Maximum levels for the addition of vitamin B_{12} 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 25 micrograms (µg) of vitamin B_{12} per daily recommended dose of a food supplement (Table 1).

For fortification of conventional foods, assuming a saturated market of fortified foods (30 % of daily energy intake comes from of fortified foods), a maximum level of 6 µg/100 grams (g) is recommended for solid foods and of 1.6 µg/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)	25 µg
Fortified solid foods (per 100 g)	6 µg
Fortified beverages (per 100 ml)	1.6 µg

2 Rationale

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

To date, no adverse health effects have been identified for vitamin B_{12} that could be used to derive a LOAEL (Lowest Observed Adverse Effect Level; lowest experimental dose at which there was an observed adverse effect on health) or NOAEL (No Observed Adverse Effect Level; highest experimental dose at which there was not an observed adverse effect on health). The former Scientific Committee on Food (SCF) of the European Commission has therefore not derived a UL for vitamin B_{12} (SCF, 2000). However, the Committee concluded that there was no evidence that vitamin B_{12} intakes at the levels observed were associated with a health risk. For example, data from the Boston Nutritional Status Survey showed that older women (> 60 years) in the 95th consumption percentile consumed up to 106 µg of vitamin B_{12} per day via food and supplements without any adverse effects being reported. The intake of vitamin B_{12} via supplements alone was 77 µg (men) and 100 µg (women) per day (SCF, 2000).

The D-A-CH Societies[2] have derived an estimated value for adequate intake for vitamin B_{12} for adolescents from 14 years and adults of 4.0 µg/day and for pregnant and lactating women of 4.5 and 5.5. µg/day, respectively. For children < 14 years lower values were set of 2.0

[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

µg/day (4 to under 7 years) and of 3.5 µg/day (10 to under 13 years), respectively (D-A-CH, 2018; Table 2).

Die European Food Safety Authority (EFSA) has derived Adequate Intake (AI) values for vitamin B_{12} of between 1.5 and 4.0 µg/day, depending on age, and of 4.5 and 5.0 µg/day for pregnant and lactating women, respectively (EFSA, 2015; Table 2).

Table 2: Dietary reference values (estimated values for adequate intake) and UL

Age groups	Estimated value for adequate intake (D-A-CH, 2018)	Adequate Intake (EFSA, 2015)	UL (SCF, 2000)
	µg/day		
4 to < 7 years	2.0	1.5	-
7 to < 10 years	2.5	2.5 (7–10 years)	-
10 to < 13 years	3.5	3.5 (11–14 years)	-
13 to < 15 years	4.0	3.5	-
15 to < 19 years	4.0	4.0 (15-17 years)	-
Adults ≥ 19 years	4.0	4.0 (≥ 18 years)	-
Pregnant women	4.5	4.5	-
Lactating women	5.5	5.0	-

2.2 Exposure

Data from the second National Food Consumption Survey (NFCS II) and results of the EsKiMo study (nutrition module in KiGGS[3]) show that vitamin B_{12} intake in Germany is generally adequate.

NFCS II data showed that men and women aged 14 years and older had median intakes of vitamin B_{12} of between 5.5 and 6.0 and between 3.7 and 4.0 µg per day, respectively, depending on age group (MRI, 2008). In the 95th percentiles, intakes ranged from 7.7 to 13.5 µg/day depending on gender and age group (MRI, 2008).

According to the data of the EsKiMo study, children aged 6 to 11 and 12 to 17 years achieved median vitamin B_{12} intakes of between 2.8 and 7.2 µg/day (boys) and between 3.6 and 4.4 µg/day (girls), depending on the age group. In the 95th percentiles, children of these age groups reached intakes between 6.0 and 16.3 µg/day (boys) and between 5.0 and 11 µg/day (girls) (Mensink et al., 2007).

2.3 Maximum levels for vitamin B_{12} in food supplements and conventional foods

2.3.1 Aspects considered in the derivation of maximum levels

– The available data indicate that in Germany the dietary reference values for vitamin B_{12} is met in all age groups, irrespective of gender, and in some cases it is even far exceeded. An adequate supply of vitamin B_{12} is therefore assured in the healthy general population.

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

- Individuals who follow a vegan diet and have very low intakes of vitamin B_{12} via conventional foods due to the absence of animal foods in their diet, are at increased risk for inadequate vitamin B_{12} intake if they do not consume this vitamin through fortified foods or food supplements.

- No UL was derived for vitamin B_{12} by the SCF (2000). Therefore, for the derivation of maximum levels, based on consumption data from the USA, an estimated intake of 100 µg/day via food supplements is used in the following, for which no adverse effects have been reported. As this value refers to the supplementary intake, the vitamin B_{12} intake via the usual diet can be disregarded. In the derivation procedure applied by the BfR, the value of 100 µg/day corresponds to the residual amount.

- In view of the fact that multiple intakes of vitamin B_{12} from different food supplements cannot be ruled out (Römer and Heuer, 2017), an uncertainty factor of 2 is taken into account in the derivation of maximum levels for food supplements.

2.3.2 Maximum levels for vitamin B_{12} in food supplements

Applying the derivation method proposed by the BfR, which provides for the residual amount to be divided equally between food supplements and fortified conventional foods [100 µg/day = 50 µg/day (food supplements) + 50 µg/day (fortified foods)], and taking into account an uncertainty factor of 2, this results in a maximum level of 25 µg vitamin B_{12} per daily recommended dose of a food supplement.

2.3.3 Maximum levels for vitamin B_{12} in conventional foods

According to the derivation procedure proposed by the BfR, a residual amount$_{FF}$ of 50 µg vitamin B_{12} is available for the fortification of conventional foods.

Assuming that the proportion of fortified foods on the market is equal to an intake of 15 % of total energy via fortified foods, allocation of the amount of 50 µg vitamin B_{12} available for fortification to 15 % of daily energy intake would result in maximum fortification levels of between 7.1 and 16.7 µg/100 kcal, depending on age. If, instead, the residual amount of 50 µg is allocated to 30 % of the total energy, maximum levels between 3.5 and 8.3 µg/100 kcal would result (Table 3).

Table 3: Daily energy intake (P95) and vitamin B_{12} levels in fortified foods assuming that 15 % or 30 % of the daily energy intake comes from foods fortified with vitamin B_{12}

Age groups	Energy intake* (P 95)	Fortification of 15% of the daily energy intake		Fortification of 30% of the daily energy intake	
		15% of daily energy intake	Vitamin B_{12}**	30% of daily energy intake	Vitamin B_{12} **
	kcal/day	kcal	µg/100 kcal	kcal/day	µg/100 kcal
4 to 6 years	2,000	300	16.7	600	8.3
7 to 9 years	2,400	360	13.9	720	6.9
10 to 11 years	2,550	383	13.1	765	6.5
12 years	3,900	585	8.5	1,170	4.3
13 to < 15 years	3,900	585	8.5	1,170	4.3
15 to < 17 years	4,700	705	7.1	1,410	3.5

Adults	3,500	525	9.5	1,050	4.8

* Data for children up to the age of 17 from EsKiMo and for adults from NFCS II

** Allocation of the residual amount of 50 µg/day of to 100 kcal portions

In order to ensure that the intake of vitamin B_{12} from fortified foods does not cause any age group to exceed the residual amount$_{FF}$ of 50 µg/day, the lowest of the vitamin B_{12} levels resulting from the calculations is proposed as the maximum level for the whole population: Assuming that 30 % of the daily energy is consumed in the form of fortified foods, the safe maximum level would be 3.5 µg/100 kcal and assuming that only 15 % of the daily energy is consumed in the form of fortified foods, the safe maximum level would be 7.1 µg/100 kcal (Table 3).

2.3.3.1 Conversion of maximum energy-based into maximum amounts per 100 g of solid foods and per 100 ml of beverages

The conversion of the energy-based maximum levels into weight- and volume-based maximum levels was based on the average energy densities of solid foods and energy-containing liquids, which were provided by Schusdziarra et al. (2010) and Bechthold (2014) as 170 kcal/100 g and 45 kcal/100 ml, respectively (Schusdziarra et al., 2010; Bechthold, 2014).

Taking into account these energy densities, the maximum amounts for vitamin B_{12} by weight and by volume are given in Table 4.

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

Vitamin B_{12} per 100 kcal	**Vitamin B_{12} per 100 g or ml**	
	Solid foods (energy density 170 kcal/100g)	**Beverages** (energy density 45 kcal/100ml)
3.5	6	1.6
7.1	12	3.2

According to EU Regulation No. 1169/2011, micronutrient contents in foods may only be claimed on the label if the amounts correspond to at least 15 % of the nutritional labelling reference value (NRV) for solid foods and at least 7.5 % of that NRV for beverages.

The NRV set for vitamin B_{12} is 2.5 µg (15 % of NRV = 0.38 µg; 7.5 % of NRV = 0.19).
The vitamin B_{12} levels calculated in Table 4 are therefore in any case to be considered as significant according to the Regulation.

2.3.3.2 Toothpaste as a carrier for vitamin B_{12}

Toothpaste is not a food in the legal sense, but a cosmetic product. However, since toothpaste fortified with vitamin B_{12} is available on the German market for vegans as a vulnerable population group with regard to vitamin B_{12} deficiency and since it can be assumed that the vitamin is absorbed to some extent via the oral mucosa when brushing the teeth, data available on this are discussed below:
A randomised, placebo-controlled study in Germany investigated the effect of a toothpaste fortified with vitamin B_{12} on the vitamin B_{12} biomarkers holotranscobalamin, total homocyste-

ine and methylmalonic acid (Siebert et al., 2017). During the 12-week intervention, 36 individuals on a vegan diet received toothpaste fortified with 100 µg/g vitamin B_{12} to be used twice daily. At the end of the intervention period, vitamin B_{12} and holotranscobalamin levels were significantly elevated in the vitamin B_{12} group compared with the placebo group. The differences were more pronounced in subjects who did not take vitamin B_{12} supplements and consequently had lower levels at baseline than in subjects with supplement use. Overall, however, the intake of vitamin B_{12} via the product was low. Also, so far only one vitamin B_{12} fortified toothpaste is on the market in Germany. Should the market share of fortified toothpastes grow in the future and thus another source of vitamin B_{12} intake emerge and prove relevant, this could have implications for the recommendations on food fortification made here.

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

"Opinions-App" of the BfR

3 References

Bechthold A (2014). Food energy densitiy and body weight. A scientific statement from the DGE. Ernahrungs Umschau 61(1): 2-11.

D-A-CH (2015). German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society. Dietary Reference Values. Complete revision of the chapter on vitamin B12 and update of the chapter on folate in the 2nd versiob of the 4th updated edition 2018. German Nutrition Society, Bonn.

EFSA (2015). EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA). Scientific Opinion on Dietary Reference Values for cobalamin (vitamin B12). EFSA Journal 13: 4150 file:///C:/Temp/j.efsa.2015.4150.pdf; last accessed 04 March 2021.

Mensink G, Heseker H, Richter A, Stahl A, Vohmann C (2007). Research report. Nutrition study as KiGGS module (EsKiMo), Robert Koch Institute.

MRI (2008). Nationale Verzehrstudie II, Ergebnisbericht, Teil 2, Max Rubner-Institut, Bundesforschungsinstitut für Ernährung und Lebensmittel.

SCF (2000). Scientic Committee on Food. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B_{12}. https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out80d_en.pdf; last accessed 04 March 2021.

Schusdziarra V, Keller 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 Enährungsmed 35: 29-41.

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

Siebert AK, Obeid R, Weder S, Awwad HM, Sputtek A, Geisel J, Keller M (2017). Vitamin B-12-fortified toothpaste improves vitamin status in vegans: a 12-wk randomized placebo-controlled study. Am J Clin Nutr. 105: 618-625.

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.

This text version is a translation of the original German text which is the only legally binding version.