

Proposed maximum levels for the addition of fluoride 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 that fluoride should not be used in food supplements and that the addition of fluoride to conventional foods should be limited to table salt (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplement (per daily recommended dose of an individual product)	no addition
Table salt (per g)	0.25 mg
Fortified conventional foods (per 100 g)	no addition

2 Rationale

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

Fluoride is not an essential nutrient; however, it is generally accepted that fluoride is important for caries prevention.

The D-A-CH Societies² have derived guidance values for the total fluoride intake (from food, drinking water and supplements), which are at 3.2 milligrams (mg) (m) or 3.9 mg (f) per day for adolescents from 15 to 18 years of age and at 3.8 mg (m) or 3.1 mg (f) per day for adults > 18 years of age (D-A-CH, 2015; Table 2).

The European Food Safety Authority (EFSA) derived Dietary Reference Values (DRVs) for fluoride, which are comparable with those by the D-A-CH societies (EFSA, 2013; Table 2).

To meet the guidance values, the use of fluoridated table salt or fluoride supplements is recommended, depending on the fluoride concentration of drinking water (at concentrations below 0.3 milligrams per liter (mg/L) and between 0.3-0.7 mg/L, but not at concentrations above 0.7 mg/L). The D-A-CH societies point out that a fluoride intake history should be conducted before fluoride tablets are prescribed by a medical doctor (D-A-CH, 2015).

In 2005, EFSA derived a UL for fluoride of 0.12 milligrams per kilogram (mg/kg) body weight/day (equivalent to approximately 7 mg/day) for all age groups 15 years and older, including pregnant and lactating women. The UL applies to intake from all sources (drinking

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 SD-A-CH societies

water, beverages, foods, including fluoridated salt, dental care products and fluoride supplements for caries prophylaxis) (EFSA, 2005; Table 2).

Table 2: Dietary reference values (guidance values for an adequate total fluoride intake) and UL

Age groups	Dietary reference values				UL (EFSA, 2005)
	(D-A-CH, 2015)		(EFSA, 2013)		
	m	f	m	f	
	mg/day				
15 - < 19 years	3.2	2.9	3.2	2.8	0.12 mg/kg bw or approx. 7 mg/d
Adults ≥ 19 years including pregnant and lactating women	3.8	3.1	3.4	2.9	

2.2 Exposure

In Germany and other European countries, no reliable data on the intake of fluoride are available. The estimated daily intake of fluoride via food is between 0.4 and 0.6 mg for adults and between 0.1 and 0.2 mg for children (DGE et al., 2015). Estimates of the total intake of fluoride are not available.

The D-A-CH dietary reference values can easily be met if black tea and/or mineral water containing fluoride are drunk regularly or if the drinking water is naturally high in fluoride (> 0.7 mg/L) (e.g. Eifel, Münsterland).

A fluoride intake close to or at the UL, i.e. of 5 to 7 mg/day, can be achieved in persons who consume black tea in high quantities or who drink (mineral) water with fluoride concentrations above 1 mg/L and also use it for cooking, as well as in those who do not use fluoride-containing dental care products properly and, in addition, take fluoride tablets, and frequently consume fish. If all fluoride sources mentioned are used, an intake of 10 mg/day cannot be ruled out (BfR, 2004b).

2.3 Aspects considered in the derivation of maximum levels for food supplements

Fluoride-containing supplements are currently only available as registered medicinal products.

Since under certain conditions - especially through use of fluoride-containing (mineral) water and the abundant consumption of black tea - fluoride intakes as high as the UL can already result, an unrestricted availability of fluoride-containing food supplements, which may be taken in addition to other possible sources, represent a risk for a high total intake of fluoride. Thus, from the BfR's point of view, there is no scope for the use of fluoride in food supplements.

2.4 Aspects considered in the derivation of maximum levels for fortified foods for general consumption

Fluoridated table salt for domestic use has been on the market in Germany since 1991. It contains 0.25 mg of fluoride per gram salt, so that an average household use of this salt of 2 g/day/person results in an additional fluoride intake of about 0.5 mg/day.

The consumption of salt is self-restricting for taste reasons and is therefore a good carrier food for micronutrients, which are to be supplied in predictable amounts.

As it is theoretically possible that total fluoride intakes from various sources reach levels close to the UL, there is no scope for further addition of fluoride to conventional foods. The addition of fluoride to other foods of normal consumption would lead to an unpredictable fluoride intake for which undesirable health effects cannot be ruled out. Fluoridated table salt should therefore remain the only available fluoride-enriched food in the view of the BfR.

Further information on the BfR website on minerals

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

BfR (2004b). Use of minerals in foods. Edited by Domke A, Großklaus R, Niemann B, Przyrembel H, Richter K, Schmidt E, Weißenborn A, Wörner B, Ziegenhagen R. BfR Wissenschaft 04/2004.

D-A-CH (2015). German Society for Nutrition, Austrian Society for Nutrition, Swiss Society for Nutrition. Reference values for nutrient intake. 2nd version of the 1st edition 2015, Neuer Umschau Buchverlag.

EFSA (2005). European Food Safety Authority. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride (Request N° EFSA-Q-2003-018) (adopted on 22 February 2005). The EFSA Journal. 192: 1-65.

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/nda_op_ej192_fluoride_corrigenum_3.pdf, last accessed 1 March 2021.

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies) (2013). Scientific opinion on Dietary Reference Values for fluoride. The EFSA Journal. 11: 3332.

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3332.pdf, last accessed 1 March 2021.

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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