

KRAFT FOODS

Application to amend the Australia New Zealand Food Standards Code

**Removal of package size restrictions for low fat cheese with
added tall oil phytosterol esters in Standard 2.5.4 Clause 3**

March 2012

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PART 1 EXECUTIVE SUMMARY

[[section 3.1.1 B of Application Handbook 1 August 2011]

This Application is made by Kraft Foods, producers of LiveActive® Light Cream Cheese and LiveActive® Light Processed Cheese Slices containing added tall oil phytosterol esters, to vary Standard 2.5.4 – Cheese, of the Australia New Zealand Food Standards Code (the Code), to remove the requirement for low fat cheese and processed cheese enriched with tall oil phytosterol to be sold in individual servings of no more than 50 g. Standard 2.5.4 currently states in clause 3 as follows:

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.*

This Application seeks to delete subclause 3 (b).

Removal of the current restriction on package size will allow for a more convenient, cost effective and environmentally responsible delivery of cheese enriched with tall oil phytosterol esters in multi-serve containers from which individual portions can be readily divided.

Consumers wishing to make a lifestyle decision to consume foods containing phytosterols in order to manage cholesterol are able to select from a number of effective food vehicles, including low fat cheese and processed cheese.

The current serving size requirement impacts primarily on soft or spreadable cheeses, including low fat cream cheese, which, in order to retain portion integrity, need to be presented in individual packages, such as mini-tubs. There is a consumer demand for LiveActive® Cream Cheese, however, this packaging requirement has a detrimental effect on market distribution and stocking, which in turn, is impairing the ability of consumers to access the product.

The packaging requirement does not impact to the same extent on the market access of other phytosterol enriched low fat cheese products. The normal presentation of processed cheese slices is multi-serve packs of individually wrapped slices and the sale of hard cheese in both multi-serve packs of unwrapped slices and individually wrapped mini-blocks is well established.

Removing the packaging restriction would also create a more harmonised regulatory outcome with our international trading partners. No restriction on individual package size for cheese products occurs in legislation anywhere else in the world, including the European Union (EU) and the United States of America (USA). In the EU, a requirement that products containing phytosterols must be presented in such a manner that they can be easily divided into portions allows spreadable products, e.g. oil spreads and spreadable soft cheeses, to be sold in multi-serve containers.

There is no safety concern associated with consumption of foods currently permitted to

contain phytosterols (or their equivalents), and no acceptable daily intake (ADI) has been established for phytosterols (or their equivalents) in Australia and New Zealand.

As concluded in FSANZ's assessment report for Application A1019: A comprehensive review of the literature does not indicate any population health risk arising from consumption of plant sterol fortified foods.

LiveActive® low fat cream cheese and low fat processed cheese tall oil phytosterol enriched products are characterised by distinctive packaging, targeted at the 50+ age group and supported by educational information and recipes for consumers. Information on the brand, use is also provided to health professionals. Consumption of low fat cheese as the vehicle of choice for dietary phytosterols has the potential to introduce an additional source of calcium, fat soluble vitamins and protein into the diet of target group consumers, when compared to edible oil spreads and other permitted food vehicles..

There is a potential for consumption by people outside the target group, including young children, which is primarily addressed by mandatory advisory labelling for foods enriched with phytosterols. Market research indicates that LiveActive® brand cheese products are recognised by and predominantly bought by the target group. FSANZ has previously concluded that there is no increased safety concern associated with consumption of foods currently permitted to contain plant sterols by children or other non-target consumers. The requested change to packaging is not a compositional change and does not raise new issues regarding the consumption of phytosterol enriched low fat cheeses by non-target group consumers.

In summary, there is a consumer demand for LiveActive® Cream Cheese as a vehicle to deliver phytosterols. However, the requirement to package the product in single serve portion control units of less than 50g has a detrimental effect on the ability of the product to gain market distribution, which in turn, is impairing the ability of consumers to access the product. The serving size restriction, was introduced during the assessment of Application A1019 address concerns raised by the Australia and New Zealand Food Regulation Ministerial Council about potential high levels of consumption of phytosterols esters from milk, rising from Applications A433, A434 and A508. There is no public health-based justification for maintaining the restriction on package size for low-fat cheese and processed cheese containing tall oil phytosterol esters.

Kraft Foods proposes that this would be a paid Application and suggests the General Procedure Maximum of 350 hours as the appropriate assessment procedure.

This application does not contain Confidential Commercial Information.

PART 2 GENERAL INFORMATION

2.1 Applicant Details

[section 3.1.2 of Application Handbook 1 August 2011]

2.1.1 Applicant

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2.2 Purpose of Application

[section 3.1.3 of Application Handbook 1 August 2011]

This Application seeks to amend Standard 2.5.4 Cheese delete sub-clause 3(b), which requires cheese and processed cheese enriched with tall oil phytosterol to be sold in individual servings, the weight of which is no more than 50 g. Removal of the current restriction on package size will allow for a more convenient, cost effective and environmentally responsible delivery of cheese enriched with tall oil phytosterol esters to consumers and to improve access and choice in terms of the form and amount of product they may purchase in order to obtain the health benefits associated with phytosterols.

The current packaging limits restrict market access and, thereby, unnecessarily restrict the availability for consumers of low fat cheese containing tall oil phytosterol esters to small, portion control packaging solutions. There are no increased safety concerns about the consumption of phytosterols in the permitted food categories so there is no public health-based justification for the current restriction.

Removing the current restriction on pack format and size for cheese and cheese products enriched with tall oil phytosterol esters in Australia and New Zealand will also provide consistency in regulations for Australia and New Zealand with regulations in the USA and Europe. The Applicant has not been able to identify this regulatory restriction in any jurisdiction other than Australia and New Zealand.

2.3 Justification for the Application

[section 3.1.4 of Application Handbook 1 August 2011]

Consumers wishing to make a lifestyle decision to consume foods containing phytosterols (phytosterols, phytosterols and their esters) in order to manage cholesterol are able to select from a number of enriched foods; edible oil spreads, breakfast cereals, milk, yoghurt, low fat cheese and processed cheese (1-7).

The National Heart Foundation Position Statement on phytosterol/phytosterol enriched foods advises that plant sterols are most effective if two to three grams are consumed per day(8). All of the above enriched products carry advisory labelling informing consumers of the appropriate amount to consume per day, thereby assisting consumer to manage their daily effective consumption of phytosterols from one or a number of food vehicles..

Cheese and processed cheese are effective vehicles for delivery of phytosterols, to consumers wishing to lower serum cholesterol levels (9).

As currently drafted, Standard 2.5.4 permits the addition of tall oil phytosterol esters to all cheeses and processed cheeses that contain less than 12% fat, provided that they are in individual portions of <50g. Kraft produces two applicable product under the LiveActive® brand in Australia:

LiveActive® Cream Cheese – sold in 4x40g mini-tub packs, each containing two serves or 2g free phytosterol equivalents. The label advises consumers that one mini-tub represents one recommended daily quantity of phytosterols, and

LiveActive® Processed cheese slices – sold in individually wrapped, portion control slices each containing one serves or 1g free phytosterol equivalents. The label advises consumers that two slices represent one recommended daily quantity of phytosterols,

Kraft Foods does not currently market phytosterol enriched cheese in New Zealand. Between 8 April 2010 and 10 July 2011, Kraft Foods had an exclusive use of tall oil phytosterol esters in cream cheese under Standard 1.5.1 -Novel Foods clause 3. No other companies have subsequently launched a phytosterol enriched cream cheese product in Australia or New Zealand.

The preferred market presentation for processed cheese slices is multi-packs containing individually wrapped, portion control slices and, consequently, the serving size requirement for the phytosterol enriched version does not adversely impact on the marketability of these products.

The standard also allows the sale of enriched yellow, block type semi-hard cheeses (e.g. tasty cheese), although, there are no such products currently on the market. Regular full fat and reduced fat block cheese products are currently available in individually wrapped single serve portions but also in multi-portion packs of cheese slices, not in individual wrappers which would meet the requirement of Standard 2.5.4 sub-clause 3(b) (the firmer physical nature of the product does not require individual wrapping to maintain portion integrity). Both of these package formats would be suitable for the sale of multi-serve phytosterol enriched low fat hard cheese under the current standard. Typically, full fat cheese contains approximately 33% fat and reduced fat cheeses 15-25% fat (NUTTAB 2010), suggesting that absence of phytosterol enriched block cheese from the Australian and New Zealand market may, in part, be due to the complexities of producing an acceptable product with <12% fat, rather than the limit on portion size.

Due to its softer consistency, in order for soft or spreadable cheeses, including cream cheese, to be sold in individual serving sized portions, to comply with sub-clause 3(b), these must be packaged in individual containers of appropriate size, such as mini-tubs. The evidence collected by Kraft suggests that this requirement disadvantages the product in terms of market access and supermarket presence.

Kraft Foods has received an increasing frequency of inquiries, since the launch in 2010, from consumers who had previously bought LiveActive® Cream Cheese, were wishing to make a repeat purchase but were unable to find the product in their local supermarket (Appendix 1). In 2010, four inquiries named LiveActive® Cream Cheese out of a total of 178 (2.3%) inquiries from consumers unable to find cream cheese, however, in 2011 this figure rose to 20 inquiries about LiveActive® Cream Cheese from a total of 164 about how to find cream cheese (i.e. 12.2%). Market research indicates that the Live Active® brand is incremental to both the 'cholesterol reduction universe' and to the cheese category (Appendix 2). Nonetheless, despite expectations based on pre-market research and consumer testing, sales of LiveActive® Cheese Slices are significantly outperforming LiveActive® Cream Cheese in mini-tubs, in terms of supermarket presence and repeat sales.

Fifty three percent of the Live Active® sales volume is from consumers who did not purchase another phytosterol enriched product and 32% of purchases were made by consumers who also purchased cholesterol reducing spreads. This suggests that consumers are using Live Active® cheese products both as a preferred sole vehicle food and also in a diet containing a range of vehicle foods to deliver phytosterols. One of the leading alternative vehicle food categories, phytosterol enriched table spreads (i.e. Flora Proactive, Logicol and Nuttex Environment) are sold in 500g or 750g multi-serve tubs with no portion control requirement. The portion control requirement for cream cheese is, by comparison, inequitable and not justified on safety grounds.

Based on the evidence for regular cream cheese, individual portion control packaging is not the market's preferred packaging solution for cream cheese (Appendix 3). Kraft Philadelphia Spreadable Cream Cheese is the leading (non-enriched) cream cheese brand in the Australian market and is sold in two package formats, a multi serve 250g tub and packs of 4x40g portion control mini-tubs. The latter is the same package format as that currently used for LiveActive® phytosterol enriched cream cheese. When sold in the 250g multi pack tub, Philadelphia has 77% market share for cream cheese in tubs, representing 23% market penetration. In contrast, when sold in 4x40g mini-tubs, Philadelphia has 89% market share of mini-tub products but this only represents a 7% market penetration. Market awareness of the 2 packaging formats comprises 87% and 61% for multi-serve and single serve tubs respectively. It is apparent that, for regular cream cheese, the market preference is for a larger multi-serve tub rather than mini-tub multi packs.

Access to supermarket shelves is dependent upon goods meeting pre-defined benchmarks in terms of sales. Retailer range reviews are undertaken by the major supermarket chains once/twice per year, per category, depending on the customer and whether the category warrants an extra review. The review will normally take place over a 3 week period, after which suppliers are notified of results and revised layout is finalised, before being issued to store, at which point consumers will see the changes. The general cycle from the presentation of a review to the in store implementation date is 6-8 weeks, not counting the preparation time before a review which can be between 6-12 weeks. Throughout the review, there is the opportunity for the supplier to present market and category performance, addressing what is driving growth/decline and why one retailer may

be winning over another.

Ranging is generally built up through an efficient assortment analysis (EAA), which ranks SKUs on a \$ value (RSV) against other like for like SKUs in the range. This can occur from a total category perspective, e.g. total dairy cheese, down to a segment level, e.g. processed slices, to a specific node, such as 205/250g processed slices. Performance is measured on \$ sales, and also growth vs. prior year, distribution, units per store per week (which feeds into turnover rates and measures efficiency on shelf) along with price per volume, and % sales sold on promotion. This is underpinned by homescan data that tracks customers loyalty and penetration, by SKU, to measure the estimated level of product switching, if a SKU were to be removed.

With regards to layouts, once a SKU is accepted, it must pass certain standards such as fitting on the shelf, case constraints (e.g. case +1) and days of supply. Once on shelf, it generally must adhere to category hurdle rates, which included meeting minimum designated Units Sold per Store per Week (UPSPW) performance standards. Which do not meet the minimum standard may suffer in terms of a loss of distribution or loss of ranging, in favour of higher performing SKUs.

In practice this means that slower moving goods will only be stocked by larger supermarket stores but not by medium and small stores in the same chain. The evidence from Philadelphia suggests that the single serve mini-tub package format is not as well recognised as a packaging solution for cream cheese products and is not as widely distributed or stocked as the 250g tub (Appendix 3).

Furthermore, the current 4x40g mini-tub package only enables labelling/brand identification to be printed on the top label. Consequently if product is stacked in supermarket fridges, identifying the product can be difficult. The proposed 240g multi serve tub can carry printing on the sides, allowing the consumer to readily identify the product (Appendix 4).

Consumers have indicated that they are unable to find LiveActive® cream cheese in supermarkets, despite having purchased it previously, suggesting that either supermarket presence is declining or the product is being displayed in a way that makes it difficult to identify, or both. Kraft Foods have therefore concluded that the 40g mini-tub packaging format, necessary to comply with the portion requirement for phytosterol enriched cheese, has a significant negative impact on both stocking decisions by supermarkets and consumer access to the LiveActive® Cream Cheese product.

In summary, there is a consumer demand for LiveActive® Cream Cheese as a vehicle to deliver phytosterols. However, the requirement to package the product in single serve portion control units of less than 50g has a detrimental effect on the ability of the product to gain market access and awareness, which in turn, is impairing the ability of consumers to access the product.

A Regulatory impact information

[section 3.1.4 of Application Handbook 1 August 2011]

2.3.1. Costs and benefits

There are no cost/benefit impediments to this requested change to increase the package size for cheese, specifically cream cheese, enriched with oil phytosterol esters as any costs for consumers, government and industry are minimal and are more than offset by the

benefits.

2.3.1.1 Consumers

There will be no health and safety related costs for consumers of LiveActive® Cream Cheese from the proposed change to remove the restriction on pack format and size. FSANZ has previously concluded that there are no public health and safety risks from consumption of approved plant sterol-fortified products (7).

Possible costs for consumers of phytosterols and their households are:

- a bigger package of a food containing added plant sterols could potentially lead to consumption of plant sterol-fortified foods in amounts more than necessary to achieve an effect. However, post-launch monitoring data in Europe by EFSA suggests that consumers do not currently achieve optimal intakes (10). In addition, there is an advisory statement on the label which serves to inform consumers of the appropriate amount to achieve the intended effect, and that there are no additional health benefits when more than 3g of plant sterols are consumed per day.
- consumers may be subjected to higher grocery costs if they purchase larger multi-serve containers of phytosterol enriched cheese and use this instead of other non-enriched equivalent products for general household use. The unit cost of LiveActive® Cream Cheese is approximately 100% greater than the cost of an enriched equivalent in a similar package, such a Philadelphia Cream Cheese, which is likely to be a significant disincentive to unnecessary use or use by other members of the household.

There are a number of benefits from the proposed amendment, for consumers who choose to consume phytosterol enriched products:

- The availability of both larger pack sizes and greater market availability of low fat cheese enriched with phytosterol esters. The current single serve pack format and size is less popular with and less well recognised by retailers and consumers of cream cheese, than multiple serve packages. As a slower moving product within the product category, cream cheese enriched with tall oil phytosterol esters in portion control mini-tubs are not currently carried by many medium and small sized retailers. This limits the ability of many consumers to access the product.
- Reduced cost. The current mini-tub package format is a premium package. Consumers will benefit from a price reduction in the unit cost (i.e. per 100g) of phytosterol enriched cream cheese packaged in multi serve tubs.
- The ability to purchase enriched cream cheese in multi-serve tubs, of a similar format and size to those in which the table spreads are sold affords consumers greater choice over the vehicle they consume to access the benefits of dietary phytosterols. The availability of a broader choice of vehicle foods could potentially increase the number of consumers choosing to consume phytosterols enriched foods to address their elevated blood cholesterol levels.
- Environmental benefits for consumers of LiveActive® Cream Cheese who will be able to buy phytosterol enriched cream cheese products in a recyclable plastic package, instead of the non-recyclable plastic/foil packaging used currently for the mini-tubs of LiveActive® Cream Cheese.

2.3.1.2 Industry

There are no net costs to industry arising from proposed amendment. There are cost savings to manufacturers associated with providing larger pack multi serve packs sizes of cheese enriched with phytosterol esters. There will be some discretionary costs associated with factory trials and new labelling but the packaging systems are already well established within the industry for other cheese products, which are sold in much larger volumes. Businesses that make a commercial decision to launch a tall oil phytosterol ester enriched cheese product in a bulk form will anticipate that benefits will exceed costs.

There is a substantial opportunity for the industry to increase sales of low fat cheeses enriched with phytosterol (or its equivalents) if the package size restriction is removed, though improved market access. The normal packaging solution for a majority of cheese and cheese products are multi-serve blocks, multi-serve packs of cheese slices (individually wrapped or not depending on the firmness of the cheese product) or multi-serve tubs. The removal of the package format and size restriction for phytosterol enriched cheeses will allow those soft cheese products which are normally sold in tubs to be presented in a multi-serve format with which retailers and consumers (the market) are more familiar.

There is benefit to industry in being able to reduce the cost of packaging per SKU through the move from portion control to multiple serve presentation. In addition to a lower cost for packaging materials, multi serve packaging lines are more efficient. The potential increase in sales volume of phytosterol enriched cream cheese due to a bigger pack size is difficult to predict. Based on a comparison with Philadelphia Cream cheese, which is available in both multi-serve 240g tubs and 4x40g single serve formats, the multi-serve pack has 23% market penetration compared to only 7% for the single serve pack. The availability of a larger pack size is likely to encourage small businesses, which do not stock the single serve product, to stock the more cost effective popular multi-serve product.

There are environmental advantages due to the potential to use a recyclable plastic (PET) packaging in place of the non-recyclable foil/plastic packaging used for the mini-tubs.

Industry may also benefit from closer alignment with regulations for products on the market in Europe and the USA and a reduced requirement to address consumer inquiries about the reasons for the pack size limitation .

2.3.1.3 Government

There would be no immediate impact on government. Governments may benefit in the long term in terms of reduced health expenditure arising from lower blood cholesterol levels in the community associated with greater uptake of consumption of plant sterols, within the target group, arising from access to a wider choice of vehicle foods.

There are no perceived additional costs on jurisdictions that enforce the food regulations as this Application requests the removal of a regulation which restricts packaging size. The proposed change to the regulation would be more closely aligned to products without packaging restrictions such as plant sterol enriched edible oil spreads.

B Impact on International Trade

This Application proposes to promote greater consistency with both Europe and the USA. There are no adverse impacts for international trade associated with the proposed amendment. Phytosterol enriched low fat cheese products are not currently sold in New

Zealand and there is no imported phytosterol enriched cheese product, from third party countries, in either market.

The current restriction could be regarded as an anticompetitive regulatory impediment to trade if anyone tried to import a multi-serve pack. Removal for the serving size requirement could facilitate international trade in the product by aligning ANZ requirements with those of trading partners, including in Europe and the USA.

2.4 Information to support the application

[section 3.1.5 of Application Handbook 1 August 2011]

2.4.2 International markets

Cheese products containing phytosterols (or their equivalents) are permitted in Europe and many other countries with no restriction on pack sizes (11).

Within the EU products containing the phytosterols must be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3 g (in case of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/phytosteranols (12). In the context of a spreadable product, such as an oil spread or a spreadable soft cheese, this requirement is met by a consumer being able to easily remove a portion, identified in packaging information, from a bulk container or tub. Data from Mintel (Appendix 5) has identified 12 various cheese products containing phytosterols (or their equivalents) available in Europe. All of the spreadable cheese products identified are presented in multi-serve containers.

A range of CoroWise® phytosterols enriched cheeses are distributed in the USA by the Lifeline Food Company, Inc., under the Lifetime brand (13). These cheese products are packaged in 8oz (227g) blocks. The Lifeline cheese promotional description states that two 1oz (28g) servings of cheese daily will meet the recommended amount necessary to achieve beneficial cholesterol reduction. The CoroWise® brand of phytosterols are distributed by Cargill in the USA and are available to consumers through a wide range of food products (14).

2.4.3 FSANZ objectives

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

(a) the protection of public health and safety;

This Application is to delete a restriction on package size and does not raise any health and safety concerns.

(b) the provision of adequate information relating to food to enable consumers to make informed choices; and

This Application provides an advantage to consumer in terms of choice in larger and more convenient pack sizes. The average consumer does not understand that there is a legislative restriction on pack size for this product in Australia and New Zealand. There are also advantages for the environment in terms of introducing a recyclable plastic package, which may influence consumer choices.

(c) the prevention of misleading or deceptive conduct.

The regulatory restriction on package size to 50g individual serve units for tall oil phytosterol ester enriched cheese was imposed without any justification in terms of the potential for misleading or deceptive conduct. The remove of the requirement for maximum package size will not impact on this situation.

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

- **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.**

The comprehensive scientific evaluations conducted by FSANZ for phytosterol enriched foods have all concluded that there are no safety concerns associated with the incorporation of these ingredients into the permitted vehicle foods (2-7). The current restriction on packaging in individual portions of no more than 50g is, therefore, not based on risk analysis using the best available scientific evidence.

This Application proposes to promote greater consistency with both Europe and the USA.

The current limitation requiring packaging in individual portions of no more than 50g forces consumers in Australia and New Zealand to purchase multiple 4x40g packages of the product if they wish to obtain enough product to deliver the proposed health benefits for one person for more than four days and to pay a price penalty for the portion control package. This is not a desirable outcome in terms of an efficient and internationally competitive food industry. The applicant proposes to introduce an additional package solution in the form of a 6 serve 240g multi-serve tub, similar to that used for other non-enriched cream cheese products and for phytosterol enriched table spreads.

The current restriction on package format to individual portion of no more than 50g does not promote fair trading in food. Buyers of phytosterol enriched products may buy table spreads in 500g multi-serve tubs containing 40g or 20 recommended daily quantities of phytosterol equivalents. In contrast, cream cheese is currently only available in packages of 4x40g portion control mini-tubs, which in addition to being a more expensive packaging solution only contains a total of 8g or 4 recommended daily quantities of phytosterol equivalents.

There are no written policy guidelines formulated by the Ministerial Council that impact on the package format of sizes for cheese enriched with phytosterol or its equivalents.

2.4.4 Applicant's Objectives

The Applicant seeks to be able to sell LiveActive® brand low fat cream cheese enriched with tall oil phytosterol esters in multi-serve packs, for example a 240g tub, similar to the 250g tub currently used for Philadelphia Cream Cheese. This packaging format has greater market recognition for buyers of cream cheese and is more likely to be stocked by medium to small supermarkets. The multi-serve packaging format will enable consumers of phytosterols greater access to low fat cream cheese as the vehicle food, particularly

those shopping in regional areas and in small to medium stores.

2.5 Assessment Procedure

[section 3.1.6 of Application Handbook 1 August 2011]

Kraft Foods proposes to proceed as a paid Application and suggests the General Procedure Maximum of 350 hours as the appropriate assessment procedure.

2.6 Confidential Commercial Information

[section 3.1.7 of Application Handbook 1 August 2011]

This application does not contain Confidential Commercial Information.

2.7 Exclusive Capturable Commercial Benefit

[section 3.1.8 of Application Handbook 1 August 2011]

Kraft Foods does not seek to have exclusive use of the larger than 50g package size for cheese enriched with tall oil phytosterol esters.

2.8 International and other National Standards

[section 3.1.9 of Application Handbook 1 August 2011]

2.8.1 International Standards

The Codex Alimentarius Commission develops and maintains commodity standards for a number of named cheese types, including cream cheese (CODEX STAN 275-1973). Codex has not, to date, elaborated standards for the use of plant sterols as functional ingredients in any foods.

2.8.2 National Standards

Table spreads enriched with plant-derived stanols were introduced into the food supply in Finland in the mid-1990s. The use of plant sterol or stanol-based foods was subsequently approved in other countries, including the United States (USA), Brazil, Switzerland (1999), Australia and New Zealand (2001).

Milk type products, yoghurt type products, salad dressings, spicy sauces, fermented milk type products, soya drinks and cheese type products containing phytosterols/phytostanols were authorised in the European Community in 2004, in accordance with Regulation (EC) No 258/97 concerning novel foods and novel food ingredients (12).

In the USA, a number of vegetable oil sterol esters and tall oil phytosterol esters have been notified under the GRAS system. In its responses, the US Food and Drug Administration (FDA) has raised no questions or objections. The GRAS notifications include addition to cream cheese and also level of addition of plant sterol and stanol esters in amounts up to 20%.

The FDA has also issued a rule, 21 CFR section 101.83 2 -Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD), revised 1 April 2011, which established conditions under which manufacturers of products containing added phytosterol and stanol esters may make a health claim (for reducing the risk of coronary

heart disease) (15, 16). Relevant foods for this claim include plant sterol esters in spreads and salad dressings, and plant stanol esters in spreads, salad dressings, snack bars and dietary supplements in soft gel form.

There do not appear to be any restrictions on package sizes in legislative requirements for phytosterol enriched cheese in Asia.

Singapore's Agri-Food and Veterinary Authority is responsible for food regulations. Food Regulation 250A (17) permits the addition of phytosterols, phytosterol esters, phytostanols or phytostanol esters in an amount no more than 3 g in a suggested daily serve to the following foods:

- (a) milk containing no more than 3 g total fat per 100 g, or 1.5 g total fat per 100 ml;
- (b) yoghurt containing no more than 3 g total fat per 100 g; and
- (c) fat spread.

The regulations do not impose any packaging restrictions on the foods that may contain added phytosterols or equivalents.

Malaysia has a guide to Nutrition Labelling and Claims, with a reference to the addition of sterols, stanols and their esters to food, without reference to pack sizes (18).

2.8.2.1 Europe

The European Commission has made a number of Decisions authorising phytosterol enriched categories of food to be placed on the market, under European Community: Regulation (EC) No. 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients:

- Commission Decision 2000/500/EC on authorizing the placing on the market of 'yellow fat spreads with added phytosterol esters' as a novel food or novel food ingredient under Regulation (EC) 258/97 of the European Parliament and of the Council. - 08 August 2000 [LEX-FAOC020938-EN] ,
- Commission Decision 2004/333/EC authorising the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No. 258/97 of the European Parliament and of the Council. - 31 March 2004 [LEX-FAOC042394-EN] , (12),
- Commission Decision 2004/335/EC authorising the placing on the market of milk type products and yoghurt type products with added phytosterol esters as novel food ingredients under Regulation (EC) No. 258/97 of the European Parliament and of the Council. - 31 March 2004 [LEX-FAOC042395-EN] ,
- Commission Decision 2004/845/EC of 12 November 2004 on authorising the placing on the market of milk based beverages with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (EUR-Lex - 32004D0845 - EN).

2.8.2.2 United States of America

The United States Code of Federal Regulations 27 CFR 101.83, revised 1 April 2011, established requirements for health claims: relating to plant sterol/stanol esters and risk of

coronary heart disease (CHD) (15).

The regulation specifies the daily dietary intake of plant sterol or stanol esters that is necessary to reduce the risk of CHD and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of plant sterol and stanol esters that have been associated with reduced risk of are:

(1) 1.3 g or more per day of plant sterol esters.

(2) 3.4 g or more per day of plant stanol esters.

The regulation also specifies that 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 USFDA has release a document for comment which proposes to update 27 CFR 101.83 (16). The proposal would amend the authorized use of the claim by modifying the nature of the substances that may be the subject of the claim for conventional foods to include nonesterified, or free, phytosterols, by expanding the types of foods that may bear the claim to include a broader range of foods, by modifying the daily dietary intake of the substance specified in the claim as necessary for the claimed benefit, by adjusting the minimum amount of the substance required for a food to bear the claim, and by making other minor changes.

PART 3 A NON-COMPOSITIONAL CHANGE TO A STANDARDISED FOOD

[section 3.6.1 of Application Handbook 1 August 2011]

The current restriction on the package size is provided by clause 3 (b) of Standard 2.5.4–Cheese.

Cheese is a standardised food and for the purposes of meeting the requirements of the Application Handbook in Part 3.6.1, the request for deletion of clause 3(b) is most appropriately treated as a change to a compositional requirement.

There is however, no actual change to the composition of cheese proposed and no foods or food standards would be affected by allowing for the sale of larger package sizes.

There is no anticipated change in the overall nutrient content of low fat cheese containing tall oil phytosterols. The Applicant hopes to increase market distribution and stocking of LiveActive® phytosterol enriched cream cheese resulting from the availability of larger multi-serve pack sizes of the currently permitted product. Increased consumption of phytosterol enriched low fat cheese should have a beneficial effect on the diet of consumers who wish to lower their serum cholesterol levels by providing greater access to a permitted class of food vehicle.

The proposed amendment is likely to remove an impediment to the sale of low fat phytosterol enriched soft cheese, such as cream cheese. LiveActive® low fat cream cheese, enriched with tall oil phytosterols is currently the only product in the market in this category. The applicant considers that that amendment is unlikely to significantly affect the saleability of phytosterol enriched low fat processed cheese spreads, nor the potential to sell enriched low fat hard cheese, since in both cases multi-serve pack options are already well established in the generic product categories.

3.1 Nutritional implications

The proposed amendment will not change the nutritional value of tall oil phytosterol enriched low fat cheese or processed cheese products.

There is the potential for greater uptake of low fat cheese as a food vehicle to deliver dietary phytosterols. In its assessment of application A1019, FSANZ noted in respect of consumption of phytosterol enriched low fat cheese, that the Australian, State/Territory and New Zealand governments, and other bodies have developed 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 serve in the case of cheese). Two of these bodies, The National Heart Foundation and the Victorian Department of Health, also recommend those with high cholesterol limit cheese intake to two to four times per week. FSANZ concluded that, 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 macro-nutrient balance. In addition, the amount recommended to achieve the optimal phytosterol intake (two serves) is consistent with the various dietary guidelines.

Analysis of representative phytosterol enriched products from Australian supermarkets in 2010 indicates that, per 2g phytosterols, low fat cream cheese and low fat processed cheese contain less fat than other food vehicles (Table 1).

Table 1 : Total fat in foods containing 2g phytosterols

| Product | serving size (g) | Total fat (g) in products providing 2g plant sterols |
|---|------------------|--|
| Kraft LiveActive® Light Cream Cheese | 40g | 3.1g |
| Kraft LiveActive® Light Cheese Slices | 41g | 4.4g |
| Extra Light Spread with phytosterols | 25g | 5.8g |
| 99% Fat free milk with phytosterols | 625g | 6.3g |
| Light/reduced fat spreads with phytosterols | 25g | 10.0g |
| Regular Spread with phytosterols | 25g | 16.3g |

<http://www.kraft.com.au/liveactive-the-benefits.aspx>

3.2 Dietary implications

The daily doses, considered optimal for the purpose of lowering blood cholesterol levels, are 2-3 g of phytosterols and/or phytosterols, which translates to 3.4-5.2 g in esterified form. This recommended daily dose is typically divided in 1-3 portions of food providing 1.7-5.2 g esters, which equates to 1-3 g phytosterol and/or free phytosterol equivalents (11).

As stated in the FSANZ Fact Sheet on plant sterols (2010), plant sterols are most effective if we eat two to three grams per day and that this is roughly equivalent to two to three serves of foods containing plant sterols.

The current 40g LiveActive® Cream Cheese mini-tub provides two serves (2g) free phytosterol equivalents and consumers are recommended to consume one mini-tub per day. The same concentration would be maintained in the product is packed in a 240g multi serve tub. The label and associated consumer education resources, eg leaflets, website, would advice consumers to consume an amount equivalent to 40g per day (Appendix 6).

The use of the product from the 240g multi-serve tub in place of a 40g single serve tub would not represent a dietary change. For a consumer who otherwise obtained their daily phytosterol intake from a product such a oil spread, the switch to low fat cream cheese has the potential to include an additional source of calcium, fat soluble vitamins and protein into their diet.

3.3 Information on consumer understanding and behaviour

Consumers wishing to make a lifestyle decision to consume foods containing phytosterols (phytosterols, phytostanols and their esters) in order to manage cholesterol are able to select from a number of enriched foods; edible oil spreads, breakfast cereals, milk, yoghurt, cheese and processed cheese.

A number of these foods, such as edible oil spreads and milk may be considered to be staple foods that a majority of consumers (including consumers with high cholesterol) are likely to consume in the non-enriched form every day, and, therefore, their replacement with phytosterol enriched versions by consumers with high cholesterol levels, represents a minor dietary adjustment.

In contrast, due to the saturated fat content, consumers with high serum cholesterol levels may be advised to avoid full fat cheese and only consume reduced fat cheese occasionally. The consumption of cheese is associated by consumers with fat, cholesterol and salt (Appendix 7). The option to consume tall oil phytosterol esters via a cheese or processed cheese product containing a low level of fat (<12%) enables these consumers to source a part or all of their daily phytosterol requirement through consumption of a pleasurable food that they have previously been advised to limit or exclude from their diet. In this regard, a decision to source all or part of their daily intake of phytosterols from low-fat cheese products represents a conscious dietary choice to prefer cheese as the vehicle food which they would otherwise exclude from their diet. Furthermore, the choice of low fat cheese also offers an advantage over some other vehicle foods in terms of its content of calcium, fat soluble vitamins and protein.

A majority of phytosterol enriched foods, other than those sold under supermarket own labels, are discrete brands supported by extensive consumer education strategies. LiveActive® low fat cream cheese and low fat processed cheese products are characterised by distinctive packaging, which distinguishes them from non-enriched counterparts, such as Philadelphia cream cheese or Kraft Singles processed cheese slices. The brand is targeted at the 50+ age group, supported by educational information and recipes for consumers (<http://www.kraft.com.au/liveactive.aspx>). Information on the brand, packaging and use is also provided to health professionals. Target consumers are advised to consume 2g phytosterols per day (40g cream cheese or 2 cheese slices) and that there are no health benefits from consuming more that 3g /day.

Market research indicates that LiveActive® brand cheese products are recognised by and

predominantly bought by the target group (Appendix 1). Consumers in the 55+ age group account for 60.1% of volume sales of LiveActive® Cheese by contrast only 4.3% is purchased by consumers <35 years. This compares with 35.0 and 15.7% of volume sales of Philadelphia cream cheese by the same age groups (Appendix 1).

In terms of life stage, the principal buyers of LiveActive® cheese are Senior Couples (34.5%), Independent singles (28.5%), and Established couples (20.3). Whereas, small scale families and start-up families only account for 3.1 and 2.1% of volume sales respectively. Older Australian consumers represent the overwhelming majority of solus buyers whilst younger buyers are more likely to buy both phytosterol enriched and non-enriched products.

In the 2nd review report on Applications A433, A434 and A508, FSANZ stated "A survey of New Zealand and Australian consumers found that users of phytosterol- enriched margarines in the target group use the products in moderation and for the appropriate health reasons. The European Food Safety Authority (EFSA) surveyed consumers on their consumption of phytosterol enriched foods. The report concluded that to date, there appears to be little over-consumption of food products with added plant sterols, stating "It is clear that only a small proportion of consumers eat two or more products with added plant sterols during the same day even with an expanding range of products available on the market. (EFSA Consumption of Food and Beverages with Added Plant Sterols in the European Union 2008).

In the FAR to A434 FSANZ committed to collaborate with the National Heart Foundation of Australia in broadly based education activities that will significantly increase the visibility of information on plant sterols in the context of heart-healthy nutrition and dietary advice.

FSANZ also committed to prepare its own educational material on phytosterol-enriched foods suitable for wide distribution to professional organisations and the general public, linking to other sources of information on plant sterols (3).

There is no proposed compositional change to the product for consumers to understand. There is, however, the potential for a change to the packaging solution that will allow the enriched cream cheese product to be sold in a format consistent with the market preference from non-enriched product. The impact on consumer behaviour resulting from a change in packaging size is expected to be greater uptake of low fat cheese as a vehicle for delivering dietary phytosterols. It may be speculated that this may in turn increase the overall uptake of phytosterol enriched within the target populations as a means of achieving lower serum cholesterol levels.

Enquirers about LiveActive® phytosterol enriched cream cheese do not understand why they cannot find the product in supermarkets. Consumers do not understand that there is a legislative restriction on the package format or size. Consumers also do not understand why there should be any package size restriction on a product that they are buying to improve their health.

The United Kingdom Food Standards Agency (UKFSA) commissioned consumer research on health claims including a case study on phytosterols (19). The report concluded that the relationship between consumers, products and claims is complex and that it is difficult to generalise about the impact on consumer understanding of the claim itself.

3.4 Potential adverse health or diet impacts on non-target population groups (e.g. age or cultural groups)

There is a potential for consumption by people outside the target group, including young children. This is primarily addressed by mandatory advisory labelling for foods enriched with phytosterols (or their equivalents).

Standard 1.2.3 requires that the label of 'foods containing added phytosterols, phytostanols or their esters' include three advisory statements to the effect that;

- the product should be consumed as part of a healthy diet
- the product may not be suitable for children under the age of five years and pregnant or lactating women
- plant sterols do not provide additional benefits when consumed in excess of three grams per day.
- FSANZ has addressed this issue in the assessment of previous applications relating to phytosterol and phytostanol enriched foods.

There is no increased safety concern associated with consumption of foods currently permitted to contain plant sterols and no ADI has been established for phytosterols (or their equivalents) in Australia and New Zealand. In the assessment report for Application A1019, FSANZ concluded: *A comprehensive review of the literature did not indicate any population health risk arising from consumption of plant sterol fortified foods (4)*. Based on an analysis of all toxicological information, FSANZ found no justification for establishing an ADI for plant sterols. The requested change to packaging is not a compositional change and does not raise new issues regarding the consumption of phytosterol enriched low fat cheeses.

3.4.1 Potential consumption by young children

The risk assessment for A1019 concluded that there is likely to be a very small proportion of children (2-3%) aged 2-16 years who consume phytosterol-fortified products. Phytosterol enriched cheese products are however, targeted specifically to people at risk of high blood cholesterol levels and current data on consumer purchases of LiveActive® cheese further supports the conclusion in A1019. There is also a labelling requirement in Standard 1.2.3 that the product bear a label to the effect that products containing phytosterols may not be suitable for children under the age of 5 years. This requirement is met, in the case of LiveActive® low fat cheese products, by a statement that they are not suitable for children, in general.

A survey undertaken by the German Federal Institute for Risk Assessment (BfR), published in 2007, on consumer perceptions and consumption of phytosterol enriched foods reported that less than 3.5% of consumers of the foods were under 18 years of age (20).

Checklist

[section 3.1.11 of Application Handbook 1 August 2011]

General Requirements (3.1)

| | |
|---|---|
| 3.1.1 Form of application | ✓ 3.1.7 Confidential Commercial Information |
| ✓ <i>Executive Summary</i> | ✓ <i>Confidential material separated in both electronic and hard copy</i> |
| ✓ <i>Relevant sections of Part 3 identified</i> | ✓ <i>Justification provided</i> |
| ✓ <i>Pages sequentially numbered</i> | |
| ✓ <i>Electronic + 2 hard copies</i> | |
| ✓ <i>Electronic and hard copies identical</i> | |
| ✓ <i>Hard copies capable of being laid flat</i> | |
| ✓ <i>All references provided</i> | |
| ✓ | |
| ✓ 3.1.2 Applicant details | ✓ 3.1.8 Exclusive Capturable Commercial Benefit |
| ✓ 3.1.3 Purpose of the application | ✓ 3.1.9 International and Other National standards |
| ✓ 3.1.4 Justification for the application | ✓ 3.1.10 Statutory Declaration |
| ✓ 3.2.5 Information to support the application | ✓ 3.1.11 Checklist/s provided with Application |
| | ✓ <i>3.1 Checklist</i> |
| | ✓ <i>Any other relevant checklists for Sections 3.2-3.7</i> |
| 3.1.6 Assessment procedure | |
| ✓ <i>General</i> | |

Standardised Foods (3.6.1)

| | |
|---|--|
| ✓ A.1 Proposed compositional change | ✓ C.1 Demonstrated consumer understanding of proposed change |
| ✓ A.2 List of foods likely to be affected | ✓ C.2 Potential adverse health or diet impacts |
| ✓ B.1 Nutritional content | |

Statutory Declaration

[section 3.1.10 of Application Handbook 1 August 2011]

Statutory Declarations Act 1959

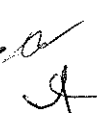
I Nicolas Georges, Director, Research & Development of KRAFT FOODS Level 6, South Wharf Tower, 30 Convention Centre Place, South Wharf, VIC 3006, make the following declaration under the Statutory Declarations Act 1959

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

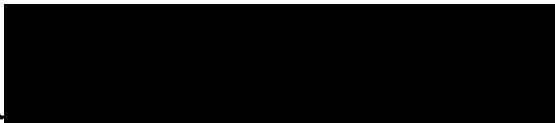
I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.



.....
[Signature of person making the declaration]

Declared at Melbourne on 15th of March 2012 

Before me:



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

15/3/12.

Angela Martinelli
Kraft Foods Australia Pty Ltd.
30 Convention Centre Place, South Wharf VIC 3006.
An Australian Legal Practitioner within the
meaning of the Legal Profession Act 2004

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

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<http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2010/plantsterolsjanuary24705.cfm>
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4. FSANZ Approval Report for A1019
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6. FSANZ 1st review report (Application A433 Phytosterol Esters Derived from Vegetable Oils in Breakfast Cereals; Application A434 Phytosterol Esters Derived from Vegetable Oils in Low-Fat Milk & Yoghurt Application A508 Phytosterols Derived from Tall Oils as Ingredients in Low-Fat Milk).
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with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council.

13. Lifetime Cheese with added plant phytosterols
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<http://www.corowise.com/>
15. USA Regulations 21 CFR Ch. I (4–1–09 Edition) § 101.83 Health claims: plant sterol/ stanol esters and risk of coronary heart disease (CHD).
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APPENDICES

[Appendices.zip]

Appendix 1 - customer inquiries liveactive cream cheese.pdf

Appendix 2 - Kraft_Cheese_Live Active and Philly duplication_29 11 2011.pdf
(comparisons of sales for LiveActive and Philly and Philly in 4x40 vs 250g tubs)

Appendix 3 - Moulton 2011

Appendix 4 - Examples of presentation of cheese in 240g multi serve tub

Appendix 5 -GNPD Plant Sterol Cheese.pdf (MINTEL search - examples of phytosterol enriched cheese product on sale in EU).

Appendix 6 – Communication of daily sterol requirement

Appendix 7 - Barriers to cheese consumption