TO:
Standards Management Officer
Food Standards Australia New Zealand
PO Box 7186
CANBERRA BC ACT 2610
AUSTRALIA

APPLICATION

USE OF PHYTOSTEROL ESTERS IN LOW-FAT CHEESE PRODUCTS

APPLICANT DETAILS

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Nature of Business: Food Manufacturer

Content

EXECUTIVE SUMMARY

Kraft seeks to apply to FSANZ for approval on the use of phytosterol esters in low fat cheese and processed cheese at the levels equivalent to 0.8g to 1.0g of free phytosterols in a 20g serve (in line with current permissions) under Standard 1.5.1 – Novel Foods and Standard 2.5.4 – Cheese of the Australia New Zealand Food Standards Code (the Code).

Kraft believes that a wider range of phytosterol-containing products should be made available to consumers needing to reduce their blood cholesterol levels to allow variety in their diet. It has also been reported that consumers of phytosterol-containing products may not be taking sufficient of these products to be of effective benefit (FSANZ 2006). With reduced-fat, portion-controlled cheeses now being available, this product category is well suited as carrier of phytosterols thus addressing the issues of variety and measurement of consumption.

Phytosterol esters were approved as a novel food ingredient, according to definitions in Standard 1.5.1 – Novel Foods, for use in edible oil spreads in 2001. In several reviews by FSANZ for approving use in additional food categories, safety concerns especially over long-term consumption, over-consumption and associated nutritional issues have been extensively assessed by FSANZ and subsequent approval for use has been granted in breakfast cereals, low fat yogurt and low fat milk to widen consumer choices for phytosterol-enriched food products. The use of phytosterols in cheese is currently permitted in US and Europe.

The efficacy of phytosterols in blood cholesterol-lowering has been well documented and reviewed. A meta-analysis of 41 trials showed that a daily intake of 2g of phytosterols reduced low-density lipoprotein (LDL) by 10% (Katan 2003). The efficacy of phytosterols in a cheese matrix has also been examined by two recent Finnish studies where daily consumption of 50g of cheese (hard cheese or fresh cheese) containing 2g of phytosterols resulted in 10-11% reduction in LDL and 6-8% reduction in total cholesterol (Korpela 2006, Jauhiainen 2006). Kraft has commissioned research to measure reductions achieved with the proposed products which will be made available as soon as the study is complete.

The introduction of phytosterol-enriched cheese products will not only offer a wider consumer choice, but when used, will also provide additional guidance to consumers as to how much they have consumed because it is presented in portion controlled, easy-to-use format. In line with profile and behaviour of current phytosterol users, these products will be targeted specifically at consumers aged 35 years and older and with concerns over their blood cholesterol levels. With Kraft's targeted marketing strategy and premium pricing coupled with the existing risk-management measures established by FSANZ (labelling and consumer education), these products will be perceived as niche products not intended for mainstream consumers.

PART A: GENERAL INFORMATION ON THE APPLICATION *(3.1)*

Note: Numbers in italics at the ends of headings refer to paragraph numbers in the Application Handbook

1. PURPOSE OF THE APPLICATION *(3.1.3 & 3.5.2 A 1)*

The purpose of the application is to seek permission for the use of phytosterol esters derived from vegetable oils in low fat cheese and low fat processed cheese. Changes will be required to the Code:

Standard 1.5.1 – Novel Foods, and
Standard 2.5.4 – Cheese

It is noted that the mandatory advisory statements relating to phytosterols in Standard 1.2.3 would apply.

Proposed changes to the Code are:

Option 1:

Standard 1.5.1 – Addition to Table to Clause 2

Column 1	Column 2
Novel Food	Conditions of Use
Phytosterol esters	… ***May only be added to cheese in accordance with Standard 2.5.4***

Standard 2.5.4 – Addition of Clause 5

5. Phytosterol Esters
Phytosterol esters may only be added to cheese -

- ***(a) such that the cheese contains no more than 6g of total fat per 100g excluding phytosterol ester; and***
- ***(b) that the cheese is supplied in a portion, the capacity of which is no more than 50g; and***
- ***(c) where the total phytosterol ester added is no less than 70g/ kg and no more than 90g/ kg.***

Option 2:

Standard 1.5.1 – Addition to Table to Clause 2

Column 1	Column 2
Novel Food	Conditions of Use
Phytosterol esters	… ***May only be added to cheese in accordance with Standard 2.5.4***

Standard 2.5.4 – Addition of Clause 5

5. Phytosterol Esters

Phytosterol esters may only be added to cheese -

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

2. JUSTIFICATION FOR THE APPLICATION *(3.1.4 & 3.5.2 A 2)*

2.1 Purpose

When delivered through food, including cheese, phytosterols have been shown to be an effective ingredient in lowering blood cholesterol among people with hypercholesteremia (Katan 2003, Korpela 2006, Jauhiainen 2006). Consequently a number of different products containing phytosterols are now available in Australia, Europe and US.

It is noted in the Second Review Report to Applications A433, A434, and A508 that the target market for phytosterol-containing margarine tends to consume less margarine than the average population, so does not get the benefit envisaged by the introduction of those products. Similar finding was also reported in a Dutch study (Fransen et al 2007). Indeed it was suggested in the Second Review Report that other fortified products would not only assist in achieving the recommended intake, but would also provide wider consumer choice. (FSANZ 2006)

With currently available products, consumers are able to take as much of the product as they think is appropriate for their needs from a bulk container. This may bear no resemblance to the amount recommended by the manufacturer and, as will be seen below, there is information to suggest that many do not consume enough to be effective. Unless the consumer weighs out the amount, they may have little idea whether they are taking sufficient to achieve optimum cholesterol-lowering effect. The cheese products in this proposal are better able to deliver an effective amount of phytosterols as they are portion-controlled. For example one cheese slice will deliver 1 gram phytosterols, and thus the consumer knows exactly how much they have consumed and can adjust the rest of their diet accordingly. In addition, these cheese products help to meet dietary recommendation of NHMRC and Dairy Australia for a variety of low-fat dairy foods.

These cheese products will be targeted at consumers with concerns of high blood cholesterol levels, the majority of which are aged 35+. The premium pricing of the products along with appropriate labelling and marketing strategy would provide a disincentive to non-intended target groups and also to dissuade excessive intake.

NHMRC and FSANZ encourage consumers to eat a variety of foods to ensure obtaining all the essential nutrients. Introduction of these products will give consumers more choice about where they will obtain their phytosterols from and thus allow them to vary their diet day to day but still obtain the phytosterols that they need.

In Australia, it has been estimated that more than 6 million adults aged 25 years and over had high cholesterol levels (more than 5.5mmol/L) (AIHW 2008). Given the high prevalence of hypercholesterolemia and limited availability of phytosterol products in the Australia today, Kraft believes there is room for introduction of additional phytosterol-enriched products.

The purpose of this proposal, therefore, is to increase the variety of foods available to consumers seeking blood cholesterol reduction and to do this via portion control to better enable measurement of intake.

2.2 Safety

The safety of phytosterols as a novel food has been extensively reviewed by FSANZ (FSANZ 2001, FSANZ 2005, FSANZ 2006) and it is currently permitted for use in edible oil spreads, breakfast cereals, low fat milk and low fat yoghurt in accordance with Standards 1.2.3, 2.4.2, 2.5.1 and 2.5.3. Products conforming to these standards have been on the market for some time although most of these have been table spreads.

Concern has been expressed that young children and pregnant women could be at risk from consuming phytosterols extra to what is in the normal diet. The specific marketing to the target group, which is over child-bearing age, the distinct labelling of the products, and the warning statements on pack as per current FSANZ requirements will all assist in minimising the exposure of these groups to the products. As the product is of necessity sold at a premium to unfortified product, the price of the product will assist in deterring all but those who wish to purchase the product for its blood cholesterol lowering property. Kraft Foods has no evidence to suggest that this approach is not working.

Phytosterols are normal components of vegetable fats, and consequently people on a vegetarian diet would consume a greater proportion of these components than the normal population. No adverse health effect has been reported in the human studies and post-launch monitoring in Europe (see section 4). It is noted that JECFA have recently issued minutes of a meeting in which they recommended an ADI of 0-40 mg/kg bw per day for phytosterols which was derived from NOEAL based on rat feeding studies and with a safety factor of 100 (JECFA 2008). The ADI of 40 mg/kg translates to 3.3g per day based on the current average Australian adult weight of 83.6kg (ABS 2008).

2.3 Cost-Benefit

The benefit to consumers, in particular consumers who have a cholesterol problem, is that they will have increased variety of the foods available to assist them in controlling cholesterol levels. For those already consuming products containing phytosterols, they will be able to vary their diet, and also more easily measure the amount they are consuming as the products are portion-controlled. For those consumers whose blood cholesterol responds to phytosterol consumption, managing cholesterol levels through diet is cheaper than through medication.

The government will benefit by it being easier for consumers with cholesterol issues to consume effective amounts of cholesterol-reducing foods and thereby reduce pressure on Public Health resources.

There is no cost to industry of introducing these changes. In fact, the benefit to industry is allowing innovation in that a potentially beneficial ingredient can be offered to consumers in a different carrier. Only those manufacturers capable of manufacturing low-fat cheeses will be able to utilise the proposed permissions.

3. SUPPORT FOR THE APPLICATION *(3.1.5)*

Supporting this application, technical information of phytosterols, safety and nutritional assessment and potential impact on consumers and industry are provided in Part B of this application. This information is presented in the format described in section 3.5 of the Application Handbook.

4. ASSESSMENT PROCEDURE *(3.1.6)*

Kraft Foods expects that this assessment will be a general procedure as per Section 2.2.5 in Application Handbook. Previous applications have resulted in extensive evaluation of phytosterols as novel foods, and this application is seeking an extension of that permission.

5. CONFIDENTIAL COMMERCIAL INFORMATION (CCI) *(3.1.7)*

All marketing information in this application relating to factors such as market trends, market size and consumer research has been purchased from third parties. For contractual reasons whilst Kraft can use this data for commercial purposes this information cannot be made available for public access. As such, such marketing information is to be held commercial in confidence and is included under annexes 6-15. Kraft is also commissioning further consumer research. This information will be forwarded as soon as it becomes available and is also to be treated as confidential commercial information.

6. EXCLUSIVE CAPTURABLE COMMERCIAL BENEFIT (ECCB) *(3.1.8)*

There is no exclusive capturable commercial benefit associated with this application.

7. INTERNATIONAL AND OTHER NATIONAL STANDARDS *(3.1.9)*

In Europe, phytosterols are permitted in yellow fat spreads, milk-based products, yoghurt products, salad dressing, spicy sauces, fermented milk type products, soy cheese and low-fat cheese products (European Commission 2004a, 2004b). In the USA, on the basis of GRAS notifications, phytosterols are permitted to be added at levels generally ranging from 0.4g to 1.0g per serving in a wide range of products including vegetable oil spreads, salad dressing, yoghurt type products, fruit juice (orange), milk-based juice beverages, cream cheese and cream-cheese like products, cheese and cream, mayonnaise, breakfast cereals, pasta and noodles, salty snacks, eggs substitutes and ground roasted coffee (GRN No 48, 61, 112, 176, 177, 181). Phytosterols have also been approved at novel food in some Asian countries. In Malaysia, plant sterols are permitted in milk, milk products, soy bean milk and soy bean drink. In China, phytostanols are permitted in margarine, milk products, salad dressings, mayonnaise, fruit juice, pasta and noodles, and instant oats.

It is noted that at the 69th meeting of the Joint FAO/WHO Expert Committee on Food Additives in June 2008 concluded that "Group ADI of 0-40 mg/kg body weight for phytosterols, phytostanols and their esters, expressed as the sum of phytosterols and phytostanols in their free form, based on an overall NOAEL of 4200 mg/kg body weight per day to which a safety factor of 100 was applied." (JECFA 2008) Given that the average weight of Australian adults, as surveyed in the National Health Survey 2004-2005, is 83.6kg (ABS 2008), the ADI of phytosterols would translate to about 3.3g per day.

PART B: INFORMATION TO SUPPORT APPLICATION *(3.5.2)*

1. KRAFT'S INTEREST IN MARKETING PHYTOSTEROL-ENRICHED CHEESE PRODUCTS *(3.5.2 A 3)*

Kraft Foods Limited (Australia/New Zealand) sits within the top 20 food and grocery companies in the region and is a subsidiary of Kraft Foods Inc, the second largest branded food and beverage company worldwide. In Australia/New Zealand, Kraft employs more than 1,300 employees who work primarily from three sites - Port Melbourne, Suttontown and Strathmerton, which produce some of Australia's most iconic brands, including Vegemite, Kraft Singles, and Philadelphia. These brands are found in most Australian households. Sales revenue is over A$650 million, with one third coming from cheese. Kraft products are exported to 55 countries around the world, including Japan, South Korea, Hong Kong and Singapore. Exporting contributes 15 per cent to the Kraft business, with dairy products - Philadelphia and Cream Cheese Spread - being the primary drivers.

1.1 Kraft's commitment to Health & Wellness

Kraft is committed to launching products that promote health and wellness in the community. As part of corporate policy, Kraft follows strict guidelines directing the types of products to be developed and marketed.

> *"Kraft takes a leading interest in the responsible marketing of food products to consumers. We understand the important role food companies play in educating consumers on nutrition and maintaining a healthy balanced lifestyle. That's why globally, we have established the Healthy Living Principles and draw upon Kraft Foods Worldwide Health & Wellness Advisory Council to ensure we're responsible when it comes to consumption of food, marketing and serving sizes. Kraft also encourages promotion of an active lifestyle through our marketing programs"* (*Kraft Healthy Living Policies and Practices, Marketing Practices)*

Kraft recognises that Health and Wellness is of increasing concern to consumers, with two issues in particular being obesity and high blood cholesterol. Kraft has been a leader in the development and marketing of fat free salad dressings and progressively lower fat cheeses in the Australian marketplace. Today, lower-fat cheeses represent over 30% of Kraft's retail cheese tonnage.

1.2 Responding to consumer needs

Over the past 12 years Australians' satisfaction with their personal health and wellbeing has been steadily declining (Annex 6). As a leading food manufacturer Kraft takes on responsibility to ensure Australian consumers are provided with healthy food options.

One of the main health concerns in Australia is obesity. As a result there is an increasing number of Australians trying to lose weight (54% in 2007) (Annex 7). For more than 15 years Kraft has successfully been working on lowering the fat levels in cheeses while trying to maintain product safety and flavour. The results can be seen in the range of cheeses now available at different fat levels as can be seen in section 6.1.

It has also been shown from our internal research that high blood cholesterol was the fastest growing health concern among Australians between 2006 and 2007 (Annex 8). Given the prevalence and correlation between elevated levels of blood cholesterol and obesity, Kraft believes the launch of a low fat, cholesterol reducing cheese will have strong market appeal, especially when presented in a portion-controlled format.

1.3 Branding and marketing of phytosterol products

Kraft plans to launch a new health and wellness phytosterol sub-brand, targeted at the 50+age group in 2009. The leading name which has been approved for Australian trade-marking is provided in Annex 9. Kraft believes a new brand name is necessary to show distinct separation of phytosterol-enriched cheese products from existing standard products such as Singles which are currently being consumed largely by children. The unique benefit of phytosterols will be clearly communicated on pack to indicate intended usage purpose. (See section 3.2.2 for further information on labelling and packaging)

Kraft's own research to date has indicated that the population age 50+ years are heavy consumers of the mainstream media, in particular Magazines, Newspapers and Television (Annex 10). Whilst the exact communication plan is still being developed, it is likely to be television led with support in targeted magazine media, such as New Idea, House & Garden and Gardeners World which all target this age group.

The phytosterol-enriched cheese products will be priced at a significant premium compared to standard products due to the costs involved. Given the higher costs of these products compared to the standard offerings, together with differentiating name and targeted marketing and advisory statements on product label, it is unlikely those who do not have cholesterol concerns will purchase the product.

1.4 Dietary intake management and communications

The advantage of the products Kraft is proposing over those that currently exist in the market is portion control in a convenient form where the entire portion is more likely to be consumed. These cheese products will be packaged in controlled serves, i.e. individual-wrapped (20.5g) cheese slices and a two-serve 40g minitub for cream cheese. Each will provide 1g phytosterols per ~20g serve. The nature of portion controlled packaging allows an easy measurement by the consumer of the amount of phytosterols they have eaten.

The key messages on label and in advertising will focus on the benefits of phytosterols and the convenience of the portion control provided by these products. The first part of the message will highlight the blood-cholesterol lowering benefit of phytosterols when consumed up to 3 grams per day as part of a healthy diet. For example, "*When included as part of a healthy diet Live Active slices / cheese spread with plant sterols can reduce your blood cholesterol absorption".* The second part of the message will indicate the amount of phytosterols a portion of the product delivers and the portion controlled nature of these products that allow consumers to better manage getting effective and appropriate quantities in convenient format. For example, "*Just two slices or one mini tub give an effective daily amount of plant sterols in a convenient format.*"

In addition, labelling and advisory statements will be provided on label as well as the marketing materials that the group of consumers the products are not intended for. For example "*This product may not be suitable for children under the age of five years and pregnant or lactating women*". Furthermore, excess consumption will be restrained by the statement: *"More than 3 gram plant sterol per day does not provide extra benefit*" (see section 3.2.2 for further information on labelling and packaging)

2. EXCLUSIVE USE OF PHYTOSTEROLS IN CHEESE PRODUCTS *(3.5.2 A 4)*

Kraft seeks exclusive permission for the use of phytosterols in the **cheese** category as defined in Standard 2.5.4.

If exclusive use is provided to Kraft Foods for the usual period of 15 months, Kraft Foods will be first to market with the foods mentioned in this application. This will assist in recovering the costs associated with the application and the research behind it. The benefit to FSANZ of providing this period of exclusivity to Kraft will be that actual information will be able to be provided about consumer usage and behaviour rather than predicted information, and this can then be used to modify the regulations in the unlikely case that this should be necessary.

3. TECHNICAL INFORMATION ON PHYTOSTEROLS *(3.5.2 B)*

3.1 Pre-approved novel food ingredient – phytosterols *(3.5.2 B 1)*

Phytosterols are naturally present at low levels in some fruits, vegetables, nuts, cereals and common vegetable oils. The form of the phytosterols intended for use is phytosterol esters derived from vegetable oils. As phytosterols are extracted from plant source, they fall within 'plant or animal extracts' category of the FSANZ's guidelines for novel food.

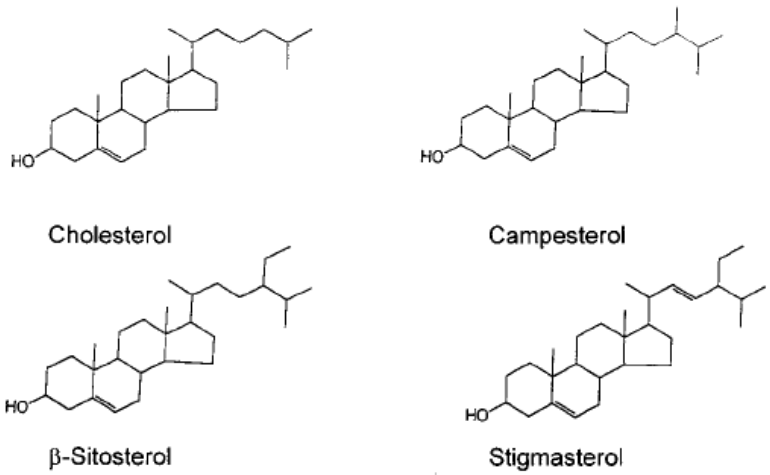
In the year 2001, FSANZ approved phytosterol esters as a novel food ingredient according to definitions in Standard 1.5.1 – Novel Foods for use in edible oil spreads. More recently, its use was extended to breakfast cereals, low fat yogurt and low fat milk as listed in the Table to clause 2 of Standard 1.5.1.

The phytosterol esters intended for use in cheese products will be in accordance with the specifications listed under Standard 1.3.4 – Identity and Purity in the Code (see section 3.1.4). Details of the technical specification are provided at Annex 1.

3.1.1 Physical and chemical properties of phytosterols *(3.5.2 B 2)*

Free phytosterols are structurally related to cholesterol found only in animals (Figure 1). Sitosterol, campesterol and stigmasterol are the major types of phytosterols found in vegetable oils. Phytosterols can be esterified by reaction with fatty acid methyl esters or free fatty acids to produce phytosterol esters. As a food ingredient, phytosterols are "free-flowing, white to off-white powders, pills or pastilles; or colourless to pale yellow liquids." The chemical names, C.A.S numbers, empirical and structural number, molecular weight and other chemical characteristics were recently documented in the new specification for phytosterols prepared for 69th JECFA meeting in 2008 (Annex 2).

Figure 1: Chemical structure of cholesterol and phytosterols



3.1.2 Impurity profile for a typical preparation *(3.5.2 B 3)*

The standard methods traditionally used for the production of phytosterols involve several refining steps that remove solvents (if used in extraction), lecithins, free fatty acids, colour, and various odours and off-flavours. The phytosterols are further purified by recrystallisation. (Annex 2)

3.1.3 Manufacturing process for phytosterols *(3.5.2 B 4)*

Phytosterols and phytostanols are isolated from deoderizer distillate (a by-product of edible oil production), or derived from tall oil (a by-product of wood pulp manufacture). They are purified by distillation, extraction, crystallization and washing resulting in products of high purity. The production of phytosterol esters is described in Annex 2.

3.1.4 Specification for identity and purity for phytosterols *(3.5.2 B 5)*

The specification for phytosterol esters derived from vegetable oils is described in Standard 1.3.4 of the Code. The phytosterol esters intended for use in Kraft cheese products will meet this specification:

Specification for phytosterol esters derived from vegetable oils

Phytosterol esters are phytosterols derived from edible vegetable oils esterified with long-chain fatty acids derived from edible vegetable oils.

Phytosterol esters + free phytosterols (%) min. 94
Free phytosterols (%) max. 10
Steradienes (%) max. 0.3
Fatty acid methylester (%) max. 0.5
Iron, Fe (ppm) max. 1.0
Copper, Cu (ppm) max. 0.5
Moisture (%) max. 0.1
Trans fatty acids (%) max. 1.0
Sterol profile (%) as below -
Cholesterol min. 0.0 max. 2.0
Brassicasterol min. 0.0 max. 6.0
Campesterol min. 20.0 max. 29.0
Campestanol min. 0.0 max. 6.0
Stigmasterol min. 12.0 max. 23.0
β-Sitosterol min. 42.0 max. 55.0
β-Sitostanol min. 0.0 max. 2.5
D5-Avenasterol min. 0.0 max. 4.0
D7-Stigmastenol min. 0.0 max. 2.0
D7-Avenasterol min. 0.0 max. 2.0
Other min. 0.0 max. 6.0

3.1.5 Analytical method for detection *(3.5.2 B 6)*

The method of identification for phytosterols is by gas chromatography. Full detail of the method of assay is described in the phytosterols specification by JECFA (Annex 2).

3.2 Description of novel foods containing phytosterols

This application covers the addition of pre-approved phytosterol esters in cheese products as specified in Standard 2.5.4 of the Code where

> ***cheese*** *means the ripened or unripened solid or semi-solid milk product which may be coated and is obtained by one or both of the following processes –*
>
> *(a) coagulating wholly or partly milk, and/or materials obtained from milk, through the action of rennet or other suitable coagulating agents, partially draining the whey which results from such coagulation; or*
>
> *(b) processing techniques involving concentration or coagulation of milk and/or materials obtained from milk which give an end product with similar physical, chemical and organoleptic characteristics as the product described in paragraph (a)*
>
> ***processed cheese*** *means a product manufactured from cheese and products obtained from milk, which is heated and melted, with or without added emulsifying salts, to form a homogeneous mass.*

The cheese products intended for adding phytosterols are low fat spreadable cream cheese and processed cheese slices where the total fat level of the cheese products does not exceed 6g/100g *before* addition of phytosterols or 14g/100 *after* addition of phytosterols (i.e. total of fat originally in the product plus added phytosterol esters). One slice of processed cheese product will provide approximately 1g of phytosterols, while a 40g mini-tub of the cream cheese which can provide several serves if used as bread spread, 2 serves if used as a cheese, or a single serve if used as a dessert, provides 2g.

3.2.1 Process of producing cheese products containing phytosterol esters

Processed cheese slices containing phytosterol esters are prepared using same process as low fat individual-wrapped cheese slices (IWS) (see Annex 3). The amount of phytosterol esters is controlled at point of addition and by periodic testing of phytosterols in finished product. The product safety and quality is managed by following standard Hazard Analysis & Critical Control Points (HACCP) and Good Manufacturing Practices (GMP) for IWS. Product packaging, storage, and distribution are also same as IWS.

Cream cheese containing phytosterol esters is prepared using same process as low fat cream cheese Philadelphia (see Annex 4). The amount of phytosterol esters is controlled at point of addition and by periodic testing of phytosterols in finished product. The product safety and quality is managed by following standard Hazard Analysis & Critical Control Points (HACCP) and Good Manufacturing Practices (GMP) for Philadelphia manufacturing. Product packaging, storage, and distribution are also the same as Philadelphia.

3.2.2 Packaging and labelling cheese products containing phytosterol esters

Kraft proposes to sell these cheese products in product formats containing individual serves, such as a wrapped 20.5g cheese slice, and 40g cream cheese tubs containing 2 servings (Annex 9). Each serving of cheese products (half tub of spreadable cream cheese or one slice of processed cheese) will contain 1g of phytosterols. The recommended intake will be 2 servings of the cheese products for a target daily intake of 2g of phytosterols.

An expected ingredient listing for both cheese products is provided as follows:

Product	Ingredient List
Low fat cream cheese with phytosterol esters	Cottage cheese (Skim milk, Starter culture, Enzymes), Cream cheese (Milk, Cream, Starter culture), Milk Solids Non Fat, Plant Sterols (contains Mixed Tocopherols (306)), Vegetable gums (407, 410), Salt, Thickener (1442), Maltodextrin (Tapioca), Food acid (330), Preservative (200).
Reduced fat processed cheese with phytosterol esters	Skim milk, Milk, Milk solids non fat, Plant sterols (contains Mixed Tocopherols (306)), Emulsifiers (331,339, 341), Salt, Acidity regulator (270), Colours (160a, 171), Preservative (200), Starter cultures, Enzymes, Vitamin D3

In addition, the product will be labelled:

- with plant sterols added
- This product 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.

Examples of product packaging for cheese products with phytosterols are provided in Annex 9.

4. SAFETY OF PHYTOSTEROLS *(3.5.2 C)*

4.1 Composition and method of extraction of phytosterols *(3.5.2 C(II) 1)*
- see section 3.1.1 and 3.1.3

4.2 Use of phytosterols in other countries *(3.5.2 C(II) 2)*
The phytosterol-enriched yellow fat spreads have been in the Europe and US markets since 1995 and 1999, respectively. Since its introduction, the range of product fortified with phytosterols has expanded to include low fat milk, yogurt and cheese products, salad dressing, fruit juice, and mayonnaise. (Table 1) Phytosterol-fortified cheese products are currently available in US, UK and some Europe countries (Annex 5)

Table 1: Product types with added phytosterols and/or phytostanols that are approved to be marketed in the EU through regulation or notification as of September 2007.

EC decision/ notification	Applicants	Ingredient	Yellow fat spreads	Milk type products	Fermented milk type products (e.g. yoghurt type products)	Milk based fruit drinks	Soya drinks	Cheese type products	Salad dressings	Spice sauces	Rye bread	Rice drinks
Pre regulation	Raisio Plc.	Benecol®	No approval needed									
2000/500/EC 2004/335/EC	Unilever	Pro.active™	x	x	x							
Notification	Cognis	Vegapure®	x	x	x	x	x	x	x	x	x	
2004/333/EC	Archer Daniels Midland Co.	CardioAid™	x	x	x		x	x	x			
Notification	Cargill Inc.	Corowise™	x	x	x	x	x	x	x	x	x	
Notification	Danone	Danacol®			x							
Notification	Triple Crown	Prolocol™		x	x			x				
2004/334/EC 2006/58/EC	Pharmaconsult Oy Ltd	Multibene®	x	x	x					x	x	
2006/59/EC	Oy Karl Fazer Ab	-									x	
2004/336/EC Notification 2008/36/EC	Teriaka Ltd	Diminicol™	x	x	x	x	x	x				x
2004/845/EC Notification	Forbes Media-Tech Inc.	Reducol™	x	x	x	x	x	x	x	x	x	
Notification	Arboris	AS-2™	x	x	x		x	x	x	x	x	
Notification	PrimaPharm B.V.	Beta sitosterol	x	x	x		x	x				
Notification	Fenchem Enterprises Ltd.	Cholevel™	x	x	x	x		x	x	x	x	
Notification	DRT	Phytopin®	x		x	x		x				
Notification	DDO Processing LLC	Nutraphyl™		x	x		x		x	x		
Notification	Degussa Food Ingredients GmbH	Cholestatin™	x	x	x	x	x	x	x	x		
Notification	Vitae-Caps S.A.	Vitasterol®	x	x	x		x	x	x	x	x	
Notification	Inpharma S.A.	-		x	x			x				
Notification	Forbes Media-Tech Inc.	Phyto-S-Sterol™	x	x	x	x	x	x	x	x	x	
Notification	Lipofoods	Lipophytol™	x	x	x	x	x	x	x	x		
2007/343/EC	Enzymotech Ltd	CardiaBeat™	x	x	x		x	x	x	x		

Source: ESFA 2008

4.3 Toxicity of phytosterols shown in animal or human studies *(3.5.2 C(II) 3)*
As phytosterols are naturally present in plants, they have been part of human diet for a long period. It was estimated that the normal dietary intake of phytosterols is between 200-400mg per day for a typical western diet (SCF 2002). However, the use of phytosterol-enriched food products would raise an individual intake to a much higher level. The toxicological assessment on phytosterol esters was previously carried out (FSANZ 2001, FSANZ 2004, FSANZ 2006, SCF 2000, SCF 2002).

Studies in animals show that phytosterols:

- are poorly absorbed in gastrointestinal tract (Sanders et al 2000)
- are not genotoxic (Wolfreys and Hepburn 2002)
- have no effect on reproductive parameters and no oestrogenic activity (Baker 1999, Waalkens-Berendsen 1999)
- are low in toxicity with NOAEL of 4.1g phytosterols/kg bodyweight derived subchronic toxicity study (Hepburn 1999)

Human studies show tolerability of high doses on humans without adverse effects. In an unpublished study as reported in Safety Assessment Report by FSANZ for Application A434, an intake of 10.7g phytosterol esters (equivalent to 6.6g phytosterols) over 12 week period was not associated with adverse toxicological effects. (FSANZ 2004) Davidson and colleagues (2001) reported no evidence of adverse effect with intake up to 9g phytosterols over an eight-week period. The post-launch monitoring study evaluated the health-related complaints during the first year of marketing in Europe and reported no indication of any unexpected health effects associated with the use of phytosterol-enriched product in the marketplace. (Lea 2006)

4.3.1 Phytosterolaemia
There are a small number of people with inborn genetic disorder of phytosterol metabolism where the body is unable to differentiate between cholesterol and non-cholesterol sterols. As such, patients with this disorder have higher blood levels of plant sterols and develop tendon and tuberous xanthomas, arthralgias and arthritis, accelerated atherosclerosis and premature coronary artery disease. However, cases of phytosterolemia are rare. (Lee 2001, SCF 2002)

4.4 Safety assessment by international agencies and other national agencies *(3.5.2 C(II) 4)*

4.4.1 Previous assessments by FSANZ
The safety of vegetable oil derived phytosterols has been previously assessed in A410 (Veg Oil Derived Phytosterols) and subsequently approved for use in edible oil spreads, breakfast cereals, low fat milk and low fat yogurt (FSANZ 2000, FSANZ 2006).

In the Second Review to the Applications A433, A434 and A508, the long term consumption of phytosterols was extensively reviewed and FSANZ concluded that

> *"Based on the large number of safety/efficacy studies in humans and toxicological studies in animal… there was no evidence to indicate adverse effects from longer term consumption of phytosterols... On the contrary, phytosterols were well tolerated, efficacious in the food*

matrices under consideration (over and above a background of low-fat diet) and raised no safety concerns in adults or children. High levels of consumption (up to 10g per day) have been shown in clinical studies to be safe, providing a safe margin of exposure when compared to the expected level of consumption of 2-3 g per day… (Phytosterols) have been available in food supply for more than 10 years without raising safety concerns." (FSANZ 2006)

4.5.2 Safety assessments by European Commission

The use of phytosterols as novel food ingredient, its long term effects of the intake and its application in a variety of foods were extensively reviewed and assessed by the Scientific Committee of Food of the European Commission (SCF 2000, SCF 2002, SCF 2003). In its evaluation of a variety of phytosterol-enriched foods (bakery products, snack products, meat products, margarine, soft cheese, yogurt or fruit milk drinks), the SCF concluded that "*on the basis of the available toxicological and nutritional data on phytosterol esters and phytosterols in accordance with the previous opinions (in 2000 and 2002), that the use of phytosterols in these foods is safe."* (SCF 2003)

4.5.3 Acceptable Dietary Intake (ADI) established by JECFA

It is noted that JECFA recently issued minutes of a meeting in which they recommended an ADI of 0-40 mg/kg bw for phytosterols where a safety factor of 100 is applied to NOAEL level of 4200mg/kg bw (JECFA 2008). This translates to 2.8g/day for a 70kg person or 3.3g/day based on the average weight (83.6kg) of Australians (ABS 2008). Given that consumers are encouraged to have a varied diet, it is expected that consumers may obtain their intake of phytosterols from a variety of sources over a period of time. The format of the proposed products will facilitate control over the amount consumed as compared to some products already in the market.

5. DIETARY EXPOSURE TO PHYTOSTEROLS *(3.5.2 D)*

5.1 Foods or food groups proposed to contain phytosterols *(3.5.2 D 1)*
Phytosterol esters are proposed to be added to low fat cheese and processed cheese. As mentioned in Section 1 of Part B earlier, Kraft intends to fortify phytosterols in a spreadable cream cheese (in 40g mini-tub format) and processed cheese slice.

5.2 Proposed level of phytosterols for each food or food group *(3.5.2 D 2)*
Phytosterol esters are proposed to be added to cheese and processed cheese at the level of no less than 70/kg and no more than 90g/kg. Consumption of 20g of cheese product would provide approximately 1g of phytosterol equivalents. These cheese products will be presented in individual slices or in a 40g tub. The nature of the presentation of these products will allow the ready assessment of actual amount of phytosterols to be consumed.

5.3 Percentage cheese anticipated to contain phytosterols *(3.5.2 D 3)*
A recent review by European Food Safety Authority reported that in UK, phytosterol-enriched products by volume only comprised 2-12% of the total spreads markets and EFSA concluded that "market share for phytosterol-enriched products in any one product category is likely less than or much less than 10%" (ESFA 2008). In US, products labelled with "lower/reduce cholesterol" or "sterols" constitutes less than 1% of total dairy sales (Nielsen Scan Data, 52 weeks ending 8/9/08). In Australia, phytosterol-enriched table spreads represent 7% volume of total table spreads market (AC Nielsen, Market Information Digest, MAT 30.3.08).

It is expected that the uptake of cheese as a phytosterol carrier will not be as great as for table spreads because spreads were first into the market. Table spreads appear to be the current preferred carrier for phytosterols as there are many more varieties of phytosterol-containing spreads on supermarket shelves than yoghurts or milks. Without the first-mover advantage, this bias towards table spreads and the fact that over 50% of the individually-wrapped processed cheese slice (IWS) market is generic brands in a category which is very price-driven, Kraft estimates that the enriched processed cheese slices will initially gain 2.5% of the market and eventually represent 3.5% of this market.

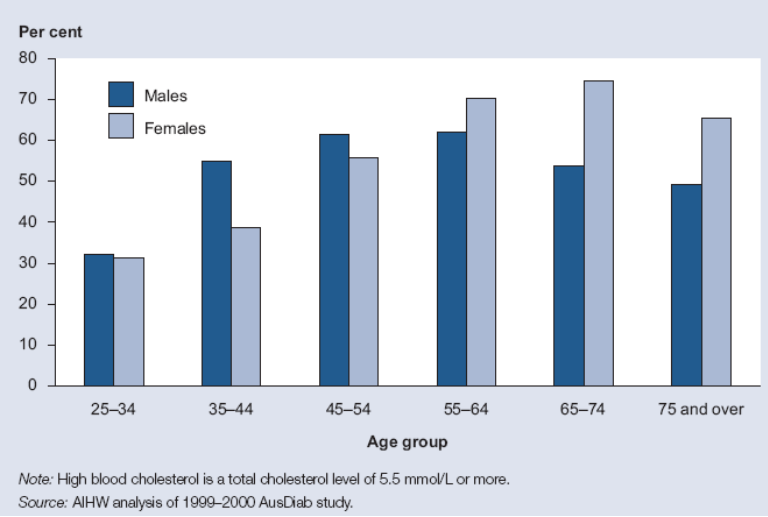
On the other hand, cream cheese buyers are more health-focused and less price-sensitive, and hence Kraft estimates that initially 4.5% of this market rising to 6% will be the phytosterol-enriched products. Current annual consumption of these products is 16,105 tonnes (IWS) and 6,427 tonnes (cream cheese) respectively.

As shown in Annex 11, Kraft expects that the eventual consumption will be a total of 47.5×10^6 serves (IWS plus Cream Cheese) which is 9% relative to the table spreads market. While it is estimated that a large percentage of these cheese serves would be consumed by current phytosterol table spread users instead of the spread with the remainder coming from new users, the worst case would be if the 9% cheese consumption was incremental. (Annex 11)

5.4 Target group and predicted consumption *(3.5.2 D 4)*

The products containing phytosterols will be targeted at consumers who are 35 years and above and have specific needs to lower their blood cholesterol levels. The AusDiab study in 1999/2000 estimated that 6 millions Australian adults have high cholesterol levels (>5.5mmol/L). At the age of 30 years, it has been reported that around 30% have high blood cholesterol. The prevalence increases sharply from the age 35 onwards and peak around age 70 for female and age 60 for male. (Figure 2) (AIHW 2008)

Figure 2: Age-specific prevalence of high blood cholesterol, 1999-2000



Source: AIHW 2008

With portion-control nature of the products and advisory statements to guide appropriate quantity to consume, Kraft anticipates the consumption level of phytosterols to be 2g/day for an individual.

The introduction of new phytosterol-enriched products is likely to replace existing table spreads, rather than adding to existing spread usage for current users. This is supported by the Irish post-launch study where the majority (69%) of the consumer surveyed used only one product type, 27% consumed two product types daily while only 4% consumed three product types per day. (Hearty 2008) In Germany where seven phytosterol products are available from five different categories (yellow fat spreads, milk, yogurt drinks, skim milk, cheese slices and bread) only 1-2% consumed three products or more during the same day. (Niemann 2007) It is expected that new users will enter the market as well because of the convenient format of the proposed products.

To validate our projection, Kraft Foods is currently carrying out research to indicate the behaviour of the target market towards usage of the proposed foods. This research is intended to ascertain:

- If current non-users among target consumers will consume phytosterol products due to the availability of this new form;
- If current phytosterol users will use this cheese product to supplement current consumption and meet the recommended levels, or allow variation in the diet while maintaining levels below the recommended upper level.

This further information is expected to be available before December 2008 and will then be appended to this application.

5.5 Current exposure levels in Australia and overseas countries *(3.5.2 D 5)*

5.5.1 Australia

The dietary exposure assessment for Applications A433 and A434 reported phytosterol-enriched breakfast cereals and table spreads could result in a mean exposure of up to 1.7g phytosterols per day and highest consumption (95th percentile) at 4.4g/day, especially among consumers aged 40-64 years. When combining all phytosterol-enriched foods (table spreads, breakfast cereals, low fat milk, and low fat yogurt) the mean phytosterol exposure and 95th percentile exposure were estimated to be 1.9g/day and 4.7g/day, respectively (FSANZ 2005, FSANZ 2006). At the proposed phytosterol levels in cheese, Kraft does not anticipate significant increase in mean and highest exposure to phytosterols. Data collection currently underway may assist in clarifying the exposure and this data will be made available as soon as it comes to hand.

5.5.2 Europe

A Dutch study reported that the consumption of phytosterol-enriched margarine by regular consumers of phytosterols was much lower than the recommended intake (Fransen 2007). In the recent review by EFSA (2008), the exposure levels of phytosterols in some European countries are summarised in Table 2. EFSA has also concluded in their latest review that "*with a greater choice of enriched products being introduced on the market it might be anticipated that dietary intakes of plant sterols will increase. So far there is no indication of this happening."*(ESFA 2008)

Table 2: Phytosterol exposure in selected European countries

	No. of enriched foods on market	Mean/ median g/day	P97.5 (P95*) g/day	>3 g per day	Daily consumption	Proportion of consumers eating respective no. of products/day				
						<1	1	2	3	4
Post-launch	2	1.0-1.9	~2.2-3.6*	5%	-	-		-	-	-
Ireland	5	2.5	6.6	23%	90%	-	69%	27%	4%	
Germany	7	-	~3	2.3%	84%	17%	72%	9%	1%	<1%
United Kingdom	3	~0.9	~3	0.5-3%	29%	53%	39%	6%	2%	

Source: EFSA 2008

Kraft thus anticipates that the addition of cheese permissions will not have a negative impact on exposure levels but more importantly have a positive effect on consumers' ability to consume appropriate amounts to see an effect.

6. NUTRITIONAL IMPACT OF PHYTOSTEROLS *(3.5.2 E)*

6.1 Nutritional properties of phytosterol-enriched cheese products

In line with general dietary guidelines with respect to fat consumption, Kraft proposes the addition of phytosterols should limit to reduced-fat cheese with total fat level as low as 6g/100g *before* addition of the phytosterol esters.

There are a number of ways in which the amount of phytosterols in these products could be expressed in the Nutrition Information Panel. Under normal food analytical methodology for fat, phytosterols and phytosterol esters would be included in the result. It is noted that products currently on the market present total fat as the sum of the saturated, trans, polyunsaturated, and monounsaturated fats and put the free sterol equivalent as a separate line. The data below is expressed in the same manner.

Kraft produces a range of cheeses with varying nutrient levels as can be seen from Table 3.

Table 3: Nutritional information of regular and reduced fat variants of Kraft Singles

	Regular Singles		Light Singles		Extra Light Singles		97% Fat Free Singles	
	Average quantity per serving*	Average quantity per 100g	Average quantity per serving*	Average Quantity per 100g	Average quantity per serving*	Average quantity per 100g	Average quantity per serving*	Average quantity per 100g
Energy	257kJ	1226kJ	217kJ	1032kJ	171kJ	812kJ	136kJ	665kJ
Protein	3.9g	18.8g	4.4g	21.0g	5.3g	25.3g	4.9g	23.9g
Fat - Total	4.6g	21.7g	3.3g	15.8g	1.7g	7.9g	Less than 1g	2.2g
- Saturated	3.0g	14.4g	2.2g	10.5g	1.2g	5.6g	Less than 1g	1.5g
Carbohydrate	1.0g	4.9g	Less than 1g	4.1g	1.1g	5.1g	2.0g	10.1g
- Sugars	1.0g	4.9g	Less than 1g	4.1g	1.1g	5.1g	2.0g	10.1g
Sodium	309mg	1472mg	290mg	1380mg	240mg	1144mg	227mg	1087mg
Calcium	168mg	800mg	168mg	800mg	168mg	800mg	164mg	800mg

** A typical serve size of individually wrapped cheese slices is 20.5g.*

To help consumers better manage their fat intake, especially saturated fat, the proposed cheese slice for phytosterol addition will be based on Kraft's lowest fat formula. Another advantage of this product is its calcium content which will assist in addressing the calcium issues that the older population faces. The expected nutritional information panel of the proposed cheese slice containing phytosterols is shown in Table 4.

Table 4: Nutrition Information Panel of cheese slice with phytosterols

Cheese Slice with Phytosterols (serve size 20.5g)		
	Average quantity per serving	Average quantity per 100g
Energy	152kJ	741kJ
Protein	4.9g	23.7g
Fat – Total (exclude sterol)	1.2g	5.7g
- Saturated	Less than 1g	1.6g
- Trans	Less than 1g	Less than 1g
- Polyunsaturated	Less than 1g	1.1g
- Monounsaturated	Less than 1g	2.9g
Plant Sterol	1.0	5.2
Carbohydrate	1.4g	6.7g
- Sugars	1.4g	6.7g
Sodium	215mg	1050mg
Calcium	146mg	712mg

(subject to change)

Kraft has been able to also achieve reduction in the fat levels of the Spreadable Philadelphia range of cream cheeses (Table 5).

Table 5: Nutrition information of regular and fat reduced variants of spreadable Philadelphia cream cheese

	Spreadable Philadelphia		Light Spreadable Philadelphia		Extra Light Spreadable Philadelphia	
	Average quantity per serving	Average Quantity per 100g	Average quantity per serving	Average Quantity per 100g	Average quantity per serving	Average Quantity per 100g
Energy	280kJ	1122kJ	187kJ	749kJ	131kJ	525kJ
Protein	1.4g	5.7g	2.0g	8.0g	3.2g	12.6g
Fat – total	6.4g	25.6g	3.4g	13.6g	1.2g	5.0g
- saturated	4.5g	17.9g	2.4g	9.5g	0.9g	3.5g
Carbohydrate	0.7g	2.7g	1.0g	3.9g	1.6g	6.3g
- Sugars	0.7g	2.7g	1.0g	3.9g	1.5g	5.9g
Sodium	81mg	322mg	66mg	264mg	67mg	269mg

** a typical serve size of spreadable cream cheese is 25g.*

As with the sliced cheese the proposed cream cheese product is based on our lowest fat variant. The expected Nutritional Information Panel of the proposed cheese slice containing phytosterols is presented in Table 6.

Table 6: Nutrition Information Panel of spreadable cream cheese with phytosterols

Light Cr Cheese with Phytosterols (serve size 20g)		
	Average quantity per serving	Average Quantity per 100g
Energy	127kJ	634kJ
Protein	2.3g	11.4g
Fat – Total (exclude sterol)	1.6g	8.1g
- Saturated	Less than 1g	3.3g
- Trans	Less than 1g	Less than 1g
- Polyunsaturated	Less than 1g	1.2g
- Monounsaturated	Less than 1g	3.6g
Plant Sterol	1.0	5.2
Carbohydrate	1.2g	5.9g
- Sugars	1.1g	5.6g
Sodium	51mg	257mg

(subject to change)

The phytosterol-enriched cheese products are expected to replace the standard products in the diet of the target consumers. These products are similar, except for phytosterols, to their standard counterparts. As such, nutrition imbalances are not expected from consuming these phytosterol-enriched cheese products. It should be noted that the cream cheese can be used as a spread as well as a cheese, and it provides lower fat per serve than even the low-fat spreads on the market despite the larger serve size.

6.2 Effects on bioavailability of other nutrients and the overall diet

Some studies have reported the consumption of phytosterol-enriched foods leading to reduction in blood levels of carotenoids (α-carotene, β-carotene, lycopene), xanthophyles (lutein/zeaxanthin and β-cryptoxanthin) and fat soluble vitamins D, E and K (Mensink 2002, Hendriks 1999). However, as these nutrients play a role in protecting LDL cholesterol from oxidation, when the degree of reduction was evaluated relative to the degree of reduction of LDL cholesterol, a significant reduction is only observed for β-carotene. (SCF 2000)

Reduction in β-carotene levels with consumption of phytosterol-enriched foods was previously evaluated by FSANZ for earlier applications. FSANZ concluded that "*the reduction does not translate into an overt nutritional issue as absolute levels remain within a broad range in existing levels in population and there is no measurable effect on retinol or Vitamin A levels. The nutritional significance of β-carotene reduction cannot be directly evaluated.*" (FSANZ 2005, FSANZ 2006)

6.3 Efficacy of phytosterols

The efficacy of phytosterols has been well-documented and reviewed. Intake of 2g/d of phytosterols has been shown to reduce low-density lipoprotein (LDL) by 10% (Katan 2003). While fat-spread is commonly used as food carrier in these studies, the efficacy of phytosterols in other food carriers has also been investigated (Table 7). These include dairy foods such as milk and yogurt, breakfast cereals as well as cheese.

Table 7: Efficacy studies on phytosterol-enriched products, excluding fat spreads

Jauhiainen 2006	Low-fat hard cheese	2g PSta / day	5.8% ↓TC, 10.3% ↓LDL
Korpela 2006	Mix of low-fat yogurt, hard cheese, fresh cheese	2g PS / day	6.5% ↓TC, 10.4% ↓LDL
Seppo 2007	Low-fat milk or yogurt or yogurt drink	2g PSta-E / day	3.8% ↓TC, 4.9% ↓LDL
Clifton 2004	Low fat bread vs bf cereal vs milk vs yogurt	1.6g PSte-E / day	Bread: 6.5% ↓LDL BfCereal: 5.4% ↓LDL LF Milk: 8.7% ↓TC, 15.9% ↓LDL LF Yogurt: 5.6% ↓TC, 8.6% ↓LDL
Nestel 2004	Mix of bf cereal* + bread* + margarine *97%fat-free	2.4g PSte-E or PSta / day	13.6% ↓LDL by PSte; 8.3% ↓LDL by PSta
	dairy spread with 50% butter fat	2.4 PSte-E / day	12.2% ↓LDL
Noakes 2005	Low fat milk vs margarine	2.0g PSte-E / day	Milk=margarine: 6-8% ↓TC, 8-10%↓LDL
	Low fat yogurt	PSte vs PSta-E	PSte: 6% ↓LDL; PSta: 5% ↓LDL
Mensink 2002	Low fat yogurt (0.7%fat)	1g PSta-E	13.7% ↓LDL
Yae 2005	Low fat yogurt	2g PSta-E / day	6% ↓TC 10% ↓LDL
Nissinen 2006	Fat-free pastilles	2.4g PSta-E/ day	9% ↓TC and 14% ↓LDL
Spilburg 2003	Fat Free Lemonade Drink (KRAFT CL!) vs Eggwhite	Soy Stanol-lecithin 1.9g/day	Chols ab: 32% (lemonade), 38% (egg white) 10.1% ↓TC, 14.3% ↓LDL (lemonade)

The efficacy of phytosterols in cheese products was examined in two Finnish studies. Korpela and colleagues (2006) reported that in a parallel-double blind study with 164 mildly or moderately hypercholesterolemic participants, daily consumption of 50g hard cheese or fresh cheese enriched with 2g phytosterols for a period of 6 weeks led to serum total cholesterol reduction by 8% in hard cheese subject group and 7% in fresh cheese group; and a LDL reduction by 11% in both hard cheese and fresh cheese groups. A similar finding was also reported by Jauhiainen and colleagues in 2006 in his randomised double blind study with 67 mildly hypercholesterolemic subjects. After 5 weeks intervention, daily consumption of 50g low fat cheese enriched with 2g of plant stanol equivalent in ester form for 5-week period was shown to decrease serum total cholesterol and LDL levels by 5.8% and 10.3% respectively.

Kraft expects the efficacy of phytosterols in our cheese products to be similar to that reported by Korpela (2006) and Jauhiainen (2006). We are currently commissioning an efficacy study to confirm the results with the products proposed.

7. POTENTIAL IMPACT ON CONSUMER UNDERSTANDING AND BEHAVIOUR *(3.5.2 F)*

7.1 Consumer awareness and understanding of phytosterols *(3.5.2 F1)*

Phytosterol-enriched products are niche products targeting consumers with concerns over their cholesterol level, consumer awareness of phytosterols is currently at moderate level but increasing. As shown in our own consumer study, one in five adult consumers claimed to be aware of phytosterols and its benefit (Annex 12).

As shown in a consumer survey commissioned by FSANZ, consumers were mixed in their levels of understanding, especially the suitability of phytosterols for children and comprehension of serving size (FSANZ 2006). We address these uncertainties with appropriate messages and portion-controlled products.

The FSANZ survey also reported that the majority of phytosterol spreads users in Australia consume the product due to health related concerns, especially cholesterol issues (FSANZ 2006). Based on the reported frequency and amount of phytosterol spreads used, the survey reported a large proportion of consumers are likely to be consuming below the optimal intake for cholesterol reduction (FSANZ 2006). (Kraft is currently commissioning research to clarify these issues and this data will be made available as it comes to hand.) While data is not available for current intake since other phytosterol-enriched products were introduced in Australia, current evidence from European countries with wider range of phytosterol-enriched products indicates that products are more likely to be under-consumed (ESFA 2008). As such, there is likely to be room for expanding consumer food choices enriched with phytosterols in Australia. Introduction of additional phytosterol-enriched products will help consumers reaching the efficacy level.

7.2 Consumer behaviour in response to phytosterols *(3.5.2 F2)*

Many consumers are actively seeking cholesterol lowering products. A recent report by Nielsen showed that 63% of Australian consumers have purchased a cholesterol-reducing margarine in the past 12 months (Annex 13).

In terms of dietary and lifestyle behaviour, the FSANZ survey has shown that consumers do not see phytosterol-enriched products as a 'silver bullet' that allow them to adopt unhealthy diet or lifestyle. From this survey, consumption of phytosterol-enriched spread was not linked to either better or worse diet and exercise measures, although a minority of consumers of phytosterol spreads claimed an improvement in their diet and exercise levels (FSANZ 2006). Kraft is commissioning a research to help provide some insight into this behaviour. Results will be made available when the report is received.

7.3 No adverse effect on non-target population group *(3.5.2 F3)*

Kraft anticipates that the intended consumer's profile should match the population segment with hypercholesterolemia. The FSANZ consumer survey on the use of phytosterols in 2006 found 50% of users were over 35 years, however, FSANZ highlighted possible underestimation due to online methodology (FSANZ 2006).

Consumer research in US and Europe has shown that the proportion of phytosterol-product users increases with age. In Europe, 75%-95% purchasers were over 45 years of age (ESFA 2008). Recent data confirms that 55% of those concerned about cholesterol are aged 50+, with a majority of the remainder aged 35+ (Roy Morgan Research 2007).

FSANZ and SCF state that consumption of phytosterol-enriched foods is not appropriate for children or pregnant or lactating women as there is no necessity for these groups to lower cholesterol. Supported by the post-launch evaluation in Europe, the existing range of phytosterol-enriched products in Europe is consumed mostly by adults of 45years or older. Less than 1% has been consumed by children (ESFA 2008). As such, Kraft does not anticipate an impact on pregnant or lactating women and children.

8. IMPACT ON THE FOOD INDUSTRY (*3.5.2 G)*

8.1 Projected impact on food industry in Australia *(3.5.2 G1)*

As supported by the US market data for phytosterol dairy products of less than 1% of total dairy sales, the overall impact of phytosterol-enriched cheese products on food industry will be low.

Kraft anticipates the sales of cheese containing phytosterols to be less than 1% of the total cheese category volume and less than 6% in their respective sub-categories. This is supported by penetration of table spreads containing phytosterols in Australia to be around 7% of spreads volume (AC Nielsen, Market Information Digest, MAT 30.3.08). For the first year of phytosterol cheese products launch we anticipate our volumes to be around 2-4% of their respective categories. This equates to 400 tonnes for the cheese slice products and 300 tonnes for the cream cheese spread products.

Cannibalisation on other products with phytosterols such as phytosterol-enriched table spread or milk is anticipated to be low, as Kraft Global studies on cannibalisation of cross category has shown to be around 8-10% (Kraft 2003). While phytosterol-enriched cheese products may replace some of the current table spread usage, it is expected to attract current non-phytosterol users with cholesterol lowering needs.

Currently adults are not consuming the daily recommended serves of dairy products, resulting in a likely lack of dairy nutrition, such as calcium. Only 14.8% of adults and 22.3% of children are currently consuming their 3 serves of Dairy per day. (Annex 14) The cheese market has also been on decline. (Annex 15) The main reason cited for this is concern over perceived cholesterol levels in cheese (Roy Morgan Research Dairy Australia, Project Two 2007). Therefore, the introduction of phytosterol-enriched cheese will not only help grow the dairy industry in Australia, it will promote innovations and serve the needs of consumers segment which require cholesterol lowering products.

8.2 Impact on international trade *(3.5.2 G2)*

Most cheese products in Australia are produced in Australia and New Zealand. It is generally only specialty cheeses that are imported, where consumption is for different occasions, such as entertaining. As such, we do not anticipate an impact on imported cheese. At this stage there is no imported cholesterol lowering cheese in Australia, so Kraft does not anticipate an impact on this area either.

PART C: STATUTORY DECLARATION

I, Allan John Poynton, Kraft Foods Limited, 187 Todd Road, Fishermans Bend, Victoria 3207, Manager, Regulatory and Scientific Affairs make the following declaration under the Statutory Declarations Act 1959:

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

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

Signature [redacted]

Declared at Fishermans Bend

on the 11th of November 2008

Before me [redacted]

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

[redacted]
Kraft Foods Limited ABN 15 004 125 071
187 Todd Road, Fishermans Bend, Vic, 3207
An Australian Legal Practitioner within the
meaning of the Legal Profession Act 2004 (Vic)

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

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GRAS Notification by ADM (GRN No. 61): *Plant sterols are GRAS in vegetable oil spreads, dressing for salad, health drinks, health bars, and yogurt-type products at a level of 1g per serving.* http://www.cfsan.fda.gov/~rdb/opa-g061.html

GRAS Notification Teriaka (GRN No. 112): *Phytosterols are GRAS in margarine and vegetable-based spreads; yogurt and yogurt-like products; milk-based juice beverages, ice-cream and non-standardised ice cream products; cream cheese and cream-cheese like productsl snack bars (health bars); salad dressing, mayonnaise, fresh dressing, and dressing for salads, and white breaks, white rolls and bunds, and comparable non-standardised white bread products.* http://www.cfsan.fda.gov/~rdb/opa-g112.html

GRAS Notification ADM (GRN No. 176): *Phytosterols are GRAS in various foods including margarine and vegetable oil spreads; dressing for salads, beverages, snack bars, dairy analogs (including soy milk, ice cream and cream substitutes), cheese and cream, baked foods, ready-to—eat breakfast cereals, mayonnaise, pasta and noodles, sauces, salty snacks, processed soups, puddings, yogurt, confections, and vegetarian meat analogs at a level up to 0.4g sterol equivalents per serving and in fruit/vegetable juices at a level up to 1g sterol equivalents per serving.* http://www.cfsan.fda.gov/~rdb/opa-g176.html

GRAS Notification by Hert Blend Foods (GRN No. 177): *Plant sterol esters are GRAS in ground roasted coffee at 1.0g per serving.* http://www.cfsan.fda.gov/~rdb/opa-g177.html

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Annex 1 - Technical Report of Phytosterol Esters from FSANZ Final Assessment Report for Application A434 (20 October 2004) - Attachment 2

FOOD TECHNOLOGY REPORT

APPLICATIONS A433 AND A434 - PHYTOSTEROL ESTERS DERIVED FROM VEGETABLE OILS

Introduction

Phytosterols (plant sterols) are natural components of cereals, fruits, vegetables and edible vegetable oils such as sunflower seed oil and, as such, are natural constituents of the human diet.

Incorporation of free sterols into edible fats/oils is not readily achieved because of their insolubility, whereas sterols esterified to fatty acids are more fat soluble. In the intestine, most sterol esters are hydrolysed to free sterols as part of the normal digestive process. Plant stanols are the hydrogenated counterparts of the plant sterols but are less abundant in nature than the corresponding plant sterols. Consequently, the normal dietary intake of plant stanols is much less than that of plant sterols [1].

These Applications are an extension to a previous Application (A410), which resulted in the approval for the use of phytosterol esters, sourced from vegetable oils, in edible oil spreads and margarines to a maximum amount of 13.7%. The Applicants are seeking to extend the use of phytosterol esters into new food matrices, namely breakfast cereals, low-fat milk and low-fat yoghurt products. The phytosterol esters under consideration in Applications A433 and A434 are identical to those previously assessed within A410.

Structure of plant sterols and stanols

Plant sterols have a role in plants similar to that of cholesterol in mammals, e.g. forming cell membrane structures. Plant sterols fall into one of three categories: 4-desmethylsterols (no methyl groups); 4-monomethylsterols (one methyl group) and 4,4-dimethylsterols (two methyl groups). The most common plant sterols are ß-sitosterol, campesterol and stigmasterol and structurally these are very similar to cholesterol, belonging to the class of 4-desmethylsterols (Fig. 1, reference 1).

Plant stanols belong to the group of 4-desmethylsterols. Plant stanols are hydrogenation products of the respective plant sterols, e.g. campestanol/campesterol and ß-sitostanol/ ß-sitosterol (Fig. 1), and are found in nature at very low levels.

When edible oils undergo normal refining, plant sterols are partially extracted together with some tocopherols (in the process of natural vitamin E production). It is estimated that 2500 tonnes of vegetable oil needs to be refined to produce 1 tonne of plant sterols [1]. Plant stanols are obtained by hydrogenation of the plant sterols. Another source of plant sterols is tall oil, derived from the process of paper production from wood and approximately 2500 tonnes of pine is required to produce 1 tonne of plant sterols. Tall oil also contains a higher proportion of plant stanols (primarily ß-sitostanol) than do vegetable oils [1].

In nature, plant sterols can be in the free form or predominantly esterified with long chain fatty acids or with phenolic acids as in rice bran oil (ferulates) and shea butter (cinnamates). In the intestine, most sterol esters are hydrolysed to free sterols as part of the normal digestive process [1]. Details provided in the applications and from comparable products internationally indicate that 1.3 g of the phytosterol esters is equivalent to 0.8 g of free phytosterols.

Production of phytosterol esters

Phytosterols are by-products from the traditional vegetable oil refining process. The crude vegetable oil is refined to remove solvents (if used in extraction), lecithins, free fatty acids, colour, and various off-odours and off-flavours. One of these refining steps is steam distillation (deodorisation) where the resulting distillate contains the phytosterol fraction. This fraction is further refined to remove fatty acids, lecithins and other compounds by fractional distillation, ethanolysis/transesterification, distillation and crystallisation from an organic solvent. The phytosterols are further purified by recrystallisation. These processes are considered standard methods traditionally used for the production of phytosterols.

The phytosterol esters are then produced from the phytosterols using food grade vegetable oil-derived fatty acids or triglycerides and applying standard methods for esterification or transesterification commonly used in the fats and oils industry [8].

Solubility

The solubility of phytosterols in edible oil products is relevant for other food matrices. The solubility of free sterols in oil is around 2 percent, while the solubility of sterol esters in oil exceeds 20 percent. Therefore, the free plant sterols are typically esterified with fatty acids from sunflower to improve solubility.

For foods such as milk, yoghurt and cereal, the esters are preferred to free phytosterols since they have improved solubility properties in oils, analogous to their solubility in edible oil spreads. For the dairy products, low-fat milk and low-fat yoghurts, the phytosterol esters are initially solubilised in a vegetable oil base which is then dispersed and homogenised into the milk, in a similar fashion to the production of low-fat milk. For breakfast cereal bars, the esters are directly added to the mixture as an ingredient during manufacture.

Phytosterol ester-enriched products are produced using the same processes and procedures as the corresponding conventional products. The additional processing step controls the amount and quality of the phytosterol esters incorporated into the product prior to further processing (including heat treatment).

The improved solubility of phytosterol esters creates a palatable product and is associated with more uniform distribution both in the product and in the gastrointestinal tract.

Stability

The physical and chemical properties of phytosterols are similar to cholesterol, since they differ only with respect to the side chain. Phytosterols and their fatty acid esters are basically very stable compounds and experience only limited damage during processing [3].

Phytosterols and phytosterol esters are known to be stable to both oxidation and heat, and remain unchanged during product processing, including the various pasteurisation treatments used to produce milk and yoghurt type products. The applicants state for the milk and yoghurt type products these treatments are:

- standard treatment for milk products (HTST – High Temperature Short Time pasteurisation) 76°C for 15 seconds
- high temperature treatment for extended shelf life milk products (UHT - Ultra High Temperature) 143°C for 4 seconds
- batch pasteurisation for yoghurt mix, 90°C for 15 minutes.

The chemical and microbial stability of the milk and yoghurt type products with added phytosterol esters have been found to be similar to standard products[5].

Specifications

Free sterols are obtained from the vegetable oil refining process where they are recovered from the steam distillate in the deodorisation process. All commercially available vegetable oil sterols are obtained by similar methods, and the esterification process is standard throughout the industry.

The specification for phytosterol esters derived from vegetable oils is the same as that given in the earlier application A410 and which is contained in Standard 1.3.4 – Identity and Purity of the *Australia New Zealand Food Standards Code* is as follows:

Specification for phytosterol esters derived from vegetable oils

Phytosterol esters are phytosterols derived from edible vegetable oils esterified with long-chain fatty acids derived from edible vegetable oils.

Phytosterol esters + free phytosterols (%)	min. 94	
Free phytosterols (%)	max. 10	
Steradienes (%)	max. 0.3	
Fatty acid methylester (%)	max. 0.5	
Iron, Fe (ppm)	max. 1.0	
Copper, Cu (ppm)	max. 0.5	
Moisture (%)	max. 0.1	
Trans fatty acids (%)	max. 1.0	
Sterol profile (%) as below:		
Cholesterol	min. 0.0	max. 2.0
Brassicasterol	min. 0.0	max. 6.0
Campesterol	min. 20.0	max. 29.0
Campestanol	min. 0.0	max. 6.0
Stigmasterol	min. 12.0	max. 23.0
β-Sitosterol	min. 42.0	max. 55.0
β-Sitostanol	min. 0.0	max. 2.5
D5-Avenasterol	min. 0.0	max. 4.0
D7-Stigmastenol	min. 0.0	max. 2.0
D7-Avenasterol	min. 0.0	max. 2.0
Other	min. 0.0	max. 6.0

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Annex 2 - New Specifications of Phytosterols, FAO JECFA Monographs 5 (2008)

PHYTOSTEROLS, PHYTOSTANOLS AND THEIR ESTERS

New specifications prepared at the 69th JECFA (2008), published in FAO JECFA Monographs 5 (2008). An ADI of 0-40 mg/kg bw, expressed as the sum of phytosterols and phytostanols in their free form, was established at the 69th JECFA (2008).

SYNONYMS

Plant sterols/stanols, Plant sterol/stanol esters, Phytosterol/Phytostanol esters

DEFINITION

Phytosterols, phytostanols and their esters are a group of steroid alcohols and esters that occur naturally in plants. The B-ring of the steroidal moiety of phytosterols is unsaturated in the 5-6 position and is saturated in phytostanols. Phytosterols and phytostanols are isolated from deoderizer distillate (a by-product of edible oil production), or derived from tall oil (a by-product of wood pulp manufacture). They are purified by distillation, extraction, crystallization and washing resulting in products of high purity. Phytosterol blends derived from either vegetable oils or tall oil may be converted to the corresponding phytostanols by catalytic saturation. Some phytosterols and phytostanols may be extracted as esters of fatty acids. Esters are also produced by reacting the sterol/stanols with fatty acids derived from food grade vegetable oils. The fatty acid ester chain may be saturated, mono- or polyunsaturated depending on the source of the vegetable oil. Commercial products may be mixtures of phytosterols, phytostanols and their esters. The production process may include the use of hexane, 1-propanol, ethanol and methanol.

Chemical names

The major free phytosterols and phytostanols are listed below. In some preparations they are esterified with vegetable oil fatty acids.

Sitosterol: (3β)-Stigmast-5-en-3-ol
Sitostanol: (3β,5α)-Stigmastan-3-ol
Campesterol: (3β)-Ergost-5-en-3-ol
Campestanol: (3β,5α)-Ergostan-3-ol
Stigmasterol: (3β)-Stigmasta-5,22-dien-3-ol
Brassicasterol: (3β)-Ergosta-5,22-dien-3-ol

Esters of sitostanol: for example, sitostanyl oleate
Esters of campesterol: for example, campesteryl oleate

C.A.S numbers

The major free phytosterols and phytostanols are listed below. In some preparations they are esterified with vegetable oil fatty acids. Esterified forms have not been assigned C.A.S numbers

Sitosterol: 83-46-5
Sitostanol: 83-45-4
Campesterol: 474-62-4
Campestanol: 474-60-2
Stigmasterol: 83-48-7
Brassicasterol: 474-67-9

Chemical formula

The major free phytosterols and phytostanols are listed below. In

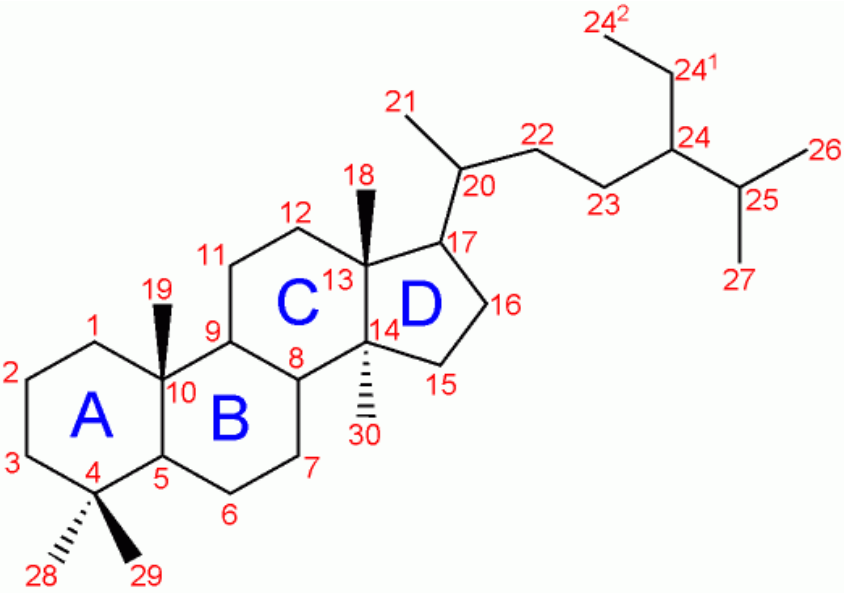
some preparations they are esterified with vegetable oil fatty acids ranging in chain-length from C14 to C18.

Sitosterol: $C_{29}H_{50}O$
Sitostanol: $C_{29}H_{52}O$
Campesterol: $C_{28}H_{48}O$
Campestanol: $C_{28}H_{50}O$
Stigmasterol: $C_{29}H_{48}O$
Brassicasterol: $C_{28}H_{46}O$

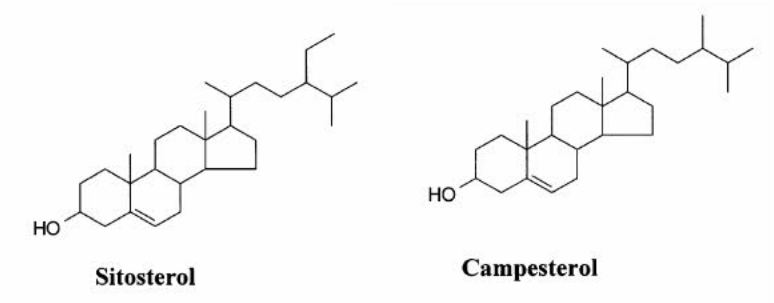
Examples of phytosteryl and phytostanyl esters:
Campesteryl oleate: $C_{46}H_{81}O_2$
Sitostanyl oleate: $C_{47}H_{85}O_2$

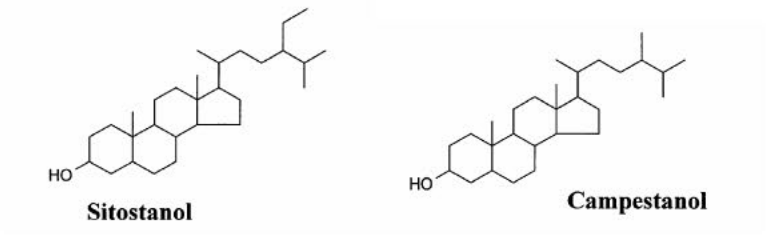
Structural formulae

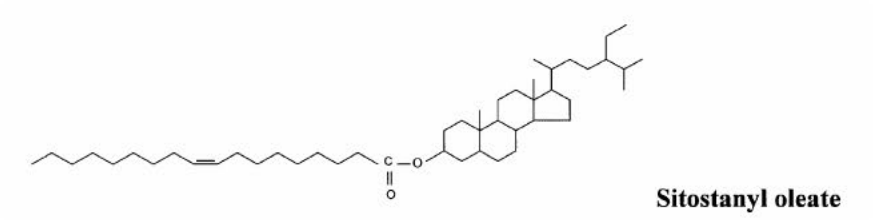
Steroid skeleton



Some examples of phytosterols, phytostanols and a phytostanyl ester







Formula weight

Sitosterol:	414.72
Sitostanol:	416.73
Campesterol:	400.69
Campestanol:	402.70
Stigmasterol:	412.67
Brassicasterol:	398.67

Examples of phytosteryl and phytostanyl esters:

Campesteryl oleate:	683.19
Sitostanyl oleate:	699.19

Assay

Products containing only free sterols and stanols: not less than 95% on a total free sterol/stanol basis.
Products containing only esterified sterols and stanols: not less than 55% sterol/stanol on a saponifed sample.
Products that are mixtures of free and esterified sterols and stanols: the content of stanols/sterols ranges between 55 and 95% as determined by measurement of free sterols/stanols in a native and saponified sample.
Difference between 55% and 95% is attributable to the fatty acid ester component.

DESCRIPTION

Free-flowing, white to off-white powders, pills or pastilles; colourless to pale yellow liquids

FUNCTIONAL USE

This preparation serves no technological purpose in food. It is added to food as a source of phytosterols and phytostanols.

CHARACTERISTICS

IDENTIFICATION

Solubility

Practically insoluble in water.
Phytosterols and phytostanols are soluble in acetone and ethyl acetate.
Phytosterol and phytostanol esters are soluble in hexane, iso-octane and 2-propanol

Gas Chromatography (Vol. 4)

The retention time for the major peak of a saponified sample in a GC chromatogram of the sample corresponds to that of the β-sitosterol/sitostanol standard using the conditions described in the Method of Assay. The relative retention times of β-sitosterol/sitostanol are approximately 1.066 and 1.073, respectively.

PURITY

Total ash (Vol. 4)

Not more than 0.1 %

Residual solvents (Vol. 4)

Hexane, 1-propanol, ethanol or methanol: 50 mg/kg either singly or in combination

Water (Vol. 4)

Not more than 4% (Karl Fischer). The selection of sample size and method of sample preparation may be based on the principles of the methods described in Volume 4 (under “General Methods, Water Determination”)

Arsenic (Vol. 4)

Not more than 3 mg/kg
Determine by the atomic absorption hydride technique. The selection of sample size and method of sample preparation may be based on the principles of the methods described in Volume 4 (under “General Methods, Metallic Impurities”).

Lead (Vol. 4)

Not more than 1 mg/kg
Determine using an AAS/ICP-AES technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4 (under “General Methods, Metallic Impurities”).

METHOD OF ASSAY

Principle

Sterols/stanols are silylated and analysed by gas chromatography with flame ionization detection (Volume 4, “Analytical Techniques, Chromatography”). Esterified sterols/stanols are first saponified and the non-polar components are extracted, dried and silylated. For quantification an internal standard is added to the sample.

Sample preparation

a. Free sterols/stanols

Accurately weigh approximately 15 mg 5α-cholestane and approximately 50 mg sterol concentrate into a reaction vial. Add approximately 1 ml methyl tert-butyl ether (MTBE) to dissolve the sample. Warm to 40 – 50° to improve solubility. Add 4.0 ml hexane

and mix. Transfer 50 µl of the solution to a small test-tube and evaporate to dryness under nitrogen at 50 – 60°. Add 60 µl N,O-Bis(trimethylsilyl)trifluoroacetamide (BSTFA) and 240 µl pyridine, mix, cap the tube and heat at 60 – 70° for approximately 30 minutes. Mix the solution after 5 – 10 minutes. Add 1.7 ml heptane, mix and transfer the solution to a GC vial.

b. Sterol/stanol esters
Accurately weigh approximately 15 mg 5α-cholestane and approximately 100 mg sterol ester accurately into a reaction vial. Add 2 ml ethanolic potassium hydroxide solution (6.6 g KOH in 50 ml ethanol), mix and heat for 90 minutes at 70°. Mix the solution every 15 minutes during saponification. Add 1 ml water and 4 ml heptane to the saponified solution and mix thoroughly for 15 seconds. Wait until the two layers separate completely and transfer the heptane extract to a test-tube. Repeat the extraction twice with 4 ml heptane, collect all three heptane extracts in the same test tube and mix thoroughly. Transfer 50 µl of the solution to a small test-tube and evaporate to dryness under nitrogen at 70 – 80°. Add 60 µl BSTFA and 240 µl pyridine, mix, cap the tube and heat at 60 – 70° for approximately 30 minutes. Mix the solution after 5 – 10 minutes. Add 1.7 ml heptane, mix and transfer the solution to a GC vial.

Equipment
Gas chromatograph, suitable for capillary columns equipped with:
- flame ionization detector (FID)
- cold on-column injector
- autosampler

Capillary column:
- Precolumn: uncoated fused silica capillary, (apolar deactivated), 1.0 m x 0.53 mm i.d. (e.g. Interscience, HRGC precolumn, code 26060370, or equivalent)
- Analytical column 1: CP SIL 13CB, (length 25 m, 0.25 mm i.d.) 0.2 µm film thickness (the dimensions of the column may be altered to accommodate commercially available columns)
- Analytical column 2: CP SIL 8CB, (length 30 m, 0.25 mm i.d.) 0.25 µm film thickness (the dimensions of the column may be altered to accommodate commercially available columns)
All columns are to be connected together with glass quick-seal connectors.

Suitable GC conditions:
- Helium carrier gas flow: 0.9 ml/min
- Detector Temperature: 325°
- FID flow air: 300 ml/min
- FID flow H_2: 30 ml/min
- FID flow makeup N_2: 30 ml/min

Procedure
Inject 0.5 µl of the sample into the gas chromatograph and run according to the following oven temperature program: 60° (for 1 min), then 15°/min up to 250°, then 2°/min up to 300° (hold for 18 min).

Peak assignment and identification of individual components
Identify the main components using a reference sample of known composition. The table of relative retention times given below should

be used as a further guide. All other peaks should be identified as unknown.

Component	Relative retention time (-)
5α-cholestane (internal standard)	0.761
Cholesterol	0.929
Cholestanol	0.934
Brassicasterol	0.958
Cholestanone	0.967
24-methylcholesterol	0.989
Campesterol	1.000
Campestanol	1.007
Stigmasterol	1.021
Unidentified stanol	1.028
δ7-campesterol	1.044
Unidentified sterol 1	1.048
Clerosterol	1.053
Sitosterol	1.066
Sitostanol	1.073
δ5-avenasterol	1.080
Unidentified sterol 2	1.094
δ7-stigmastenol	1.103
δ7-avenasterol	1.115
Unidentified sterol 3	1.133

Calculation of result

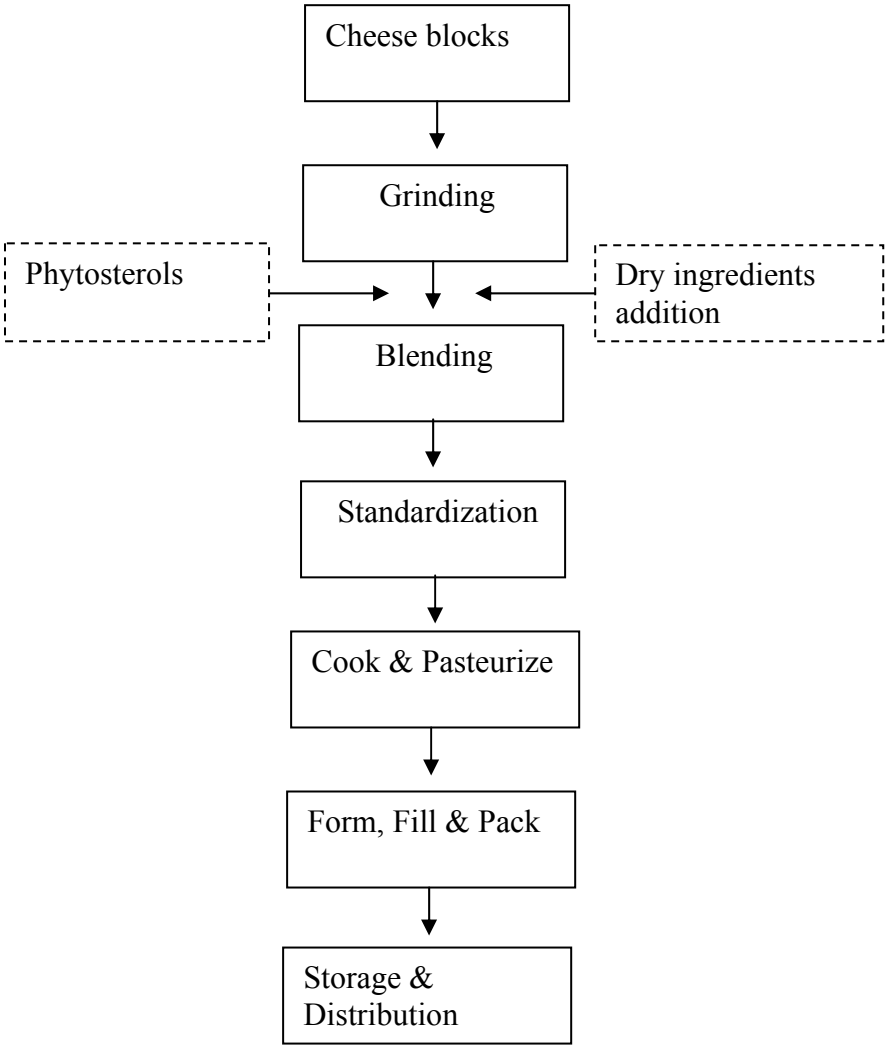
Calculation of the concentration of the individual components (mg/kg)

$$C_I = \frac{C_{IS} \times V_{IS} \times A_{component} \times PURITY_{IS} \times 10^6}{A_{IS} \times W_s \times RF}$$

where:
C_I = component
C_{IS} = internal standard concentration (mg/ml)
V_{IS} = internal standard volume (ml)
$A_{component}$ = peak area of individual component
$PURITY_{IS}$ = purity internal standard (%)
A_{IS} = internal standard peak area
W_s = sample weight (mg)
RF = response factor of FID, RF = 1.05 for stanols and 1.00 for other components

Report all sterols/stanols individually. Report the sum of the unidentified sterols/stanols as “unknown sterols/stanols”. Report all other peaks in the chromatogram as unknowns (sum value).

Annex 3 - Production Process for Individual Wrapped Cheese Slices



Annex 4 - Production Process for Cream Cheese