Proposed maximum levels for the addition of boron 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 0.5 milligrams (mg) of boron per daily recommended dose of a food supplement (Table 1).

Given that estimated boron intakes from all sources may in children and adolescents result in levels that meet or exceed the Tolerable Upper Intake Level (UL) or the Acceptable Daily Intake (ADI), food supplements containing boron should carry a note indicating that they are not suitable for children and adolescents (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	0.5 mg Consumer information*
Conventional solid foods (per 100 g)	No addition
Beverages (per 100 ml)	No addition

* not suitable for children and adolescents

2 Rationale

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

For boron, the European Food Safety Authority (EFSA) derived a UL of 10 mg per day for adults (EFSA, 2004). The derivation was based on adverse effects that occurred in animal studies, as no appropriate human data were not available. Boron ingestions in pregnant rats resulted in decreased fetal body weight. A UL of 9 mg per day was extrapolated for adolescents (15 to 17 years) and age-dependent ULs of 3 to 7 mg per day were extrapolated for younger children (1 to 14 years) (Table 2).

Table 2: Tolerable Upper Intake Level (UL)

Age groups	UL (EFSA, 2004)
	mg/day
1 to 3 years	3
4 to 6 years	4

[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.

Age groups	UL (EFSA, 2004)
	mg/day
7 to 10 years	5
11 to 14 years	7
15 to 17 years	9
Adults ≥ 18 years including pregnant and lactating women	10

In 2013, EFSA published a scientific re-evaluation of boric acid (E 284) and sodium tetraborate (borax) (E 285) used as food additives (EFSA, 2013). The Panel concluded that boric acid and sodium tetraborate do not raise concerns of genotoxicity. However, feeding studies in rats, mice and dogs had shown that the male reproductive system was adversely affected by boric acid and sodium tetraborate. EFSA concluded that the adverse effects found with boric acid were similar to those of other borates, indicating that boron was the toxic active agent. According to EFSA, data on toxicokinetics did not reveal any differences between experimental animals and humans. The Panel concluded that based on the No Observed Adverse Effect Level (highest experimental dose at which there was not an observed adverse effect on health; NOAEL) of 9.6 mg boron per kg body weight (bw) per day derived from a rat developmental toxicity study and applying an uncertainty factor of 60, a group ADI of 0.16 mg boron per kg bw per day can be established (EFSA, 2013).

Based on this ADI and using the age-dependent body weight (median) (EFSA, 2012), the following acceptable daily intakes were set:

- Adults (70 kg): 11.2 mg
- Adolescents 14 to 18 years (60.0 kg): 9.6 mg
- Adolescents 10 to 14 years (42.0 kg): 6.7 mg
- Children 3 to 10 years (21.7 kg): 3.5 mg
- Children 1 to 3 years (11.6 kg): 1.9 mg.

EFSA classified boron as a non-essential nutrient. To date, no specific physiological, biochemical function of the mineral has been identified in humans or higher animals. Dietary Reference Values have not been derived by EFSA (EFSA, 2004) or by the D-A-CH Societies[2] (D-A-CH, 2019).

2.2 Exposure

No boron exposure data were reported in the second National Food Consumption Survey (NFCS II).

In 2006, the BfR published an Opinion titled "Addition of boric acid or borax to food supplements" (BfR, 2006), in which the boron intake of the population was estimated on the basis of exposure scenarios. According to this, increased boron intakes may result from the consumption of boron-rich foods and/or mineral waters as well as from boron-containing medicines or occupational activities involving boron exposure. It was estimated that in the *worst case* (intake of boron-rich foods and boron-rich mineral water), boron intakes of about 9 mg/day may result in adults (without the use of boron-containing food supplements). For

[2] German-Austrian-Swiss Nutrition Societies

school children (no information on age was provided in the literature used for the BfR opinion), an intake of about 8 mg/day was estimated in the *worst-case scenario* (boron-rich plant-based diet and boron-rich mineral water, without additional boron intake via food supplements). Since no age-specific data can be provided for boron exposure in children, the BfR considers the boron intake in the group of adolescents (15 to 17 years) to be comparable to that in adults *(worst case*: about 9 mg per day).

With a *worst-case intake of* 8 mg boron per day by school children, the UL is already exceeded in the corresponding age groups (7- to 14-year-olds). Also, at a *worst-case intake* of 9 mg per day, 15- to 17-year-olds would already reach the UL for their age group.

The above-mentioned EFSA opinion from 2013 (EFSA, 2013) also pointed out that the exposure to boron can lead to intake levels exceeding the ADI due to its natural occurrence in foods and other sources (food contact materials, feed, cosmetics, oral hygiene products, etc.). For example, it has been estimated that a child with a body weight of 15 kg and a daily dietary intake of 1 kg of foods could have an additional boron intake via food contact materials only of 0.4 mg boron per kg bw per day and would thus exceed the ADI only through this source.

2.3 Aspects considered in the derivation of maximum levels for boron

The estimated boron intakes from all sources (boron-rich foods, boron-rich mineral waters, food contact materials, etc.) in children and adolescents may lead to the UL or ADI being exceeded. For children and adolescents, therefore, there remains no scope for additional boron intakes from food supplements or fortified foods.

2.3.1 Maximum levels for boron in food supplements

For adults, a residual amount of 1 mg per day remains available for supplementary intakes. It is recommended that this amount be added to food supplements alone, since boron fortification of conventional foods cannot be recommended due to the risk of exceeding the UL or ADI in children and adolescents. For this reason, it is also recommended that food supplements containing boron should carry a note informing the consumer that these products are "Not suitable for children and adolescents" (or similar wording).

Recent research revealed that boron-containing food supplements are being advertised (VBZ, 2019), although no health claims have been permitted in the European Union[3]. This could stimulate certain consumer groups to purchase boron-containing products, and it cannot be ruled out that more than one boron-containing food supplement is used under certain conditions. In view of the knowledge gaps in relation with boron (BfR, 2006), an uncertainty factor of 2 is applied in deriving a maximum level for food supplements, resulting in a maximum amount of 0.5 mg per recommended daily dose of a food supplement for adults.

Residual amount$_{FS}$ = 1 mg ÷ 2 = 0.5 mg per daily recommended dose of a food supplement

[3] EU-Register of Health Claims: https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=search

2.3.2 Maximum levels for boron in conventional foods

In view of the above reasons, fortification of conventional foods with boron is not recommended.

Further information on the BfR website on minerals

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

D-A-CH (2019). German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society (eds.). Dietary Reference Values. 2nd version of the 5th, updated edition, German Nutrition Society, Bonn.

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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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