



19 February 2010
[5-10]

APPLICATION A1019

EXCLUSIVE USE OF PHYTOSTEROL ESTERS IN LOWER-FAT CHEESE PRODUCTS

APPROVAL REPORT

Executive Summary

Purpose

An Application was received from Kraft Foods Limited on 14 November 2008 which sought an amendment to the *Australia New Zealand Food Standards Code* (the Code) to permit the addition of phytosterol esters derived from tall oil (TO) phytosterol esters as a novel food ingredient in lower-fat cheese and lower-fat processed cheese. The Applicant has requested exclusive use of this permission. In accordance with the Applicant's request, the regulatory measures, if approved, will provide exclusive use for TO phytosterol esters in Kraft lower-fat cheeses (LiveActive® brand) for a period of 15 months from the date of gazettal. These products consist of a cheese spread (mini-tub) and processed cheese slices.

FSANZ has used the general term 'lower-fat cheeses' throughout this Report meaning cheese and processed cheese with a fat content of less than 12 g/100 g.

The use of TO phytosterol esters in food is not currently permitted in the Code. In addition, no forms of plant sterols are currently permitted to be added to cheese or processed cheese.

The specific objectives in considering this Application are to:

- protect public health and safety in relation to the proposed addition of TO phytosterol esters to lower-fat cheese and lower-fat processed cheese
- ensure adequate information relating to lower-fat cheese and lower-fat processed cheese fortified with TO phytosterol esters is provided to consumers to enable informed choice
- prevent misleading or deceptive conduct by ensuring that TO phytosterols esters can deliver an effect through lower-fat cheese and lower-fat processed cheese.

FSANZ has previously concluded that consumption of plant sterol-fortified foods raises no safety concerns and a reference health standard is not warranted. FSANZ re-evaluated the evidence underpinning this conclusion, and included new scientific information that has become available since the previous assessment in 2005.

There is no basis for changing the previous conclusion that plant sterols are safe for human consumption at the levels proposed to be used in particular foods. An independent, external expert was asked to peer review this updated risk assessment and provide comments, particularly on the FSANZ analysis of the toxicological evidence. The reviewer agreed with the FSANZ evaluation, confirming that a reference health standard is not required.

Some population studies have investigated whether the modest increase in serum plant sterols in normal consumers is associated with a heart disease risk. A comprehensive review of the literature does not indicate any population health risk arising from consumption of plant sterol fortified foods.

FSANZ concludes that approval of TO phytosterol esters in lower-fat cheese and lower-fat processed cheese poses no increased health risk when compared to currently approved plant sterol-fortified foods. Furthermore, plant sterols added to lower-fat cheese and lower-fat processed cheese can deliver a cholesterol-lowering effect. The key risk assessment findings are detailed in **Supporting Document 1**¹.

A small proportion of non-target consumers (e.g. children aged 2–16 years) is likely to consume lower-fat cheeses containing plant sterols. This does not raise a health concern; however, it is less likely that they will receive a benefit from consuming these products. FSANZ therefore considers the consumption of plant sterol-fortified products by these groups is unnecessary unless advised by a medical practitioner.

In order to ensure appropriate use of TO phytosterol esters in lower-fat cheese and processed cheese, the following food regulatory measures are proposed:

- retain the current mandatory advisory statements in Standard 1.2.3
- prescribe restrictions on the fortified food, namely:
 - (i) that cheese or processed cheese must contain no less than 70 g/kg and no more than 90 g/kg TO phytosterol esters
 - (ii) the cheese or processed cheese is supplied in a portion, the capacity of which is no more than 50 g
 - (iii) that foods containing added plant sterols must not be used as ingredients in other foods
 - (i) the cheese or processed cheese must not contain more than 12 g total fat/100 g cheese.

The Applicant is proposing to undertake additional non-regulatory initiatives such as targeted marketing of the product and development of educational material to support these regulatory risk management measures. FSANZ was advised by the Applicant that the non-regulatory activities will be undertaken concurrently with the release of the plant sterol fortified cheese products. This will be maintained on an ongoing basis commensurate with the consumer acceptance of these products.

The key risk management issues are discussed in Section 6.

Assessing the Application

The Application was assessed under the General Procedure with one round of public consultation.

¹ Supporting Document 1: Risk Assessment Report

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- whether there are other measures that would be more cost-effective than a variation to Standards 1.5.1 and 2.5.4 that could achieve the same end
- any relevant New Zealand standard
- any other relevant matters.

Decision

To amend Standard 1.3.4 – to insert a specification for phytosterol esters derived from tall oils to cover the Exclusivity period of 15 months from the date of gazettal

To amend Standard 1.5.1 – Novel Foods to permit the exclusive use of phytosterol esters derived from tall oils to LiveActive® brand cheese and processed cheese in accordance with Standard 2.5.4 – Cheese.

To amend Standard 2.5.4 – Cheese to permit the addition of phytosterol esters derived from tall oils, to cheese and processed cheese containing no more than 12 g fat per 100 g cheese and in amounts of no less than 70 g/kg and no more than 90 g/kg total phytosterol esters.

Reasons for Decision

- there are no safety, nutritional or efficacy concerns with the addition of TO phytosterol esters to lower-fat cheese or lower-fat processed cheese
- there are benefits to industry, consumers and Government in terms of enhanced market opportunities and trade, increased product availability and potential reduction in a health-related risk marker
- lower-fat cheese and lower-fat processed cheese are considered suitable vehicles for TO phytosterol esters and they can effectively be incorporated into the food matrix
- approval for addition to lower-fat cheese and lower-fat processed cheese is consistent with Ministerial policy guidance on the *Addition to Food of Substances other than Vitamins and Minerals*²
- the proposed risk management strategy is considered sufficient to manage the low risk associated with consumption of the fortified food

²<http://www.foodstandards.gov.au/foodstandards/changingthecode/ministerialcouncilpolicyguidelines/policyguidelineonthe4132.cfm>

- maintaining a prohibition on the addition of TO phytosterol esters to lower-fat cheese or lower-fat processed cheese is not justified on the basis of the available scientific evidence.

Consultation

Public submissions were invited on the Assessment Report. Comments were specifically requested on the following:

- scientific aspects of the application, in particular, any information relevant to the safety assessment
- information on Australia and New Zealand consumers' knowledge of plant sterols
- information that would assist in an assessment of the appropriateness and effectiveness of current labelling statements on foods containing plant sterols
- parties that might be affected by having this application approved or rejected
- potential costs and benefits to consumers, industry and government.

A total of 14 submissions were received. A summary of these is provided in **Attachment 2** to this Report. The main issues raised in public comments are discussed in this Report.

The following Table summarises the changes in the Report and/or drafting from Assessment to Approval for Application A1019.

Issue	FSANZ Action
A number of clarifications and/or suggestions were submitted in regard to the drafting at Assessment. Refer to section 10.1.11 of the Approval report for detail.	<p>As a consequence, FSANZ has amended the drafting at Assessment as following:</p> <ul style="list-style-type: none"> • deleted the reference to total fat excluding any added phytosterols. This is consistent with other permissions in Code for low-fat milk and yoghurt. (The intent of the previous drafting was to specify the maximum fat content related to milk fat excluding added plant sterols.) • The class of food in Column 3 of the Table to clause 3 of Standard 1.5.1 now refers to 'cheese and processed cheese' as the class of food, rather than 'reduced-fat cheese' as the maximum limits for fat (<12g/100g) are specified in the drafting. <p>In addition, further clarification has been provided in regard to the relationship between the permitted addition of tall oil phytosterol esters and free phytosterols/serve in Section 10.1.10 of the Approval report.</p>
The total fat should be increased from 9 g fat per 100 g cheese to the European maximum level of 12 g fat per 100 g cheese.	<ul style="list-style-type: none"> • FSANZ has amended the proposed maximum fat content from 9 g to 12 g fat/100g cheese in order to harmonise with existing overseas regulations and because there are no health and safety concerns at this level. The Applicant has agreed to this amendment.

Issue	FSANZ Action
<p>Recommended that the term 'reduced-fat' not be used to describe the foods in this application, or subsequent documents in light of reduced-fat not being defined in the Code. There are also a number of cheeses that would meet this definition, without needing a reduction in their fat content (e.g. ricotta).</p>	<ul style="list-style-type: none"> <li data-bbox="603 226 1369 353">• For clarity, FSANZ has used the general term 'lower-fat cheeses' throughout this report meaning cheese and processed cheese with a fat content of less than 12g/100g.

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SUPPORTING DOCUMENT

The following materials, which were used in the preparation of this Assessment Report, are available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1019phyt4161.cfm>

SD1: Risk Assessment Report

INTRODUCTION

A paid Application was received from Kraft Foods Ltd on 14 November 2008. The Application sought to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of tall oil phytosterol (TO) esters as a novel food ingredient in cheese and processed cheese under Standard 1.5.1 – Novel Foods and Standard 2.5.4-Cheese. Under Standard 1.5.1, the Applicant also seeks exclusive use of TO phytosterol esters in lower-fat cheese products under the (LiveActive®) brand for a period of 15 months.

The Applicant is seeking specific permission to add TO phytosterol esters to cheese and processed cheese (<12 g fat per 100 g cheese) at levels equivalent to 1.1 g of free phytosterols per 20 g serve of cheese. This is consistent with the levels currently permitted in edible oil spreads, milk and yoghurt and breakfast cereals. The Applicant has advised that the product will be presented in a portion-controlled³, easy-to-use format to assist consumers' awareness of how much plant sterol is contained within each serve, and to enable them to consume the optimal amount to achieve the intended effect. These products consist of a cheese spread (mini-tub) and processed cheese slices.

1.1 Definitions and terminology

The Application pertains to cheese and processed cheese each with a fat content of no more than 12 g/100 g cheese. While the two products to which the Applicant seeks to add TO phytosterols can be described as reduced fat, there are some cheeses which may not require a reduction in their fat content in order to satisfy this condition.

For the purposes of this report, FSANZ has replaced the term 'reduced fat cheese' used to describe the food vehicle at Assessment with the general term 'lower-fat cheeses'. Lower-fat cheeses mean cheese and processed cheese with a fat content of less than 12 g/100 g.

The following additional terms are used in this report:

<i>Plant sterols</i>	Collective term referring to all free and esterified phytosterols and phytostanols, regardless of the biological source.
<i>Phytosterols</i>	Free (non-esterified) steroid alcohols occurring in plants e.g. β -sitosterol, campesterol, stigmasterol. Dietary intake of plant sterols is expressed in terms of free phytosterols.
<i>Plant sterol equivalents</i>	The total free (non-esterified) phytosterol and phytostanol content of the product/preparation/commercial mixture
<i>Phytostanols</i>	Any of the fully saturated phytosterols e.g. sitostanol, campestanol
<i>Phytosterol esters</i>	Phytosterols esterified with food grade fatty acids derived from vegetable oils.
<i>Phytostanol esters</i>	Phytostanols esterified with food grade fatty acids derived from vegetable oils.

1. The Issue / Problem

The Applicant is requesting permission to add TO phytosterols to lower-fat cheeses packaged in portions less than 50 g, in order to increase the variety of products available to those seeking blood cholesterol reduction and to do so via portion control to enable better measurement of plant sterol intake.

³ One cheese slice will deliver 1.1 g phytosterols and thus the consumer knows exactly how much they have consumed; whereas, one mini-tub will provide 2 serves/day .

The use of TO phytosterol esters in food is not currently permitted in the Code. In addition, no forms of plant sterols are currently permitted to be added to lower-fat cheeses. FSANZ considered the Applicant's TO phytosterol product (LiveActive®) would be considered a novel food under Standard 1.5.1 and therefore required a pre-market safety assessment before this product can be sold in Australia or New Zealand.

2. Current Standard

2.1 Background

The purpose of Standard 1.5.1 is to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale in Australia or New Zealand. Approved novel foods are listed in the Table to clause 2 of Standard 1.5.1.

Under subclause 3(4) of Standard 1.5.1 a novel food or food ingredient may be sold for a 15 month exclusive use period in a specified brand and class of food, and may be subject to any specified conditions of use. Permission for exclusive use of a novel food is listed in the Table to clause 3 of Standard 1.5.1. The exclusive use permission reverts to a general permission after the exclusive use period expires.

There are additional regulations which currently apply to foods permitted to contain plant sterols. The Standards relevant to this Application are:

- Standard 1.3.4 – Identity and Purity
- Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations
- Standard 1.2.4 – Labelling of Ingredients
- Standard 1.2.9 – Legibility Requirements.

2.2 Permissions for the addition of Plant sterols

Permission to use phytosterol esters derived from vegetable oils as a novel food ingredient in edible oil spreads came into effect on 14 June 2001. This permission was limited to edible oil spreads and margarines primarily because of a lack of information relating to the safety and effectiveness of plant sterols in lowering cholesterol when present in a broader range of foods.

In November 2006, further permissions for the addition of phytosterol esters to breakfast cereals⁴, low-fat milk and low-fat yoghurt⁵, and tall oil derived phytosterols to edible oil spreads and low-fat milks⁶ were approved.

⁴ Phytosterol esters can only be added to breakfast cereals if they contain no more than 30 g/100 g total sugars and no less than 3 g/100 g fibre. FSANZ (2006) Application A433 – Phytosterol Esters derived from Vegetable Oils to Breakfast Cereals. 2nd Review Report. 4 October 2006. FSANZ, Canberra

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa433phytosterolestersinfibreifibreincreasedbreadandcerealbars/index.cfm>

⁵ FSANZ (2006) Application A434 – Phytosterol Esters derived from Vegetable Oils to Lower-fat Milks and Yoghurt. 2nd Review Report. 4 October 2006. FSANZ, Canberra

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa434phytosterolestersinlowfatmilkandlowfatyoghurt/index.cfm>

⁶ FSANZ (2006) Application A508 – Phytosterols derived from a Tall Oil Source as ingredients in low fat milk. 2nd Review Report. 4 October 2006. FSANZ, Canberra

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa508phytosterolsderivedfromalloils/index.cfm>

At the time these permissions were sought, the scientific evidence showed plant sterols to be efficacious at a daily intake of approximately 2-3 g of free phytosterols, with no additional benefit if more was consumed. No safety limit had been set internationally and the limited studies conducted on the safety of plant sterols indicated consuming plant sterols up to 10 g per day resulted in no negative health effects. Based on this evidence FSANZ permitted plant sterols to be added to allowable foods within the efficacious range of 0.8 to 1.0 g per quantity (average serving size) of food.

In addition, FSANZ determined that while there was no adverse physiological effect, children, pregnant and lactating woman do not derive a benefit from consumption of plant sterols and do not generally need to reduce their blood cholesterol levels. To limit consumption by groups who would not derive a benefit from these products, and to limit the consumption by the target groups to the efficacious amount, the Code requires products containing plant sterols to be labelled with the following statements:

- when consuming the product, it should be consumed as part of a healthy diet⁷
- the product may not be suitable for children under the age of five years and pregnant or lactating women⁸
- plant sterols do not provide additional benefits when consumed in excess of three grams per day⁹.

2.2.1 Other related Applications

Application A 604 – Phytosterols in Fruit Juice & Fruit Juice Drinks sought permission to add unesterified phytosterols from edible vegetable oils to fruit juices and fruit drinks (minimum 25% juice). This was at Draft Assessment and being progressed under the FSANZ Act as was in force prior to 1 July 2007. However, on 19 August 2009, the Applicant notified FSANZ that they were withdrawing the Application.

Application A1024 – Equivalence of Plant Stanols, Sterols and their Fatty Acid Esters seeks consolidation of the specifications and permissions for plants sterols, sterols and their fatty acid esters in the Code and adopt that published by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) in 2008. Draft variations relating to this Application have been approved by the FSANZ Board.

2.3 Relevant Overseas Regulations

In Europe, phytosterols and their esters are permitted in a wide variety of foods¹⁰ including lower-fat (≤ 12 g/100 g) cheese type products.

⁷ Plant sterols are permitted only in foods that are compatible with a healthy diet (e.g. lower-fat milk, lower-fat yoghurt) and breakfast cereal that is not marketed to children. The 'healthy diet' message is consistent with other public health messages in relation to diet and chronic disease.

⁸ 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, nor do children generally need to reduce their cholesterol levels.

⁹ 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. This statement is intended to allow consumers to use the products cost-effectively.

¹⁰ Foods authorised to contain plant sterols include yellow fat spreads, milk-type products, fermented milk-type products, cheese-type products, yoghurt type products, milk-based fruit drinks, soya drinks,

Plant stanols and their esters are permitted for use without requiring pre-market assessment, as they were for sale in a Member State before the Regulation came into effect. The European Commission (EC) has determined that phytosterols, phytostanols and their esters are functionally and compositionally equivalent, with similar safety and efficacy. As such, they are consolidated and regulated as a single substance, with the same specifications for use and labelling requirements. The EC requires that all foods with added plant sterols must be labelled with the following information:

- they are intended exclusively for those who wish to lower their blood cholesterol
- patients on cholesterol lowering medications should only consume these foods under medical supervision
- consumption of plant sterols is not appropriate for people with special dietary needs (i.e. pregnant and breastfeeding women and children under 5)
- foods with added plant sterols should be consumed as part of a balanced diet
- consumption should not exceed 3 g of added sterols a day¹¹.

The regulation also requires that manufacturers must clearly define portion sizes.

On 31 July 2009, the European Food Safety Authority (EFSA) issued an opinion on plant sterols and plant stanol ingredients to assist risk managers across the European Union to implement cholesterol-lowering claims¹². The opinion was delivered after requests for claim authorisation advice from the European Commission and France, and collates data backing three positive stanol/sterol cholesterol-lowering opinions issued to date. The opinion – which references more than 80 clinical trials and issues guidance on dosage between 1.5 and 2.4 g of plant sterols and stanols – notes the efficacy has been demonstrated in margarines, mayonnaise, salad dressings, milk, yoghurts and cheese but in other formats the efficacy is less well established.

In the USA, the Food and Drug Administration (FDA) has raised no objection to a number of food products that may contain plant sterols and stanol esters in amounts up to 20%, on the basis of GRAS notifications. Notifications include vegetable oil spreads, salad dressings, health drinks, cereal health bars, yoghurt type products, fruit juice (orange) and vegetable oils for baking and frying. The FDA has also allowed manufacturers of products containing added phytosterol and stanol esters to make a health claim (for reducing the risk of coronary heart disease). There are a number of specific restrictions with which the products must comply before such a health claim may be made. Foods that are allowed to use this interim health claim include sterol esters in spreads and salad dressings, and stanol esters in spreads, salad dressings and snack bars.

When making a health claim in the USA, manufacturers are required to comply with specific labelling requirements as follows:

- plant sterol/stanol esters should be consumed as part of a diet low in saturated fat and cholesterol

rice drinks, spicy sauces, salad dressings and certain rye breads. See OJ L 105, 14.4.2004, p 40 and OJ L 105, 14.4.2004, p 43.

¹¹ Commission Regulation EC 608/2004. OJ L 97 1.4.2004 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:097:0044:0045:EN:PDF>

¹² [http://www.efsa.europa.eu/cs/BlobServer/Scientific Opinion/nda_op_ej1175_plantsterols_stanols_summary_en.0.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific%20Opinion/nda_op_ej1175_plantsterols_stanols_summary_en.0.pdf?ssbinary=true)

- the daily dietary intake of plant sterol or stanol esters that is necessary to reduce the risk of coronary heart disease (CHD) and the contribution one serving of the product makes to the specified daily dietary intake level
- the daily dietary intake of plant sterol or stanol esters should be consumed in two servings eaten at different times of the day with other foods
- the claim states that diets that include plant sterol/stanol esters 'may' or 'might' reduce the risk of heart disease
- the claim uses the following terms 'heart disease' or 'coronary heart disease'
- the claim uses the term 'plant sterol esters' or 'plant stanol esters' except that if the sole source of the plant sterols or stanols is vegetable oil, the claim may use the term 'vegetable oil sterol esters' or 'vegetable oil stanol esters'
- the claim does not attribute any degree of risk reduction for CHD to diets that include plant sterol/stanol esters
- the claim does not imply that consumption of diets that include plant sterol/stanol esters is the only recognised means of achieving a reduced risk of CHD.

3. Objectives

The specific objectives in considering this Application are to:

- protect public health and safety in relation to the proposed addition of TO phytosterol esters to lower-fat cheese
- ensure adequate information relating to TO phytosterol ester lower-fat cheese is provided to consumers to enable informed choice
- prevent misleading or deceptive conduct by ensuring that TO phytosterols can deliver an effect through lower-fat cheese; and mandating appropriate labelling measures.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

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

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;

- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

3.1 Policy Guideline on Addition to Food of Substances other than Vitamins and Minerals

Under its section 18 objectives, FSANZ must have regard to any written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council). The Ministerial Council has provided a Policy Guideline on the *Addition to Food of Substances other than Vitamins and Minerals*. A copy of the Policy Guideline can be located from FSANZ's website¹³.

The Policy Guideline provides 'high order' and 'specific order' policy principles and additional guidelines for the addition of substances other than vitamins and minerals to food. The 'high order' principles reflect FSANZ's statutory objectives described above.

'Specific order' policy principles are provided for both substances added for a technological function as well as for 'Any Other Purpose'. The purpose for addition of TO phytosterols to lower-fat cheeses falls under 'Any Other Purpose' and therefore regard has been given to the policy guidance in the assessment of this Application

4. Questions to be answered

The key questions which FSANZ has considered as part of this assessment are:

- Are the chemical properties of the plant sterols mixtures and manufacturing processes proposed by the Applicant, technologically suitable for addition to lower-fat cheeses?
- What new information relevant for assessing the safety of plant sterols in lower-fat cheeses has become available since previous FSANZ reviews of their safety?
- Are the plant sterols mixtures proposed for use capable of lowering cholesterol when added to lower-fat cheeses?
- What impact could the introduction of lower-fat cheeses fortified with TO phytosterols have on the consumption patterns of this food type in Australian and New Zealand consumers?
- Considering existing permissions for plant sterols fortified foods, what is the estimated impact on total plant sterols intakes from the addition of plant sterols fortified cheeses to the diet?

¹³<http://www.foodstandards.gov.au/foodstandards/changingthecode/ministerialcouncilpolicyguidelines/policyguidelineonthe4132.cfm>

RISK ASSESSMENT

5. Risk Assessment Summary

FSANZ has previously assessed and characterised the risk from consumption of plant sterol-fortified edible oil spread, breakfast cereal, low fat milk and low fat yoghurt for the Australian and New Zealand population groups.

The approach taken in the risk assessment was to consider relevant data on the chemical and physical characteristics, safety, fitness for purpose, public health implications and dietary intake of plant sterols to characterise the risk of setting out permissions for the use of TO phytosterol esters in lower-fat cheese products. Given the comprehensive nature of previous assessments concerned with plant sterols, the primary focus of this risk assessment was to review the scientific evidence, and consider any new information that has become available over recent years, particularly since the most recent assessment by FSANZ in 2005. This evaluation is in **Supporting Document 1**¹⁴.

The key findings from the risk assessment are:

- on the basis of the manufacturing process for TO phytosterol esters and their properties when added to lower-fat cheeses, these products will deliver a consistent amount of phytosterols, and are likely to remain stable during storage under usual conditions
- the evidence demonstrates that the use of plant sterols in lower-fat cheeses at the proposed level does not raise any food safety concerns
- previous assessments have concluded that a reference health standard is not warranted. There is no new toxicological evidence that would indicate the need to change previous conclusions regarding the safety of plant sterols fortified foods.
- a reduction in the absorption of beta-carotene with intake of plant sterols is expected, however this has no significant nutritional impact. Consumption of additional fruits and vegetables partially compensates for this phenomenon.
- consumption of plant sterol-fortified foods has no impact on the risks of developing cardiovascular disease.
- consumption of lower-fat cheeses containing plant sterols can potentially lower LDL cholesterol levels in the blood.
- if consumers adhere to the recommended number of serves of plant sterol-fortified lower-fat cheeses, daily intake of plant sterols is estimated at 2.2 g, which is within the range shown to be optimal for a cholesterol-lowering effect.
- a small proportion (<3%) of children (aged 2-16 years) is likely to consume lower-fat cheeses containing added TO phytosterol esters, however this is not considered to raise a health concern.

The results of numerous short-term and sub-chronic toxicity studies show no adverse effects associated with plant sterols administered to animals at high doses.

¹⁴ Supporting Document 1-Risk Assessment Report

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

The potential for plant sterol fortified foods to adversely affect the risk of cardiovascular disease was investigated. This merited evaluation because patients with a rare lipid disorder that results in hyperabsorption of dietary plant sterols develop early atherosclerosis and coronary heart disease. Some population studies have therefore investigated whether the modest increase in serum plant sterols which occurs when plant sterol fortified foods are consumed by normal individuals is associated with a heart disease risk. A comprehensive review of the literature does not indicate any population health risk arising from consumption of plant sterol fortified foods. Even with consumption of sterol fortified foods, the levels of plant sterols in the blood remain at less than 1% of total sterols. Plant sterols are not present in sufficient amounts to be considered as an additional risk factor for cardiovascular disease under normal circumstances.

RISK MANAGEMENT

6. Issues

FSANZ's regulatory approach differs depending on the nature of the risks identified and there are a number of approaches used to manage identified risks. These include specification, compositional and/or labelling requirements, and where necessary, restriction or prohibition. Drawing on the conclusions from the risk assessment, the following sections discuss approaches to managing any identified public health and safety risks and other broader issues requiring consideration in the development of regulations for addition of TO phytosterols to lower-fat cheeses.

6.1 Risk to public health and safety

FSANZ understands that the safety of plant sterol-fortified foods is critical considering that these foods may be consumed over a long period of a person's life (e.g. 20 years or greater).

The 2nd Review Report for Applications A433, A434, and A508 comprehensively assessed the risk to public health and safety of plant sterols.¹⁵ It concluded that:

there was no indication of adverse effects from long-term high consumption of plant sterols for the general population. While there are no long-term (>12 months) studies available, the medium and short term effects were well studied and extrapolation of these results to identify long term effects was appropriate

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<http://www.foodstandards.gov.au/srcfiles/A508%20TOPs%20SRR%20FINAL.pdf#search=%22a508%20sECOND%20REVIEW%20REQUEST%22>

- there was no evidence of an adverse interaction between cholesterol lowering medication and plant sterols from food sources
- the consumption of phytosterols can lower beta carotene levels. The association between reduced beta carotene levels and plant sterols was not considered significant in the context of fluctuations that occur naturally and could not be associated with an adverse impact on nutritional status. However, due to the potential effect, consumption by consumers without elevated blood cholesterol is undesirable.

The current risk assessment found there is no new evidence to change these conclusions. FSANZ considers that the risk profile (i.e. the nature, likelihood and severity of the identified risks) associated with the consumption of plant sterols remains unchanged since the previous assessment.

Based on this risk assessment, FSANZ concludes that approval of TO phytosterol esters in lower-fat cheeses poses no increased health risk when compared to currently approved plant sterol-fortified foods.

6.1.1 *Consumption by children, pregnant and lactating women*

The risk assessment concludes that there is a very small proportion of children (approximately 2% in 2007) aged 2-16 years who consume plant sterol-fortified products. This is despite the mandatory requirement that all plant sterol-fortified products be labelled with a statement to the effect that the product may not be suitable for children under 5 years and pregnant or lactating women.

If TO phytosterol esters were permitted to be used in lower-fat cheeses, it is likely there will be some incidental intake of plant sterols by children aged 2-16 years and pregnant and lactating women.

FSANZ considers that the consumption of plant sterols fortified lower-fat cheeses by children aged 2-16 years, pregnant and lactating women does not raise a health concern. It is less likely however, that they will receive a benefit from consuming these products. FSANZ considers therefore, the consumption of plant sterol-fortified products by these groups is unnecessary unless advised by a medical practitioner.

Therefore, for consistency with the current plant sterol-fortified products currently approved for use and the overseas approach to these products, FSANZ proposes to apply the mandatory advisory statement (see Section 6.3) to discourage consumption by children under 5 years and pregnant or lactating women of plant sterol fortified lower-fat cheeses.

6.2 **Consistency with Policy Guidelines**

As noted in Section 3.1, FSANZ is required to have regard to the Policy Guideline on the Addition of Substances other than Vitamins and Minerals to foods, particularly the specific order policy principles for substances added for 'Any other Purpose'. These specific order policy principles state that:

The addition of substances other than vitamins and minerals to food where the purpose of the addition is for any other purpose other than to achieve a solely technological function should be permitted where:

- a) the purpose for addition can be articulate clearly by the manufacturer (i.e. the stated purpose); and*
- b) the addition of the substance to food is safe for human consumption; and*

- c) *the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and*
- d) *the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population; and*
- e) *the presence of the substance does not mislead the consumer as to the nutritional quality of the food.*

The following section discusses the issues in relation to the policy principles c), d) and e). With respect to a), the purpose for adding plant sterols to foods is clear and does not require further discussion. With respect to b), the safety of plant sterols has been addressed in the previous section.

6.2.1 *Consistency with stated purpose*

At Assessment FSANZ considered whether the addition of TO phytosterol esters to lower-fat cheeses is consistent with policy principle c). Based on the current evidence, FSANZ concludes that a LDL cholesterol lowering effect is achieved at doses from 1-3 g of plant sterols per day when delivered through hard and fresh lower-fat cheeses and other dairy foods. These ranges of reduction in LDL cholesterol from the consumption of plant sterol-fortified products fall within ranges previously accepted by FSANZ.

6.2.2 *Potential to create a significant negative public health impact*

As noted above, the safety of plant sterols has been previously discussed in Section 6.1 and **Supporting Document 1**. FSANZ concludes that the total amount of phytosterols likely to be consumed from all sources, including lower-fat cheeses, in all consumers, poses no health and safety risk.

At Assessment consideration was given to the public health impact resulting from a change in consumption patterns and consistency with national nutrition guidelines. FSANZ concluded that consumption of lower-fat cheeses, at likely levels of consumption, are unlikely to impact adversely on macronutrient balance. In addition, noting national nutrition guidelines with respect to fat and dairy products, FSANZ concluded that consumption of the food vehicles at likely levels of consumption would generally be consistent with these guidelines.

There was concern raised by one submitter that addition of phytosterol to processed cheese may adversely impact sodium intakes. It was noted that processed cheeses tend to have higher sodium content than some other cheese types, notably cheddar type cheeses. On the basis that these products target those who are conscious of their health, they recommended that a sodium limit be applied to these products.

Sodium levels in processed cheeses are generally higher than that found in non-processed cheeses due to technological requirements such as the addition of emulsifying salts used to manufacture processed cheese. For example, FSANZ data reports the sodium levels of processed cheddar cheese (<10% fat) is 1440 g/100 g or 288mg per 20 g slice; in contrast, the average level of sodium in cheddar cheese (<15% fat) is 670 mg/100 g or 134 mg per 20 g slice¹⁶.

In having regard to Ministerial policy guidance, FSANZ is required to consider the potential for a negative public health impact from the addition of a substance to a food.

¹⁶ NUTTAB 2006

In this situation, this includes the potential change in consumption patterns resulting from the addition of TO phytosterols to processed cheese, the magnitude of any change and the resulting impact on public health.

It is possible that sodium intakes could be adversely affected either through substitution of lower sodium containing cheese with a higher sodium plant sterol fortified cheese, or a greater consumption of a higher sodium plant sterol fortified cheese. As noted in the Risk Assessment Report (**Supporting Document 1**) there are limited data on the actual consumption patterns of users of cheeses containing plant sterols to inform our assessment. Information from the more mature plant sterol market in Europe suggests that only a small proportion of users of plant sterol fortified products consume cheese containing plant sterols (usually as a second or third choice of plant sterol products) and that within this proportion, only a small minority do so on a daily basis. So while possible, this information suggests that a change in consumption patterns (if any occur) is likely to be seen in only a small minority of users of plant sterol products. Furthermore, as only a small number of users appear to consume cheese containing plant sterols daily, the magnitude of any change in consumption is likely to be small across the entire target group.

The main source of sodium in the diet is from sodium chloride (salt), which probably contributes in the order of 90% of dietary sodium. FSANZ's estimation of current salt intakes from processed foods suggests that cheese (including both processed and non-processed varieties) contributes approximately 5% to total salt intakes.¹⁷ This suggests that cheese contributes a comparatively small proportion of the total sodium intake in the population.

In light of the information above, FSANZ considers that the addition of TO phytosterol esters to processed cheese is unlikely to result in a significant negative public health impact.

6.2.3 Potential to mislead consumers as to the nutritional quality of the product

At Assessment FSANZ considered whether the addition of TO phytosterols to lower-fat cheeses is likely to mislead consumers as to the nutritional quality of the product. FSANZ proposed to extend the labelling provisions currently required for existing plant sterol-fortified products to plant sterol-fortified lower-fat cheese products. This includes the mandatory requirement for nutrition information panels. These measures should provide sufficient information to consumers so that they are not misled as to the nutritional quality of the product.

6.3 Labelling of phytosterol-containing products

Currently mandatory labelling requirements for phytosterol containing foods are set out in Standard 1.2.3 of the Code¹⁸. Recent data from Australia and New Zealand, the United Kingdom and Germany indicate that plant sterol-fortified spread users have mixed understandings of the role of plant sterol-fortified products and current mandatory labelling information.

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<http://www.foodstandards.gov.au/educationalmaterial/factsheets/factsheets2009/howmuch sodium and salt4340.cfm>

¹⁸ The current requirements are labelling statements to the effect that –

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

There seems to be low levels of label readership in all areas studied; misunderstanding of the role of plant sterols by respondents in the UK; and a low degree of familiarity with all of the labelling information in all areas. Additional information is at Section 7.5 in **Supporting Document 1** to this Report.

It is uncertain why this is so. The issue of legibility of advisory statements was raised during the public consultation process for the three previous applications that sought permission to add plant sterols to a broader range of foods (Applications A433, A434 and A508). Comments were raised in relation to the lack of prominence of these advisory statements and the location of these statements on the packages. For example, it was noted that sometimes these statements were located on the underside of the package or on the removable outer packaging.

Standard 1.2.9 – Legibility Requirements sets out the legibility requirements for the labelling of packaged and unpackaged foods. The Standard requires that any word, statement, expression or design that is prescribed to be contained, written or set out in a label must be legible and prominent such as to afford a distinct contrast to the background and in the English language. The Editorial note to clause 2 in Standard 1.2.9 states that the Standard will be reviewed within 24 months of the Gazettal of the Editorial note. This review was due to commence by 9 November 2008 and was specifically prompted by the three previous phytosterol applications.

In July 2009, members of the Implementation Sub-Committee (ISC) were asked to provide advice on whether the previous concerns raised by jurisdictions in relation to the legibility of advisory statements on phytosterol-containing products were still current and whether the Standard was difficult to enforce. The pending review of labelling policy and law was also noted. ISC members did not raise any new issues with respect to the legibility of advisory statements or enforcement of the Standard. FSANZ has therefore deferred the review of Standard 1.2.9 until after the Ministerial Council review of labelling policy and law has been completed, and within the context of a broader review of labelling standards.

6.3.1 Declaration of Plant Sterols in the Ingredient List

The Table to clause 2 in Standard 1.5.1 requires that the specific name of the plant sterol mixture be listed in the ingredient list of the product. Where phytosterol esters are added to a food, the names 'phytosterol esters' or 'plant sterol esters' must be used and where tall oil phytosterols are added to a food, the names 'tall oil phytosterols' or 'plant sterols' must be used. In the related Application (A1024) that FSANZ is currently considering, it was proposed at Assessment to remove the specific requirement in Standard 1.5.1 relating to the declaration of the plant sterol mixture (phytosterol esters or tall oil phytosterols) and rely on the general ingredient labelling requirements within Standard 1.2.4.

Under Standard 1.2.4 – Labelling of Ingredients, ingredients must be listed in the statement of ingredients using the common name of the ingredient, a name that describes the true nature of the ingredient or where applicable, a generic name as set out in the Standard. These general requirements also apply to plant sterols. FSANZ considers that these general terms are sufficient in terms of providing consumers with adequate information about the ingredients in the product and to prevent misleading or deceptive conduct. Therefore, the current specific requirements in Standard 1.5.1 relating to the declaration of the plant sterol mixture in the ingredient list, namely, 'phytosterol esters' or 'plant sterol esters' have been removed. This is reflected in the drafting amendments at Attachment 1A for the Approval Report for Application A1024¹⁹.

¹⁹ <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1024equi4316.cfm>

6.3.2 *Declaration of Plant Sterols in the Nutrition Information Panel*

Under clause 5 in Standard 1.2.8 – Nutrition Information Requirements, the amount of plant sterols per serving and per 100 g of the food must be declared in the nutrition information panel (NIP) if a nutrition claim is made about plant sterols. This also allows consumers to monitor their consumption of plant sterols.

In Application A1024 the concept of ‘plant sterol equivalents’ is introduced to rationalise and simplify the various forms of plant sterols that would be permitted by this Application. A ‘plant sterol equivalent’ represents 60% of the plant sterol fatty acid ester. A potential issue raised by Application A1024 is that currently the requirements in Standard 1.2.8 do not specify the form of plant sterols to be declared in the NIP and therefore whether the amount to be declared should reflect the ‘free’ form or the esterified form. As the mandatory advisory statements relate to the consumption of 2-3 g plant sterol equivalents (that is in the ‘free’ form), a declaration in the NIP that represents the esterified form has the potential to mislead consumers in terms of consuming an advised amount.

To address this issue, under Application A1024, Standard 1.2.8 has been amended such that where declaration of plant sterols is required in the NIP the amount that is declared reflects the ‘plant sterol equivalent’. It is intended however that the more familiar term ‘plant sterols’ continue to be used to facilitate consumer understanding and provide consistency with the advisory statement in the Table to clause 2 in Standard 1.2.3 (though use of this term is not mandated). This amendment also provides greater clarity from an enforcement perspective. Another important point is to ensure consistency between the term used for the NIP declaration and the mandatory advisory statement to ensure appropriate consumer information is provided. The drafting is contained in Attachment 1A of the Approval Report for Application A1024 and has not been specifically amended in the drafting for Application A1019.

6.4 Effectiveness of plant sterol fortification of foods in public health protection

A question was raised in similar Applications whether the fortification of foods with plant sterols is an effective public health strategy, given that the fortified foods have a price premium, and may be inaccessible to those on low incomes within the target population. It was suggested that the availability of these products would most likely benefit those in higher socio-economic groups, whereas the greatest risk of cardiovascular disease is shown to be in lower-economic groups.

A second question was raised on whether it is appropriate for consumers to invest in these products rather than dietary staples consistent with dietary guidelines for cardiovascular health, which may be cheaper and which may also provide effective health outcomes.

FSANZ considers these questions go to areas outside its scope as a standard setting body. These permissions are voluntary rather than mandatory. The risk assessment concludes that plant sterol-fortified foods can lower LDL cholesterol. The consumption of plant sterol-fortified foods is essentially just one option whereby consumers can do this. Restricting permissions on the conjecture that they are less likely to be used by those with highest risk would not be consistent with FSANZ’ statutory objectives.

6.5 Case-by-case approach to Applications

The intent of Standard 1.5.1 is to prohibit the sale of novel foods and novel food ingredients unless they are listed in the Table to clause 2. This approach was decided upon during formulation of the standard in order that an appropriate and adequate risk-based safety assessment could be undertaken before approval was granted.

FSANZ is taking a case-by-case approach to ensure there is evidence to support the efficacy of plant sterols in different plant sterol-fortified foods, to consider dietary intakes and facilitate a cautious expansion of the use of these novel food ingredients on the basis of their limited history of use.

In addition, the Policy Guideline on *Addition of Food of Substances other than Vitamins and Minerals*, states the following:

The potential for the addition of substances to influence consumption patterns in a way which could lead to negative public health impacts can be managed in the regulatory context on a case-by-case basis.

FSANZ considers the current approach to these Applications is consistent with this Ministerial Policy Guideline. This approach is also consistent with that used by the former Scientific Committee on Food (SCF) of the European Commission in its evaluation of commercial phytosterols preparations (2000, 2002, and 2003)²⁰.

FSANZ also notes that although the continuing novelty of plant sterols is debatable, this continuing assessment of plant sterols within the novel foods framework is protective of public health and safety.

6.6 Risk management measures

6.6.1 Regulatory measures

FSANZ concludes that extending permissions to TO phytosterol esters in lower-fat cheeses poses minimal public health and safety risks to consumers. However, FSANZ proposes to retain its current approach and:

- retain the current mandatory advisory statements in Standard 1.2.3
- prescribe conditions of use, namely:
 - (i) that cheese must contain no less than 70 g/kg and no more than 90 g/kg TO phytosterol esters;
 - (ii) the fat content must not be more than 12 g total fat/100 g cheese;
 - (iii) the cheese is supplied in a portion, the capacity of which is no more than 50 g and
 - (iv) that foods containing added plant sterols must not be used as ingredients in other foods.

6.6.2 Non-regulatory measures

In addition to the above regulatory measures, FSANZ encourages the use of available information to support education initiatives on the use of plant sterol-fortified products in the community.

²⁰ SCF (2000). Opinion on a request for the safety assessment of the use of phytosterol esters in yellow fat spreads. Opinion adopted by the Scientific Committee on Food on 6 April 2000, available online at http://europa.eu.int/comm/food/fs/sc/scf/out56_en.pdf
SCF (2002). General view on the long term effects of the intake of elevated levels of phytosterol from multiple dietary sources, with particular attention to the effects on b-carotene. Opinion adopted by the Scientific Committee on Food on 26 September 2002, available online at http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html
SCF (2003). Opinion of the Scientific Committee on Food on Applications for Approval of a Variety of Plant Sterol-Enriched Foods. Adopted on 13 March 2003.

There are several sources of information available to health professionals and consumers on plant sterol-fortified products including the National Heart Foundation, FSANZ and National State and Territory health departments^{21 22 23 24 25}.

In addition, the Applicant has advised FSANZ that it plans to undertake educational initiatives, such as:

- launch of a new health and wellness phytosterol sub-brand, targeted at the 50+ age group
- use of a new brand name to demonstrate distinct separation of plant sterol-fortified cheese products from existing standard products such as 'Kraft Singles' which are currently being consumed largely by children
- television and targeted use of magazine media unique to the target group (50+) to promote these products to the target population
- distributing educational material to medical and nutrition professionals
- displaying specific marketing information on product packages.

FSANZ was advised by the Applicant that the non-regulatory activities will be undertaken commensurate with the release of the plant sterol-fortified cheese products. This will be maintained on an ongoing basis commensurate with the consumer acceptance of these products.

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand.

Novel foods or novel food ingredients are required to be listed in Standard 1.5.1 before they can be sold in Australia or New Zealand. As LiveActive® brand is a novel food and requires pre-market approval under Standard 1.5.1, it is not appropriate to consider non-regulatory options to address this Application.

Two regulatory options have been identified for this Application:

²¹ FSANZ (2007) Fact Sheet: Plant Sterols (also known as phytosterols)
<http://www.foodstandards.gov.au/educationalmaterial/factsheets/factsheets2010/plantsterolsjanuary24705.cfm> Accessed 27 January 2010.

²² NHF(2007) Position Statement on phytosterols/stanol enriched foods. National Heart Foundation of Australia.
<http://www.heartfoundation.org.au/SiteCollectionDocuments/HF%20Phytosterols%20Stanols%20CVD%20PositionSt.pdf>. Accessed 12 June 2009.

²³ NHF(2007) Qs and As on plant sterol enriched foods for the general population. National Heart Foundation of Australia.
<http://www.heartfoundation.org.au/SiteCollectionDocuments/HF%20Phytosterol%20Stanol%20QA%20General.pdf>. Accessed 12 June 2009.

²⁴ DHS (2009) Fact Sheet: Fats and Oils. State of Victoria.
http://www.betterhealth.vic.gov.au/BHCV2/BHCARTICLES.NSF/pages/Fats_and_oils?OpenDocument. Accessed 12 June 2009.

²⁵ DAA (2008) Fact Sheet: Plant Sterols. Dietitians Association of Australia.
<http://www.daa.asn.au/index.asp?PageID=2145842757>. Accessed 12 June 2009.

Option 1: Reject Application, thus not approving the exclusive use of the LiveActive® brand in lower-fat cheese

Option 2: Approve the exclusive use of the LiveActive® brand in lower-fat cheese

8. Impact Analysis

8.1 Affected Parties

Parties affected by the regulatory options outlined above may include:

- consumers, especially target groups such as adults over 40 years of age with health concerns about high serum cholesterol and non-target groups such as pregnant and lactating women and children
- the manufacturing and retail sectors of the food industry
- Government generally, where a regulatory decision may impact on trade or World Trade Organization (WTO) obligations, and State, Territory and New Zealand enforcement agencies

8.2 Benefit Cost Analysis

In developing food regulatory measures for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts.

The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party. Where medium to significant competitive impacts or compliance costs are likely, FSANZ seeks advice from the Office of Best Practice Regulation (OBPR) to estimate compliance costs of regulatory options.

FSANZ has liaised with the OBPR. They approved a preliminary assessment of this Application which has concluded that there were no business compliance costs involved and/or minimal impact and consequently a detailed Regulation Impact Statement (RIS) is not required.

8.2.1 Option 1: *Reject Application, thus not approving the exclusive use of the Live Active® brand in lower-fat cheeses*

8.2.1.1 Consumers

There is no publicly available consumer research as to whether they are satisfied with the current range of plant sterol-fortified foods or whether those consumers currently consuming plant sterol-fortified products would prefer additional food choices in order to decrease their cholesterol levels.

Benefits to consumers of this option may be that there would be less consumer confusion in regard to the most effective way to reduce cholesterol; less chance of overconsumption by target and non-target groups; and less chance of incidental consumption by children, pregnant and lactating women.

Overall, there is a potential cost to consumers with this option in terms of the lack of availability and choice of these specific products. Consumers would not be able to purchase a product that may allow the achievement of an optimal intake of plant sterols on a daily basis.

8.2.1.2 Industry

There is an identifiable opportunity cost to the food industry in terms of a loss of product range and marketing opportunities.

The manufacturer of Live *Active*[®] would be disadvantaged as it would be unable to take advantage of market opportunities to develop and sell these products. They would have incurred a cost in research and development and not achieve the exclusivity requested.

8.2.1.3 Government

There would be no immediate impact on government. There are no benefits to the Government in maintaining a prohibition as there may be a health benefit to consumers compared to the cost of purchasing drugs. There are no perceived costs on jurisdictions that enforce the food regulations although this option may reduce burden on enforcement officers, and reduce diversion of nutrition education resources away from other strategies such as promotion of fruit and vegetable consumption.

8.2.2 Option 2: Approve the exclusive use of the LiveActive[®] brand in lower-fat cheeses

8.2.2.1 Consumers

There is a reported benefit to consumers from consuming plant sterols leading to a reduction in their blood cholesterol. Approval would offer consumers a greater choice to obtain an optimal daily quantity of plant sterols in one serve. The evidence also shows that consumption of lower-fat cheeses under specified conditions, which equate to normal use by consumers, poses no public health and safety risks.

A possible cost, albeit unlikely, is that a wider range of foods containing added plant sterols may lead to consumption of plant sterol-fortified foods in amounts more than necessary to achieve an effect. However, post-launch monitoring data in Europe suggests that consumers do not currently achieve optimal intakes. In addition, there is an advisory statement on the label which serves to inform consumers of the appropriate amount to achieve the intended effect.

8.2.2.2 Industry

This option would provide an alternative novel food ingredient and would increase market opportunities for other future manufacturers of lower-fat cheeses. It would also facilitate greater regulatory alignment with products on the market in Europe and the USA.

8.2.2.3 Government

In the long-term, governments may benefit in terms of health expenditure from lower blood cholesterol in at risk populations associated with the normal and informed use of cheese products although the extent of this benefit is difficult to quantify. A potential cost to jurisdictions that enforce the Code, is the methodology that needs either to be developed or update to test for the presence of plant sterols in foods. However, as there are currently methods available for detection and consequently enforcement of plant sterols in food, these costs should be minimal.

8.3 Comparison of Options

Option 1 does not provide benefits to industry, consumers or enforcement agencies. Option 1 denies industry access to a new novel food ingredient and associated market opportunities. It also denies consumers access to foods containing TO phytosterol esters and any potential benefits from those foods. This option cannot be justified on the basis of protection of public health and safety. It also imposes costs on consumers of loss of choice of new products where their safety has been established.

Option 2 provides benefits to industry in terms of product innovation and development and marketing of foods containing TO phytosterol esters. Consumers may benefit from being able to purchase an increased range of foods with added plant sterols to assist in lowering cholesterol levels. Option 2 does not subject consumers, the community or governments to other costs.

Overall, **Option 2** is preferred because it more clearly achieves the objectives of this assessment: providing a reasonable assurance of the safety of consuming TO phytosterol ester fortified lower-fat cheeses, providing information to consumers that will contribute to the safe consumption of TO phytosterols esters and allows manufacturers and businesses a new source of plant sterols for inclusion in lower-fat cheeses.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

This Application was of interest to a broad range of stakeholders. On this basis the public consultation ensured opportunity to comment on the proposed measures.

FSANZ does not propose any additional communication initiatives to those discussed above.

An updated fact sheet was developed which is available on the FSANZ Website.

FSANZ followed its standards setting process including public notification of all reports, public consultation and decisions relating to this Application.

10. Consultation

10.1 Issues raised in Public Consultation

The Assessment Report was released for public comment from 15 September to 4 November 2009. As this Application was assessed under a General Procedure, there was only one round of public comment.

A total of 14 submissions were received, and a summary of these is provided in **Attachment 2** to this Report. FSANZ has taken the submitters' comments into account in preparing the Approval Report for this Application.

10.1.1 Public health and safety issues

10.1.1.1 Sodium content of processed cheese containing tall oil phytosterol esters

One submitter noted that processed cheese has a significantly higher sodium content than natural cheese (such as cheddar) and recommended that FSANZ consider applying a maximum sodium content of 750 mg/100 g to cheese containing tall oil phytosterols, to align with the National Heart Foundation of Australia Tick criteria.

FSANZ response

Sodium levels in processed cheeses are generally higher than that found in non-processed cheeses due to technological requirements such as the addition of emulsifying salts used to manufacture processed cheese. FSANZ data have reported the sodium levels of processed cheese (<10% fat) is 1440 mg/100 g; in contrast, the reported level of sodium in cheddar cheese (<15% fat) is 670 mg/100 g²⁶.

As noted in Section 6.2.2, there is little information on the substitution patterns of users of cheese containing plant sterols. The information from the mature plant sterol market in Europe does suggest that very few users of plant sterol fortified products consume cheese containing plant sterols. Where they do, only a minority do so on a daily basis. Furthermore FSANZ dietary assessment data suggest that cheese is a small contributor to total salt intakes from processed foods.²⁷

For these reasons, FSANZ considers that permitting the addition of phytosterols is unlikely to have a negative public health impact and therefore does not warrant applying a sodium restriction on cheese containing tall oil phytosterols esters.

Furthermore, there has been a move among industry groups to reformulate specific product lines with lower salt content. The Applicant has provided information that the processed cheese which they seek to add tall oil phytosterol esters to is likely to contain approximately 1050 mg sodium/100 g. While this is greater than that found in cheddar cheese, it is less than that the average found in lower-fat processed cheeses.

These products are required to display their sodium content in the Nutrition Information Panel should consumers wish to compare the sodium levels of different products.

10.1.1.2 Efficacy of TO phytosterols in lower-fat cheeses

One submitter noted that the current drafting permits the addition of tall oil phytosterol esters to cheeses with a fat content less than 9 g fat/100 g, such as cottage cheese. They requested that FSANZ further investigate the efficacy of tall oil phytosterol esters in lower-fat cheese matrices (i.e. cheeses with a fat level of less than 9 g fat /100 g cheese). If efficacy was not demonstrated at lower fat levels, consideration should be given to setting a minimum fat level for lower-fat cheese products.

FSANZ response

With respect to the efficacy in lower fat food matrices, the 13 studies examining the efficacy of plant sterols in lower fat dairy products used dairy foods with widely varying fat contents.

²⁶ NUTTAB 2006

²⁷

<http://www.foodstandards.gov.au/educationalmaterial/factsheets/factsheets2009/howmuch sodium and salt4340.cfm>

The fat content of the dairy products in these studies range from 0.1 g / 100 g (in yoghurt) to 17 g/100 g in hard cheese. All of the lower fat dairy products besides cheese had a fat content less than 3 g/100 g. The evidence shows that plant sterols can deliver a cholesterol lowering effect in dairy products with lower fat contents than proposed by the Applicant. FSANZ considers the efficacy of tall oil phytosterol esters in lower-fat cheese matrices (i.e. fat levels less than 9 g fat/100 g cheese) is well demonstrated.

10.1.1.3 Alignment with overseas regulations

One submitter suggested that the maximum fat content be increased from 9 g fat /100 g cheese to a maximum level of 12 g fat /100 g cheese to align with current regulations set out by the European Community for cheese type products containing plant sterols.

FSANZ response

The European Community currently permits on the market cheese type products containing plant sterols/stanols where the fat content is less than 12g/100g and where the milk fat and/or protein has been partly or fully replaced by vegetable fat or protein.²⁸ One submitter has suggested raising the maximum fat limit to align with this permission.

FSANZ considers that the potential negative public health impact of this amendment to be minimal. As noted previously, only a small number of users of plant sterols products tend to consume cheese products as a source of plant sterols. FSANZ dietary assessment data also indicate cheese is a relatively small contributor to saturated fat intakes in Australia and New Zealand (8% and 6 % respectively), albeit on par with other products such as potato based products (A 5%, NZ 7%), pies and pasties (A 7%, NZ 5%), and other dairy products (excluding milk and butter)(NZ 5%).²⁹

Therefore, FSANZ has proposed to amend the proposed maximum fat content to 12 g fat/100 g cheese in order to harmonise with existing overseas regulations. The Applicant has agreed to this amendment.

10.1.1.4 Use of the term 'reduced-fat'

One submitter recommended that the term 'reduced-fat' not be used to describe the foods in this application, or subsequent documents in light of reduced-fat not being defined in the Code. There are also a number of cheeses that would meet the criteria of 9 g fat/100 g cheese, without being reduced-fat versions (e.g. ricotta).

FSANZ response

The term 'reduced-fat' was used in the Assessment Report as a descriptor for the two products to which the Applicant seeks to add tall oil phytosterols.

²⁸ CD 2004/333/EC authorising the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients. . OJ L 105, 14.4.2004.

²⁹ Saturated fat intakes were estimated with the DIAMOND computer program using a second day nutrient adjustment methodology and were based on data from the 1995 Australian National Nutrition Survey. For details on FSANZ's Dietary Intake Assessment methodology please refer to the FSANZ website

<http://www.foodstandards.gov.au/educationalmaterial/scienceinfsanz/dietaryexposureassessmentsatfsanz/>

The Applicant has provided information which indicated that the proposed products (a lower-fat cream cheese and lower-fat processed cheese) met the guidelines for use of the term 'reduced-fat' set out in the Code of Practice on Nutrient Claims in food labels and in advertisements (CoPoNC) and the Dietary Guidelines for Australian Adults.³⁰

FSANZ is aware that some cheeses (e.g. ricotta, cottage) have less than 9 g fat/100 g cheese although they do not have higher fat counterpart which would allow them to make a 'reduced-fat' claim.

FSANZ has replaced the term reduced-fat cheese with 'lower-fat cheeses', (meaning cheese and processed cheese with a fat content of less 12 g/100 g) in this report when referring to the food vehicles.

10.1.1.5 Reductions in β -Carotene

On submitter commented that they considered a 25% reduction of serum carotenoids significant and sought additional reassurance from FSANZ that there were no negative health impacts for consumers. A recent paper suggests that there is a relationship between antioxidants, including carotenoids, and the early development of diabetes. FSANZ suggested that individuals who were diabetic would be under medical supervision and therefore received advice on their consumption of phytosterol enriched foods. This may not be the case however for consumers who were in a pre-diabetic state and it is questioned whether reliance on medical supervision is sufficient.

FSANZ response

These issues were previously addressed in the 2nd Review Report for Applications A433, A434 and A508 and FSANZ is aware of the paper³¹ that the submitter has referred to in their submission.

Consuming plant sterol fortified foods is associated with a reduction in serum levels of some fat-soluble vitamins and vitamin precursors, particularly β -carotene, a precursor of vitamin A. However, after standardisation of vitamin levels for reduced levels of LDL-cholesterol, no significant changes in mean serum levels of β -carotene, α -tocopherol or other fat-soluble vitamins with consumption of plant sterols have been reported. The evidence from numerous studies shows that vitamin levels remain within a broad natural range considered to be typical of variable diets. In addition, clinical studies have demonstrated that increasing consumption of fruits and vegetables, particularly varieties rich in carotenoids, compensates for lower absorption of fat-soluble vitamins. Overall, consumption of plant sterols does not result in changes in vitamin levels that could be considered nutritionally significant.

10.1.1.6 Potential for excess consumption of plant sterols or consumption by very young children

Two submitters commented that they remained concerned at the potential for excess consumption of plant sterols and one commented that FSANZ had not considered consumption of these products by very young children aged 0-2 years.

³⁰ Note: industry also uses CoPoNC as a guidance tool.

³¹ Ford E.S. et al. The metabolic syndrome and antioxidant concentrations: findings from the third National Health and Nutrition Examination Survey.. *Diabetes* 2003; 52: 2346-52

FSANZ response

FSANZ considered possible extremes of plant sterols intake in previous evaluations, and estimated the 95th percentile of intake of plant sterols to be 4.8 g/day, assuming complete replacement of regular foods with their plant sterol fortified counterparts. Even if consumers then ate two serves of lower-fat cheese on top of this, intake of plant sterols would be 7 g per day. There is no evidence to suggest this level of intake presents any food safety concerns and market research suggests it is very unlikely that consumers would sustain such a level of intake. European market research reviewed as part of this assessment has shown that increased product availability does not appear to be linked to high intake of plant sterols. Generally there seem to be very few consumers whose plant sterol intake would exceed 3 g/day.

A 2007 survey of Australian children showed that approximately 2% of Australian children reported consuming products containing added plant sterols. This survey information enabled FSANZ for the first time to estimate intakes of plant sterols in children aged 2-16 years. Intakes were considerably lower in these children than predicted in previous FSANZ estimates of intake that assumed replacement of existing foods with foods fortified with plant sterols.

FSANZ generally uses food consumption data from national nutrition surveys (NNSs) to predict intake of nutrients or related substances. Australian NNSs do not include children aged under two years and New Zealand surveys do not include children aged under five years. In some cases, FSANZ will use a theoretical diet to estimate intake in infants, (e.g. if there is an increased risk to infants compared to two year olds), but did not do so with this Application as there was no indication that plant sterols present any food safety concerns for infants. In addition, given the low level of consumption found in 2-16 year olds in 2007, it is unlikely that infants would consume these products on more than a very occasional basis. In addition, FSANZ is proposing to retain the current advisory statement about suitability for use in children under the age of five years.

FSANZ concludes that there is no food safety concerns associated with consumption of foods enriched with plant sterols.

10.1.2 Approach to determining the efficacy of TO phytosterols in lower-fat cheeses

One submitter noted that FSANZ used a totality of evidence to support the efficacy of tall oil sterol esters in cheese products, even though no study had been undertaken that demonstrated the reduction of LDL cholesterol resulting from consumption of either of the product formats proposed. It was suggested that this was a change in the FSANZ risk assessment approach as all previous phytosterol products had been required to demonstrate efficacy in the actual matrix. This change in approach should be reflected as a potential alternative method of demonstrating efficacy in the *FSANZ Application Handbook*.

10.1.2.1 FSANZ response

The original FSANZ position was to require efficacy on all new plant sterol-fortified products. However, as the robustness and extent of the data base has increased in relation to plant sterol products, FSANZ has been able to assess efficacy of these products via using a more generic approach. This is particularly highlighted in Application A1024.

The *Application Handbook* should not be used to identify every approach FSANZ will ultimately take in its risk assessments.

10.1.3 Nutrition advice

One submitter noted that, in respect to the target consumers of phytosterol products, the recommendation to consume two serves of cheese per day, as is mentioned in this Application, is inconsistent with current dietary advice for consumers following a heart healthy or cholesterol lowering diet.

10.1.3.1 FSANZ response

At Assessment FSANZ referred to two serves of cheese (total amount 40 g) as being consistent with national nutrition guidelines. This was the Applicant's recommended intake to achieve the optimal amount of plant sterols if cheese were the only phytosterol fortified product consumed.

National nutrition guidelines and bodies, such as the National Heart Foundation provide nutrition advice to assist consumers achieve good health and nutrition. The National Heart Foundation has advised that the latest recommendation is to *include small portions of cheese (one to two slices or 20-40 grams) up to four times a week. Lower fat cheeses, such as light tasty cheddar, ricotta, cottage and light mozzarella, are healthier choices.*³² Cheese and processed cheese with less than 12 g fat/100 g cheese are considered lower fat choices by the National Heart Foundation.

Additionally, information on consumption patterns from mature phytosterol markets, although limited, indicate that most target consumers do not consume cheese containing plant sterols on a daily basis.

FSANZ therefore considers that the recommended serving is not inconsistent with nutrition guidelines.

10.1.4 Consideration of plant sterols as novel foods and the validity of the 15-month exclusivity provisions in Standard 1.5.1

As plant sterols now have a history of consumption and have passed a safety assessment, they should be viewed as no longer novel. Therefore, consideration should be given to removing plant sterols as novel foods, once the exclusivity period expires.

One submitter contends that if exclusivity is granted, the reason is invalid as the Applicant will benefit to the exclusion of all other manufacturers and consumers will lose product competition and price competition.

Another submitter suggested that the clause 3 in Standard 1.5.1 will only give permission to the brand LiveActive® and thus it might be argued that other manufacturers could add tall oil phytosterols to lower-fat cheeses as a precedent is being set by LiveActive® and the exclusive use only applies to one brand, but not necessarily other brands. It was suggested that the exclusive use of tall oil phytosterols esters in lower-fat cheeses be restricted to a company i.e. Kraft Foods Limited, rather than a specific brand. It is further suggested that the brand LiveActive® should not appear in the Standard and the class of food should be reduced-fat cheeses in the plural.

³² personal communication November 2009

10.1.4.1 FSANZ response

The issue in regard to when a novel food is not longer novel will need to be considered in a separate process, other than this Application. It should be noted that in the current Editorial note in Standard 1.5.1, FSANZ is required to review the standard after 3 years and before 5 years from the date of gazettal. Therefore, FSANZ concludes that this would be the appropriate mechanism and time to consider the novel foods standard and exclusivity provisions. If needed, an Applicant could make a specific application to vary the exclusivity provisions of clause 3 of Standard 1.5.1.

The issue of exclusivity was addressed in Proposal P305 – Permission for Exclusivity of Use of Novel Foods and agreed by the Ministerial Council³³. The intention of amending Standard 1.5.1 to include specific provision for exclusive permissions was to make clear that an applicant requesting approval of a novel food is able to apply for a variation to the Standard for a specific brand and class of food. An applicant is required to specify the brand and class of food for which they are seeking exclusivity. An approval for exclusive permission, if approved, would result in an amendment to Standard 1.5.1 to provide exclusivity for the specified brand and class of food for a period of 15 months and would then revert to a general approval for that specific class of food.

In regard to the issue of exclusivity applying only to one brand, FSANZ is of the understanding that a separate Application would be required for permission for another brand of cheese containing plant sterols, until the permissions revert to the general permissions in the Table to clause 2 after the 15-month exclusivity period expires.

It is a requirement of clause 3 to provide a brand name. There is no need to specifically state reduced or lower-fat cheese under the class of the food in Column 3 of the Table to clause 3 of Standard 1.5.1, because there is a maximum limit prescribed for fat under proposed permissions for addition of TO phytosterols to cheese.

10.1.5 Labelling and the legibility of current advisory statements

There was general support for retaining all the current advisory statements on plant-sterol enriched foods, with only one submitter suggesting that the statement in regard to the suitability of these products for children under the age of five years and pregnant or lactating women could be deleted due to a low probability that these products will be consumed by these non-target groups.

A submitter suggested that the legibility of advisory statements on plant-sterol fortified foods is inconsistent and provided specific examples. FSANZ was requested to review this matter and consider whether more stringent requirements need to be associated with advisory statements on plant-sterol fortified products, although no specific suggestions were put forward by that submitter.

Other submitters suggested that the advisory statements on the product be amended to recommend that people using plant sterols should choose at least one daily serve of fruit or vegetables high in β -carotene. This would also be consistent with food products containing phytosterols / phytosterols in Europe where the product label states that consumers should include fruit and vegetables in their diet. FSANZ was requested to consider whether this should also be a requirement for stanol / sterol enriched foods in Australia and New Zealand.

³³ <http://www.foodstandards.gov.au/foodstandards/proposals/proposalp305permissi3617.cfm>

It was suggested that additional advisory statements be considered which recommend that individuals with chronic health conditions seek medical advice before consuming foods with added plant sterols.

Another submitter suggested that FSANZ should adopt all the labelling statements required by the EC as it will provide clarity for consumption of these products. As an absolute minimum FSANZ should adopt stronger wording with respect to the suitability of these products for children under the age of five years and pregnant or lactating women by replacing 'may' not be suitable with 'are' not suitable. The same submitter believes that the mandatory advisory statements should be required to be in a prominent position on the front and at least 12 to 14 font so that the target group can read the labels. In addition, consumers should be advised (on the label) that any cholesterol reductions will be reversed if consumption ceases.

10.1.5.1 FSANZ response

The issue of legibility of plant sterol-enriched products was addressed in section 6.3 of this report. Due to the limited risk of consumption of plant sterol enriched products FSANZ concludes that there is insufficient reason to review these current advisory statements. FSANZ would like to note that ISC members did not raise any new issues with respect to the legibility of advisory statements or enforcement of the Standard. The review of labelling policy and law will inform further consideration regarding legibility.

In regard to the European approach of labelling of plant-sterol fortified products with a recommendation that consumers using phytosterols should choose at least one daily serve of fruit or vegetables high in β -carotene, this issue was extensively considered in the 2nd Review Report for Applications A433, A434 and A508.

On the basis of expert advice FSANZ received during the Second Review, the previous statement on fruits and vegetables was considered not justified on the grounds that the reduction in serum β -carotene is not indicative of any nutritional deficiency and is within natural variation. Therefore, the current mandatory statement to the effect that *when consuming plant sterol enriched foods, these should be consumed as part of a varied and healthy diet* was considered to be more appropriate in the context of general dietary advice.

In regard to consumption of plant-sterol fortified foods by non-target groups, FSANZ concludes that there 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-fortified products to be able to make well-informed decisions on foods that are appropriate to their health needs.

10.1.6 Methods of analysis for plant-sterol foods

One submitter proposed in regard to the method of analysis, the form in which the phytosterols and esters are expressed should be stipulated, for analytical and nutritional reasons. Furthermore, they stated there does not appear to be any analytical methods that have been proposed by the Applicant and the costs of developing a method do not appear to have been fully taken into account in the assessment report.

10.1.6.1 FSANZ response

The Applicant did not propose a method of analysis. FSANZ is of the understanding that there are methods available for detecting plant sterols in foods.

FSANZ has not evaluated the various analytical methods it notes below for suitability and applicability. However, it provides this information from an assessment of the scientific literature, as assistance to enforcement agencies.

Plant sterols have been permitted to be added to food in the Code since June 2001, with the first permission being for the addition of phytosterol esters to edible oil spreads. Since this time the permissions for addition of various plant sterols has been expanded to include permissions for addition of phytosterol esters also to breakfast cereals, low-fat milk and low-fat yoghurt. As well tall oil phytosterols have been permitted to be added to edible oil spreads and low-fat milk. Therefore, analytical methods would have already been required to be developed to ensure compliance for these permissions and it is likely that they can be used or modified to ensure complete analytical capability to meet the requirements from this Application.

The JECFA Chemical and Technical Assessment Report for 'Phytosterols, Phytostanols and their Esters'³⁴ has a section on analytical methods. Three references relevant to analyse plant sterols in foods are provided in this report and are noted to be relevant for any jurisdiction or analytical laboratory aiming to develop a method for determining compliance of levels of plant sterols in food within the permissions in the Code. A GC-FID method commonly used is based on the AOAC Official Method 994.10 for 'Cholesterol in Food'³⁵. Most analytical methods are based on an ISO method³⁶. Another reference for determining plant sterols in various food matrices is Laakso (2005).

Restricting methods to a particular prescribed method or particular group of methods would have costs to the community as alternative equally appropriate methods could not readily be used for compliance monitoring. FSANZ has no details on the costs involved in developing a method of analysis for plant sterol-fortified foods.

10.1.7 RIS and consideration by the Office of the Best Practice Regulator (OBPR)

It was noted that FSANZ liaised with OBPR who concluded that there were no business compliance costs and/or minimal impact and that a detailed RIS was not required. It was requested that FSANZ elaborate on this in the Approval Report.

10.1.7.1 FSANZ response

In accordance with the requirements of the FSANZ Act and the Council of Australian Governments (COAG) guidelines, FSANZ's Regulatory Impact Statements (including cost-benefit analyses) consider the impact of various options on all sectors of the community, including consumers, the food industry and governments in Australia and New Zealand.

The Regulatory Impact Statement relies on input from stakeholders and is subject to clearance from Office of Best Practice Regulation (OBPR), which promotes the Government's objective of improving the effectiveness and efficiency of regulation.

Where medium to significant competitive impacts or compliance costs are likely, FSANZ consults further with stakeholders and OBPR to estimate compliance costs of regulation.

³⁴ Joint FAO/WHO Expert Committee on Food Additives (JECFA), 2008. Phytosterols, phytostanols and their esters. Chemical and Technical Assessment 1-13. Available at http://www.fao.org/ag/agn/agns/jecfa/cta/69/Phytosterols_CTA_69.pdf

³⁵ AOAC Official Method 994.10 for 'Cholesterol in Foods' AOAC International, Gaithersburg (USA)

³⁶ ISO 12228:1999. Animal and vegetable fats and oils – Determination of individual and total sterols contents – gas chromatographic method. International Organisation for Standardization, Geneva, Switzerland.

The level of analysis is commensurate to the issue and the regulatory impacts of the application or proposal.

In relation to this Application, a Best Practice Regulation Preliminary assessment did not identify any additional costs or issues for affected parties. This was approved by OBPR (OBPR Ref 10202), and they confirmed that the proposed changes to permit the addition of phytosterol esters as a novel food ingredient in lower-fat cheeses on an exclusive basis would appear to be of a minor or machinery of government nature and to not substantially alter existing regulatory arrangements.

No further quantitative estimates, including additional enforcement costs from any parties were provided. Any costs incurred by manufacturers (then passed on to the consumers) would be voluntary and determined by market forces rather than regulatory pressures. Affected consumers could always choose to buy a less expensive product.

There were no public health and safety issues identified. Approval of this Application would allow industry to use another food matrix which could be appropriately marketed in order to reduce blood cholesterol levels in the target population. This Application would provide greater choice and therefore FSANZ's Cost Benefit Analysis concluded that there could be a net benefit from this application.

10.1.8 Non-regulatory activities

One submitter was interested in knowing over what period of time the Applicant would undertake additional non-regulatory activities. If this was not effectively produced and disseminated by industry, there may be a significant impact on Government and non-Government organisations to provide dietary advice to consumers.

10.1.8.1 FSANZ response

FSANZ was advised by the Applicant that the non-regulatory activities would be undertaken at the time of release of the plant sterol-fortified cheese products. They would be maintained on an ongoing basis commensurate with the consumer acceptance of these products.

10.1.9 Broader permissions for cheese versus limiting the permission to lower-fat cheese slices and cream cheese products.

FSANZ should explain in the Approval Report the rationale behind providing a broader permission in cheese, rather than limiting the permission to lower-fat cheese slices and cream cheese products.

10.1.9.1 FSANZ response

The rationale was to facilitate a broader permission in the future and to encourage industry innovation without the need for a specific new application for each cheese product.

10.1.10 Portion sizes and clarification of the 1.1 g/serve level

Clarification was sought on the 50 g maximum portion size contained in the draft variation. A serve size of 20 g appears to be more relevant to the application. Discussion was requested in the Approval Report on the justification for and nature of any portion/serve size specified in the proposed draft Variation.

It is noted that although the submission of Kraft Foods was for 0.8-1.0 g phytosterol equivalents per 20 g serve, FSANZ has chosen to base the permission on 1.1 g per serve.

However, it is not clear at which point on the scale of permitted addition (i.e. 70-90 mg/kg) the final concentration of 1.1 g of free phytosterols per 20 g serve applies. It would be helpful if clause 3 (c) in Standard 2.5.4 also stated the equivalent amount of free phytosterol in the product, resulting from the addition of tall oil phytosterol esters.

10.1.10.1 FSANZ Response

The level of 1.1 g of free phytosterol/serve is equivalent to the total phytosterol ester added at 90 g/kg. This provides between 0.87-1.10 g phytosterol equivalents per 20 g serve (70-90 g total phytosterol esters/kg) of which two serves are recommended by the Applicant per day.

The key elements in relation to portion size are as follows:

- The products are lower-fat cheeses, portion-controlled and approximately three portions of cheese would deliver the recommended 3 g, but the recommendations for consumption of the cheeses address two portions.

The portion sizes and presentations that Kraft has requested permissions to use fall within these criteria, and are presented as examples. (The cream cheese mini-tub is equivalent to 4-6 serves if used as a spread, two serves if used as a cheese, or one serve if used as a dessert).

In summary, the cream cheese mini-tub (with a maximum of 40 g) provides two serves/day (20 g/serve which is 2 g free phytosterol equivalents); whereas, the individual cheese slices (20 g/serve) will provide 1 g of free phytosterol equivalents and two serves/day are required to be in the efficacious range.

The upper limit of 50 g per portion is to accommodate the typical serving size of 25 g for spreadable cream cheese in a mini-tub.

10.1.11 Issues in relation to the drafting at Assessment

A number of clarifications and/or suggestions were submitted on the drafting at Assessment:

- whether phytosterol esters would be counted in the total fat but free phytosterols would not?
- there is inconsistency in units in the drafting g/100 g versus g/kg
- in Column 1 of the Table to clause 3 to standard 1.5.1, the novel food is called 'Phytosterol Esters derived from Tall Oils'. In Column 4 it refers to 'tall oil phytosterol esters'. The Standard should refer to these substances either one way or the other, not both
- suggest that column 1 should list the novel food as 'tall oil phytosterol esters' as that is how it is referred to in the rest of the Standard
- in Column 4 - Conditions of Use it reads: *The requirements in clause 2 of Standard 1.2.3*. For the purposes of clarity it should read: *The novel food must comply with the requirements in clause 2 of Standard 1.2.3*

- in column 4 - Conditions of Use it reads: *May only be added to cheese in accordance with Standard 2.5.4*. For the purposes of clarity and readability, it should read: *The novel food may only be added to lower-fat cheese in accordance with Standard 2.5.4*.
- for the purposes of readability subclause 3(a) should be amended to read: *that contains no more than 9 g of total fat per 100 g, excluding free phytosterols*
- in subclause 3(c) the words 'tall oil' should be included before the words 'phytosterol ester'

10.1.11.1 Evaluation

FSANZ has taken these suggestions into account and has revised the drafting where necessary (refer to Attachment 1A):

In summary:

- FSANZ has deleted the reference to total fat excluding any added phytosterols to be consistent with other permissions in the Code for low-fat milk and yoghurt (the intent of the previous drafting and permissions was that the reference to total fat was related to milk fat and excluded any added phytosterols). Therefore, the same intent would exist for cheese.
- In respect to inconsistency in expression of the units in the drafting, this is the usual way that total fat and upper limits for phytosterol esters are usually expressed in foods in other standards in the Code. However, due to this issue being a generic issue in other standards in the Code, FSANZ will endeavour to address these inconsistencies throughout the Code in a separate process.
- The term 'cheese' has replaced the term reduced-fat in the conditions in the Table to clause 3. A revision to use the term lower-fat cheeses has been made in the Reports.

10.1.12 Concurrent consideration of Application A1024

Some submitters noted that FSANZ was concurrently assessing two plant sterol Applications, being this Application and Application A1024.

The issue some submitters have raised is how this general permission should be written. If Application A1024, is approved by the Ministerial Council and it is agreed that various forms of plant sterols are equivalent in terms of their safety and efficacy then some submitters believe that the permission for plant sterols that can be added to lower-fat cheeses should be the generic form of plant sterols i.e. 'phytosterols, phytostanols and their esters' and not the specific type of plant sterols that A1019 relates to, being 'tall oil phytosterol esters'.

10.1.12.1 FSANZ response

The two plant sterol Applications are being assessed and considered concurrently. Under the FSANZ Act, FSANZ must consider both Applications separately and not assume that one or other or both of the Applications would be successful and therefore may have an impact on the other Application. Since the draft variations at Approval for both Applications still need to be considered by the Ministerial Council, FSANZ cannot at this stage confirm the final form of drafting for Application A1019 once the 15-month exclusivity period is completed and by what mechanism it will be amended. FSANZ is aware of the various options that may be available and will deal with them at that time.

Should both Applications be approved, and after the exclusive use period has expired, a specific permission for the use of tall oil phytosterols esters in lower-fat cheese will sit alongside a generic permission for the use of plant sterols in the other permitted foods. The acceptance of Application A1024 would indicate that there is agreement about the equivalence of different types of plant sterols. It might be straight forward to establish equivalence (of efficacy and safety) of all plant sterols in lower-fat cheese based on the evaluation with low-fat milk and yoghurts already conducted as part of the assessment performed for this Application.

If Application A1019 is approved, the exclusive permission is only valid for 15 months. This exclusive permission is limited to the Applicant's brand of cheese products. After the 15 months have expired then the exclusive permission listed in the Table to clause 3 needs to be removed and the permission reverts to a more general permission in the Table to clause 2. As a minimum, the new general permission would mean that other cheese manufacturers can use the permission and produce their own products that meet the conditions of use. FSANZ will consider whether the permissions which replace the exclusive permission are 'phytosterol esters derived from tall oils' or the more generic permission for 'phytosterols, phytosterols and their esters'. FSANZ notes the support of some submitters that the generic permission is the one that should be given once the exclusivity period expires.

Should FSANZ agree to proceed, it will need to determine how to amend the Code to convert the specific exclusivity permission for cheese into a general permission for all plant sterols and not just for phytosterol esters from tall oils after the 15-month exclusivity period expires.

10.2 World Trade Organization (WTO)

As members of the WTO, Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amending the Code to permit the use of TO phytosterol esters as novel food ingredients in lower-fat cheeses was not notified to the WTO under either the Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements, as the permission is unlikely to have a significant effect on international trade, particularly since FSANZ would be expanding an existing permission. There are no relevant international standards and the potential food uses of phytosterol esters under the proposed variation are limited in terms of market size.

CONCLUSION

11. Conclusion and Decision

It is concluded that approval for the use of tall oil phytosterol-esters as a novel food does not pose a public health and safety risk and satisfies the requirements in the FSANZ Act.

Decision

To amend Standard 1.3.4 – to insert a specification for phytosterol esters derived from tall oils to cover the Exclusivity period of 15 months from the date of gazettal

To amend Standard 1.5.1 – Novel Foods to permit the exclusive use of phytosterol esters derived from tall oils to LiveActive® brand cheese and processed cheese in accordance with Standard 2.5.4 – Cheese.

To amend Standard 2.5.4 – Cheese to permit the addition of phytosterol esters derived from tall oils, to cheese and processed cheese containing no more than 12 g fat per 100 g cheese and in amounts of no less than 70 g/kg and no more than 90 g/kg total phytosterol esters.

Reasons for Decision

- there are no safety, nutritional or efficacy concerns with the addition of TO phytosterol esters to lower-fat cheese or lower-fat processed cheese
- there are benefits to industry, consumers and Government in terms of enhanced market opportunities and trade, increased product availability and potential reduction in a health-related risk marker
- lower-fat cheese and lower-fat processed cheese are considered suitable vehicles for TO phytosterol esters and they can effectively be incorporated into the food matrix
- approval for addition to lower-fat cheese and lower-fat processed cheese is consistent with Ministerial policy guidance on the *Addition to Food of Substances other than Vitamins and Minerals*
- the proposed risk management strategy is considered sufficient to manage the low risk associated with consumption of the fortified food
- maintaining a prohibition on the addition of TO phytosterol esters to lower-fat cheese or lower –fat processed cheese is not justified on the basis of the available scientific evidence.

12. Implementation and Review

It is proposed that the draft variations come into effect on the date of gazettal.

ATTACHMENTS

- 1A Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)
- 1B Draft variations to the *Australia New Zealand Food Standards Code* (indicating changes from drafting at Assessment)
- 1C Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)
- 2 Summary of Submissions

Draft variations to the Australia New Zealand Food Standards Code (at Approval)

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

The Editorial note below has been provided for completeness only. It has been shaded to highlight that it is not part of the approval of the amendments to the Standards.

Editorial notes are not, by virtue of the definition of 'standard' part of a draft standard and therefore not subject to the standards development process under Part 3 of Food Standards Australia New Zealand Act 1991.

To commence: on gazettal

[1] Standard 1.3.4 of the Australia New Zealand Food Standards Code is varied by inserting in the Schedule –

Specification for tall oil phytosterol esters

Tall oil phytosterol esters are phytosterols derived from Tall Oil Pitch esterified with long-chain fatty acids derived from edible vegetable oils

Phytosterol Content

Phytosterol esters + free phytosterols	No less than 97%
Free Phytosterols after saponification	No less than 59%
Free phytosterols	No more than 6%
Steradienes	No more than 0.3%

Sterol profile based on input sterols

Campesterol	No less than 4.0% and no more than 25.0%
Campestanol	No more than 14.0%
B-sitosterol	No less than 36.0% and no more than 79.0%
B-sitostanol	No less than 6.0% and no more than 34%
Fatty acid methylester	No more than 0.5%
Moisture	No more than 0.1%
Solvents	No more than 50 mg/kg
Residue on ignition	No more than 0.1%

Heavy Metals

Iron	No more than 1.0 mg/kg
Copper	No more than 0.5 mg/kg
Arsenic	No more than 3 mg/kg
Lead	No more than 0.1 mg/kg

Microbiological

Total aerobic count	No more than 10,000 cfu/g
Combined moulds and yeasts	No more than 100 cfu/g
Coliforms	Negative

E. coli
Salmonella

Negative
Negative

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

[2.1] *omitting wherever occurring in Column 2 of the Table to clause 2 –*

The requirements in clause 2 of Standard 1.2.3.

substituting –

The food must comply with the requirements in clause 2 of Standard 1.2.3.

[2.2] *inserting in the Table to clause 3 –*

Tall oil phytosterol Esters	LiveActive®	Cheese and Processed Cheese	<p>The food must comply with the requirements in clause 2 of Standard 1.2.3.</p> <p>The name 'tall oil phytosterol esters' or 'plant sterol esters' must be used.</p> <p>May only be added to cheese and processed cheese in accordance with Standard 2.5.4.</p> <p>Foods to which tall oil phytosterol esters have been added may not be used as ingredients in other foods.</p> <p>The tall oil phytosterol esters must comply with the specification for LiveActive® tall oil phytosterol esters in Schedule 1 of Standard 1.3.4.</p>
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[3] **Standard 2.5.4** of the Australia New Zealand Food Standards Code is varied by –

[3.1] *inserting after clause 2 –*

3 Tall Oil Phytosterol Esters

Tall oil phytosterol esters may only be added to cheese and processed cheese –

- (a) that contains no more than 12 g total fat per 100 g; and
- (b) that is supplied in an individual portion, the weight of which is no more than 50 g; and
- (c) where the tall oil phytosterol ester is added at no less than 70 g / kg and no more than 90 g / kg.

Editorial note:

See clause 3 of Standard 1.5.1 which provides for the exclusive use of tall oil phytosterol esters in cheese and processed cheese in accordance with the provisions of that clause.

[3.2] *updating the Table of Provisions to reflect the above variations*

Draft variations to the *Australia New Zealand Food Standards Code* (indicating changes from drafting at Assessment)

The Editorial note below has been provided for completeness only. It has been shaded to highlight that it is not part of the approval of the amendments to the Standards.

Editorial notes are not, by virtue of the definition of 'standard' part of a draft standard and therefore not subject to the standards development process under Part 3 of Food Standards Australia New Zealand Act 1991.

Note: New Items were subsequently added to the draft variations at Approval and as a result, the Item numbers in the draft variations at the Assessment stage do not correspond with Item numbers at Approval.

The 'Item [number]' referred to in Attachment 1B corresponds, unless otherwise indicated, to the Item number referred to in Attachment 1A.

1. Item [1]

1.1 At Assessment

No amendment proposed.

1.2 At Approval

[1] **Standard 1.3.4** of the *Australia New Zealand Food Standards Code* is varied by inserting in the Schedule –

Specification for tall oil phytosterol esters

Tall oil phytosterol esters are phytosterols derived from Tall Oil Pitch esterified with long-chain fatty acids derived from edible vegetable oils

Phytosterol Content

Phytosterol esters + free phytosterols	No less than 97%
Free Phytosterols after saponification	No less than 59%
Free phytosterols	No more than 6%
Steradienes	No more than 0.3%

Sterol profile based on input sterols

Campesterol	No less than 4.0% and no more than 25.0%
Campestanol	No more than 14.0%
B-sitosterol	No less than 36.0% and no more than 79.0%
B-sitostanol	No less than 6.0% and no more than 34%
Fatty acid methylester	No more than 0.5%
Moisture	No more than 0.1%
Solvents	No more than 50 mg/kg
Residue on ignition	No more than 0.1%

Heavy Metals

Iron	No more than 1.0 mg/kg
Copper	No more than 0.5 mg/kg
Arsenic	No more than 3 mg/kg
Lead	No more than 0.1 mg/kg

Microbiological

Total aerobic count	No more than 10,000 cfu/g
Combined moulds and yeasts	No more than 100 cfu/g
Coliforms	Negative
<i>E. coli</i>	Negative
<i>Salmonella</i>	Negative

2. Item [2]

2.1 At Assessment

No amendment proposed.

2.2 At Approval

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

3. Item [2.1]

3.1 At Assessment

No amendment proposed.

3.2 At Approval

[2.1] *omitting wherever occurring in Column 2 of the Table to clause 2 –*

The requirements in clause 2 of Standard 1.2.3.

substituting –

The food must comply with the requirements in clause 2 of Standard 1.2.3.

4. Item [2.2]

4.1 At Assessment

[1] **Standard 1.5.1** of the Australia New Zealand Food Standards Code is varied by *inserting in the Table to clause 3 –*

Table to clause 3

Column 1	Column 2	Column 3	Column 4
Novel Food	Brand	Class of Food	Conditions of Use
Phytosterol Esters derived from Tall Oils	LiveActive®	Cheese	<p>The requirements in clause 2 of Standard 1.2.3.</p> <p>The name 'tall oil phytosterol esters' or 'plant sterols esters' must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.</p> <p>May only be added to cheese in accordance with Standard 2.5.4.</p> <p>Foods to which tall oil phytosterol esters have been added may not be used as ingredients in other foods.</p>

4.2 *At Approval*

[2.2] *inserting in the Table to clause 3 –*

Tall oil phytosterol Esters	LiveActive®	Cheese and Processed Cheese	<p>The food must comply with the requirements in clause 2 of Standard 1.2.3.</p> <p>The name 'tall oil phytosterol esters' or 'plant sterol esters' must be used.</p> <p>May only be added to cheese and processed cheese in accordance with Standard 2.5.4.</p> <p>Foods to which tall oil phytosterol esters have been added may not be used as ingredients in other foods.</p> <p>The tall oil phytosterol esters must comply with the specification for LiveActive® tall oil phytosterol esters in Schedule 1 of Standard 1.3.4.</p>
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5. Item [3.1] – for the Draft variation at Assessment

5.1 At Assessment

[3.1] *inserting in the* Table of Provisions, *after* 2 Composition of cheese –

5.2 At Approval

Amendment not included.

6. Item [3.1]

6.1 At Assessment

[3.2] *inserting after* clause 2 –

3 Tall Oil Phytosterol Esters

Tall Oil Phytosterol Esters may only be added to cheese –

- (a) such that the cheese contains no more than 9 g total fat per 100 g excluding free phytosterols; and
- (b) the cheese is supplied in a portion package, the capacity of which is no more than 50 g; and
- (c) where the total phytosterol ester added is no less than 70 g / kg and no more than 90 g / kg.

Editorial note:

See clause 3 of Standard 1.5.1 which provides for the exclusive use of tall oil phytosterol esters in cheese in accordance with the provisions of that clause.

6.2 *At Approval*

[3.1] *inserting after clause 2 –*

3 Tall Oil Phytosterol Esters

Tall oil phytosterol esters may only be added to cheese and processed cheese –

- (a) that contains no more than 12 g total fat per 100 g; and
- (b) that is supplied in an individual portion, the weight of which is no more than 50 g; and
- (c) where the tall oil phytosterol ester is added at no less than 70 g / kg and no more than 90 g / kg.

Editorial note:

See clause 3 of Standard 1.5.1 which provides for the exclusive use of tall oil phytosterol esters in cheese and processed cheese in accordance with the provisions of that clause.

7. Item [3.2]

7.1 *At Assessment*

No amendment proposed.

7.2 *At Approval*

[3.2] *updating the Table of Provisions to reflect the above variations*

**Draft variations to the *Australia New Zealand Food Standards Code*
(at Assessment)**

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

The Editorial note below has been provided for completeness only. It has been shaded to highlight that it is not part of the approval of the amendments to the Standards.

Editorial notes are not, by virtue of the definition of ‘standard’ part of a draft standard and therefore not subject to the standards development process under Part 3 of Food Standards Australia New Zealand Act 1991.

To commence: on gazettal

[1] *Standard 1.5.1 of the Australia New Zealand Food Standards Code is varied by inserting in the Table to clause 3 –*

Table to clause 3

Column 1	Column 2	Column 3	Column 4
Novel Food	Brand	Class of Food	Conditions of Use
Phytosterol Esters derived from Tall Oils		Cheese	<p>The requirements in clause 2 of Standard 1.2.3.</p> <p>The name ‘tall oil phytosterol esters’ or ‘plant sterols esters’ must be used when declaring the ingredient in the ingredient list, as prescribed in Standard 1.2.4.</p> <p>May only be added to cheese in accordance with Standard 2.5.4.</p> <p>Foods to which tall oil phytosterol esters have been added may not be used as ingredients in other foods.</p>

[3] *Standard 2.5.4 of the Australia New Zealand Food Standards Code is varied by –*

[3.1] *inserting in the Table of Provisions, after 2 Composition of cheese –*

3 Tall Oil Phytosterol Esters

[3.2] *inserting after clause 2 –*

3 Tall Oil Phytosterol Esters

Tall Oil Phytosterol Esters may only be added to cheese –

- (a) such that the cheese contains no more than 9 g total fat per 100 g excluding free phytosterols; and
- (b) the cheese is supplied in a portion package, the capacity of which is no more than 50 g; and
- (c) where the total phytosterol ester added is no less than 70 g / kg and no more than 90 g / kg.

Editorial note:

See clause 3 of Standard 1.5.1 which provides for the exclusive use of tall oil phytosterol esters in cheese in accordance with the provisions of that clause.

Attachment 2

Summary of Submissions

Submitter	Comment
Australian Food and Grocery Council	Supports the Application
National Foods Australia Pty Ltd	<p>Supports the Application</p> <p>But recommends a maximum sodium content of 750 mg/100 g apply. This is in contrast to approximately 1300mg of sodium per 100g that would normally be contained in processed cheese. The lower recommended sodium level aligns with the National Heart Foundation of Australia Tick criteria.</p> <p>The recommended modification also aligns with the amount of sodium needed for the production of many natural cheeses, such as cheddar cheese. Processed cheese has significantly higher sodium content than natural cheese because of the addition of sodium phosphate salts. These sodium phosphate salts can be replaced with non-sodium salts reducing the total sodium content of the product to that of many natural cheeses, such as cheddar cheese which contains 550-660 mg of sodium per 100 g.</p> <p>Considers that the current mandatory advisory statement discouraging consumption by children under 5 years and pregnant and lactating women of plant sterol fortified products are sensible and advantageous in helping to protect these sensitive population groups.</p>
Forbes Medi-Tech Inc Canada	<p>Supports the Application</p> <p>However, disagrees with the 15-month exclusivity period and proposes that maximum fat content be increased from 9 g fat per 100 g cheese to the European maximum level of 12 g fat per 100 g cheese.</p> <p>Contends that if exclusivity is granted, the reasons are invalid. The applicant will benefit to the exclusion of all other manufacturers. Consumers will lose product competition and price competition.</p>
Raisio Nutrition Ltd	<p>Supports the Application</p> <p>However, with the proviso, that after the mandatory period, if FSANZ have enacted legislation accepting application A1024 seeking equivalence of plant stanols, sterols & their fatty acid esters the legislation will be adapted to fit in with this status.</p> <p>Believes that over consumption is not a risk issue.</p> <p>Adequate pack warning will alert consumers as to the difference in the product and its specific use.</p>
Food Technology Association of Australia	<p>Supports the Application</p> <p>With following comments:</p> <p>1. Clause 3 in Standard 1.51 will only give permission to the brand <i>LiveActive</i>® and thus it might be argued that other manufacturers could add Tall Oil Phytosterols to reduced-fat cheeses as a precedent is being set by <i>LiveActive</i>® and the exclusive use only applies to one brand but not necessarily other brands.</p>

Submitter	Comment
	<p>2. Suggested that the exclusive use of TO Phytosterols in reduced fat cheeses be restricted to a company, i.e. Kraft Foods Limited, rather than a specific brand.</p> <p>3. Further suggested that the brand <i>LiveActive</i>® should not appear in the Standard.</p> <p>4. The Class of Food should be 'reduced-fat cheeses' in the plural.</p> <p>5. The question is asked as to whether Tall Oil Phytosterols can still be regarded as 'non-traditional' and therefore 'Novel' as Tall Oil Phytosterols have been a part of the Australia/New Zealand diet since 2002?</p>
<p>Population Health Queensland</p>	<p>Neither accepts nor rejects the Application, but intend to review their position depending on the provision of additional information.</p> <p>Concerned over case-by-case approach for approval of each phytosterol-containing food.</p> <p>Suggested that the legibility of advisory statements on phytosterol-containing foods is inconsistent and provided examples of labels to support this.</p> <p>Interested in knowing over what period of time the Applicant will undertake additional non-regulatory activities. If this was not effectively produced and disseminated by industry, there may be a significant impact on Government and non-Government organisations to provide dietary advice to consumers.</p> <p>In regard to the method of analysis, the form in which the phytosterols and esters are expressed should be stipulated, for analytical and nutritional reasons. There does not appear to be any analytical methods that have been proposed by the Applicant. The costs of developing a method do not appear to have been fully taken into account in the assessment report.</p> <p>Noted that FSANZ liaised with OBPR who concluded that there were no business compliance costs and/or minimal impact and that a detailed RIS was not required. Requested that this be elaborated on in the Approval report.</p> <p>Commented on the interpretation of the current drafting-whether phytosterol esters would be counted in the total fat but free phytosterols would not be. Questioned whether this was what was intended in the drafting. Highlighted the potentially confusing inconsistency in units in the drafting g/100 g versus g/kg.</p>
<p>New Zealand Food Safety Authority (NZFSA)</p>	<p>Supports the Application</p> <p>Has reviewed the FSANZ Risk Assessment Report, and agrees with the FSANZ conclusion that a reference health standard is not necessary.</p> <p>Agrees that the current mandatory advisory statements that apply to the current plant sterol fortified products should also apply to tall oil phytosterol esters added to reduced-fat cheese products.</p> <p>Asks that FSANZ explain in the Approval Report the rationale behind providing a broader permission, rather than limiting the permission to reduced fat cheese slices and cream cheese products.</p> <p>Believes that cream cheese falls within the definition of cheese in clause 1 (b) of Standard 2.5.4. Therefore agree that the proposed drafting will allow the permission sought. It will however also allow the addition of tall oil phytosterol esters to other low fat cheeses, such as cottage cheese which is lower in fat.</p>

Submitter	Comment
	<p>Considers the efficacy of tall oil phytosterol esters in lower-fat cheese matrixes (i.e. fat levels lower than 9 g per 100 g cheese) should be discussed in the Approval Report. If efficacy is not demonstrated at lower fat levels, consideration should be given to setting a minimum fat level for reduced fat cheese products.</p> <p>Seeks clarification on the 50 g maximum portion size contained in the draft Variation. A serve size of 20 g appears to be more relevant to the application. Therefore, considers that discussion is required in the Approval Report on the justification for and nature of any portion/serve size specified in the proposed draft Variation.</p> <p>It is not clear at which point on the scale of permitted addition (i.e. 70-90 mg/kg) the final concentration of 1.1 g of free phytosterols per 20g serve applies. It would be helpful if clause 3 (c) to standard 2.5.4 also stated the equivalent amount of free phytosterol in the product, resulting from the addition of tall oil phytosterol esters.</p> <p>A number of suggestions were provided on the drafting:</p> <ul style="list-style-type: none"> • in Column 1 of the Table to clause 3 to standard 1.5.1, the novel food is called 'Phytosterol Esters derived from Tall Oils'. In Column 4 it refers to 'tall oil phytosterol esters'. The Standard should refer to these substances either one way or the other, not both • suggest that column 1 should list the novel food as 'tall oil phytosterol esters' as that is how it is referred to in the rest of the Standard • in Column 4 - Conditions of Use it reads: <i>The requirements in clause 2 of Standard 1.2.3</i>. For the purposes of clarity it should read: <i>The novel food must comply with the requirements in clause 2 of Standard 1.2.3</i> • in column 4 - Conditions of Use it reads: <i>May only be added to cheese in accordance with Standard 2.5.4</i>. For the purposes of clarity and readability, it should read: <i>The novel food may only be added to lower-fat cheese in accordance with Standard 2.5.4</i>. • for the purposes of readability subclause 3(a) should be amended to read: <i>that contains no more than 9 g of total fat per 100 g, excluding free phytosterols</i> • in subclause 3(c) the words 'tall oil' should be included before the words 'phytosterol ester' <p>The proposed amendment to the Table in clause 3 has the registered trademark symbol inserted at the end of the word LiveActive. LiveActive is not a registered trademark in New Zealand. Understands that an application was made by Kraft in July 2009, but it has not yet been registered. Suggests that the status of any New Zealand registration is checked at the time the Approval Report is drafted.</p>
National Heart Foundation of Australia	<p>Supports the Application</p> <p>On the basis of the scientific literature, believes that there would not be any adverse effects to public health and safety in approving this application.</p> <p>Therefore supports reduced-fat cheese as a valid food vehicle for the addition of phytosterol esters.</p>

Submitter	Comment
	<p>Supports the current FSANZ mandatory advisory statement: <i>this product may not be suitable for children under the age of five years and pregnant or lactating women</i>. Only recommends plants sterols for adults with raised LDL-cholesterol; they are not needed for the general population.</p> <p>The advisory statements on the product should be amended to recommend that people using phytosterols should choose at least one daily serve of fruit or vegetables high in beta-carotene. Suggest that information is provided by the manufacturer with the product.</p>
Kraft Foods Ltd (the Applicant)	<p>Supports the Application</p> <p>It is noted that although the submission of Kraft Foods was for 0.8 g - 1.0 g phytosterol equivalents per 20 g serve, FSANZ has chosen to base the paper on 1.1 g per serve.</p> <p>Description of the Cream Cheese packaging. The submission by Kraft Foods mentioned a mini tub providing two serves rather than a twin tub.</p> <p>Questions the need for the statement: 'this product may not be suitable for children under the age of five years and pregnant or lactating women'. Given the way these products are targeted, there is a low probability that these products will be consumed by these demographics. Further, given the small size of these packs and the requirements to provide all the required information, it will be difficult to make the warning statements noticeable. Removing one allows the others to become more prominent.</p>
Dietitians Association of Australia	<p>Supports the Application</p> <p>Concern is raised over the possible overconsumption of this and other phytosterol /phytostanol enriched products.</p> <p>Supports the continued use of the current FSANZ mandatory advisory statement: <i>this product may not be suitable for children under the age of five years and pregnant or lactating women</i>.</p> <p>Recommends that people using phytosterols should also choose at least one daily serve of fruit or vegetables high in beta-carotene. This is an important key message for the Applicant to consider in any communications to the target group.</p> <p>Food products containing phytostanols / phytosterols in Europe state people should include fruit and vegetables in their diet on the product label. Asks FSANZ to consider whether this should also be a requirement for stanol / sterol enriched foods in Australia and New Zealand.</p> <p>Notes the concurrent application A1024 - Equivalence of Plant Stanols, Sterols and their Fatty Acids Esters is being considered. If this Application is approved, suggests the permission should potentially be widened to include other sources of sterols and stanols, not just tall oil phytosterol esters, as the research appears to demonstrate similar efficacy.</p>
Department of Human Services, Victoria	<p>Supports the Application</p> <p>However has concerns about the classification of tall oil phytosterol esters as a novel food and the exclusive use of this permission.</p> <p>To ensure regulatory consistency, this Application should be considered in conjunction with A1024.</p>

Submitter	Comment
	<p>As FSANZ has concluded that reductions in carotenoids from consumption of plant sterols does not pose a health risk and can be mediated by an increased consumption of dietary carotenoids, suggests that this be explicitly stated on the labels as per the approach in Europe. This would replace the current statement:</p> <p>The product should be consumed as part of a healthy diet.</p> <p>As plant sterols now have a history of consumption and have passed a safety assessment, they should be viewed as no longer novel. Therefore, consideration should be given to removing plant sterols as novel foods, once the exclusivity period expires.</p> <p>As the drafting refers to a maximum fat level (<9g/100g) it is recommended that the term 'reduced-fat' not be used to describe the foods in this application, or subsequent documents in light of reduced-fat not being defined in the Code. There are also a number of cheeses that would meet this definition, without being reduced-fat versions (e.g., ricotta).</p>
SA Health	<p>Concerned about the reduction in levels of beta carotene linked with phytosterol consumption, particularly for individuals with levels already at the lower end of the natural range. A 25% reduction of serum carotenoids is considered significant and therefore seeks additional reassurance from FSANZ that there are no negative health impacts for consumers.</p> <p>Supports maintaining the current labelling requirements for all phytosterol enriched food products. In addition, suggested that additional advisory statements be considered which recommend that individuals with chronic health conditions seek medical advice before consuming foods with added phytosterols.</p> <p>There are now a number of different phytosterol enriched foods on the market in Australia and New Zealand. The recommendation is that consumption of 1-3g per day of phytosterol esters is optimal. This application is intended to provide up to 2.2 g phytosterols via the consumption of 2 slices of cheese, meaning that consumption of other phytosterol enriched foods would quickly take intakes to more than 3g.</p> <p>Despite research from EFSA showing that most purchasers of these products consume only 1-2 serves per day on a regular basis, concerns are still raised regarding the potential for excess consumption of phytosterol enriched foods.</p> <p>A holistic assessment of intakes across the whole food supply in Australia and New Zealand rather than a case by case approach to approvals is recommended prior to granting any additional permission.</p>
Food and Nutrition Special Interest group (FANSIG) Public Health Association of Australia	<p>Does not support approval</p> <p>Considers that plant-sterol enriched foods are unnecessary for the prevention and management of chronic disease and that a healthy diet leads to a more effective outcome.</p> <p>Concerns over medicalisation of food supply and possible self diagnosis and treatment rather than seeking appropriate dietary and medical advice.</p> <p>Maintains that applications for approval of plant sterol-enriched products should be concurrent rather than on a case-by-case basis.</p>

Submitter	Comment
	<p>The advisory statement limiting consumption to a maximum of 2-3 serves/day implies a therapeutic dose.</p> <p>FSANZ has not considered the effects of consumption of plant sterol-enriched products in the 0-2 year age group. Urges FSANZ to adopt the precautionary principle in respect of non-target consumers.</p> <p>FSANZ should adopt all the labelling statements required by the European Commission as it will provide clarity for consumption of these products. As an absolute minimum FSANZ should adopt stronger wording with respect to the suitability of these products for children under the age of five years and pregnant or lactating women by replacing 'may' not be suitable with 'are' not suitable.</p> <p>Believes that the mandatory advisory statements should be required to be in a prominent position on the front and at least 12 to 14 font so that the target group can read the labels.</p> <p>Also believes that consumers should be advised (on the label) that any cholesterol reductions will be reversed if consumption ceases.</p> <p>Believes that pamphlets, websites and industry initiated advertising are insufficient to satisfactorily educate the general population (particularly those from low socioeconomic backgrounds). However, did NOT suggest what the best way was.</p>
Unilever Australasia	<p>Supports the Application</p> <p>Although there are no public health and safety concerns, supports retaining the labelling statement 'this product may not be suitable for children under the age of five years and pregnant or lactating women' as these groups are not the target audience.</p> <p>Noted that FSANZ used a totality of evidence to support the efficacy of tall oil sterol esters in low fat cheese products, even though no study has been undertaken that demonstrates the reduction of LDL cholesterol in either of the product formats proposed.</p> <p>This is a change in the FSANZ risk assessment approach as all previous phytosterol products have been required to demonstrate efficacy in the actual matrix. This change in approach should be reflected as a potential alternative method of demonstrating efficacy in the Application Handbook.</p> <p>In respect to consistency with current nutrition advice, recommending two serves of cheese per day, even low fat cheese as is mentioned in this application, is inconsistent with current dietary advice for consumers following a heart healthy or cholesterol lowering diet.</p>