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Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods

BfR Opinion No 009/2021 issued 15 March 2021

The market for food supplements and fortified foods is both highly diverse and growing at a steady pace. Roughly, a third of adults in Germany take food supplements on a regular basis, with vitamin and mineral preparations being particularly popular. Conventional foods are also sometimes fortified with vitamins and minerals. Such products are often advertised as being able to compensate for insufficient nutrient intake via the daily diet.

As a rule of thumb, it can be said that a balanced and varied diet provides the healthy body with sufficient amounts of essential nutrients. In Germany, available data on nutrient intakes indicate that only a few vitamins and minerals - such as vitamin D, calcium, folic acid and iodine - are not being consumed by some groups in accordance with the dietary intakes recommended by the German Nutrition Society (DGE). However, this cannot be generally equated to an insufficiency or even a deficiency.

Food supplements may therefore be advisable in isolated cases. Yet they are not necessary for most of the population, which has a good nutrient status. This is exemplified even more by the observation that supplements tend to be taken by people with healthier lifestyles and well-balanced diets. International scientific studies have also demonstrated that no positive effects on health are to be expected from an additional intake of micronutrients beyond their actual requirements. Use of high-dose food supplements and additional consumption of fortified foods may lead to high intake levels that therefore increase the risk of an excessive intake of the respective micronutrients. EU regulations for food supplements and fortified foods therefore foresee the setting of uniform maximum levels for these products at the EU level.

The German Federal Institute for Risk Assessment (BfR), which has been involved in assessing the health risks of vitamins and minerals for approximately the last two decades, published an initial set of recommendations for maximum levels of vitamins and minerals in food supplements and fortified foods in 200. These recommendations have now been updated to reflect the current state of knowledge.

The updated recommendations have taken the tolerable upper intake levels (ULs), as derived by the European Food Safety Authority (EFSA) for the corresponding nutrients, into account. The UL defines the quantity of the nutrient that, as a chronic daily intake from all sources, would not be associated with adverse health effects, based on the current state of knowledge. In addition, the reference values for nutrient intake derived by the Austrian, German and Swiss nutrition societies (‘D-A-CH’ societies, i.e. ÖGE, DGE and SSG/SSN) and by EFSA have also been taken into account, as well as the vitamin and mineral intakes from the usual diet, as determined by dietary surveys (National Food Consumption Survey, NFCS II and EsKiMo study) conducted in Germany.

The BfR maximum recommended levels are intended to limit nutrient intake via food supplements and fortified foods in such a way that ensures a significant additional nutrient intake from consumption of these products while simultaneously protecting the majority of the population that are adequately supplied with nutrients from excessive nutrient intake. These recommendations are offered to risk management as a basis for discussion in the context of ultimately establishing regulations on maximum levels at the EU level.

Individual documents for maximum levels recommended per substance

Fat-soluble vitamins:

Vitamin A:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-vitamin-a-to-foods-including-food-supplements.pdf

Beta-carotene:
https://www.bfr.bund.de/cm/349/maximum-levels-for-the-addition-of-beta-carotene-to-foods-including-food-supplements.pdf

Vitamin D:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-vitamin-d-to-foods-including-food-supplements.pdf

Vitamin E:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-vitamin-e-to-foods-including-food-supplements.pdf

Vitamin K:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-vitamin-k-to-foods-including-food-supplements.pdf

Water-soluble vitamins:

Vitamin B_1, B_2, pantothenic acid:
https://www.bfr.bund.de/cm/349/maximum-levels-for-the-addition-of-vitamin-b1-vitamin-b2-and-pantothenic-acid-to-foods-including-food-supplements.pdf

Niacin:
https://www.bfr.bund.de/cm/349/maximum-levels-for-the-addition-of-niacin-to-foods-including-food-supplements.pdf

Vitamin B_6:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-vitamin-b6-to-foods-including-food-supplements.pdf

Folic acid:
https://www.bfr.bund.de/cm/349/maximum-levels-for-the-addition-of-folic-acid-to-foods-including-food-supplements.pdf

Vitamin B_{12}:
https://www.bfr.bund.de/cm/349/maximum-levels-for-the-addition-of-vitamin-b12-to-foods-including-food-supplements.pdf

Biotin:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-biotin-to-foods-including-food-supplements.pdf

Vitamin C:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-vitamin-c-to-foods-including-food-supplements.pdf

Minerals and trace elements:

Sodium:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-sodium-to-foods-including-food-supplements.pdf

Chloride:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-chloride-to-foods-including-food-supplements.pdf

Potassium:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-potassium-to-foods-including-food-supplements.pdf

Calcium:
https://www.bfr.bund.de/cm/349/maximum-levels-for-the-addition-of-calcium-to-foods-including-food-supplements.pdf

Phosphorus/phosphate:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-phosphorus-phosphate-to-foods-including-food-supplements.pdf

Magnesium:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-magnesium-to-foods-including-food-supplements.pdf

Iron:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-iron-to-foods-including-food-supplements.pdf

Iodine:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-iodine-to-foods-including-food-supplements.pdf

Fluoride:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-fluoride-to-foods-including-food-supplements.pdf

Zinc:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-zinc-to-foods-including-food-supplements.pdf

Selenium:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-selenium-to-foods-including-food-supplements.pdf

Copper:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-copper-to-foods-including-food-supplements.pdf

Manganese:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-manganese-to-foods-including-food-supplements.pdf

Chromium:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-chromium-to-foods-including-food-supplements.pdf

Molybdenum:
https://www.bfr.bund.de/cm/349/maximum-levels-for-the-addition-of-molybdenum-to-foods-including-food-supplements.pdf

Boron:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-boron-to-foods-including-food-supplements.pdf

Silicon:
https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-silicon-to-foods-including-food-supplements.pdf

1 Subject of the assessment

The BfR has updated its recommended maximum levels for the above vitamins and minerals in food supplements and in fortified foods.

The BfR notes here that the derivation of maximum levels for specific products is not a primary task in the field of risk assessment. Instead, the work presented here - based on the tolerable upper intake levels (ULs) derived from risk assessment activities (e.g. as conducted by the European Food Safety Authority (EFSA)) - aims to highlight options that are intended to serve as the basis for management decision-making when specifying maximum levels for food supplements as well as for conventional foods.

The following section introduces the methodology used by the BfR to derive maximum levels for individual products.

2 Legal foundation

Both 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, and 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, envisage the specification of maximum amounts for the addition of vitamins and minerals to food supplements as well as to other conventional foods. According to article 5 (1) of Directive 2002/46/EC and article 6 (3–5) of Regulation (EC) No 1925/2006, the following should be accounted for:

- tolerable upper intake levels[1] (ULs) of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different groups of consumers;
- intakes of vitamins and minerals from other dietary sources (exposure)
- dietary reference intake values of vitamins and minerals for the population.

In accordance with Regulation (EC) No 1925/2006, the following shall also be taken into account for vitamins and minerals whose reference intakes are close to the 'safe upper levels'[2]:

- The contribution of individual products to the overall diet of the population in general or of sub-groups of the population
- The established nutrient profile of the product [BfR: not yet established] as provided for by Regulation (EC) No 1924/2006 (the Nutrition and Health Claim Regulation).

3 Underlying data

3.1 Tolerable upper intake levels (ULs)

The ULs that had been derived on the basis of risk assessments by the former Scientific Committee on Food (SCF) of the EU Commission as well as ULs derived by EFSA (EFSA, 2006) were used as the basis for deriving the maximum amounts for individual products. In

[1] A tolerable upper intake level is the daily chronic intake of a nutrient considered tolerable

[2] The English wording of this Regulation refers to a 'safe upper level'. In the BfR's opinion, this term is in fact synonymous with the 'tolerable upper intake level' (UL).

cases where the SCF or EFSA had not determined a numeric UL in their risk assessments for a micronutrient, a decision was made either to use comparable data from SCF/EFSA (e.g. orientation values) or ULs provided by the former US Institute of Medicine (IOM), or, if applicable, recent risk assessments conducted by the BfR itself.

Unless stated otherwise, derivations of maximum levels for food supplements were carried out for adolescents aged 15 and over, and adults. Accounting for children aged under 15 would, as a result of the lower ULs, not have yielded any practicable maximum levels for adults and adolescents. Since, in comparison to adults, lower ULs had typically been derived for adolescents aged between 15 and 17, this age group was usually selected as the reference group and - where available - the ULs for adolescents aged 15 to 17 were used as the basis for the derivation of maximum levels.

In contrast, fortified foods are consumed by the whole population, which also includes children aged 15 years and under. When deriving maximum levels for fortified foods, the ULs of younger children aged four and up were therefore also taken into account[3].

3.2 Population reference intakes

The dietary reference values used were those of the German-speaking nutrition societies (D-A-CH, 2015). Where the reference values derived by the D-A-CH societies were outdated in individual cases, the more recent dietary reference values (DRVs) established by EFSA were used instead.

3.3 Nutrient intakes from other sources

In Germany, micronutrient intakes from the usual diet have been most recently determined for adults - namely for the population aged from 14 to 80 years - in the second National Food Consumption Survey (NFCS II). Intakes for children aged from 7 to 17 were surveyed in the EsKiMo study (part of the KiGGS child health study) and intakes for younger children aged from 0.6 to 5 years collected by the VELS study[4].

In the NFCS II, food consumption data were collected in 2005–2006 by means of a computer-assisted survey consisting of three separate survey methods conducted in parallel, namely: a) one diet history interview (DISHES 05); b) two 24-hour recalls (EPIC-Soft) conducted on separate days; and c) a seven-day weighing protocol.

In the surveys conducted according to the first two methods, all respondents were involved (n = 15,371 with DISHES 05 and n = 13,926 with EPIC-Soft), whereas the seven-day weighing protocol was conducted only with a subpopulation of 1,000 individuals (MRI, 2008a, Krems et al., 2006). The nutrient intakes were calculated and published separately for each method by linking the food consumption data to the nutrient data for the most recent German Nutrient Database (BLS): the results of the diet history interviews were published in the summary report from the MRI (2008b), and results from the 24-hour recalls in the 12th Nutrition Report (DGE, 2012). The nutrient intakes determined from the seven-day weighing protocol were published in scientific articles as part of a comparison of methods (Eisinger-Watzl et al., 2015, Eisinger-Watzl et al., 2016). In addition, the intake data resulting from the diet history

[3] Also accounted for here was the fact that children in general also have lower energy intakes than adults.

[4] VELS study = a consumption study to determine food intakes for infants and young children in order to estimate the acute risk of toxicity owing to the presence of residues from plant protection products

interviews were also supplied by the Max Rubner Institute (MRI) electronically, as a scientific use file[5].

The diet history method (DISHES 05) was used to collect data on the normal consumption of respondents during the last four weeks, starting from the time of the survey. This method provides good estimations of the long-term intake of nutrients if foods are categorised into groups or foods that are regularly consumed are taken into account. Recipes are (largely) stored as standard recipes and therefore do not account for any variation occurring in the preparation/manufacture and the resulting consumption quantities. Due to the presence of consumption data for individual days, the 24-hour recall method (EPIC-Soft) is also suitable for use in exposure assessments considering both acute and chronic health risks. However, the use (averaging-out) of two measurements from individual days to calculate the chronic intake is associated with uncertainties. These uncertainties must be accounted for in particular in statements concerning detailed food groups or for exposure estimates involving a high percentage of individuals who do not consume certain foods. As well as underestimating the proportion of the population that consumes a certain food, the 24-hour recall method also runs the risk of overestimating the upper percentiles of nutrient consumption.

Since particularly the upper intake percentiles were to be considered when deriving maximum amounts, the BfR therefore relied primarily on the intake data that had been calculated from the diet history interviews (MRI, 2008b). Since the data from the EsKiMo study were also collected using diet history interviews (Mensink et al., 2007), this also allowed to achieve a better level of agreement between the consumption data for the age groups that were surveyed both in NFCS II as well as in the EsKiMo study (14- to 17-year-olds).

In summary, the derivations of maximum levels for food supplements in general were based on the NFCS II data from the diet history interviews (MRI, 2008b). Adolescents aged 15 and over are covered in NFCS II by the age group of 14- to 18-year-olds. In order to derive maximum levels for conventional foods, consumption data from the EsKiMo and VELS studies were used for younger children.

Where other intake data were consulted on a case-by-case basis, the need to do so has been justified separately in the respective section for the micronutrients affected.

4 Derivation procedure

As discussed by the BfR on previous occasions (BfR, 2004 a and b), the initial step in deriving maximum levels was to determine a ‘residual amount’ for the addition of a nutrient to food supplements and to conventional foods, by calculating the difference between the UL and the 95th intake percentile from the normal diet (P95). The ULs and 95th intake percentiles used here were taken from the same age group. This was typically the age group of 15- to 17-year-olds:

$$UL_{15–17\ years} - P95_{15–17\ years} = \text{residual amount}$$

For nutrients for which no ULs and/or suitable stratified intake data were available, case-by-case analyses were conducted, and the recommended maximum levels for food supplements and fortified foods have been justified separately in the respective sections.

[5] https://www.mri.bund.de/de/institute/ernaehrungsverhalten/forschungsprojekte/nvsii/scientific-use-file/; date of last access: 9 March 2021.

4.1 Derivation of maximum levels for nutrients with small margin between UL and P95

For substances with a small margin between the UL and the 95th intake percentile (e.g. zinc), the 'residual amount' was allocated only to the category of food supplements and thus fortification of conventional foods was not envisaged:

low residual amount ↪ residual amount = residual amount$_{\text{food supplements (FS)}}$

The maximum amounts for food supplements were obtained following the division of the resulting 'residual amount' by an uncertainty factor (UF) - typically 2 - for potential multiple exposure from various food supplement products, alongside other scientific uncertainties:

$$\text{maximum level}_{FS} = \underline{\text{residual amount}_{FS}} \,/\, \underline{\text{UF}}$$

4.1.1 Rationale for using an uncertainty factor when deriving maximum amounts for food supplements

Food supplements are available on the market both as mono-preparations and as multivitamin and/or multimineral preparations. In addition, food supplements whose principal ingredients are "other substances with a nutritional or physiological effect" also often contain additional vitamins and minerals. Since both the NFCS II and other available consumption studies provide only limited data in relation to the consumption of food supplements and their formulations, there is a considerable degree of uncertainty concerning the multiple intake of micronutrients from various supplements.

A survey of adults conducted nationwide in Germany (Heinemann et al., 2015) has shown that approximately 20% of those taking supplements used two products, while 7% used three products. Furthermore, Willers et al. (2016) have determined that the vitamins C and E as well as the minerals magnesium and zinc were consumed from two to four products by 11–16% of those that used food supplements. A recent evaluation of the NFCS II data (Römer and Heuer, 2017) also shows that, of the respondents who stated that they took supplements (approx. 25%), around 20% took two supplement products, while 9% took three or more. In terms of multiple exposure to individual micronutrients from various food supplement products, it has been shown that the range of multiple exposure from two or more supplements was 1.7–10.8%, with the maximum proportion of multiple exposure being observed for vitamin E (10.8%) and vitamin C (8.5%), as well as for magnesium (5.7%) and calcium (5.5%). Multiple exposure to the same nutrient from the consumption of three or more supplements was a rare occurrence in the NFCS II data. With the exception of vitamin E (1.7%), the intake of at least three supplements with a single nutrient was less than 1% for those interviewed (Römer and Heuer, 2017). In considering these results, it should be remembered that the details from the NFCS II on the supplements used as well as the nutrient data contained in the MRI supplement database date back to the years 2005 to 2007. Changes in the consumption behaviour of the population and in the nutrient formulations of the individual products over the last ten years cannot be excluded. It should also be noted that no data on product name and/or manufacturer could be collected in NFCS II for some of the supplements. For biotin,

niacin and pantothenic acid, for example, there is therefore a considerable degree of uncertainty in terms of the results (Römer and Heuer, 2017).

To account for these considerable uncertainties, the BfR recommends the use of an uncertainty factor (UF) of 2 when deriving maximum levels for the addition of micronutrients to food supplements. The BfR considers this factor of 2 to be justified both by the data from the scientific literature (Heinemann et al., 2015, Willers et al., 2016) as well as by the recent evaluation of the NFCS II data (Römer and Heuer, 2017), alongside other scientific uncertainties.

4.2 Derivation of maximum levels for nutrients with larger margins between UL and P95

In the case of substances with large margins between the UL and the 95th intake percentile, the 'residual amount' was split - typically equally - between food supplements and conventional foods. Further steps were taken for food supplements as already described above in section 4.1.

higher residual amount

$$\text{residual amount} = \text{residual amount}_{FS} + \text{residual amount}_{\text{Fortified foods (FF)}}$$

The 'residual amount$_{FF}$' was allocated to the estimated daily energy intake from fortified foods (based on servings of 100 kcal). This was determined as follows.

To ensure a high level of protection, the age-stratified 95th percentiles of energy intake were used as the basis for calculations[6]. The proportion of 'foods fortifiable' found in the foods actually consumed was also determined, by investigating all of the food codes specified as being consumed in NFCS II (with the exception of unprocessed foods, alcoholic beverages, coffee, tea and water) in terms of their fortifiability. This resulted in roughly 30% of products consumed being classified as 'fortifiable'. Working from this basis, a simplified assumption was then made that no more than a third of the food consumed on a day-to-day basis (expressed in energy units) are potentially being consumed in the form of fortified foods. In practical terms, however, one may assume that only a portion of foods theoretically fortifiable is indeed fortified with a specific micronutrient.

From NFCS II, the actual energy consumption from fortified foods cannot be calculated for Germany, due to a lack of appropriate data. While the BfR has determined this value as 8% from the EsKiMo study data, a high level of uncertainty applies to this figure. Alongside the fact that the consumption studies completed in Germany to date cannot be utilised for the determination of reliable data about the actual energy contribution stemming from fortified foods, the market of fortified foods has also developed considerably over the last few years, and this is a trend that can be expected to continue into the future. In the case of deriving maximum levels for the fortification of conventional foods, the BfR therefore recommends basing these derivations on an estimate of at least 15% of energy consumed from fortified foods. This is equivalent to half of the maximum estimate of energy consumable from fortified foods. Alternatively, the utilisation of higher estimates, up to a maximum of 30% of energy consumed from fortified foods, would also be a possible approach.

Rationales comparable to the one proposed here have been used as the basis for model calculations published by researchers working in other EU countries. As examples, Flynn et al.

[6] P95 of energy intake – adults: approx. 3,500 kcal/day (NFCS II); children and adolescents aged between 4 and 18: age-dependent, between approx. 2,000 and 4,000 kcal/day (VELS/EsKiMo/NCFS II)

(2003) and Rasmussen et al. (2006) assumed that no more than 50% of foods consumed were theoretically fortifiable, and calculated intake levels to be expected for micronutrients from fortified foods in a set of individual model scenarios. Kloosterman et al. (2007) also assumed, on the basis of consumption patterns found in the Dutch population, that a maximum of 30% of energy consumed could be sourced from fortified foods (i.e. would be theoretically fortifiable) and applied an estimate of 15% of daily energy intake from fortified foods in the context of a Dutch model.

Depending on the estimate used for the energy intake from fortified foods, a range of maximum levels are accordingly allocated per 100 kcal of a foodstuff.

The BfR has calculated optional maximum levels for both scenarios, i.e. where

a) 15% of energy consumed is sourced from fortified foods; and where

a) 30% of energy consumed is sourced from fortified foods.

As a last step, the additional amounts per 100 kcal of food were converted into weight-based values. For vitamin D, for example, this was achieved by an appropriate rounding of the average calorie content of a defined food group. This figure was then used as a factor for converting the calculated amounts per 100 kcal into food group-specific amounts per 100 g of product. The procedures used for other nutrients are explained in the respective individual documents.

In the process of deriving maximum levels for the addition of micronutrients to fortified foods, all food groups were included whose fortification is not legally restricted by article 4 of Regulation (EC) No 1925/2006. In the case of nutrients where the derivation procedure did not result in significant amounts (according to Regulation (EU) No 1169/2011, this means 15% of the reference value for nutrition labelling in 100 g of product) for all foods potentially fortifiable, the following two options were basically considered:

a) The derived maximum levels for the addition of the respective micronutrient are below the amount, defined above as significant, and cannot therefore be claimed on the product according to current legislation.

b) Other food (categories) beyond those stated in article 4 of Regulation (EC) 1925/2006 are excempted from fortification with micronutrients, so as to enable the addition of significant amounts ≥15% of the reference value for nutrition labelling for the remaining food groups. For restrictions of this kind, the BfR has recommended the following selection criteria:
   - contributions made by individual food groups to overall food consumption;
   - frequency of consumption of foods as well as the proportion of those that consume certain types of food;
   - consumption patterns in relation to specific foods (e.g. peak consumption[7])
   - composition of foods in terms of macronutrients (e.g. unfavourable nutrient profiles)

In deriving maximum levels for fortified foods, the BfR followed option b).

Since the selection of criteria can vary in the case of different micronutrients, these have been justified separately in the respective individual documents for the micronutrients concerned (e.g. vitamin D and iodine).

[7] Foods with high peak consumption typically have strongly fluctuating consumption quantities

Further information on the topic of vitamins and minerals from the BfR website

Topic page on the assessment of vitamins and minerals in foods:
https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html

BfR 'Opinions app'

5 References

BfR (2004a). Verwendung von Vitaminen in Lebensmitteln. Herausgegeben von Domke A, Großklaus R, Niemann B, Przyrembel H, Richter K, Schmidt E, Weißenborn A, Wörner B, Ziegenhagen R. BfR Wissenschaft 03/2004.

BfR (2004b). Verwendung von Mineralstoffen in Lebensmitteln. Herausgegeben von Domke A, Großklaus R, Niemann B, Przyrembel H, Richter K, Schmidt E, Weißenborn A, Wörner B, Ziegenhagen R. BfR Wissenschaft 04/2004.

D-A-CH (2015). Deutsche Gesellschaft für Ernährung, Österreichische Gesellschaft für Ernährung, Schweizerische Gesellschaft für Ernährung. Referenzwerte für die Nährstoffzufuhr. 2. Auflage, 1. Ausgabe 2015, Neuer Umschau Buchverlag.

DGE (2012). 12. Ernährungsbericht. Deutsche Gesellschaft für Ernährung e. V. (Hrsg.), Bonn, 2012.

EFSA (2006) Tolerable Upper Intake Levels for Vitamins and Minerals. Scientific Committee on Food, Scientific Panel on Dietetic Products, Nutrition and Allergies. European Food Safety Authority. http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf; last accessed 09 March 2021.

Eisinger-Watzl M, Straßburg A, Ramünke J, Krems C, Heuer T, Hoffmann I (2015). Comparison of two dietary assessment methods by food consumption: results of the German National Nutrition Survey II. Eur J Nutr. 54: 343-54.

Eisinger-Watzl M, Straßburg A, Krems C Hoffmann I (2016). Underreporting: Ernährungserhebungsmethoden der NVS II im Vergleich Proceedings of the German Nutrition Society, Vol. 21, S. 92.

Flynn A, Moreiras O, Stehle P, Fletcher RJ, Müller DJ, Rolland V (2003). Vitamins and minerals: a model for safe addition to foods. Eur J Nutr. 42: 118-30.

Heinemann M, Willers J, Bitterlich N, Hahn A (2015). Verwendung von Nahrungsergän zungsmitteln mit Vitaminen und Mineralstoffen – Ergebnisse einer deutschlandweiten Verbraucherbefragung. Journal für Verbraucherschutz und Lebensmittelsicherheit 10: 131-142.

Kloosterman J, Fransen HP, de Stoppelaar J, Verhagen H, Rompelberg C (2007). Safe addition of vitamins and minerals to foods: setting maximum levels for fortification in the Netherlands. Eur J Nutr. 46: 220-9.

Krems C, Bauch A, Götz A, Heuer T, Hild A, Möseneder J, Brombach C (2006). Methoden der Nationalen Verzehrsstudie II. Ernährungs-Umschau. 53: 44-50.

Mensink GBM, Heseker H, Richter A, Stahl A, Vohmann C (2007). Ernährungsstudie als KiGGS-Modul (EsKiMo). Robert Koch-Institut, Universität Paderborn.

MRI (2008a). Max Rubner-Institut. Nationale Verzehrstudie II, Ergebnisbericht, Teil 1. Max Rubner-Institut, Bundesforschungsinstitut für Ernährung und Lebensmittel.

MRI (2008b). Max Rubner-Institut. Nationale Verzehrstudie II, Ergebnisbericht, Teil 2. Max Rubner-Institut, Bundesforschungsinstitut für Ernährung und Lebensmittel.

Rasmussen SE, Andersen NL, Dragsted LO, Larsen JC (2006). A safe strategy for addition of vitamins and minerals to foods. Eur J Nutr. 45: 123-35.

Römer K, Heuer T (2017). Mehrfacheinnahme von Nahrungsergänzungsmitteln (NVS II). Bericht des Max Rubner-Instituts vom 12.05.2017.

Willers J, Heinemann M, Bitterlich N, Hahn A (2015). Welche Bedeutung besitzt die Mehrfachverwendung von Nahrungsergänzungsmitteln? Daten einer deutschlandweiten Verbraucherbefragung. J Verbr Lebensm. 11: 43–51.

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States (‘Laender’) on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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