

Notification Dossier

Simplified Procedure For Substantial Equivalence

**To the UK Food Standards Agency
Advisory Committee on Novel Foods and Processes (ACNFP)**

**ACNFP Secretariat
Food Standards Agency
Room 515B Aviation House
125 Kingsway
London WC2B 6NH**

PHYTOSTEROLS AND PHYTOSTEROL ESTERS FOR USE AS A NOVEL FOOD INGREDIENT IN PRIOR APPROVED FOOD APPLICATIONS

November 16, 2005

Applicant Manufacturer

**DDO Processing, LLC
3117 Southside Ave.
Cincinnati, OH 45204**

Distributors

**Bunge LTD
50 Main St.
White Plains, NY 10606**

**Procter and Gamble Company
1 Procter & Gamble Plaza
Cincinnati, OH 45202**

**Peter Cremer NA, LP
3117 Southside Ave.
Cincinnati, OH 45204**

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1. ADMINISTRATIVE INFORMATION

Name of Applicant/Manufacturer:

DDO Processing LLC

3117 Southside Ave.
Cincinnati, OH 45204
513-471-7200
513-471-7709 fax
rlbitzer@petercremerna.com

Distributors:

Bunge LTD

50 Main St.
White Plains, NY 10606
914-684-3239
914-684-3417 fax
marcsamson@bunge.com

Procter and Gamble Company

1 Procter & Gamble Plaza
Cincinnati, OH 45202
513-626-3500
513-626-1082
appleby.db@pg.com

Peter Cremer NA, LP

3117 Southside Ave.
Cincinnati, OH 45204
513-471-7200
513-471-7709 fax
rlbitzer@petercremerna.com

Authorized Agent for Notification:

James W. Barnett, Jr., Ph.D., DABT
AAC Consulting Group
7361 Calhoun Place
Suite 500
Rockville, MD 20855
512-266-2620
512-266-9736-fax
jbarnett@aacgroup.com

Name of Ingredient :

Phytosterols and Phytosterol Esters (Generic Term Used in Document-Phytosterols)

Sold commercially under the brand name Nutraphyl

Date of Notification:

November 16, 2005

2. INTRODUCTION AND BASIS FOR THE NOTIFICATION

Regulation (EC) No 258/97 on novel foods and novel food ingredients provides for a simplified procedure for manufacturers to introduce novel food ingredients to market in the EU by making a notification in accordance with Article 5. This procedure is applicable to food ingredients extracted from plants that can be shown to be “substantially equivalent” to an existing or approved novel food ingredient in its composition, nutritional value, metabolic handling, intended uses, safety and levels of undesirable substances.

The applicant and its distributors are requesting that the UK Food Standards Agency (UK FSA) and the Advisory Committee on Novel Foods and Processes (ACNFP) review the information

and data provided in this notification and confirm that the novel ingredient proposed as phytosterols acceptably meets the criteria for substantial equivalence. If acceptable, the UK FSA is requested to forward its favourable opinion to the EC and other Member States for comment and a formal decision by the European Commission.

The first approval for the use of phytosterols as a novel food ingredient was granted to Unilever for the use of phytosterol esters as a novel food ingredient in yellow fat spreads in European Commission Decision 2000/500/EC of 24 July 2000.

In 2004, the Commission issued further Decisions on 31 March 2004 concerning the use of a number of products containing phytosterol ingredients by:

Archer Daniels Midland	(2004/333/EC)
Pharmaconsult Oy	(2004/334/EC)
Unilever	(2004/335/EC)
Teriaka Ltd	(2004/336/EC)

The products in each case differ slightly but are summarised as:

- Yellow fat spreads as defined by Council Regulation 2991/94 (excluding cooking and frying fats, and spreads based on butter or other animal fat).
- Salad dressings including mayonnaise.
- Milk type products, such as semi-skimmed and skimmed milk type product, possibly with addition of fruits and or cereals.
- Fermented milk type products such as yoghurts, soya drinks and cheese-type products (fat content <12 g per 100 g) where the milk fat and or protein has been partly or fully replaced by vegetable fat or protein.
- Spicy sauces.

Yellow fat spreads, milk type products, yoghurt type products and spicy sauces were approved under decision 2004/334. In addition, other applications for milk-based fruit-containing drinks, yoghurt-type products, salad dressings, soya drinks and cheese-type products using the same phytosterol specifications as those for 2004/334 have been approved under decisions 2004/333/EC and 2004/336/EC. Decisions 2004/333-336/EC do not specify the source of the approved phytosterols. Nonetheless, phytosterols used must meet the generalized specifications in Annex 2 of these decisions.

In September 2000, a separate application was made by Novartis (now Forbes Medi-Tech) to allow milk based beverages with added phytosterols to be placed on the market. A decision (2004/845/EC) in accordance with Directive 258/97 was issued on 12 November 2004. The specification for this product differs from the March 2004 decisions (2004/333-336/EC) in that up to 35% β -sitostanol and campestanol up to 15% were permitted. Based on this decision and the Opinion of the Scientific Committee on Food on Applications for Approval of a Variety of

Plant Sterol-Enriched Foods (5 March 2003), the sterol specifications for plant derived phytosterols and phytosterol esters for food addition have been generalized for approval of new applications based on the SCF recommendations. The specification from 2004/845/EC decision to Forbes Medi-Tech that is recommended in the SCF Opinion (5 March 2003) and applicable to further decisions on plant sterol composition for use in enriched foods is given in Table 1 below.

Table 1. Composition Specification of Plant Phytosterols and Phytosterol Esters For Addition to Novel Foods	
Composition	EU Specification
β-sitosterol	<80%
β-sitostanol	<35%
Campesterol	<40%
Campestanol	<15%
Stigmasterol	<30%
Brassicasterol	<3%
Other phytosterols	<3%
Total sterols	99*

*- Phytosterols and phytostanols extracted from sources other than vegetable oil, suitable for food, have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/ phytostanol ingredient (*determined by GC-FID or equivalent method*).

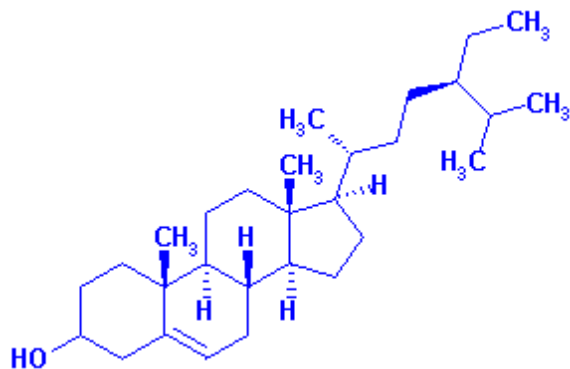
The European Commission Directorate-General for Health and Consumer Protection has recently posted a listing of novel food notifications as of September 2005. Since July of 2004, as listed from Numbers 27-50, there have been approximately 19 notifications approved in the UK, Finland, and Ireland for phytosterols and phytosterol esters from vegetable and tall oil sources for multiple food types, generally under substantial equivalence to phytosterols authorized by Commission Decision 2004/845/EC. As listed in Numbers 42-43, the Finland food authorities have approved the addition of phytosterols and phytosterol esters for the same spectrum of consumer products that is being requested in this notification for the Forbes Medi-Tech products.

As the following presents, this notification dossier documents the substantial equivalence of the notified phytosterols and phytosterol esters compared to the phytosterols and phytosterol esters composition referred to in Commission Decision 2004/845/EC. The tall oil derived sitosterol of the notified product has a slightly higher value (up to 87%). This notification shows that the consumption of phytosterols and phytosterol esters, if used as intended, will not result in adverse public health effects as affirmed by the SCF Opinion (5 March 2003). The slightly higher sitosterol content proposed is not considered to pose any differences in potential health effects than is reflected in the SCF Opinion for a composition of phytosterols that may contain up to 80% sitosterol.

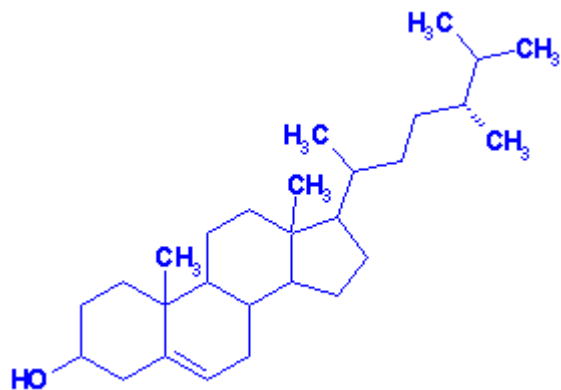
3. IDENTITY, COMPOSITION AND SPECIFICATIONS

Plant sterols, also called phytosterols, are present in all plants and in foods containing plant-based raw materials. Vegetable oils are rich in free phytosterols and their fatty acid esters. In normal diets, vegetable oils and products using these oils are generally acknowledged to be the richest sources of phytosterols. Tall oil from tree sources such as pine trees is another common source of phytosterols, mainly derived as a by-product of paper pulp processing.

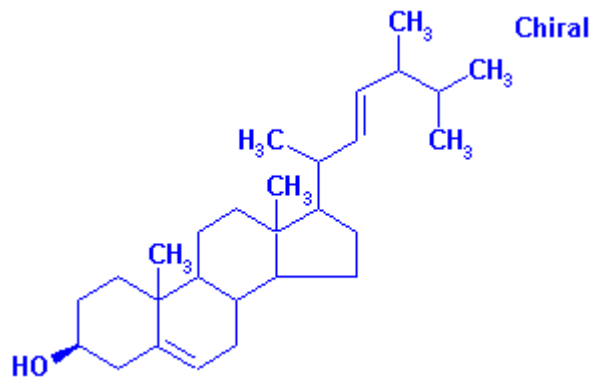
The principal plant sterols are as follows: β -sitosterol which comprises 45-95 % of the total sterols present in plant oils, campesterol which may total 30 % of the total sterols in seed oils and stigmasterol which may account for as much as 25 % of the total sterols of seed oils. Brassicasterol is also present in appreciable amounts in plant seed oils such as rapeseed or canola oil. The structures of the major phytosterol compounds are represented by the following chemical formulae:



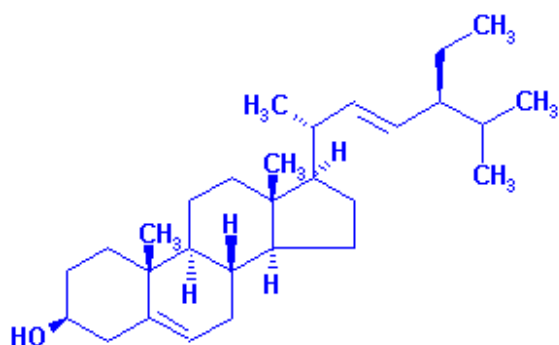
Sitosterol
RN: 5779-62-4



Campesterol
RN: 474-62-4



Brassicasterol
RN: 83-48-7



Stigmasterol
RN: 474-67-9

The phytosterols and phytosterol esters that are the subject of this equivalency assessment are comprised primarily of the sterols mentioned above. The products will be supplied separately in two product identities and in alternative forms for addition to foods; purified phytosterols as a white, crystalline solid or ‘prill’ and purified phytosterol esters as a waxy semi-solid, creamy white paste or yellow viscous liquid. The phytosterol esters are produced by transesterification of the refined phytosterol product with vegetable oil fatty acids ranging in chain length from C₆ to C₂₂.

The chemical/physical properties and specifications of the phytosterol and phytosterol ester products of this notification are shown in Table 2 for tall oil-sourced materials

Table 2. Properties and specifications of food- grade phytosterols and phytosterol esters		
Property	Sterols	Sterol Esters
Specification		
Total sterol and ester content	92-99 min.	97 min
Free sterols (%)	92 min.	6 max
Acid value	2 max.	2 max.
Moisture %	1 max.	1 max.
Residue on ignition (%)	0.5 max.	0.5 max.
Lead by AA	<0.1 ppm	<0.1 ppm
Heavy metals	10 ppm max.	10 ppm max.
Solvent (methanol or heptane)	10 ppm max	10 ppm max
Physical properties		
Specific gravity	0.870	0.932
Appearance	White crystalline solid	Waxy semi-solid (creamy paste)
Solubility	Slightly soluble in mineral oil and vegetable oils; Insoluble in water, ethanol and propylene glycol	Soluble in mineral oil and vegetable oils; Insoluble in water, ethanol and propylene glycol
Melting point (°C)	135-145	14-28

The composition of the phytosterol and phytosterol ester products for this notification are shown in Table 3.

Table 3. Product composition of the notified phytosterol and phytosterol esters derived from tall oil		
Constituent	Sterols (%)	Sterol esters %)
Total as sterols/esters	99 min.	97 min.
β-sitosterol	<87%	<87%
β-sitostanol	<35%	<35%
Campesterol	<40%	<40%
Campestanol	<15%	<15%
Stigmasterol	<30%	<30%
Brassicasterol	<3%	<3%
Other sterols and stanols	<3%	<3%

Analysis for protein has not been conducted on the phytosterol products from soy or other sources due to the fact that it is highly unlikely that residual or unaltered protein allergens would be found in the phytosterol products after the heating and distillation operations. This judgment is confirmed by the EU Directive 2005/26/EC of 21 March 2005 establishing a list of food ingredients or substances provisionally excluded from allergen labeling requirements which included the phytosterols and phytosterol esters derived from soybean oil. Compliance with the specification established in Decision 2004/845/EC indicates there are no concerns related to tall oil derived material.

As the composition data in Table 2 and 3 demonstrate, there is essentially the same composition and purity of the constituents in the phytosterols and phytosterol esters of the subject notification and prior notified substances given in the EU specifications for phytosterols in Table 1, with the exception of a slightly higher sitosterol content. These product compositions are in general compliance with the phytosterol (ester) profile and purity criteria as required by the latest Decisions of the European Commission and SCF on the use of plant sterols in foods (2004/333-336/EC and 2004/336/EC). Thus, they are considered to be ‘substantially equivalent’ to the prior authorised phytosterols and their esters.

4. SOURCES AND MANUFACTURING PROCESS

The process patent for the production of phytosterols from tall oil and other sources is described in U.S. Patent # 6.896.941 issued to Rohr *et al.* in January 2005. The full patent may be found at www.freepatentsonline.com/6846941.pdf. The crude tall oil pitch is generally derived from paper pulp production processes from pine and other pulpwood trees. In the Rohr process of phytosterol purification, crude tall oil pitch is hydrolyzed and saponified with calcium hydroxide or calcium chloride in water and the calcium salts of fatty acids and other saponified materials with a lower melting point are separated from the unsaponified fraction by means of a thin film evaporator run at 180-230⁰C and 100-500 mbar. The crude sterols (~55%) thus separated are dissolved in heptane and then water added to form a hemi-hydrate crystal. Following precipitation, the crystals are filtered off and washed with heptane. The sterols are then redissolved in heptane and following vacuum removal of heptane solvent, the purified phytosterol crystals are prilled for packaging. The end product contains 99% sterols and stanols.

The phytosterol ester product is produced via trans-esterification of the phytosterols with oilseed-derived fatty acids in the range of C₆ to C₂₂.

5. ANALYTICAL DETERMINATION OF PRODUCT COMPOSITION

Analytical results shown in Table 4 below present the composition of five production lots of tall oil-derived phytosterol product. The Certificates of Analysis for the analytical data on tall oil-derived phytosterol product lots are in Appendix A and methods of analysis in Appendix B. The phytosterol ester product would be equivalent in composition as it is made by addition of fatty acids to this product. These data also demonstrate that the composition of this product from the manufacturing process is generally consistent with EU requirements and substantially equivalent to the approved tall oil phytosterols that have been the subject of multiple notifications, with the exception of a slightly elevated sitosterol composition in the range of approximately 82-86%.

Lot #	349M4	192M5	194M5	225M5	267M5	271M5
Date of Manufacture	12/14/04	7/10/2005	7/12/2005	8/11/05	9/23/05	9/27/05
Brassicasterol	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Campesterol	6.2%	6.1%	6.2%	5.9%	5.6%	5.5%
Stigmasterol	0.8%	0.5%	0.8%	0.8%	0.8%	0.9%
Sitosterol	83.8%	83.1%	86.3%	83.1%	82.0%	81.8%
Avenasterol	NA	NA	NA	NA	NA	NA
Other sterols	NA	NA	NA	NA	NA	NA
Campestanol	0.8%	0.8%	0.7%	0.8%	0.7%	0.8%
Sitostanol	10.5%	10.5%	10.2%	11.1%	10.3%	10.8%
Total Sterol + Stanol	100.0%	101.0%	104.2%	101.8%	99.4%	99.8%

6. PROPOSED NOVEL FOODS AND INTAKE ESTIMATIONS

6.1. Proposed Novel Food Types

The phytosterols and phytosterol esters that are the subject of this notification are comprised of the tall oil-derived sterols mentioned above in the specifications and their respective esters. The intended application of these phytosterols and phytosterol ester products will be for use as an ingredient in various foods that have been notified and accepted by the EC and UK in prior notifications and formal Decisions.

This notification does not propose to add any additional food types or increased levels of addition than those already notified and approved by the EC and the UK.

As noted before, the intended foods proposed for addition by this notification include:

- Yellow fat spreads as defined by Council Regulation 2991/94 (excluding cooking and frying fats, and spreads based on butter or other animal fat). The yellow fat spreads will contain 1g (free) phytosterols in 12.5g spread or up to up to 8 % w/w of added phytosterols (equivalent to 14 % w/w phytosterol esters) as currently defined in Commission Decisions 2000/500/EC and 2004/335/EC.

- Salad dressings including mayonnaise. These will be packaged in single serving packs containing 1.0 g phytosterols or 1.6 g phytosterol esters per serving.
- Milk type products, such as semi-skimmed and skimmed milk type products, possibly with addition of fruits and or cereals. The 'milk' type products will be packaged in standard cartons containing 1.6 g phytosterol ester or 1g free phytosterols per 250 mL serving.
- Fermented milk type products such as yoghurts, soya drinks and cheese type products (fat content <12 g per 100 g) where the milk fat and or protein has been partly or fully replaced by vegetable fat or protein. The fermented milk type products will be packaged in individual packs or multipacks. Each serving container will contain 1.6 g phytosterol esters or 1 g free phytosterols.
- Spicy sauces. These will be packaged in single serving packs containing 1.0 g phytosterols or 1.6 g phytosterol esters per serving.

The recommended intake on the labels of these novel foods will be 2-3 servings per day from the range of foods containing phytosterols. This will be equivalent to a daily intake of 2-3 g free phytosterols. Further labelling aspects are described in Section 6.3 below.

6.2. Estimation of Consumer Intake

The addition of plant sterols and sterol esters to foods will not be conducted by the applicant, but they will supply the product to novel food manufacturers. The addition of substantially equivalent phytosterols and phytosterol esters to the prior approved food types in the specified amounts is unlikely to increase the dietary intake of these ingredients by the consumer for several reasons. Consumer use will be competitive with products already on the market and therefore only share the existing market with these products. No notable expansion of this market is envisaged. Thus, the overall intake of phytosterols by the consumer will not be affected because there will be only alternative, not cumulative, consumption of multiple foods within a food type or category. Similarly, as no new uses or additional food product types are being requested by the notification, no increase in consumer intake above the current amounts of phytosterols is anticipated. This will be further assured by compliance with the labelling regulations cited below by the food processors.

This assessment is supported by the post marketing surveillance conducted by Unilever on the consumer intakes associated with yellow fat spreads containing phytosterols, in accordance with the requirements of Decision 2000/500. A document reporting the findings of this Post Launch Monitoring was submitted to the European Commission (EC) in January 2002. This report concluded that yellow fat spreads containing phytosterol esters were being bought and consumed by the target population, albeit at levels below those originally anticipated. In general, intakes per household were similar, irrespective of the number of people in the household, indicating that usage was predominately by one person in each household and confirming the pre-market assumptions about the type of consumer that will purchase cholesterol-lowering products.

The yellow fat spread has had a low market share (0.1-2.5%) across most EU yellow fat spread markets. The approved range extensions of other approved novel foods will be targeted at the

‘cholesterol concerned’ and, due to the cost of phytosterols, will carry premium prices significantly above standard or unfortified products. The proposed and prior approved products are expected to be purchased by a similar target population to the spread, with market shares likely to be less than 1.0% in each category.

6.3. Labelling of Novel Foods with Phytosterols

Regulation (608/2004/EC) concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and phytostanol esters has been in force since April 2004. This requires all foods sold in the EU containing such materials to comply with the labelling requirements below. As a vendor supplying the phytosterols to food processors, DDO Processors, Inc. and its agents will advise the end product novel food manufacturer of the requirements of Regulation 608/2004/EC, Article 2, indicating that they should comply with all labelling, food pack size and serving requirements, namely:

“For labelling purposes, phytosterol, phytosterol ester, phytostanol and phytostanol ester shall be designated respectively by the terms ‘plant sterol’, ‘plant sterol ester’, ‘plant stanol’ or ‘plant stanol ester’ or their plural form, as appropriate. Without prejudice to the other requirements of Community or national law concerning the labelling of foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters shall contain the following:

1. In the same field of vision as the name under which the product is sold there shall appear, easily visible and legible, the words; ‘with added plant sterols/plant stanols’;
2. The amount of added phytosterols, phytosterol esters, phytostanols or phytostanol esters content (expressed in % or as g of free plant sterols/plant stanols per 100 g or 100 ml of the food) shall be stated on the list of ingredients;
3. There shall be a statement that the product is intended exclusively for people who want to lower their blood cholesterol level;
4. There shall be a statement that patients on cholesterol lowering medication should only consume the product under medical supervision;
5. There shall be an easily visible and legible statement that the product may not be nutritionally appropriate for pregnant and breastfeeding women and children under the age of five years;
6. Advice shall be included that the product is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels;
7. In the same field of vision as the particular required under point 3 above, there shall be a statement that the consumption of more than 3 g/day of added plant sterols/plant stanols should be avoided;
8. There shall be a definition of a portion of the food or food ingredient concerned (preferably in g or ml) with a statement of the plant sterol/plant stanol amount that each portion contains.”

In addition, manufacturers of finished foods will be reminded of the obligation for novel food products to be presented by the novel food supplier in such a manner that they can easily be 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 the case of three portions) of added phytosterols/phytosterols (or phytosterol esters calculated as free sterols/stanols). Spicy sauces and salad dressings shall be packed as single portions. The amount of phytosterols/phytosterols per container of beverages shall not exceed 3 g.

6.4. Process for Producing Notified Novel Foods

The novel foods and food types containing phytosterols and phytosterol esters will be made using the same process and procedures as conventional foods of these types and no additional food safety controls are considered necessary beyond controlling the amount and quality of phytosterol esters added. Storage and distribution temperatures used will be the same as conventional foods and the same Hazard Analysis and Critical Control Point (HACCP) schemes will be used to control product safety and quality.

The microbiological stability of the prior approved novel foods proposed in this notification containing phytosterols is governed by the same principles as conventional food products of the same types. Formulation and process rules currently used to ensure safety of conventional milk, cheese and yoghurt type products, yellow fat spreads, spicy sauces, soya and salad dressings, are equally applicable to the new products made with phytosterols and have been used in setting formulations. The accepted principles of Good Manufacturing Practice (GMP) used for conventional food products will be used to control quality and safety during manufacture. Milk and yoghurt type products containing phytosterol esters have been tested for their microbiological and chemical stability over time, including the impact of pasteurisation, and these have been found to be similar to standard products.

7. SAFETY ASSESSMENT

Phytosterols and phytosterol esters are considered to be equivalent with regard to their potential toxicological effects, metabolic handling and biological activity. The SCF reported in 2003 (SCF 2003): “The toxicological information available on non-esterified phytosterols is less extensive than that on phytosterol esters with fatty acids evaluated for the use in yellow fat spreads (SCF, 2000) and on the phytostanol esters used in margarine and other types of products (SCF, 2002). Phytosterol esters, however, are hydrolysed by pancreatic cholesterol esterase (SCF, 2000) and are similar to free phytosterols in the ability to lower cholesterol absorption in rats, suggesting that the liberated phytosterols are the active moieties of the esters. Thus, the safety assessment of the plant sterol-enriched foods can largely be based on the data reviewed and evaluated by the Committee in its opinions on phytosterol esters in yellow fat spreads (SCF, 2000) and on long-term effects of elevated levels of phytosterols from multiple dietary sources (SCF, 2002).”

There are many published safety studies on plant phytosterols and phytosterol esters demonstrating their low order of toxicity. It is important to note that man does not synthesize these compounds and exposure is strictly from vegetable sources in the diet. Further, plant sterols are an essential component of the membranes of all eukaryotic organisms. Phytosterols and phytosterol esters do not produce adverse effects even at high doses except in individuals with

sitosterolemia, an inherited and very rare lipid disorder. In studies with Cytellin, a lipid lowering drug, doses as high as 24 g/day were tolerated with no adverse effects in humans for years.

An Acceptable Daily Intake (ADI) can be calculated from the NOAEL/safety factor method JECFA (1987). The generally accepted ADI for phytosterols based on animal studies at the highest doses tested is about 130 mg/kg/day. This may be a conservative estimate as there were no adverse toxicological findings at the highest dose level tested (equivalent to 5% phytosterols in the diet) and an effect level could not be determined due to the nutritional limitations of testing higher doses. This ADI is also consistent with the assessment of the US FDA in their acceptance of GRAS notifications on phytosterols. As noted in the Lipton GRAS document and ADM GRAS notification GRN 000061 (FDA, 2001), the ADI for phytosterols based on animal studies at the highest doses tested was 130 mg/kg/day. This equates to a daily intake of 9.1 g/day for a 70 kg adult.

With proper labelling, it is considered unlikely that consumption will exceed 3 g/day, even if the sterols and sterol esters are present in multiple and competing novel foods on the market. In conclusion, dietary plant sterols and sterol esters are considered to be a safe and effective means for lowering blood cholesterol levels in consumers.

8. REFERENCES

JECFA (1987). Principles for the Safety Assessment of Food Additives and Contaminants in Food. Environmental Health Criteria 70. World Health Organization. Geneva.

Available online at: <http://www.inchem.org/documents/ehc/ehc/ehc70.htm>

FDA (2001) Agency Response Letter to ADM on GRAS Notice 000061 for plant sterols and plant sterol esters.

Available online at: <http://www.cfsan.fda.gov/~rdb/opa-g061.html>

SCF (Scientific Committee on Food) (2000). Opinion on a request for the safety assessment of the use of phytosterol esters in yellow fat spreads. Opinion adopted by the Scientific Committee on Food on 6 April, 2000.

Available online at: http://europa.eu.int/comm/food/fs/sc/scf/out56_en.pdf.

SCF (Scientific Committee on Food) (2002). General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β -carotene. Opinion adopted by the Scientific Committee on Food on 26 September 2002.

Available online at: http://europa.eu.int/comm/food/fs/sc/scf/out143_en.pdf.

SCF (Scientific Committee on Food) (2003). Opinion applications for approval of a variety of plant sterol-enriched foods. Opinion adopted by the Scientific Committee on Food on 5 March, 2003.

Available online at: http://europa.eu.int/comm/food/fs/sc/scf/out174_en.pdf.