

FOOD SUPPLEMENTS – POPULAR, BUT SAFE?

Position paper from the German Consumer Associations and the Federation of German Consumer Organisations (Verbraucherzentrale Bundesverband e.V. – vzbv) on food supplements

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CONSUMER RELEVANCE

Ginkgo to improve one's memory or vitamin D for a strong immune system – food supplements (FS) are often advertised as 'miracle cures'. Many consumers are confused by the adverts for food supplements and wonder whether they are sufficiently supplied with certain nutrients and vitamins. However, studies show that there is no general deficiency of nutrients in the German population and that providing nutrients in excess of requirements does not have any positive health effects. The intake of food supplements is therefore of no benefit to most people. In addition, it can harbour considerable health risks about which consumers are often not well informed, for example side effects and interactions due to the parallel intake of several food supplements or of medication and food supplements.

SUMMARY

Scientific studies show that the majority of the population in Germany is well supplied with nutrients.¹ It is also scientifically well documented that additional nutrient intake in excess of requirements has no positive effect on health.² Nevertheless, according to surveys, more than 75 per cent of adults take food supplements.³

Food supplements are legally regarded as foodstuffs. Unlike pharmaceuticals, there is no official review of safety, quality and efficacy before they are placed on the market – contrary to the expectations of many consumers. To date, there is neither an authorisation procedure for food supplements nor binding maximum quantities for the minerals and vitamins they contain. Market checks by the German Consumer Associations and the results of official food controls show time and again that some sellers, especially in online retail, social media influencers and in direct sales, offer food supplements with dosages that exceed the scientific recommendations of the German Federal Institute for Risk Assessment (BfR) and the European Food Safety Authority (EFSA) for the intake of vitamins and minerals by far.^{4, 5} This harbours health risks for consumers.^{6, 7} Particularly problematic from the point of view of the Federation of German Consumer Organisation (Verbraucherzentrale Bundesverband – vzbv) and the German Consumer Associations is the fact that a large number of children's food supplements are available on the market, often in very high or excessive doses, which also resemble sweets in their presentation or dosage form, posing a risk of accidental overdose.⁸

Food supplements should preferably only be taken after consulting a doctor. In reality, however, they are often taken as self-medication, often in parallel with the intake of

¹ Max Rubner-Institut: The German National Nutrition Survey II, 2008, <https://www.mri.bund.de/en/institutes/nutritional-behaviour/research-projects/nvsii/>, last accessed: 01/12/2024

² German Federal Institute for Risk Assessment (BfR): Aktualisierte* Höchstmengenvorschläge für Vitamine und Mineralstoffe in Nahrungsergänzungsmitteln und angereicherten Lebensmitteln, BfR Opinion No 006/2024 reissued 22/02/2024, <https://www.bfr.bund.de/cm/343/aktualisierung-2024-hoechstmengenvorschlaege-fuer-folsaeure-in-lebensmitteln-inklusive-nahrungsergaenzungsmitteln.pdf>, last accessed: 01/12/2024

³ Statista Consumer Insights: Wie verbreitet sind Nahrungsergänzungsmittel in Deutschland?, 2023, <https://de.statista.com/infografik/24797/umfrage-zum-konsum-von-nahrungsergaenzungsmitteln-in-deutschland>, last accessed: 01/12/2024

⁴ Klartext Nahrungsergänzung: Verbraucherwarnungen zu Nahrungsergänzungsmitteln, <https://www.klartext-nahrungsergaenzung.de/node/21536>, last accessed: 01/12/2024

⁵ Klartext Nahrungsergänzung: Übersicht Marktchecks, <https://www.klartext-nahrungsergaenzung.de/markt-meldung/marktchecks>, last accessed: 01/12/2024

⁶ European Food Safety Authority (EFSA): Overview on Tolerable Upper Intake Levels as derived by the Scientific Committee on Food (SCF) and the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), June 2024, <https://www.efsa.europa.eu/sites/default/files/2024-05/ul-summary-report.pdf>, last accessed: 01/12/2024

⁷ German Federal Institute for Risk Assessment (BfR): Hochdosierte Nahrungsergänzungsmittel mit Vitamin D können langfristig die Gesundheit beeinträchtigen, BfR Press Release No 27/2023, www.bfr.bund.de/de/presseinformation/2023/27/hochdosierte-nahrungsergaenzungsmittel-mit-vitamin-d-koennen-langfristig-die-gesundheit-beeintraehtigen-313691.html, last accessed: 01/12/2024

⁸ Klartext Nahrungsergänzung: Nahrungsergänzungsmittel für Kinder sind meist zu hoch dosiert, <https://www.klartext-nahrungsergaenzung.de/aktuelle-meldungen/lebensmittel/nahrungsergaenzungsmittel-fuer-kinder-sind-meist-zu-hoch-dosiert-25949>, last accessed: 01/12/2024

medically prescribed medication⁹, without the attending physicians being aware of this.¹⁰ Due to possible side effects and interactions as well as the potential influence on laboratory parameters, this harbours similar health risks as the simultaneous consumption of several food supplements.¹¹ In a survey commissioned by vzbv in November 2024, 28 per cent of respondents stated that they had bought several food supplements in the past six months.¹² To date, there is no official register that systematically records the side effects and interactions of food supplements.

The increasing use of plant extracts (so-called botanicals) in food supplements is largely unregulated under national and European law.¹³ However, plant-based food supplements are by no means harmless, as the promised positive effects of botanicals are not scientifically proven and health risks have not been well investigated.^{14, 15}

Food supplements may only carry health claims if they are scientifically proven and authorised in accordance with Regulation (EC) No 1924/2006 (Health Claims Regulation).^{16, 17} However, often there are food supplements on the market that are advertised by manufacturers and influencers with unauthorised and misleading health claims.

In order to ensure consumer health protection, it is therefore necessary to urgently review and revise the legal status of food supplements.

The German Consumer Associations and vzbv recommend the following:

- ❖ introduce official authorisation procedures for food supplements at EU level before they enter the market (on the principle of “prohibited unless authorised”). Until an EU-wide authorisation procedures are introduced, the German government should introduce corresponding authorisation procedures at national level;
- ❖ set EU-wide maximum amounts of vitamins and minerals added to food supplements, differentiated by age group, particularly with respect to children. If the regulatory proposal announced at EU level is further delayed, the German government

⁹ Knopf, Hiltraud: Selbstmedikation mit Vitaminen, Mineralstoffen und Nahrungsergänzungsmitteln in Deutschland, 2017, Bundesgesundheitsblatt, 60(3):268–276, <https://edoc.rki.de/bitstream/handle/176904/2940/26asMp9YIOa0s.pdf>, last accessed: 01/12/2024

¹⁰ Vidonsky Lütthold R et al. (2024): Exploring GP and patient attitudes towards the use and deprescribing of dietary supplements: a survey study in Switzerland, BMC Primary Care 25:359. <https://doi.org/10.1186/s12875-024-02605-z>, last accessed: 01/12/2024

¹¹ Campos MJ, Czapka-Matysik M, Pena A.: Food Supplements and Their Use in Elderly Subjects – Challenges and Risks in Selected Health Issues: A Narrative Review. Foods 2024;13(16):2618, <https://doi.org/10.3390/foods13162618>, last accessed: 01/12/2024

¹² Federation of German Consumer Organisations (vzbv): Representative Consumer Survey by forsa on behalf of vzbv, 2024, https://www.vzbv.de/sites/default/files/2025-01/Jahresendbefragung_Tabellenband_Nahrungserg%C3%A4nzungsmittel.pdf, last accessed: 06/01/2025

¹³ So-called botanicals include substances and preparations from plants, algae, fungi or lichens. With a few exceptions, there are no bans, see Annex III of Regulation (EC) 1925/2006.

¹⁴ German Federal Institute for Risk Assessment (BfR): Communication 39/2024: Ashwagandha: food supplements with potential health risks, <https://www.bfr.bund.de/cm/349/ashwagandha-food-supplements-with-potential-health-risks.pdf>, last accessed: 01/12/2024

¹⁵ Federal Office of Consumer Protection and Food Safety (BVL): Gleiche Regeln für Nahrungsergänzungsmittel in Europa. Europäische Lebensmittelsicherheitsbehörden legen Liste kritischer Stoffe vor, 06/06/2024, https://www.bvl.bund.de/SharedDocs/Pressemitteilungen/01_lebensmittel/2024/2024_06_06_PM_Nahrungsergaenzungsmittel_HoA.html, last accessed: 01/12/2024

¹⁶ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, <https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=celex%3A32006R1924>, last accessed: 01/12/2024

¹⁷ European Commission: EU Register of Health Claims, <https://ec.europa.eu/food/food-feed-portal/screen/health-claims/eu-register>, last accessed: 01/12/2024

must take action at national level. It is also necessary to clarify that food supplements are not intended for consumption by infants and toddlers.

- ❖ introduce a legally binding positive list of “other substances” added to food supplements, which clearly defines which substances may be added to food supplements. If a regulation at EU level is further delayed, the German government must take action at national level;
- ❖ publish EFSA assessments of health claims for plant-based substances in foods and a legal regulation at European level based on these assessments.
- ❖ establish a reporting office to systematically record the side effects and interactions associated with food supplements on national level.

I. SITUATION ANALYSIS AND NEED FOR REGULATION

The FS market is growing continuously. In 2023, German pharmacies alone recorded 3.1 billion euros of FS sales.¹⁸ In a representative survey commissioned by vzbv in 2024, more than half of respondents (54 percent) said they had purchased FS in the last six months.¹⁹ According to Statista Consumer Insights, almost 75 percent of Germans surveyed in 2023 said they had consumed vitamins in the form of FS in the last 12 months, 36 percent minerals, and 33 percent FS containing plants/herbs. Only 23 percent stated that they had not consumed any FS.²⁰

However, the German National Nutrition Survey (NVS II) has shown that nutritional supply in Germany maintains a high level all year round and there is no general nutritional shortage. This means that people in Germany are generally well supplied with nutrients, meaning that – with the exception of risk groups²¹ – they do not need any food supplements.^{22, 23}

International scientific studies also show that taking micronutrients in excess of the required amount is not expected to have any positive effects on health.²⁴

¹⁸ IQVIA: Infografik, Vitamine und Mineralstoffe, Kräuterezubereitungen und Nahrungsergänzung – Rezeptfrei aus der Apotheke – Trends im Jahr 2023, <https://www.iqvia.com/-/media/iqvia/pdfs/germany/library/infographic/vitamine-und-mineralstoffe-krauterzubereitungen-und-nahrungserganzung.pdf>, last accessed: 01/12/2024

¹⁹ Federation of German Consumer Organisations (vzbv): Representative Consumer Survey by forsa on behalf of vzbv, 2024, https://www.vzbv.de/sites/default/files/2025-01/Jahresendbefragung_Tabellen-band_Nahrungserg%C3%A4nzungsmittel.pdf, last accessed: 06/01/2025

²⁰ Statista.de: Wie verbreitet sind Nahrungsergänzungsmittel in Deutschland?, 2023, <https://de.statista.com/infografik/24797/umfrage-zum-konsum-von-nahrungsergaenzungsmitteln-in-deutschland>, last accessed: 01/12/2024

²¹ For some people, however, the intake of food supplements is important, for example in the case of a vegan diet (vitamin B12), intended or existing pregnancy (folic acid), the elderly (especially vitamins D and B12), malnutrition, diets below 1,200 kcal, or in the absence of or insufficient exposure of the skin to sunlight (vitamin D).

²² Max Rubner-Institut: German National Nutrition Survey II, 2008, <https://www.mri.bund.de/de/institute/ernaehrungsverhalten/forschungsprojekte/nvsii>, last accessed: 01/12/2024

²³ Max Rubner-Institut: Oft zu gut versorgt durch Nahrungsergänzungsmittel – Aktuelle Auswertung des Max Rubner-Instituts, 2013, <https://idw-online.de/de/news544708>, last accessed: 01/12/2024

²⁴ German Federal Institute for Risk Assessment (BfR): Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods, BfR Opinion No 03/2021 issued 15/03/2021,

The German Consumer Associations have been observing for years that more and more FS are being placed on the market that merit criticism for their contents and dosage. For example, plant-based products with questionable health effects, such as isoflavones, are entering the market as FS despite occupying a grey zone between medicinal drugs and regular FS. Frequently, problematic substances from traditional Asian medicine are also included, such as ashwagandha²⁵ or red rice²⁶. Products containing vitamins and minerals may also pose a health risk in the form of over consumption. The problem is that, unlike medicinal drugs, which require authorisation, are not tested by an independent body for quality, safety and efficacy (with regard to the health-related advertising claims used) before they are placed on the market.

The need to close regulatory gaps in this area was already recognised by the German parliamentary groups of CDU/CSU, SPD and Alliance 90/The Greens in 2021 and by the European Parliament in January 2024.^{27, 28, 29}

In order to effectively protect consumers from potential health risks and deception associated with food supplements, vzbv and the German Consumer Associations call for the following:

1. INTRODUCE AUTHORISATION PROCEDURES FOR FOOD SUPPLEMENTS – EXISTING REGULATIONS ARE INSUFFICIENT

Consumers expect food supplement products to be effective and safe. Almost seven out of ten respondents to a representative vzbv survey are in favour of products being authorised by state authorities before they enter the market to ensure product safety.³⁰ However, this is currently not the case.

In theory, the supplier is responsible for the safety of its product; however, this has proven problematic in recent years, particularly in relation to FS.³¹ The German Food

<https://www.bfr.bund.de/cm/349/updated-recommended-maximum-levels-for-the-addition-of-vitamins-and-minerals-to-food-supplements-and-conventional-foods.pdf>, last accessed: 01/12/2024

²⁵ German Federal Institute for Risk Assessment (BfR): Communication 39/2024: Ashwagandha: food supplements with potential health risks, <https://www.bfr.bund.de/cm/349/ashwagandha-food-supplements-with-potential-health-risks.pdf>, last accessed: 01/12/2024

²⁶ German Federal Institute for Risk Assessment (BfR): A questionable way to lower cholesterol: food supplements containing red yeast rice to be taken only on medical advice, BfR Opinion No 003/2020 issued 15/01/2020, <https://www.bfr.bund.de/cm/349/a-questionable-way-to-lower-cholesterol-food-supplements-containing-red-yeast-rice-to-be-taken-only-on-medical-advice.pdf>, last accessed: 01/12/2024

²⁷ Motion of parliamentary groups of CDU/CSU and SPD: Gesundheitlichen Verbraucherschutz bei Nahrungsergänzungsmitteln und angereicherten Lebensmitteln verbessern, 20/04/2021, Bundestag printed paper 19/28783, <https://dip.bundestag.de/vorgang/gesundheitlichen-verbraucherschutz-bei-nahrungserg%C3%A4nzungsmitteln-und-angereicherten-lebensmitteln-verbessern/276915?f.deskriptor=Datenbank&rows=25&pos=1>, last accessed: 01/12/2024

²⁸ Motion of parliamentary group Alliance 90/The Greens: Nahrungsergänzungsmittel besser regulieren, 12/05/2020, Drucksache 19/19135, <https://dip.bundestag.de/vorgang/nahrungserg%C3%A4nzungsmittel-besser-regulieren/262181>, last accessed: 01/12/2024

²⁹ Implementation report on Regulation (EC) No 1924/2006 on nutrition and health claims made on foods – European Parliament resolution of 18 January 2024 on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (2023/2081(INI)), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AC_202405729, last accessed: 01/12/2024

³⁰ Federation of German Consumer Organisations (vzbv): Representative Consumer Survey by forsa on behalf of vzbv, 2024, https://www.vzbv.de/sites/default/files/2025-01/Jahresendbefragung_Tabellenband_Nahrungserg%C3%A4nzungsmittel.pdf, last accessed: 06/01/2025

³¹ Article 14 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying

Supplements Regulation (NemV) only requires notification to the Federal Office of Consumer Protection and Food Safety (BVL) – but even this formality is not carried out properly by all manufacturers. All market checks carried out by the German Consumer Associations found FS that had not been registered.³²

Even products that are registered often prove problematic, as demonstrated by WDR (German public-broadcasting institution) research at federal state level.³³ Problematic findings include ingredients that are not authorised, excessively high doses, and numerous cases of improper labelling. The high level of consumer protection required by Directive 2002/46/EC is lacking.

The market for popular sports and lifestyle food supplements has also grown strongly in recent years.³⁴ These products often contain drugs that either require authorisation or are no longer permitted, or other pharmacologically active substances with potentially serious side effects.³⁵ The German National Monitoring Programme (BÜp) 2021 tested 87 pre-workout boosters. Almost half of the samples (44.8 percent) included potentially harmful substances, such as dimethylethanolamine (DMAE) or synephrine. In combination with caffeine, synephrine can seriously damage the heart.³⁶

Particularly when it comes to direct sales, online and mail order purchases, and distribution via social media, consumers are insufficiently protected against unauthorised health claims and dubious promises about products' effectiveness. In this context, the steady increase in influencer advertising for food supplements also raises concerns, especially as many influencers with a wide reach do not label the product advertising as such³⁷ and significant violations of the Health Claims Regulation were identified by food control authorities.³⁸

Products from these sources pose not just economic, but also health risks to consumers. For example, if consumers self-medicate with FS, instead of seeking medical treatment, relying on health claims made by product manufacturers or influencer testimonials.

down procedures in matters of food safety, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20240701>, last accessed: 01/12/2024

³² Klartext Nahrungsergänzung: Übersicht Marktchecks, <https://www.klartext-nahrungsergaenzung.de/markt-mei-nung/marktchecks>, last accessed: 01/12/2024

³³ Problems with 48 percent of FS in 2021, according to Quarks.de: Nahrungsergänzungsmittel. Fast jede zweite Probe beanstandet, 2023/2024, <https://www.quarks.de/gesundheits/sind-nahrungsergaenzungsmittel-gefaehrlich>, last accessed: 01/12/2024

³⁴ FS in the lifestyle sector include products aimed at boosting performance, libido/virility, weight loss, beauty products.

³⁵ German Research Foundation (DFG): Permanent Senate Commission on Food Safety: Zusatz von pharmakologisch aktiven Substanzen zu Produkten, die als Nahrungsergänzungsmittel und Lifestyle-Lebensmittel vermarktet werden, 2015, <https://www.dfg.de/resource/blob/171588/47835973fbaec863b1a9a6e79ca2e5a4/sklm-nahrungsergaenzungsmittel-data.pdf>, last accessed: 01/12/2024

³⁶ Federal Office of Consumer Protection and Food Safety: Gesundheitsrisiken bei Sportlernahrung, 2021, https://www.bvl.bund.de/SharedDocs/Pressemitteilungen/01_lebensmittel/2021/2021_12_02_PM_Sportlernahrung.html, last accessed: 01/12/2024

³⁷ European Commission: Press Release Feb 14, 2024: Investigation of the Commission and consumer authorities finds that online influencers rarely disclose commercial content, https://ec.europa.eu/commission/presscorner/detail/en/ip_24_708, last accessed: 01/12/2024

³⁸ Chemisches und Veterinäruntersuchungsamt Stuttgart (CVUA): Gesundheitsversprechen für Nahrungsergänzungsmittel auf Instagram – häufig abseits der Legalität, 25/04/2022, https://www.cvuas.de/pub/bei-trag.asp?subid=0&Thema_ID=2&ID=3577, last accessed: 01/12/2024

The new challenges posed by international trade with FS are set against the lack of a harmonised legal framework at European level and, in Germany, official food controls that are organised at regional level. The following findings show just how important international cooperation is: While the supplier is responsible for the safety of its product, there have been many problems in recent years, particularly in relation to FS. The numerous reports of potential health risks sent to the European Rapid Alert System for Food and Feed (RASFF) clearly demonstrate this. FS were found to contain the following³⁹:

- ❖ levels of pyrrolizidine alkaloids, coumarin/cinnamaldehyde, heavy metals, polycyclic aromatic hydrocarbon (PAH)
- ❖ pharmacologically active substances (for example, sibutramine, sildenafil), psychoactive substances (for example, tetrahydrocannabinol [THC]), poisonous chemicals such as dinitrophenol [DNP]
- ❖ prohibited novel foodstuffs (for example, cannabidiol [CBD], epimedium)
- ❖ substances prohibited under Annex III of Regulation (EC) No 1925/2006⁴⁰ (for example, ephedra, yohimbe)
- ❖ excessive doses (for example of vitamins and minerals)
- ❖ prohibited micronutrient compounds (for example silver, benfotiamine, magnesium aspartate)

A solution could be a publicly accessible register of approved FS. An online register of this type would make it easier for consumers to find FS that have been tested and approved by authorities. This could in particular tackle the risks posed by online and mail order purchases of FS that are not allowed on the market. Such public databases already exist, for example, in Hungary and Denmark.⁴¹

POSITION

The German Consumer Associations and vzbv call for the introduction of authorisation procedures for FS in the European single market to ensure consumer protection from both a health and financial perspective.

Until the necessary legislation has been introduced at the European level, an authorisation procedure is needed at the national level to evaluate FS with respect to product safety, correct labelling, and the accuracy of advertising claims. A mere requirement to register products at the BVL (pursuant to Section 5 Nem-V) is insufficient. It would also make sense to have a publicly accessible list of authorised food supplements for consumers.

³⁹ European Commission: RASFF Window (notifications register), <https://webgate.ec.europa.eu/rasff-window/screen/search>, last accessed: 01/12/2024

⁴⁰ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0046>, last accessed: 01/12/2024

⁴¹ Danish Veterinary and Food Administration/Fødevarestyrelsen: Food Supplements Register ("Kosttilskudsregister"), <https://foedevarestyrelsen.dk/portaler/kosttilskudsregister>, last accessed: 01/12/2024

2. SET BINDING MAXIMUM LEVELS OF VITAMINS AND MINERALS – DIFFERENTIATED BY AGE GROUP, PARTICULARLY WITH RESPECT TO CHILDREN

The setting of maximum levels of certain vitamins and minerals, as stated by the Directive 2002/46/EC, has still not been implemented. To date, Germany has no binding legislation on this matter. However, authorities need legally binding maximum levels in order to take action when products exceed the dose.

The Tolerable Upper Intake Levels (ULs) set by the European Food Safety Authority (EFSA) have only recommendatory character. These values generally refer to the intake of these substances from all sources, such as food supplements, fortified or enriched foods and foods for general consumption. Food control authorities cannot refer to these values as a basis for complaints.

The European Commission currently works on setting harmonised maximum levels with Member States.⁴² The European Parliament strongly supported such a regulation in January 2024.⁴³ If a maximum level regulation at European level is further delayed, the German government needs to enact a regulation at national level to ensure consumer health protection.

The recommendations for maximum levels of vitamins and minerals in food supplements updated by the BfR in 2024 could form the basis of the legislation. The underlying safety model takes into account the requirements of the Food Supplement Directive and, according to scientific assessments, is very well suited to protecting consumers from overdoses. As these recommendations only apply to adolescents aged 15 and over and adults, separate definitions are also required for children aged 4 to 15. And: It must be made clear that food supplements are generally not intended for infants and toddlers. Due to the special need for protection of this age group, there is the special Regulation (EU) No. 609/2013, which regulates foods for special consumer groups (infant formula, follow-on formula, complementary foods and foods for the dietary management of patients, including infants) separately.

As the BfR recommendations are not binding, their practical significance when it comes to food controls is currently limited. When it comes to substances for which there is no recommended maximum level based on risk assessment, the reference values for nutritional intake should not be exceeded.⁴⁴ This would also correspond to the stated purpose of FS, which is to supplement daily nutritional intake.

The health risks of high-dose food supplements are manifold. If high-dose food supplements and possibly fortified or enriched foods are consumed in addition to the normal diet, the risk of undesirable health effects increases.

⁴² European Commission: Food safety – vitamins and minerals added to food (minimum and maximum levels), Initiative, <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12750-Food-safety-vitamins-and-minerals-added-to-food-minimum-and-maximum-levels-en>, last accessed: 01/12/2024

⁴³ European Parliament Resolution of 18 January 2024 on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (2023/2081(INI)), https://www.europarl.europa.eu/doceo/document/TA-9-2024-0040_EN.html, last accessed: 01/12/2024

⁴⁴ German Nutrition Society (DGE): Referenzwerte für Nährstoffzufuhr, <https://www.dge.de/wissenschaft/referenzwerte>, last accessed: 01/12/2024

The German Research Foundation's Senate Commission on Food Safety has issued several statements on this in recent years.^{45, 46, 47, 48} BfR, for example, draws attention to the fact that excessive amounts of vitamin D can lead to effects ranging from muscle weakness and lethargy to irregular heartbeat and vascular calcification.⁴⁹ The Drug Commission of the German Medical Association (Arzneimittelkommission der deutschen Ärzteschaft) have also documented cases of poisoning due to excessive doses of vitamin D (acute renal failure).⁵⁰

Market research carried out by the German Consumer Associations in December 2020 found that 57 percent of FS containing magnesium (24 out of 42 products tested) exceeded the daily maximum level of 250 milligrams of magnesium as recommended for FS by the BfR and EFSA (Figure 1).^{51, 52, 53} On average, these excessively dosed products contained 416 milligrams of magnesium daily. This is a critical amount, as it requires only 300 mg of magnesium daily to cause problems with the digestive system.

⁴⁵ German Research Foundation (DFG): Permanent Senate Commission on Food Safety: Zusatz von pharmakologisch aktiven Substanzen zu Produkten, die als Nahrungsergänzungsmittel und Lifestyle-Lebensmittel vermarktet werden, 2015, <https://www.dfg.de/resource/blob/171588/47835973f9beac863b1a9a6e79ca2e5a4/sklm-nahrungsergaenzungsmittel-data.pdf>, last accessed: 01/12/2024

⁴⁶ German Research Foundation (DFG): Permanent Senate Commission on Food Safety: Toxicological evaluation of red mould rice, 2012, <https://www.dfg.de/resource/blob/171286/af99a6ebade380eced5e1a07a9c35573/131206-sklm-red-mould-rice-update-data.pdf>, last accessed: 01/12/2024

⁴⁷ German Research Foundation (DFG), Permanent Senate Commission on Food Safety: Isoflavone als Phytoestrogene in Nahrungsergänzungsmitteln und diätetischen Lebensmitteln für besondere medizinische Zwecke, 2006, <https://www.dfg.de/resource/blob/169014/1887dee032d10535b32f7453891eda/sklm-phytoestrogene-2008-de-data.pdf>, last accessed: 01/12/2024

⁴⁸ German Research Foundation (DFG), Permanent Senate Commission on Food Safety: Stellungnahme zur Beurteilung von Nahrungsergänzungsmitteln mit anderen Stoffen als Vitaminen und Mineralstoffen, 2006, <https://www.dfg.de/resource/blob/169018/10a18c2d4cbc46ca667a3746d54b179f/sklm-stellungnahme-nem-26092006-data.pdf>, last accessed: 01/12/2024

⁴⁹ German Federal Institute for Risk Assessment: Hochdosierte Nahrungsergänzungsmittel mit Vitamin D können langfristig die Gesundheit beeinträchtigen, Stellungnahme 065/2023, 07/12/2023, <https://www.bfr.bund.de/cm/343/hochdosierte-nahrungsergaenzungsmittel-mit-vitamin-d-koennen-langfristig-die-gesundheit-beeintraechtigen.pdf>, last accessed: 01/12/2024

⁵⁰ Drug Commission of the German Medical Association (Arzneimittelkommission der deutschen Ärzteschaft – AkdÄ): Hyperkalzämie durch Überdosierung mit Vitamin D, 2017, <https://www.akdae.de/arzneimittelsicherheit/drug-safety-mail/newsdetail/drug-safety-mail-2017-42>, last accessed: 01/12/2024

⁵¹ Klartext Nahrungsergänzung: Marktcheck "Magnesiumhaltige Nahrungsergänzungsmittel": Oft überdosiert, 2022, <https://www.klartext-nahrungsergaenzung.de/node/13398>, last accessed: 01/12/2024

⁵² German Federal Institute for Risk Assessment (BfR): BfR assesses recommended maximum daily level for intake of magnesium via food supplements, 2017, <https://www.bfr.bund.de/cm/349/bfr-assesses-recommended-maximum-daily-level-for-intake-of-magnesium-via-food-supplements.pdf>, last accessed: 01/12/2024

⁵³ European Food Safety Authority (EFSA): Scientific Committee on Food, Scientific Panel on Dietetic Products, Nutrition and Allergies: Tolerable upper intake levels for Vitamins and Minerals, 2006, https://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf, last accessed: 01/12/2024

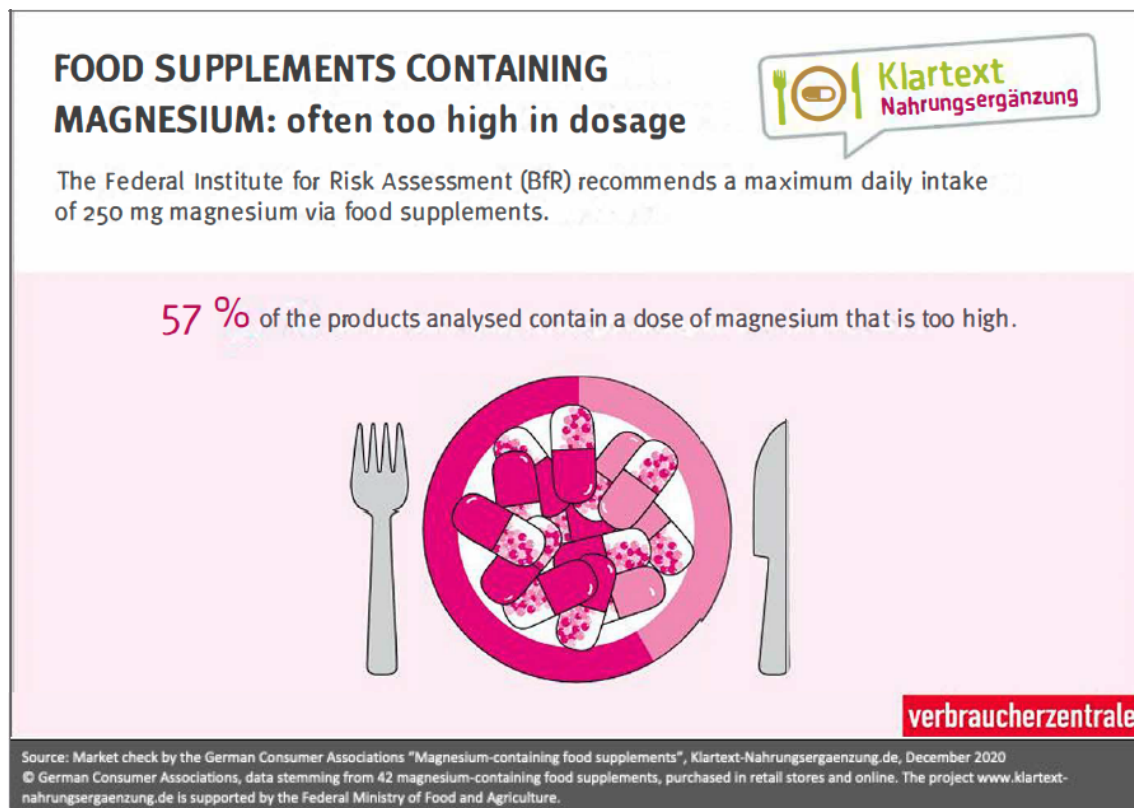


Figure 1: Food supplements containing magnesium: doses often too high! (As of: December 2020)

The findings of a market check carried out by the German Consumer Associations concerning FS for children also confirm the need to introduce national regulation on maximum levels of vitamins and minerals (Figure 2). The investigation found products the vitamin or mineral content of which clearly exceeded the BfR's maximum level recommendations for adolescents aged 15 and above. Approximately 70 percent of products exceeded the DGE reference values for children.⁵⁴ This could lead to high doses of fat-soluble vitamins A and D accumulating in the body and negatively impacting children's health.

It should be noted in this context that food supplements for infants and children have not been explicitly regulated by law. However, the CVUA Karlsruhe concludes from the current legal situation that food supplements are not intended for infants and toddlers and advises against such products, even for older children.⁵⁵ However, there are many food supplements on the market that are specifically aimed at this age group, and such products are also frequently advertised by influencers. In an investigation by the CVUA Karlsruhe in 2023, many children's food supplements were identified as unlawful due to unauthorised substances, exceeding safe maximum daily amounts and misleading presentation.⁵⁶ From the point of view of vzbv and the German Consumer Associations,

⁵⁴ Klartext Nahrungsergänzung: Nahrungsergänzungen für Kinder. Marktcheck der Verbraucherzentralen, Wiederholung/Aktualisierung 2023, https://www.verbraucherzentrale.de/sites/default/files/2023-08/2023_07_10_marktcheck-nem-fuer-kinder-2023.pdf, last accessed: 01/12/2024

⁵⁵ Chemisches und Veterinäruntersuchungsamt Karlsruhe (CVUA Karlsruhe): Nur das Beste fürs Kind? Nahrungsergänzungsmittel für die Kleinsten geben Anlass zu großen Bedenken, https://www.ua-bw.de/pub/bei-trag.asp?subid=2&Thema_ID=1&ID=3840, last accessed: 01/12/2024

⁵⁶ Chemisches und Veterinäruntersuchungsamt Karlsruhe (CVUA Karlsruhe): Nur das Beste fürs Kind? Nahrungsergänzungsmittel für die Kleinsten geben Anlass zu großen Bedenken, https://www.ua-bw.de/pub/bei-trag.asp?subid=2&Thema_ID=1&ID=3840&lang=DE&Pdf=No, last accessed: 01/12/2024

there is an urgent need to clarify that food supplements are not suitable for infants and toddlers. Products for this age group are regulated separately in Regulation (EU) No. 609/2013 on foods for specific consumer groups.

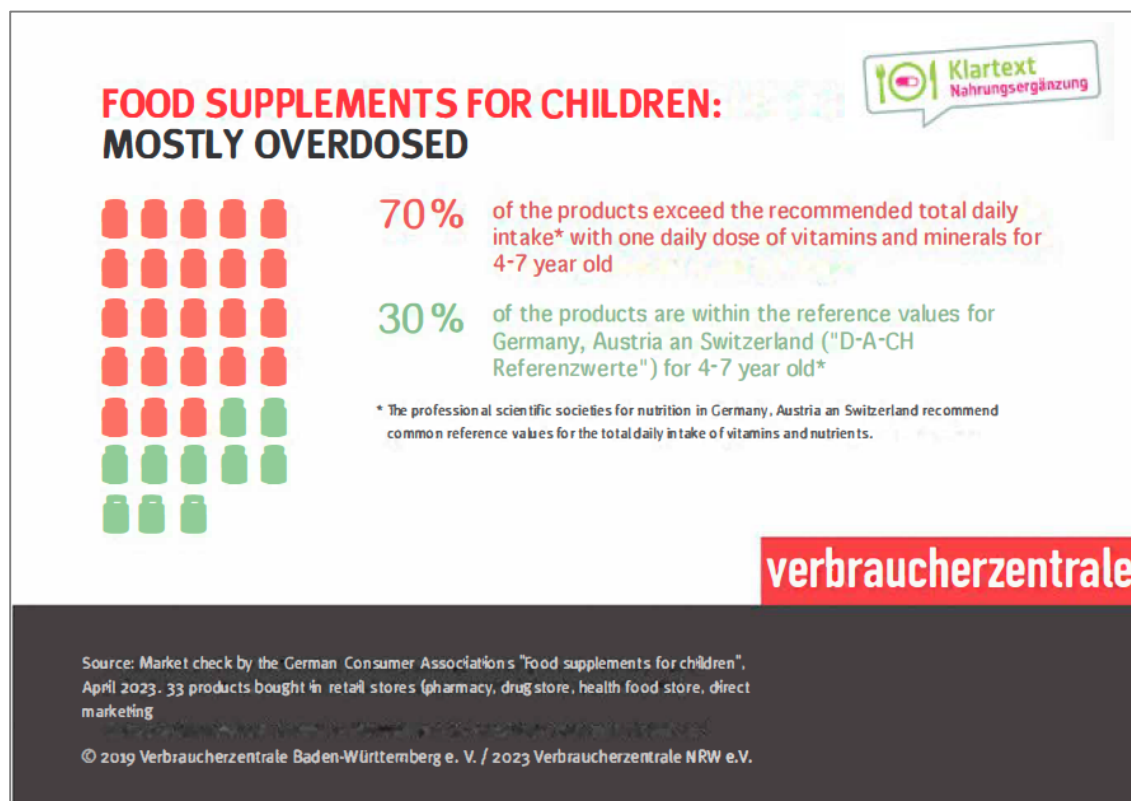


Figure 2: Food supplements for children: most doses are too high (as of: April 2023)

POSITION

In order to ensure consumer health protection, the European Commission must set standardised maximum levels for vitamins and minerals in food supplements across Europe. If the regulation announced at EU level is further delayed, the German government must set legally binding maximum levels at national level, as other EU Member States have already done. The recommendations for maximum levels of vitamins and minerals in food supplements updated by the BfR in 2024 could form the basis for a national regulation.

Separate maximum levels must be set for children, who are a vulnerable group. Differentiation by age group must be part of this. The youngest target group should provide the benchmark, for example when it comes to products aimed at the whole family. When it comes to substances for which there is no recommended maximum level based on risk assessment, the reference values for nutritional intake should not be exceeded. It also needs to be clarified that food supplements are not suitable for infants and toddlers.

3. INTRODUCE LEGALLY BINDING POSITIVE LIST OF “OTHER SUBSTANCES” IN FOOD SUPPLEMENTS

Directive 2002/46/EC⁵⁷ and the German Food Supplements Regulation (NemV) regulate which vitamins and minerals and their permitted combinations may be added to food supplements.⁵⁸ However, with the exception of six substances that are now prohibited under Annex III of Regulation (EC) No. 1925/2006, there are no negative or positive lists in Germany for the so-called other substances that may be added to food supplements. These ‘other substances with a nutritional effect’, such as amino acids, essential fatty acids and botanicals, are therefore not regulated – neither are they defined, nor are there purity requirements, quality standards or maximum permitted quantities. This regulatory gap is particularly serious with regard to botanicals, as these make up the majority of substances added to food supplements. For example, in late 2021 the BfR determined that the acceptable daily intake of curcumin (extracted from the curcuma root) in FS via the use of piperine (the main alkaloid in black pepper) may be exceeded in order to increase its bioavailability; effects harmful to the liver cannot be ruled out.⁵⁹

Due to the concentration of isolated nutritional and other substances, FS can pose health risks and should therefore be assessed differently to conventional food. The German Consumer Associations and vzbv demand that all substances added to FS need to be subject to authorisation and to be included in an EU-wide positive list.

A market check from the German Consumer Associations on isoflavones from soy and red clover in 2019 showed that 64 percent of the 22 products tested exceeded – in some cases significantly – the guideline values for daily intake provided by the EFSA.⁶⁰ A follow-up test in October 2024 (identical products) showed that 41 per cent still exceeded these values, but the improvement was only achieved by the fact that four isoflavone supplements containing too high a dose were no longer available (Figure 3).⁶¹ However, these guideline values only apply to healthy women after menopause. For the actual target group – women going through menopause – there is currently no reliable recommended daily dose. Products containing high doses of isoflavones are suspected of increasing the risk of breast cancer.

⁵⁷ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0046>, last accessed: 01/12/2024

⁵⁸ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, <https://eur-lex.europa.eu/eli/reg/2006/1925/oj/eng>, last accessed: 01/12/2024

⁵⁹ German Federal Institute for Risk Assessment (BfR): Curcumin in food supplements, BfR Opinion No 040/2021 issued 14/12/2021, <https://www.bfr.bund.de/cm/349/curcumin-in-food-supplements-acceptable-daily-intake-may-be-exceeded.pdf>, last accessed: 01/12/2024

⁶⁰ Klartext Nahrungsergänzung: Isoflavonhaltige Nahrungsergänzungsmittel – Hilfe in den Wechseljahren? Marktcheck der Verbraucherzentralen, 2019, https://www.klartext-nahrungsergaenzung.de/sites/default/files/2019-11/VZ_Bericht_Marktcheck_NEM-Isoflavonen-Stand_24-10-2019_aktualisiert.pdf, last accessed: 01/12/2024

⁶¹ Klartext Nahrungsergänzung: Isoflavonhaltige Nahrungsergänzungsmittel – Hilfe in den Wechseljahren? Marktcheck der Verbraucherzentralen, Nachprüfung 2024, <https://www.klartext-nahrungsergaenzung.de/node/101107>, last accessed: 01/12/2024



Figure 3: Food supplements containing isoflavones: most doses are too high!

In addition, 53 per cent of the products did not carry any of the recommended warnings. The information on the maximum duration of use was missing for 82 per cent and the recommendation to seek medical advice before taking products containing isoflavones was missing for 76 per cent.⁶²

Even the basic information according to Art. 4 and Art. 9 of Regulation (EU) 1169/2011 (Food Information to Consumers Regulation) was missing in 59 per cent of the food supplements tested.⁶³ No wonder that more and more consumers feel poorly informed about the potential health risks of food supplements. According to a representative consumer survey commissioned by vzbv in 2024, 54 per cent of respondents felt 'rather

⁶² According to the European Food Safety Authority, women after the menopause should take products containing soya isoflavones for a maximum of ten months and products containing red clover isoflavones for a maximum of three months. Source: Bundesamt für Risikobewertung: Nahrungsergänzungsmittel mit isolierten Isoflavonen: Bei Einnahme in und nach den Wechseljahren Orientierungswerte für Dosierung und Anwendungsdauer einhalten, 2015, <https://bfr.bund.de/cm/343/nahrungsergaenzungsmittel-mit-isolierten-isoflavonen-bei-einnahme-in-und-nach-den-wechseljahren-orientierungswerte-fuer-dosierung-und-anwendungsdauer-einhalten.pdf>, last accessed: 01/12/2024

⁶³ Regulation (EU) 1169/2011 (Food Information to Consumers Regulation), Article 4: Principles governing mandatory food information: 1. Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories: (b) information on the protection of consumers' health and the safe use of a food. In particular, it shall concern information on: (i) compositional attributes that may be harmful to the health of certain groups of consumers; Article 9: List of mandatory particulars 1. In accordance with Articles 10 to 35 and subject to the exceptions contained in this Chapter, indication of the following particulars shall be mandatory: (g) any special storage conditions and/or conditions of use; <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169>, last accessed: 01/12/2024

poorly' or 'very poorly' informed about the potential health risks of food supplements, compared to 'only' 33 per cent in 2022.⁶⁴

POSITION

In order to effectively protect consumers from health risks, the German Consumer Associations and vzbv call on the European legislator to approve positive lists for all substances added to food supplements. To date, only vitamins and minerals have been regulated accordingly. This legally binding positive list must specify the definitions, purity requirements, quality standards and permitted quantities of the respective substances. As such a legislative process on European level usually takes several years, the German legislator should promptly introduce national, binding legislation, based, for example, on the list of substances provided by the BVL and the federal states.⁶⁵

4. HEALTH CLAIMS ABOUT PLANT SUBSTANCES (BOTANICALS) IN FOOD

With the Health Claims Regulation, which entered into force in 2007, the EU aimed to create a European framework to protect consumers against unfounded health claims.⁶⁶ According to this, health claims are only permitted if they are scientifically proven. The plan was to fully implement the Regulation by 2010. However, the evaluation of submitted health claims for botanicals has been put on hold for years. All plant based substances tested by the EFSA up to that point had received a negative evaluation.⁶⁷

The European Parliament has explicitly disapproved of the continued suspension of the evaluation of health claims on botanicals and called on the European Commission and EFSA to finally take action regarding the 'on hold' claims.⁶⁸

Many sellers take advantage of the unclear legal situation and continue to advertise with unapproved health claims, especially in online retail. In this context, the increasing influencer marketing for food supplements is also problematic – because botanicals in particular are advertised on social media with unapproved and unverified health claims. This harbours risks for consumers in particular if they take food supplements on their own initiative instead of seeking medical treatment for health issues. The large number and fast pace of such social media postings poses an increasing challenge for official food control authorities. In addition, many food supplements are very similar to pharmaceuticals in their presentation, which leads to confusion and deception of consumers.

⁶⁴ Federation of German Consumer Organisations (vzbv): Representative Consumer Survey by forsa on behalf of vzbv, 2024, https://www.vzbv.de/sites/default/files/2025-01/Jahresendbefragung_Tabellenband_Nahrungserg%C3%A4nzungsmittel.pdf, last accessed: 06/01/2025

⁶⁵ Federal Office of Consumer Protection and Food Safety (BVL): Stofflisten des Bundes und der Bundesländer, https://www.bvl.bund.de/EN/Tasks/01_Food/01_tasks/11_HoA_WG_FS_en/HoA_WG_FS_en_node.html, last accessed: 01/12/2024

⁶⁶ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, <https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=celex%3A32006R1924>, last accessed: 01/12/2024

⁶⁷ European Food Safety Authority: Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern on request of EFSA. EFSA Journal 2009;7(9):281. <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2009.281>, last accessed: 01/12/2024

⁶⁸ European Parliament resolution of 18 January 2024 on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (2023/2081(INI)), https://www.europarl.europa.eu/doceo/document/TA-9-2024-0040_EN.html, last accessed: 01/12/2024

There is an urgent need for action here, as the Federal Court of Justice also recognised in a recent ruling.⁶⁹ The Federal Council had already called on the Federal Government in 2021 to ensure that the European Commission fully implements Regulation (EC) No. 1924/2006 and resumes the evaluation of the on-hold health claims for botanicals. This is urgently required in the interests of consumer protection.⁷⁰ This is also the conclusion of a comprehensive evaluation of Regulation (EC) No. 1924/2006 commissioned by the European Commission.⁷¹

POSITION

The German Consumer Associations and vzbv call on the European Commission to ensure a timely legal regulation for the on-hold claims for botanicals and their preparations.

5. ESTABLISH REPORTING OFFICE TO SYSTEMATICALLY RECORD FOOD SUPPLEMENT-RELATED SIDE EFFECTS AND INTERACTIONS

Consumers suffering from health problems often take FS based on their own assessment and without seeking medical advice because they confuse the products with medicinal drugs or expect a comparable effect from them. Self-medication using FS has increased significantly.⁷²

The blurred line between FS and medicinal drugs makes it difficult for consumers, and in some cases also medical staff, to differentiate between them. Substances such as vitamins and certain botanicals are used in both product groups, and the advertising claims are also similar. In addition, FS are packaged similarly to medicinal drugs and are often not clearly separated from drugs and other typical medicinal products in stores. As a result, the majority of consumers falsely assume that FS are subject to the same kind of effectiveness and safety tests as medicinal drugs before they enter the market.⁷³ The legal distinction between FS and medicinal drugs, which by definition must have a pharmacological effect, is also problematic. “Pharmacological effect” is a vague legal concept and is not suitable as a differentiation criterion from a scientific perspective. Increasingly, authorities are called on to clarify such questions before the courts (for example melatonin, cannabidiol [CBD]).

⁶⁹ Bundesgerichtshof (Federal Court of Justice – BGH): Court order of 01/06/2023 – I ZR 109/22, <https://open-jur.de/u/2471277.html>, last accessed: 01/12/2024

⁷⁰ Bundesrat: Entschließung des Bundesrates – Umsetzung der Health Claims Verordnung – ausstehende Bewertung gesundheitsbezogener Aussagen zu pflanzlichen Stoffen durch die EU, Bundestag printed paper 36/21 (Beschluss) of 12/02/2021, [https://www.bundesrat.de/SharedDocs/drucksachen/2021/0001-0100/36-21\(B\).pdf](https://www.bundesrat.de/SharedDocs/drucksachen/2021/0001-0100/36-21(B).pdf), last accessed: 01/12/2024

⁷¹ European Commission: Evaluation of the Regulation on nutrition and health claims, https://food.ec.europa.eu/safety/labelling-and-nutrition/nutrition-and-health-claims/evaluation-regulation-nutrition-and-health-claims_en, last accessed: 01/12/2024

⁷² Knopf, Hiltraud: Selbstmedikation mit Vitaminen, Mineralstoffen und Nahrungsergänzungsmitteln in Deutschland, 2017, Bundesgesundheitsblatt, 60(3):268–276, <https://edoc.rki.de/bitstream/handle/176904/2940/26asMp9YIOa0s.pdf>, last accessed: 01/12/2024

⁷³ Klartext Nahrungsergänzung: Umfrage: Das halten Verbraucher von Nahrungsergänzungsmitteln, 2023, <https://www.klartext-nahrungsergaenzung.de/wissen/lebensmittel/nahrungsergaenzungsmittel/umfrage-das-halten-verbraucher-von-nahrungsergaenzungsmitteln-1905>, last accessed: 01/12/2024

FS are often consumed alongside prescribed medication, a fact often unknown to the medical staff treating a patient and which can pose health risks.⁷⁴ Simultaneous consumption of several FS can also be harmful to health. A representative survey commissioned by vzbv reveals that more than a quarter of those surveyed had purchased several FS at the same time in the preceding six months.⁷⁵ Thus, doctors may not be in a position to prevent reciprocal effects between FS and drugs, for example between ginkgo and blood thinners or liver problems due to the consumption of ashwagandha⁷⁶, which can pose a significant health risk. Plant-based FS in particular can interact with drugs and influence their effectiveness.^{77, 78} The vitamin biotin can change the laboratory test results of blood or urine samples.⁷⁹

To date, however, FS products are not obliged to include warnings of potential health risks. Directive 2002/46/EC does not require a nutravigilance system to systematically record the side effects and interactions associated with FS. There is no systematic overview or evaluation procedure. Therefore, a reporting centre for side effects and interactions of food supplements, which is also accessible to consumers, would be useful. According to the BVL⁸⁰, a reporting system of this kind was established in the Federal Portal⁸¹ in late April 2024 to record side effects associated with cosmetics. Other examples that could serve as models include the CFSAN Adverse Event Reporting System (CAERS) from the American Food and Drug Administration or the online reporting of side effects offered by the Federal Institute for Drugs and Medical Devices

⁷⁴ Vidonscky Lüthold R et al. (2024): Exploring GP and patient attitudes towards the use and deprescribing of dietary supplements: a survey study in Switzerland. BMC Primary Care 25:359, <https://doi.org/10.1186/s12875-024-02605-z>, last accessed: 01/12/2024

⁷⁵ Federation of German Consumer Organisations (vzbv): Representative Consumer Survey by forsa on behalf of vzbv, 2024, https://www.vzbv.de/sites/default/files/2025-01/Jahresendbefragung_Tabellenband_Nahrungserg%C3%A4nzungsmittel.pdf, last accessed: 06/01/2025

⁷⁶ German Federal Institute for Risk Assessment (BfR): Communication 39/2024: Ashwagandha: food supplements with potential health risks, <https://www.bfr.bund.de/cm/349/ashwagandha-food-supplements-with-potential-health-risks.pdf>, last accessed: 01/12/2024

⁷⁷ Klartext Nahrungsergänzung: Goji-Beeren in Kapseln – Wirkung nicht bewiesen, 2024, <https://www.klartext-nahrungsergaenzung.de/node/5655>, last accessed: 01/12/2024

⁷⁸ Klartext Nahrungsergänzung: Ginkgo ist nicht gleich Ginkgo, 2023, <https://www.klartext-nahrungsergaenzung.de/node/6618>, last accessed: 01/12/2024

⁷⁹ German Federal Institute for Risk Assessment (BfR): Biotin in food supplements can influence laboratory test results, 2019, <https://www.bfr.bund.de/cm/349/biotin-in-food-supplements-can-influence-laboratory-test-results.pdf>, last accessed: 01/12/2024

⁸⁰ Federal Office of Consumer Protection and Food Safety (BVL): Unerwünschte Wirkungen von Kosmetik online melden, 2024, https://www.bvl.bund.de/SharedDocs/Pressemitteilungen/03_verbraucherprodukte/2024/2024_PM_Bundesportal.html, last accessed: 01/12/2024

⁸¹ Federal Ministry of the Interior and Community: Cosmetics: Report undesirable effects and damage to health, 2024, <https://verwaltung.bund.de/leistungsverzeichnis/EN/leistung/99118045261000/herausgeber/LeiKa-102889186/re-gion/00>, last accessed: 01/12/2024

(BfArM) and the Paul-Ehrlich-Institut.^{82, 83, 84} Within the EU, Czech consumers can submit reports via the National Institute of Public Health (SZU)⁸⁵, while French consumers can do so via the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)⁸⁶. Belgium has also been offering a nutrивigilance system since 01 January 2024.⁸⁷ Hungary launched a new nutrивigilance website⁸⁸ in March 2024 to make reporting easier for both consumers and health professionals. A BfR publication from 2022 provides an overview of nutrивigilance systems in EU Member States.⁸⁹

POSITION

The German Consumer Associations and vzbv urge the German Federal Government to establish a reporting office to systematically record the side effects and interactions related to food supplements.

They call on the relevant professional associations to do more educational work with both patients and doctors and in the healthcare professions regarding interactions between food supplements and medicines and to consistently ask about the use of food supplements during treatments in order to minimise health risks.

II. LIST OF FIGURES

Figure 1: Food supplements containing magnesium: doses often too high! (As of: December 2020)

Figure 2: Food supplements for children: most doses are too high (as of: April 2023)

Figure 3: Food supplements containing isoflavones: most doses are too high!

⁸² Federal Institute for Drugs and Medical Devices (BfArM) / Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institut): Portal for online reporting of side effects, https://nebenwirkungen.bund.de/nw/EN/home/home_node.html, last accessed: 01/12/2024

⁸³ U. S. Food and Drug Administration: CFSAN Adverse Event Reporting System (CAERS), <https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers>, last accessed: 01/12/2024

⁸⁴ U.S. Food and Drug Administration (FDA): How to Report a Problem with Dietary Supplements, 2018, <https://www.fda.gov/food/dietary-supplements/how-report-problem-dietary-supplements>, last accessed: 01/12/2024

⁸⁵ National Institute of Public Health, Czech Republic: Nutrивigilance – Zdraví, výživa a potraviny (Health, nutrition, and food), <http://nutrivigilance.szu.cz/>, last accessed: 01/12/2024

⁸⁶ French Agency for Food, Environmental and Occupational Health & Safety (ANSES): Nutrивigilance, <https://www.anses.fr/en/content/everything-you-need-know-about-nutrивigilance-scheme>, last accessed: 01/12/2024

⁸⁷ Federal Public Service: Public Health, Food Chain Safety and Environment, <http://www.health.belgium.be>, last accessed: 01/12/2024

⁸⁸ NUTRIVIGILANCIA Hungary, <https://nutrivigilancia.hu/>, last accessed: 01/12/2024

⁸⁹ "Nutrивigilance of food supplements in Europe". BfR-BVL Joint Meeting: Super(?)foods and Supplements – Risky or Healthy?, version: 01/07/2022, <https://www.bfr.bund.de/cm/349/nutrивigilance-of-food-supplements-in-europe.pdf>, last accessed: 01/12/2024