European Food Safety Authority

The Efsa Journal (2008) 133, 1-21

SCIENTIFIC COOPERATION & ASSISTANCE

EFSA/DATEX 03

A Report from the Data Collection and Exposure Unit in Response to a Request from the European Commission

Consumption of Food and Beverages with Added Plant Sterols in the European Union

Issued on 20 February 2008

Largo Natali Palli 5/A
I-43100 Parma

EFSA Switchboard +39 0521 036 111
EFSA Fax +39 0521 036 110

Summary

Plant sterols are structurally related to cholesterol and can be divided into phytosterols and phytostanols, phytostanols being the saturated form of the phytosterols. Scientific studies indicate that consumption of 1.5-3 g of plant sterols per day can significantly reduce the level of low-density lipoprotein cholesterol in individuals if consumed as part of a healthy diet.

To take advantage of the cholesterol-lowering effect, an increasing number of food products with added plant sterols or plant sterol esters have become available on the EU market. Unfortunately, the consumption of high doses of plant sterols can also significantly reduce the blood levels of carotenoids. As a prudent precaution it has thus been suggested that intakes of plant sterols should not exceed 3 g per day.

Regular consumers of products with added plant sterols have been estimated to constitute about 10-15% of the population. In general there seems so far to be little over-consumption of food products with added plant sterols, rather the average consumer exposure to plant sterols is on the low side of what is considered an effective dose. However, there seems to be an established subgroup of maybe 1-4% of the population with intakes greater than the recommended 3 g of plant sterols sustained for more than a year.

More than half of consumers of the products belong to the intended target group, particularly at sustained levels of intake. Thus more than 60% of the consumers of food products with added plant sterols had high blood cholesterol levels and a large majority belonged to the over 45 age group. However, there is some leakage with whole families consuming the products without belonging to the target group, including a few children.

The special information required on product labels for these types of food is rarely understood. A high proportion of the consumers are not aware of the dietary guidelines in relation to phytosterol products and the importance to also consume sufficient fruit and vegetables to prevent a reduction in plasma carotenoids levels.

In conclusion it is still difficult to estimate actual or predict future intakes of phytosterol based on the information available. This is in part due to the dynamic situation of the market. It is clear that only a small proportion of consumers eat two or more products with added plant sterols during the same day even with an expanding range of products available on the market. This could be due to the currently available product range and might change with a change in the product mix. However, the price premium afforded to the products is considered as a natural barrier to excessive intakes in the general population.

Table of Content

Background as provided by the European Commission

An intake of 1 to 3 g per day of added plant sterols (phytosterols, phytosterol esters, phytostanols and phytostanol esters) lowers LDLc (low density lipoprotein cholesterol) blood levels by about 5 to 15%, but no additional effect on cholesterol levels is derived from higher intake of phytosterols. However, phytosterols apparently interfere with the absorption of carotenoids and lead to a reduction of carotenoids blood levels.

In several opinions the Scientific Committee on Food (SCF) and the European Food Safety Authority (EFSA) agreed that on the basis of the available data it may be concluded that intakes not exceeding 3 g per day of added phytosterols in the diet from any particular food are safe. However, mainly because of its effect on carotene levels in blood, it was recommended to take measures ensuring that intakes of added phytosterols of more than 3 g per day would be avoided.

Therefore, in implementing recommendations by the SCF, the Commission adopted specific rules for labelling phytosterols in Commission Regulation (EC) No. 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters:

1. Clear indication that the food contains added phytosterol.
2. Declaration of amount of phytosterols per 100 g of food.
3. Statement that the food is exclusively for people who want to lower their blood cholesterol levels.
4. Statement that patients on cholesterol lowering medication should consume such foods only under medical supervision.
5. Statement that the food is not nutritionally appropriate for pregnant and breast feeding women and children under the age of five years.
6. Statement that the food should be part of a balanced diet, including regular consumption of fruits and vegetables to help maintain carotenoids levels.
7. Statement that consumption of more than 3 g per day of added phytosterols should be avoided.
8. Requirement to define a portion and to indicate the amount of phytosterols in a portion.

Furthermore, when authorising foods with phytosterols, special provisions for the presentation of such foods should be applied:

1. They have to be presented in such a manner that they may be easily divided into portions (containing either max 1 g (three portions/day) or max 3 g of phytosterols (one portion/day).
2. A container of beverages may not contain more than 3 g of phytosterols.
3. Certain foods have to be packed as single portions.

So far, the addition of phytosterols has been authorised for foods falling into one of the following categories of food:

- Yellow fat spreads, as defined by Council Regulation (EC) No. 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat;
- Milk type products, such as semi-skimmed and skimmed milk type products, milk based (fruit) beverages and yoghurt type products, cheese type products (fat content ≤ 12 g/100 g) where the milk fat and/or protein has been reduced or partly or fully replaced by vegetable fat and/or protein, and soya drinks;
- Spicy sauces and salad dressing including mayonnaise.
- Certain rye breads.

However, Member States have expressed concerns as to whether these measures are sufficient to ensure that consumers are in a position to avoid intakes of more than 3 g per day.

In Statements of the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) on requests from the Commission related to novel food applications on fruit juices and nectars, as well as rice drinks, all with added phytosterols, EFSA also stressed that quantitative intake data of phytosterols added to foods in the EU are needed for an adequate assessment and conclusion with respect to risk of intakes of added phytosterols exceeding 3 g per day. Rice drinks have since received a favourable opinion from the Standing Committee on the Food Chain and Animal Health.

Community Interest

The Council (COREPER of 19 October 2005) insists that it is necessary to further assess the cumulative consumption of plant sterols from different existing products in the light of the opinion of the former Scientific Committee on Foods (SCF) of 4 April 2003 and to determine whether, in the light of the risks recognised by the SCF, risk mitigation measures limited to labelling and presentation are sufficient.

In view of the specific request by the Council and the Community interest in this matter, the European Commission has decided to seek the scientific and technical assistance of the European Food Safety Authority.

Terms of Reference as provided by the European Commission

In accordance with Article 31 of Regulation (EC) No. 178/2002, the European Commission requests the European Food Safety Authority:

1. To search for and collect data on the consumption of foods with added phytosterols and to analyse and summarise these.
2. To identify whether the exposure of individuals to such foods would lead to intakes of phytosterols/phytostanols exceeding 3 g per day.

Definitions

Carotenoids	A range of molecules useful to plants and animals, the most common carotenoids include lycopene and the vitamin A precursor β-carotene.
Esterification	Addition of fatty acids to the plant sterol molecule to make it fat soluble
GRAS	Generally recognised as safe
Hydrogenation	Addition of hydrogen atoms to the double bonds of a molecule, e.g. hydrogenation of unsaturated fats to produce saturated fats
Plant sterols	Term used to collectively describe phytosterols, phytostanols and their respective esterified forms in this report

Assessment

Preamble

This report in response to the European Commission request covers a literature review undertaken to identify existing information and studies attempting to estimate current and future intake of plant sterols through food. In the report plant sterols will be used as the collective, generic description of phytosterols and phytostanols as well as their esters. Three independent market research studies attempting to quantify real intakes of plant sterols were identified covering the Irish, British and German markets. Some industry market research information was made available. Finally, three recent theoretical studies employing modelling approaches to estimate plant sterol intake were published by researchers in Finland, the Netherlands and Germany, respectively, and will be used to estimate intake from multiple sources.

The data available to date give a fairly good understanding of the current situation in some selected EU Member States. However, it is only a snapshot in time with the dynamism of the market in mind.

Introduction and Objectives

Plant sterols are natural constituents of plants and are part of the broad group of isoprenoids. The sterols have many essential functions in plant cells; they regulate the fluidity and permeability of cell membranes and act as biogenetic precursors of compounds involved in plant growth, e.g. brassinosteroids. In addition, they are substrates for the synthesis of numerous secondary plant metabolites such as glycoalkaloids and saponins (Hartmann, 1998).

Plant sterols are structurally related to cholesterol and can be divided into phytosterols and phytostanols, phytostanols being the saturated form of the phytosterols (Figure 1). Phytosterols and phytostanols both exist in free or esterified form. Free sterols form part of the cell wall and have important structural functions (Normén, 2001), while sterol esters are storage products in the cell (Lorentz *et al.*, 1989).

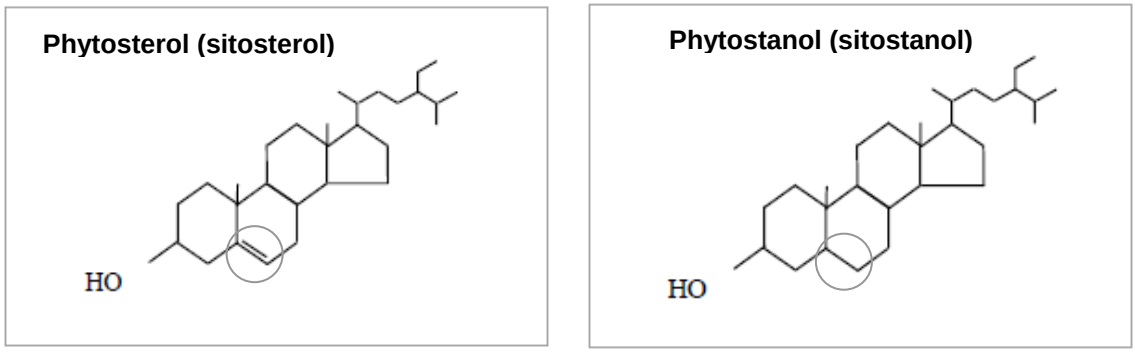

Figure 1: The structural formulas of phytosterol and phytostanol, respectively, with the difference between the molecules marked with circles (modified from Raulio *et al.*, 2001).

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 β-sitosterol, campesterol and stigmasterol and structurally these are very similar to cholesterol, belonging to the class of 4-desmethylsterols. There is a natural supply of plant sterols in the normal diet with the most common phytosterols being ß-sitosterol and its 22-dehydroanalog stigmasterol. Campesterol also occurs widely in plants (Nguyen, 1999; Gylling and Miettinen, 2000a,b). A normal diet also contains small amounts of saturated phytostanol derivatives of respective sterol with about 10% of the sterols being in stanol form (Ostlund, 2002). Major sources of naturally occurring plant sterols are seeds,

vegetable fats and oils, and nuts. According to a recent study in Finland, cereal and cereal products, especially rye, were the major sources of phytosterols, followed by margarine (Valsta *et al.*, 2004).

Several studies have looked at the dietary intake from natural sources. A detailed Finnish study calculated an average daily intake of 300 mg of phytosterols, though in a diet with large amounts of vegetable oils the figure was as high as 500 mg (Valsta, 1995). An Irish study calculated a mean intake of 254 mg/day (Poulsen, 2007). There seems to be general agreement that the normal Western diet would contribute a daily supply of plant sterols in the range of 150-400 mg per person (SCF, 2002a). It should be noted that vegetarian diets are closer to the upper range.

It has been found that plant sterols in the diet reduce the cholesterol absorption in humans and there is some evidence that levels of naturally occurring plant sterols might reduce blood cholesterol to a small degree. However, for an effective reduction higher doses are required. Scientific studies indicate that consumption of 1.5-3 g of plant sterols per day can significantly reduce the level of low-density lipoprotein cholesterol in individuals if consumed as part of a healthy diet (Normén *et al.*, 2004). It can be concluded that the estimated average intake of 300 mg of naturally occurring plant sterols in the diet constitutes only about 10-20% of the recommended intake of 1.5-3 g through added plant sterols and this fairly low contribution will not be taken into account in the following presentation.

To take advantage of the cholesterol-lowering effect, an increasing number of food products with added plant sterols or plant sterol esters have become available on the EU market. Foods with added phytosterols or phytosterol esters require a novel food authorisation according to regulation 258/97/EC[1] since they were not used significantly as food in the European Union before 15 May 1997. Foods with added phytostanol esters do not need a novel food authorisation since they were already used as food within the EU before the introduction of the novel food legislation.

Unfortunately, the consumption of high doses of plant sterols can also significantly reduce the blood levels of carotenoids and, to a lesser extent, other essential fat-soluble micro nutrients. Berger *et al.* (2004) summarised results from studies concerning the effects of free and esterified phytosterols as well as phytostanol esters on serum carotenoid status and fat-soluble vitamins. Some studies showed a significant reduction in the levels of carotenoids, tocopherol, and lycopene while others described no such effects. Katan *et al.* (2003) reported a significant reduction only for ß-carotene (-12.1%), not for α-carotene or lycopene when the mean changes were adjusted for change in total serum cholesterol. Although the consequences of a persistently decreased blood concentration of carotenoids on human health are largely unknown, there could be a concern during pregnancy, lactation or infancy when vitamin A requirements are greater than normal. As a prudent precaution it has thus been suggested that intakes of plant sterols should not exceed 3 g per day (SCF, 2003).

In order to inform consumers that they should avoid excessive or inappropriate consumption of plant sterol containing products, EC regulation 608/2004[2] imposes a statutory requirement for all products with added plant sterols to be labelled in a manner that indicates the maximum daily dose of such compounds. The labelling should also advise individuals who are likely to be most susceptible to a reduced vitamin status (namely pregnant or nursing women and children under 5 years of age) to avoid consuming these products.

Approved products

There is strong competition in the European food market for generic food products often resulting in low profit margins. Companies are thus seeking niche markets where the profit

[1] OJ L43, p1, 14/02/1997
[2] OJ L97, p45, 01/04/2004

margins can be improved. Functional foods, which are foods with dietary components that may provide a health benefit beyond basic nutrition, provide such niche markets. Phytosterol/stanol enriched foods provide an opportunity to confer an added advantage to consumers and can be priced accordingly.

Since a margarine enriched with phytostanol esters was first launched in Finland in 1995 a growing range of phytosterol or phytostanol enriched food products followed in Finland as well as in other countries. It has been easier to launch products containing added phytostanol esters since they do not require individual approvals and currently there are eight food groups containing food products with added phytostanol esters on the European market, namely yoghurt drinks, yoghurt, milk drinks, soy drinks, spreads, oatmeal, cream cheese, fruit drinks, and olive oil. Phytosterol enriched yellow fat spreads entered the Australian and US markets in 1999 and the EU market in 2000. Since the approval of the first food category for the EU market, a further nine original approvals have been issued for addition of phytosterol to other food categories. The latest additions to the approved list were rye bread in 2006 and rice drinks in 2008. The approvals and broad notifications as of February 2008 are shown in Table 1.

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		

Furthermore, through a simplified procedure, a number of companies have notified the European Commission of their intention to market foods of similar character to already approved products covered in the table. The notification procedure only requires a national competent food authority to deem their product substantially equivalent to already approved products. Phytosterol-enriched fruit juices and nectars are still awaiting approval.

Intake recommendations

The manufacturers recommended daily consumption for some of the products and the resultant intake of phytosterols are listed in Table 2. It is clear that the manufacturers target a daily intake of between 1.5-3 g of phytosterol for an average person, covering the beneficial range as noted by the Scientific Committee on Food (SCF, 2002a). In many cases the portion size provides about a third of the recommended daily phytosterol intake and the manufacturers suggest accordingly that the specific product should be consumed three times a day or other phytosterol-enriched products should be consumed to supplement the intake.

Table 2: Examples of added phytosterol/stanol concentrations in some selected foods and the recommended daily consumption level.

Product category	Common packing size	Recommended consumption	Phytosterol concentration	Daily intake
Yellow fat spreads	250 g	3x8-10 g/day	7.5-8 g/100 g	2-2.3 g
Milk type products	1000 ml	2-3x250 ml/day	0.3 g/100 ml	1.5-2.4 g
Yoghurt type products	65-125 ml	1-2x65-125 ml/day	0.6-3.1 g/100 ml	1.5-2 g
Cheese type products	125 g	3x30 g/day	2.2 g/100 g	2.1 g
Cream cheese	200 g	40-60 g/day	5.0 g/100 g	2-3 g
Milk-based soft drink	1000 ml	350 ml/day	0.5 g/ 100 ml	1.8 g
Rye bread	750 g	3x80 g/day	0.8 g/100 g	2 g

There is a growing concern that, as the number of enriched product categories increases, consumers might use several products simultaneously and receive higher doses of plant sterols than intended.

Objectives

Responding to the concerns expressed above and reflecting the terms of reference issued by the Commission, the aim of this review is to look at overall consumption of foods with added plant sterols to understand who consumes the products, and whether consumption is within recommended limits.

In interpreting and responding to the terms of reference the following five objectives will be addressed:

- Review plant sterol enriched products available in EU Member States;
- Estimate the market share of plant sterol enriched products in the total population and in subgroups of the population;
- Considering currently available products and market penetration, provide an estimate of the current distribution of exposure levels in selected Member States;
- Assess consumer awareness of product label information; and
- Considering likely future additional enriched products, provide an estimate of likely future exposure levels.

Materials and Methods

The study consisted of a review of some published and unpublished consumer and market research information and a meta-analysis of information published in the scientific literature.

To review the available range of plant sterol enriched products in Europe, EFSA contact points in most EU Member States were asked to supply information for the respective country.

To estimate the market share of plant sterol enriched products in the total population and in subgroups of the population, commercial information supplied by Unilever, Coca Cola and Raisio as well as market research information provided by Frost & Sullivan was used.

To estimate the current distribution of individual exposure to plant sterol enriched products four reports described below were used. The fourth report was also used to assess consumer awareness of product label information.

- As part of the Commission approval of the addition of phytosterols to yellow fat spreads, the applicant was required to produce a post-launch marketing report on consumption of the product by target and non-target groups to estimate actual phytosterol intakes. The report, first tabled in January 2002 and later published in a scientific journal (Lea and Hepburn, 2006), covered information gathered through telephone care lines and market surveys to check consumer usage patterns. The market surveys were undertaken in the Netherlands, the United Kingdom, France, Germany and Belgium with detailed usage information covering about 2,000 households in total. Intake calculations were performed at household level and based on the number of yellow fat spread packs bought during a 12- to 13-week period.

- As part of the NOFORISK project a survey was undertaken of 486 Irish consumers of products with added phytosterol (Poulsen, 2007). At the time of the survey, products from five of the ten food groups permitted to contain added phytosterol had been launched on the Irish market, namely yellow fat spreads, yoghurt-type products, milk-based fruit drinks, milk-type products and cheese-type products. Participants were recruited at supermarkets and asked to complete a detailed questionnaire. Consumption of products with added phytosterol was recorded at brand level to ensure that accurate information on phytosterol intakes could be calculated.

- The Bundesinstitut für Risikobewertung in cooperation with some of the Verbraucherzentralen (Consumer Associations) developed a questionnaire to explore consumption patterns for products with added phytosterols in Germany (Niemann *et al.*, 2007). At the end of 2006 seven foods were on sale in Germany which contained added phytosterols or phytostanols: two yellow fat spreads (introduced in 2000 and 2003), two yoghurt drinks (introduced in 2004), one skim milk product (introduced in 2005), one cheese in slices and one sunflower seed loaf of bread (both introduced in 2006). All those products, if consumed at the recommended level, would each provide a daily intake of 2 g of phytosterol. In November 2006, just over 1,000 buyers of at least one plant sterol-containing product were interviewed in four different regions of Germany.

- The Food Standards Agency funded the market research company TNS to explore consumption patterns of products with added phytosterol in the United Kingdom, the awareness among consumers of those products of the guidelines on daily consumption, and the level of any consumption among 'nutritionally inappropriate' groups (Kemplay and Nordfjord, 2006). At the time of the research only spreads, yoghurt pots and yoghurt drinks were available on the UK market. The research was undertaken in two stages. In the first stage a Family Food Panel consisting of 11,000 individuals was utilised to establish who was consuming these products, in what quantities and how often. In the second stage 2,000 adults were interviewed as part of an Omnibus survey to understand consumption motivators and awareness of labelling guidelines.

To estimate likely future exposure scenarios, three studies described below were identified that attempted to calculate potential plant sterol intakes using a modelling approach. Situations in which consumers make simultaneous use of several products enriched with phytosterols were simulated in the dietary models. Those findings were contrasted against commercial market projections for the next five years.

- Based on consumption information for 2,874 Finnish adults in the National FINDIET 1997 study, dietary plant sterol intakes in four different age and gender cohorts were calculated in model simulations (Raulio *et al.*, 2001). The foods used in the simulation and their sterol contents were selected on the basis of existing permits and current permit applications with eight different food categories identified.
- The "Monitoring Project on Risk Factors for Chronic Disease" used a food frequency questionnaire to provide consumption and demographic data for almost 23,000 individuals in the Dutch population aged between 20 to 60 years (De Jong *et al.*, 2004). Plant sterol intake was assessed with virtual replacement of one to four ordinary foods in the diet with enriched products. Foods were selected based on decisions already taken with regard to market admittance and current applications for market approval for phytosterols and phytostanols. The doses recommended by the producers were used and the most likely combinations of food for different segments of the Dutch population selected in eleven different simulation scenarios.
- The German National Food Consumption Study contains 7-day weighed dietary records from more than 23,000 participants collected between 1985 and 1989. Using, the consumption information, hypothetical servings of ten different products selected from novel food applications supplemented with 0.3 to 2 g of plant sterols were estimated (Kuhlmann *et al.,* 2005).
- A consultancy report prepared by Frost & Sullivan estimating the growth potential of the plant sterol market complements the simulation studies (Anon., 2006b).

Results

Plant sterol enriched products available in EU Member States

Food companies in the United Kingdom, Finland, Sweden, Spain, France, Germany, Portugal, the Check Republic, Austria, Italy, Greece, Belgium, Ireland, Denmark, and the Netherlands in the EU, as well as USA and Norway have all applied for permission or notified about their intention to offer products with added phytosterols on the European market. Products available on the market as of late 2007 in the respective EU Member State as indicated by official country representatives and other sources are illustrated in Table 3.

Spreads and fermented milk type products, like yoghurt and yoghurt drinks, were most commonly available. Finland seemed to have the largest variety of available product types, followed by Belgium, Germany and the United Kingdom.

Phytosterol/stanol-enriched products that are or could be marketed outside the EU include juices, ice creams, snack bars, white or whole-grain breads and buns, cereals, confectionery products and cooking oils. In addition, GRAS status was recently given for phytosterol esters for use as an ingredient in ground roasted coffee (FDA, 2005), for phytosterols and phytosterol esters for use in pasta, noodles, soups, and puddings (FDA, 2006a), and phytosterols for use in different egg products (FDA, 2006b).

Table 3: Information as of late 2007 covering plant sterol enriched products available in the respective EU Member State as provided by official Member State representatives and other sources.

Member State	Product groups represented	Member State	Product groups represented
Austria	Yoghurt drink	Italy	Yoghurt drink, milk, cheese spread
Belgium	Yoghurt, yoghurt drink, milk, soy drink, margarine, spread, cheese spread	Latvia	Spread
		Lithuania	Yoghurt drink
Bulgaria	Not known	Luxembourg	Margarine, spread, cheese spread, yoghurt, yoghurt drink
Cyprus	Spread, milk		
Czech Republic	Yoghurt, yoghurt drink, milk, margarine	Malta	Yoghurt drink, spread
Denmark	Yoghurt, yoghurt drink, milk	Netherlands	Yoghurt, yoghurt drink, spread
Estonia	Spread	Poland	Yoghurt drink, spread
Finland	Milk, buttermilk, spread, yoghurt, yoghurt drink, porridge, pasta, chicken meat balls, frankfurters	Portugal	Yoghurt, yoghurt drink, milk, olive oil
		Romania	Not known
France	Yoghurt, yoghurt drink, milk, margarine, spread, dessert	Slovakia	Not known
Germany	Yoghurt drink, fruit beverage, milk, margarine, soy drink, cheese, bread	Slovenia	Yoghurt drink, spread
Greece	Yoghurt, margarine, olive-oil spread, cheese spread	Spain	Yoghurt, yoghurt drink, milk, olive-oil spread
Hungary	Margarine	Sweden	Milk, spread, rye bread
Ireland	Yoghurt, yoghurt drink, spread, cheese spread, soy drink	United Kingdom	Yoghurt, yoghurt drink, milk, cheese, spread, fruit beverage, soy drink

Market share of plant sterol enriched products

Although products with added phytostanol do not require novel food approval, products containing phytosterols comprise about two thirds of the plant sterol market with one third for phytostanol products (Anon., 2006b). This could partly be due to the fact that it is more expensive to produce phytostanols, the compounds requiring both hydrogenation and esterification while phytosterols require only esterification. Non-esterified products are gradually being introduced simplifying the production process.

So far, plant sterol enriched products encompass only a small part of the respective food segment although exact figures are difficult to come by. In Germany, yellow fat spreads with added phytosterols comprised a steady 2% of the spreads market in 2004 to 2006 according to one report (Anon., 2006a). In the United Kingdom, consumer research showed that plant sterol enriched products by volume comprised 2-12% of the total spreads market, between 0-15% of the yoghurt and yoghurt drink market and between 0-6% of the total milk market (Anon., 2005). The large uncertainty factor was due to the fact that people indicated that they consumed both enriched and normal product but without specifying the exact split between the two. A recent study in Finland among 30,000 people aged 35-84 years, found that 4.5% of the study group used phytostanol ester margarines as the yellow fat spread of choice (Simojoki *et al.*, 2005).

It can be concluded that the market share for plant sterol enriched products in any one product category is likely less than or much less than 10%.

Although market share is unclear, what is clearer is that phytosterol-enriched products command a market premium with prices up to five times higher compared to their conventional counterparts (Table 4).

Table 4: Phytosterol compared to standard product prices in the UK market in 2005 (Anon., 2006b).

	Brands with plant sterols			Standard brands
	Benecol	**Flora pro.activ**	**Danacol**	
Spreads	£7.98 per kg	£7.46 per kg	-	£1.80 per kg
Health drinks	£8.10 per kg	£6.20 per kg	£4.95 per kg	£2.20 per kg
Yoghurt	£3.80 per kg	£4.00 per kg	£2.80 per kg	£2.10 per kg

It has been speculated that the price premium is likely to act as a deterrent to the regular purchase of plant sterol enriched products by consumers not part of the target group for the product and thus not benefiting directly by consuming them.

Using forward projections for the market of plant sterol compounds (Anon., 2006b), the total European market for 2007 can roughly be estimated at about 9,500 tonnes worth close to €160 million of which 80% were used in food products. The concentration of plant sterols (expressed as free plant sterols) in the finished products varies between 0.3% by weight in milk type products to 8% in spreads. Given that yellow fat spreads are by far the most common on the market commanding a 75% share of added plant sterols used in 2005, it can be estimated that roughly 72,000 tonnes of yellow fat spreads with added plant sterols were sold in Europe in 2007. This would indicate a market value of €700 million for yellow fat spreads in Europe. To this should be added the contribution from other products with added plant sterols that cannot be quantified at this stage.

Current exposure levels in selected Member States

An attempt was made to summarise exposure information to plant sterols provided in four different studies. Since the studies all had different designs a number of assumptions had to be made to fit the information into a common table. Thus approximations were made from the information provided. The results are presented in Table 5.

Table 5: Phytosterol exposure information re-calculated from the information provided in four separate studies.

	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%	

The method for selection of participants varied between the four different studies. In the United Kingdom and the post-launch monitoring studies a survey of a general consumer panel was used while the other two studies surveyed only consumers of phytosterol enriched products. This procedural difference explains the recorded inconsistency in daily consumption prevalence.

The post-launch monitoring study across five countries showed median daily intakes in one-person households of 12-24 g of the yellow fat spread in regular users of the product. High-end consumers at the 95th percentile level had daily intakes varying between 27 to 45 g/day at household level. Based on the amount of yellow fat spread consumed with an allowed maximum of 8% free phytosterols, corresponding daily phytosterol intakes would vary between 1.0 to 1.9 g at the median consumption level and between 2.2 and 3.6 g at the high consumption level. The product was found to be purchased predominantly by adults with 79-95% in the over 45-year age group depending on the country studied. The survey only reviewed phytosterol intakes from yellow fat spreads, but noted that some of the consumers also purchased products containing added phytostanol. The phytostanol intake was not quantified.

The mean intake of added phytosterol for Irish adults consuming enriched products was 2.45 g/day with a range of 0.21-9.84 g/day. High consumers at the 97.5th percentile level had an intake of 6.61 g/day. There were no significant differences in intakes of added phytosterols across the age groups. Optimal intakes of phytosterols in the range of 1.5-3.0 g/day were reported by 54% of respondents, while 23% had suboptimal intakes below 1.5 g/day and 23%

had intakes above the recommended 3 g/day. A majority of the respondents (90%) consumed the products every day and more than half (58%) had been regular consumers for more than a year. A higher proportion of long-term consumers exceeded the recommended maximum intake level of 3 g/day.

It was not possible to calculate the mean intake of added phytosterol in the German study. However, 22% of consumers of two or more products, or 2.3% of all respondents, were likely to exceed the recommended maximum daily intake of 3 g. This is close to the 97.5th percentile intake level. The average age of the buyers in the German survey was 58.5 years with 77.8 % over 45 years old. In relation to the daily consumption pattern, 72% consumed one product daily, while daily consumption of two products was recorded for 9% of the households, three products for 1% of the households and two and one household reported daily consumption of four and five products, respectively.

Over one quarter of respondents in the UK survey (28%) claimed to have consumed phytosterol products during the last 6 months and 13% daily or more often. Consumers of spreads claimed the most frequent consumption, with 55% of users consuming them daily or more often and another 25% regularly but not every day. A third of yoghurt drinks users claimed to take them daily and another third regularly but not daily. Yoghurt pots were consumed slightly less frequently. From consumption frequency indicated in the publication and average phytosterol concentrations for individual product categories an average intake of 0.9 g/day was calculated. The corresponding 97.5th percentile intake level was estimated at about 3 g/day. The majority of consumption was heavily skewed towards those aged 45 years and over with 90% of all phytosterol consumption occasions, while the under 5s accounted for only 1%.

AC Nielsen (Anon., 2006c) used their "Homescan" consumer panel of 10,000 private households to examine in detail purchase of multiple products with added plant sterols. The panel is constructed to demographically represent all private households in the United Kingdom. Purchasers of cholesterol reducing foods tended to be loyal to one category of food with limited cross purchasing evidence (Figure 2).

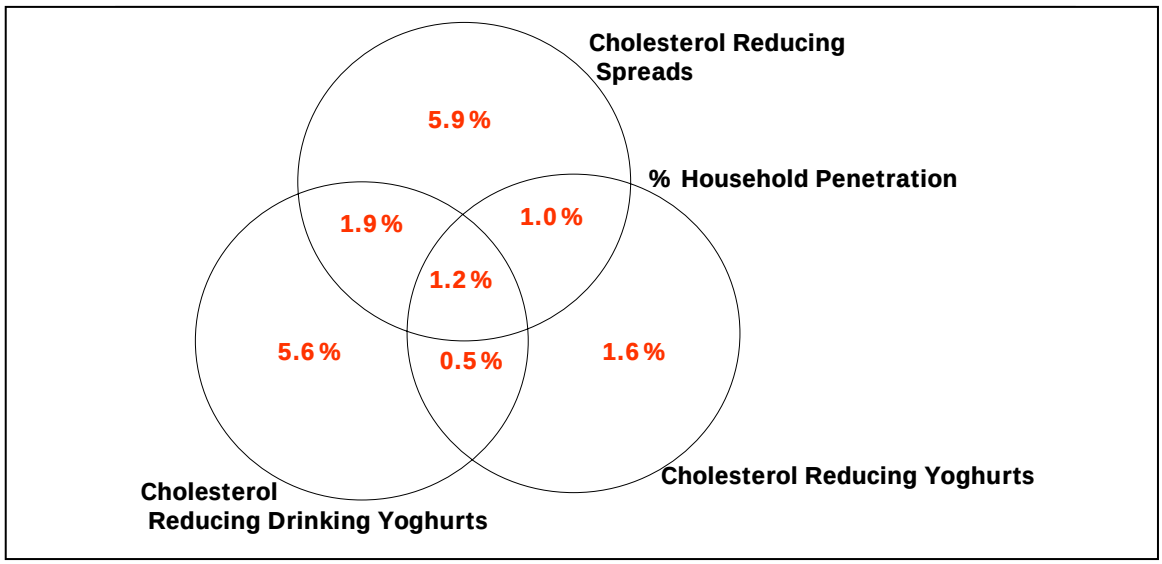

Figure 2: Cholesterol reducing food category cross purchasing after AC Nielsen (Anon., 2006c).

Some 9.2, 4.3 and 10% of UK households purchased drinking yoghurt, yoghurts or spreads, respectively. Only 1.2% of households purchased cholesterol reducing foods from all three categories. While 3.1, 2.2 and 1.7% purchased spreads and drinking yoghurt, spreads and yoghurts and drinking yoghurt and yoghurts, respectively. Spreads and drinking yoghurt had the greatest penetration but this was at or below 10% in each case.

Consumer awareness of product label information

Consumption guidelines with regard to minimum and maximum amounts and the target group for the products were investigated.

Based on the findings in the UK study, the authors claimed that there were low levels of both label readership and knowledge of the dietary guidelines in relation to phytosterol products. There was particular confusion among consumers over the distinction between cholesterol lowering yoghurts and similar products designed to maintain a healthy digestive system.

A majority of respondents in Ireland (62%) reported that they did read food label warnings on phytosterol products, but only 38% were actually aware of the importance of consuming five or more portions of fruit and vegetables per day.

Barely 4% of the respondents in Germany knew that their phytosterol intake should be limited to 3 g. Of the 27% that knew there was a target group for the products, only 38% correctly nominated children as not being a target. In total, just 1% of respondents correctly nominated an intake and a target group limit. Only 4% could nominate the reason for the recommended increase in the intake of fruit and vegetables when regularly consuming products with added phytosterol.

Over half of the respondents had been introduced to phytosterol-containing products through advertising, but only about 15% by their doctor. About 60% of the respondents gave high cholesterol levels as the reason for consuming products with added phytosterol, while 17% indicated that they bought the products for general health reasons. High cholesterol blood levels had been detected in 89% of the respondents giving high cholesterol levels as the reason for buying the product, while the remaining 11% did not base the reasoning on an actual measurement or did not know if a measurement had been performed. The amount of phytosterol consumed was related to the medical background with a mean intake of 2.63 g/day in the former and 2.13 g/day in the latter group in the Irish study.

Consumption among other members of the household not affected by high cholesterol blood levels was fairly common, particularly spreads, where 44% claimed their partner consumed them as well. Consumption among children was low, with 8% and less than 1% claiming occasional or regular use, respectively, in children less than 5 years of age.

Likely future exposure levels

Sales of phytosterol ingredients in Europe are predicted to more than double by 2012 according to the Frost & Sullivan report (Anon., 2006b). It is also likely that the product range will continue to expand. Modelling used to predict future exposure scenarios when consuming one to four products simultaneously is summarised in Table 6.

Table 6: Phytosterol exposure information as calculated by simulations.

	Median/Mean exposure g/day when eating respective no. of products/day				**P95 (P90*) exposure g/day when eating respective no. of products/day**			
	1	2	3	4	1	2	3	4
Finland	1.8-3.0	2.8-4.5	4.5-5.3	6.5-8.9	-	-	-	-
Germany	0.5-1.2	1.3-2.4	1.8-3.5	2.0-4.2	2.7-5.5	4.3-9.1	4.9-9.1	5.1-10.2
The Netherlands	2.4	0.6-3.7	3.1-5.1	2.2-5.8	4.9*	1.4-6.9*	6.0-8.8*	4.1-9.6*

The actual exposure will vary with the product mix. Consumers of one product per day at the median or mean level recorded in respective simulation will not exceed the 3 g limit for any product category. However, consuming two products if the combination is margarine and yoghurt, margarine and cheese or rye bread and cheese for males, but not for females, breached the limit in the Finnish simulation. A maximum of 8.9 g per day was recorded for a combination of rye bread, cream cheese, low fat yoghurt and snack bars in young males.

High consumers will breach the recommended 3 g limit more often. In the German simulation when all food types were enriched with an effective dosage of 2 g plant sterols per suggested food serving, a maximum exposure of 10.2 g/day was calculated when consuming four food types per day at the highest enrichment level.

The German simulation is shown in detail in Figure 3. It included from six to ten products with an effective dosage of 0.3 g, 1-2 g or 2 g plant sterols per proposed food serving. The recorded average amount consumed of only one enriched product did not provide the respective user with an effective plant sterol dosage per day, while high consuming individual users in the high dose scenario still exceeded the level of 3 g plant sterols per day depending on the amount of food consumed.

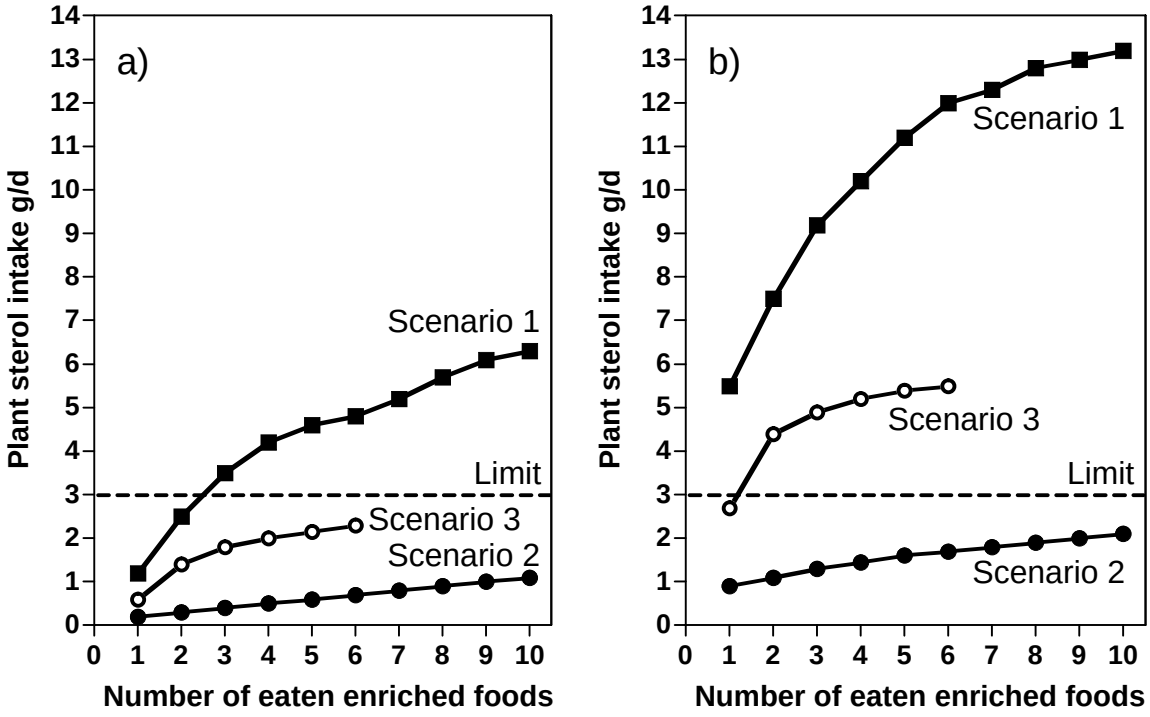

Figure 3: Modelled intakes of phytosterol in the German population in three different scenarios of 2 g (1), 0.3 g (2) or 1-2 g (3) per proposed food serving (modified after Kuhlmann *et al.*, 2005). Amounts of the foods are either consumed at average levels (a) or at the 95th percentile level (b).

Median intakes of plant sterols varied between 0.6 to 5.8 g per day in the different scenarios used in the Dutch study assuming that all products of a certain type was fully replaced in the diet. Considering current enrichment applications and traditional Dutch food patterns, a most realistic future scenario containing three plant sterol enriched foods (margarine, yoghurt and cheese) would result in consumers of high amounts of those foods at the upper 10% of the population reaching a level of 8.8 g per day. However, when comparing data from actual consumption of respective product rather than manufacturers recommended levels, mean intake levels were 5-10% lower for most of the food groups.

Discussion

Detailed interpretation of the information collected has been difficult because of the relative novelty of plant sterol enriched products on the European market, the dynamism of the market with several recent new product introductions and, in many cases, a limited market share making it more difficult to identify appropriate consumers.

A range of food products with added plant sterols are available in most EU Member States. Food products with added phytosterols sorted into ten food categories have been approved for

sale in the European Union. Food products with added phytostanols, not needing approvals, cover a similar range of products with a few additions like fruit juice, pasta and meat products, the latter two in market trials. It was observed that food products with added plant sterols are sold in at least 24 EU Member States. The most common products were yellow fat spreads, yoghurt type products and yoghurt drinks.

It was most difficult to estimate the market share of food products with added plant sterols as part of the respective food category. For some recently introduced products the market share would be much less than 1%, while for established products like yellow fat spreads the market share was estimated to be somewhere between 2-4.5% in general and possibly up to 10% in some more mature market segments.

The post-launch monitoring study of 2002 indicated that at that time the intended target group in respect to age predominantly purchased the product, but there was no information available to indicate whether or not the users needed to lower their blood cholesterol levels. Only in the Netherlands and Belgium did about 5% of the regular users of this one product exceed a phytosterol intake of 3 g/day.

Later studies confirm that users of products with added plants sterols are frequently older than 45 years of age and purchase the products to lower their cholesterol blood levels. However, some use the product for general health reasons with a proportion of users confusing yoghurt products with similar products promoted for improving gut health. In some cases whole families consume the products with an estimated 3.5% of the users being children outside the target group, with a few exceptions, and living in families where no member was part of the target group. Reassuringly, the consumption among children in the under-5 age group when measured was less than 1% of the total number of consumers.

The market surveys and simulation studies give a conflicting view of actual exposure to plant sterols from enriched food products. On one hand real life observations indicate that many consumers do not reach exposure levels effective in reducing cholesterol blood levels even when using a mix of different products. On the other hand simulation studies show exposure levels well above the recommended limit of 3 g/day when using multiple products. A reasonable explanation seems to be that the simulated levels represent only consumers who are faithful to the simultaneous use of several enriched products. In practice, this would be counterbalanced by many less enthusiastic users. Close to 33% of the German respondents alternated between two or more enriched products, but only 10% consumed two or more products during the same day. Nevertheless, even in real life there was an established subgroup identified with intakes greater than recommended levels sustained for more than a year. Around 1% of such users consumed three products a day.

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. During the German survey products from five different food categories were available on the market, yet only 1-2% consumed three products or more during the same day. Furthermore, the number of eating occasions was not indicated so it is not possible to know whether the recommended intake was achieved for each product individually or by the combined intake.

Several of the authors raised the limitations of simulation studies to estimate plant sterol intake. Indeed, predictions were seen as hypothetical and representing worst-case scenarios. They were likely to be biased to the upper end when compared to actual consumption information on household level with the frequency of consumption appearing to be less than anticipated.

Compulsory labelling on all types of plant sterol products was introduced to identify target groups for the products, to advise against consumption of more than 3 g of plant sterols per day and to recommend an increased fruit and vegetables consumption.

Although many respondents claimed to have read the product labels, there was a general lack of recall and understanding of the requirements for consumption of products with added plant sterols. From the users' profile it was clear that the special information required on product labels for these types of food are rarely understood by users.

A high proportion of the consumers were not aware of the importance to consume sufficient fruit and vegetables to prevent a reduction in plasma carotenoid levels.

Conclusions

In general there seems so far to be little over-consumption of food products with added plant sterols, rather some consumers don't eat enough of the products to gain a real benefit. Modelling showed that consumption on more than three occasions per day or daily consumption of two or more products each at their respective recommended intake level was necessary to exceed a daily intake of 3 g of plant sterols.

More than half of the products are consumed by the target group of over 45 years of age to alleviate high blood cholesterol levels, particularly at sustained levels of intake although a significant proportion claimed they expected general health benefits.

It was clear that the special information required on product labels for these types of food are rarely understood by users. There were low levels of both label readership and knowledge of the dietary guidelines in relation to phytosterol products. A high proportion of the consumers were not aware of the importance to also consume sufficient fruit and vegetables to prevent a reduction in plasma carotenoid levels.

In conclusion it is still difficult to estimate actual intakes of phytosterol based on the information available. This is in part due to the dynamic situation of the market with several new products launched over the past two years. The market is expected to double over the next five years. However, the price premium afforded to the products seems to be acting as a natural barrier to excessive intakes in the general population.

Acknowledgements

This document was written by Stefan Fabiansson, head of the Data Collection and Exposure Unit, EFSA and reviewed by EFSA staff and external experts.

Experts who contributed to the development and review of the report included Katharina Adler of the German Federal Ministry of Food, Agriculture and Consumer Protection, Hubert Deluyker and Silvia Valtueña Martínez of the European Food Safety Authority, Shuhana Begum of the United Kingdom Food Safety Agency and Aine Hearty of the University College Dublin, Ireland. Their contributions are gratefully acknowledged.

Market research submitted by external parties and considered by EFSA included information from Eva Skoog and Annet Roodenburg of Unilever, Colette Shortt of McNeil Nutritionals Ltd., Ingmar Wester of Raisio Group and Michael Knowles of Coca-Cola European Union Group. The respective report is listed in the reference list under the market research company. Hedi Mühlbauer of TNS Healthcare GmbH kindly prepared a proposal for further market research across the European Union Member States.

References

Anon. (2005). TNS Superpanel and TNS Family Food Panel (personal communication).

Anon. (2006a). AC Nielsen Trend Navigator "Functional Food". Available at http://www.acnielsen.de/pubs/documents/ACNielsen_TrendNavigator_FunctionalFood_final.pdf.

Anon. (2006b). Strategic analysis of the European phytosterols market. Market Report. Frost & Sullivan Research Service, London, United Kingdom.

Anon. (2006c). AC Nielsen "Homescan" consumer monitor of purchase of fast moving consumer goods 2006 (personal communication).

Berger, A., Jones, P.J.H. and Abumweis, S.S. (2004). Plant sterols: factors affecting their efficacy and safety as functional food ingredients. *Lipids Health Dis. 3*:5.

De Jong, N., Pijpers, L., Bleeker, J.K. and Ocké, M.C. (2004). Potential intake of phytosterols/- stanols: results of a simulation study. *Eur. J. Clin. Nutr.* 58: 907-919.

FDA (US Food and Drug Administration). 2005. Agency response letter GRAS notice no. 000177. Available at http://www.cfsan.fda.gov.

FDA (US Food and Drug Administration). 2006a. Agency response letter GRAS notice no. 000176. Available at http://www.cfsan.fda.gov.

FDA (US Food and Drug Administration). 2006b. Agency response letter GRAS notice no. 000181. Available at http://www.cfsan.fda.gov.

Gylling, H. and Miettinen, T.A. (2000a). Plant sterols in nutrition - promise or threat for the future. *Scand. J. Nutr.* 44,104S.

Gylling, H. and Miettinen, T.A. (2000b). Plant sterols in nutrition. *Scand. J. Nutr.* 44: 155-157.

Hartmann, M.-A. (1998). Plant sterols and the membrane environment. *Trends Plants Sci.* 3: 170-175.

Katan, M.B., Grundy, S.M., Jones, P., Law, M., Miettinen, T. and Paoletti, R. (2003). Efficacy and safety of plant stanols and sterols in the management of blood cholesterol levels. *Mayo Clin. Proc.* 78: 965-978.

Kemplay, G. and Nordfjord, H. (2006). Consumer research on the consumption of phytosterols. TNS, London, United Kingdom.

Kuhlmann, K., Lindtner, O., Bausch, A., Ritter, G., Woerner, B. and Niemann, B. (2005). *Br. J. Nutr.* 93, 377-385.

Lea, L.J. and Hepburn, P.A. (2006). Safety evaluation of phytosterol-esters. Part 9: Results of a European post-launch monitoring programme. *Food Chem. Toxicology* 44, 1213-1222.

Lorentz, R. T., Haeckler, K. & Fenner, G. (1989). Analysis of steryl esters. In ***Analysis of Sterols and Other Biologically Significant Steroids,*** Edited by Nes, W. D. & Parish, E. J., Academic Press Inc, San Diego, pp: 33-48.

Nguyen, T.T. (1999). The Cholesterol-Lowering Action of Plant Stanol Esters. *J. Nutr.* 129, 2109-12.

Niemann, B., Sommerfeld, C., Hembeck, A. and Bergmann, C. (2007). Lebensmittel mit Pflanzensterinzusatz in der Wahrnehmung der Verbraucher. Bundesinstitut für Risikobewertung, pp1-62, Berlin, Germany. Available at: http://www.bfr.bund.de/cm/238/lebensmittel_mit_pflanzensterinzusatz_in_der_wahrnehmung_der_verbraucher%20.pdf.

Normén, L. (2001). Phytosterols - effects of intake on cholesterol absorption and colorectal cancer risk, PhD Thesis. Department of Clinical Nutrition, Göteborg University, Göteborg, Sweden.

Normén, L., Frohlich, J. and Trautwein, E. (2004). Role of plant sterols in cholesterol lowering. In: *Phytosterols as Functional Food Components and Nutraceuticals*, P.C. Dutta (ed.), pp. 243-315. Marcel Dekker Inc., New York.

Ostlund, R.E. Jr. (2002). Phytosterols in human nutrition. *Annu. Rev. Nutr.* 22: 533-549.

Poulsen, M. (2007). Noforisk - Quantitative risk assessment strategies for novel foods. 3rd periodic activity report, pp. 150-156. National Food Institute, Technical University, Denmark.

Raulio, S., Nurttila, A. and Mannonen, L. (2001). Adding phytosterols and -stanols to food – modelling the amount received by Finnish adults. Publication of the National Food Agency, Helsinki, Finland.

SCF (Scientific Committee on Food) (2002a). 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 ß-carotene. Opinion adopted by the Scientific Committee on Food on 26 September, 2002. Available online at: http://ec.europa.eu/food/fs/sc/scf/out143_en.pdf.

SCF (Scientific Committee on Food) (2002b). Opinion of the Scientific Committee on Food on a report on Post Launch Monitoring of "yellow fat spreads with added phytosterol esters". Available online at: http://ec.europa.eu/food/fs/sc/scf/out144_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://ec.europa.eu/food/fs/sc/scf/out174_en.pdf.

Simojoki, M., Luoto, R., Uutela, A., Rita, H., Boice, J.D., McLaughlin, J.K. and Puska, P. (2005). Use of plant stanol ester margarine among persons with and without cardiovascular disease: Early phases of the adoption of a functional food in Finland. *Nutr. J.* 4: 20.

Valsta, L.M. (1995). Effects of rapeseed oil on serum lipoproteins and plasma fatty acids. Comparison of Strictly and Partially Controlled Human Dietary Interventions. Väitöskirja. Kansanterveyslaitos A 19/1995, Helsinki, Finland.

Valsta, L.M., Lemström, A., Ovaskainen, M.-L., Lampi, A.-M., Toivo, J. Korhonen, T. and Piironen V. (2004). Estimation of plant sterol and cholesterol intake in Finland: quality of new values and their effect on intake. *Br. J. Nutr.* 92: 671-678.