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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<sub>1</sub>, B<sub>2</sub>, 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<sub>6</sub>:

<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<sub>12</sub>:

<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>

# The BfR's recommended maximum levels for vitamins and minerals in food supplements and fortified foods

Year	... food supplements* (per daily recommended intake of a product)		... fortified foods for general consumption			
<b>Vitamin A</b>						
2021	Option 1	No addition	Margarine and blended fat products	1.0 mg/100 g		
	Option 2	0.2 mg	Other foods for general consumption	No addition		
<b>! Recommended note:</b> Vitamin A supplementation during pregnancy only after medical consultation.						
2004	For adults	0.4 mg	Margarine and blended fat products	1.0 mg/100 g		
	For children between 4 and 10 years old	0.2 mg	Other foods for general consumption	No addition		
<b>Beta-carotene</b>						
2021		3.5 mg	<b>Option 1:</b> Assuming that only 15 % of daily energy intake is ingested from fortified foods:			
			Solid foods	1.7 mg/100 g		
			Drinks	0.45 mg/100 ml		
			<b>Option 2:</b> Limit addition to “breakfast cereals”, “dairy products” and “juices and soft drinks” with maximum levels corresponding to 15 % and 7.5 % of the reference value for labelling:			
2021		3.5 mg	Solid foods	0.72 mg/100 g		
			Drinks	0.36 mg/100 ml		
2004		2.0 mg	<b>Option 3:</b> Restriction of the addition of beta-carotene for nutritional purposes to <b>solid</b> foods			
				No addition		
<b>Vitamin D</b>						
2021		20 µg	Milk and dairy products, including cheese	1.5 µg/100 g		
			Bread and cereals (excluding pastries)	5.0 µg/100 g		
			Spreadable fats and cooking oil	7.5 µg/100 g		
			UV-irradiated edible mushrooms <sup>1</sup>	10.0 µg/100 g		
			UV-irradiated milk <sup>1</sup>	3.2 µg/100 g		
			Other foods for general consumption	No addition		
2004	For people < 65 years old	5 µg	Margarine and blended fat products	2.5 µg/100 g		
			For people > 65 years old	10 µg	Cooking oils	20 µg/l
					Other foods for general consumption	No addition

\* The proposed maximum levels refer to adults (2004) or people over the age of 15 and adults (2021) unless otherwise indicated.

# The BfR's recommended maximum levels for vitamins and minerals in food supplements and fortified foods

Year	... food supplements* (per daily recommended intake of a product)	... fortified foods for general consumption	
<b>Vitamin E</b>			
2021	30 mg	Solid foods Drinks	
		7 mg/100 g 2 mg/100 ml	
2004	15 mg	15 mg**	
		<i>! Consider limiting addition to individual food groups and linking addition to the food's polyene fatty acid content</i>	
<b>Vitamin K</b>			
2021	Vitamin K <sub>1</sub>	80 µg	No addition
	Vitamin K <sub>2</sub>	25 µg	
	<i>! Recommended note: People taking anticoagulant drugs should seek medical advice before taking any food supplements that contain vitamin K.</i>		
2004	80 µg	80 µg**	
<b>Vitamin B<sub>1</sub></b>			
2021	No maximum levels	No maximum levels	
2004	4 mg	1.3 mg**	
<b>Vitamin B<sub>2</sub></b>			
2021	No maximum levels	No maximum levels	
2004	4.5 mg	1.5 mg**	
<b>Niacin</b>			
2021	Nicotinamide	160 mg	Nicotinamide
			37 mg/100 g 10 mg/100 ml
	<i>! For products with a daily recommended dose of more than 16 mg per food supplement: Note that pregnant women should refrain from taking such products (possibly also including a justification, if applicable)</i>		
	Nicotinic acid	4.0 mg	Nicotinic acid
	Inositol hexanicotinate	4.4 mg	Inositol hexanicotinate
			No addition No addition
2004	Nicotinamide	17 mg	Nicotinamide
	Nicotinic acid	No addition	Nicotinic acid
			17 mg** No addition

\* The proposed maximum levels refer to adults (2004) or people over the age of 15 and adults (2021) unless otherwise indicated.

\*\* Related to the expected daily intake of a food.

# The BfR's recommended maximum levels for vitamins and minerals in food supplements and fortified foods

Year	... food supplements* (per daily recommended intake of a product)	... fortified foods for general consumption		
<b>Vitamin B<sub>6</sub></b>				
2021	3.5 mg	Solid foods	0.85 mg/100 g	
		Drinks	0.23 mg/100 ml	
2004	5.4 mg		1.2–1.6 mg**	
<b>Pantothenic acid</b>				
2021	No maximum levels	No maximum levels		
2004	18 mg		6 mg**	
<b>Vitamin B<sub>12</sub></b>				
2021	25 µg	Solid foods	6 µg/100 g	
		Drinks	1.6 µg/100 ml	
2004	3–9 µg	<i>! Consider limiting vitamin addition to certain food groups</i>		
<b>Folic acid</b>				
2021	For women of child-bearing age and pregnant women in the first trimester to reduce the risk of neural tube defects	200 µg	<b>Option 1:</b> Assuming that only 15 % of daily energy intake is ingested from fortified foods:	
		400 µg	Solid foods	80 µg/100 g
			Drinks	20 µg/100 ml
				<b>Option 2:</b> (Corresponds to 15 % or 7.5 % of the reference value for labelling)
		400 µg	Solid foods	30 µg/100 g
			Drinks	15 µg/100 ml
				<b>Option 3:</b> Restriction to ...
		400 µg	Breakfast cereals and dairy products	50 µg/100 g or 100 ml
Juices and soft drinks	15 µg/100 ml			
		<b>Option 4:</b> Restriction to ...		
2004	400 µg	Solid foods	80 µg/100 g	
			200 µg**	

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\*\* Related to the expected daily intake of a food.

# The BfR's recommended maximum levels for vitamins and minerals in food supplements and fortified foods

Year	... food supplements* (per daily recommended intake of a product)	... fortified foods for general consumption	
<b>Biotin</b>			
2021	No maximum levels <b>! Recommended note</b> on food supplements containing biotin: People who have to undergo laboratory testing should inform their doctor or the laboratory staff that they are taking/have recently taken biotin.	No maximum levels	
2004	180 µg		60 µg**
<b>Vitamin C</b>			
2021	250 mg	Solid foods	60 mg/100 g
		Drinks	16 mg/100 ml
2004	225 mg		100 mg**
<b>Sodium</b>			
2021	No addition for nutritional purposes	<b>! Exception:</b> Special drinks to offset increased sodium losses	No addition  1,150 mg/l (Minimum quantity: 460 mg/l)
2004	No addition for nutritional purposes	<b>! Exception:</b> Drinks that are specifically intended to offset significant losses in healthy consumers (e.g., as a result of increased sweating)	No addition
<b>Chloride</b>			
2021	No addition for nutritional purposes	No addition for nutritional purposes	
2004	No addition for nutritional purposes	No addition for nutritional purposes	

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\*\* Related to the expected daily intake of a food.

# The BfR's recommended maximum levels for vitamins and minerals in food supplements and fortified foods

Year	... food supplements* (per daily recommended intake of a product)	... fortified foods for general consumption				
<b>Potassium</b>						
2021	500 mg	<b>Option 1:</b> As an exception, non-significant maximum levels could be accepted, assuming that 30 % of daily energy comes from fortified foods: <table border="1" data-bbox="1025 491 2163 582"> <tr> <td>Solid foods</td> <td>120 mg/100 g</td> </tr> <tr> <td>Drinks</td> <td>32 mg/100 ml</td> </tr> </table>	Solid foods	120 mg/100 g	Drinks	32 mg/100 ml
		Solid foods	120 mg/100 g			
		Drinks	32 mg/100 ml			
		<b>or</b> Assuming that only 15 % of daily energy is ingested from fortified foods: <table border="1" data-bbox="1025 657 2163 748"> <tr> <td>Solid foods</td> <td>240 mg/100 g</td> </tr> <tr> <td>Drinks</td> <td>64 mg/100 ml</td> </tr> </table>	Solid foods	240 mg/100 g	Drinks	64 mg/100 ml
Solid foods	240 mg/100 g					
Drinks	64 mg/100 ml					
<b>Option 2:</b> Limit to selected food groups when using significant amounts of potassium: <table border="1" data-bbox="1825 823 2163 898"> <tr> <td> <math>\geq 300</math> mg/100 g or  <math>\geq 150</math> mg/100 ml                 </td> </tr> </table>	$\geq 300$ mg/100 g or $\geq 150$ mg/100 ml					
$\geq 300$ mg/100 g or $\geq 150$ mg/100 ml						
<b>Option 3:</b> No addition of potassium for nutritional purposes. Under this condition, the available residual amount of a total of 2,000 mg/day could be allocated to the food supplement category alone. <table border="1" data-bbox="1825 1002 2163 1042"> <tr> <td>No addition</td> </tr> </table>	No addition					
No addition						
2004	500 mg	<b>! Exception:</b> For the purpose of restoration (to offset potassium losses that occur during food processing) possibly with simultaneous reduction of the salt content in processed foods. <table border="1" data-bbox="1825 1002 2163 1042"> <tr> <td>No addition</td> </tr> </table>	No addition			
No addition						
<b>Calcium</b>						
2021	500 mg <b>! For supplements with more than 250 mg calcium per daily dose of a product: Note that the consumption of another food supplement containing calcium should be avoided</b>	Limit fortification to products consumed as substitutes for foods naturally rich in calcium, such as substitutes for milk and dairy products: Maximum levels amounting to the natural "equivalent", e.g. addition of calcium to a milk substitute drink: <table border="1" data-bbox="1825 1265 2163 1305"> <tr> <td>120 mg/100 ml</td> </tr> </table>	120 mg/100 ml			
120 mg/100 ml						
2004	500 mg	Limit fortification to dairy product substitutes to which calcium is added in amounts comparable to the concentration in dairy products or specially labelled drinks (30 % of the reference value for labelling/100 g or 100 ml)				

\* The proposed maximum levels refer to adults (2004) or people over the age of 15 and adults (2021) unless otherwise indicated.

# The BfR's recommended maximum levels for vitamins and minerals in food supplements and fortified foods

Year	... food supplements* (per daily recommended intake of a product)	... fortified foods for general consumption	
<b>Phosphorus/phosphate</b>			
2021	No addition for nutritional purposes	No addition for nutritional purposes	
2004	Phosphate 250 mg	No addition for nutritional purposes	
<b>Magnesium</b>			
2021	250 mg <b>! Note:</b> It is recommended to divide this amount into two or more servings per day	Solid foods	31 mg/100 g
		Drinks	8 mg/100 ml
2004	250 mg <b>! Note:</b> Divide into two single doses, if necessary	Solid foods and drinks 15–28 mg/100 kcal or 22.5 mg/100 ml	
<b>Iron</b>			
2021	6 mg <b>! Note</b> indicating that men, post-menopausal women and pregnant women should only take iron after consulting a doctor	<b>Option 1</b>	No addition
		<b>Option 2:</b> Limit addition to “breakfast cereals” and set a maximum level conforming to the fortification practice established in Germany regarding the iron content and the iron compounds used.	
2004	No addition	No addition	
<b>Iodine</b>			
2021	100 µg For pregnant and breastfeeding women	Table salt	2,500 µg/100 g
	150 µg	<b>! Note:</b> Even at 3,000 µg/100 g, no health impairments are expected according to BfR Opinion No. 005/2021 of 9 February 2021	
		Other foods for general consumption	No addition
2004	100 µg <b>! Note:</b> This limit does not apply to dietetic food supplements, e.g., for pregnant and breastfeeding women.	No fortification of foods for general consumption Limit to iodised salt 2,500 µg/100 g	
<b>Fluoride</b>			
2021	No addition	Table salt	0.25 mg/g
		Other foods for general consumption	No addition
2004	No addition	Table salt	0.25 mg/g
		Other foods for general consumption	No addition

\* The proposed maximum levels refer to adults (2004) or people over the age of 15 and adults (2021) unless otherwise indicated.

# The BfR's recommended maximum levels for vitamins and minerals in food supplements and fortified foods

Year	... food supplements* (per daily recommended intake of a product)	... fortified foods for general consumption	
<b>Zinc</b>			
2021	6.5 mg		No addition
2004	2.25 mg <i>! Note: No supplementation for children and adolescents under the age of 17</i>		No addition
<b>Selenium</b>			
2021	45 µg	Option 1: Assuming that 30 % of daily energy is ingested from fortified foods and fortification is limited to <b>solid</b> foods:	10 µg/100 g
		Option 2: Assuming that only 15 % of daily energy is ingested from fortified foods:	
		Solid foods	22 µg/100 g
		Drinks	6 µg/100 ml
2004	25–30 µg		No addition
<b>Copper</b>			
2021	1 mg <i>! Consumer information: Not for children and adolescents</i>		No addition
2004	No addition		No addition
<b>Manganese</b>			
2021	0.5 mg		No addition
2004	No addition		No addition
<b>Chromium</b>			
2021	60 µg	Solid foods	15 µg /100 g
		Drinks	4 µg /100 ml
2004	60 µg		No addition

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# The BfR's recommended maximum levels for vitamins and minerals in food supplements and fortified foods

Year	... food supplements* (per daily recommended intake of a product)	... fortified foods for general consumption
<b>Molybdenum</b>		
2021	80 µg	Assuming that 30 % of daily energy is ingested from fortified foods: Solid foods Drinks
		19 µg /100 g 5 µg /100 ml
2004	80 µg <i>! Note: Proposed maximum level not for children up to and including ten years of age</i>	No addition
<b>Boron</b>		
2021	0.5 mg <i>! Note: Not for children and adolescents</i>	No addition
2004	<i>Not taken into account when maximum levels were derived</i>	<i>Not taken into account when maximum levels were derived</i>
<b>Silicon</b>		
2021	For the addition of ... Silicon dioxide 350 mg Silicic acid (silica gel) 100 mg Choline-stabilised orthosilicic acid 10 mg Organic silicon (monomethylsilanetriol) 10 mg <sup>2</sup> <sup>2</sup> Safe intake level for daily intake, approved in the context of novel food authorisation procedure	Silicon compounds have not been approved for fortification so far, therefore no addition proposed here
2004	<i>Not taken into account when maximum levels were derived</i>	<i>Not taken into account when maximum levels were derived</i>

## References

BfR (2021). Stellungnahme Nr. 005/2021 des BfR vom 9. Februar 2021. Rückläufige Jodzufuhr in der Bevölkerung: Modellszenarien zur Verbesserung der Jodaufnahme (German only): [www.bfr.bund.de/cm/343/ruecklaeufige-jodzufuhr-in-der-bevoelkerung-modellszenarien-zur-verbesserung-der-jodaufnahme.pdf](http://www.bfr.bund.de/cm/343/ruecklaeufige-jodzufuhr-in-der-bevoelkerung-modellszenarien-zur-verbesserung-der-jodaufnahme.pdf); last accessed: 03.03.2021.

Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods by the BfR (2021): [www.bfr.bund.de/cm/349/updated-recommended-maximum-levels-for-the-addition-of-vitamins-and-minerals-to-food-supplements-and-conventional-foods.pdf](http://www.bfr.bund.de/cm/349/updated-recommended-maximum-levels-for-the-addition-of-vitamins-and-minerals-to-food-supplements-and-conventional-foods.pdf)

Recommended maximum levels by the BfR (2004):  
[www.bfr.bund.de/cm/350/use\\_of\\_minerals\\_in\\_foods.pdf](http://www.bfr.bund.de/cm/350/use_of_minerals_in_foods.pdf)  
[www.bfr.bund.de/cm/350/use\\_of\\_vitamins\\_in\\_foods.pdf](http://www.bfr.bund.de/cm/350/use_of_vitamins_in_foods.pdf)

\* The proposed maximum levels refer to adults (2004) or people over the age of 15 and adults (2021) unless otherwise indicated.

## 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<sup>1</sup> (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'<sup>2</sup>:

- 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

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<sup>1</sup> A tolerable upper intake level is the daily chronic intake of a nutrient considered tolerable

<sup>2</sup> 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<sup>3</sup>.

### 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<sup>4</sup>.

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

<sup>3</sup> Also accounted for here was the fact that children in general also have lower energy intakes than adults.

<sup>4</sup> 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<sup>5</sup>.

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:

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

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.

<sup>5</sup> <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<sub>food supplements (FS)</sub>

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:

$$\text{maximum level}_{\text{FS}} = \frac{\text{residual amount}_{\text{FS}}}{\text{UF}}$$

##### 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



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

The 'residual amount<sub>FF</sub>' 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<sup>6</sup>. 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.

<sup>6</sup> 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/NFCS 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 exempted from fortification with micronutrients, so as to enable the addition of significant amounts  $\geq 15\%$  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<sup>7</sup>)
  - 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).

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<sup>7</sup> 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](https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html)



BfR 'Opinions app'

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## 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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