Proposed maximum levels for the addition of vitamin B_6 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 a maximum level of 3.5 milligrams (mg) of vitamin B_6 per daily recommended intake of a food supplement (Table 1).

For the fortification of conventional foods, assuming a "saturated" market of fortified foods (30 % of the daily energy intake comes from fortified foods), a maximum level of 0.85 mg/100 g is recommended for solid foods and of 0.23 mg/100 millilitres (ml) for beverages (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	3.5 mg
Other fortified solid foods (per 100 g)	0.85 mg
Drinks (per 100 ml)	0.23 mg

2 Rationale

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

In 2000, the former Scientific Committee on Food (SCF) of the European Commission derived a UL for vitamin B_6 in view of the risk of neurological adverse effects (peripheral neuropathies) observed in a study by Dalton and Dalton (1987) with average doses of vitamin B_6 of about 100 mg per day. Applying uncertainty factors (two times a justified uncertainty factor of 2), a UL of 25 mg per day was established for adults. For children and adolescents, ULs ranging from 7 mg (4- to 6-year-olds) to 20 mg (15- to 17-year-olds) per day were derived as a function of body weight (SCF, 2000; Table 2).

For vitamin B_6, the recommended intake for adolescents from 15 years of age on and adults is between 1.4 and 1.6 mg per day (m) and 1.2 mg per day (f), depending on age (D-A-CH, 2015).

The European Food Safety Authority (EFSA) has derived population reference intakes (PRI) for vitamin B_6 of 1.7 mg/day for 15- to 17-year-olds and of 1.7 mg (males) and 1.6 mg (females) per day for adults (EFSA, 2016; Table 2).

[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.

Table 2: Dietary reference values and UL

Age groups	Dietary reference values		UL (SCF, 2000)
	(D-A-CH, 2015)	(EFSA, 2016)	
	mg/day		
4 to < 7 years	0.5	0.7	7
7 to < 10 years	0.7	1.0 (7 – 10 years)	10 (7 – 10 years)
10 to < 13 years	1.0	1.4 (11 – 14 years)	15 (11 – 14 years)
13 to < 15 years	1.4		
15 to < 19 years	1.6 (m) 1.2 (f)	1.7 (15 – 17 years)	20 (15 – 17 years)
Adults	1.4 - 1.5 (m) 1.2 (f)	1.7 (m) 1.6 (f)	25
Pregnant women	1.9	1.8	25
Lactating women	1.9	1.7	25

2.2 Exposure

Data on the intake of vitamin B_6 in Germany are available from the second National Food Consumption Survey (NFCS II). According to this study, the median daily intake for 14- to 18-year-olds was 2.6 mg (m) and 2.0 mg (f), and for adults it decreased with increasing age in the range of 2.0 to 2.6 (m) and 1.7 to 1.9 mg (f). The 95th percentiles for 14- to 18-year-olds were 6.3 mg (m) and 5.4 mg (f) per day, respectively, and for adults, decreasing with age, in the range of 3.4 to 6.8 mg (m) and 3.0 to 4.7 mg (f) per day, respectively (MRI, 2008).

Data for children and adolescents show that intakes of vitamin B_6 for 6- to 11-year-old boys were 1.4 to 1.6 mg per day at the median and for girls of the same age of 1.3 to 1.5 mg per day; the 95th percentiles of daily intake ranged from 2.9 to 3.8 mg (boys) and from 2.1 to 3.2 mg (girls). For 12- to 17-year-old boys and girls, median vitamin B_6 intakes ranged from 2.0 to 2.8 mg per day and from 1.8 to 1.9 mg per day, respectively; the 95th percentiles of intake for these age groups ranged from 5.7 to 7.6 mg and 5.0 to 6.6 mg per day, respectively (Mensink et al., 2007).

2.3 Maximum levels for vitamin B6 in food supplements and conventional foods

Taking into account the derivation procedure proposed by the BfR and under the requirement that food supplements be of no harm to consumers from 15 years of age, this results in a total "residual amount" of 13.7 mg per day to be divided equally between food supplements and conventional foods:

$$\text{Residual amount} = UL_{\text{15-to 17-year-olds}} - P95_{\text{diet 15-to 17-year-olds}}$$

$$\text{Residual amount} = 20\ \text{mg/day} - 6.3\ \text{mg/day} = 13.7\ \text{mg/day}.$$

Accordingly, rounded, 7 mg of vitamin B_6 is available for each of the two categories.

2.3.1 Maximum levels for vitamin B_6 in food supplements

Since a possible multiple intake of food supplements with vitamin B_6 cannot be excluded (Römer and Heuer, 2017), an uncertainty factor of 2 is taken into account in the derivation of maximum levels for food supplements, so that on the basis of the available data a maximum level of 3.5 mg results for the addition of vitamin B_6 to food supplements per daily recommended dose of an individual product (7 / 2 = 3.5).

The BfR recommends for the addition of vitamin B_6 to food supplements a maximum level of 3.5 mg per recommended daily dose of a single product.

2.3.2 Maximum levels for vitamin B_6 in conventional foods

For the fortification of conventional foods, a total amount of rounded 7 mg (residual $amount_{FF}$) is available for vitamin B_6. Allocating this amount to the estimated daily energy intake from fortified foods and assuming that 15 % to a maximum of 30 % of the daily energy is consumed from fortified foods, this results in maximum levels of vitamin B_6 of between 0.5 and 2.3 mg/100 kilocalories (kcal), depending on age (Table 3).

In order to ensure that the addition of vitamin B_6 to conventional foods does not cause any of the age groups to exceed the residual $amount_{FF}$ of 7 mg per day, the lowest of the vitamin B_6 levels resulting from the calculations in Table 3 is proposed as the maximum level for the whole population, i.e.: 0.5 mg/100 kcal assuming that the market of fortified foods is "saturated" (30 % of the daily energy come from fortified foods) and 1.0 mg/100 kcal assuming that only a part of the fortifiable foods is actually fortified/consumed (15 % of the energy intake comes from fortified foods) (Table 3).

Table 3: Daily energy intake (P95) and levels of vitamin B_6 assuming that 15 % or 30 % of the energy intake comes from fortified foods

Age groups	Energy intake*	Fortification of 15 % of the energy intake		Fortification of 30 % of the energy intake	
		15 % of daily energy intake	Vitamin B_6**	30 % of daily energy intake	Vitamin B_6**
	kcal/day	*kcal*	*mg/100 kcal*	*kcal*	*mg/100 kcal*
4 to 6 years	2,000	300	2.3	600	1.2
7 to 9 years	2,400	360	1.9	720	1.0
10 to 11 years	2,550	383	1.8	765	0.9
12 years	3,900	585	1.2	1,170	0.6
13 to < 15 years	3,900	585	1.2	1,170	0.6
15 to < 17 years	4,700	705	1.0	1,410	0.5
Adults	3,500	525	1.3	1,050	0.7

* Data for children (P 95) up to the age of 17 years from EsKiMo (Mensink et al., 2007), for adults (P 95) from NFCS II (MRI, 2008).

** if the residual amount of 7 mg/day is allocated to 100 kcal-servings

2.3.2.1 Conversion of energy-based maximum levels into maximum levels per 100 g of solid foods or 100 ml of beverages

The conversion of energy-based maximum levels into maximum amounts per 100 g of solid foods or 100 ml of beverages was performed using data from Schusdziarra et al. (2010) and Bechthold (2014).

Taking into account the average energy densities (170 kcal/100 g for solid foods and 45 kcal/100 ml for energy-dense liquids such as juices and soft drinks), the maximum amounts by weight and by volume for the addition of vitamin B_6 to conventional foods are given in the following table (Table 4).

Table 4: Conversion of energy-based to weight and volume-based maximum levels

Vitamin B_6 per 100 kcal	**Vitamin B_6 per 100 g or ml**	
	Solid foods (energy density: 170 kcal/100 g)	**Beverages** (energy density: 45 kcal/100 ml)
1.0 mg	1.7 mg	0.45 mg
0.5 mg	0.85 mg	0.23 mg

If one considers as an additional criterion in setting maximum levels that the amounts of vitamins added to a food should be significant in order to be allowed to be claimed in the labelling of the product in accordance with the Regulation (EU) No 1169/2011[2], Annex XIII: Reference values, at least 15 % of the respective reference value for labelling must be contained in solid foods (per 100 g) and at least 7.5 % of the respective reference value in beverages (per 100 ml).

In the above-mentioned Regulation, the nutrient reference value (NRV) for vitamin B_6 is 1.4 mg. Accordingly, additions of vitamin B_6 of ≥ 0.21 mg/100 g (at least 15 % of the NRV in solid foods) and ≥ 0.1 mg/100 ml (at least 7.5 % of the NRV in beverages) would be considered as significant. The maximum levels calculated in Table 4 meet these criteria for labelling and claiming of added vitamin B_6.

For the fortification of conventional foods, assuming a "saturated" market of fortified foods (30 % of daily energy intake comes from fortified foods), a maximum level of 0.85 mg/100 g is recommended for solid foods and 0.23 mg/100 ml for beverages. Assuming that only a smaller proportion of fortifiable foods are actually fortified/consumed (15 % of energy intake from fortified foods), higher maximum levels of 1.7 mg/100 g for solid foods and 0.45 mg/100 ml for beverages would be possible (Table 4).

[2] Conditions for claiming products with the claim "source of..." or "rich in...", according to EU Regulation 1924/2006 (Health Claim Regulation)

Further information on the BfR website on vitamins

A-Z Index on vitamins: https://www.bfr.bund.de/en/a-z_index/vitamins-130216.html

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

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3 References

Bechthold A (2014). Dietary energy density and body weight. Ernährungs Umschau international. 1: M14-23.

D-A-CH (2019). German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society (eds.). Dietary Reference Values. Complete revision of the chapters Vitamin B6 and Zinc in the 2nd version of the 1st edition 2019, German Nutrition Society, Bonn.

Dalton K, Dalton MJT (1987). Characteristics of pyridoxine overdose neuropathy syndrome. Acta Neurol Scand. 76: 8-11.

EFSA (2016). Dietary Reference Values for Vitamin B_6. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). Adopted: 21 April 2016, EFSA Journal. 14: 4485. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4485/epdf, last accessed 04 March 2021.

Mensink GBM, Heseker H, Richter A, Stahl A, Vohmann C (2007). Research report nutrition study as KiGGS module (EsKiMo). Robert Koch Institute, 13353 Berlin, University of Paderborn, 33098 Paderborn.

MRI (2008). Max Rubner Institute. National Nutrition Survey II, Results Report, Part 2. Max Rubner-Institut, Federal Research Institute of Nutrition and Food.

Römer K, Heuer T (2017). Multiple intake of NEM (NVS II). Report of the Max Rubner Institute from 12.05.2017.

SCF (2000). Scientific Committee on Food. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B_6. https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out80c_en.pdfhttp://ec.europa.eu/food/fs/sc/scf/out80c_en.pdf, last accessed 4 March 2021.

Schusdziarra V, Kellner M, Mittermeier J, Hausmann M, Erdmann J (2010). Energy intake, food quantity, and frequency of consumption of main and snack meals in normal-weight individuals. Aktuel Ernahrungsmed. 35: 29-41.

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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