Proposed maximum levels for the addition of selenium 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 45 micrograms (µg) of selenium per daily recommended dose of a food supplement (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum level
Food supplements (per daily recommended dose of an individual product)	45 µg

With regard to the fortification of conventional foods with selenium, calculations resulted in maximum levels which, according to Regulation (EU) No 1169/2011, would partly have to be considered as insignificant and therefore not be allowed to be advertised according to the current legal situation (Regulation (EC) No 1924/2006). In view of this, the BfR proposes the following options for setting maximum levels for the fortification of conventional foods with selenium:

Option 1: Assuming a "saturated" market of fortified foods (30 % of daily energy intake from fortified foods), a maximum level of 10 µg/100 grams (g) is recommended while limiting fortification to solid foods.

Option 2: Assuming that only parts of fortifiable foods are actually fortified with selenium (15 % of the energy intake from fortified foods), higher maximum levels of 22 µg/100 g for solid foods and 6 µg/100 millilitres (ml) for beverages would be possible. The level of protection would be lower under this option than under the assumption of a saturated market.

2 Rationale

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

The former Scientific Committee on Food (SCF) of the European Commission (2000) has derived a UL of 300 µg selenium per day for adults (SCF, 2000). For children and adolescents, ULs of between 90 µg (4- to 6-year-olds) and 250 µg (15- to 17-year-olds) per day have been derived, depending on body weight (SCF, 2000; 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.

For selenium, the recommended intake for adolescents aged 15 years and older is between 60 (women) and 70 (men) µg per day (D-A-CH, 2015; Table 2).

Adequate Intake values for selenium of 70 µg/day for 15- to 17-year-old adolescents and adults have been derived by the European Food Safety Authority (EFSA) (EFSA, 2014; Table 2).

Table 2: Dietary reference values and UL

Age groups	Dietary reference values		UL (SCF, 2000)
	(D-A-CH, 2015)	(EFSA, 2014)	
	µg/day		
4 to < 7 years	20	20	90
7 to < 10 years	30	35 (7–10 years)	130 (7–10 years)
10 to < 13 years	45	55 (11–14 years)	200 (11–14 years)
13 to < 15 years	60		
15 to < 19 years	70 (m) 60 (f)	70	250 (15–17 years)
Adults	70 (m) 60 (f)	70	300
Pregnant women	60	70	300
Lactating women	75	85	300

2.2 Exposure

No intake data for selenium were determined in the second National Food Consumption Survey (NFCSII).

EFSA estimated (based on consumption data from various EU countries including Germany and data from an EFSA database on selenium content in foods) that the average selenium intake of adults in the EU is between 31 and 66 µg/day (EFSA, 2014).

For children between 3 and < 10 years of age, daily median selenium intakes between 32.6 µg (girls) and 38.0 µg (boys) were estimated based on data from the EsKiMo study (nutrition module in KiGGS[2]), and the 95th intake percentiles (P95) were at 57.1 and 71.6 µg/day, respectively (EFSA, 2014). According to this study, older children and adolescents aged 10 to < 18 years had median daily selenium intakes ranging from 37.3 µg (girls) to 39.5 µg (boys), and the 95th intake percentiles (P95) ranged from 63.8 µg (girls) to 67.4 µg (boys) (EFSA, 2014).

2.3 Maximum levels for selenium in food supplements

Taking into account a selenium intake for high consumers (P95) of about 70 µg/day, the application of the derivation procedure proposed by the BfR results in a residual amount of 180 µg per day:

$$\text{Residual amount} = UL_{\text{15-to 17-year-olds}} - P95_{\text{Diet of 15-to 17-year-olds}}$$

$$\text{Residual amount} = 250\ \mu g/day - 70\ \mu g/day = 180\ \mu g/day.$$

[2] German Health Interview and Examination Survey for Children and Adolescents

If the residual amount is divided equally between food supplements and conventional foods, 90 µg/day of selenium is available for each of the two categories.

Due to scientific uncertainties with regard to a possible multiple exposure to selenium via food supplements containing selenium, in accordance with the procedure followed by the BfR for other essential minerals and vitamins, an uncertainty factor of 2 is taken into account in the derivation of maximum levels for food supplements, resulting, on the basis of the available data, in a maximum level for the addition of selenium to food supplements of 45 µg per daily recommended dose of a food supplement (90 µg/day / 2 = 45 µg/daily dose of a food supplement).

For the addition of selenium to food supplements, the BfR recommends a maximum level of 45 µg per daily recommended dose of a food supplement.

2.4 Maximum level for selenium in fortified foods for general consumption

For fortification of conventional foods, an amount of 90 µg/day (residual amount available for fortified foods (FF)) is available for selenium.

If this amount is divided among the estimated daily energy intake from fortified foods, maximum levels of between 6 and 30 µg/100 kcal result, depending on age and assuming that 15 % to a maximum of 30 % of the daily energy comes from fortified foods (Table 3).

In order to ensure that the addition of selenium to fortified foods does not cause any of the age groups to exceed the residual amount$_{FF}$ of 90 µg/day, the lowest of the selenium values resulting from the calculation is proposed as maximum level for the population, i.e.:
6 µg/100 kcal, based on the assumption that the market of fortified foods is "saturated" (30 % of the daily energy from fortified foods), and 13 µg/100 kcal, based on the assumption that a smaller part of the fortifiable foods is actually fortified/consumed (15 % of the energy intake from fortified foods) (Table 3).

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

Age groups	Energy intake*	Fortification of 15% of energy intake		Fortification of 30% of energy intake	
		15 % of daily energy intake	Selenium**	30 % of daily energy intake	Selenium**
	kcal/day	*kcal*	*µg/100 kcal*	*kcal*	*µg/100 kcal*
4 to < 7 years	2,000	300	30	600	15
7 to < 10 years	2,400	360	25	720	13
10 to < 12 years	2,550	383	24	765	12
12 years	3,900	585	15	1,170	8
13 to < 15 years	3,900	585	15	1,170	8
15 to < 17 years	4,700	705	13	1,410	6
Adults	3,500	525	17	1,050	9

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

** The residual amount$_{FF}$ of 90 µg/day is allocated to 100 kcal portions

2.4.1 Conversion of energy-based maximum levels into maximum levels per 100 g of solid foods or 100 ml of beverages

The conversion of energy-based maximum levels into maximum amounts per 100 g of solid foods or 100 ml of beverages was performed using data from Schusdziarra et al. (2010) and Bechthold (2014).

Taking into account the average energy densities of 170 kcal/100 g for solid foods and of 45 kcal/100 ml for energy-containing liquids such as juices and soft drinks), the maximum levels by weight and by volume for the addition of selenium to conventional foods are given in the following table (Table 4).

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

Selenium per 100 kcal	**Selenium per 100 g or ml**	
	Solid foods (energy density: 170 kcal/100 g)	**Beverages** (energy density: 45 kcal/100 ml)
6 µg*	10 µg	3 µg
13 µg**	22 µg	6 µg

* assuming that 30 % of the energy comes from fortified foods

** assuming that 15 % of the energy comes from fortified foods

If an additional criterion in setting maximum levels is that the amounts of selenium added to a food should be significant in order to be allowed to be claimed in the labelling of the product, according to Regulation (EU) No 1169/2011, Annex XIII (reference amounts), at least 15 % of the respective nutrient reference value for labelling (NRV) should be contained in solid foods (per 100 g) and at least 7.5 % in beverages (per 100 ml).

According to that Regulation, the NRV for selenium is 55 µg. Maximum levels for selenium of ≥ 8.25 µg/100 g (at least 15 % of the NRV in solid foods) and of ≥ 4.1 µg/100 ml (at least 7.5 % of the NRV in beverages) would thus be considered significant amounts. Therefore, only the maximum levels based on the assumption that the market of fortified foods is "unsaturated" (15 % of energy intake from fortified foods), as calculated in Table 4, would meet the conditions for labelling and claiming of selenium added to conventional foods.

The BfR suggests that in cases of insignificant fortification levels, further food categories, beyond those mentioned in Article 4 of Regulation (EC) No 1925/2006, should be exempted from fortification. In the case of selenium, for example, it should be considered to limit fortification to solid foods with a maximum level of 10 µg/100 g (corresponding to the assumption of a 'saturated' market or 30 % of the daily energy from selenium fortified foods).

Another option would be to set a maximum level of 22 µg/100 g for solid foods and of 6 µg/100 ml for beverages, assuming that a smaller part of fortifiable foods is actually fortified/consumed (15 % of the energy intake from fortified foods) (Table 4).

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

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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