

Nutrients supply? Plate rather than pill!

BfR Frequently Asked Questions on Food Supplements

The growing use of vitamins, minerals, trace elements and other substances in food supplements which are offered for sale as capsules, tablets, powders or in liquid form as foods to supplement the general diet constitutes a challenge for consumer protection. Consumers must be protected not only from possible health risks but also from misleading information. In view of the wide and steadily growing range of food supplement products and the increasing distribution of food supplements via the internet, the BfR has put together answers to frequently asked questions on this subject.

What are food supplements?

Food supplements are foods. They are intended to supplement the general diet. Food supplements may contain a broad spectrum of nutrients or other substances with a specific nutritional or physiological effect. They may be, for instance, vitamins, minerals, trace elements, amino acids, fatty acids, fibre, plants or herbal extracts which are added in concentrated form either individually or as a combination. Food supplements are sold in a dosed form, for instance as tablets, capsules, coated

tablets, powders or liquids for intake in small, measured amounts. In contrast to other foods, food supplements may, among other things, come with a recommended intake along with other specific information for consumers, e.g. that they should be stored out of the reach of small children. The ingredients of food supplements may not, by definition, have any pharmacological effects. If a product of this kind has pharmacological effects, it falls under a different category than food supplements, e.g. under medicinal products which require official authorisation.



Which substances and what amounts of these substances may be added to food supplements?

The German Food Supplements Regulation (NemV) specifies which vitamins and minerals and corresponding compound sources may be added to foods. Furthermore, other nutrients and substances with a specific nutritional or physiological effect may also be added to food supplements, but there are presently no provisions regulating which specific substances (e.g. amino acids, fatty acids, fibre, plants, herb extracts etc.) may be added. All the same, certain substances are equated with additives in Germany which means they are subject to prohibition with a reservation regarding the granting of permission. They may only be added to foods including food supplements when they have been explicitly approved through legal provisions for the respective purpose.

There are no binding maximum levels for the ingredients of food supplements either on the German national or the European level. However, the Food Supplements Directive (Directive 2002/46/EC) issued in 2002 already in principle makes provisions for the foreseen setting of binding maximum levels for vitamins and essential minerals throughout Europe. Uniform maximum levels throughout Europe are desirable from the point of view of risk assessment. In 2018, the BfR revised its proposals for maximum levels for vitamins and essential minerals in food supplements, taking into account also intake via other sources, including intake via fortified foods (see Weißenborn, A., Bakhiya, N., Demuth, I. et al. *J Consum Prot Food Saf* (2018) 13:25. <https://doi.org/10.1007/s00003-017-1140-y>).

How can one identify products as food supplements?

One main identifying characteristic of supplements is that they must be labelled as such, i.e. as a “food supplement”. In addition to the details stipulated in the so-called Food Information Regulation (REG (EU) No. 1169/2011), they must – amongst others – bear information about the recommended daily intake as well as a warning that this amount must not be exceeded. Furthermore, the packaging must bear the information that food supplements should not be used as a substitute for a balanced, diverse diet and that they should be stored out of the reach of small children.

Claims to cure, alleviate or prevent disease are currently prohibited in Germany both in product advertising and on packaging. However, claims to reduce a risk of disease are possible, provided that they have been scientifically assessed by the European Food Safety Authority (EFSA) in line with Regulation (EC) 1924/2006 (the so-called Health Claims Regulation) and have been explicitly authorised by the EU Commission.

Do food supplements in Germany require official authorisation?

As food supplements are foods, they are covered by the basic provisions of the German Food and Feed Code of Law (LFGB) as well as all other legislation of the European Union in the area of food law. Amongst other things, foods must be safe, consumers may not be misled by the information on the package and disease-related claims are prohibited. However, claims to reduce a risk of disease are possible after they have undergone official examination and been approved.

Food supplements are not subject to mandatory approval regulations. Pursuant to the German Food Supplements Regulation (NemV), food supplements must be registered with the Federal Office of Consumer Protection and Food Safety (BVL). Responsibility for the safety of products and compliance with food law provisions lies with manufacturers and distributors. Monitoring of food supplements placed on the market and of manufacturing companies is the task of the food monitoring authorities of the German federal Laender.

Under what circumstances may food supplements which do not comply with German food law provisions be placed on the market?

Food supplements or other foods which do not comply with German food law provisions may only be placed on the market in Germany if they fulfil the precondition that they have been granted an exemption pursuant to §68 of the Food and Feed Code Law (LFGB) or based on a general decree pursuant to §54 LFGB.



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An application for a general decree can be submitted to the Federal Office of Consumer Protection and Food Safety (BVL) for food supplements which have been legally placed on the market in another Member State of the European Union. The application may only be rejected on compelling grounds of health protection or if the German authorities consider the supplement to be a medicinal product.

Domestic manufacturers or manufacturers from non-EU Member States also have the option of submitting an application for an exemption pursuant to §68 of the Food and Feed Code Law (LFGB) to the BVL. In this case, facts must justify the assumption that no risk to human health is to be expected. Here too, the precondition applies that the product in question is indeed to be classified as a food.

How safe are food supplements?

Food supplements are foods. They must be safe. The food manufacturers are primarily responsible for ensuring that food supplements do not harm health and do not mislead the consumer through their appearance or advertising. However, in contrast to medicinal products food supplements do not undergo any official authorisation procedure, during which actual health safety must be proven, prior to placing on the market. The products available on the German market are controlled by random sample checks performed by the official food monitoring bodies.

Are there any differences between food supplements and medicinal products and, if so, what are they?

Medicinal products are intended to heal, alleviate, prevent or identify diseases, suffering, physical defects or health disorders, to replace active substances produced by the human or animal body, or to influence the condition, state or function of the body or the mental state. They are subject to, among others, the provisions of the Medicinal Products Act. Their ingredients are pharmacologically active. Medicinal products are subject to official authorisation by the Federal Institute for Drugs and Medical Devices (BfArM) or approval by the competent bodies of the European Union. During both types of authorisation procedure, their quality, efficacy and safety must be proven. Besides other important information on safe use, possible side effects that may occur during proper intake must be listed in a package leaflet.

Food supplements are foods and are subject to, among others, the provisions of the Food and Feed Code Law (LFGB). They are intended to supplement the diet and must be safe. Unlike medicinal products, they do not require official authorisation for which their safety must be proven. Food supplements may not be advertised by the use of any disease-related claims. However, claims to reduce the risk of disease are admissible provided that they have been scientifically assessed and confirmed by the European Food Safety Authority (EFSA) in line with Regulation (EC) 1924/2006 (the so-called Health Claims Regulation) and have been explicitly authorised by the EU Commission. It is prohibited to mislead consumers.

The mere fact that a food supplement is on the market does not mean that the consumer can assume that this is a worthwhile or valuable food. Food supplements may also be on the market when their nutritional-physiological value is questionable.

Who decides whether a product is a medicinal product or a food supplement?

It is possible that certain ingredients contained in food supplements are also used in medicinal products. Furthermore, food supplements are placed on the market in the same forms as medicinal products like tablets, capsules, powders or liquid preparations. This highlights the impression that food supplements and medicinal products appear to be, in some cases, very similar.

Under the federal system of the Federal Republic of Germany it is the federal Laender that check whether products have been legally placed on the market. They are responsible for organising official monitoring of medicinal products and foods. Within the framework of their competences, the monitoring authorities decide, based on an individual review, on the classification of a product as a medicinal product requiring official authorisation or as a food. Formal responsibility lies with the public authorities of the federal Land in which the product is on the market or in which the manufacturer, importer, supplier or distributor has its head office.

Because of differences in legal situations, products offered for sale on the Internet from outside Germany may be marketed in the countries of origin as food supplements but may be classified as medicinal products in Germany.

Who monitors food supplements?

It is primarily the food manufacturer and therefore the producer, importer, supplier or distributor who is responsible for the safety and labelling of food supplements. There is no official monitoring of the products prior to their placing on the market along the lines of official authorisation. Once the product is on the market, it is subject to monitoring by the German federal Laender. They monitor the products which are on the market by performing random sample checks for their compliance with the statutory provisions.

Can one purchase food supplements on the internet without having any cause for concern?

Irrespective of the distribution channel, the relevant German and European food law provisions naturally also apply to food supplements which are sold on the Internet. However, there have been reports of individual cases in which non-marketable food supplements were sold on the Internet. One example from the past concerned muscle-enhancing products. Investigations by the monitoring authorities in Germany had shown that some products sold on the internet as food supplements contained anabolic agents which had not been listed as ingredients.

When purchasing food supplements on the Internet, consumers should bear in mind that the use of the internet as a gateway to global markets offers not only opportunities but may also be linked to risks. In the case of the direct purchase of food supplements on the Internet from manufacturers/distributors outside Germany, it cannot simply be assumed that the products sold as food supplements comply with German and European food law provisions. Furthermore, consumers should thoroughly check whether the suppliers are reputable before buying food supplements.

Is a food supplement necessary and advisable?

The large number of food supplements on the market wrongly give the consumer the impression that sufficient nutrient intake is not possible solely from a diet comprising traditional foods. In principle a balanced, diverse diet supplies a healthy body with all the essential substances. In most cases, the intake of food supplements is therefore unnecessary.

However, there are exceptions to this general rule. An unbalanced or inadequate diet may lead to insufficient intake of essential nutrients. During pregnancy and breastfeeding there is an elevated need for specific nutrients. The intake of essential nutrients by elderly people may also be insufficient, for instance, as a consequence of chewing or swallowing disorders or a loss of appetite. The chronically ill may also have an elevated requirement for essential nutrients. In such cases, dietary supplementation may be necessary or advisable. Whenever a food supplement is used as an additional measure to treat or heal diseases like a chronic gastrointestinal tract disorder, however, this should always be done under medical supervision.

Data on nutrient intake indicate that the intake of a small number of vitamins and minerals like vitamin D, calcium, folic acid and iodine by some groups in the population does not meet the intake recommendations of the German Nutrition Society (DGE). However, this cannot generally be equated to insufficient supply or even a deficiency. In individual cases, however, dietary supplementation may be advisable. For instance, the intake of additional calcium by people who do not consume any dairy products may be considered. For several years now, table salt has been fortified with iodine in order to improve the iodine intake on a broad basis in the population in Germany.

Nevertheless, the best nutritional strategy is still a balanced, diverse diet with plenty of fruit and vegetables. Food supplements do not represent substitutes of equal value.

Can food supplements be taken together with medicinal products?

Food supplements should only be taken together with medicinal products over longer periods of time after consulting a physician. Interaction with specific medicinal products cannot be ruled out and the effects of some medicinal products may be weakened or amplified, thereby possibly affecting treatment in an undesirable manner.

Are there any forms of food supplementation which the BfR recommends?

For the purposes of improving or reliably ensuring the adequate intake of folic acid, women planning to have a baby, or pregnant women, are advised to add food supplements to their diet. The vitamin folic acid has a positive impact on the complete closing of the neural tube in the embryo and reduces the risk of neural tube defects like “split spine” (Spina bifida) in newborn babies. The BfR FAQs on folic acid contain more detailed information.

What does the BfR do in order to protect consumers from the possible risks arising from food supplements?

In the past, the BfR has adopted comprehensive stances on the possible risks from food supplements and has informed consumers about problems which could be linked to the consumption of these products. BfR opinions on food supplements or substances added to food supplements are used by management institutions at the federal level and by federal Land authorities to aid decision-making and as a basis for risk-reducing measures.



About the BfR

Do nanoparticles promote the occurrence of allergies? Does apple juice contain too much aluminium? The German Federal Institute for Risk Assessment, or BfR for short, is responsible for answering questions on all aspects of the health assessment of foods and feeds, consumer products and chemicals. Through its work, it makes a decisive contribution towards ensuring that food, products and the use of chemicals have become safer in Germany. The Institute's main tasks comprise the assessment of existing health risks and identification of new ones, the development of recommendations to limit risks and the transparent communication of this process. This work results in the scientific advice given to political decisionmakers. To help with the strategic alignment of its risk communication, the BfR conducts its own research in the field of risk perception. The Institute is independent in its scientific assessments, research and communication. The BfR belongs to the portfolio of the Federal Ministry of Food and Agriculture (BMEL).

i More information at: www.bfr.bund.de/en

> A-Z-Index > Food supplements

> Publications > Flyer > Lebensmittelsicherheit: Nahrungsergänzungsmittel im Sport (in German only)

> Publications > Science Magazine "BfR2GO", Issue 01/2018, p. 22: Food supplements in sports

> FAQ > Folate and folic acid

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