

Proposed maximum levels for the addition of zinc 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 the addition of zinc to food supplements a maximum level of 6.5 milligrams (mg) per daily recommended dose per individual product.

With regard to a possible multiple use of zinc-containing food supplements, an uncertainty factor of 1 was applied in deriving the maximum amount. Therefore, for food supplements with more than 3.5 mg zinc per daily intake, it is recommended to provide an advice on the label to refrain from the consumption of further zinc-containing food supplements (Table 1).

Since the proposed maximum level for food supplements allows UL exceedances in adolescent males and in males of various age groups who achieve high zinc intakes from the usual diet (95th intake percentile), there is no scope for additional zinc intake via fortified foods. Therefore, with a maximum level of 6.5 mg/day for food supplements, fortification of conventional foods with zinc cannot be recommended (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	6.5 mg
Fortified conventional foods (per 100 g)	no addition

2 Rationale

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

The UL for adults derived by the former Scientific Committee on Food (SCF) of the European Commission (2003) is 25 mg/day and for adolescents aged 15-17 years 22 mg/day (Table 2).

The D-A-CH Societies² derived recommendations for dietary intake of zinc that are at 11.0 mg/day and 14.0 mg/day for females and males, respectively, between 15 and 18 years of age. For adults, the recommended intake values range between 7 and 16 mg per day, depending on phytate³ intake (D-A-CH, 2019; Table 2).

The European Food Safety Authority (EFSA) derived for zinc Population Reference Intake values of 11.9 mg (w) and 14.2 mg/day (m) for adolescents aged 15 to 17 years. For adults,

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

³ Phytic acid or phytates are naturally present in foods and have a negative effect on the bioavailability of zinc.

intake recommendations between 7.5 and 16.3 mg/day were derived depending on the daily phytate intake (EFSA, 2014; Table 2).

Table 2: Dietary reference values (recommended intake values) and UL

Age groups	Phytate intake	Recommended intake		Phytate intake	Population reference intake (PRI)		UL (SCF, 2003)
	(D-A-CH, 2019)			(EFSA, 2014)			
		female	male		female	male	
mg/day							
15-17 yrs.		11.0	14.0		11.9	14.2	22
≥ 18 yrs.							
	330	7.0	11.0	300 (intake level 1)	7.5	9.4	25
	660	8.0	14.0	600 (intake level 2)	9.3	11.7	
	990	10.0	16.0	900 (intake level 3)	11.0	14.0	
				1,200 (intake level 4)	12.7	16.3	

2.2 Exposure

In the second National Food Consumption Survey (NFCS II), for adolescents aged 14-18 years median intakes of zinc were determined of 8.8 mg/day (f) and 11.9 mg/day (m) and in the 95th percentile of 15.8 mg/day (f) and 20.6 mg/day (m). In female adults (19-80 years), median intakes were between 8.6 and 9.5 mg/day and in the 95th percentile between 13.7 and 15.5 mg/day, depending on the age group. In male adults (19-80 years), median intakes ranged from 10.4 to 12.3 mg/day and in the 95th percentile from 16.8 to 22.9 mg/day, depending on the age group (MRI, 2008).

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

Applying the procedure proposed by the BfR for the derivation of maximum levels for food supplements and fortified foods, even if the entire residual amount⁴ of 1.4 mg/day available for additional zinc intake would be added to the category food supplements, the resulting maximum amounts would no longer make a significant contribution to the daily zinc intake (maximum amount of 0.7 mg/day assuming an uncertainty factor of 2 with regard to possible multiple exposure via several food supplements and other scientific uncertainties and of 1.4 mg/day assuming an uncertainty factor of 1).

Therefore, it is recommended that the maximum amount of zinc in food supplements be based on intakes that can make a significant contribution to zinc intake, balancing the potential benefits of such supplementation against the potential disadvantages of potentially exceeding the UL. Under these conditions, it is recommended to take the following into consideration:

- a) observed zinc intakes in individuals with very low zinc intakes, i.e. the 5th intake percentile of males in the NFCS II:

⁴ UL_(15- to 17-year-olds) - P95_(dietary intake of 15- to 17-year-olds) = residual amount → 22 mg/day - 20.6 mg/day = 1.4 mg/day

14-80 years = 6.5 mg/day with a range of 6.3 to 7.0 mg/day⁵, depending on age group (MRI, 2008).

- b) Dietary reference values by EFSA⁶ for men 18 years and older, averaging the intake recommendations stratified by daily phytate intake for the lowest and highest intake levels of phytate: (9.4 mg/day + 16.3 mg/day) / 2 = 12.85 mg/day; rounded 13 mg/day.

The difference between zinc intakes observed in the 5th intake percentile of men aged 14 to 80 years (6.5 mg/day) and the averaged intake recommendation by EFSA for men 18 years and older (13 mg/day) is 6.5 mg zinc/day.

With an additional intake of 6.5 mg zinc/day,

- a) on the one hand, individuals with very low intakes of zinc could significantly improve their intake.
(It can be roughly assumed that at least 95% of females ≥ 18 years of age with phytate intakes at the 1st to 3rd phytate intake level (see Table 2) and at least 95% of males ≥ 18 years of age with phytate intakes at the 1st and 2nd phytate intake level meet or exceed the EFSA recommendations for zinc intake. Zinc intakes would also be significantly improved in women ≥ 18 years of age with phytate intakes at the 4th phytate intake level or in men ≥ 18 years of age with phytate intakes at the 3rd and 4th phytate intake level and very low zinc intakes (5th intake percentile).
- b) the UL may be exceeded by adolescents with high dietary zinc intakes (95th intake percentile) from normal foods (20.6 mg/day + 6.5 mg/day = 27.1 mg/day), on the other hand.
This could still be considered as acceptable when weighed against the possible benefit mentioned above. This also applies to possible UL exceedances in adult males with the highest zinc intakes in the 95th intake percentile, i.e. the 19- to 24-year-olds (22.9 mg/day + 6.5 mg/day = 29.4 mg/day).

In order to allow for zinc supplements that make a significant contribution to zinc intake, in deriving maximum levels for zinc in food supplements, an uncertainty factor of 1 was applied with regard to possible multiple exposure to zinc from several food supplements. Therefore, it is recommended that food supplements containing more than 50 % of this amount, i.e. rounded 3.5 mg zinc/daily recommended dose, be labelled with an advice to refrain from consuming further food supplements containing zinc.

2.4 Aspects taken into account in the derivation of maximum levels for fortified foods

In deriving maximum levels for zinc in food supplements, the additional zinc intake via fortified foods was excluded in order to allow food supplements with zinc levels that make a significant contribution to the daily zinc intake. As the proposed maximum level for food supplements allows for UL exceedances in male adolescents and in adult men of different age groups with high zinc intakes from the usual diet (95th intake percentile)⁷, there is no scope

⁵ 5th intake percentile of females (14-80 years): 5.1 mg/day, with a range of 4.4 to 5.4 mg/day, depending on age group; range in the age group 19-80 years: 4.7 to 5.4 mg/day

⁶ The derivation of maximum levels was based on the Dietary Reference Values by EFSA (2014) because at that time, the updated reference values of the D-A-CH Societies (D-A-CH, 2019) were not yet available.

⁷ Adolescent males (14-18 years): 20.6 mg/day + 6.5 mg/day = 27.1 mg/day,
19- to 24-year-old men: 22.9 mg/day + 6.5 mg/day = 29.4 mg/day.

for additional zinc exposures via fortified foods. It is therefore advised to refrain from fortifying conventional foods with zinc.

Moreover, the BfR points out that the Joint Commission of Experts on the Classification of Substances of the German Federal Institute for Drugs and Medical Devices (BfArM) and the German Federal Office of Consumer Protection and Food Safety (BVL) aim to prepare an opinion on the differentiation of foods fortified with zinc from medicinal products containing zinc for oral administration.

Further information on the BfR website on zinc

A-Z Index to Zinc: https://www.bfr.bund.de/en/a-z_index/zinc-201988.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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25- to 34-year-old men: 22.5 mg/day + 6.5 mg/day = 29.0 mg/day,
35- to 50-year-old men: 20.9 mg/day + 6.5 mg/day = 27.4 mg/day,
51- to 64-year-old men: 19.0 mg/day + 6.5 mg/day = 25.4 mg/day

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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