



# Results from a post-launch monitoring survey on consumer purchases of foods with added phytosterols in five European countries



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## ARTICLE INFO

### Article history:

Received 28 May 2013

Accepted 10 August 2013

Available online 14 August 2013

### Keywords:

Consumer

Intake

Phytosterols

Plant sterols

Post-launch monitoring

Purchase data

## ABSTRACT

Phytosterols (plant sterols and stanols), in the form of phytosterol-esters, are used in food products as active ingredients to lower elevated blood low density lipoprotein-cholesterol concentrations. In Europe, plant sterol-esters gained Novel Foods authorisation in 2000. As a requirement of the authorisation, Unilever developed a post-launch monitoring program to monitor the use of products with added phytosterols.

This paper reports findings from the 2011 post-launch monitoring survey on consumer purchase behaviour of foods with added phytosterols.

91,000 households in the Netherlands, Belgium, United Kingdom, France and Germany were included. 11,612 purchased foods with added phytosterols, including spreads, salad dressings, milk- and yoghurt-type products.

The results show that 71–82% of households purchasing products with added phytosterols were 1–2 person households. These households were also purchasing the majority of the volume sold in each country (75–85%). The average phytosterol intakes per household were 0.35–0.86 g/day; well below the 1.5–3.0 g/day phytosterols needed to achieve a significant blood cholesterol lowering benefit.

Post-launch monitoring is an accepted and useful tool to estimate the consumption behaviour amongst different consumer groups. Data show that average phytosterol intakes per household were well below 1 g/day, suggesting that overconsumption is unlikely.

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## 1. Introduction

Phytosterols, which includes both plant sterols and plant stanols, are naturally occurring compounds found in plant-based foods such as vegetable oils, grains, seeds, nuts, legumes, fruits and vegetables. Phytosterols are part of the normal diet and habitual intakes vary from 200 to 300 mg/day with a typical Western diet (Escarriol et al., 2009; Hearty et al., 2009; Klingberg et al., 2008a, 2008b; Normén et al., 2001; Valsta et al., 2004) and from 500 up to 1000 mg/day amongst vegetarians (Jenkins et al., 2001; Vuoristo and Miettinen, 1994). Phytosterols have been shown in a vast number of human intervention studies to actively lower serum total and especially low density lipoprotein (LDL)-cholesterol at the appropriate daily intakes. A daily intake of around 2 g of phytosterols lowers LDL-cholesterol by on average 10% (AbuMweis et al., 2008; Demonty et al., 2008; Katan et al., 2003; Muso-Veloso et al., 2011). Due to their pro-

ven cholesterol lowering properties, phytosterols have been frequently added as an active ingredient in foods.

Products with added phytosterols are intended for use by consumers who need to lower their serum LDL-cholesterol concentrations as part of a healthy diet. Recommended intakes for phytosterols are between 1.5 and 3.0 g/day in order to achieve a LDL-cholesterol lowering effect of 7–11.3% (EFSA, 2012). Intakes above 3 g/day, as mandated by the labelling regulation, are not recommended due to little additional benefit and as a prudent precaution to avoid possible reduction in concentrations of blood carotenoid, esp. beta-carotene, a precursor to vitamin A (Reg. 608/2004). Although the health effects of chronically low blood carotenoid concentrations are largely unknown, there could be cause for concern during developmental phases when requirements are higher than normal such as during pregnancy, lactation or infancy (EFSA, 2008). In addition, cholesterol-lowering is typically not a priority for these groups. Therefore children under the age of 5 years as well as pregnant and lactating women are advised not to consume products with added phytosterols (EC No 608, 2004).

In order to incorporate phytosterols into foods, both plant sterols and plant stanols are typically esterified with dietary fatty acids to form plant sterol- or stanol-esters. Despite their similarity, plant sterols and stanols are subject to different legal rules as the use of

**Abbreviations:** BE, Belgium; EC, European Commission; EFSA, European Food Safety Authority; FR, France; GE, Germany; LDL-cholesterol, low density lipoprotein cholesterol; NL, Netherlands; PLM, post launch monitoring; SCF, Scientific Committee on Foods; UK, United Kingdom.

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plant sterol-esters as an active ingredient in foods within Europe requires pre-market approval under the Novel Foods Regulation. Novel Foods are foods and food ingredients which have not been used for human consumption to a significant degree within the European Community before May 15th 1997. These foods must undergo a safety assessment before being placed on the European market. Because plant stanols were in use before the implementation of the Novel Foods Regulation, products with added plant stanols are not subject to this regulation. In 2000, Novel Foods authorisation was granted to Unilever for the use of plant sterol-esters in yellow-fat vegetable spreads and later in 2004 for use in milk- and yoghurt-type products (EC 500, 2000; EC 335, 2004). One of the conditions of the authorisation in 2000 was that Unilever should establish a post-marketing surveillance system in order to monitor the use of the products once on the market (EC 500, 2000). As no such system existed for foods, Unilever developed a post-launch monitoring (PLM) programme. The first PLM took place from 2000 to 2001 and the results were submitted and assessed by the Scientific Committee on Foods (SCF) of the European Commission (EC) and gained a positive opinion (SCF, 2002). The full results have been published and showed that intakes of spreads with added plant sterols by purchasing households, 15–18 g/day of spread, equivalent to 1.13–1.35 g plant sterols, for regular consumers, were lower than originally assumed (Lea and Hepburn, 2006).

Since the first Novel Foods authorisation for the use of plant sterol-esters in yellow fat spreads, other authorisations have taken place for the use of plant sterol-esters in a variety of food formats. In addition, in 2009 the European Commission authorised a health claim of disease risk reduction due to the LDL-cholesterol lowering effect of phytosterols based on positive opinions by EFSA (EC No 983, 2009; EC No 376, 2010). The Novel Foods authorisations in combination with the authorisation of the health claim has led to an increasing belief that the use of food products containing added phytosterols available on the market may have also increased. The concern is twofold; first, a consumer may use several products simultaneously, resulting in intakes which may be exceeding the 3 g/day as stipulated by the labelling regulation and second, children under the age of 5 years as well as pregnant and lactating women may be consuming phytosterols even though these products are not intended for their use. Therefore, additional PLM focusing on consumer purchase behaviour is warranted. The aim of this paper is to describe the results from the most recent PLM survey commissioned by Unilever in 2011. This market research addresses household purchase behaviour of various foods with added phytosterols available on the market in five European countries, over a time span of one year.

## 2. Methods

### 2.1. Data collection

The data used for the PLM were collected by Europanel™, London, UK by making use of consumer data from two independent market research organisations, GfK® (for Germany, the Netherlands and Belgium) and KantarWorldPanel™ (for the United Kingdom and France). These organisations gather quantitative data on a continuous basis from registered households called panels. A panel is built as a representative sample based on the demographic quotas for a country, typically available from national census data. There are three recruitment criteria to be included in a panel: household size, age of the primary shopper and region. After recruitment and inclusion into a panel, further household demographic data is obtained including social class, employment status, education, the presence of children in the household, media usage, etc. The panel composition is updated annually to reflect changes in the population demographics.

The panellists scan their purchases when returning home from the supermarket. The data is gathered electronically using a special in-home barcode reader which transfers the data to a central database. It provides information on the date of purchase, store name, store location, total items purchased, barcodes, prices and special offers. This method provides information on purchase behaviour, is

non-invasive and less susceptible to the typical biases which occur during questionnaires or surveys. Furthermore, panel members are not aware of the exact research question or the product(s) under study.

### 2.2. Study sample

Households included were from the United Kingdom (UK), Germany (GE), France (FR), the Netherlands (NL) and Belgium (BE). Market research data in a total of 91,000 households was collected and analysed. Only those households which purchased foods with added phytosterols within the one year data collection period were included in the analysis, 11,612 households in total. No distinction was made between households which purchased products with added phytosterols regularly and households which purchased a product with added phytosterols only infrequently during the study period. For each household demographic information on the age of the head of household, the number of members in a household and the presence of children under the age of 5 years were collected. A cut off value of 35 years of age was used as this was the cut-off used in the data collection. Furthermore, it identifies an adult population, which is a proxy indicator for the appropriate consumer group as products with added phytosterols are intended for use by consumers who need to lower their cholesterol.

### 2.3. Products included

The products with added phytosterols included in the PLM are spreads, salad dressings, milk- and yoghurt-type products and yoghurt-drinks with added phytosterols marketed by both Unilever and other companies (Table 1). For each country, a different list of products was included in the study based on the products available in that particular market during the year (2011) in which the data was collected.

Although the products included in the study contain varying amounts of phytosterols, for the purpose of this analysis all of the products within a particular format (i.e. spreads) were assumed to have the same amount of added phytosterols expressed as free phytosterol equivalents (Table 1).

### 2.4. Data analysis

Upon collection of the consumer purchase data from the panel, it was scaled up to reflect the purchase behaviour of the total population by multiplying the ratio of the panellist population to the total population. This was possible as the panels are composed of representative samples of the population in a country. Therefore, the proportion of the total panel purchasing products with added phytosterols also reflects the proportion of the total population within a country purchasing products with added phytosterols (Table 2).

Based on the variety of food formats to which phytosterols can be added, the quantity of phytosterols in a product can be expressed either in grams (g) (e.g. spreads) or in millilitres (mL) (e.g. milk-type products). Therefore, the volume of products sold was converted to kilograms (kg) using a ratio of 1000 mL to 1 kg. Further, each product format also contains different phytosterol contents per 100 g product. Therefore, the phytosterol contents used (expressed as free phytosterol equivalents) were defined as: 0.075 kg phytosterols per kg of spread, 0.006 kg phytosterols per kg of yoghurt-type products, 0.003 kg phytosterols per kg of milk-type products, 0.02 kg of phytosterols per kg of yoghurt-drinks and 0.085 kg phytosterols per kg of salad dressing.

The quantity of phytosterols per kilogram of product (i.e. 0.075 kg phytosterols/kg of spread) was then multiplied by the total volume in kilograms of each product format (i.e. spread) sold in a country, resulting in a phytosterol volume. The phytosterols volumes were then summed across all product types, resulting in the total volume in kilograms of phytosterols sold per country. The total kilograms of phytosterols sold divided by the kilograms of total product sold per country, resulted in a phytosterols concentration per country. The phytosterol concentration is based on what is sold per country on a national level and differs for each country depending on the product formats available and the volumes of the product formats sold. For the different countries the estimated phytosterol concentrations (kg phytosterols/kg of products) were 0.036 (UK), 0.064 (GE), 0.039 (FR), 0.040 (NL), and 0.044 (BE).

Using the estimated phytosterol concentration, the household purchase and estimated daily intake of phytosterols per household was determined per country. Distribution analysis was used; therefore households were clustered into small, evenly sized groups (clusters), based on the volume (g) of products purchased in a year (i.e. the lowest cluster was defined as households who purchased between 0 and 200 g per year, the highest cluster varied per country dependent on the maximum volume of products purchased by a household). The upper limit of each cluster volume range (i.e. 200 g) was then multiplied by the representative phytosterol concentration of each country's product repertoire. This resulted in the estimated yearly phytosterol consumption for each household in the cluster, which was then divided by 365 days to determine the daily phytosterol intake per household. These calculations are based on the national product repertoire as the calculation of the actual repertoire (i.e. which products are purchased by consumers who purchase between 0 and 200 g per year) of a particular cluster would be statistically unviable due to the varying number of households in each cluster.

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