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## **Plant sterol enriched foods as perceived by consumers**

Project report on a joint project of consumer advice centres and BfR

### **verbraucherzentrale**

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- Verbraucherzentrale Nordrhein-Westfalen e.V.
- Verbraucherzentrale Sachsen e.V.
- Verbraucherzentrale Bundesverband e.V.

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Plant sterol enriched foods as perceived by consumers

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## 1 Introduction

More and more foods are appearing on the market to which plant sterols\* have been added. Their consumption is said to reduce cholesterol and this is attributed to the addition of plant sterols. This means that in Germany, too, there are foods on the market to which effective amounts of a substance have been added because of its specific impact on a medically accepted risk factor. Plant sterols are, therefore, functional ingredients. The foods containing them as an ingredient are classified as functional foods. There are no legal provisions specifically for functional foods. These products can, therefore, be placed on the market as foods for general consumption or as foods intended for particular nutritional uses (dietary foods).

### 1.1 Plant sterols as functional food ingredients

Plant sterols are natural components of plant cells and have a similar structure to human cholesterol. In plants they occur as free sterols, esterified with fatty acids or phenolic acids or also coupled to sugar residues. All foods containing vegetable fats (e.g. oil, nuts, seed, cereals, beans etc. and products manufactured from them) also contain small amounts of plant sterols. Between 5 and 10% of plant sterols are absorbed from food in the intestines of healthy individuals whereas most of the rest is excreted in faeces. A European has an average daily intake from conventional foods of between 0.2 and 0.4 g plant sterols whereas vegetarians ingest roughly twice that amount [1].

Plant sterol preparations used in foods are normally concentrates of plant oils or they are extracted from tall oil, a wood processing by-product. They are either used as free sterols or as fatty acid esters. All sterols have a double bond in their basic structure. If this double bond is chemically broken up, then plant stanols are formed from the sterols which are found, for instance, in products of the Benecol® brand.

The regular consumption of foods enriched with plant sterols reduces the overall cholesterol level by up to 10% and the LDL cholesterol level by up to 15%. The effective dose is between 1 and 2 g daily. Higher doses do not increase this effect [1]. An effective dose per daily portion is added to most products. The size of the daily portion of a concrete product is normally based on the customary daily intake of the comparable conventional food. Some plant sterol enriched foods on the market complement each other (e.g. bread, spreads and cheese) which means that there is the possibility of unwitting consumption of several times the effective daily dose.

The simple effective dose corresponds on average to five times the normal consumption of plant sterols up to now. The parallel consumption of foods enriched with plant sterols can, in extreme cases, increase the daily consumption of these substances to levels of 10 g per day, i.e. approximately 30 times the normal intake [2-5]. So far, there have been no reports of serious damage to health from the consumption of plant sterols in toxicological studies, clinical trials or in food consumption studies in humans. The consumption of effective amounts of plant sterols, however, reduces the uptake of carotinoids and fat-soluble vitamins from foods. The largest reduction, a drop of up to 33% in the absorption of  $\beta$ -carotene (also known as provitamin A), was observed following the daily consumption of 3 g plant sterols over a year. Up to now, no statements could be made about whether a reduction in carotinoid intake over an extended period of time can damage health. This cannot, however, be ruled out for people with a poor vitamin A status or elevated needs, like for instance pregnant and breastfeeding women. This adverse effect of plant sterols can, nonetheless, be compensated by the increased consumption of fruit and vegetables [1].

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\*For the purposes of this document the term "plant sterols" includes both plant sterols and plant stanols.

Like cholesterol, plant sterols also have an atherogenic potential when they occur at high concentrations in the blood plasma of human beings. Healthy people have a blood plasma level under 1 mg/dl whereas the cholesterol level is around 200 mg/dl. There have, however, been reports of a congenital disruption of sterol intake (phytosterolaemia or  $\beta$ -sitosterolaemia), which manifests in a highly elevated absorption of plant sterols from foods. The patients have a 10 to 100 times higher plant sterol level in their blood plasma and suffer in particular from benign tendon and skin nodules (xanthomatosis), a disrupted cholesterol metabolism and arteriosclerosis. Frequently, they develop premature coronary heart diseases [6]. Around the world less than 100 cases of this disease have been described.

Besides reducing the cholesterol level, the consumption of effective amounts of plant sterols leads to a slight, dose-dependent increase in the plant sterol level in blood plasma. The available studies were not sufficient in order to answer the question whether a slight increase in the plant sterol level must already be seen as a risk factor for the onset of arteriosclerosis. Further studies are needed [1;5]<sup>\*</sup>.

## 1.2 The responsible, informed consumer

The consumer model, on which the legal requirements of consumer protection and legislation in the European Union are based, draws on the so-called information model. According to this model, a shopper is placed in a position to make a rational decision in line with the market situation by having all the information required for his purchase at his disposal. The average consumer is deemed to be responsible, i.e. well-informed, critical, attentive and reasonable [7]. Hence in its judgements the European Court of Justice holds that, in the case of foods, the shopper must be given all the information required to assess the quality of food by means of EU-wide, uniform labelling provisions. In order to facilitate the correct use of foods enriched with plant sterols as well, the European Commission adopted Regulation 608/2004/EC that sets out these additional labelling provisions.

Foods containing effective amounts of plant sterols in a daily portion are solely intended for consumers wishing to lower the cholesterol level in their blood. This purpose is laid down as a mandatory component of additional labelling. Furthermore, the packaging of the products must also carry an intake recommendation and state that consumption of more than 3 g plant sterols per day is to be avoided. Attention must also be drawn to the fact that these products are not suitable for pregnant women, breastfeeding women or small children under the age of five. Furthermore, the label must include the suggestion of eating these products, if possible, as part of a diet that is rich in fruit and vegetables. Lastly, it should be pointed out that patients on cholesterol-lowering medication should only consume these foods under medical supervision. The reasons for the individual instructions on use do not have to be stated on the label. They are given in the expert safety assessment reports that have been published for the products for which an authorisation application has been submitted.

Using the model and the prescribed instructions on use, the behaviour of the well-informed and reasonable consumer of plant sterol enriched foods can be characterised as follows:

- He has consciously decided to lower his cholesterol level by eating plant sterol enriched foods. This decision is based on rational reflection including knowledge of his own cholesterol level and the ability to judge these parameters with regard to his own health. He is sure of his decision because he has benefited from expert medical diagnosis and advice.

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<sup>\*</sup>Other questions examined during the course of the authorisation procedure had to do with the need for a detailed specification, the possibility of contamination with harmful substances from the sulphite lyes of the paper industry in sterols, the lack of toxicological data, the possible cumulative uptake of sterols from various foods, consumption by pregnant women and children, potential hormone effects and possible effects on the gallbladder, liver and kidneys.

- He is capable of understanding the additional instructions on use for plant sterol enriched foods as warning signals about use-related risks to which he exposes himself if he fails to comply with them.
- He has obtained comprehensive information about the type and scale of these use-related risks in order to form an opinion on whether he wishes to expose himself to them.
- He regulates his daily consumption of these products in such a way that it remains within the recommended maximum intake for plant sterols.
- If he lives in a family (particularly with children), he has taken steps to ensure that other members of his family use the products correctly, too. For instance, he may store the products separately from other, conventional foods.

### 1.3 Issue

According to Article 14 of the European Regulation laying down the general principles and requirements of food law, food may not be placed on the market if it can damage human health (Article 14, paras 1 and 2, Regulation 178/2002/EC). Hence this means that, in terms of the law, the European consumer can rely almost blindly on the safety of products placed legally on the food shelves. According to para 3 (b) of Article 14 however "*the information provided to the consumer including information on the label or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods*" is to be included in this legally guaranteed safety. In other words, the legislator only assumes responsibility for the safety of products within the framework of their correct use. This constraint takes on unprecedented importance in the field of nutrition when it comes to foods to which uncommon amounts of substances with a dose-dependent effect have been added up to now. The responsibility of the consumer manifests itself here less in his right to information and more in the information obligation imposed on him.

The goal of this project is to characterise the actual consumer of these products and to analyse the legal situation and market situation of foods enriched with plant sterols in Germany. The focus of interest is on whether the actual consumers were members of the target population, on establishing what consumers know about these products, on assessing correct use as well as on determining the scale of incorrect use of these foods through their consumption by people who were not members of the target population or through the exceeding of the recommended daily intake. This project aims to determine the extent to which actual consumers really match the consumer model profile and whether further measures are needed to protect the health of consumers of these products.



## 2 Legal Foundations

Foods enriched with plant sterols to reduce cholesterol were not sold in the European Union prior to 15 May 1997. These products are, therefore, novel foods and their marketing comes under Regulation 258/97/EC (Novel Foods Regulation). The Regulation envisages two possible procedures for the marketing of novel foods and food ingredients: an authorisation procedure in accordance with Article 4 and a notification procedure in accordance with Article 5. The main component of the authorisation procedure according to Article 4 is the scientific safety assessment of the food or food ingredient for which an application for marketing authorisation has been submitted by a manufacturer or distributor. The safety assessment is done on a case-by-case basis and the responsible food safety agencies of all EU Member States are involved. In controversial cases the competent European Food Safety Authority, EFSA, is asked for its evaluation. The European Commission takes the authorisation decision on the basis of the results of the scientific safety assessment and publishes them as a legal act in the Official Journal of the European Communities. Each decision may contain binding requirements for the labelling of the respective food and also stipulate that the applicant must observe and report on certain consequences of the market launch of the product. For instance Unilever was required to monitor the use of its product after the market launch of the margarine "*becel pro-activ*" and to report back one year later whether the margarine reaches and is correctly used by the target population and whether consumption of the product produces the expected effects (Article 3 of Decision 2000/500/EC).

Each authorisation decision pursuant to Article 4 only entitles the applicant to place the product on the market for which the application has been made. This decision cannot be transferred to other products or other manufacturers. Other manufacturers who wish to add a plant sterol product that has already undergone assessment to a food, for whose use an authorisation decision is already available, must notify their product on market launch to the European Commission in accordance with the simplified procedure set out in Article 5. This notification must be accompanied by a scientific report from a recognised institution confirming the so called "Substantial Equivalence" of the notified food with an already tested product.

The first plant sterol enriched novel food approved for placing on the market by the European Commission on 24 July 2007 was the Unilever margarine "*becel pro-activ*". Up to the end of 2006 the companies listed in Table 1 submitted further applications for the addition of various plant sterol products to dairy products, bakery products, sausage products, dressings and sauces, rice drinks, soya drinks and fruit juices. So far eight authorisation decisions have been taken. The decisions were still pending for the applications concerning the addition of plant sterols to sausage products, fruit juice drinks, rice drinks and oil. So far around 70 manufacturers have notified substantial equivalent products pursuant to Article 5 of the Regulation within the EU (see Annex 10.3).

**Table 1: Applications pursuant to Article 4 of Regulation (EC) No 258/97 (Novel Foods Regulation)**

No.	Application date, Company	Product group	EU decision
1.	28.05.1998 Unilever, London	Yellow fat spreads with plant sterols	24.07.2000 2000/500/EC
2.	30.03.2000 Pouttu, Helsinki	Sausage products with plant sterols	unadjusted
3.	29.08.2000 Oy Karl Fazer, Helsinki	Rye bread with plant sterols	24.01.2006 2006/59/EC
4.	07.09.2000 Novartis-Consumer Health, Brussels	Milk-based drinks with plant sterols	12.11.2004 2004/845/EC
5.	15.05.2001 Teriaka Ltd, Helsinki	Yellow fat spreads, milk-based fruit drinks, yoghurt products, cheese products with plant sterols	31.03.2004 2004/336/EC
6.	24.09.2001 Pharmaconsult Oy Ltd., Espoo	Rye bread with plant sterols	24.01.2006 2006/58/EC
7.	08.10.2001 Pharmaconsult Oy Ltd., Espoo	Spreads, seasoned sauces, dairy products, yoghurt products with plant sterols	31.03.2004 2004/334/EC
8.	02.11.2001 Archer Daniels Midland Company	Spreads, dressings, dairy products, fermented dairy products, soya drinks, cheese products with plant sterols	31.03.2004 2004/333/EC
9.	07.08.2002 Unilever, Essex	Dairy products, yoghurt products with plant sterols	31.03.2004 2004/335/EC
10.	12.10.2004 Teriaka Ltd., Vantaa	Rice drink with plant sterols	unadjusted (EFSA opinion on 15.02.2006)
11.	28.10.2004 Coca Cola, Brussels	Fruit juices and nectars with plant sterols	unadjusted
12.	04.05.2005 Enzymotech Ltd. Migdal Ha Emeq	Multoil: Oil with plant sterols	15.05.2007 2007/343/EC

As per: 15.05.2007

Not all plant sterol enriched foods are governed by the provisions of the Novel Foods Regulation. One exception is the ingredient in the brand Benecol® of the Finnish company, Raisio. This product contains plant stanols that were already used as a food ingredient in margarine in 1995, i.e. prior to the entry into force of the Novel Foods Regulation. What is, therefore, required in Germany for the manufacture and import of a Benecol® product is either an exemption pursuant to § 68 LFGB – Food and Feed Code (formerly § 37 LMBG – Foods and Other Commodities Act) or a general order pursuant to § 54 LFGB (formerly § 47a LMBG) which must be obtained from the Federal Office of Consumer Protection and Food Safety (BVL). Up to now, national marketing approvals of this kind have only been issued by BVL for Benecol® products comparable to a food containing plant sterols which has been assessed and authorised pursuant to Article 4 of the Novel Foods Regulation.

Within the framework of the safety assessment of novel food applications pursuant to Article 5 of the Regulation, the former Scientific Committee on Food\* (SCF) in Europe has assessed various plant sterol products ([http://ec.europa.eu/food/fs/sc/scf/outcome\\_en.html](http://ec.europa.eu/food/fs/sc/scf/outcome_en.html)). It has also

\*EFSA was founded in 2002 in the course of the restructuring of European food legislation. The tasks of all scientific committees of the European Commission, which dealt with food and feed safety, have been reassigned to EFSA.

published a general opinion on the multiple consumption of foods of this kind [1]. In this report a recommendation was formulated – based on the dose-response relationship, the recognised risk potential and uncertainties – that daily consumption of more than 3 g plant sterols should be avoided. In its opinion on multiple consumption SCF stressed that the existence of various foods, each with an effective dose per daily intake, made additional management steps necessary to ensure that these products are consumed by the target population and to counteract the excessive intake of these substances by consumers. The European Commission's response to these assessments was its adoption of Regulation No 608/2004/EC on 31 March 2004. It lays down the above-mentioned additional labelling provisions for foods enriched with plant sterols (see Annex 10.4). This Regulation entered into force on 20 April 2004.



### 3 Market Situation

The general market for foods in Europe can be described as a largely saturated mass market with a diverse product offering and considerable predatory competition leading to low profit margins [9]. In this context the emergence of functional foods is linked to the specialised niche markets for groups of people with special dietary needs covered by the segment of dietary foods. According to the provisions of the German Ordinance for Dietary Foods, people with digestive, absorption or congenital metabolic disorders, people in special physiological circumstances like for instance pregnancy and lactation as well as infants and small children are recognised as groups of individuals with special nutrition requirements (Ordinance for dietary foods §1 para 1). Given the purpose of dietary foods, their labels must carry information about the target population and the type of suitability of the food for the target population. Hence, until recently, dietary products were the only foods for which defined exemptions had been granted from the ban on disease risk reduction claims for foods\*. As the Ordinance for Dietary Foods also contains relatively comprehensive provisions on composition and, where appropriate, on the suitability of dietary foods too, this market segment is relatively clearly demarcated and has more or less retained its niche character.

Although some plant sterol enriched foods were sold as dietary foods in Germany, these foods go beyond the provisions of the Ordinance for Dietary Foods when it comes to the following point: the claimed effect "*for consumers wishing to lower their cholesterol level*" targets the subjective state of mind of potential shoppers which is in no way tied *per se* to the actual existence of an elevated cholesterol level. Hence, there is no objective criterion on the basis of which a group of consumers within the intendment of the Ordinance can be determined and distinguished from the population at large. Products containing plant sterols, therefore, have the niche trait of a "food with a claimed indication" and open up the fundamental possibility of tapping the capacity of the general food market.

In Europe plant sterol enriched foods to reduce cholesterol have been around as a product category for about six years (the Finnish Benecol® margarine for 11 years but only in Finland). They occupy a corner of the relatively young multi-niche market of functional foods. The major market research institutions have described it as a future-centric market with high growth rates and high profit margins. In October 2006 the trend navigator "Functional Food" by the ACNielsen Company indicated a stable market share of around 2% of sales volume for cholesterol-lowering margarines between 2004-2006 in Germany. This would account for around 10% of the sales revenue volume in the margarine segment. The price analysis for this period confirms that cholesterol-lowering margarines could be sold for on average five times the price of conventional spreads ([http://www.acnielsen.de/pubs/documents/ACNielsen\\_TrendNavigator\\_FunctionalFood\\_final.pdf](http://www.acnielsen.de/pubs/documents/ACNielsen_TrendNavigator_FunctionalFood_final.pdf)).

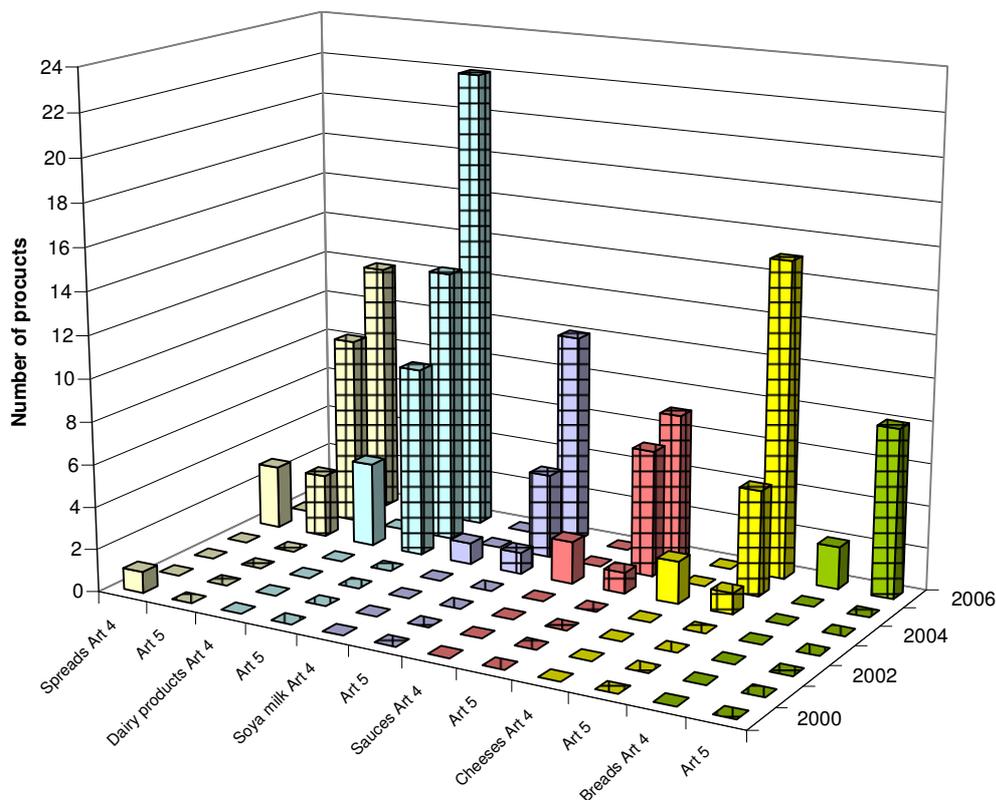
A similar development is clearly expected for other plant sterol enriched foods. Hence, an increase in the number of products containing plant sterols on the German food market is to be expected over the next few years. This will probably affect product categories and plant sterol products for which authorised pioneer products already exist. The simple reason lies in the fact that the start-up costs (research, development and safety assessment) for these "copycat" products are lower than for original innovations.

The growing number of products on the market is obvious from the frequency of notifications pursuant to Article 5 of the Novel Foods Regulation (see Fig. 1). Furthermore, the efforts of manufacturers to extend the product range can be seen from the number of applications in accordance with Article 4 of the above Regulation (see Table 1).

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\*In enacting Regulation (EC) No 1924/2006 in December 2006 the European Commission created the preconditions for health claims on foods for general consumption.

**Fig. 1: Number of plant sterol enriched products authorised pursuant to Article 4 of Regulation 258/97/EC or notified pursuant to Article 5 to the European Commission up to 31 December 2006**



At the end of 2006 a total of seven products with plant sterols were on the food shelves in Germany (see Table 2). They included two margarines, two yoghurt drinks, one milk, one sliced cheese and one sunflower seed bread. At the beginning of 2007 the introduction of another yoghurt drink and a drink on a soya milk basis was announced.

**Table 2: Plant sterol enriched products on the German food market**

Product	Company	Launched on	Package unit	Recommended portion	Plant sterols/ food
becel pro-active diet margarine	Unilever	August 2000	250 g	10 g	7.5 g/100 g
deli activ reform margarine	Walter Rau	October 2003	250 g	25 g	2 g/25 g
becel pro-active diet milk	Unilever	April 2004	1 l	250 ml	0.3 g/100 ml
becel pro-active diet yoghurt drink	Unilever	June 2004	100 ml	100 ml	2 g/100 ml
Benecol® yoghurt drink	Emmi	November 2003	65 ml	65 ml	2 g/65 ml
ColActiv sliced cheese	Westland	September 2006	125 g	3 slices	2.2 g/100 g 0.7 g/slice-30 g
Keimling active sunflower seed bread	Kampfmeyer	October 2006	750 g	4 slices (each 60 g)	0.5 g/60 g

As per: December 2006

## 4 The Consumer Survey

### 4.1 Methods

#### 4.1.1 The questionnaire

A questionnaire was developed to record consumption motivation, perception of labelling and handling of the product (see Annex 10.1). The questionnaire was designed for a 10 minute interview with purchasers of the product at the point of sale (POS) with written recording of the answers on paper. It contains a total of 19 questions broken down into the following groups:

- I) *Target population accuracy and consumption motivation* (8 questions)
  - Who consumes the products?
  - Which products were consumed how frequently?
  - Why were the products consumed?
  - Who recommended the products?
- II) *Do the shoppers/users take an informed decision* (7 questions)
  - a) *about their own physiological situation*
    - Is the user familiar with his/her cholesterol level?
    - Has the user been diagnosed as having a cardiovascular illness?
    - Is the user on medication?
    - Is consumption under medical supervision?and
  - b) *about the products they eat*
    - How do the plant sterols reach the foods?
    - Awareness of the target populations, non-target populations and maximum intakes
    - Reasons for the reference about eating fruit and vegetables
    - Storage of the products
- III) *Socio-demographic details* (4 questions)
  - Age, gender, family structure and education

Almost all the questions were designed as open questions. Only the question about the type and frequency of normally consumed products was supported by diagrams. For most of the questions only one answer was permitted. However, several answers were possible for a few questions. The length of the interview and understandability of the questionnaire were tested on 27 September 2006 by one interviewer in two different EDEKA supermarkets in Hanover. The shoppers showed an interest and did not have any problems understanding the questionnaire.

#### 4.1.2 Recording of data

The Institut für Markt-und-Gesellschaft e.V. (imug e.V.) was commissioned to draw up the interview schedule and to carry out the interviews. The method it chose was a survey of shoppers at the point of sale although, with this method, the group of respondents was not completely identical with the group of product users. The alternative method of telephone interviews with representatively distributed households was rejected as it was not possible to estimate what proportion of the German population eats plant sterol enriched foods. It seemed questionable whether sufficient users of the products could be reached in this way.

For the interviews supermarket customers who had at least one of the products from Table 2 in their shopping basket were approached directly.

This survey aims to provide reliable and representative information on the typical purchaser and user groups of plant sterol enriched foods. The representativeness of the statements was to be secured by means of:

- A sufficiently large total number of shoppers questioned  $n = 1,002$ .
- Sufficient scattering of the selected supermarkets of the chains Toom, EDEKA and Real. In total, shoppers in 33 different supermarkets were interviewed that were located in areas with differing social structures (see Annex 10.2).
- Significant geographical distribution of the survey sites in Germany (see Fig. 2). Around 250 interviews were conducted in each of the four regions North, West, East and South Germany.
- A sufficient distribution of the interviews conducted throughout the opening hours of the respective supermarkets (normally between 9 am and 7 pm) on the survey days Thursday, Friday and Saturday.

The survey was conducted on the above-mentioned days in five consecutive weeks between 9 October and 18 November 2006. The interviewers informed the participants that the survey was anonymous.

#### 4.1.3 Data processing

As part of the preparations for the evaluation, the recorded data were saved in a corresponding file. New variables were established to compare the groups and characterise the users. They are listed below:

- Age groups:  $< 45$  and  $\geq 45$  years of age
- Number of people in the household: 1, 2,  $> 2$  persons
- Households with/without children under the age of 5
- Households with/without children aged between 5-17
- Households with/without children
- Education level:
  - low (special school, lower secondary)
  - medium (intermediate secondary, polytechnic secondary school)
  - high (final school-leaving certificate, university of the applied sciences, university)
- Number of users in the household
- Age group of the users:  $< 5$  years of age, 5-17 years of age, 18-45 years of age,  $> 45$  years of age
- Target population classification:
  - Target population (when a high cholesterol level was given as the reason for consumption)
  - Other consumers (when other consumption reasons were given or unreflected consumption during the family meals was indicated)

#### 4.1.4 Identifying the users of plant sterol enriched foods

The respondent group consisted of purchasers of the products whose personal details about age and gender were recorded, too. However, in their households the shoppers were not always or were not the only users of plant sterol enriched foods. From the combined answers to questions 1 (Who eats the products in your household?) and question 18 (Size of household and age structure), the users of the plant sterol enriched foods were identified. By combining the information from questions 1, 17 and 18 the age structure of the users could be determined.

**Fig. 2: Regional distribution of the supermarkets of the chains Toom, EDEKA and Real in which the purchasers of plant sterol enriched foods were interviewed**



### 4.1.5 Data analysis

The data were analysed using SPSS 12.0.2 for Windows. In order to obtain information about the entire random sample, descriptive statistics were used. The chi square test was used to compare the groups. A significance level of  $\alpha = 0.05$  was assumed for all statistical tests. Overall it was evaluated whether the response behaviour differed in terms of age, gender, number of persons in the household, children in the household, education, region or market. Furthermore, it was tested whether behaviour differed between users who belonged to the target population for these foods and other users. To this end, some answer categories were combined. Test results were only mentioned in the section on results if they showed significant differences.

## 4.2 Results

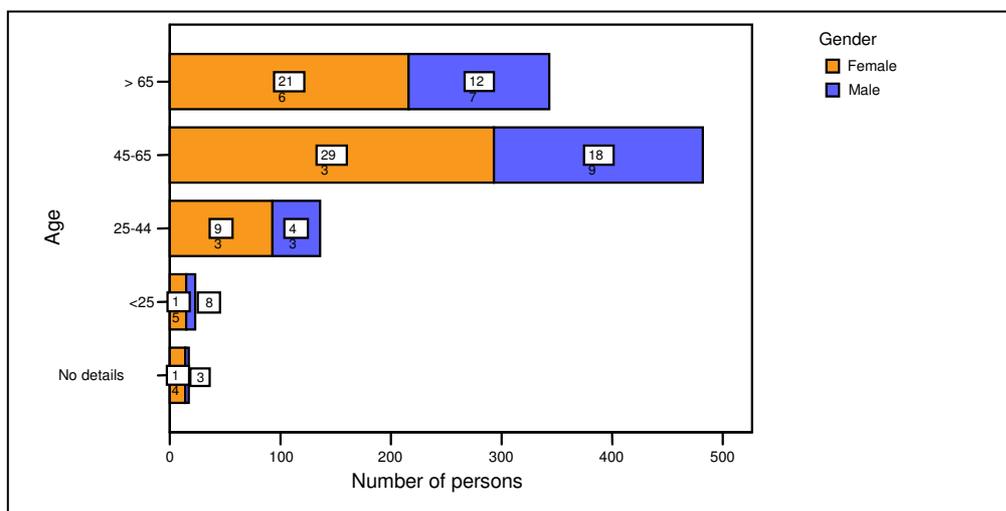
### 4.2.1 Description of the shopper population interviewed

During the survey 1,002 adults were interviewed from the population at large who had purchased at least one of the products from Table 2 in one of the 33 supermarkets. Around 75-80% of the people approached were willing to take part. One person from the group of respondents was excluded from the random sample because the "*edible oil enriched with plant sterols*" indicated by her was not for sale on the German market. This may have been a misclassification of the product "*becel Omega3 edible oil*", which was also advertised with the claim "*cholesterol-aware diet*".

### Sociodemography

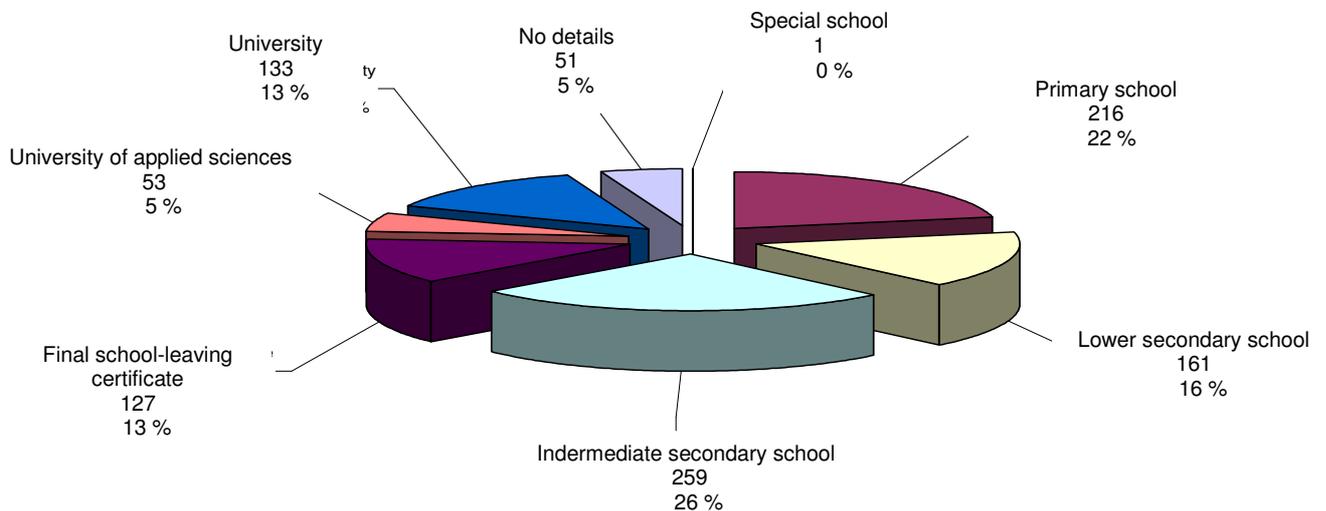
Fig. 3 gives the age and gender structure of the shoppers interviewed. Two-thirds of the respondents (63% or 631 individuals) were female and one-third (37% or 370 individuals) male. The average age of the purchasers of plant sterol enriched foods was 58.5 (SD = 13.97). The largest proportion of the shoppers (48.2% or 482 individuals) consisted of older adults (45-65 years of age) followed by the group of old-age pensioners (34.3% or 343 individuals). Very young adults (< 25 years of age) accounted for a small (2.3% or 23 individuals) proportion of the random sample whereas the age group of potential parents of minors (25-44 years of age) accounted for 136 individuals or 13.6% of the respondents. The youngest person at the time of the survey was 17 and the oldest 93.

Fig. 3: Age and gender of the shoppers interviewed



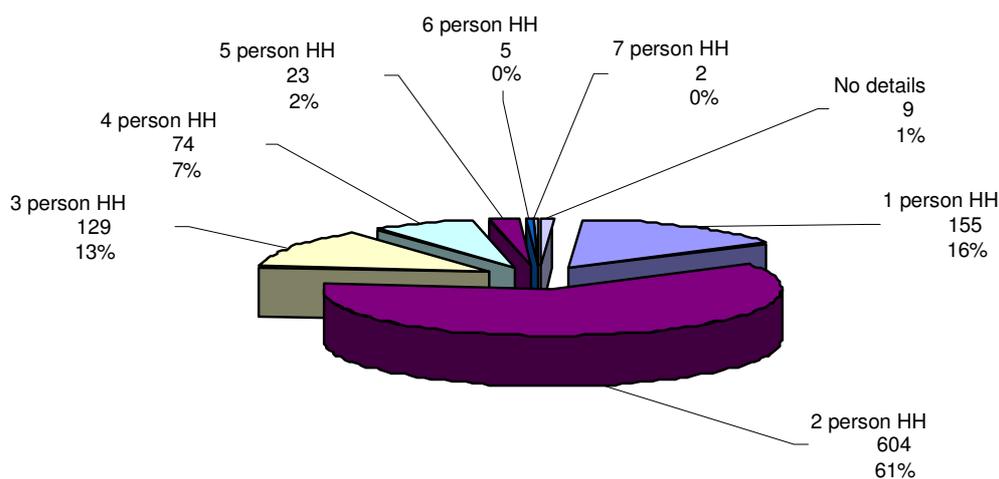
The education level of the shoppers interviewed is presented in Fig. 4. According to that one-third of the respondents had completed university or a university of the applied sciences; one-quarter had an intermediate school-leaving certificate and almost 40% had a lower school-leaving certificate.

**Fig. 4: Education level of the shoppers interviewed**



The size and age pattern of households are given in Figure 5 and Table 3. Around three-quarters of the households were one or two person households whereas three to six people lived in one-quarter of the households. 149 children lived in 11% of the households; 35 of them were under the age of 5.

**Fig. 5: Size of households**



In the one and two person households around 90% of the household members were over the age of 45 whereas 10% were up to age 45. In these households there were a total of four children over the age of five. In the multi-person households the share of over 45s was between 26 and 49%; the share of other adults was between 21 and 66%, the share of infants between 3 and 8% and the share of other children and adolescents between 9 and 30%. Nine of the persons interviewed did not provide any details about size of household or structure.

**Table 3: Age pattern in the households**

Persons in the household	Number of households	Children		Adults		N1*	N2**	Errors (N1-N2)
		< 5 years	5-17 years	18-45 years	> 45 years			
No details	9							
Total	992	35	116	463	1,570	2,205	2,184	21
1	155	0	0	17	135	155	152	3
2	604	0	4	113	1,088	1,208	1,205	3
3	129	16	36	158	174	387	384	3
4	74	11	46	112	120	296	289	7
5	23	6	22	46	36	115	110	5
6	5	1	4	14	11	30	30	0
7	2	1	4	3	6	14	14	0

\* N1 is calculated by multiplying the number of households by the number of people in the household.

\*\* N2 is the sum of all persons in the households assigned to the age groups in question 18.

In the case of full recording of the data N1 must = N2. The differences observed result from the fact that seven people indicated the size of household but did not allocate the household members to the age groups. In addition, two people did not allocate all household members to age groups.

The survey sites were more or less evenly spread across the regions North, South, East and West. Around two-thirds of the interviews (67%) were conducted in Real supermarkets, around one-third (29%) in Toom supermarkets and 4% in EDEKA supermarkets.

#### 4.2.2 User pattern and reasons for consumption

*Which people in the household consumed the product(s) containing plant sterols?*

Tables 4 and 5 give an overview of the people who consumed the plant sterol enriched foods in the households. The data from both tables were used to characterise the users. In around one-half of households (55%) one defined person, either the purchaser, the partner of the purchaser or another adult, consumed the food(s) with plant sterols. In just over a third of the households (38%) the products were eaten by both partners. This third contains all cases of the user group "my partner and I", 17 cases of household size 2 from the user groups "the entire family" and "whoever who wants to", as well as 5 cases from the user group "Other" in which the respondents indicated user couples (e.g. grandparents or parents-in-law) as other users. In 6.5% of the multi-person households the plant sterol enriched foods were eaten by between 3 and 6 people. In the consumption groups "the entire family" and "whoever wants to" there was a total of 13 children under the age of five as well as 40 other minors.

In the two cases in the consumption group "only my children" this was a household with four grown up children and one household with one minor (5-17 years of age) and one already grown up child. Since neither of the two respondents indicated any other constraints, all six "children" were considered to be users.

**Table 4: Consumption within the households interviewed (as %)**

Who eats the products (as %)		Just me	My partner and I	Only my partner	Only my children	The entire family	Whoever wants to	Other
Total		41	36	10	0	7	1	5
Age of shoppers	< 45	28	20	13	1	18	1	19
	>= 45	43	39	9	0	5	1	3
Gender of shoppers	Female	37	35	12	8	8	1	7
	Male	47	37	5	0	7	1	3
People in the household	1	88	3	4	0	0	0	5
	2	33	52	11	0	2	1	1
	> 2	28	17	10	1	26	1	16
Households with children	Total	22	14	17	1	29	1	16
	< 5 years	29	10	6	0	35	0	19
	5-17 years	21	13	18	1	29	1	16

The other people who consumed the products in 5% of the households were mainly grandparents, parents-in-law or parents and/or fathers or mothers. In a few cases more distant relatives, neighbours, friends, and, in one case, the friend of children, were indicated. All 55 respondents, who indicated "others" as users also indicated the other people as the sole users. The user groups "only my partner" and "other" differ from the other groups in that none of the shoppers interviewed was also a user of the products. In all evaluations attention should, therefore, focus on whether the shoppers interviewed or the users of the products were the subject matter of the evaluation.

No significant differences in the distribution of the consumer groups could be identified between the regions and the three supermarket chains. The level of education of the shoppers interviewed did not have any significant impact on the user pattern of the households either. In total based on the information on size of household and age structure (question 18) 1,559 users of plant sterol enriched foods were identified amongst the 2,205 household members of the 1,001 respondents. The 54 children amongst the users corresponded to a share of 3.5% whereby 0.8% were under the age of five (see Table 5).

**Table 5: Number and age structure of users in the consumption groups**

User group	Number of persons* in the household	Cases	Users	Users per group	Age structure of the users				
					< 5	5-17	18-45	> 45	No details
Total				1559	13	41	240	1213	52
Only me		409	409	409	0	0	41	360	8
My partner and I		357	714	714	0	0	67	635	12
Only my partner		96	96	96	0	0	17	70	9
Only my children**	4	1	2	6	0	1	5	0	0
	6	1	4						
The entire family	2	13	26	253	13	39	102	97	2
	3	28	84						
	4	28	108						
	5	5	25						
	6	1	6						
Whoever wants to***	2	4	8	19	0	1	6	12	0
	3	1	3						
	4	2	8						
Other*	1	48	48	62	0	0	2	39	21
	2	5	10						
	3	1	3						
	No details	1	1						

- \* In the user group "other" this information does not describe the number of people in the household but the number of users in the household. This is 1 if the other person is clearly named (e.g. father-in-law or neighbour). In five cases it is 2, as the other persons were indicated as a couple (e.g. grandparents or parents-in-law) and in one case a shared flat is given with three people as users. In one case no further details were given about the other user.
- \*\* Two respondents indicated that "only the children" were the users of the products. Of them one lives in a four-person household and one in a six-person household. Only one of the children in this group was a minor (5-17 years of age); the other "children" were already grown up.
- \*\*\* In the user group "whoever wants to" the maximum possible number of users corresponds to the number of people in the household.

### *Which products containing plant sterols were purchased and how frequently were the products eaten?*

The most frequently sold product by far was the margarine "becel pro-activ", which was used by 85% of the respondents. Here there was an age effect. Older users bought this margarine significantly more frequently (86% compared with 79%;  $p < 0.05$ ). Most users of this product ate this margarine daily (84%) or frequently (7%). The other products were chosen by between 5 and 23% of shoppers and eaten daily on a lower scale (see Table 6). "Becel pro-activ" yoghurt drink was purchased significantly more frequently by younger people (30% to 21%;  $p < 0.05$ ). The distribution of product use did not differ either regionally or between the age groups. Household size and level of education did not have any effect on product choice either. Overall people with the consumption reason "elevated cholesterol level" tended more towards daily consumption of at least one of the plant sterol enriched foods than other users (87% versus 70%).

**Table 6: Consumption frequency of products (as %)**

	Consumption yes	Daily/ almost daily	Frequently	Rarely	For the first time	No details
Becel pro-activ diet margarine	85	of which: 84	7	5	3	1
Deli activ margarine	17	of which: 54	13	21	11	1
Becel pro-activ diet yoghurt drink	23	of which: 36	29	28	5	2
Emmi Benecol yoghurt drink	9	of which: 40	20	29	6	5
Becel pro-activ diet milk	11	of which: 28	32	31	6	3
Col actif sliced cheese	5	of which: 13	30	47	8	2

The use of several plant sterol enriched foods in the household is presented in Table 7 without any consideration of consumption frequencies for the individual products. Around two-thirds of shoppers (66%) only used one plant sterol enriched food. Two products were more or less regularly consumed by 25%, three products by 6% and four products by 2% of the households. Eight people indicated the use of more than four plant sterol enriched products. No regional differences or impact of age, education or household size could be identified either concerning the multiple use of plant sterol enriched foods.

**Table 7: Multiple consumption without considering consumption frequency**

	Number of products											
	1		2		3		4		5		6	
	%	n	%	n	%	n	%	n	%	n	%	n
Total	66	656	25	247	6	64	2	24	1	6	0	2
Age	65	114	24	43	7	13	2	4	1	1	0	0
≤ 45 years	66	532	25	200	6	49	3	20	1	5	0	2
People in the household												
1	68	106	25	39	4	6	2	3	0	0	0	0
2	65	390	25	152	7	39	3	17	1	4	0	1
> 2	66	152	24	55	8	18	2	4	1	2	0	1
Households with children												
of whom < 5	59	63	29	31	8	9	2	2	1	1	1	1
of whom 5-17	55	17	26	8	13	4	6	2	0	0	0	0
	61	54	29	26	8	7	0	0	1	1	1	1

Furthermore, the daily consumption of several products containing plant sterols was considered. In 9% or 90 households two plant sterol enriched foods were consumed daily, in 1% or 14 of the households three products daily, in two households four products daily and in one household even five products daily. In 72% or 723 households only one product was consumed daily. In 94% of cases this was one of the two margarines, in 5% of the cases one of the two yoghurt drinks and in 1% the "becel pro-activ" milk. Cheese was the only product that was not consumed daily on its own. It was a second or third product for the six people who ate it daily. In households with children in which the products were eaten by the entire family, several plant sterol enriched foods were consumed daily.

Consumption data were not recorded in the interviews and that's why the scale of plant sterol intake above 3 g daily could not really be ascertained. However, with the help of the data in Table 2 (amount of plant sterol per portion food and recommended intake), the theoretical intake of plant sterols was calculated for multiple users. Out of the 107 people who consumed more than one product daily (question 8 in Annex 10.1), 22% would have a daily intake of more than 3 g plant sterols if they consumed the recommended portions of the products.

#### *Why do users eat plant sterol enriched foods?*

In Table 8 the reasons for the consumption of plant sterol enriched foods for all age groups, which result from the answers to question 1 ("*Who eats plant sterol enriched foods in your household?*"), were evaluated separately. In the groups "*just me*", "*only my partner*", "*only my children*" and "*other*" the reasons given clearly referred to the product users summed up in the respective group. In the groups "*my partner and I*" the consumption reasons were recorded for the "*I*" (question 2) and also the consumption reasons for the "*partner of I*" (question 1b) and then evaluated. In the groups "*the entire family*" and "*whoever who wants to*" the reasons given were only linked to the respondents. In these cases no statement can be made about the consumption reasons of the other users in the household. Some of the respondents gave several reasons for eating these foods. Table 8, however, only lists the reasons mentioned first.

In all groups comprising defined users per household ("*just me*", "*only my partner*", "*other*"), between 73 and 84% of the users indicated that they used the products because of their elevated cholesterol level. In the two cases "*only my children*" an elevated cholesterol level was also given as the reason for consumption. Between 5 and 17% of the respondents in these groups indicated the wish "*to protect my health*" as a reason for motivation. Between 1 % and 5% gave as reasons "*compensation for an unhealthy lifestyle*", "*lose weight/pay attention to my figure*", "*because it tastes good*" or "*other*". In the groups "*my partner and I*" and "*the entire family*" the reason "*elevated cholesterol level*" was only given, by contrast, by 53% and 45% of the respondents respectively. Overall the different reasons for consumption in these

two groups were more widely distributed whereby for 17 to 34% the wish "*to protect their health*" was the second most frequently given reason. More than half of the respondents (59%), who did not give an elevated cholesterol level as the reason for consumption, mentioned "protecting my health" as the first reason whereas 7% indicated compensation for an unhealthy lifestyle and 19% no health-related reason. In these households the products were eaten in 16% of the cases by the entire family whereas that only applied to 5% of the people who indicated their reason for consumption as being "*elevated cholesterol level*".

Out of the 113 people who gave several reasons for the consumption of these products, the reasons "*to protect my health*", "*lose weight/pay attention to my figure*" and "*because it tastes good*" were given with a relatively similar degree of frequency as the second reason. The other reasons for use of these foods could be divided between health reasons and general reasons. The latter included existing cardiovascular problems, diabetic metabolism, sclerosis of the liver, cow milk allergies and digestive problems. The general reasons included solidarity with their partner, the fact that only this margarine was on the table, the low fat composition and easy spreadability of the margarine but also curiosity and belief in the generally healthy character of the products.

The consumption reason "*elevated cholesterol level*" was indicated significantly more frequently by older than by younger shoppers (> 45 years of age: 74% and ≤ 45 years of age: 52%;  $p < 0.001$ ). People with minors in their households indicated by contrast, less frequently than people without children in the household "*elevated cholesterol level*" as the reason for consumption (58% compared with 71%;  $p < 0.01$ ). 72% (38 out of 53) of the children who consumed the products during family meals, therefore, live in households of shoppers who indicated other consumption reasons. The level of education had no impact on consumption motivation.

**Table 8: Reasons given for consumption by the users of plant sterol enriched foods**

Reasons for consumption	Just me		My partner		... and I		Only my partner		Only my children		The entire family		Whoever wants to		Other		Total	
	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n
Total	100	49	100	357	100	357	100	96	100	2	100	75	100	7	100	55	100	1,358
Elevated cholesterol level	73	299	53	188*	53	190*	84	80	100	2**	45	34	72	5	81	45**	62	843*
Compensation for an unhealthy lifestyle	2	8	2	6	2	7	1	1	0	0	7	5	0	0	2	1	2	28
Protect my health	17	67	17	61	20	72	5	5	0	0	34	25	14	1	7	4	17	235
To lose weight/pay attention to my figure	2	9	2	6	2	5	2	2	0	0	4	3	0	0	4	2	2	27
Because it tastes good	3	13	3	13	4	14	3	3	0	0	5	4	14	1	0	0	4	48
Other	3	13	5	20	3	11	4	4	0	0	4	3	0	0	4	2	4	53
No details	0	0	18	63	16	58	1	1	0	0	1	1	0	0	2	1	9	124

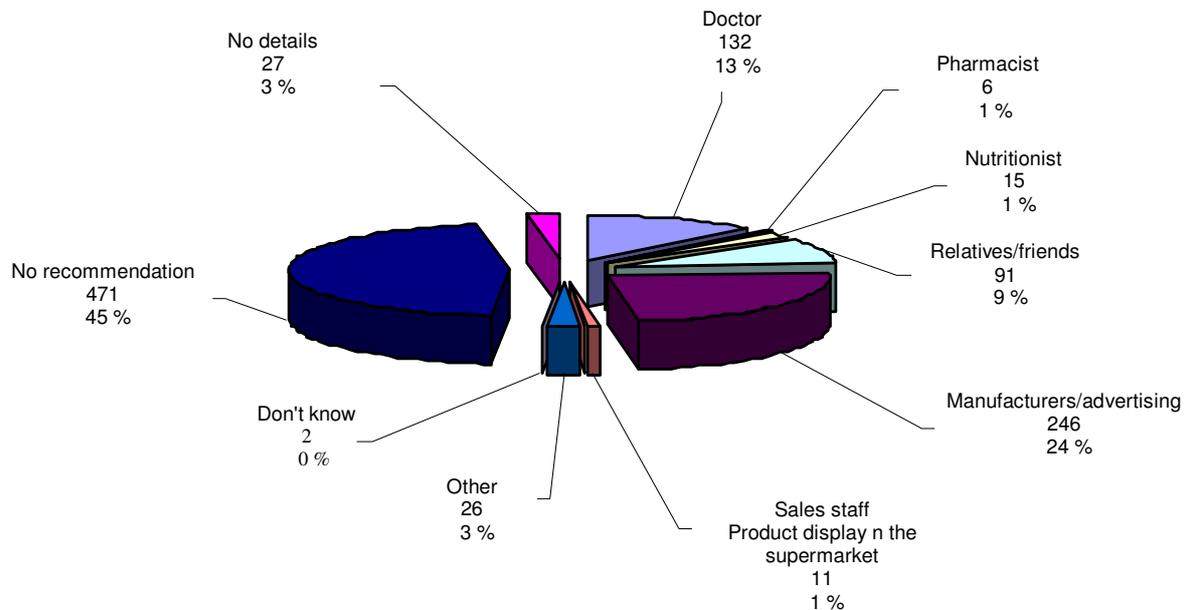
\* In the consumption group "my partner and I" 357 people indicated a consumption reason both for themselves and their partners. 105 people mentioned an "elevated cholesterol level" for themselves and their partners. 83 people indicated an "elevated cholesterol level" only for themselves and not for their partners and 85 people chose a different reason for themselves and an "elevated cholesterol level" for their partners.

\*\* n stands for the number of respondents (= number of cases). In the consumption group "only my children" there were six product users in the two cases with the consumption reason "elevated cholesterol level". In the group "other" the 45 cases with the reason "elevated cholesterol level" encompassed 49 product users. Overall 738 respondents therefore gave an "elevated cholesterol level" as the consumption reason for 851 product users.

### Who recommended the consumption of plant sterol enriched foods?

Almost half the purchasers (46%) of plant sterol enriched foods decided to purchase these products without any specific purchase recommendation and 9% were made aware of these products by comments from relatives or friends (see Fig. 6). 13% of the shoppers were advised by their doctors to use these products and 2% followed the advice of pharmacists or nutritionists. 24% reacted to product promotion in the media and 1% of shoppers reacted to active displays in the supermarkets. The majority of persons and institutions under "other", who recommended the purchase of the product, can be summed up under advertising in the media (Internet, newspapers, Galileo, media reports) and shops (special offers, health food stores) and medical advice (hospitals, health insurance funds). Furthermore, mention was made of one lecture, gut feeling and the habit of always choosing *Becel* products. A few people (23) indicated several product recommendations. Fig. 6 gives the distribution of the 1,027 answers.

**Fig. 6: Product recommendation**



A separate evaluation of product recommendations by people who gave an elevated cholesterol level as the reason for consumption and other users shows that consumers in the target population used plant sterol enriched foods after receiving professional advice (doctors, pharmacists, nutritionists) four times more frequently than other users (19.2% versus 4.6%).

### 4.2.3 The responsible, informed consumer

#### 4.2.3.1 Awareness of the physiological situation

*Had the cholesterol level been measured in the users of the products who indicated an elevated cholesterol level as the reason for consumption?*

Out of the shoppers, 738 people for 851 product users\* indicated an elevated cholesterol level as the reason for consumption (see Table 8). Furthermore, they were asked whether this statement was based on the actual measurement of the cholesterol level. This question was evaluated using consumption motivation in question 1 and the results are presented in Table 9. In the group "my partner and I" the answers were evaluated separately for questions 2 and 1b and in the consumption groups "only my children" and "other" the number of product users was determined in the relevant cases. 89% of the people who gave an elevated cholesterol level as the reason for consumption were based on a measurement; in 8% it was not based on a measurement and 3% didn't know whether a measurement had been taken. The elevated cholesterol level had been measured in the case of the children who were indicated in two households as the sole users of the plant sterol enriched foods.

It had also been measured in 93% (me in the group "just me") and in 96% (me in the group "my partner and I") of the respondents who used the products themselves and in 83% (partner in the group "only my partner") and 87% (partner in the group "my partner and I) of the respective partners. Ignorance about a measurement of the cholesterol level was highest in the user group "other" (31%) and second highest in the statements about partners (3% and 4%). In the consumption group "the entire family" the proportion of people who indicated an elevated cholesterol level as the reason for consumption but did not confirm this by having their cholesterol level measured was 24%. This was three times higher than in the total respondents (8%).

*Are the users of the products also on cholesterol-lowering medication and, if so, what kind?*

41% of the users with the consumption reason "elevated cholesterol level" indicated that they also took medication (see Table 10). The share of people on medication was lowest in the groups "the entire family" and "whoever wants to" with 18% and 20% and highest in the group "other" with 62%. The group "other" mainly encompassed grandparents, parents and parents-in-law which led to a very high proportion of already very old users which could perhaps explain the higher proportion of people on medication. Furthermore, the level of education seemed to have a significant effect ( $p < 0.05$ ). 48% of respondents with a low and 44% with a medium compared with 26% of respondents with a high level of education also took medication to reduce their cholesterol level.

79 of the relevant people for this question could also describe their medicinal product. 36 different medicinal products were indicated: in 62 cases lipid reducers (56 x statins, 3 x fibrates, 2 x Ezetimibe® and 1 x omega 3 fatty acids), in 10 cases cardiovascular medicine (7 x beta blockers, 2 x ACE inhibitors and 1 Ca antagonist) and in six cases other medication (3 x antidiabetic agents, 2 x analgesics and 1 hepaticum).

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\* The 851 product users with the consumption reason "elevated cholesterol level" result from Table 8 taking into account the fact that the two cases of the consumer group "only my children" stand for six product users and the 45 cases in the group "other" stand for 49 product users.

**Table 9: Measurement of an elevated cholesterol level (number of cases)**

Measurement	Just me		My partner		... and I		Only my partner		Only my children		The entire family		Whoever wants to		Other		Total	
	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n
Total	100	299	100	188	100	190	100	80	100	2	100	34	100	5	100	45	100	843
Yes	93	278	87	164*	96	183*	83	66	100	2**	74	25	80	4	58	26**	89	748*
No	7	20	10	19	3	6	14	11	0	0	24	8	0	0	11	5	8	69
Don't know	0	0	3	5	1	1	4	3	0	0	0	0	0	0	31	14	3	23
No details	0	1	0	0	0	0	0	0	0	0	3	1	20	1	0	0	0	3

\*In the consumption group "*my partner and I*" 273 people indicated for themselves and/or for their partners an elevated cholesterol level as the reason for consumption (105 for both, 83 only for themselves and 85 only for their partners). Of them 244 people confirmed that their elevated cholesterol level had been measured (103 for both, 80 only for themselves and 61 only for their partners).

\*\*In the consumption group "*only my children*" the details were referred to all six product users and in the group "*other*" the 26 cases encompass 28 product users. Overall, therefore, 645 respondents for 754 product users indicated that an elevated cholesterol level had been measured.

**Table 10: Taking of cholesterol-lowering medication**

Medication	Just me		My partner		... and I		Only my partner		Only my children		The entire family		Whoever wants to		Other		Total	
	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n
Total	100	299	100	188	100	190	100	80	100	2	100	34	100	5	100	45	100	843
Yes	39	116	40	76	44	83	48	38	0	0	18	6	20	1	62	28	41	348
No	60	178	45	106	54	103	51	41	100	2	76	26	60	3	13	6	55	465
Don't know	1	4	3	5	2	3	1	1	0	0	3	1	0	0	24	11	3	25
No details	0	1	1	1	1	1	0	0	0	0	3	1	20	1	0	0	1	5

*Was a cardiovascular disease diagnosed for the users of the products?*

Of the respondents 28% or 284 people indicated that the user of the product already had a cardiovascular disease. This was far less pronounced amongst respondents under the age of 45 (12% with a cardiovascular disease) than amongst older ones (34% with a cardiovascular disease;  $p < 0.001$ ). Besides education (39% low, 24% medium, 26% high;  $p < 0.001$ ), membership of the target population (33% for target persons, 16% for other consumers;  $p < 0.001$ ) had a significant effect. Both factors were linked to age in that overall the younger people had a higher level of education and gave "elevated cholesterol level" less frequently as a reason for consumption.

*Were the products taken after consulting a doctor?*

People who take cholesterol-lowering medication should only consume plant sterol enriched foods under medical supervision. It was, therefore, examined whether this warning was heeded. One-third of the people (36%), who indicated that they were on medication, also stated that they had discussed their use of these products with a doctor. More than half (53%) indicated that they hadn't discussed this with a doctor and 11% didn't know or did not give any details. Aside from the people who said they were taking medication, a further 101 respondents indicated that they had discussed the use of these products with their doctor. Irrespective of medication a total of 21% of the respondents or 212 people indicated using the products after consulting a doctor. This was done significantly more frequently by the older respondents (25%) than by the younger respondents (12%;  $p < 0.001$ ) and by target persons (27%) than by other consumers (5 %;  $p < 0.001$ ).

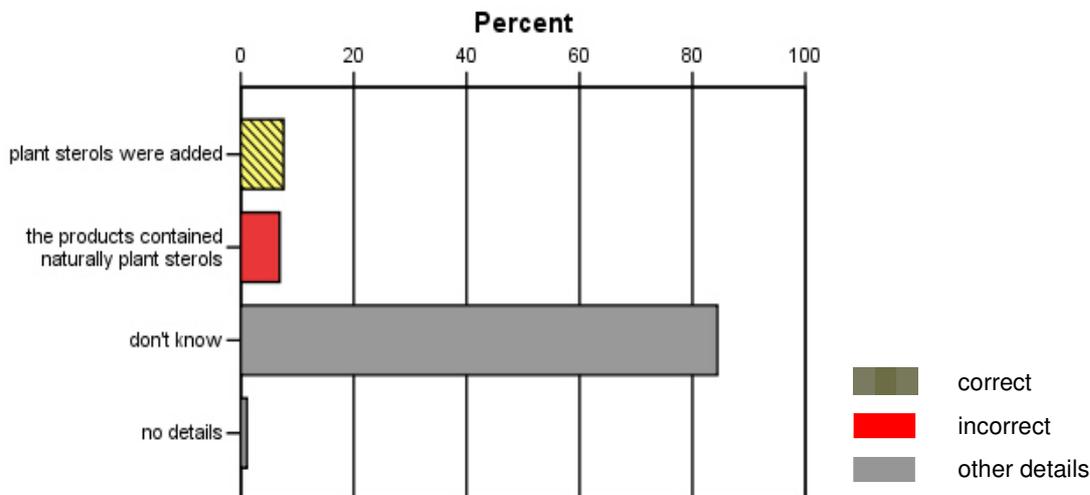
#### 4.2.3.2 Perception of product labelling

The additional labelling provisions for plant sterol enriched foods aim to inform consumers about the correct use of the products. From the angle of consumer protection this additional information also serves to avoid incorrect use, the long-term health effects of which are unknown. A series of questions, therefore, sought to ascertain the degree to which the information provided in the instructions reaches consumers and is taken on board by them. All evaluations of these questions refer in principle to the shoppers interviewed, of whom 85% were product users.

*Where do the plant sterols contained in the products come from?*

The answers to this question are presented in Fig. 7. Only 8% of the respondents knew that the plant sterols were added to the products whereas 7% thought they were naturally ingredients. By far the largest share of respondents (84%) did not know where the substances in the products came from and 1% did not give any details. No differences in respect of age, gender or region were observed in the distribution of this knowledge. Of the respondents with a high level of education, however, 11% knew that plant sterols had been added to the products whereas only 6% and 7% respectively of respondents with a low or medium level of education were aware of this ( $p < 0.05$ ).

Fig. 7: Origin of plant sterols in the products



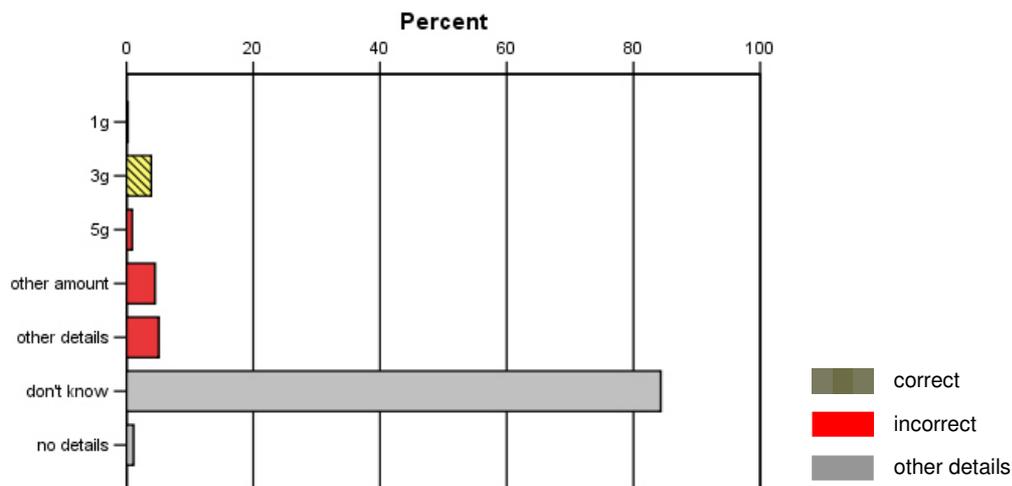
*Can the same amounts of plant sterol enriched foods be consumed as the corresponding "normal" foods?*

Around half of the respondents (49%) were of the opinion that products containing plant sterols could be consumed on the same level as the corresponding "normal" products. 21% of the respondents thought that this was not the case and 29% didn't know. Only 1% of respondents did not supply any details. The responses to this question showed that older respondents (51%) equated the consumption of these products with conventional products significantly more frequently than younger respondents (38%;  $p < 0.05$ ). Slightly fewer people with a high level of education than people with a low level of education thought that the products could be consumed in the same way (46% versus 51%). More people with a high level of education thought this was not the case than people with a low level of education (27% versus 18%). However, this effect was not significant. Also in the case of people from households with children, there is a similar trend compared to households without children (35% compared with 50% same level of consumption and 31% versus 20% not the same consumption;  $p < 0.01$ ).

*What levels of plant sterols should not be exceeded daily?*

When answering this question the respondents were given the correct recommendation of a maximum intake of 3 g plant sterols per day sandwiched between two incorrect amounts of 1 g and 5 g per day. Furthermore, they had the possibility of indicating other amounts in grams of plant sterols or as a portion of the food (see Fig. 9).

Overall only 4% of the respondents knew that the recommended maximum daily intake of plant sterols was 3 g per day (5% with a higher level of education, 4% with a medium level of education and 3% with a low level of education). 84% of the respondents were not familiar with the recommendation and 1% believed that 5 g plant sterols per day was the recommended maximum intake whereas two of the respondents selected a recommended maximum intake of 1 g per day.

**Fig. 8: Recommendation for the maximum daily intake of plant sterols**

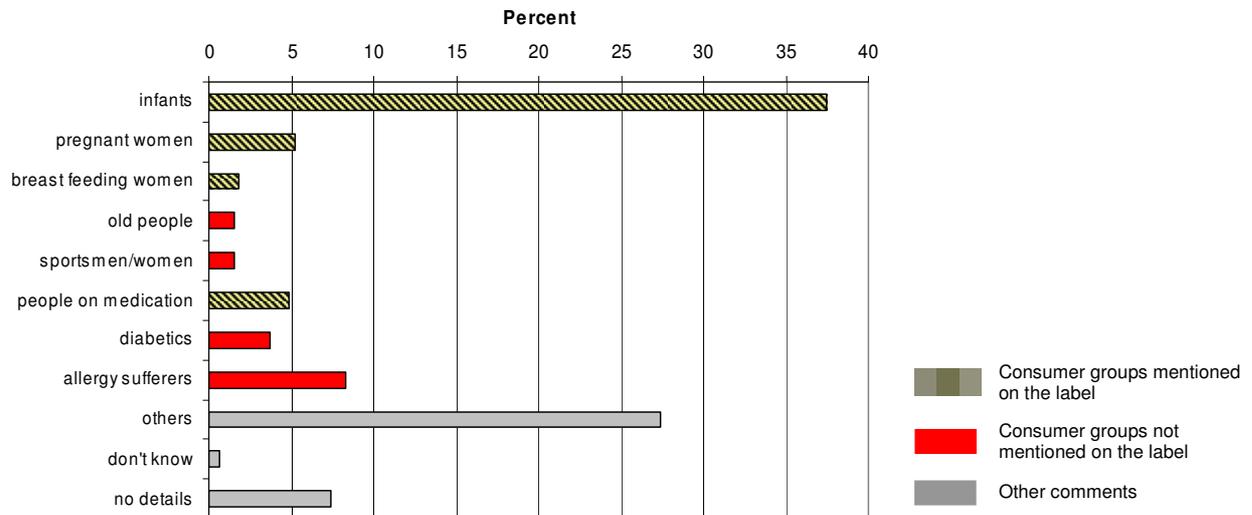
45 people indicated other amounts of plant sterols as the maximum daily intake. The range of opinions extended from 1.2-2 g per day (3x) over 10-50 g per day (39x) up to 100 g per day (3x). Another 51 people expressed their views on the recommended maximum intake in portion sizes of the corresponding foods or in consumption frequencies. The amounts expressed were largely in the range of the actual consumption recommendations for these foods.

#### *Are the products containing plant sterols suitable for all consumers?*

More than half the respondents (56%) believed that the products were suitable for all consumers. 27% of the respondents did not believe this; 16% didn't know and 1% did not answer this question. The answers to this question differed significantly ( $p < 0.01$ ) depending on the education level of the respondents. Only 50% of people with a high level of education believed that these products were suitable for all consumers compared with 60% of people with a low education level and 63% with a medium level of education. Two-person and more households answered less frequently "don't know" (14 and 15%) compared with one-person households (25%;  $p < 0.05$ ).

#### *For which consumer groups were the products not suited?*

This question was only answered by 27% or 267 people who felt that the products were not suitable for general consumption. They were given the choice of the groups listed in Fig. 9. The table lists all groups mentioned on the label (infants, pregnant and breastfeeding women, people on lipid-reducing medication) and other arbitrarily combined groups. Furthermore, additional groups could be named. As multiple answers could be given to this question, the percentages given in Fig. 9 refer to the total of 325 responses given by 267 respondents.

**Fig. 9: Consumer groups listed for whom the products are not suited**

With regard to the consumer groups for whom the non-suitability of the products was clear, small children were mentioned most frequently (38%), followed by pregnant women (5%) and people on cholesterol-reducing medication (5%). Breastfeeding women were only selected in 2% of cases. The share of erroneously included consumer groups was 8% for allergy sufferers and 2% for sportsmen/women and old people. Some of the 267 people interviewed (89) indicated other groups of individuals for whom the products were not suitable in the column *others*. Most of the respondents (58x) indicated above all "*people who don't need to take the product (because they were healthy or do not have an elevated cholesterol level)*". Others assumed that in particular people who were on medication and suffered from other diseases should not take the products.

#### *Why should people who ate products containing plant sterols also regularly eat fruit and vegetables?*

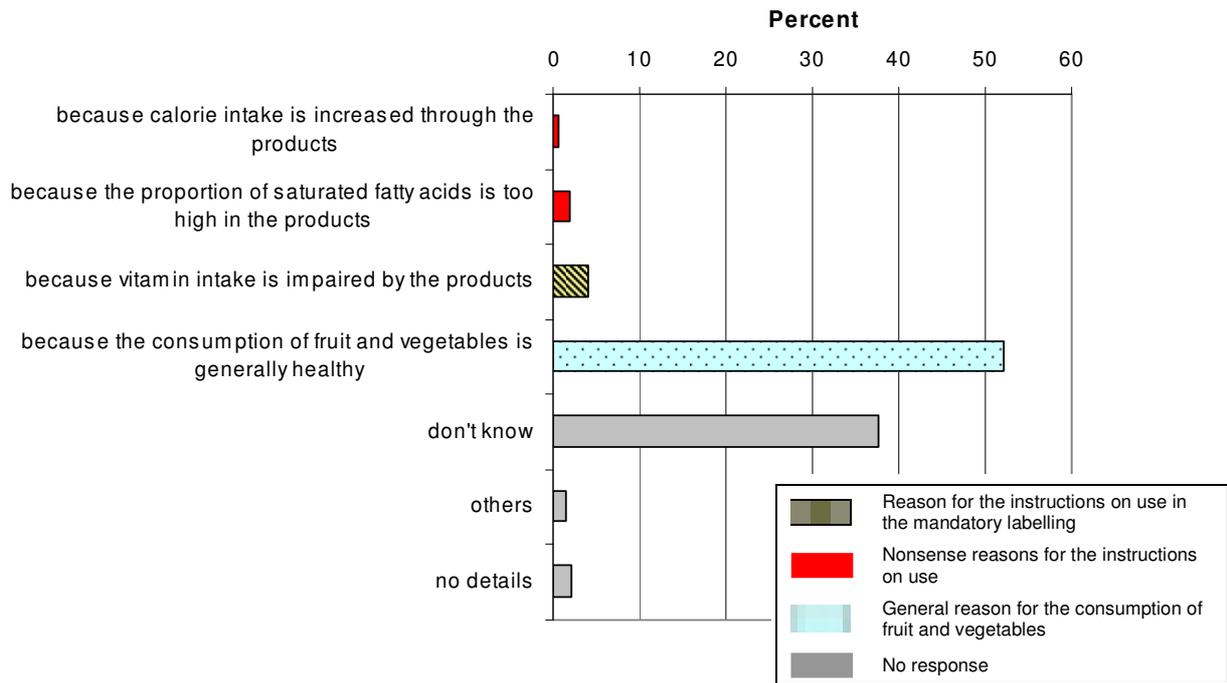
This question sought to determine to what extent consumers were aware of the fact that regular consumption of plant sterol enriched foods reduces the uptake of carotinoids and fat-soluble vitamins. This reason was presented to the respondents together with three other reasons. As multiple answers could be given here too, the evaluation in Fig. 10 again refers to the number of answers (1,020) and not to the number of respondents (1,001).

Only 4% of the answers to the question about the reasons for the recommended intake of fruit and vegetables when taking products containing plant sterols selected the actual reason for the inclusion of this instruction in the additional mandatory labelling. Around half of the respondents (52%) believed that the generally healthy image of fruit and vegetables was the reason for the recommendation and 38% did not know why this indication was explicitly given. Out of the 15 people who indicated other reasons, three also indicated additional vitamin intake.

#### *Where were the products stored?*

The vast majority (94% of the respondents) kept the plant sterol enriched foods with other foods in the fridge whereas 3% of the respondents kept the products in a separate compartment in the fridge. 2.5% did not respond and three people kept the products in the basement, in a cupboard or in a larder. In the households with children under the age of five, 7% of the respondents kept the products in a separate fridge compartment.

**Fig. 10: Reasons given for recommending the consumption of fruit and vegetables**



### 4.3 Discussion

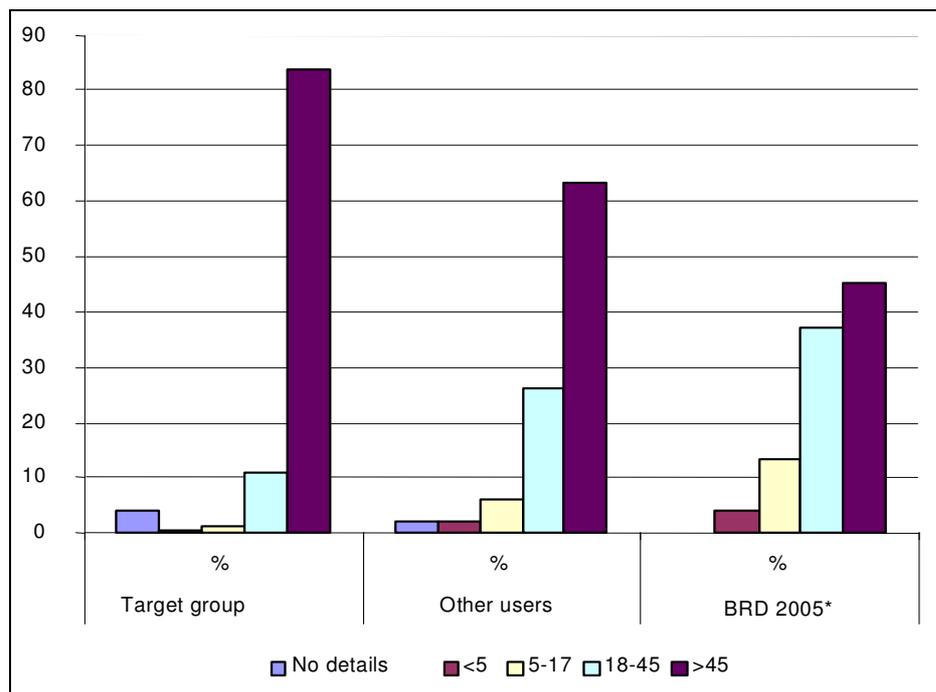
Foods, to which effective amounts of plant sterols have been added, reduce the cholesterol level in the blood plasma of the people who regularly eat them. They are, therefore, intended for people wishing to reduce their cholesterol level. The expectation is that this group of consumers mainly includes older people who suffer more frequently than the general population from cardiovascular diseases. Furthermore, it is expected that these consumers eat these products instead of their conventional counterparts. However, the regular consumption of effective amounts of plant sterols also reduces the uptake of carotinoids and some fat-soluble vitamins from food and increases the amount of plant sterols circulating in the consumers' bodies. At the present time it is not possible to predict whether the consumption of effective amounts of plant sterols could result in adverse health effects in the long-term. Given the added uncertainty about whether the plant sterols circulating in the body are to be deemed an independent risk factor for the onset of arteriosclerosis, precautionary health protection measures are needed to avoid the consumption of these products by children and healthy non-target persons [5;8].

#### 4.3.1 Reaching the target population and correct use

The main criterion for separating the target population from the public at large is an elevated cholesterol level which can only be recognised through measurement. Out of the respondents, 738 shoppers for 851 product users indicated an elevated cholesterol level as the reason for their consumption. Out of them, 645 shoppers for 754 users also confirmed that this statement was based on measurements. Referred to 1,559 total users identified in the households for the 1,001 respondents, between 48% and 55% of the product users matched the target population for these foods. Just under half of the consumers (45%) did not correspond to the target population. These other consumers were either people who had decided to take the products for reasons other than an elevated cholesterol level or people who simply ate the product because their families or partners did. The latter group included 13 infants and 40 other minors. Together with one child, for whom an elevated cholesterol level was given as the reason for consumption in the consumption group "*only my children*", there were a total of 3.5% minors amongst the product users (0.8% < 5 years of age and 2.7% between 5 and 17 years of age).

Out of the shoppers who gave reasons for their consumption of plant sterol enriched foods other than an elevated cholesterol level, 59% indicated the wish to protect their health and 7% expressed the intention of compensating for an unhealthy lifestyle as the primary reason for consumption. Roughly one in five or 19% of these shoppers (this corresponded to 8% of the total number of respondents) did not indicate any special health reason for the consumption of these foods. The vast majority of shoppers, therefore, expected to derive a health benefit from the consumption of these products and this expectation was not generally tied to an elevated cholesterol level. A large proportion of shoppers clearly saw the purpose of these products as being more a quality statement about a "healthy lifestyle" than a product linked to a "physiological indication". It must be assumed that this perception was passed over to children and was accepted by these users, who simply consume these products because they were there.

Amongst the product users the target population corresponded more to the expected consumer type than other users. Table 5 revealed that 78% of all consumers were over the age of 45; however differentiation by membership of the target population revealed major differences. In the target population 84% of people were over 45 compared with 64% of the other users. Furthermore, almost all minors amongst the product users were amongst other consumers. The composition of other users was far closer to the overall German population which had a share of 45% of people over the age of 45 (see Fig. 11).

**Fig. 11: Age pattern of product users compared with the overall population**

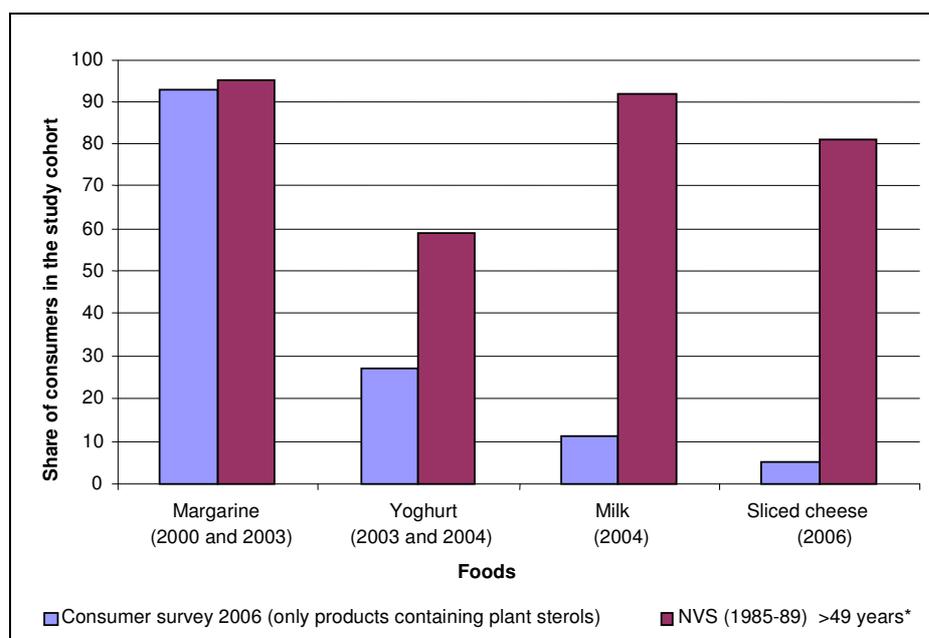
\* These data for the German population come from "Fachserie 1 Reihe 1.3 – 2005" of the Federal Statistical Office

Also the proportion of people who already suffered from cardiovascular diseases was two times higher in the target population 33% compared with 16% and consumption was based four times more frequently on a doctor's recommendation than for other users (19% versus 5%). A major proportion of the target population (41%) was also on medication for an elevated cholesterol level. Only around one-third of them had, however, discussed consumption of these products with their doctor. Both the product users who belonged to the target population and the other consumers were distributed over all consumption groups. However, in the households of the shoppers who gave reasons other than an elevated cholesterol level for consumption, the products were consumed three times more frequently (16%) by the entire family than in the households of shoppers who were part of the target population (5%). Most of the minors (38 out of 53 or 72%) who simply consume these products because they were available, lived in the households of shoppers who did not belong to the target population. In the households of other product shoppers, these products were used less frequently every day compared to the shoppers in the target population however (70% versus 87%).

At the time of this survey (November 2006) two margarines, two yoghurt drinks, one milk and one sliced cheese product containing plant sterols were available on the German food market. Another product, a sunflower seed loaf, had just been launched. During the evaluation phase of the study two other products were launched, a yoghurt drink and a fruit juice containing drink on a soya protein basis. All products contained an effective dose of plant sterols in a normal portion of the respective food which basically means that there was a possibility of excessive dietary intake of plant sterols. No concrete consumption data could be recorded during the interviews; however the frequency of consumption of products was recorded in each case. It became clear that in 11% of the purchaser households two or more products were consumed daily. In 6% or six of these households the products were eaten by the entire family and in two of these households there were three minors. A realistic estimate of plant sterol intake therefore, requires the recording of intake amounts. Based on the available data it can merely be said that 21.5% of daily multiple users (equivalent to 2.3% of the total respondents) would ingest more than 3 g plant sterols per day if they ate the recommended portions for all the products indicated.

Given that after its launch in 2000 the margarine "*becel pro-activ*" was the only product containing plant sterols on the German market for three years\* and given that the dairy products were launched at the end of 2003 and in 2004 and cheese shortly before the commencement of this survey in September 2006, it comes as no surprise that the consumption of plant sterols is mainly in the form of margarine. The results for multiple users can, therefore, only be seen as an initial snapshot at the beginning of an expanding range of foods with effective amounts of plant sterols. They provide indications of possible development trends, which can only be confirmed over the next few years. Fig. 12 shows that the food "*margarine fortified with plant sterols*" was eaten within the population interviewed by an almost equal proportion of people as the food "*margarine*" within the older population at large (depicted using a study cohort from the first National Food Consumption Survey (NVS) from 1985-89). In the case of the other plant sterol enriched foods, the proportion of shoppers amongst the respondents compared to the share of consumers of conventional products in the older population at large was lower, the shorter the period the respective food had been on the market. This situation indicated that product shoppers did indeed use the margarine instead of conventional margarine and that other products containing plant sterols were initially and largely noticed and purchased by people who were already familiar with the prototype of these foods.

**Fig. 12: Consumption of plant sterol enriched foods compared with the consumption of conventional foods by the older German population (over the age of 49)**



\* From Kuhlmann *et al.*, 2005

#### 4.3.2 Perception of the special labelling of plant sterol enriched foods

Besides the claim "*for consumers wishing to lower their cholesterol level*", which is supplemented and reinforced on all products by the claim "*proven to reduce the cholesterol level*", the other important pieces of information when it comes to avoiding foreseeable misuse were: the recommended portion of the respective product, the recommended maximum daily intake of 3 g plant sterols and reference to the product's unsuitability for pregnant women, breastfeeding women and infants. Whereas the claimed purpose seems to effectively convey the special property of the products both to the target population and to consumers with a general desire for a healthy diet, the constraints on use were only noticed by very few consumers on the whole. A total of only 11 people or 1% of the respondents knew that attention

\* In October 2003 the margarine "Deli-Reform Active" enriched with a plant stanol was launched onto the market.

should be paid to the intake amount of the products, that the consumption of plant sterols should not exceed 3 g per day and that the products were not suitable for all consumer groups. Of those who were aware that the products were not intended for the population at large, only one-third mentioned infants and only 5% pregnant and lactating women as the groups who should not consume these products. If the responses to the question about the reason for the special recommendation to eat the products in conjunction with plenty of fruit and vegetables were included, then only five people answered all four questions correctly. The lack of knowledge, however, varied for each individual question. For instance one in five people knew that attention should be paid to the intakes of the products (21%) and one in four people (27%) knew that the products were not suitable for all consumers but only one in 25 people knew about the recommended maximum intake of 3 g plant sterols (4%) and one in 25 people was aware of the reason for the recommendation for fruit and vegetable consumption (4%). There were no significant differences in knowledge of the instructions on use between the various consumption groups. Level of education doesn't seem to have scarcely any impact at all. Only amongst the other shoppers who knew that attention should be paid to the amount of product consumed, were there significantly more respondents with a high level of education. The low level of familiarity with labelling and the distribution of the few correct responses within the consumer groups did not point to a significant impact of labelling on the actual consumption of these foods.

The low recall rates of the contents of the instructions on use amongst product shoppers contrasted with the attention which consumers generally paid, according to their own statements, to the labelling of foods. In the study "*What consumers want to know*" between 52% and 54% of consumers indicated that they almost always or frequently heeded the list of ingredients, the nutrition information or the information on additives to foods [10]. Also A. Engelage, who evaluated numerous consumer surveys on the perception of quality traits of foods in her dissertation "*Quality perception of foods – The consumer image in case law and science*" reports that 65% of consumers indicated that they frequently used the statutory labelling elements of foods. She discovered that individual labelling elements were, however, weighted differently and that the most frequently read piece of information was shelf life. Lists of ingredients and nutrition information were deemed to be useful by two-thirds of consumers but it was mainly health-conscious consumers who consciously read them. However, this information was only partially correctly understood by consumers and only classified as particularly important by between 20-30% [7]. In this context the low recall rates of information displayed on plant sterol enriched foods seemed to correspond to the typical perception patterns of labelling elements depicting complex situations.

The product trait "*proven to lower the cholesterol level*" was heeded far more by the product users interviewed than constraints on use. Also the very subjective nature of the purpose "*for consumers wishing to lower their cholesterol level*" seemed to raise general health awareness amongst some product users rather than prompt a rational examination of the concrete physiological need to consume these products. This type of perception correlated with the results of Hagemann and Scholderer who compared intellectual models of the risks and benefits of novel foods from experts and consumers using three examples (a genetically modified potato and a conventionally grown rice both with reduced toxin content as well as plant sterol enriched foods). Based on all three examples the authors established that most of the comments by consumers on biological processes in conjunction with the risks and benefits were very abstract; they scarcely ever drew on causal relationships and only rarely did they extend beyond simple statements like "cholesterol is unhealthy" or "toxins were unhealthy". Furthermore, a tendency was observed amongst consumers for excessive generalisation of the individual positive or negative properties of specific products. Based on the frequency of associations between terms, they quantified the spontaneous perception of plant sterols by consumers as a very simple association pattern in which health aspects were clearly predominant. In this context plant sterols were associated four to five times more fre-

quently with health benefits than with health risks. 53 Danish consumers were involved in the study who were not necessarily purchasers of the reference foods [11].

#### 4.3.3 The actual consumer and labelling as risk management

By way of summary the model of the comprehensively informed, in touch and attentive consumer of plant sterol enriched foods can be set against the following image of the actual consumer based on the results obtained:

- 80% of consumers decided to eat the products and 20% simply ate the products in a family or partner context. In 55% of cases the reason for consumption was an elevated cholesterol level about which 48% were sure. 25% had other reasons which were mainly health related but could not be objectified.
- 21% of consumers, who consciously decided to eat these products, had consulted a doctor.
- 0.5% of consumers were able to correctly list the additional instructions on use and 1% the three most important ones. 27% of consumers knew that these foods should not be eaten by everyone and 21% that attention should be paid to the recommended intake. Furthermore, 8% knew that the plant sterols had been added to foods, 4% were familiar with the recommended maximum intake of plant sterols and 4% knew that consumption of these products reduced the intake of carotinoids and fat-soluble vitamins.
- 83% were regular consumers who ate at least one product daily and 11% tended to eat several products daily. 2.3% currently had the potential to exceed the recommended maximum intake level of plant sterols through multiple consumption.
- 94% of consumers with children in their households stored the products with other conventional foods in the fridge and 29% of them ate them with the entire family.

The consumer of plant sterol enriched foods identified in this study only appeared to match a few aspects of the model of a well-informed and attentive consumer. Both the ability to quote back the contents of the instructions on use as well as consumption behaviour indicated that the information provided on labelling was very incomplete and selectively digested by consumers. These results correlated with general findings on consumer product perception and the factors that influenced purchase decisions. Alvensleben assumed particularly in the case of foods (and other articles of daily use) that purchase decisions were taken on the basis of habit with little cognitive involvement. In this context, product perception depended rather on key emotional information and the frequency of repetition of the claims rather than on the cognitive grasping of the accompanying information. In a situation where consumers with limited information processing capacity were constantly bombarded with a growing flood of information, its uptake and processing were necessarily selective and preference was given to information which was relevant, pleasant and easy to understand. The risk perception of lay people was, therefore, subject to systematic distortions which were influenced by specific risk characteristics (e.g. voluntary – involuntary, caused by humans – occurring naturally, controllability etc.) [12].

From these findings the conclusion can be drawn that people who should not eat these products were not sufficiently protected against consumption of these products by their labels. The same applies to avoiding elevated intakes of plant sterols through multiple consumption. It is true that the potential for exceeding the recommended intakes was relatively low overall amongst users of the products but there were signs that new products with plant sterols were particularly popular with people who already ate other products of this kind. Furthermore, some people ate three to five of these products daily. For instance the sliced cheese, the sixth product on the German market, was already purchased by 5% of respondents in the

second month after its market launch. Almost all those shoppers (93%) also used one of the two margarines. The fact that the consumption of plant sterols up to now had largely remained within the recommended limits could be attributed rather to the low number and range of products of this kind on the market.

The need for additional measures to avoid the cumulative intake of elevated amounts of these substances from various foods and to reach the target population was clearly articulated as a precautionary health protection measure in the safety assessment of plant sterols as novel food ingredients [8]. The measures discussed were both special labelling provisions for these foods as well as restrictions on the addition of plant sterols to suitable food categories. The arguments for these restrictions were summed up by the Standing Committee on the Food Chain and Animal Welfare of the European Commission. In particular the following should not be fortified with plant sterols: foods which were attractive to children and which children like eating as well as drinks where the amounts consumed vary considerably but which have a high fat and sugar content and whose composition already impedes "the lowering of the cholesterol level". The Committee identified bakery goods, soft drinks, meat products, ice-cream, sugar products and cereal bars as the food categories which correspond to these criteria. Edible oils, spreads, dressings, sauces and dairy products were, by contrast, deemed to be suitable carriers by the Committee ([http://ec.europa.eu/food/fs/rc/scfcah/general/out06\\_en.pdf](http://ec.europa.eu/food/fs/rc/scfcah/general/out06_en.pdf)). Finally, the labelling of plant sterol enriched foods was implemented as a measure to protect consumers in Regulation 608/2004/EC whereas no limitations on carrier foods for these substances had been specified in legal provisions up to now.



## 5 Conclusions

Under the current circumstances 45% of consumers did not belong to the target population and 3.5% of consumers were minors. Almost all these children were not part of the target population and most of them lived in families in which the parents were not members of the target population either. The high proportion of other consumers, the failure to comply with the advice on discussing consumption of these products with a doctor for consumers on medication and the low degree of familiarity with the labelling information indicated that the special labelling of products containing plant sterols alone was not to be seen as an effective way of guaranteeing the correct use of these products. Given that nothing can be said at present about the adverse long-term effects of the consumption of effective amounts of plant sterols, correct use of the products was, nonetheless, a precautionary health protection measure.

The consumer advice centres, therefore, call for the following measures:

- The target population "*for people with a proven elevated cholesterol level*" should be clearly and unequivocally stated in the mandatory labelling of plant sterol enriched foods. There is, therefore, a need to amend Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterolesters, phytostanols and/or phytostanol esters.
- The labelling must also clearly indicate that the products should not be consumed as a preventive measure if the consumer does not have an elevated cholesterol level.
- In the retail trade the products containing plant sterols (similar to gluten-free products and products for diabetics) should be displayed separately from conventional products.
- Further food categories with added plant sterols should not be authorised either through the Novel Foods Regulation or through the LFGB (the Food and Feed Code).
- In principle, the safety assessment of food ingredients with a dose-dependent effect must be done on the basis of an overall concept in which provision is made for restricting the type and number of carrier foods for the ingredient.



## 6 Summary

The regular consumption of plant sterol enriched foods reduces cholesterol by up to 10%. At the end of 2006 there were seven plant sterol enriched foods on the market in Germany. They include two margarines (introduced 2000 and 2003), two yoghurt drinks (introduced 2004), a skimmed milk (introduced 2004), sliced cheese and a sunflower loaf (introduced 2006). All products contain an effective dose of plant sterols (about 2 g) in a typical daily portion and are intended for consumers wishing to lower their elevated plasma cholesterol level. For the sale of plant sterol enriched foods, authorisation is required pursuant to Regulation 258/97/EC (Novel Foods Regulation) or in accordance with the national legal provisions of the LFGB (the Food and Feed Code). Each authorisation decision is based on a safety assessment of the product. In 2004 the European Commission issued additional labelling provisions for plant sterol enriched foods in Regulation 608/2004/EC which inform consumers of the purpose of these foods, the maximum recommended intake of plant sterols, the risk groups for consumption, the reference that consumption of the products when on cholesterol-lowering medication should be discussed with a doctor as well as other instructions on consumption. This measure is designed to concentrate consumption of the recommended intake of these products in the target population.

The aim of this project was to characterise the way in which the consumers of these products perceived and responded to the special labelling provisions. The main focus was on whether actual consumers were members of the target population, on assessing intake of more than 3 g plant sterols per day through the consumption of various plant sterol enriched foods and on establishing what consumers know about these products. In order to answer these questions more than 1,000 adults were interviewed who had at least one food containing plant sterols in their shopping baskets at the point of sale in one of the 33 supermarkets. 1,001 questionnaires were evaluated statistically.

56% of the consumers interviewed named one concrete consumer in their families. 41% of the shoppers only mentioned themselves, 10% indicated their partner only and 5% indicated other people (e.g. fathers, mothers, mothers-in-law and/or fathers-in-law, grandmothers and/or grandfathers and, in one case, a neighbour) as the consumers of the plant sterol enriched foods. In two cases children were indicated as the consumers of the products alone. The other 44% of shoppers indicated that the products were eaten within the family either by both partners (36%) or by the entire family (7%) or by whoever who wanted to (1%). Based on the information from the respondents on family structure and consumption behaviour, 1,559 consumers of products containing plant sterols could be calculated. Out of these consumers 1,213 people or 77.8% were adults over the age of 45, 240 people or 15.4% were adults aged between 18 and 45 and 54 people or 3.5% were minors (13 infants and 41 children aged between five and 17). 52 consumers or 3.3% did not provide any information about age.

738 shoppers indicated for 851 consumers the wish to reduce an elevated cholesterol level as the reason for consumption. 645 of these shoppers were able to confirm that an elevated cholesterol level had been measured in the case of 754 consumers. Referred to the 1,559 total consumers recorded in the households of the 1,001 respondents, this meant that between 48% and 55% of the consumers matched the target population for these foods. Just under half of consumers (45%) did not match the target population. These other consumers were either people who decided to consume these products for reasons other than an elevated cholesterol level or people who simply ate the products because they were available in the households of their families or partners. The latter group includes 53 of the 54 children under the age of 18.

Around two-thirds of shoppers (66%) only used one food containing plant sterols. Two products were consumed by 25%, three products by 6% and four products by 2% of the house-

holds more or less regularly. 9% of the households ate two plant sterol enriched foods daily and 1% of the households consumed three products daily. Two respondents indicated that in their households four different products were eaten daily and one person indicated daily consumption of five products. Owing to the lack of information about the amounts consumed, the intake of plant sterols could not be calculated. However, the consumers in 21.5% of the 107 households in which two or more products were consumed daily, would have an intake of more than 3 g plant sterols per day if the recommended portions were consumed.

28% of the respondents indicated that the user of the products already had a cardiovascular disease. 41% of the product users, who ate these foods because of an elevated cholesterol level, were also on medication for this condition. Only one-third of the consumers had, however, discussed consumption of these products with their doctor. Independently of medication, 13% of the respondents indicated consuming the products on the advice of doctors and 2% followed the advice of pharmacists or nutritionists. Almost half of the purchasers (46%) of plant sterol enriched foods decided to buy the products without any specific purchase recommendation and 9% chose the products after being told about them by relatives or friends. 24% had reacted to product promotion in the media and 1% to active displays in the supermarkets.

Besides the claim "*for users wishing to lower their cholesterol level*", the recommended portion of the respective product, reference to the recommended maximum daily intake of 3 g plant sterols and mention of the unsuitability of these products for pregnant women, breastfeeding women and infants, were the key pieces of information to combat foreseeable improper use. These constraining instructions on use were only heeded by a few consumers. Only 11 people or 1% of the respondents were aware that attention should be paid to the consumption volume of the products, that the consumption of plant sterols should not exceed 3 g per day and that the products were not suitable for all consumer groups. Only 5 of the 11 people were also able to explain the reasons behind the instruction that the product should be consumed together with a high level of fruit and vegetables. The lack of knowledge about each instruction varies. For instance, one in five people knew that attention should be paid to the consumption amounts of the products (21%) and one in four (27%) that the products were not suitable for all consumers but only one in 25 was familiar with the recommended maximum daily intake of 3 g plant sterols (4%) and again only one in 25 was familiar with the reasons behind the recommendation of eating fruit and vegetables (4%). Out of the 27% respondents who were aware that the products were not intended for the population at large, only one-third mentioned infants and only 5% pregnant and breastfeeding women as groups who should not eat these products.

Both the high proportion of consumers who were not members of the target population as well as the low level of familiarity with the information on the label amongst purchasers of these products indicated that labelling had no significant impact on the actual consumption of these foods. Labelling alone was not, therefore, a sufficient measure to guarantee precautionary health protection through the correct use of plant sterol enriched foods.

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## 10 Annex

### 10.1 The questionnaire



### Questionnaire for users of cholesterol-lowering foods enriched with plant sterols/plant stanols

Hello,

We are conducting a survey on the use of cholesterol-lowering foods on behalf of the consumer advice centres. I see that you about to purchase *Becel Pro Aktiv*. May I ask you a few questions. The survey just takes a few minutes.

#### 10.1 Multiple mentions possible

**1. Who eats foods enriched with plant sterols/plant stanols in your household (this is the name given to these foods)? (open question)**

- Just me
- My partner and I
- Only my partner
- Only my child(ren)
- The whole family
- Whoever wants to
- Other \_\_\_\_\_



**1b. Why does your partner eat foods enriched with plant sterols/plant stanols? (open question)**

- Elevated cholesterol level
- Compensation for an unhealthy lifestyle and diet
- To protect health
- To lose weight/pay attention to his/her "figure"
- Because it tastes good
- Other

**2. Why do you or "the main user" eat foods enriched with plant sterols/plant stanols? (open question)**

- Elevated cholesterol level
- Compensation for an unhealthy lifestyle and diet
- To protect health
- To lose weight/pay attention to his/her "figure"
- Because it tastes good
- Other \_\_\_\_\_

**3. Did someone recommend to you (or the user) the purchase of cholesterol-lowering products? (open question)**

- Physician
- Pharmacist
- Nutritionist
- Relatives/friends
- Manufacturer – advertising (e.g. television or magazine)
- Sales staff – product display in the supermarket (e.g. sales person, information sheet, tasting)
- Other \_\_\_\_\_
- No recommendation

**4. If the interview partner or "the main user" wishes to lower his/her cholesterol level by taking these products: Has an elevated cholesterol level been measured for you or "the main user"? (open question)**

- Yes
- No
- Don't know

**5. Do you or "the main user" of the products eat the products in addition to cholesterol-lowering medication? (open question)**

- Yes: Name, if known \_\_\_\_\_
- No
- Don't know

**6. Have you or "the main user" of the products been diagnosed as having a cardiovascular disease? (open question)**

- Yes
- No
- Don't know

**7. Are you or "the main user" of the products eating them after consulting a doctor? (open question)**

- Yes
- No
- Don't know

**8. Which products were eaten/purchased? (Table) – How frequently were the products eaten by the main user?**

	Yes	No	Daily/almost daily	Frequently (at least once a week)	Rarely	For the first time
Becel ProActive® margarine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Deli active margarine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Becel ProActive® milk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Becel ProActive® yoghurt drink	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Emmi Benecol yoghurt drink	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Westland ColActiv sliced cheese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**9. Where do you keep these products? (open question)**

- In the fridge with other foods
- In a separate compartment in the fridge
- Other \_\_\_\_\_

**10. Do you know where the plant sterols/plant stanols in the products come from? (open question)**

- Were added
- Naturally
- Don't know

**11. Do you think that the same amounts of these products can be consumed as of "normal" products? (open question)**

- Yes
- No
- Don't know

**12. Do you know what amount of plant sterols per day should not be exceeded? (open question)**

- 1 g
- 3 g
- 5 g
- Please give amount: \_\_\_\_\_
- Other amount, e.g. pack size: \_\_\_\_\_
- Don't know

**13. Why do you think that the consumption of these products should be combined with regular consumption of fruit and vegetables? (open question)**

- Because these products lead to an elevated calorie intake
- Because the share of saturated fatty acids in these products is too high
- Because vitamin intake can be impaired by these products
- Because the consumption of fruit and vegetables is healthy anyway
- Don't know

**14. Do you think that these products are suitable for all consumers? (open question)**

- Yes (Filter: continue with question 16)
- No
- Don't know (Filter: continue with question 16)

**15. If not, for which groups are they not suitable? (open question)**

- Infants
- Pregnant women
- Breastfeeding women
- Old people
- Sportsmen/women
- People who were on cholesterol-lowering medication
- Diabetics
- Allergy sufferers
- Other: \_\_\_\_\_

That was the last question. To conclude we just need to ask you a few personal questions:

**Socio-economic data**

16. **Age:** \_\_\_\_\_ (years)

17. **Gender:**

- Female  
 Male

18. **How many people live permanently in your household, including you? Please include children (enter number)**

Total \_\_\_\_\_ persons

of whom

- \_\_\_ were under the age of 5  
\_\_\_ were aged between 5 and 17  
\_\_\_ were aged between 18 and 45  
\_\_\_ were over the age of 45

19. **What school or university qualification do you have?**

- Special school certificate  
 Primary school certificate  
 Lower school-leaving certificate  
 Intermediate school-leaving certificate/polytechnic secondary school  
 Final school-leaving certificate  
 Degree from a university of the applied sciences  
 University degree

---

Would you please be so kind as to give us your telephone number. Our market research institute (imug) would like to make random checks amongst our interview partners to check that this survey really took place. That is the only reason for giving us your telephone number. It will not be stored or passed on to anyone else.

Tel. no.: \_\_\_\_\_

---

To be completed by the interviewer:

Name of interviewer: \_\_\_\_\_ Date: \_\_\_\_\_

Supermarket name/place: \_\_\_\_\_

## 10.2 List of supermarkets

### Survey of cholesterol-lowering foods

#### Supermarket chain used

Region	Market	Post code	Place	Street
North	Toom	22041	Hamburg/Wandsbek	Waldörfer Straße 146
North	Toom	22609	Hamburg/Elbe EKZ	Osdorfer-Landstraße 131
North	E-Center	28219	Bremen/Walle	Waller Heerstraße 101
North	E-Center	30659	Hanover	Adolf-Emmelmann-Straße 5
North	E-Center	30453	Hanover	Am Bahndamm 17
North	Real	30916	Isernhagen	Opelstraße 3-5
North	Real	30453	Hanover-Linden	Davenstedter Straße 80
North	Real	38122	Braunschweig	Otto von Guericke-Straße 2
West	Toom	50996	Cologne/Rodenkirchen	Hauptstraße 128
West	Toom	53347	Alfter/Oedekoven	Ziegelweg 1
West	Real	44145	Dortmund	Bornstraße 160
West	Real	44339	Dortmund	Deutsche Straße 4
West	Real	44867	Bochum/Wattenscheid	Ottostraße 40-43
West	Real	44809	Bochum	Riemker Straße 13
West	Real	51105	Cologne/Gremberg	Gremberger Straße 200
West	Real	40549	Düsseldorf-Heerd	Schießstraße 31
West	Real	40217	Düsseldorf-Bilk	Friedrichstraße 152
East	Toom	99427	Weimar/Schöndorf	Ernst-Buse-Straße
East	Toom	07745	Jena/Burgau	Keßlerstraße 12
East	Real	99099	Erfurt	Hermesdorfer Straße 4
East	Real	99094	Erfurt	Gothaer Straße 22
East	Real	04430	Leipzig/Burghausen	Miltitzer Straße
East	Real	19061	Schwerin	Grabenstraße 1
East	Real	13507	Berlin	Am Borsigturm 2
East	Real	12435	Berlin-Treptow	Am Treptower Park 14
South	Toom	63069	Offenbach	Odenwaldring 70
South	Real	90431	Nuremberg	Virnsberger Straße 2-4
South	Real	90439	Nuremberg	Schwabacher Straße 99
South	Toom	85221	Dachau	Kopernikusstraße 2
South	Real	93059	Regensburg	Donaustauer Straße 128
South	Real	65205	Wiesbaden-Nordenstadt	Ostring 2
South	Real	55128	Mainz	Essenheimer Straße 222
South	Real	65428	Rüsselsheim	Außerhalb 14 a

### 10.3 Notifications of plant sterol enriched foods in accordance with Article 5 of Regulation 258/97/EC

Company	Company office	Date	Phytosterol product	Products
Teriaka Ltd.	FIN	16.07.2004	Phytosterols/phytostanols	Dairy products, soya drinks
PENASANTA S.A.	ESP	04.08.2004	Phytosterols/phytostanols	Dairy products (also fermented)
Cognis Deutschland GmbH & Co. KG	DE	04.08.2004	Phytosterol esters	Dairy products, yoghurts, yellow fat spreads
Danone	FRA	12.08.2004	Phytosterols/phytostanols	Yoghurts
NOVANDIE	FRA	09.09.2004	Phytosterol esters	Yoghurts
Dairygold	IRE	29.09.2004	Phytosterol esters	Yellow fat spreads
LACTOGAL Productos Alimentweres S.A.	POR	21.10.2004	Phytosterol esters	Dairy products, yoghurts
Teriaka Ltd.	FIN	16.11.2004	Phytosterols/phytostanols	Dairy products (fermented)
Cargill, Health & Food Scientific Affairs	USA	13.12.2004	Phytosterols/phytostanols	Yellow fat spreads, salad dressings, mayonnaise, seasoned sauces, dairy products, cheese products
Danone Vitapole (for Compagnie Gervais Danone)	FRA	13.12.2004	Phytosterol esters	Dairy products (fermented)
Forbes Medi-Tech Inc.	CAN	06.06.2005	Phytosterols/phytostanols	Yellow fat spreads, salad dressings, dairy products (fermented), soya drinks, cheese products, yoghurts, seasoned sauces, fruit drinks on a milk basis
Forbes Medi-Tech Inc.	CAN	06.06.2005	Phytosterols/phytostanols	Yellow fat spreads, salad dressings, dairy products (also fermented), soya drinks, cheese products, yoghurts, seasoned sauces, milk drinks
Forbes Medi-Tech Inc.	CAN	06.06.2005	Phytosterols/phytostanols	Yellow fat spreads, salad dressings, dairy products (also fermented), soya drinks, cheese products, yoghurts, seasoned sauces, fruit drinks on a milk basis
Cognis Deutschland GmbH & Co. KG	GER	29.06.2005	Phytosterols/phytostanols	Yellow fat spreads, salad dressings, mayonnaise, dairy products, seasoned sauces, milk drinks
NOVANDIE	FRA	29.06.2005	Phytosterol esters	Yoghurts, dairy products
MIFA AG Frenkendorf	CH	29.06.2005	Phytosterol esters	Yellow fat spreads
Juustoportti Oy	FIN	30.06.2005	Phytosterols/phytostanols	Yoghurts
Kerry Foods	IRE	04.07.2005	Phytosterols/phytostanols	Yellow fat spreads
Robert Wisemans & Sons Limited	UK	26.07.2005	Phytosterol esters	Dairy products
Homann Feinkost GmbH & Co.	DE	03.08.2005	Phytosterol esters	Salad dressings
Estavayer Lait S.A.	CH	03.08.2005	Phytosterol esters	Dairy products, yoghurts
Fayrefield Foods Ltd.	UK	03.08.2005	Phytosterol esters	Yellow fat spreads
Dr. Lena Nyberg (Skane Mejerier)	SE	08.09.2005	Phytosterol esters	Yoghurts
Lácteos Garcia Baquero S.A.	ESP	08.09.2005	Phytosterol esters	Cheese products
Nöm AG	AUT	09.09.2005	Phytosterol esters	Dairy products
Degussa Food Ingredients GmbH	DE	13.10.2005	Phytosterols/phytostanols	Yellow fat spreads, salad dressings, dairy products (also fermented), soya drinks, cheese products, yoghurts, seasoned sauces, milk drinks

**Annex 10.3 (contd.)**

Company	Company office	Date	Phytosterol preparation	Products
Walter Rau Lebensmittelwerke GmbH & Co. KG	DE	07.12.2005	Phytosterol esters	Yellow fat spreads
Triple Crown AB	SE	08.12.2005	Phytosterol esters	Dairy products, yoghurts
Westland Kaasspecialiteiten B.V.	NL	21.02.2006	Phytosterol esters	Cheese products
PrimaPharm B.V.	NL	21.02.2006	Phytosterol esters	Yellow fat spreads, dairy products (also fermented), yoghurts, cheese products, soya drinks
Vitae-Caps S.A.	ESP	21.02.2006	Phytosterol esters	Yellow fat spreads, dairy products, yoghurts
Glanbia Consumer Foods	IRE	21.02.2006	Phytosterol esters	Yoghurts
Dragsbæk	DK	31.03.2006	Phytosterol esters	Yellow fat spreads
Tucano Vertriebs GmbH & Co. KG	DE	31.03.2006	Phytosterol esters	Soya drinks
Oy Foodfiles Ltd.	FIN	27.04.2006	Phytosterol esters	Yellow fat spreads, dairy products (also fermented), yoghurts, soya drinks, cheese products, salad dressings, mayonnaise, seasoned sauces
Latteria Sociale Merano	ITA	27.04.2006	Phytosterol esters	Yellow fat spreads, dairy products (also fermented), yoghurts, cheese products, soya drinks
Renoldy - Producao e comercializacao de leite e produtos lácteos Lda.	POR	19.05.2006	Phytosterol esters	Dairy products
trentinalatte S.P.A.	ITA	24.05.2006	Phytosterol esters	Yoghurts, cheese products, dairy products (also fermented), soya drinks, yellow fat spreads
Cognis Deutschland GmbH & Co. KG	DE	09.06.2006	Phytosterol esters	Rye bread
Kingdom Cheese Company	SCO	26.06.2006	Phytosterol esters	Cheese products
Karwendel-Werke Huber GmbH & Co. KG	DE	20.07.2006	Phytosterol esters	Cheese products
Kampffmeyer Food Innovation GmbH	DE	20.07.2006	Phytosterol esters	Rye bread
Inpharma SA	CH	24.07.2006	Phytosterol esters	Dairy products (also fermented), yoghurts, cheese products
DDO processing LLC	USA	28.07.2006	Phytosterol esters	Dairy products (also fermented), soya drinks, salad dressings, seasoned sauces
Granarolo S.p.a.	ITA	31.07.2006	Phytosterol esters	Dairy products (fermented), yoghurts
Walter Rau Lebensmittelwerke GmbH & Co. KG	DE	03.08.2006	Phytosterol esters	Yellow fat spreads
Forbes Medi-Tech Inc.	CAN	03.08.2006	Phytosterol esters	Rye bread
Granarolo S.p.a.	ITA	16.08.2006	Phytosterol esters	Dairy products (fermented), yoghurts
Centrale del latte di Vicenza	ITA	06.09.2006	Phytosterol esters	Yoghurts
ABAFODDS s.r.l	ITA	07.09.2006	Phytosterol esters	Soya drinks
Cargill R&D Centre Europe	BE	12.09.2006	Phytosterol esters	Rye bread

**Annex 10.3 (contd.)**

Company	Company office	Date	Phytosterol preparation	Products
Stuffer S.p.A.	ITA	15.09.2006	Phytosterol esters	Dairy products
Trento e Borgo Scarl	ITA	15.09.2006	Phytosterol esters	Dairy products (fermented), yoghurts
Nöm AG	AUT	19.09.2006	Phytosterol esters	Dairy products
Vitae-Caps S.A.	ESP	27.09.2006	Phytosterol esters	Yellow fat spreads, dairy products (also fermented), cheese products, salad dressings, soya drinks
Heideblume Molkerei	DE	29.09.2006	Phytosterol esters	Dairy products, yoghurts, seasoned sauces, salad dressings
Les Derives Resiniques et Terpeniques	FRA	06.11.2006	Phytosterol esters	Yellow fat spreads, fruit drinks on a milk basis, yoghurts, cheese products
Forbes Medi-Tech Inc.	CAN	06.11.2006	Phytosterol esters	Cheese products
VIVARTIA S.A.	GR	06.11.2006	Phytosterol esters	Dairy products (also fermented), yoghurts, soya drinks, cheese products
Triple Crown AB	SE	07.11.2006	Phytosterol esters	Cheese products, rye bread
Vitae-Caps S.A.	ESP	16.11.2006	Phytosterol esters	Dairy products, salad dressings, mayonnaise, seasoned sauces, rye bread
Fenchem Enterprise Ltd.	CHN	17.11.2006	Phytosterol esters	Yellow fat spreads, dairy products (also fermented), milk drinks, salad dressings, mayonnaise, seasoned sauces, rye bread
Cargill R & D Centre Europe	BE	23.11.2006	Phytosterol esters	Yellow fat spreads, salad dressings, mayonnaise, seasoned sauces, Dairy products (also fermented), soya drinks, cheese products, rye bread
Milko ek. för.	SE	20.12.2006	Phytosterol esters	Cheese products
Romi Smilfood B.V.	NL	26.12.2006	Phytosterols/phytostanols	Yellow fat spreads

## 10.4 Commission Regulation (EC) No 608/2004 of 31 March 2004 on the labelling of foods and food ingredients with added phytosterols, phytosterolesters, phytostanols and/or phytostanolesters

L 97/44

EN

Official Journal of the European Union

1.4.2004

### COMMISSION REGULATION (EC) No 608/2004 of 31 March 2004

#### concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>(1)</sup>, as amended by Directive 2003/89/EC<sup>(2)</sup>, and in particular Article 4(2) and Article 6(7) thereof,

Whereas:

- (1) Phytosterols, phytosterol esters, phytostanols and phytostanol esters reduce serum cholesterol levels but may also reduce the  $\beta$ -carotene levels in blood serum. Member States and the Commission therefore consulted the Scientific Committee on Food (SCF) about the effects of consumption of phytosterols, phytosterol esters, phytostanols and phytostanol esters from multiple sources.
- (2) The Scientific Committee on Food (SCF) in its opinion '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  $\beta$ -carotene' of 26 September 2002 confirmed the need to label phytosterols, phytosterol esters, phytostanols and phytostanol esters as specified in Commission Decision 2000/500/EC of 24 July 2000 on authorising the placing on the market of 'yellow fat spreads with added phytosterol esters' as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council<sup>(3)</sup>. The SCF also indicated that there was no evidence of additional benefits at intakes higher than 3 g/day and that high intakes might induce undesirable effects and that it was therefore prudent to avoid plant sterol intakes exceeding 3 g/day.
- (3) Products containing phytosterols/phytostanols should thus be presented in single portions containing either maximum 3 g or maximum 1 g of phytosterols/phytostanols, calculated as free phytosterols/phytostanols. Where this is not the case, there should be a clear indication of what constitutes a standard portion of the food, expressed in g or ml, and of the amount of phytosterols/phytostanols, calculated as free phytosterols/phytostanols, contained in such a portion. In all events, the composition and labelling of products should be such as to allow users to easily restrict their consump-

tion to maximum 3 g/day of phytosterols/phytostanols through the use of either one portion containing maximum 3 g, or three portions containing maximum 1 g.

- (4) In order to facilitate consumer understanding it appears appropriate to replace on the label the word 'phyto' with the word 'plant'.
- (5) Decision 2000/500/EC allows the addition of certain phytosterol esters to yellow fat spreads. It sets out specific labelling requirements in order to ensure that the product reaches its target group, namely people who want to lower their blood cholesterol levels.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

#### Article 1

This Regulation shall apply to foods and food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters.

#### Article 2

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 foodstuffs, 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;

<sup>(1)</sup> OJ L 109, 6.5.2000, p. 29.

<sup>(2)</sup> OJ L 308, 25.11.2003, p. 15.

<sup>(3)</sup> OJ L 200, 8.8.2000, p. 59.

1.4.2004

EN

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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.

*Article 3*

Foods and food ingredients with added phytostanol esters already on the market in the Community or 'yellow fat spreads with added phytosterol esters' that were authorised by Commission Decision 2000/500/EC produced from six months after entry into force of this Regulation shall comply with the labelling provisions of Article 2.

*Article 4*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 31 March 2004.

*For the Commission*  
David BYRNE  
*Member of the Commission*

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