Risiken erkennen – Gesundheit schützen

Frequently Asked Questions on Plant Sterols

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Foods that have been enriched with plant sterols are sold on the German market. The foods are said to lower high cholesterol levels. The current offering in the retail trade encompasses margarines as well as dairy products, cheese and bread. The European Commission has approved the addition of plant sterols to fruit juices on a milk basis, soya beverages, spices and salad sauces too. The addition of plant sterols must be indicated on the packaging. The level of sterols is limited to prevent the daily intake from products of this kind exceeding three grams and in order to rule out any possible adverse health effects. Because plant sterols can inhibit the intake of vitamins, the recommendation is given on the packaging that more fruit and vegetables should be eaten. Children under the age of five, pregnant and lactating women should nonetheless not consume the enriched foods. Anyone who takes cholesterol lowering medication should consult a doctor before taking these products.

The Federal Institute for Risk Assessment (BfR), together with the consumer centres of the Federal States and their federal association (vzbv) examined whether the wording on the packaging is noticed by consumers and whether they follow the advice and whether foods enriched with plant sterols reach their actual target route – individuals with elevated cholesterol levels. The results of the study on consumer behaviour have been published in the BfR Wissenschaft series and can be accessed on the website under "Publications" (in German). Below the BfR has compiled frequently asked questions about plant sterols and their use in foods.

What are sterols?

Sterols are a group of fat-like substances which occur naturally in the animal and plant kingdom. The most well known animal sterol is cholesterol, the most frequently occurring plant sterols are ß-sitosterol, campesterol and stigmasterol. They have a similar structure to cholesterol. Their basis molecular framework contains a double bond. If this double bond is hydrolysed, saturated plant stanols are formed from the unsaturated plant sterols. Synonyms for plant sterols are phytosterols.

Where does one find plant sterols in nature and how are they produced?

Plant sterols are to be found in all fat-containing foods of plant origin like oils, nuts, seeds, cereals, beans and products made from them. They are components of the plant cell membrane and are either present as free sterols, as esters with fatty or phenolic acids (e.g. ferulic acid in oryzanol) or are coupled to sugar residues. Some insects, insect larvae, worms, shrimps and prawns can convert plant sterols into cholesterol and use them for their own metabolism. Mammals and human beings are not able to do this and cannot produce plant sterols themselves either. Saturated plant stanols only occur at low levels in nature.

Plant sterols also occur as by-products in the refining of vegetable oils or are extracted as tall oil, a by-product from the timber industry. The sterol mixtures may be hydrolysed to stanols, esterised with fatty acids and purified.

Are plant sterols essential for man?

Plant sterols are not essential for man and are scarcely used at all in the human metabolism. Healthy people only take up around 5 – 10% of plant sterols from food. Via the portal vein they reach the liver and are excreted into the intestines through bile. Most plant stanols are not absorbed at all but are excreted in faeces.

How do plant sterols act in metabolism?

Dietary plant sterols or plant sterols for medicinal products push cholesterol out from the micelles in the small intestine by means of which fat, cholesterol and other fat soluble dietary components are absorbed. The body then takes up less cholesterol and reacts by increasing self-controlled synthesis. It cannot however completely compensate for the inhibition of absorption which means that the cholesterol level falls. The 2 – 3 gram sterols daily reduce the cholesterol level in blood plasma of human beings by around 10%. This effect cannot be increased further by further raising the plant sterol dose. The daily consumption of efficacious amounts of plant sterols also reduces the intake of vitamins – particularly ß-carotene – from food and raises the plant sterol level in the blood plasma.

Phytosterolaemia and ß-sitosterolaemia is a very rare, congenital disruption of the plant sterol uptake mechanism which is characterised by elevated absorption of dietary plant sterols. This is a genetic disease. Around the world there have been reports of less than 100 cases. The patients have a 10 – 100 times higher plant sterol level in blood plasma and suffer above all from benign tendon and skin nodules (xanthomatosis), a disrupted cholesterol metabolism and arteriosclerosis. Frequently they already develop coronary heart diseases in adolescence.

What are plant sterols used for?

For about 50 years plant sterols have been used in cholesterol-lowering medications. The most important active substance is ß-sitosterol. For about 15 years plant sterols and stanols or their ester compounds have also been tested to a greater degree for cholesterol-lowering use in fat-containing foods like margarine, oil, butter and mayonnaise. In the meantime plant sterols can now be added technologically to low-fat foods as well. Because of the use of plant sterols and the related cholesterol-lowering effect, the foods enriched in this way are also described as "functional foods".

Which foods are enriched with plant sterols?

At the end of 2006 seven foods were on sale in Germany which were enriched with plant sterols: two margarines (introduced 2000 and 2003), two yoghurt drinks (introduced 2004), one skimmed milk (introduced 2005), one cheese in slices and one sunflower seed bread (both introduced in 2006). All products contain the daily dose of plant sterols (approx. 2g) and are intended for consumers who would like to reduce their high plasma cholesterol level. Other products have since been placed on the market.

Finland has longer experience with the use of cholesterol-lowering food. A margarine was already placed on the market there in 1995 which contains the plant stanol ester product "Benecol®“.

What statutory provisions govern the use of plant sterols in foods?

In terms of law plant sterols are novel food ingredients. Foods to which plant sterols have been added must be tested in accordance with the Novel Foods Regulation and either

authorised or notified. Only "Benecol®" products are exempt from this regulation because margarine with Benecol® was already marketed on a significant scale in one EU Member State prior to the entry into force of the regulation in May 1997. The Federal Ministry for Food, Agriculture and Consumer Protection issues exemptions or orders in accordance with national German provisions for products containing "Benecol®".

How are foods tested which are enriched with plant sterols?

Novel foods and food ingredients are not freely marketable. Foods to which plant sterols have been added must undergo toxicological and nutritional-medical tests in accordance with the provisions of the Novel Foods Regulation before they may be sold in Europe. From these safety assessments we know that the maximum reduction of the plasma cholesterol level by 10% is achieved through 1 to 2g plant sterols daily and that an increase in the dose does not raise this effect any further. The daily consumption of effective amounts of plant sterols also inhibits the intake of certain carotinoids and fat-soluble vitamins from food and increases the plant sterol level in blood plasma. As it cannot be reliably assessed whether adverse health effects could result from these two effects in the long-term, the European Food Safety Authority (EFSA) has recommended restricting the daily consumption of plant sterols to three grams.

Authorisation is issued for one product of a manufacturer. It cannot be transferred to other products or other manufacturers. Manufacturers who would like to add a plant sterol preparation which has already been assessed to a food, whose use has been authorised, must notify their product in accordance with a simplified procedure. The notification must be accompanied by a scientific report which confirms the essential similarity of the notified food with the already tested product. The European Commission currently has corresponding notifications from more than 70 manufacturers.

Do foods, to which plant sterols have been added, have to carry special labelling?

Since 2004 enriched foods of this kind must carry information about the purpose of the food (lowering cholesterol) and indicate the recommended maximum daily intake (2 – 3 grams). From the labelling it must be clear that children under the age of five, pregnant and lactating women should not consume enriched products of this kind for precautionary reasons because the foods can inhibit the uptake of specific vitamins. All other consumers should consume more fruit and vegetables than is customary to offset this effect. Consumers who are on medication for high cholesterol levels should consult a doctor about the consumption of these foods.

Is labelling sufficient to protect consumers?

A nationwide survey carried out by the Federal Institute for Risk Assessment together with the consumer bureaus involving more than 1,000 purchases of plant sterol-containing foods shows that the current labelling of products of this kind is clearly not sufficient in order to protect consumers. Furthermore this study shows that almost half of the purchasers did not have a proven higher cholesterol level. Consumers who are on medication for a high cholesterol level indicated that they frequently consumed the foods without complying with the recommendation to talk to their doctors. The consumer bureaus and BfR therefore recommend that on the packaging it should be clearly stated that plant sterol-containing foods should only be consumed by individuals with a high cholesterol level who do not belong to one of the above-mentioned risk groups. The number of products enriched with plant sterols should be

restricted, in the opinion of BfR, in order to ensure that the recommended daily intake of three grams plant sterols is not exceeded.