

Proposed maximum levels for the addition of copper 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 for copper in food supplements that are also intended for young people from 15 years onwards a maximum level of zero.

For food supplements that have adults as a target group and are not intended for (children and) adolescents, the BfR recommends a maximum level of 1 milligram (mg) per daily recommended dose per food supplement together with an advice on the label that the product is not suitable for children and adolescents (Table 1).

It is recommended that copper should not be used to fortify conventional foods (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	1 mg Consumer information: Not for children and adolescents.
Conventional food (per 100 g)	no addition

2 Rationale

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

The UL for copper derived by the former Scientific Committee on Food (SCF) of the European Commission is 5 milligrams per day (mg/day) for adults. For adolescents 15 years and older, an UL of 4 mg/day was determined based on the lower body weight. In deriving the UL, particular consideration was given to one human study, in which a NOAEL (No Observed Adverse Effect Level; highest experimental dose at which there was not an observed adverse effect on health) of 10 mg/day was established for the intake of copper with respect to an adverse effect on the liver. An uncertainty factor of 2 was considered in the derivation (SCF, 2003; Table 2).

The D-A-CH Societies² derived the following estimated values for an adequate intake of copper: for adolescents 15 years and older and adults: 1-1.5 mg/day (D-A-CH, 2015, Table 2).

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 German Nutrition Societies

The European Food Safety Authority (EFSA) has derived the following *Adequate Intake* (AI) values for copper: men and women above 18 years: 1.6 mg/day and 1.3 mg/day, respectively, and children and adolescents aged 10 to under 18 years: 1.3 mg/day (m) and 1.1 mg/day (f) (EFSA, 2015, Table 2).

Table 2: Dietary reference values (estimated values for an adequate intake) and UL

Age groups	Dietary reference values		UL (SCF, 2003)
	(D-A-CH, 2015)	EFSA (2015)	
mg/day			
10 - < 18 years	1 – 1,5	1.1 (f) - 1.3 (m)	4 (from 15 years)
Adults ≥ 18 years	1 – 1,5	1.3 (f) - 1.6 (m)	5

2.2 Exposure

The 2008 report of the second National Food Consumption Survey (NFCS II) does not contain any data on the intake of copper (MRI, 2008). However, intake data collected by 24-h recall in the NFCS II indicate that, depending on sex and age, adolescents from 15 years of age and adults show median dietary intakes of copper of 1.2 to 1.5 mg/day (f) and 1.5 to 1.8 mg/day (m). The 95th percentile of copper intake is highest among 35- to 50-year-old men (2.8 mg/day) and 51- to 64-year-old women (2.4 mg/day), whereas the 95th percentiles of 15- to 18-year-olds are somewhat lower, at 2.3 mg/day (m) and 1.9 mg/day (f) (Krems et al., 2012).

For adults, earlier data on copper intake, which were taken into account by the SCF (2003) in deriving an UL for copper, are available from the NFCS I. According to these data, at that time, the median intake of men and women was 2.2 mg/day and 1.8 mg/day respectively, and the 97.5th percentiles were at 4.0 mg/day and 3.3 mg/day, respectively (Heseker et al., 1994).

In 2015, EFSA published intake data for adults from various European countries (not from Germany). According to these data, the median intake for adult men is in the range of 1.1 to 1.6 mg/day and for women in the range of 1.0 to 1.4 mg/day, and the 95th percentiles of copper intake in adults range from 1.9 to 2.8 mg/day (m) and from 1.7 to 2.4 mg/day (f) (EFSA, 2015).

The EsKiMo study (nutrition module in KiGGS³) conducted in Germany provides data on the intake of copper via food in 12- to 17-year-olds. According to these data, the median copper intake of this age group is 2.5 mg (m) and 2.0 mg (f) per day. The 95th percentile of this age group is 4.3 mg (m) and 3.7 mg (f) per day (Mensink et al., 2007).

Significant intakes of copper can occur through consumption of drinking water, so that at relatively high copper concentrations in drinking water, this can account for up to 50 % of total copper intake (EFSA, 2015).

2.3 Aspects taken into account in the derivation of maximum levels for food supplements

³ German Health Interview and Examination Survey for Children and Adolescents

The UL derived by the SCF (2003) as well as dietary intake data obtained from the EsKiMo study and the NFCS II were used as a basis for the derivation of maximum levels for copper. In addition, the intake data for adults from other European countries published by EFSA were also taken into account.

In the age group of 15 to 17-year-olds, the 95th percentile (P95) of dietary copper intake (= baseline consumption) reaches or exceeds the UL of 4 mg/day derived for this age group. This means that there is no scope for adding copper to food supplements for adolescents aged 15 and over.

In adults, according to EFSA (2015) (without data from Germany) and to the NFCS II (24h recall data for 35- to 50-year-old men), the P95 of copper intake is at 2.8 mg/day and thus below the UL for adults (5 mg/day). In accordance with the derivation procedure proposed by the BfR, this leaves a margin to the UL of 2.2 mg/day, which would be available for the addition of copper to food supplements.

Since there is uncertainty as to whether several food supplements with copper are consumed under certain circumstances, apart from other scientific uncertainties, an uncertainty factor of 2 is considered appropriate in deriving the maximum level for copper. Thus, based on the available data ($2.2 / 2 = 1.1$), a maximum level, rounded, of 1 mg per daily recommended dose of a food supplement is proposed for copper in food supplements for adults. The calculation assumes that conventional foods are not fortified with copper (in accordance with current practice).

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

Based on the data available on the estimated dietary intake of copper (see 2.2), there is no scope for fortifying conventional foods with copper.

Further information on the BfR website on the subject of copper

A-Z Index on copper: https://www.bfr.bund.de/en/a-z_index/copper-129962.html

Topic page on the assessment of vitamins and minerals in foods:
https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html



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3 References

D-A-CH (2015). German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society (eds.). Dietary Reference Values. 2nd version of the 1st edition 2015, Neuer Umschau Buchverlag.

EFSA (2015). European Food Safety Authority. Scientific opinion on dietary reference values for copper. Panel on Dietetic Products, Nutrition and Allergies. The EFSA Journal. 13: 4253. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4253.pdf, last accessed 01 March 2021.

Heseker H, Adolf T, Eberhardt W, Hartmann S, Herwig A, Kübler W, Matiaske B, Moch KJ, Schneider R, Zipp A (1994). Zipp: Food and nutrient intake of adults in the Federal Republic of Germany. VERA-Schriftenreihe, Band III, Wiss. Fachverlag Dr. Fleck, Niederkleen.

Mensink GBM, Heseker H, Richter A, Stahl A, Vohmann C (2007). Nutrition study as a KiGGS module (EsKiMo). Robert Koch Institute, University of Paderborn.

MRI (2008). Max Rubner Institute. National Nutrition Survey II, Results Report, Part 2. Max Rubner-Institut, Federal Research Institute of Nutrition and Food.

Krems C, Walter C, Heuer T, Hoffmann I. Food Consumption and Nutrient Intake - Results of the National Food Consumption Survey II. In: German Nutrition Society (ed.). 12th Nutrition Report 2012. DGE, Bonn, 2012.

SCF (2003). Scientific Committee on Food. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Copper. https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out176_en.pdf, last accessed: 01 March 2021.

About the BfR

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