CLARITY ON FOOD SUPPLEMENTS

vzbv's position on food supplements

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INHALT

I. BACKGROUND

Food supplements are foodstuffs that are intended to supplement the general nutritional intake. They are concentrated nutrients or other substances with a nutritional or physiological effect and are marketed in 'dose' form, such as capsules, tablets and pills[1].

Most consumers who take food supplements have not been diagnosed with a nutrient deficiency and do not in fact have one. The National Nutrition Survey II[2] shows that nutrient intake in Germany is at a high level throughout the year. Clearly, Germany does not have a vitamin deficiency problem. The vast majority of the population has a diet that provides them with an adequate amount of nutrients.

Despite this, the market for food supplements is growing all the time. Revenue in this segment totalled €1.1 billion in 2015, which accounts for approximately 2 percent of the overall health product market[3]. And this does not include online sales, direct sales or mail order (with the exception of online pharmacies).

1. REPRESENTATIVE SURVEY REVEALS CONSUMER EXPECTATIONS

A representative survey recently conducted by the Forsa Institute on behalf of the German consumer associations shows that 51 percent of consumers believe that food supplements are either 'quite beneficial' or 'very beneficial' to their health[4]. Among the consumers who actually take food supplements, this rises to 83 percent. However, these people generally have a good enough diet in the first place and do not in fact need them[5].

If nutrient intake is adequate, taking food supplements will not improve people's physical or mental performance, enhance the body's immune system or result in any demonstrable slowing of the ageing process.

2. DANGER OF OVERDOSE, GAPS IN THE LAW

'Self-medication' using food supplements can even have negative effects. Multiple supplements are often taken at the same time and, in some cases, together with medication containing micronutrients. This is making it increasingly difficult for people to get a realistic picture of the quantity of nutrients they are receiving. This is risky, because overdosing on certain nutrients contained in food supplements, such as selenium or zinc, can, depending on the toxicity, cause severe problems. However, maximum safe

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[1] See section 1 of the German Food Supplement Regulation (Nahrungsergänzungsmittelverordnung, NemV), https://www.gesetze-im-internet.de/bundesrecht/nemv/gesamt.pdf

[2] https://www.mri.bund.de/de/institute/ernaehrungsverhalten/forschungsprojekte/nvsii/

[3] Nahrungsergänzungsmittel [food supplements], QuintilesIMS (IMS HEALTH GmbH & Co. OHG), 2016 http://www.ims-health.com/files/web/Germany/Publikationen/Infografiken/Nahrungsergaenzungsmittel-Infografik-IMSHealth-102016.pdf

[4] Survey and summary of results: https://www.verbraucherzentrale.de/umfrage-das-halten-verbraucher-von-nahrungsergaenzungsmitteln

[5] Oft zu gut versorgt durch Nahrungsergänzungsmittel [nutrient intake often excessive]. Press release by the Max Rubner Institute dated 22 August 2013: https://idw-online.de/de/news544708

levels announced in the European Food Supplements Directive back in 2002[6], which could give authorities the power to take swift action, have still not materialised.

3. GERMAN CONSUMER ASSOCIATIONS PRODUCE UP-TO-DATE MARKET RESEARCH ON FOOD SUPPLEMENTS CONTAINING MAGNESIUM

According to recent market research by the German consumer associations, 64 percent of food supplements containing magnesium (27 of 42 tested products) exceeded the maximum levels of magnesium recommended by the Federal Institute for Risk Assessment (BfR)[7] and the European Food Safety Authority (EFSA)[8] for food supplements (250 mg/day). The average dose of magnesium provided by the products in question was 423 mg per day. The highest daily dose discovered in a food supplement sold in pharmacies was an incredible 1,163 mg.

HOW MUCH IS TOO MUCH?

Confusion illustrated by varying recommendations for magnesium

Recommendations for maximum daily dose

D-A-CH9 reference value10 for overall nutrient intake	300–350 mg
Reference amounts for daily intake (dietary reference value) according to the FIC11	375 mg
Maximum tolerable daily intake (EFSA) (UL)12;13	250 mg
BfR maximum daily intake recommendations for food supplements	250 mg

4. NO LEGISLATION FOR MAXIMUM INTAKE OF VITAMINS AND MINERALS, ‘OTHER SUBSTANCES’ ARE NOT REGULATED

The majority of substances, i.e. the ‘other substances’ that have a specific nutritional effect such as amino acids, essential fatty acids and plant and herb extracts (botanicals), are not regulated in any way. They are not defined and there are no purity requirements, quality standards or permitted maximum intake levels. Nearly one in five food supplements contain primarily plant or herb extracts. Although this does not sound like many, the quantities are clearly relevant when more than 177 million packs of food supplements are sold in Germany each year[14]. And that number doesn’t even include

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[6] Directive 2002/46/EC, article 5

[7] http://www.bfr.bund.de/cm/350/verwendung_von_mineralstoffen_in_lebensmitteln_bfr_wissenschaft_4_2004.pdf

[8] http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf

[9] D-A-CH stands for Germany, Austria and Switzerland, https://de.wikipedia.org/wiki/D-A-CH

[10] D-A-CH reference values for nutrient intake for people aged 25 and above, published by the German Nutrition Society, 2015

[11] Food Information to Consumers Regulation

[12] for easily soluble magnesium salts (chloride, sulfates, aspartates, lactates) and magnesium oxide in food supplements, water or enriched food and beverage products), http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf

[13] UL= upper level

[14] Absatz von Nahrungsergänzungsmittel steigt weiter [Food supplement sales rise further]. aid newsletter no. 46 dated 15 November 2016. Figure covers sales from April 2015 to March 2016.

internet sales or direct and mail order purchases, which is precisely where many problematic plant-based products are found.

5. DISTINCTION FROM MEDICINES UNCLEAR

Consumers find the health product market confusing. Not only are food supplements sold in medicine-like forms (tablets, capsules, vials), but there is also no clear way of distinguishing them from medicines. Substances such as vitamins and certain plant extracts are found in both product groups and the advertising messages are similar. Consumers are unable to clearly tell them apart from their labelling or locations in the store.

The result is that consumers see food supplements not as a food, which they are according to the current law, but as a product that has a proven effect, similar to a medicine. The recent Forsa Institute survey commissioned by the German consumer associations reveals that almost half of those surveyed and most purchasers of food supplements mistakenly assume that the products they are buying have been checked for efficacy and safety before being launched on the market[4]. In fact, food supplements only need to be registered. They do not undergo any official approval processes and are not tested for efficacy and safety. Although the distributors of food supplements are responsible for ensuring that their products are safe, there have still been numerous safety-related problems in recent years, for example with pyrrolizidine alkaloids[15], coumarin/cinnamaldehyde[16], heavy metals, polycyclic aromatic hydrocarbons (PAHs), pharmacological substances and unauthorised ingredients (micronutrient compounds, novel foods, excessive doses[17]).

6. INADEQUATE LABELLING, INSUFFICIENT MONITORING

In Germany, food supplements have the highest non-compliance ratio of all food product groups. On average, 30 percent of food supplements tested by the official food monitoring authorities in Germany were found to be non-compliant (the numbers vary greatly between federal states)[18]. And very few products sold online or by direct sales were tested. Unauthorised ingredients and excessive doses were the main reasons for non-compliance. The many cases of insufficient labelling show that the high level of protection called for in the EU food supplement directive is not being provided (Recital 5: “In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling.”[19]).

This is particularly relevant in cases where advertisements claim that food supplements can cure or alleviate illnesses. As well as posing economic dangers for consumers, who may be misled as to the impact/efficacy of what they are taking, there are also real

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[15] Fragen und Antworten zu Pyrrolizidinalkaloiden in Lebensmitteln. Aktualisierte FAQ des BfR [Questions and answers on pyrrolizidine alkaloids in foods. Updated BfR FAQs] dated 28 September 2016, www.bfr.bund.de/de/fragen_und_antworten_zu_pyrrolizidinalkaloiden_in_lebensmitteln-187302.html

[16] Hohe tägliche Aufnahmemengen von Zimt: Gesundheitsrisiko kann nicht ausgeschlossen werden. [High daily intake of cinnamon: risk to health cannot be ruled out.] BfR health evaluation no. 044/2006 dated 18 August 2006

[17] Analysis by the European Rapid Alert System for Food and Feed (RASFF) 2011–2015

[18] Bavaria, 2013: 13 percent; Schleswig-Holstein, 2014: 71 percent; Saxony-Anhalt, 2013: 43.3 percent of food supplements generally and 63 percent of mail order food supplements

[19] Directive 2002/46/EC of the European Parliament and the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

risks if, for example, they forego medical treatment in the expectation of the supplement delivering on its promises. Although there is a legal framework here in the shape of the health claims regulation (bearing in mind that around half of the claims submitted have not yet even been evaluated), the relevant checks and controls appear insufficient. Consumers in Germany rightly expect the market surveillance authorities in charge of food to carry out these types of checks in pharmacies too, for example.

An additional problem is the insufficient monitoring of online sales of food supplements. For the oversight of the global sales network, there is currently a lack of both harmonised legalisation at European level and a properly organised approach to food inspection at local-authority level. The example of Netherlands-based company Hittich[20], which is able to falsely advertise its products in Germany with impunity, shows how important it is for different countries to work together. Consumers expect the food supplements that they buy to be safe, at the very least on domestic online marketplaces such as German Amazon and German eBay, and from mail order. But here, too, there is still a lack of coordinated action on the part of authorities within EU Member States.

[20] http://www.vzbv.de/meldung/landgericht-berlin-verbietet-unlautere-gesundheitswerbung-fuer-vitamin-b12-pillen

II. VZBV'S POSITION

- **Regulation stipulating maximum levels of vitamins and minerals**
  The existing 'positive list' for vitamins and minerals is insufficient because there are still no rules stipulating maximum levels, even though these were announced in EU legislation back in 2002[21]. Regulation stipulating maximum levels of vitamins and minerals is urgently needed to protect people's health. If necessary, Germany will have to move ahead on its own in this area.

- **Positive list for 'other substances'**
  Because they contain concentrations of isolated nutrients and carry risks, food supplements must be treated differently than conventional foods. The ingredients therefore need to be approved using positive lists. Up to now, only vitamins and minerals have been regulated in this way. The use of 'other substances', such as botanicals (plant extracts), is still unregulated in Germany. This is in contrast to other EU Member States (such as Belgium, France and Italy, see BELFRIT list[22]). Definitions, purity requirements, quality standards and permitted amounts must therefore be specified for 'other substances'. If this regulatory gap is not swiftly closed at EU level, Germany must introduce its own rules.

- **Approval process for food supplements**
  Until this happens, it is essential that all food supplements registered in Germany (in accordance with section 5 NEM-V) are inspected/approved for efficacy and safety – and the accuracy of advertising messages verified – before the supplements are first brought to market.

- **Publicly accessible directory/database of authorised food supplements**
  An online directory would make it easier for consumers to check whether food supplements have been officially tested and approved. This would be particularly helpful in countering the risks of non-compliant food supplements being purchased online and by mail order.

- **Setting up a reporting channel for unexpected effects and side effects of food supplements ('nutrivigilance' system)**
  Consumers must have their own reporting channel. It could be designed following the example of the Safety Reporting Portal of the US Food and Drug Administration (FDA)[23] or on the reporting channel for drug side effects used by Germany's Federal Institute for Drugs and Medical Devices (BfArM)[24].

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[21] Directive 2002/46/EC, article 5

[22] http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/stoffliste/07_Geelen_Vortrag_SL.html?nn=5606032

[23] http://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/

[24] http://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/RisikenMelden/NW-MeldungVerbr/_node.html