

23 September 2009
[16-09]

APPLICATION A1019

EXCLUSIVE USE OF PHYTOSTEROL ESTERS IN

REDUCED-FAT CHEESE PRODUCTS

ASSESSMENT 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 phytosterol esters as a novel food ingredient in reduced-fat cheese (e.g. individually wrapped cheese slices and tubs of spreadable cheese). The Applicant has requested exclusive use of this permission. In accordance with the Applicant's request, the regulatory measures for tall oil phytosterol esters in reduced-fat cheese, if approved, will provide exclusive use for tall oil phytosterol esters in Kraft reduced-fat cheese (LiveActive®) for a period of 15 months from the date of gazettal.

The Applicant advises that extending permissions to reduced-fat cheese would increase the variety of products available to those seeking blood cholesterol reductions and do so in a manner which would enable better measurement of plant sterol intake.

The use of tall oil 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 reduced-fat cheese.

The specific objectives in considering this Application are to:

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

FSANZ has previously concluded that consumption of plant sterol-fortified foods raised no safety concerns and a reference health standard is not warranted. In 2008, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a group Acceptable Daily Intake (ADI) for plant sterols of 40 mg/kg bw. FSANZ has re-evaluated the basis for this ADI and finds no justification for establishing an ADI for plant sterols.

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 tall oil phytosterol esters in reduced-fat cheeses poses no increased health risk when compared to currently approved plant sterol-fortified foods. Furthermore, plant sterols added to reduced-fat cheese can deliver a cholesterol-lowering effect. The key risk assessment findings are detailed in **Supporting Document 1**¹.

A small proportion of children aged 2–16 years are likely to consume reduced-fat cheese products 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 tall oil phytosterol esters in reduced-fat 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:
 - that reduced-fat cheese must contain no less than 70 g/kg and no more than 90 g/kg tall oil phytosterol esters
 - the cheese is supplied in a portion, the capacity of which is no more than 50 g
 - that foods containing added plant sterols must not be used as ingredients in other foods
 - the cheese must not contain more than 9 g total fat/100 g cheese excluding tall oil phytosterol esters.

The Applicant has proposed 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.

The key risk management issues are discussed in Section 6.

Assessing the Application

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

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
- there are no 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

¹ Supporting Document 1: Risk Assessment Report

- any relevant New Zealand standard
- any other relevant matters.

Preferred Approach

The preferred approach is to:

Amend Standard 1.5.1 – Novel Foods to permit the addition of phytosterol esters derived from tall oils to cheese in accordance with Standard 2.5.4 – Cheese.

Amend Standard 2.5.4 – Cheese to permit the addition of phytosterol esters derived from tall oils, to cheese containing no more than 9 g fat per 100 g cheese (excluding tall oil phytosterol esters), and in amounts of no less than 70 g/kg and no more than 90 g/kg total phytosterol esters.

Reasons for Preferred Approach

- there are no safety, nutritional or efficacy concerns with the addition of tall oil phytosterol esters to reduced-fat 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
- reduced-fat cheese is considered a suitable vehicle for tall oil phytosterol esters and they can effectively be incorporated into the food matrix
- approval for addition to reduced-fat 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
- maintaining a prohibition on the addition of tall oil phytosterol esters to reduced-fat cheese is not justified on the basis of the available scientific evidence.

Consultation

FSANZ acknowledges that this Application will be of interest to a broad range of stakeholders and has applied a general communication strategy to this Application. This will involve advertising the availability of the Assessment Report for public comment in the national press and making the reports available on the FSANZ website.

In addition, individuals and organisations that make submissions on this Application will be notified at each stage of the Application. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify the Ministerial Council of its decision. Stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the FSANZ website.

² Refer to Supporting Document 2

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 4 November 2009

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND Tel (04) 473 9942**

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SUPPORTING DOCUMENTS

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/standardsdevelopment/applications/applicationa1019phyt4161.cfm>

SD1: Risk Assessment report

SD2: Policy guidance on the *Addition to Food of Substances other than Vitamins and Minerals*

INTRODUCTION

A paid Application was received from Kraft Foods Ltd on 14 November 2008. The Application seeks to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of tall oil phytosterol (tall oil) esters as a novel food ingredient in cheese (<9 g fat per 100 g 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 tall oil phytosterol esters in its reduced-fat cheese product LiveActive[®] for a period of 15 months.

The Applicant is seeking specific permission to add tall oil phytosterol esters to cheese (<9 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 the consumer's awareness of how much plant sterol is contained within each serve, and to consume the optimal amount to achieve the intended effect.

The Applicant has also advised FSANZ that the purpose of the Application is to increase the variety of foods available to consumers seeking blood cholesterol reduction and to deliver this in a manner which is portion controlled to better enable measurement of intake.

This Assessment Report discusses the issues involved in the proposed addition of tall oil phytosterol esters to reduced-fat cheese, and seeks comments from stakeholders on the risk assessment, preferred risk management approach and proposed draft variations to the Code.

1.1 Definitions and terminology

The following 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>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.

Under the Code of Practice on nutrient claims in food labels and in advertisements (CoPoNC)⁴ and the Dietary Guidelines for Australian Adults,^{5 6} a reduced-fat product contains no more than 75% of the total fat content of the same quantity of a reference food, in this case a full fat cheese.

³ One cheese slice will deliver 1.1 g phytosterols and thus the consumer knows exactly how much they have consumed.

⁴ ANZFA (1995) Code of Practice on Nutrient Claims in food labels and in advertisements.

⁵ NHMRC (2003) Dietary Guidelines for Australian Adults.

<http://www.nhmrc.gov.au/publications/synopses/files/n33.pdf>. Accessed 20 August 2009.

⁶ FSANZ is not aware of any definition of reduced-fat for New Zealand.

The Applicant has provided information that an equivalent full fat cheese contains >21 g fat/100 g cheese. Therefore, cheese with <9 g fat/100 g could be considered a reduced-fat food.

1. The Issue / Problem

The Applicant is requesting permission to add tall oil phytosterols to reduced-fat cheese products 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.

The use of tall oil 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 reduced-fat cheese. FSANZ considers the Applicant's tall oil phytosterol product (LiveActive®) would be considered a novel food under Standard 1.5.1 and therefore requires 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 the Novel Food 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 sub-clause 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 'healthy' breakfast cereals (low sugar and high fibre)⁷, reduced-fat milk and reduced-fat yoghurt⁸, and tall oil derived phytosterols to edible oil spreads and reduced-fat milks⁹ were approved. 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 per day, 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 0.8-1.0 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 diet¹⁰
- the product may not be suitable for children under the age of 5 years and pregnant or lactating women¹¹
- plant sterols do not provide additional benefits when consumed in excess of 3 g per day¹².

2.2.1 Other related Applications

Application A 604 – Phytosterols in Fruit Juice and Fruit Juice Drinks seeks 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 application system in the FSANZ Act prior to 1 October 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 to adopt the specifications published by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) in 2008. This is currently at Assessment stage.

⁷ FSANZ (2006) Application A433 – Phytosterol Esters derived from Vegetable Oils to Breakfast Cereals. Second Review Report. 4 October 2006. FSANZ, Canberra

⁸ FSANZ (2006) Application A434 – Phytosterol Esters derived from Vegetable Oils to Reduced-fat Milks and Yoghurt. Second Review Report. 4 October 2006. FSANZ, Canberra

⁹ FSANZ (2006) Application A508 – Phytosterols derived from a Tall Oil Source as ingredients in low fat milk. Second Review Report. 4 October 2006. FSANZ, Canberra

¹⁰ Plant sterols are permitted only in foods that are compatible with a healthy diet (e.g. reduced-fat milk, reduced-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.

¹¹ 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.

¹² 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.

2.3 Relevant Overseas Regulations

In Europe, phytosterols and their esters are permitted in a wide variety of foods¹³ including reduced-fat (≤ 12 g/100 g) cheese type products. 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 day¹⁴.

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 claims¹⁵. 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 1.5-2.4 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.

¹³ Foods authorised to contain plant sterols under Regulation (EC) 258/97 include yellow fat spreads, milk-type products, yoghurt-type products, milk-based fruit drinks, soy drinks, rice drinks, spicy sauces, salad dressings and certain rye breads.

¹⁴ 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>

¹⁵ http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/nda_op_ej1175_plantsterols_stanols_summary_en.0.pdf?ssbinary=true

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
- the daily dietary intake of plant sterol or stanol esters that is necessary to reduce the risk of coronary heart disease 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 coronary heart disease 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 coronary heart disease.

3. Objectives

The specific objectives in considering this Application are to:

- protect public health and safety in relation to the proposed addition of tall oil phytosterol esters to reduced-fat cheese
- ensure adequate information relating to tall oil phytosterol ester reduced-fat cheese is provided to consumers to enable informed choice
- prevent misleading or deceptive conduct by ensuring that tall oil phytosterols can deliver an effect through reduced-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 is in **Supporting Document 2**¹⁶.

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 tall oil phytosterols to reduced-fat cheese falls under ‘Any Other Purpose’ and therefore regard will be given to the policy guidance in the assessment of this Application. The relevant specific order policy principles are stated below.

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.*

¹⁶ Supporting Document 2: Policy Guideline on the *Addition to Food of Substances other than Vitamins and Minerals*.

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 reduced-fat cheese?
- what new information relevant for assessing the safety of plant sterols in reduced-fat cheese 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 reduced-fat cheese?
- what impact could the introduction of reduced-fat cheese fortified with tall oil 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?

5. RISK ASSESSMENT

FSANZ has previously assessed and characterised the risk from consumption of plant sterol-fortified edible oil spreads, breakfast cereals, low fat milks and low fat yoghurts for the Australian and New Zealand population groups.

The approach taken in this risk assessment report is 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 tall oil phytosterol esters in reduced-fat cheese products. Given the comprehensive nature of previous assessments concerned with plant sterols, the primary focus of this risk assessment report is 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**¹⁷.

The key findings from the risk assessment are:

- on the basis of an assessment of the properties of the tall oil phytosterol esters and the manufacturing process by which they are added to reduced-fat cheese, it is concluded they will deliver a consistent amount of phytosterols and they are likely to remain stable during storage under usual conditions
- on the basis of the available safety data, the use of plant sterols in reduced-fat cheese 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 small reduction in the absorption of carotenes with intake of plant sterols is explained by the reductions in serum levels of carrier LDL cholesterol attributed to plant sterols. It is not considered to be of nutritional significance and is partially compensated by additional fruits and vegetables in the diet

¹⁷ Supporting Document 1-Risk Assessment Report

- consumption of plant sterols is not associated with any increase in cardiovascular disease risk
- consumption of reduced-fat cheese products 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 reduced-fat cheese, 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) are likely to consume reduced-fat cheese containing added tall oil 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. 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 tall oil phytosterols to reduced-fat cheese.

6.1 Risk to public health and safety

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

The Second Review Report for Applications A433, A434, and A508 comprehensively assessed the risk to public health and safety of plant sterols.¹⁸ 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
- 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 tall oil phytosterol esters in reduced-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 likely to be a very small proportion of children (2-3%) aged 2-16 years who consume phytosterol-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 tall oil phytosterol esters were permitted to be used in reduced-fat cheese, it is likely there will be some incidental intake of plant sterols from these products by children aged 2-16 years and pregnant and lactating women. Evidence from the European market indicates that the proportion of people consuming reduced-fat cheese products with plant sterols is much lower than for other plant sterol fortified products.

FSANZ considers that the consumption of plant sterols fortified reduced-fat cheese 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.

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

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 sterols fortified reduced-fat cheese.

FSANZ invites comment on the advantages and disadvantages of applying the current mandatory advisory statement (below) discouraging consumption by children under 5 years and pregnant or lactating women of plant sterol fortified products-

‘this product may not be suitable for children under the age of five years and pregnant or lactating women’

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’.

The Policy Guidance also includes in relation to implementation: *Negative public health impact may be prevented by ensuring that, if it is considered likely that an unhealthy consumption pattern may result from an addition of a substance, certain foods could be prevented from having substances added.*

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

For this Assessment, FSANZ considered the purpose for adding tall oil phytosterol esters to reduced-fat cheeses is to lower blood low density lipoprotein (LDL) cholesterol levels in hypercholesterolaemic individuals.

In considering whether the addition of tall oil phytosterol esters to reduced-fat cheese meets policy principle c), the primary focus of FSANZ’s assessment is on the ability of the fortified food to lower blood LDL cholesterol. A secondary focus is whether the introduction of tall oil phytosterol-fortified reduced-fat cheese would provide greater choice to consumers.

The efficacy of tall oil phytosterol esters to lower LDL cholesterol when delivered through reduced-fat cheese is discussed in **Supporting Document 1** to this Report. Based on the current evidence, it is concluded 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 reduced-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.

It is important to note that in addition to the amount of plant sterols and the food matrix through which they are consumed, genetic variation, ethnicity, hormonal status, frequency and timing of consumption, baseline diet and cholesterol levels of the subject all influence the effectiveness of phytosterols to lower cholesterol. FSANZ dietary modelling indicates there is a small but increasing proportion of the target population in Australia which currently consume reduced-fat cheeses.

In addition, post market consumption data from Europe (See **Supporting Document 1**) indicates that consumers do choose plant sterol-fortified reduced-fat cheese as a source of plant sterols. Therefore FSANZ concludes that extending permissions to reduced-fat cheese would provide an additional source of plant sterols in a food vehicle which is consumed by the target population.

Based on this assessment, FSANZ concludes that the addition of tall oil esters to reduced-fat cheese is consistent with policy principle c).

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 reduced-fat cheese, in all consumers, poses no health and safety risk.

FSANZ also considered the potential public health risk that could arise from a change to consumption patterns, if permissions were given. In particular, FSANZ considered the likelihood that these permissions would result in a change to the overall energy or macronutrient (e.g. saturated fat) intake, which could lead to a negative public health effect in consumers.

It is well known that high energy (leading to obesity) and saturated fat intakes is causally associated with an increased risk to health. The Australian, State/Territory and New Zealand governments, and other bodies have undertaken interventions to reduce these risk factors including the development of guidelines for healthy eating. With respect to cheese, these guidelines recommend the general population consume reduced-fat dairy products, including cheese, and suggest a total daily intake of approximately two serves (2 x 40 g serve in the case of cheese)^{19 20 21 22 23}. Two of these bodies also recommend those with high cholesterol to limit cheese intake to two to four times per week^{19 20}.

With respect to reduced-fat cheese, the food itself is lower in energy and saturated fat compared to full fat alternatives but confers nutritional benefits such as calcium, fat soluble vitamins and protein. Eating reduced-fat cheese within the context of a normal diet is not likely to impact adversely on macronutrient balance. In addition, the amount recommended to achieve the optimal phytosterol intake (two serves) is consistent with the various dietary guidelines as noted above.

As noted in the Risk Assessment Report (**Supporting Document 1**) there is limited data on the intake of processed cheese and cream cheese products in Australia and New Zealand and the consumption patterns of consumers of plant sterol-fortified cheeses.

¹⁹ NHF (2009) Healthy eating and drinking tips. National Heart Foundation. <http://www.heartfoundation.org.au/SiteCollectionDocuments/Dietary%20fats%20healthy%20eating%20messages%20FINAL.pdf>. Accessed on 5 June 2009.

²⁰ State of Victoria (2007) Cholesterol – healthy eating tips. [http://www.betterhealth.vic.gov.au/bhcv2/bhcv2/bhcv2/pdf/Cholesterol_healthy_eating_tips/\\$File/Cholesterol_healthy_eating_tips.pdf](http://www.betterhealth.vic.gov.au/bhcv2/bhcv2/bhcv2/pdf/Cholesterol_healthy_eating_tips/$File/Cholesterol_healthy_eating_tips.pdf). Accessed on 5 June 2009

²¹ National Heart Foundation (2009) Position statement on phytosterol/stanol enriched foods. National Heart Foundation. <http://www.heartfoundation.org.au/SiteCollectionDocuments/HF%20Phytosterols%20Stanols%20CVD%20PositionSt.pdf>. Accessed 5 June 2009.

²² The Jean Hailes Foundation (2008) Heart Disease: Women and Heart Disease. The Jean Hailes Foundation. <http://www.healthforwomen.org.au/content/view/90/123/>. Accessed 5 June 2009

²³ Ministry of Health (2003) Food and Nutrition Guidelines for Healthy Adults: A Background Paper. <http://www.moh.govt.nz/moh.nsf/pagesmh/2606>. Accessed 24 July 2009.

The dietary exposure assessment suggests that the intake of reduced-fat cheeses in Australia and New Zealand is consistent with national dietary guidelines. In addition, information from the more mature plant sterol-fortified market in Europe suggests that:

- consumers of plant sterol-fortified products tend to use one product at a time, with only a small proportion consuming 2 or 3 plant sterol-fortified products per day
- consumers of plant sterol-fortified products do not consume cheese spreads on a daily basis
- consumers eat cheese as the second or third choice in addition to a primary plant sterol-fortified product.

This information is in **Supporting Document 1**.

On this evidence, FSANZ considers that the fortification of reduced-fat cheese with plant sterols is not likely to alter consumption patterns in a manner which would result in an increased overall energy or saturated fat intake, or lead to a negative public health effect. FSANZ concludes therefore, that the addition of tall oil esters to reduced-fat cheese is consistent with policy principle d).

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

Consumer research from Australia and New Zealand indicates that consumers do not see plant sterol-fortified products as ‘magic bullets’ and that consumption of these products does not lead to poor lifestyle behaviour patterns. Data from the more mature plant sterol market in Europe suggest that plant sterol-fortified products are consumed in a manner that is appropriate for the food product i.e. they are not consumed on a daily basis, they are consumed as a second or third choice of plant sterol-fortified product, and that overall, the consumption of phytosterols from fortified products is low. This data suggests that consumers don’t see these products as providing something beyond their intended role i.e. to reduce elevated cholesterol.

FSANZ proposes that the mandatory advisory statements currently required for existing plant sterol-fortified products be extended to plant sterol-fortified reduced-fat cheese products. FSANZ considers that these measures should provide sufficient information to consumers so that they are not misled as to the nutritional quality of the product.

These labelling aspects are further discussed in Section 6.3 below.

6.3 Labelling of phytosterol-containing products

Currently labelling requirements for phytosterol containing foods are set out in Standard 1.2.3²⁴. 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.

²⁴ 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 or whether the Standard was difficult to enforce. ISC members did not raise any 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.

6.4 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.

In addition, FSANZ notes that this approach is 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)²⁵.

6.6 Risk management measures

6.6.1 Regulatory measures

FSANZ concludes that extending permissions to tall oil phytosterol esters in reduced-fat cheese 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:
 - that reduced-fat cheese must contain no less than 70 g/kg and no more than 90 g/kg tall oil phytosterol esters;
 - the fat content must not contain more than 9 g total fat/100 g cheese excluding tall oil phytosterol esters;
 - the cheese is supplied in a portion, the capacity of which is no more than 50 g and
 - that foods containing added plant sterols must not be used as ingredients in other foods.

²⁵ 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.

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. 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^{26 27 28 29 30}. 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+) will be used to promote these products to the target population
- distributing educational material to medical and nutrition professionals
- displaying specific marketing information on product packages.

FSANZ invites comment on the proposed options for managing any risks associated with plant sterol-fortified reduced-fat cheese

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[®] 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.

²⁶ FSANZ (2007) Fact Sheet: Plant Sterols(also known as phytosterols)
<http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2006/plantsterolsalsoknow3399.cfm>
Accessed 15 June 2009.

²⁷ 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.

²⁸ 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.

²⁹ 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.

³⁰ DAA (2008) Fact Sheet: Plant Sterols. Dietitians Association of Australia.
<http://www.daa.asn.au/index.asp?PageID=2145842757>. Accessed 12 June 2009.

Two regulatory options have been identified for this Application:

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

Option 2: Approve the exclusive use of LiveActive® in reduced-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 has sought advice from the Office of Best Practice Regulation (OBPR) to estimate compliance costs of regulatory options.

FSANZ has liaised with the OBPR subsequently approving, 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 Live Active® in reduced-fat cheese

8.2.1.1 Consumers

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

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. This will depend on what marketing and promotion of such products is permitted since health and nutrition claims could not be made.

No benefits to consumers are identified as the risk assessment has determined that there are no public health and safety risks from consumption of plant sterol-fortified products.

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.

8.2.2 Option 2: Approve the exclusive use of LiveActive[®] in reduced-fat cheese

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 reduced-fat cheese 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 reduced-fat cheese. 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 the community associated with the normal and informed use of cheese products although the extent of this benefit will be difficult to quantify.

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 LiveActive® 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 LiveActive®. 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 tall oil phytosterol ester reduced-fat cheese products; providing information to consumers that will contribute to the safe consumption of tall oil phytosterols; and providing a fair trading aspect to allow manufacturers and businesses a new source of plant sterols for inclusion in reduced-fat cheese.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

This Application may be of interest to a broad range of stakeholders. On this basis, the public consultation will ensure that these specific sectors of industry have the opportunity to comment on the proposed measures.

FSANZ is proposing conditions of use and labelling statements to ensure that consumers receive the message that consuming 2-3 serves/day is appropriate. The current risk management options (such as mandatory labelling requirements, portion size restrictions) address the issue of consumption by non-target groups.

The Applicant has also proposed additional strategies to increase consumer awareness on the use of the products. These include the establishment of a consumer information line to assist consumers with advice on the purchase and consumption of plant sterol-fortified foods; advertising to be specific for the target audience; and the distribution of educational material to health professionals.

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

FSANZ will follow its standards setting process including public notification of all reports, public consultation and decisions relating to this Application. Future information relating to this Application will be advertised through the notification circulars. Copies of reports can be found at <http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa1019phyt4161.cfm>.

FSANZ seeks public comment to assist with assessment of the application on:

- 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.

10. Consultation

FSANZ acknowledges that this Application may have impacts on a specific industry sectors, Health Departments, consumers and health organisations. On this basis the public consultation will ensure that these specific sectors have the opportunity to comment on the proposed measures.

10.1 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 tall oil phytosterol esters as novel food ingredients in reduced-fat cheese will not be 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 Preferred Option

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.

Preferred Approach

The preferred approach is to amend Standard 1.5.1 – Novel Foods to permit the addition of phytosterol esters derived from tall oils to cheese in accordance with Standard 2.5.4 – Cheese.

Amend Standard 2.5.4 – Cheese to permit the addition of phytosterol esters derived from tall oils, to cheese containing no more than 9 g fat per 100 g cheese(excluding tall oil phytosterol esters), and in amounts of no less than 70 g/kg and no more than 90 g/kg total phytosterol esters.

The draft variations are at **Attachment 1**.

11.1 Reasons for Preferred Approach

FSANZ recommends the proposed draft variations to Standards 1.5.1 and 2.5.4 for the following reasons.

- there are no safety, nutritional or efficacy concerns with the addition of tall oil phytosterol esters to reduced-fat 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
- reduced-fat cheese is considered a suitable vehicle for tall oil phytosterol esters and they can effectively be incorporated into the food matrix
- approval for addition to reduced-fat cheese is consistent with Ministerial policy guidance on the *Addition to Food of Substances other than Vitamins and Minerals*³¹
- 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 tall oil phytosterol esters to reduced-fat 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

1. Draft variations to the *Australia New Zealand Food Standards Code*

³¹ Refer to Supporting Document 2

Attachment 1

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

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	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>

[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.