

Proposed maximum levels for the addition of chromium 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 amount of 60 micrograms (μg) of chromium per daily recommended dose of a food supplement (Table 1).

For fortification of conventional foods, a maximum level of 15 μg per 100 grams (g) for solid foods and 4 μg per 100 millilitres (ml) for beverages is recommended, assuming a "saturated" market of fortified foods (30 % of daily energy intake from fortified foods) (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	60 μg
Fortified solid foods (per 100 g)	15 μg
Fortified beverages (per 100 ml)	4 μg

2 Rationale

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

Due to insufficient data, the former Scientific Committee on Food (SCF) of the European Commission was not able to derive a UL for chromium (SCF, 2003).

The *Panel on Food Additives and Nutrient Sources added to Food* (ANS) of the European Food Safety Authority (EFSA) concluded that there is no health concern regarding the safety of chromium(III) added for nutritional purposes to conventional foods, including food supplements and foods for particular nutritional uses, provided that the intake of chromium(III) from these sources does not exceed 250 μg per day. This is in line with the value set by the World Health Organisation (WHO) for the supplementary intake of chromium not to be exceeded (EFSA, 2010a)².

According to EFSA, the addition of chromium(III) picolinate to foods for particular nutritional uses and to conventional foods (fortified foods), including food supplements, is also not of

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 "...the Panel concluded that the safety of chromium(III) as a nutrient added to PARNUTS and foods intended for the general population (including food supplements) is not of concern, provided that the intake of chromium (III) from these sources does not exceed 250 $\mu\text{g}/\text{day}$, the value established by the WHO for supplemental intake of chromium that should not be exceeded".

concern provided that the total amount of chromium does not exceed 250 µg per day (EFSA, 2010b)³.

The D-A-CH Societies⁴ have set estimated values for an adequate intake of chromium that are for adolescents and adults (15 years and older) in the range of 30 to 100 µg per days (D-A-CH, 2019). For 7- to under-15-year-old children, a range of 20 to 100 µg per day and for 4- to under-7-year-old children, a range of 20 to 80 µg per day was set (Table 2).

Table 2: Dietary reference values

Age groups	Estimated values for an adequate intake (D-A-CH, 2019*)
	µg/day
4 to < 7 years	20–80
7 to < 15 years	20–100
≥ 15 years and adults	30–100

* The D-A-CH Dietary reference values for chromium are based on a derivation from the year 2000.

According to EFSA, only results from studies with patients who were supplemented with chromium in long-term parenteral nutrition indicate that chromium could be essential for humans. Overall, the data are, however, insufficient to derive an *average requirement*. Also, according to EFSA, there is no scientific evidence that chromium intake could be beneficial in healthy people. From EFSA's point of view, setting of an AI (*Adequate Intake*) or PRI (*Population Reference Intake*) for chromium was therefore not considered appropriate (EFSA, 2014).

2.2 Exposure

The second National Food Consumption Survey (NFCS II) did not provide any exposure data on chromium.

In Germany, duplicate studies revealed a mean dietary chromium intake (\pm standard deviation) of 61 ± 31 µg per day (women) and 84 ± 55 µg per day (men) (Anke et al., 1998, cited in: D-A-CH, 2015).

EFSA's Contaminants Panel estimated chromium intakes in children in Europe using data from 17 Member States, including Germany. According to these data, chromium intakes in children 4–17 years of age range, depending on age, on average (medians of lower-bound and upper-bound values) between 54.3–71.2 µg and 63.5–83.4 µg per day, and in the 95th percentiles between 93.3–114.9 µg and 116.4–141.4 µg per day (EFSA, 2014).

2.3 Aspects considered in the derivation of maximum levels for chromium

³ "The Panel concluded that the uses of chromium(III) picolinate as a source of chromium added for nutritional purposes to PARNUTS and foods intended for the general population (fortified foods and food supplements) would not be of concern provided that the amount of total chromium does not exceed 250 µg/day, the value established by the WHO for supplemental intake of chromium that should not be exceeded".

⁴ German-Austrian-Swiss Nutrition Societies

As the SCF was unable to derive a UL for chromium due to a lack of data, the BfR in deriving maximum levels refers to the guidance value of 250 µg chromium for an additional daily intake with no health concerns according to EFSA. As this guidance value only takes into account the supplementary intake, the intake via the usual diet can be neglected.

Since chromium compounds are listed in Annex II of Regulation (EC) 1925/2006 and can thus be used for the fortification of conventional foods, the BfR recommends that the residual amount available for supplemental intake of 250 µg per day be divided equally between food supplements and fortified foods.

2.3.1 Maximum levels for chromium in food supplements

Since multiple exposure to chromium-containing food supplements cannot be ruled out and, in addition, there are gaps in knowledge on the effects of chromium, an uncertainty factor of 2 is taken into account in the derivation of maximum levels for food supplements. This results in a maximum amount for chromium of 60 µg per recommended daily dose of a food supplement.

Residual amount_{FS} = 125 mg ÷ 2 = 62.5 (rounded to 60) µg/daily dose of a food supplement

2.3.2 Maximum levels for chromium in fortified foods

The residual amount available for fortification of conventional foods is 125 µg per day (residual amount_{FF}). If this amount is divided to the estimated daily energy intake from fortified foods and under the assumption that 15 to a maximum of 30 % of the daily energy intake is consumed from fortified foods, this results in maximum chromium levels of between 9 and 42 µg per 100 kilocalories (kcal), depending on age (Table 3).

To ensure that none of the age groups exceeds the guidance value of 250 µg per day, the lowest levels resulting from the calculations are proposed as maximum levels, i.e.: 9 µg per 100 kcal, assuming that 30 % of the daily energy intake is fortified with chromium, and 18 µg per 100 kcal, assuming that only 15 % of the daily energy intake is fortified with chromium (Table 3).

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

Age groups	Energy intake*	Fortification of 15 % of daily energy		Fortification of 30 % of daily energy	
		15 % of daily energy intake	Chromium**	30 % of daily energy intake	Chromium**
	kcal/day	kcal	µg/100 kcal	kcal	µg/100 kcal
4 to < 7 years	2,000	300	42	600	21
7 to < 10 years	2,400	360	35	720	17
10 to < 12 years	2,550	383	33	765	16
12 years	3,900	585	21	1,170	11
13 to < 15 years	3,900	585	21	1,170	11
15 to < 17 years	4,700	705	18	1,410	9
Adults	3,500	525	24	1,050	12

* P95 for children up to the age of 17 from EsKiMo (Mensink et al., 2007), for adults (P 95) from NFCS II (MRI, 2008)

** Allocation of the residual amount_{FF} of 125 µg per day to 100 kcal portions

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

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

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

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

Chromium per 100 kcal	Chromium per 100 g or ml	
	Solid foods (energy density: 170 kcal/100 g)	Beverages (energy density: 45 kcal/100 ml)
9 µg*	15 µg	4 µg
18 µg**	30 µg	8 µg

* assuming that 30 % of the energy consumed is fortified

** assuming that 15 % of the energy consumed is fortified

If one considers as an additional criterion for setting maximum levels that the amounts added to a food should be significant in order that claims be allowed on the product in accordance with Regulation (EC) No 1924/2006⁵, then according to Regulation (EU) No 1169/2011 at least 15 % of the respective nutrient reference value 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 chromium, the NRV is 40 µg; 15 % of this corresponds to an amount of 6 µg, and 7.5 % corresponds to 3 µg. Thus, the maximum levels by weight and by volume calculated in Table 4 are above those levels to be considered as 'significant', and therefore foods would be eligible to bear claims.

Further information on the BfR website on the subject of 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

⁵ Conditions for the claiming 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>; last accessed 05 March 2021. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0009:0025:DE:PDF>

3 References

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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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