Danone Vitapole (France)	fermented milk type products	23 November 2004
Cognis (Germany)	yellow fat spreads, salad dressings (including mayonnaise), milk type products, spicy sauces, milk based fruit drinks	20 April 2005
Forbes Medi-Tech Inc. (Canada)	yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products spicy sauces, milk based fruit drinks (for plant sterol esters)	22 April 2005
Forbes Medi-Tech Inc (Canada)	yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products spicy sauces, milk based fruit drinks (for Reducol™ sterols)	22 April 2005
Juustoporti Oy (Finland)	yoghurt type products	10 May 2005
Estavayer Lait (Switzerland)	milk type and yoghurt type products	11 May 2005
Forbes Medi-Tech Inc. (Canada)	yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products spicy sauces, milk based fruit drinks (for Phyto-S-Sterols™)	20 May 2005
Novandie (France)	yoghurt type products and other diary products	27 May 2005

[10] Compiled using the following sources: The European Commission (DG Sanco), the UK Food Standards Agency Advisory Committee on Novel Foods and Processes (ACNFP), and the Finnish Food Safety Authority (Evira). Date of last information 8 May, 2006.

Notifier	Food Format	Date of Notification
MIFA AG (Switzerland)	yellow fat spreads	30 May 2005
Distribuigao Alimentar SA (Portugal)	milk based beverages	17 June 2005
Robert Wiseman & Sons Ltd.	milk based beverages	27 June 2005
Kerry Foods (Ireland)	yellow fat spreads	5 July 2005
Homann Feinkost GmbH & Co (Germany)	salad dressings and mayonnaises	5 July 2005
Walter Rau Lebensmittel-werke GmbH & Co	yellow fat spreads	13 July 2005
Fayrefield Foods Ltd.	yellow fat spreads	13 July 2005
Lacteas Garcia Baquero, SA (Spain)	cheese type products	22 July 2005
Granarolo S.p.a. (Italy)	fermented mil (yoghurt) type products	5 August 2005
SkUnemejerier (Sweden)	yoghurt type products	26 August 2005
Nom AG (Austria)	milk type products	2 September 2005
Degussa Food Ingredients GmbH (Germany)	yellow fat spreads, salad dressings; fermented milk type products, soya drinks; cheese type products; yoghurt type products, spicy sauces, milk based fruit drinks,	27 September 2005
Triple Crown AB (Sweden)	yoghurt type products and milk type products	11 November 2005
Westland Kaasspecialiteiten (The Netherlands)	cheese type products	12 January 2006
Prima Pharm (The Netherlands)	yellow fat spreads	16 January 2006
Poligono Industrial Torrehierro (Spain)	yellow fat spreads, yoghurt type products, milk type products	30 January 2006
Glanbia (Ireland)	yoghurt type products	7 February 2006
Dragsbark (Denmark)	yellow fat spreads	23 March 2006
Tucano Vertriebs GmbH & Co. (Germany)	soya drinks	13 March 2006

The following plant sterol/stanol containing food products are currently being marketed in the United Kingdom:

Food Company/Retailer	Product format
Unilever (Flora pro.activ)	· spreads (different variants i.e. low fat, light, olive) · yoghurts · milk · yoghurt drinks (1-a-day)
McNeil Nutritional Ltd. (Benecol)	· spreads (different variants light, olive) · cream cheese · yoghurt (1-a-day & range concept) · yoghurt drinks (1-a-day) · orange juice
Fayrefield Foods	· cheese
Danone (Danacol)	· mini-drinks (1-a-day)

Food Company/Retailer	Product format
Tesco (own range)	· spreads · yoghurts · milk · yoghurt drinks (1-a-day)
Asda (own range)	· yoghurt drinks (1-a-day)

NOTE: Products containing phytosterols/phytostanols should be presented in either single portions containing a maximum 3g of phytosterols/phytostanols (i.e. 1-a-day concept) or three portions containing maximum 1 g (10).

References:

1. Regulation (Ec) No 258/97 Of The European Parliament And Of The Council of 27 January 1997 concerning novel foods and novel food ingredients.

2. European Commission (2000). Commission Decision 2000/500/EC of 24 July 2000 on authorising the placing on the market of "yellow fat spreads with added phytosterol esters" as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal of the European Communities, 08.08.2000, L200/59.

3. European Commission (2004). Commission Decision 2004/333/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal of the European Union, 14.04.2004, L105/40.

4. European Commission (2004). Commission Decision 2004/334/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, milk type products, yoghurt type products, and spicy sauces with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal of the European Union, 14.04.2004, L105/43.

5. European Commission (2004). Commission Decision 2004/335/EC of 31 March 2004 on authorising the placing on the market of milk type products and yoghurt type products with added phytosterol esters" as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal of the European Union, 14.04.2004, L105/46.

6. European Commission (2004). Commission Decision 2004/336/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, milk based fruit drinks, yoghurt type products and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal of the European Union, 14.04.2004, L105/49.

7. European Commission (2004). Commission Decision 2004/845/EC of 12 November 2004 on authorising the placing on the market of milk based beverages with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal of the European Union, 11.12.2004, L336/14.

8. European Commission (2006). Commission Decision 2006/58/EC of 24 January 2006 authorising the placing on the market of rye bread with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal of the European Union, 3.2.2006, L31/18.

9. European Commission (2006). Commission Decision 2006/59/EC of 24 January 2006 authorising the placing on the market of rye bread with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council. Official Journal of the European Union, 3.2.2006, L31/21.

10. Commission Regulation (EC) No. 608/2004 (of 31 March 2004) concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters. Official Journal of the European Union, 1.4.2004, L97/44.

ATTACHMENT 3

Consumer aspects of plant sterol enriched foods

FSANZ used a number of international studies to understand how consumers view and use these products, including research we commissioned. The 4 key findings were

- Plant sterol enriched products occupy a niche market of highly differentiated consumers.
- Consumers are an older section of the population and use is motivated by health concerns.
- Under consumption of plant sterol enriched products in the target audience is a greater issue than over consumption.
- Consumers of these products do not view them as 'magic bullets' that will resolve them of further responsibility for healthy behaviour.

A number of key consumer issues were raised in the Second Review request. These include:

- ***Target audience:*** including the possibility that those outside the target group of consumers will be primary consumers, such as children or pregnant or lactating women;
- ***Consumption levels:*** including frequency and quantity of enriched product and the potential for consumption in excess of recommended amounts;
- ***Understanding and comprehension:*** including the interpretation of serving sizes and label information; and
- ***Dietary and lifestyle behaviours:*** including possible changes to diet and exercise, such as an increased consumption of cholesterol/saturated fats or a reduction in the level of exercise.

There is a lack of data concerning the responses of consumers to plant sterol enriched products in Australian and New Zealand. However there are a number of international studies that show consistent results with respect to key issues of concern. FSANZ is confident that some conclusions can be drawn about how Australian and New Zealand consumers are likely to react to these products.

In addition to drawing on relevant consumer research and published scientific literature FSANZ requested the applicants to provide any additional data. Some of these data were provided on a commercial in confidence basis. An important source of data on plant sterol consumption levels and demographics of consumers was a post launch monitoring study of plant sterol enriched spreads in the European Union (SCF 2002).

FSANZ commissioned a survey of adult Australian and New Zealand consumers to provide additional data. Noting that the only allowable plant sterol products currently available for purchase in Australia and New Zealand are spreads, a random sample of users of this group of products were used as a proxy for the potential users of a broadened range of plant sterol enriched products. A random sample of users of non-plant sterol enriched spreads was used as a control group to test for differences between the two groups of spread users. The survey collected data using an on-line panel of adult consumers administered by TNS Social Research. The on-line approach used to collect data is likely to deliver a sample younger than the general population.

Target Audience

Plant sterol enriched products appear to occupy a small niche market.

Plant sterol enriched products are likely to be a niche product in Australia and New Zealand appealing to a small, but highly differentiable market segment. Existing Australian market data confirms that plant sterol enriched spreads are a small proportion of the overall spread market. In the 12 months to late September 2005, enriched spreads accounted for 3.7% by volume of the total Australian spread market (data supplied by Goodman Fielder). This is higher than equivalent market shares in the European Union at 1-1.5% and the United States at approximately 0.5% (data supplied by Goodman Fielder).

Most users of plant sterol enriched products are older adults.

There are no Australian data that provide a measure of the number of individuals who use plant sterol enriched spreads. Such data would require a very large random survey of the population to achieve a satisfactory sample of users given their low prevalence[11]. However international studies carried out in the European Union confirm that plant sterol enriched spreads are used by a minority of adults. Finnish studies found 4.5% to 4.7% of adults older than 35 used enriched spreads (Anttolainen *et al.* 2001; Simojoki *et al.* 2005). The Finnish studies excluded individuals under 35 as they were very uncommon users of enriched spreads (less than 0.07% of 24-35 year olds used plant sterol enriched spreads (Anttolainen *et al.* 2001)). In the United States approximately 2% of the general population consume plant sterol enriched foods or beverages (2004 Gallop Study of Cholesterol Lowering Options provided by Goodman Fielder).

Consumer research has consistently found a range of psycho-social and demographic variables influence health-related attitudes and behaviours to food (e.g. Childs and Poryzees 1998; Worsley and Scott 2000; Cox and Anderson 2004; Ikeda 2005). Accordingly the use of plant sterol enriched products is not uniform across socio-demographic groups. International research has generally found that the proportion of enriched product users increases with increasing age. In Finnish research using 1997-1998 data sets the mean age of enriched spread users was 59 years (Anttolainen *et al.* 2001). More recent research puts the highest incidence of Finnish enriched spread use at 9% for those aged 65-74. At the next decadal cohort older (75-84), and younger (55-64), 6% of each used enriched spreads (Simojoki *et al.* 2005). In Europe between 75 and 95% of purchasers were over 45 years of age (SCF 2002).

[11] At 3.7% market share a sample of at least 8,000 consumers would be required to deliver a sample of at least 300 enriched spread users.

The FSANZ survey found 50% of users were over 35 years. There was no significant difference in the age of users of enriched spreads and those who do not use enriched spreads. The age of users in this survey however may be an underestimate as the on-line methodology would be likely to generate a positive bias for younger respondents. The Finnish studies were carried out using mail-out methods and the data from the EU were collected using in-household techniques which are likely to reduce any age bias due to methodology.

Most purchasers of plant sterol enriched products do not have children in the household.

Plant sterol enriched products are primarily targeted to adults. The potential that children may incidentally consume these products was raised in the second review request. European research found that 79%-91% of households that had purchased plant sterol enriched spreads had no children (SCF 2002).

Purchasers are motivated by concern about their health, particularly cholesterol.

Health concerns are one category of motive that may influence food choice decisions, others include cost, convenience, familiarity and sensory appeal (Steptoe et al. 1995). In the FSANZ survey, plant sterol enriched spread users were asked what their primary motivations are for purchasing an enriched spread. Health related concerns were the primary motivation for the largest group of enriched spread users followed by convenience (Table 1). This is an expected finding with the majority of individuals motivated by health related issues with cholesterol being the major issue. Seven percent of enriched spread users reported their primary motivation for using enriched spread as 'someone else in my household prefers it so I use it too'.

Table 1: Motivations for using an enriched spread

Motivation	Proportion of enriched spread users
Health-related (total)	***68***
To lower cholesterol levels	30
To prevent me getting high cholesterol problems	20
To improve my health	13
Doctor/Health professional advised me to use it	5
Convenience (total)	***12***
Someone else in my household prefers it so I use it too	7
Pack size	4
It's the brand that's available at my local shop	1
Sensory appeal (total)	***9***
Flavour/taste	5
I like the texture/it spreads easily	4
Familiarity and Naturalness (total)	***9***
It contains natural ingredients	5
It's my usual brand	3
It contains the ingredients I prefer	1
Others (total)	***2***

Consumption levels

There is no evidence that consumers of plant sterol enriched products consume too much – the reverse appears to be true.

The FSANZ survey found that adults who used plant sterol enriched spreads used them differently to those who did not use sterol enriched spreads. While nearly all consumers of both plant sterol enriched and non-enriched spreads used them for spreading on bread and toast (98% and 97% respectively), the consumers of enriched spreads were less likely to use the spread in cooking and baking than the consumers of non-enriched spread (53% and 78% respectively). Similar proportions of each group used their spread at least daily (Table 2). Those who used enriched spreads were more likely to use less on their bread and toast than those who did not use enriched spreads. The majority of enriched spread users (73%) used less than 2 teaspoons on average for spreading on bread and toast, while the majority (87%) of other spread users used more than 2 teaspoons (Table 3). Such a finding is consistent with a health based motivation that may be linked to reduction in fat intake more generally.

Table 2: Frequency of spread use on bread and toast

Frequency of use	Enriched spread users (%)	Other spread users (%)
More than once a day	44	53
Around once a day	35	19
Around 2-3 times a week	17	26
Less than 2 times a week	4	2

Table 3: Quantity of spread used on bread and toast

Quantity of spread used	Enriched spread users (%)	Other spread users (%)
Less than 1 teaspoon	32	5
1 to less than 2 teaspoons	41	7
2-6 teaspoons	25	45
More than 6 teaspoons	3	42

Based on reported levels and frequency of plant sterol enriched spread use, it is likely that a proportion of consumers will not receive enough plant sterol through their current consumption of enriched spreads on bread and toast.

Data collected from the European Union covering the breadth of plant sterol enriched products available (including spreads, milks, yoghurts and drinking yoghurts) found the median intake of plant sterols/stanols ranged from 0.11 gram/day in Spain to a high of 0.45 gram/day in the Netherlands. At the 95th percentile the intake ranged from 0.67 gram/day in Spain to a high of 2.9 gram/day in the Netherlands (Bradford 2006, unpublished data). The United Kingdom, arguably the EU country most similar to Australia and New Zealand, had a median intake of 0.31 gram/day and 95th percentile intake of 2.36 gram/day.

The evidence indicates that current intakes of plant sterols only from enriched spreads are below the optimal intake recommended for cholesterol reduction. As this could be due to the nature of the food vehicle, the availability of additional plant sterol-enriched products will increase the range of choice for consumers. Post-market monitoring in other countries, where additional enriched products have been available for some time, suggests however that increased product availability is not linked to excess consumption of plant sterols.

Recent data collected in the UK across the major phytosterol-enriched products provide additional evidence that products are more likely to be under-consumed (ACNFP 2006; Bradford 2006, unpublished report).

Understanding and comprehension

Consumers have mixed understandings of the role of these products and labelling information.

Concerns about consumers' understanding of target audience, purpose and recommended serving size were raised in the second review request from the Ministerial Council. The FSANZ survey suggested that consumers were mixed in their levels of understanding and comprehension with respect to these issues. Forty-eight percent of enriched spread consumers were aware of the terms 'plant sterol' or 'phytosterol'. Fifty-eight percent perceived the main benefit of plant sterols to reduce cholesterol level and 25% were not sure of the main benefit. There were some age differences in the perceived benefits of plant sterols, with fewer younger people (less than 35 years old) identifying cholesterol reduction as the main benefit and more of them responding that they were unsure.

Table 4 indicates the main sources of information about plant sterols for users of enriched spreads. Articles and advertising were the most common sources of information, though doctors and other health professionals, supermarket and peer networks are also important sources of information. Data from the US indicate that health professionals were a more important source of information than advertising and print media for adults (2004 Gallop Study of Cholesterol Lowering Options provided by Goodman Fielder).

Table 4: Sources of information about plant sterols

Main sources of information	Proportion of enriched spread users (%)
Articles in newspapers, mags., TV	62
Advertising	58
Doctor/health professional	42
Supermarket	36
Family/friend recommended product	30
Manufacturers website	12

In addition to these sources of information, consumers also gain information from the packaging and labels. The survey tested enriched spread users' knowledge of the products with respect to plant sterols in a broader dietary context, serve sizes and target audience (Table 5). The findings indicate some areas of limited understanding, particularly with regards to the suitability of plant sterol enriched products for children. There was some awareness of appropriate serve size with the majority of consumers aware that extra serves would not deliver extra benefits, though recognising that eating extra serves was not harmful. Nonetheless, only 36% considered they had sufficient serve size information.

Plant sterol enriched margarines were not perceived as a 'magic bullet' with 89% of consumers recognising they still need to be concerned about other fats in their diet despite the use of plant sterol enriched spreads.

Table 5: Knowledge about plant sterol enriched products

Statement	Desirable response	Proportion
Diet-related statements		
If I use plant sterol margarines, I don't have to worry about the other fats in my diet	False	89%
If I currently have health problems, I should check with my doctor before using this product	True	56%
I should eat extra fruit and vegetables if I eat plant sterol margarine	True	38%
Serve size statements		
The more of this product I eat, the better it is for me	False	66%
Extra serves might be bad for my health	False	53%
I have enough information to decide how much plant sterol margarine I should consume each day	True	36%
Target audience statements		
Everybody can eat plant sterol margarine	False	38%
Plant sterol margarines are not suitable for children	True	26%

Dietary and lifestyle behaviours

A key concern raised in the second review request is the extent to which the consumption of plant sterol enriched products will lead to changes in dietary or lifestyle behaviours that are contrary to the National Dietary Guidelines or recommended exercise regimens. The contention is that consumers of plant sterol enriched products may gain a benefit from consumption of these products and consequently be less concerned about their health and accordingly be less inclined to adopt appropriate diet and lifestyle behaviours. For example consumers may eat more saturated fats as they believe their consumption of plant sterol enriched products will counteract their indulgence. As there was no evidence to support or refute this contention the FSANZ survey specifically sought to collect data in order to better understand the motivations and likely behaviours of people in response to plant sterol enriched foods.

Consumers do not see plant sterol enriched spreads as a 'silver bullet' that will absolve them of further responsibility for healthy behaviour.

An experimental study designed to identify the existence or not of causal links was outside the scope of the FSANZ survey, rather a quasi-experimental design was used in order to identify associations between enriched spread use or not on the one hand and diet and exercise behaviours on the other (Table 6). The test group was those who used plant sterol enriched spreads and the control group was those who did not use plant sterol enriched spreads. Two types of measures were used: 1) objective self-reported measures of diet and exercise derived from the Australian National Health Survey (ABS 2006); and 2) subjective self-reported measures of perceived impacts of plant sterol margarine consumption on diet and exercise.

If there was an association between plant sterol enriched spread use and diet or exercise then there would be a significant difference in the responses of the test and control groups for each of these measures. Additionally, if users are aware of any diet or exercise changes that *they* attribute to use of enriched spread this will be picked up in the subjective measures.

Table 6: Survey design to test for impact on diet and exercise behaviour

Measures	Test group	Control group
Objective measure of diet	✓	✓
Subjective measure of impact on diet	✓	×
Objective measure of exercise	✓	✓
Subjective measure of impact on exercise	✓	×

Consumers of plant sterol enriched spreads do not exercise less or eat worse than non-consumers.

In summary the survey found no significant differences between the test and control groups in the level of exercise they carried out. In terms of diet there was a demographic distinction with younger users of enriched spreads having a better diet than those who didn't use enriched spreads. There was no significant differences in diet between test and control groups of those 35 years and older. There were a minority of enriched spread users who reported that their diet and exercise had improved since using plant sterol enriched spreads. Consumption of plant sterol enriched spread was not linked to either better or worse diet and exercise measures, though a minority of consumers considered they had improved diet and exercise levels.

Diet was measured through the usual daily intake of fruit and vegetables. Individuals who had consumed 2 or more serves of fruit and 4 or more serves of vegetable a day were considered to have met their dietary intake of fruit and vegetables. A minority of both consumers and non-consumers of plant sterol enriched spreads surveyed satisfied this requirement. There were no significant differences in the proportion who satisfied this requirement between enriched and other spread users who were over 35 years of age. There was a slight age difference with younger (less than 35) enriched spread users being more likely to meet the fruit and vegetable requirements than younger people who did not use enriched spreads.

In terms of subjective impact on diet 55% reported their diet had stayed about the same since using enriched spreads and 43% reported it had improved (Table 6). Additionally 89% of respondents who used plant sterol enriched margarines noted considered the statement *If I use plant sterol margarines, I don't have to worry about the other fats in my diet* to be false. The consumption of plant sterol enriched spread may, at worst, be associated with no poorer diet than non-consumption of enriched spreads, and at best, be associated with a better diet for those under 35 years.

Exercise was measured adopting the approach of the National Health Survey (ABS 2006) which categorises individual's level of exercise into one of four 1 of 4 exercise level categories (sedentary, low, moderate, high) based on exercise time and intensity. Approximately 50% of respondents had low levels of exercise. There were no significant differences between plant sterol enriched spread users and other spread users in the level of exercise performed.

In terms of subjective impact on exercise levels, 71% reported their level of exercise had stayed about the same since using enriched spreads and 26% reported it had increased (Table 7). The consumption of plant sterol enriched spread may, at worst, be associated with no lesser levels of exercise than non-consumption of enriched spreads.

Table 7: Changes in diet and exercise levels since using plant sterol enriched spreads

Exercise/diet changes since using enriched spread	Exercise (%)	Diet (%)
Exercise increased a lot / Diet much healthier	8	11
Exercise increased a little / Diet somewhat healthier	18	32
Stayed about the same	71	55
Exercise decreased a little / Diet somewhat less healthy	1	1
Exercise decreased a lot / Diet much less healthy	2	0

The diet and the exercise findings highlight that those who consume plant sterol enriched spreads do not have significantly worse diets and exercise levels than those who do not use plant sterol spreads. This evidence does not support the contention that use of plant sterol enriched spreads are associated with less healthy diet and lifestyle choices. While the evidence does not suggest that those who consume plant sterol enriched spreads make healthier diet and lifestyle choices than those who do not consume these spreads, self-assessments of enriched spread users suggest there have been some improvements in diet and exercise for some individuals.

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ATTACHMENT 4

Phytosterols Dietary Exposure Assessment Report for the Second Review

Previous phytosterol exposure estimates

For applications A433, A434 and A508, estimates of dietary exposure were conducted assuming the concentration of free phytosterols was 0.8 g/serve (except for reduced and low fat milk in A508 which was assumed to contain 0.9 g/serve). Estimated exposures to free phytosterols from these three applications (and a combination of A433 and A434 which were assessed concurrently) were up to between 1.7 g/d and 1.9 g/d for mean consumers of free phytosterols and up to between 4.4 g/d and 4.8 g/day for 95th percentile consumers of free phytosterols across all of the population groups assessed.

Table 1 shows a summary of the dietary exposure assessments and results for A433, A434, A433 + A434 and A508.

Table 1: Summary of dietary exposure assessments previously reported at Final Assessment

	Application			
	A433 **Phytosterol esters in breakfast cereals**	**A434** **Phytosterol esters in low fat milk and yoghurt**	**A433 + A434**	**A508** **Tall oil Phytosterols in low fat milk**
Concentrations used*	0.8g/serve table spreads 0.8g/serve breakfast cereals	0.8g/serve table spreads 0.8g/serve reduced fat milk 0.8g/serve reduced fat yoghurt	0.8g/serve table spreads 0.8g/serve breakfast cereals 0.8g/serve reduced fat milk 0.8g/serve reduced fat yoghurt	0.8g/serve table spreads 0.9g/serve reduced fat milk
Population groups assessed	Australia: 2 years+, 40-64 years, 65 years+, 2-12 years, females 16-44 years New Zealand: 15 years+, 40-64 years, 65 years+, females 16-44 years			
Mean exposure*#	≤ 1.7 g/d	≤1.9 g/d	≤ 1.9 g/d	≤ 1.9g/day
95th percentile exposure*#	≤ 4.4 g/d	≤ 4.7 g/d	≤ 4.7 g/d	≤ 4.8g/day

* As free phytosterols.
# Less than or equal to the value presented across all of the population groups assessed.

Additional assessment

An additional assessment has been conducted by FSANZ to determine the estimated exposure to phytosterols should the concentration in the foods assessed previously in other applications be equal to 1.0 g/serve as free phytosterols. All food groups, population groups, food consumption data, serve sizes and methodologies remained the same as in previous assessments. This additional assessment was not conducted for A433 and A434 combined, however, it can be seen from Table 1 that estimated exposures for this scenario were similar to when the applications were assessed separately.

As expected, assuming foods contain 1.0 g free phytosterols per serve, the estimated exposures were slightly higher compared to previous estimates using a lower concentration. Estimated exposures were up to between 2.1 g/day and 2.4 g/day for mean consumers of free phytosterols and up to between 5.5 g/day and 5.9 g/day for 95th percentile consumers for free phytosterols across all of the population groups assessed. A summary of these results are shown in Table 2.

The target group of 40-64 years had the highest levels of exposure. Children aged 2-12 years (Australia only) and females of child bearing age (16-44 years) had lower exposures than the target group. (See Table 3 for further details on exposure for each population sub-group assessed).

Table 2: Summary of estimated dietary exposure to free phytosterols assuming a concentration of 1.0 gram of free phytosterols per serve

	Estimated dietary exposure for consumers of phytosterols*# (grams/day)	
Application	**Mean**	**95th percentile**
A433	≤ 2.1	≤ 5.5
A434	≤ 2.4	≤ 5.9
A508	≤ 2.3	≤ 5.8

* As free phytosterols.
# Less than or equal to the value presented across all of the population groups assessed.

Table 3: Estimated dietary exposure to free phytosterols assuming a concentration of 1.0 gram of free phytosterols per serve for various population groups assessed

			Estimated exposure (g/day)*	
Application	**Country**	**Population group**	**Mean**	**95th percentile**
A433	Australia	2 years+	1.8	5.0
		40-64 years	1.9	5.1
		65 years+	1.9	5.0
		2-12 years	1.4	3.5
		Females 16-44 years	1.6	4.1
	New Zealand	15 years+	2.0	5.4
		40-64 years	2.1	5.5
		65 years+	2.0	4.8
		Females 16-44 years	1.7	4.3

Application	Country	Population group	Estimated exposure (g/day)*	
			Mean	95th percentile
A434	Australia	2 years+	2.0	5.3
		40-64 years	2.1	5.4
		65 years+	2.2	5.4
		2-12 years	1.6	4.3
		Females 16-44 years	1.8	4.4
	New Zealand	15 years+	2.2	5.7
		40-64 years	2.4	5.9
		65 years+	2.3	5.3
		Females 16-44 years	1.9	4.6
A508	Australia	2 years+	2.0	5.2
		40-64 years	2.1	5.3
		65 years+	2.1	5.3
		2-12 years	1.5	4.2
		Females 16-44 years	1.7	4.3
	New Zealand	15 years+	2.2	5.6
		40-64 years	2.3	5.8
		65 years+	2.2	5.2
		Females 16-44 years	1.8	4.6

* As free phytosterols.

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