

## Proposed maximum levels for the addition of magnesium 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 magnesium to food supplements a maximum amount of 250 milligrams (mg) per recommended daily dose of an individual food supplement. It is recommended that this amount be divided into two or more servings per day.

For the fortification of conventional foods, a maximum level of 31 mg/100 grams (g) is recommended for solid foods and of 8 mg/100 millilitres (ml) for beverages under the assumption that the market of fortified foods is 'saturated', i.e. that 30 % of daily energy intake comes from fortified foods (Table 1).

**Table 1: Proposed maximum levels**

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	250 mg
Solid foods (per 100 g)	31 mg
Beverages (per 100 ml)	8 mg

### 2 Rationale

#### 2.1 Tolerable Upper Intake Level<sup>1</sup> (UL) and Dietary Reference Values

The former Scientific Committee on Food (SCF) of the European Commission (SCF, 2001) derived a UL of 250 mg/day for the supplementary intake of readily dissociable magnesium salts and compounds such as magnesium oxide taken up via food supplements or fortified foods for individuals aged four years and over (this amount does not include magnesium intakes from the usual diet or natural magnesium in foods)<sup>2</sup>. Since in most of the studies used to derive the UL, magnesium intake was divided into two or more servings per day, the Committee noted that the UL applies to additional intakes distributed in two or more servings per day.

The derivation of the UL by the SCF was based on mild diarrhea, which may occur in a small percentage of adults at supplemental intakes of approximately 360-365 mg magnesium and

<sup>1</sup> 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.

<sup>2</sup> No adverse effects have been observed in healthy individuals in relation with magnesium intakes from conventional foods. Therefore, and because human studies used to derive ULs for magnesium have not considered magnesium intakes from usual foods and beverages, the ULs derived by the SCF or other scientific bodies apply only to additional magnesium intakes from food supplements or fortified foods (i.e., in addition to normal intakes from usual foods and beverages).

which has been identified as an early adverse effect of excessive supplemental magnesium intakes (SCF, 2001).

Meanwhile, there are indications that mild diarrhoea can occur in a small percentage of adults even with additional intakes of 300 mg/day (Roffe et al., 2002; Supakatisant and Phupong, 2015). The BfR regards these findings as a confirmation of the UL of the SCF of 250 mg/day for additional intakes.

The intake recommendations for magnesium of the D-A-CH Societies<sup>3</sup> differ according to age (decreasing with increasing age), between 300 and 350 mg/day for females aged 15 and over and between 350 and 400 mg/day for males aged 15 and over (D-A-CH, 2015; Table 2).

An *Adequate Intake (AI)* of 250 mg/day was set by the European Food Safety Authority (EFSA) for females aged 10 to < 18 years and of 300 mg/day females from 18 years of age and for males aged 10 to < 18 years. For males aged 18 years and older, 350 mg/day were set (EFSA, 2014; Table 2).

**Table 2: Dietary reference values**

Age groups	Recommended intake (D-A-CH, 2015*)		Adequate Intake (AI) (EFSA, 2014)
	male	female	
	mg/day		
4 to < 7 years	120	120	3 - < 10 years: 230 (f/m)
7 to < 10 years	170	170	
10 to < 13 years	230	250	10 - < 18 years: 250 (f); 300 (m)
13 to < 15 years	310	310	
15 to < 19 years	400	350	
19 to < 25 years	400	310	> 18 years: 300 (f); 350 (m)
≥ 25 years	350	300	

\* latest revision: 2013

## 2.2 Exposure

In the second National Food Consumption Survey (NFCS II), median intakes of 335 mg/day (f) and 412 mg/day (m) and in the 95th percentile of 553 mg/day (f) and 700 mg/day (m) were determined in adolescents aged 14 to 18 years (MR, 2008).

In adult women (19 to 80 years), median intakes were between 334 and 378 mg/day and in the 95th percentile between 537 and 598 mg/day, depending on the age group. In adult males aged 19 to 24 years, the median intake was at 435 mg/day and in the age groups 25 to 80 years age-dependent between 389 and 454 mg/day. The 95th percentiles of these intakes (19-80 years) ranged from 596 to 809 mg/day, depending on age group (MRI, 2008).

<sup>3</sup> German-Austrian-Swiss Nutrition Societies

### 2.3 Maximum levels for food supplements

Since the UL derived by the SCF only applies to supplemental magnesium intakes, magnesium intake via the usual diet can be disregarded when deriving maximum levels for food supplements.

Due to the mild, transient effects (mild diarrhoea/laxative effects) on which the derivation of the UL for magnesium was based, it is recommended to follow the approach proposed by the BfR in 2004 for this mineral and to set a maximum level per food supplement for magnesium at the level of the UL of 250 mg/day (BfR, 2004b). It is recommended to divide this amount into two or more food supplement portions per day.

### 2.4 Maximum levels for fortified foods

In the available human studies that were used for the derivation of the UL, magnesium was administered in concentrated form as boluses (tablets, dragees, concentrated liquid solution, etc.), as typical for medicinal products or food supplements.

No adverse effects have been observed so far with magnesium intake via common foods. However, there is a lack of suitable studies examining the occurrence of adverse effects from consumption of fortified conventional foods, i.e. when additional magnesium is ingested in small portions throughout the day and in combination with a more or less complex food matrix. Therefore, there is some scientific uncertainty in this regard.

It should also be taken into account that a number of magnesium-containing compounds may be used as food additives for technological purposes and that some magnesium-containing additives may be used '*quantum satis*' (as much as necessary) in different food categories.

In view of the mild, transient effects (mild diarrhoea/laxative effects) observed with high intakes of magnesium salts and under the conditions that apply to the consumption of fortified foods<sup>4</sup>, it seems justifiable to use magnesium for fortification of conventional foods, in addition to its use in food supplements, with the maximum level proposed for food supplements, i.e. 250 mg/day.

It is recommended to use the residual amount of 250 mg/day, corresponding to 100 % of the UL derived for supplemental magnesium intakes, also for food fortification.

However, in the light of the maximum level proposed for food supplements and in view of the fact that magnesium is also used in the form of magnesium-containing additives for technological purposes, this approach appears to be justifiable only if the estimated conditions of a 'saturated' market (i.e. the assumption that 30 % of daily energy is supplied from fortified foods) are used as a basis for deriving maximum levels for food fortification.

If the amount of 250 mg magnesium/day is distributed over the estimated daily energy intake from fortified foods of 30 %, maximum magnesium levels of between 18 and 42 mg/100 kcal are obtained depending on age (Table 3). To ensure that none of the age groups exceeds the respective age-specific UL, the lowest of the values is proposed as maximum level, i.e. 18 mg/100 kcal (Table 3).

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<sup>4</sup> Consumption of small portions throughout the day, in conjunction with a more or less complex food matrix.

**Table 3: Daily energy intakes (P95) of the population and magnesium levels assuming that 30 % of the daily energy intake comes from fortified foods**

Age groups	Energy intake (P95)*	Fortification of 30 % of the energy intake	
		30 % of daily energy intake	Magnesium**
	kcal/day	kcal	mg/100 kcal
4 to 6 years	2,000	600	42
7 to 9 years	2,400	720	35
10 to 11 years	2,550	765	33
12 years	3,900	1,170	21
13 to < 15 years	3,900	1,170	21
15 to < 17 years	4,700	1,410	18
Adults	3,500	1,050	24

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

\*\* Allocation of the residual amount of 250 mg/day to 100 kcal-servings

#### 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 into weight- and volume-based maximum levels was carried out taking into account the average energy densities of solid foods (170 kcal/100 g) and energy-containing liquids such as juices and soft drinks (45 kcal/100 ml), determined by Schusdziarra et al. (2010) and Bechthold (2014).

As shown in Table 4, assuming a "saturated" market of fortified foods, the resulting maximum levels are 31 mg/100 g for solid foods and 8 mg/100 ml for beverages.

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

Magnesium per 100 kcal	Magnesium per 100 g or ml	
	Solid foods (energy density: 170 kcal/100 g)	Beverages (energy density: 45 kcal/100 ml)
18 mg*	31 mg	8 mg

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

The derived maximum levels for solid foods (31 mg/100 g) and beverages (8 mg/100 ml) are below the amounts to be considered significant according to the EU Food Information Regulation (magnesium levels  $\geq 56.3$  mg/100 g (15 % NRV) and  $\geq 28.1$  mg/100 ml (7.5 % NRV), respectively).

However, it should be borne in mind that the maximum fortification level of 80 mg/l proposed for beverages corresponds to the maximum level set for magnesium in table water in the

Mineral and Table Water Regulation (77 mg/l total magnesium concentration). In the case of solid foods, the maximum level proposed of 31 mg/100 g may help to increase the magnesium content of a food product in which magnesium is naturally present to such an extent that the product may then be allowed to carry a claim.

There would only be scope for increasing the amount of magnesium in fortified foods to 15 % of the NRV in solid foods or to 7.5 % in beverages if the fortification with magnesium was very strongly restricted to individual food categories. In this case, a restriction to individual categories of solid foods would seem appropriate, since the maximum level for beverages would still be well below the threshold of significance of 7.5 %, even when assuming a market that is only 'partially saturated' (fortification of 15 % of the daily energy intake).

#### Further information on the BfR website on magnesium

A-Z Index on magnesium: [https://www.bfr.bund.de/en/a-z\\_index/magnesium-202878.html](https://www.bfr.bund.de/en/a-z_index/magnesium-202878.html)

Topic page on the assessment of vitamins and minerals in foods:  
[https://www.bfr.bund.de/en/vitamins\\_and\\_minerals-54417.html](https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html)



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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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