Proposed maximum levels for the addition of vitamin C 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 250 milligrams (mg) of vitamin C per daily recommended dose of a food supplement (Table 1).

For fortification of conventional foods, based on the assumption of a "saturated" market of fortified foods (30 % of daily energy intake comes from fortified foods), a maximum level of 60 mg per 100 g for solid foods and of 16 mg per 100 millilitres (ml) for beverages is recommended (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	250 mg
Fortified solid foods (per 100 g)	60 mg
Fortified beverages (per 100 ml)	16 mg

2 Rationale

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

The European Food Safety Authority (EFSA) was unable to derive a UL for vitamin C due insufficient data. However, it considered that a supplemental daily intake of 1,000 mg of vitamin C in addition to the usual dietary intake is not associated with adverse gastrointestinal effects, whereas higher additional intakes may increase the risk for such effects (EFSA, 2004). EFSA indicated that these conclusions apply to all forms of vitamin C, i.e. in addition to ascorbic acid, also to its salts and esters such as ascorbyl palmitate (EFSA, 2004). Furthermore, EFSA concluded that no increased risk of kidney stones was found in individuals with a habitual intake of 1.5 mg of vitamin C per day.

The D-A-CH Societies[2] provide intake recommendations of between 30 and 85 mg per day for 4- to under 15-year-old children (Table 2). For older children and adolescents as well as for adults, age- and gender-dependent intake recommendations were derived: for 15- to under 19-year-olds 90 mg per day (female) and 105 mg per day (male), and for adults (19 to 65 years and older) 95 mg per day (female) and 110 mg per day (male). For pregnant

[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

women (from the 4th month of pregnancy) and for lactating women, 105 mg and 125 mg per day are recommended (D-A-CH, 2019; Table 2).

In 2013, EFSA derived Population Reference Intakes (PRIs) for vitamin C ranging between 20 and 70 mg per day for 1–14 year old children and of 90 mg and 100 mg per day, respectively, for 15–17 year old female and male adolescents. For adult women and men, 95 mg and 110 mg per day, respectively, are recommended. Compared to women aged 18 years and older, increased intakes by 10 and 60 mg per day, respectively, are recommended for pregnant and lactating women (EFSA, 2013; Table 2).

Table 2: Dietary reference values

Age groups	Recommended intake (D-A-CH, 2019*)		Population Reference Intake (EFSA, 2013)	
	male	female	male	female
	mg/day			
4 to < 7 years	30		30	
7 to < 10 years	45		45	
10 to < 13 years	65		45 (10 years), 70 (11-14 years)	
13 to < 15 years	85		70 (11-14 years)	
15 to < 19 years	105	90	100 (up to 17 years)	90 (up to 17 years)
19 to < 25 years	110	95	110 (from 18 years)	95 (from 18 years)
25 to < 51 years	110	95	110	95
51 to < 65 years	110	95	110	95
≥ 65 years	110	95	110	95
Pregnant women		105*		+ 10
Lactating women		125		+ 60

* last revised in 2015

** from the 4th month

2.2 Exposure

According to the second National Food Consumption Survey (NFCS) II, the median vitamin C intake of 14- to 18-year-old adolescents in Germany was 138 mg (male) and 139 mg (female) per day. Men and women between 19 and 80 years of age had median age-dependent intakes of 125 mg to 132 mg and 123 mg to 141 mg per day, respectively. The intake of the 95th percentile of 14- to 18-year-old adolescents was at 393 mg (male) and 356 mg (female) per day, respectively, while that of 19- to 80-year-old men and women ranged in an age-dependent manner between 279 mg to 367 mg and 289 mg to 330 mg per day, respectively (MRI, 2008).

In children and adolescents, vitamin C intake was determined as part of the EsKiMo study (nutrition module in KiGGS[3]) conducted by the Robert Koch Institute (RKI) in 2006 (Mensink,

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

2007). According to this, children aged between six and eleven years had a median intake of between 85 mg and 99 mg per day (male) and between 78 mg and 100 mg per day (female) of vitamin C. The 95th intake percentiles ranged from 175 mg to 256 mg per day (male) and from 190 mg to 260 mg per day (female). Median intakes of 12- to 17-year-olds ranged from 141 mg to 176 mg per day (male) and from 162 mg to 178 mg per day (female). The 95th intake percentiles of this age group ranged from 368 mg to 527 mg per day (male) and from 400 mg to 527 mg per day (female) (Mensink et al., 2007).

The median vitamin C intake of the German population is thus far above the D-A-CH intake recommendations.

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

As EFSA was unable to derive a UL for vitamin C due to insufficient data, the BfR in deriving the maximum levels refers to the supplementary daily intake amount of 1,000 mg of vitamin C - hereinafter referred to as the "orientation value" -, which, according to EFSA (2004), was not associated with adverse gastrointestinal effects. As this orientation value only refers to the supplementary intake, the usual dietary intake of vitamin C can be neglected in the derivation of maximum levels.

This amount of a maximum of 1,000 mg of supplemental vitamin C per day, which EFSA (2004) considered unlikely to pose a risk of adverse health effects, was also used by other EU member states (Belgium[4], France[5], Italy[6], Norway[7]) as a basis for setting maximum levels (Weissenborn and Ortgies, 2018). However, in contrast to the other EU member states, the BfR herewith provides suggestions on how the orientation value of 1,000 mg per day can be divided between food supplements and fortified conventional foods. This also takes into account that in Germany numerous foods are already fortified with vitamin C (e.g. juices, confectionery) and that, according to the NFCS II, multiple use of vitamin C-containing food supplements has to be taken into account (based on all interview days, 7.4 % of the respondents took two vitamin C supplements) (MRI, 2017).

2.3.1 Maximum levels for vitamin C in food supplements

The BfR recommends that the available amount of 1,000 mg per day for additional intakes of vitamin C (EFSA orientation value) be divided equally between food supplements and fortified conventional foods. Taking into account an uncertainty factor of 2, this results in a maximum level for vitamin C of 250 mg per daily recommended dose of a food supplement.

Residual amount$_{FS}$ = 500 mg ÷ 2 = 250 mg per daily dose of a food supplement

2.3.2 Maximum levels for vitamin C in conventional foods

The residual amount available for fortification of conventional foods is 500 mg per day (residual amount$_{FF}$). Allocating this amount to the estimated daily energy intake from fortified foods

[4] https://www.health.belgium.be/fr/arrete-royal-du-3-mars-1992-nutriments; last access 04 March 2021.

[5] https://www.economie.gouv.fr/dgccrf/complements-alimentaires-nutriments-autorises; last access 04 March 2021.

[6] http://www.salute.gov.it/imgs/C_17_pagineAree_1268_5_file.pdf; last access 04 March 2021.

[7] https://lovdata.no/dokument/SF/forskrift/2004-05-20-755#KAPITTEL_5; last access 04 March 2021.

and assuming that 15 % to a maximum of 30 % of the daily energy is consumed from fortified foods, this results in maximum levels for vitamin C of between 35 and 167 mg per 100 kcal, depending on age (Table 3).

In order to ensure that none of the age groups exceeds the orientation value of 1,000 mg/day, the lowest of the levels resulting from the calculations are proposed as maximum levels: 35 mg per 100 kcal assuming that 30 % of the daily energy intake is fortified with vitamin C, and 71 mg per 100 kcal assuming that only 15 % of the daily energy intake is fortified with vitamin C (Table 3).

Table 3: Daily energy intakes (95th percentile, P95) and vitamin C levels assuming that 15 % or 30 % of the energy intake comes from fortified foods

Age groups	Energy intake*	Fortification of 15 % of the daily energy intake		Fortification of 30 % of the daily energy intake	
		15 % of daily energy intake	Vitamin C**	30 % of daily energy intake	Vitamin C**
	kcal/day	kcal	mg/100 kcal	kcal	mg/100 kcal
4 to < 7 years	2,000	300	167	600	83
7 to < 10 years	2,400	360	139	720	69
10 to < 12 years	2,550	383	131	765	65
12 years	3,900	585	85	1,170	43
13 to < 15 years	3,900	585	85	1,170	43
15 to < 17 years	4,700	705	71	1,410	35
Adults	3,500	525	95	1,050	48

* P95 data for children up to the age of 17 from VELS (Heseker et al., 2003) and EsKiMo (Mensink et al., 2007), for adults (P95) from NFCS II (MRI, 2008).

** Allocation of the residual amount$_{FF}$ of 500 mg per day to 100 kcal portions

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

The conversion of the energy-based maximum levels into weight- and volume-based maximum levels is carried out by use of the average energy densities determined by Schusdziarra et al. (2010) and Bechthold (2014) for solid foods (170 kcal per 100 g) and for energy-containing liquids such as juices and soft drinks (45 kcal per 100 ml).

Taking into account the average energy densities, the maximum levels by weight and by volume for the addition of vitamin C to conventional foods are provided in the following table (Table 4).

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

Vitamin C per 100 kcal	Vitamin C per 100 g or 100 ml	
	Solid foods (energy density: 170 kcal per 100 g)	**Beverages** (energy density: 45 kcal per 100 ml)
35 mg*	60 mg	16 mg
71 mg**	120 mg	32 mg

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

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

If one considers as an additional criterion for setting maximum levels that the amounts added to a food should be significant in order to be allowed to be claimed on the product in accordance with Regulation (EC) No 1924/2006[8], then according to Regulation (EU) No 1169/2011 at least 15 % of the respective nutrient reference value for nutrition labelling per 100 g or 100 ml of food must be contained in solid foods and at least 7.5 % of the respective reference value in beverages.

For vitamin C, the reference value for nutrition labelling is 80 mg; 15 % of this corresponds to an amount of 12 mg, and 7.5 % corresponds to 6 mg. Thus, the weight- and volume-based maximum levels in Table 4 are to be considered as 'significant' and therefore would be allowed to be labelled.

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

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[8] Conditions for labelling of products with the 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

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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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