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Update (2024): Proposed maximum levels for Vitamin B₆ in foods including food supplements

→ Updates the annex to vitamin B₆ of opinion no. 009/2021 of 15 March 2021

The term vitamin B₆ refers to a range of chemically related compounds with vitamin activity, namely pyridoxine, pyridoxal and pyridoxamine as well as the associated coenzymes pyridoxal phosphate and pyridoxamine phosphate. Vitamin B₆ is water-soluble and is naturally present in many foods of both animal and plant origin.

Furthermore, in the European Union, certain forms of vitamin B₆ may be used in food supplements and to fortify foods intended for general consumption. The German Federal Institute for Risk Assessment (BfR) has proposed maximum levels for these uses - most recently in 2021.

In 2023, the European Food Safety Authority (EFSA) revised its risk assessment of vitamin B₆ and reduced the previous Tolerable Upper Intake Level (UL) for adults from 25 to 12 mg per day. The BfR has now taken this as an opportunity to update its proposed maximum levels for vitamin B₆ in food supplements and fortified foods.

The proposed maximum levels are intended for regulatory authorities and are to serve as a basis for setting binding maximum levels at EU level.

The accompanying main opinion 'Updated proposed maximum levels for vitamins and minerals in food supplements and fortified foods' can be found [here](#).

1 Result

The German Federal Institute for Risk Assessment (BfR) recommends a maximum level of 0.9 milligrams (mg) of vitamin B₆ per daily recommended intake of a food supplement for people aged 15 and over (Table 1).

Table 1: Proposed maximum levels for vitamin B₆

Food category	Maximum level
Food supplement (per daily recommended intake of an individual product)	0.9 mg

For the fortification of conventional foods with vitamin B₆, the calculations resulted in maximum levels that would have to be classified as non-significant in accordance with Regulation (EU) No. 1169/2011 and therefore may not be labelled according to the current legal situation (Regulation (EC) No. 1924/2006). In view of this, the BfR proposes the following options for setting maximum levels for the fortification of conventional foods with vitamin B₆:

- Option 1:** Based on the assumption of a ‘saturated’ market for fortified foods (30% of daily energy intake in the form of fortified foods), a maximum level of 0.27 mg/100 grams (g) is recommended, while limiting fortification to solid foods.
- Option 2:** With the assumption that only a proportion of fortifiable foods will actually be fortified with vitamin B₆ in the future (15% of energy intake in the form of fortified foods), higher maximum levels for the addition of vitamin B₆ would be possible: 0.54 mg/100 g for solid foods and 0.14 mg/100 millilitres (ml) for beverages. The level of protection under this option would be lower than with an assumption of a saturated market.

2 Rationale

2.1 Tolerable Upper Intake Level¹ (UL) and Dietary Reference Value

The former *Scientific Committee on Food* (SCF) of the EU Commission had derived a UL for the total daily intake of vitamin B₆ in 2000, in view of an existing relevant risk of the occurrence of neurological adverse effects (peripheral sensory neuropathies) (SCF, 2000). This derivation was derived, amongst other things, from data from a study by Dalton and Dalton (1987) involving moderate doses of vitamin B₆ in the region of 100 mg per day.

In 2023, EFSA reassessed the scientific data on vitamin B₆ and reduced the previous UL for adults from 25 to 12 mg per day based on the study by Dalton and Dalton (1987) already considered by the SCF (2000) and further human data from case reports and animal experimental findings from a study with beagle dogs (Phillips et al., 1978), which support the human data (EFSA, 2023). The occurrence of peripheral neuropathies was again selected as the endpoint.

For children and adolescents, lower ULs ranging from 4.5 mg (4 to 6-year-olds) to 10.7 mg (15 to 17-year-olds) per day were derived based on body weight (allometric scaling: body weight in kg^{0.75}) (EFSA, 2023; Table 2).

¹ *Tolerable Upper Intake Level* = tolerable upper limit for the daily chronic intake of a nutrient

For vitamin B₆, the recommended intake for adolescents aged 15 and over and adults is between 1.4 mg (women) and 1.6 mg (men) per day (D-A-CH, 2019). The EFSA has derived *population reference intakes* (PRI) for vitamin B₆ of 1.7 mg per day for 15- to 17-year-olds and 1.7 mg (men) and 1.6 mg (women) per day for adults (EFSA, 2016; Table 2).

Table 2: Dietary reference values (recommended intake) and UL

Age groups	Dietary reference values		UL (EFSA, 2023)
	D-A-CH (2019)	EFSA (2016)	
	mg/day		
4 to < 7 years	0.7	0.7	4.5
7 to < 10 years	1.0	1.0 (7-10 J.)	6.1 (7-10 J.)
10 to < 13 years	1.2	1.4 (11-14 J.)	8.6 (11-14 J.)
13 to < 15 years	1.5 (m)*, 1.4 (f)**		
15 to < 19 years	1.6 (m)*, 1.4 (f)**	1.7 (15-17 J.)	10.7 (15-17 J.)
Adults	1.6 (m)*, 1.4 (f)**	1.7 (m)*, 1.6 (f)**	12
Pregnant women			
1. Trimester	1.5	1.8	12
2nd + 3rd trimester	1.8		
Breastfeeding	1.6	1.7	12

* m = male, ** w = female

2.2 Exposure

Data on the intake of vitamin B₆ in Germany is available from the National Food Consumption Survey II (NFCS II). According to this, the median daily intake among 14- to 18-year-olds was 2.6 mg (male) and 2.0 mg (female), whilst for adults the domain ranged from 2.0 to 2.6 mg (male) and 1.7 to 1.9 mg (female), decreasing with increasing age. The 95th percentiles for 14- to 18-year-olds were 6.3 mg (m) and 5.4 mg (w) per day and for adults, decreasing with increasing age, in the range of 3.4 to 6.8 mg (m) and 3.0 to 4.7 mg (w) per day (MRI, 2008).

Data for children and adolescents from the EsKiMo II study show that the median intake of vitamin B₆ was 1.2 mg per day for 6- to 11-year-old boys and 1.0 to 1.1 mg per day for girls of the same age; at the 95th percentile, intakes were between 3.0 and 3.1 mg (boys) and between 2.1 and 2.4 mg (girls) per day. For 12- to 17-year-old boys and girls, the median vitamin B₆ intakes were found to be between 1.6 and 2.0 mg and 1.4 to 1.6 mg per day respectively; at the 95th percentile for these age groups, intakes ranged from 4.6 to 7.1 mg and 3.5 and 5.0 mg per day respectively (Mensink et al., 2021).

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

Taking into account the derivation method proposed by the BfR and on the condition that no impairments of health are to be expected from food supplements for all consumers over the age of 15, this results in a total 'residual amount' of 3.6 mg per day to be divided equally between food supplements and other fortified foods:

$$\text{residual amount}_{\text{Total}} = \text{UL}_{15\text{-to } 17\text{-year-olds}} - \text{P95}_{\text{diet (15- to 17-year-olds)}}$$

$$\text{residual amount}_{\text{Total}} = 10.7 \text{ mg/day} - 7.1 \text{ mg/day} = 3.6 \text{ mg/day}.$$

Accordingly, 1.8 mg of vitamin B₆ is available for each of the two categories.

2.3.1 Maximum levels for vitamin B₆ in food supplements

As the possibility of multiple intakes of food supplements containing vitamin B₆ cannot be ruled out (Römer and Heuer, 2017), an uncertainty factor of 2 is taken into account when deriving the maximum levels for food supplements, resulting in a maximum level for the addition of vitamin B₆ to food supplements of 0.9 mg in relation to the daily dose of a product ($1.8 \text{ mg}/2 = 0.9 \text{ mg}$).

The BfR recommends a maximum level of 0.9 mg per recommended daily intake for the addition of vitamin B₆ to food supplements for persons aged 15 years and over.

2.3.2 Maximum levels for vitamin B₆ in conventional foods for general consumption

For the fortification of other foods, a total amount of 1.8 mg (residual amount_{FF}) is available for vitamin B₆. Allocating this amount to the estimated daily energy intake from fortified foods and assuming that 15% to a maximum of 30% of daily energy is taken up from fortified foods, this results in maximum levels of vitamin B₆ between 0.16 and 0.60 mg/100 kilocalories (kcal), depending on age (Table 3).

In order to ensure that the addition of vitamin B₆ to conventional foods does not cause any age groups to exceed the residual amount_{FF} of 1.8 mg per day classified as safe for health, the lowest of the calculations for the entire population is proposed as the maximum level: 0.16 mg/100 kcal, with the assumption that the market for fortified foods is 'saturated' (30% of daily energy intake in the form of fortified foods) and 0.32 mg/100 kcal, under the assumption that only a proportion of fortified foods is actually fortified and consumed (15% of energy intake in the form of fortified foods) (Table 3).

Table 3 Daily energy intake (P95) and levels of vitamin B₆ 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	0.60	600	0.30
6 to 8 years	2.100	315	0.57	630	0.29
9 to 11 years	2.400	360	0.50	720	0.25
12 to 14 years	3.400	510	0.35	1.020	0.18
15 to 17 years	3.800	570	0.32	1.140	0.16
Adults	3.500	525	0.34	1.050	0.17

* Data for children (P 95) aged between 4 and 6 from VELS (Kersting et al., 2003; here: P 90) and EsKiMo (Mensink et al., 2007), for 6- to 17-year-olds from EsKiMo II (Mensink et al., 2021), for adults (P 95) from NFCS II (MRI, 2008)

** when dividing the remaining amount of 1.8 mg/day of LM into 100 kcal portions

2.3.2.1 Conversion of energy-based maximum levels to maximum levels per 100 g of solid food or 100 ml of beverages

The conversion of energy-based maximum levels into maximum levels per 100 g of solid food or 100 ml of beverages was carried out 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 levels by weight and by volume for the addition of vitamin B₆ to conventional foods are given in the following table (Table 4).

Table 4 Conversion of energy-based maximum levels 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)
0.16 mg*	0.27 mg	0.07 mg
0.32 mg**	0.54 mg	0.14 mg

* with the assumption that 30% of the energy is taken up from fortified foods

** assuming that 15% of energy is taken up from fortified foods

If, as an additional criterion in setting maximum levels, it is taken into account that the amounts of vitamins added to a food must be significant in order – under current legal situation² – to be permitted to be claimed on the product, then, in accordance with Regulation (EU) No. 1169/2011, Annex XIII (reference intakes), solid foods (per 100 g) must contain at least 15% and beverages (per 100 ml) at least 7.5% of the respective reference intake for labelling purposes.

The aforementioned Regulation specifies 1.4 mg as the nutrient reference value (NRV) for vitamin B₆. Accordingly, additions of vitamin B₆ amounting to ≥ 0.21 mg/100 g (at least 15% of the NRV in solid foods) and ≥ 0.11 mg/100 ml (at least 7.5% of the NRV in beverages) would be classified as significant.

The maximum levels calculated in Table 4 meet the criteria for the labelling and promotion of added vitamin B₆ in full only for the ‘unsaturated’ market scenario (15% of energy intake in the form of fortified foods).

The BfR proposes that, in cases where the fortification levels are non-significant, further foods (or categories of foods) – in addition to those specified in Article 4 of Regulation (EC) No. 1925/2006 – should be exempted from fortification. In the case of vitamin B₆, for example, it would be conceivable to restrict fortification to solid foods and to set a maximum level of 0.27 mg/100 g (corresponding to the assumption of a ‘saturated’ market or 30% of the daily energy intake in the form of foods fortified with vitamin B₆).

Another option would be to set a maximum amount of 0.54 mg/100 g for solid foods and 0.14 mg/100 ml for beverages (Table 4), under the assumption that only a proportion of the fortified food is actually fortified with or consumed as vitamin B₆ (15% of the energy intake in the form of fortified foods).

² Conditions for the labelling of products with the claim ‘source of...’ or ‘rich in...’, in accordance with EU Regulation 1924/2006 (Health Claims Regulation)

Further information on the BfR website regarding vitamins and food supplements

Topic page at microco.info on vitamin B₆
<https://www.microco.info/vitamins/vitamin-b6/>

Topic page on the assessment of vitamins and minerals in food:
<https://www.bfr.bund.de/en/food-safety/assessment-of-substance-risks-in-foods/assessment-of-vitamins-and-minerals-in-food/>

Questions and answers about food supplements:
<https://www.bfr.bund.de/en/service/frequently-asked-questions/topic/frequently-asked-questions-on-food-supplements/>

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