

## Maximum levels for the addition of vitamin B<sub>1</sub>, vitamin B<sub>2</sub> and pantothenic acid 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

For the vitamins B<sub>1</sub>, B<sub>2</sub> and pantothenic acid, no Tolerable Upper Intake Levels<sup>1</sup> (ULs) were derived and no adverse health effects were observed even at intakes far above the recommended intakes.

From the point of view of the German Federal Institute for Risk Assessment (BfR), based on the current state of knowledge, it is therefore not necessary to set maximum levels for these three vitamins for the addition to food supplements and fortification of conventional foods.

### 2 Rationale

#### 2.1 Vitamin B<sub>1</sub>

##### 2.1.1 Tolerable Upper Intake Level (UL) and Dietary Reference Value

In 2001, the former Scientific Committee on Food (SCF) of the European Commission, when evaluating vitamin B<sub>1</sub> to derive a Tolerable Upper Intake Level (UL), noted that very few human data on adverse effects from intake of thiamine were available and that no systematic dose-response studies had been conducted with this vitamin. Furthermore, the SCF pointed out that absorption of vitamin B<sub>1</sub> into the body decreases at doses of 5 milligrams (mg) per day or more and that ingested thiamine is excreted in the urine (SCF, 2001). Neither the SCF nor the then US Institute of Medicine (IOM) were able to define toxicological parameters such as a Lowest Observed Adverse Effect Level (lowest experimental dose at which there was an observed adverse effect on health; LOAEL) or a *No Observed Adverse Effect Level* (highest experimental dose at which there was not an observed adverse effect on health; NOAEL) on the basis of the available data and to derive a UL for vitamin B<sub>1</sub> (IOM, 2000; SCF, 2001).

Overall, on the basis of the available data from clinical studies and in view of the many years of experience with high vitamin B<sub>1</sub> doses, including in therapeutic use, it is assumed that the toxicity of vitamin B<sub>1</sub> is very low, and, in the context of total intakes observed in the general population, a risk of adverse health effects has not been identified (SCF, 2001).

The D-A-CH Societies<sup>2</sup> have derived recommended intakes for vitamin B<sub>1</sub>, taking into account the age- and gender-specific guidance values for energy intake and the values of physical activity levels (PAL) used to derive them. With PAL values of 1.4 and the corresponding guidance energy values, daily intakes of 0.7 to 1.4 mg (m) and 0.7 to 1.1 mg (f) are recommended for children and adolescents from 4 to under 19 years of age, and between

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<sup>1</sup> 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.

<sup>2</sup> German-Austrian-Swiss Nutrition Societies

1.1 mg and 1.3 mg (m) and 1.0 mg (f), respectively, for adults, depending on age (D-A-CH, 2019; Table 1).

The European Food Safety Authority (EFSA) published population reference intake values for vitamin B<sub>1</sub> intakes in 2016, recommending vitamin B<sub>1</sub> intakes of 0.4 mg per 1,000 kcal for all age groups, regardless of gender or special life situations such as pregnancy and lactation. At PAL values of 1.6 and the energy guidance values based on them, this corresponds to between 0.6 and 1.24 mg per day (m) and between 0.56 and 0.96 mg per day (f) for children and adolescents aged 4 to 17 years, and to between 0.96 and 1.13 mg per day (m) and between 0.78 and 0.91mg per day (f) for adults aged 18 years and older (EFSA, 2016; Table 1).

**Table 1: Dietary reference values (recommended intake)**

Age groups	Recommended intake (D-A-CH, 2019*)		Population Reference Intake (PRIs) (EFSA, 2016)	
	Male	female	Male	female
	mg/day			
4 to < 7 years	0.7		0.60–0.68	0.56–0.64
7 to < 10 years	0.9	0.8	0.73–0.82	0.68–0.76
10 to < 13 years	1.0	0.9	0.82–0.92	0.77–0.85
13 to < 15 years	1.2	1.0	0.99–1.06	0.89–0.92
15 to < 19 years	1.4	1.1	1.14–1.24**	0.94–0.96 (< 18 years)
Adults	1.1–1.3	1.0	0.96–1.13	0.78–0.91 (≥ 18 years)
Pregnant women				
1st trimester				+ 0.03
2nd trimester		1.2		+ 0.11
3rd trimester		1.3		+ 0.21
Lactating women		1.3		+ 0.21

\*last revised in 2015

### 2.1.2 Exposure

According to the second National Food Consumption Survey (NFCS) II, the median intake of vitamin B<sub>1</sub> in 14- to 18-year-old men and women in Germany is 1.9 and 1.4 mg per day, respectively. The 95th percentiles of intakes in this age group are 4.7 mg (men) and 3.7 mg (women) per day. Males and females 19 years of age and older have median intakes of between 1.3 and 1.8 mg per day and between 1.1 and 1.3 mg per day, respectively, depending on age. The 95th percentile for these men and women is between 2.4 and 4.9 mg per day and between 2.0 and 3.2 mg per day, respectively, decreasing with age (MRI, 2008).

Data for children and adolescents from the EsKiMo study (nutrition module KiGGS<sup>3</sup>) show that the median intake of vitamin B<sub>1</sub> in 6- to 11-year-old boys was between 1.1 and 1.3 mg per day and between 0.9 and 1.2 mg per day in girls of the same age; in the 95th percentile, vitamin B<sub>1</sub> intakes of these age groups were between 2.2 and 2.6 mg per day (boys) and between 1.6 and 2.3 mg per day (girls). For 12- to 17-year-old boys and girls, median intakes ranged from 1.7 to 2.2 mg per day and 1.4 and 1.5 mg per day, respectively; the 95th percentiles of vitamin B<sub>1</sub> intake in these age groups ranged from 4.0 to 5.1 mg per day in boys and from 4.1 to 4.6 mg per day in girls (Mensink et al., 2007).

### 2.1.3 Maximum levels for vitamin B<sub>1</sub> in food supplements and conventional foods

No UL was derived for vitamin B<sub>1</sub>, and no adverse health effects were observed even when high amounts were consumed. In view of the very low toxicity of vitamin B<sub>1</sub>, the BfR is of the opinion that it is presently not necessary to set a maximum level for this vitamin, both for food supplements and for fortification of conventional foods.

## 2.2 Vitamin B<sub>2</sub>

### 2.2.1 Tolerable Upper Intake Level (UL) and Dietary Reference Value

In view of the few human studies in which high doses of vitamin B<sub>2</sub> were administered, the data available for a reliable risk assessment on this vitamin are insufficient. The SCF has therefore not been able to derive a UL for vitamin B<sub>2</sub> (SCF, 2000). This also took into account a human study (of low quality) with intakes of 400 mg vitamin B<sub>2</sub> per day for three months, in which mild symptoms such as diarrhoea were reported by individual subjects, but these could not be clearly defined as vitamin B<sub>2</sub>-dependent adverse effects (SCF, 2000).

Intake recommendations for vitamin B<sub>2</sub> have been derived by the D-A-CH societies and are 0.8 mg per day for 4- to under-7-year-old boys and girls and between 1.0 and 1.6 mg per day (m) and between 0.9 and 1.2 mg per day (w) for the other age groups of children and adolescents up to under 19 years. For adult men and women, 1.3-1.4 mg per day and 1.0-1.1 mg per day, respectively, are recommended, depending on age (D-A-CH, 2019; Table 2). The intake reference values derived by EFSA for vitamin B<sub>2</sub> range from 0.7 to 1.6 mg per day for children and adolescents aged 4 to under 18 years and 1.6 mg per day for adult men and women, regardless of age (EFSA NDA Panel, 2017; Table 2).

**Table 2: Dietary reference values**

Age groups	Recommended intake (D-A-CH, 2019*)		Population Reference Intake (PRI) (EFSA, 2017)
	Male	female	
	mg/day		
4 to < 7 years	0.8		0.7
7 to < 10 years	1.0	0.9	1.0 (< 11 years)
10 to < 13 years	1.1	1.0	1.4 (≥ 11 years)
13 to < 15 years	1.4	1.1	
15 to < 19 years	1.6	1.2	1.6 (< 18 years)
Adults	1.3–1.4	1.0–1.1	1.6 (≥ 18 years)

<sup>3</sup> German Health Interview and Examination Survey for Children and Adolescents

Pregnant women		
2nd trimester	1,3	1.9
3rd trimester	1,4	
Lactating women	1,4	2,0

\* last revised in 2015

### 2.2.2 Exposure

According to the NFCS II, the median intake of vitamin B<sub>2</sub> in males and females aged 14 to 18 years is 2.2 mg per day and 1.7 mg per day, respectively, and the 95th intake percentiles for this age group are 5.4 mg per day and 4.5 mg per day, respectively. Adults aged 19 years and older have median intakes of between 1.6 and 2.1 mg per day (m) and between 1.4 and 1.6 mg per day (f), depending on age; the 95th percentiles are between 3.0 and 6.0 mg per day and between 2.7 and 4.1 mg per day, respectively, decreasing with increasing age (MRI, 2008).

Data for children and adolescents from the EsKiMo study show that median intakes of vitamin B<sub>2</sub> in 6- to 11-year-old boys ranged from 1.4 to 1.5 mg per day and from 1.2 to 1.5 mg per day in girls of the same age group; the 95th percentiles of vitamin B<sub>2</sub> intake ranged from 2.6 to 3.3 mg per day for boys and from 2.1 to 2.7 mg per day for girls of these age groups. For 12- to 17-year-old boys and girls, median intakes for vitamin B<sub>2</sub> ranged from 1.9 to 2.4 and from 1.7 to 1.8 mg per day, respectively, and the 95th percentiles of vitamin B<sub>2</sub> intake ranged from 5.3 to 6.3 mg per day for boys and from 4.6 to 5.5 mg per day for girls of the same age (Mensink et al., 2007).

Riboflavin and riboflavin-5'-phosphate are approved food colorants which may be used *quantum satis* (as much as required) in a variety of foods (ZZuV, 1998). The resulting intake levels are not known.

### 2.2.3 Maximum levels for vitamin B<sub>2</sub> in food supplements and conventional foods

No UL has been established for vitamin B<sub>2</sub>, and no adverse health effects have been observed when consuming amounts well above the intake reference values. Data from clinical studies indicate that the observed vitamin B<sub>2</sub> intakes from all sources do not pose a risk to human health. Although, on the basis of the limited data available, it cannot be concluded that vitamin B<sub>2</sub> has no potential for adverse health effects at high intakes, the BfR considers that, on the basis of the data currently available, it is not necessary to set a maximum level for food supplements and for fortification of conventional foods.

## 2.3 Pantothenic acid

### 2.3.1 Tolerable Upper Intake Level (UL) and Dietary Reference Value

No systematic dose-response studies have been conducted with pantothenic acid or calcium pantothenate or panthenol. Therefore, neither the SCF (2002) nor the US Institute of Medicine (IOM, 2000) were able to define toxicological parameters such as LOAEL or NOAEL and to derive a UL for pantothenic acid. Overall, a low toxicity of pantothenic acid is assumed on the basis of the available scientific data (IOM, 2000; SCF, 2002).

For pantothenic acid, estimated values for an adequate intake were derived by the D-A-CH Societies, ranging from 4 to 6 mg per day for children and adolescents depending on age and 6 mg per day for adults aged 19 years and older (D-A-CH, 2019; Table 3). EFSA derived *Adequate Intake (AI)* values for pantothenic acid of 4 and 5 mg per day for children and adolescents aged 4 to 17 years and 5 mg per day for adults (EFSA, 2014; Table 3).

**Table 3: Dietary reference values**

Age groups	Estimated values for an adequate intake (D-A-CH, 2019*)	Adequate Intake (AI) (EFSA, 2014)
	mg/day	
4 to < 7 years	4	4
7 to < 10 years	5	4 (< 11 years)
10 to < 13 years	5	5
13 to < 15 years	6	5
15 to < 19 years	6	5 (< 18 years)
Adults	6	5
Pregnant women	6	5
Lactating women	6	7

\*last revised in 2015

### 2.3.2 Exposure

Data on the intake of pantothenic acid were determined in the NFCS II on the basis of two 24-hour recalls by applying the *Multiple Source Method (MSM)*. According to this, the median intakes of 15- to 18-year-old males and females were 4.0 and 3.1 mg per day, respectively, and those of adult males and females ranged from 4.2 to 4.5 mg per day and from 3.3 to 3.7 mg per day, respectively, depending on age (DGE, 2012).

For pantothenic acid intake by children and adolescents, data from the EsKiMo study indicated that 6- to 11-year-old boys and girls had median intakes of 4.3 and 4.0 mg per day, respectively, and the 95th percentile of intakes were 8.7 and 7.8 mg per day, respectively, in these age groups. For 12- to 17-year-old boys and girls, the median intakes were 7.2 and 5.5 mg per day, respectively, and the 95th percentiles of intake were at 17.4 and 16.9 mg per day, respectively (Mensink et al., 2007).

### 2.3.3 Maximum levels for pantothenic acid in food supplements and conventional foods

No UL was set for pantothenic acid and no adverse health effects were observed when consuming amounts far above the observed intakes from all sources. Although it cannot be concluded that pantothenic acid has no potential for adverse health effects at high intakes, from the BfR's point of view it is presently not necessary to establish maximum levels for food supplements and for the fortification of conventional foods.

**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](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](https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html)



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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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