Proposed maximum levels for the addition of vitamin D to foods including food supplements

The accompanying main opinion "**Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods**" can be found here: 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

1 Results

The German Federal Institute for Risk Assessment (BfR) recommends the following maximum amounts for vitamin D for the addition to food supplements and for the fortification of conventional foods (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplement (per daily recommended dose of an individual product)	20.0 µg
Milk and milk products, including cheese (per 100 g)	1.5 µg
Bread and cereal products (except pastry) (per 100 g)	5.0 µg
Spreadable fats and edible oils (per 100 g)	7.5 µg
UV-irradiated edible mushrooms* (per 100 g)	10.0 µg
UV-irradiated milk* (per 100 g)	3.2 µg
Other food (per 100 g)	no addition

* UV-irradiated foods are subject to Regulation (EC) 258/97 on Novel Foods. The authorisations to place these foods on the market refer only to the foods themselves and not to products made from them.

2 Rationale

2.1 Tolerable Upper Intake Level[1] (UL) and Dietary Reference Value

The Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) of the European Food Safety Authority (EFSA) has derived a UL (EFSA, 2012) and Adequate Intake (AI) values (EFSA, 2016; Table 2).

In Germany, the D-A-CH Societies[2] derived dietary reference values for vitamin D in 2012 (D-A-CH, 2015), which differ from the previous reference values in that the endogenous synthesis of vitamin D through sun exposure of the skin is no longer taken into account (Table 2).

Table 2: Dietary reference values (estimated values for adequate vitamin D intake in the absence of endogenous synthesis) and UL

Age	Dietary reference values		UL
	DGE (2012)	EFSA (2016)	EFSA (2012)
	µg/day		

[1] Tolerable Upper Intake Level = Maximum level of total chronic daily intake of a nutrient (from all sources) considered to be unlikely to pose a risk of adverse health effects to humans.

[2] German-Austrian-Swiss Nutrition Societies

1 to 10 years	20	15	50*
from 11 years old and adults	20	15	100

* The derivation of maximum levels for the addition of vitamin D to foods is based on the UL for children 1-10 years of age of 50 µg/day.

2.2 Exposure

The vitamin D status (internal exposure) is best determined by the serum concentration of 25-hydroxyvitamin D_3 (25-OH-D_3), as this reflects both the dietary intake and the endogenous synthesis. With regular outdoor exposure, endogenous synthesis in the skin is the main contributor to vitamin D supply (80% to 90%), while oral intake makes only a minor contribution (10% to 20%) (Holick, 2007; Linseisen et al., 2011). The dietary reference value for vitamin D of the D-A-CH Societies corresponds to a plasma concentration of 50 nanomoles per litre (nmol/l) 25-OH-D3.

Tables 3 and 4 provide an overview of the standardised mean serum concentrations in Germany from data of the German Health Interview and Examination Survey for Adults (DEGS1) and the German Health Interview and Examination Survey for Children and Adolescents (KiGGS), stratified by age groups and gender. Data were classified according to the thresholds proposed by the former US Institute of Medicine (IOM) for Vitamin D supply levels, i.e. "adequate for bone health" (≥ 50 nmol/l), "increased risk of inadequate bone health" (30-50 nmol/l), and "increased risk of rickets in children or osteomalacia in adults" (< 30 nmol/l). Based on serum levels, under current conditions approximately 33 to 52% of adults and 40 to 80% of children achieve 25-OH-D_3 serum concentrations at or above the dietary reference value (Tables 3 and 4).

Table 3: Vitamin D status of adult women and men in Germany (DEGS)

Gender and age	Mean serum 25(OH)D concentrations in nmol/l	Categories of 25-OH-D_3 concentrations according to IOM (2011) in %		
		< 30 nmol/l	30- < 50 nmol/l	≥ 50 nmol/l
Women	**49.7**	**14.7**	**41.0**	**44.3**
18 – 29 years	54.2	14.4	34.6	51.0
30 – 39 years	51.5	18.7	33.0	48.3
40 – 49 years	50.0	14.8	39.3	45.9
50 – 59 years	48.1	14.9	42.2	42.9
60 – 69 years	48.4	9.8	48.5	41.7
70 – 79 years	45.2	15.9	51.1	33.0
Men	**49.3**	**15.7**	**40.5**	**43.7**
18 – 29 years	50.5	16.2	39.7	44.1
30 – 39 years	48.0	19.0	42.7	38.4
40 – 49 years	49.0	19.4	36.0	44.6
50 – 59 years	48.6	13.3	44.9	41.8
60 – 69 years	51.3	9.9	38.1	52.1
70 – 79 years	48.3	14.9	43.6	41.5

Table 4: Vitamin D status of children and adolescents in Germany (KiGGS)

Gender and age	Mean serum 25(OH)D concentrations in nmol/l	Categories of 25-OH-D_3 concentrations according to IOM (2011) in %		
		< 30 nmol/l	30- < 50 nmol/l	≥ 50 nmol/l
Girls	**53.2**	**12.5**	**33.5**	**54.0**

Gender and age	Mean serum 25(OH)D concentrations in nmol/l	Categories of 25-OH-D_3 concentrations according to IOM (2011) in %		
		< 30 nmol/l	30- < 50 nmol/l	≥ 50 nmol/l
0 – 2 years	63.8	5.7	19.7	74.6
3 – 6 years	55.3	9.1	31.8	59.1
7 – 10 years	51.4	12.2	36.7	51.1
11 – 13 years	46.7	18.9	41.4	39.6
14 – 17 years	53.5	13.9	32.0	54.2
Boys	**53.7**	**12.5**	**32.7**	**54.8**
0 – 2 years	66.3	4.9	15.5	79.6
3 – 6 years	54.6	11.5	31.5	57.0
7 – 10 years	53.8	10.9	31.6	57.5
11 – 13 years	52.1	11.0	39.2	49.8
14 – 17 years	49.4	18.3	36.8	44.9

2.3 Aspects considered in the derivation of maximum levels for food supplements

An amount of 20 micrograms (µg) per daily recommended dose of an individual food supplement is proposed as a maximum level for food supplements. This amount results from the difference between the UL and the baseline consumption in the 95th percentile of 15- to 17-year-olds[3] (= 23 µg/day, rounded down to 20 µg/day).
The derived maximum level also corresponds to the estimated value for an adequate daily intake (without taking endogenous synthesis into account) derived by the D-A-CH Societies. It also corresponds to the level considered as nutritional or physiological in the context of nutrition/nutritional supplementation by the Joint Commission of Experts of the German Federal Office of Consumer Protection and Food Safety (BVL) and the German Federal Institute for Drugs and Medical Devices (BfArM) (BVL/BfArM, 2017).

2.4 Aspects considered in the derivation of maximum levels for fortified conventional foods

In the context of deriving maximum levels for fortification of conventional foods with vitamin D, a target mean intake of approx. 10 µg/day vitamin D[4] at the population level was aimed at. Another condition was that the 95th percentile of vitamin D intake should be below the UL of 50 µg/day for children in the age group of 1-10 years. Fortification levels were calculated according to a model proposed by Hirvonen et al. (2006), in which fortification of many foods with rather low amounts was shown to be more appropriate for achieving the targets than fortification of only a few foods with higher amounts of vitamin D. Suitable levels for addition were identified by modelling vitamin D intake in various scenarios, based on the assumption that about 30 % of the daily energy is taken up by consumption of fortified foods.

The model calculations were conducted by use of data from the National Food Consumption Survey (NFCS II; Diet-History-Interviews, MRI, 2008). For the addition of vitamin D, only

[3] $UL_{15\text{- to 17-year-olds}}$ - $P95_{\text{baseline consumption of 15- to 17-year-olds)}}$ = residual amount → 100 µg/day - 7 µg/day = 93 µg/day
Residual amount divided equally between food supplements and fortified foods
→ Residual $amount_{FS}$ = 46.5 µg/day; application of an uncertainty factor of 2 for possible multiple exposure: 46.5/ 2 = 23 µg/day

[4] Taking into account the expected intake distribution, high percentiles of intake (e.g. 95th percentile) would meet the dietary reference value of 20 µg per day. A higher mean vitamin D intake would, however, lead to respectively higher intakes and thus to an increased risk of exceeding the UL.

those foods were selected that are consumed regularly and with little variation by all population groups (bakery products, dairy products, spreadable fats and edible oils). Foods for which consumption varies greatly (peak foods), or that are consumed infrequently and in small quantities, that have an unfavourable nutrient profile (high fat and sugar content) or are usually stored for long periods of time and are consumed primarily for pleasure were not considered as suitable for fortification. Foods already fortified with vitamin D on the market were included in the fortification scenarios.

Appropriate fortification levels were identified based on the assumption that approximately 1 to 1.5 µg of vitamin D per 100 kilocalories (kcal) are to be added to a food.
To translate this into standardised maximum levels per 100 grams (g) of a food product, foods were aggregated into categories and the mean energy content of foods within these categories was calculated and rounded to the nearest 100. This value served as the basis for setting the respective maximum levels of vitamin D per 100 g of foods in each of the food categories considered.

The maximum levels determined were incorporated into the German Nutrient Data Base (BLS) 3.01 and, by use of consumption data from the NFCS II and the EsKiMo study (nutrition module in KiGGS[5] for children between 6 and 17 years of age), compliance with the above criteria was evaluated. In the worst case scenario (i.e. all fortified foods contain the maximum amount suggested for vitamin D and foods are consumed exclusively in their fortified form, including UV-treated milk and mushrooms), the vitamin D intake at the 95th percentile of adults would be approximately 37 µg/day and in children between 12 and 13 years 38 µg/day (Table 5).

Furthermore, it was examined whether the addition of the proposed maximum level of vitamin D in foods of the selected food groups complies with the provisions of Regulation 1169/2011/EC (for nutrient labelling, food must contain at least 15 % of the reference value (for vitamin D: 5 µg)), which was the case in all food groups.

Table 5: Vitamin D intake from the usual diet (base diet) and on the basis of three different fortification scenarios

Percentiles	Vitamin D intake in µg/day			
	VitD base diet	VitD base diet + fortified foods	VitD base diet + fortified foods + UV milk	VitD base diet + fortified foods + UV-milk + UV-mushrooms
NFCS II (14- to 80-year-olds) N = 15,371				
5	0.90	7.53	7.81	7.93
50	3.19	16.78	17.59	17.77
95	11.10	33.20	36.46	36.75
EsKiMo (only 12- to 13-year-old children) N = 416				
5	0.70	8.84	10.07	10.14
50	1.81	17.96	20.48	20.65
95	4.89	31.46	37.67	37.76

[5] German Health Interview and Examination Survey for Children and Adolescents

In the fortification scenario "VitD-base diet+fortified foods+UV-milk+UV-mushrooms", the calculated intake of vitamin D was above the UL of 50 µg/day in 1.5% of the children and above the UL of 100 µg/day in 0.01% of adults. As this is a worst-case scenario, the intakes of vitamin D to be actually expected as a consequence of the proposed maximum levels for the addition of vitamin D to conventional foods tend to be overestimated.

Further information on the BfR website on vitamin D

Vitamin D: Taking high-dose supplements unnecessary: https://www.bfr.bund.de/cm/349/vitamin-d-consumption-of-high-dose-food-supplements-is-unnecessary.pdf

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

"Opinions app" of the BfR

3 References

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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. It advises the German federal government and German federal 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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