Proposed maximum levels for the addition of vitamin E 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 30 milligrams (mg) of vitamin E per daily intake of a food supplement (Table 1).

Men aged 55 years and older should be advised through appropriate risk communication measures that uncontrolled supplementation of vitamin E may increase the risk of prostate cancer.

For fortification of conventional foods, assuming a "saturated" market of fortified foods (30 % of daily energy intake from fortified foods), a maximum level of 7 milligrams per 100 grams (7 mg/100 g) is recommended for solid foods and of 2 milligrams per 100 millilitres (2 mg/100 ml) for beverages (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	30 mg
Fortified solid foods (per 100 g)	7 mg
Fortified beverages (per 100 ml)	2 mg

2 Rationale

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

In 2003, the former Scientific Committee on Food (SCF) of the European Commission derived a UL for vitamin E (α-tocopherol equivalents) of 300 milligrams per day (mg/day) for adults (SCF, 2003). For children and adolescents, ULs ranging from 120 mg (4- to 6-year-olds) to 260 mg (15- to 17-year-olds) per day were derived, depending on body weight (SCF, 2003).

Intervention studies, some of which were conducted or published only after the derivation of the UL by the SCF, indicate increased risks of adverse health effects from vitamin E supplementation even below 300 mg/day: For example, a systematic review and meta-analysis of controlled intervention studies revealed that vitamin E supplementation at doses of about 130 to 200 mg/day increased the risk for hemorrhagic stroke (Schürks et al., 2010). Furthermore, in a large intervention study (SELECT) with more than 35,500 healthy men, the intake of vitamin E supplements at doses of 400 IU or 268 mg/day was associated with an increased risk of prostate cancer (Klein et al., 2011; Kristal et al. 2014).

[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.

On the basis of human study data, the Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) derived an Acceptable Daily Intake (ADI) of 0.15-2 mg/kg body weight (bw) for α-tocopherol (JECFA, 1987) and justified this with adverse clinical and biochemical effects observed with intakes of vitamin E at high doses, partly due to self-medication. For adults, this results in an acceptable daily intake of 105-140 mg vitamin E, taking into account the reference body weight of 70 kg defined by the European Food Safety Authority (EFSA) (EFSA, 2012). For the 15- to 17-year-olds (or 14- to < 18-year-olds), for whom EFSA considered a reference weight of 61.3 kg to be appropriate, this would translate into a slightly lower acceptable daily intake of 92-123 mg/day of vitamin E.

The D-A-CH Societies[2] published age and gender-based estimated values for adequate intake of vitamin E (tocopherols), ranging from 8 mg/day for 4- to 7-year-old children to 12 and 15 mg/day for 15- to under 19-year-old females and males, respectively. For adult women and men ≥ 19 years of age, estimated values for adequate intakes range from 11 to 15 mg/day (D-A-CH, 2015; see Table 2).

EFSA derived an Adequate Intake (AI) of 9 mg/day for children aged 3 to < 10 years. For all other persons from 10 years on, AIs of 11 mg/day (female) and 13 mg/day (male) were derived (EFSA, 2015; see Table 2).

Table 2: Dietary reference values for vitamin E (as α-tocopherol equivalents)

Age groups	**Estimated values for an adequate intake (D-A-CH, 2015*) in mg/day**		***Adequate Intake* (AI) (EFSA, 2015)**
	male	**female**	
	mg/day		
4 to < 7 years	8	8	3 - < 10 J.: 9
7 to < 10 years	10	9	
10 to < 13 years	13	11	≥ 10 J.: 11 (w); 13 (m)
13 to < 15 years	14	12	
15 to < 19 years	15	12	
19 to < 25 years	15	12	
25 to < 51 years	14	12	
51 to < 65 years	13	12	
≥ 65 years	12	11	
Pregnant women		13	
Lactating women		17	

* last revised: 2012

2.2 Exposure

[2] German-Austrian-Swiss Nutrition Societies

In the second National Food Consumption Survey (NFCS II), median intakes of vitamin E of 13.0 mg/day (f) and 16.2 mg/day (m) and in the 95th percentile of 35.8 mg/day (f) and 38.2 mg/day (m) were reported in adolescents aged 14 to 18 years (MRI, 2008).
In adult women (19 to 80 years), age-dependent median intakes of 11.3 to 12.7 mg/day and in the 95th percentile of 23.0 to 28.9 mg/day were recorded. In adult men aged 19 to 24 years, median intakes ranged from 12.4 to 14.5 mg/day, depending on age group; in the 95th percentile, age-dependent intakes ranged from 24.6 to 39.6 mg/day (MRI, 2008).

The intake of vitamin E in children was determined in the EsKiMo study (nutrition module in KiGGS[3]) conducted by the Robert Koch Institute (RKI) in 2006: According to this study, boys and girls aged 6 to 11 years had dietary intakes of vitamin E between 8.8 and 9.3 mg and between 8.3 and 9.7 mg per day, respectively; the 95th intake percentiles of this age group was between 19.6 to 20.6 mg and between 14.1 to 20.9 mg per day, respectively. Among older children (12 to 17 years), the median (P95) intakes were between 14.3 and 17.4 (38.0–43.4) mg and between 13.3 and 14.2 (32.6–54.1) mg per day, respectively (Mensink et al., 2007).

2.3 Aspects considered in the derivation of maximum levels for vitamin E

Vitamin E is used in form of approved food additives E306 (tocopherol-containing extracts of natural origin), E307 (alpha-tocopherol), E308 (gamma-tocopherol) and E309 (delta-tocopherol) in industrial food processing. Tocopherols are used as antioxidants for product stabilisation in fat-containing foods such as edible fats, cooking oils, frying fats, shortenings, dressings, desserts and chewing gum (generally permitted for foods without maximum quantity restrictions or *quantum satis*). The intake of vitamin E added to foods as an additive is not known. In principle, it has to be taken into account that an increasing intake of polyunsaturated fatty acids also increases the demand for vitamin E, which is needed to protect fatty acids from peroxidation.

Although a UL for vitamin E (260 mg/day for 15- to 17-year-olds) had been derived by the SCF in 2003, the BfR is of the opinion that the available study results, in particular from the SELECT study, that point towards adverse effects have to be taken into account in the derivation of maximum levels.

On the basis of the SELECT study results, Kristal et al. concluded that men 55 years of age and older should avoid vitamin E supplements at doses above the dietary reference value for vitamin E (Kristal et al., 2014).

From the available scientific data, no positive health effects can be derived from intakes of vitamin E above the physiological requirements.

Against this background, a pragmatic approach is taken in deriving maximum levels for vitamin E, on the basis of which it is proposed that the supplementary intake of vitamin E be limited to levels within the range of nutritional intake.

2.3.1 Maximum level for vitamin E in food supplements

For food supplements, based on nutritional requirements, a maximum level of 30 mg vitamin E per daily recommended dose of a food supplement is proposed.

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

This amount corresponds to 200% of the estimated value for an adequate vitamin E intake derived by the D-A-CH Societies for males aged 15-25 years and is about at the same level as the vitamin E intake determined in the NFCS II for the 95th percentile of males (33 mg/day).
In addition, the dose of 30 mg/day, proposed per daily recommended dose of a food supplement, was also used in combination with other vitamins and minerals in the placebo-controlled SU.VI.MAX study in more than 5.000 men to investigate whether this micronutrient supplement intervention of nutritional doses over 8 years had an effect on the risk of prostate cancer. In this study, healthy men who had normal prostate specific antigen (PSA) concentrations at baseline showed a statistically significant reduction in prostate cancer risk, whereas men who had an elevated PSA at baseline were found to have a borderline increase in risk (Meyer et al., 2005). These study results indicate that in healthy individuals, vitamin E supplementation at dose levels suggested here, taken over many years, were not associated with an increased risk of adverse health effects. The results also suggest that in individuals at increased risk of prostate cancer, vitamin E supplementation may increase the risk of cancer. However, as vitamin E was not taken as a mono-preparation in the SU.VI.MAX study, but in combination with other micronutrients, no reliable conclusion about the risk of vitamin E supplementation for men with an increased risk of prostate cancer can be drawn from these data.

Results of an evaluation of NFCS II data on intake of multiple food supplements conducted by the Max Rubner-Institute (MRI) (Römer and Heuer, 2017) show that a multiple exposure to vitamin E through parallel use of more than one food supplement cannot be ruled out.

From the point of view of the BfR, with a maximum level of 30 mg per daily recommended dose of a food supplement product, an intake of several vitamin E-containing food supplements per day (up to a total amount of 60 mg) would be tolerable. However, men aged 55 years and older should be advised through appropriate risk communication measures that an uncontrolled supplementation of vitamin E may increase the risk of prostate cancer.

2.3.2 Maximum level of vitamin E in fortified conventional foods

In analogy to *2.3.1*, a total amount of 60 mg/day should not be exceeded for the fortification of conventional foods with vitamin E, based on the nutritional requirement.

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 intake is consumed from fortified foods, results in maximum levels of vitamin E of between 4.3 and 20 mg/100 kcal, depending on age (Table 3).

To ensure that the addition of vitamin E to fortified foods does not cause any of the age groups to exceed the residual amount allocated for fortification of conventional foods of 60 mg/day, the lowest of the vitamin E levels resulting from the calculations is proposed as the maximum level for the entire population, i.e. 4.3 mg/100 kcal based on the assumption that the fortified food market is "saturated" (30% of daily energy in the form of fortified foods) and 8.5 mg/100 kcal, assuming that a lower proportion of fortifiable foods is actually fortified/consumed (15% of energy intake comes from fortified foods) (Table 3).

Table 3: Daily energy intake (P95) and vitamin E levels, 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 the daily energy intake	Addition of vitamin E**	30 % of the daily energy intake	Addition of vitamin E**
	kcal/day	*kcal*	*mg/100 kcal*	*kcal*	*mg/100 kcal*
4 to < 7 years	2,000	300	20.0	600	10
7 to < 10 years	2,400	360	16.7	720	8.3
10 to < 12 years	2,550	383	15.7	765	7.8
12 years	3,900	585	10.3	1,170	5.1
13 to < 15 years	3,900	585	10.3	1,170	5.1
15 to < 17 years	4,700	705	8.5	1,410	4.3
Adults	3,500	525	11.4	1,050	5.7

* 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 amount of 60 mg/day is allocated to 100 kcal portions

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

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

Taking into account the average energy densities, i.e. 170 kcal/100 g for solid foods and 45 kcal/100 ml for energy-containing liquids such as juices and soft drinks, the maximum amounts by weight and by volume for the addition of vitamin E 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 E per 100 kcal	Vitamin E per 100 g or ml	
	Solid foods (energy density: 170 kcal/100 g)	**Beverages** (energy density: 45 kcal/100 ml)
4.3 mg*	7 mg	2 mg
8.5 mg**	15 mg	4 mg

* assuming that 30 % of the energy comes from fortified foods

** assuming that 15 % of the energy comes from fortified foods

If an additional criterion in setting maximum levels is that the amount of a nutrient added to a food should be significant in order to be allowed to be claimed in the product labelling in accordance with the current regulation[4], then according to Regulation (EU) No 1169/2011, Annex XIII (reference values), at least 15 % of the respective reference value for labelling (NRV) would have to be contained in solid foods (per 100 g) and at least 7.5 % in beverages (per 100 ml).

In that Regulation, the NRV for vitamin E is set at 12 mg. Accordingly, levels of ≥ 1.8 mg/100 g (at least 15 % of the NRV) of vitamin E in solid foods and levels of ≥ 0.9 mg/100 ml (at least 7.5 % of the NRV) in beverages would be considered as significant. The maximum levels calculated in Table 4 would thus meet the criteria for labelling and claiming of added vitamin E.

For the fortification of conventional foods, a maximum level of 7 mg/100 g for solid foods and of 2 mg/100 ml for beverages is recommended, based on the assumption of a "saturated" market of fortified foods (30 % of the daily energy intake comes from fortified foods). Assuming that a lower proportion of fortifiable foods is actually fortified/consumed (15 % of energy intake in the form of fortified foods), higher maximum levels of 15 mg/100 g for solid foods and 4 mg/100 ml for beverages would be possible (Table 4).

Further information on the BfR website on the subject of 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/de/bewertung_von_vitaminen_und_mineralstoffen_in_lebensmitteln-54416.html
https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html

"Opinions app" of the BfR

3 References

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[4] Conditions for labelling of products with a claim "source of..." or "rich in...", according to EU Regulation 1924/2006 (Health Claim Regulation). http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0009:0025:DE:PDF; last accessed 05 March 2021.

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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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