Maximum levels proposed for the addition of calcium 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 calcium to food supplements a maximum level of 500 milligrams (mg) of calcium per recommended daily dose of a food supplement. The total daily intake of calcium from food supplements should not exceed 500 mg per day. Therefore, for individual food supplements with additions of more than 250 mg calcium per daily recommended dose, a note is suggested indicating to refrain from the use of further calcium-containing food supplements (Table 1).

Since the proposed maximum amount for food supplements in male adolescents and in men of different age groups who reach high calcium intakes from the usual diet (95th intake percentile, P95), exceedances of the Tolerable Upper Intake Level (UL) are possible, there is actually no scope for an additional calcium exposure via fortified foods.

With a maximum daily intake of 500 mg via food supplements, fortification of conventional foods with calcium should be limited to a few food groups consumed as substitutes for conventional foods that are naturally rich in calcium (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product) It is recommended that if more than 250 mg of calcium per daily dose is added to a single food supplement, a note should be affixed indicating that no further calcium-containing food supplement should be consumed.	500 mg
Restriction of fortification to certain food groups: Products consumed as substitutes for other conventional foods naturally rich in calcium, such as substitutes for milk and milk products Example: Addition of calcium to a milk substitute drink (per 100 ml)	At the level contained in the natural "counterpart" 120 mg

2 Rationale

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

In 2003, the former Scientific Committee on Food (SCF) of the European Commission derived a UL for adults of 2,500 mg per day. This value was re-evaluated and confirmed by

[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.

EFSA in 2012. In both the SCF evaluation and the EFSA re-evaluation, the data were considered insufficient to derive ULs for infants, children and adolescents. Nevertheless, it was noted that even at the highest intakes of calcium in the European comparison, no risk of adverse health effects had be identified in these age groups so far (EFSA 2012). In this context, the EFSA opinion also considered the intakes of German adolescents of the age group 12–17 years as the highest calcium intakes in adolescents (P95 of intakes via conventional foods, supplements and fortified foods: 2,515 mg per day; Flynn et al., 2009).

EFSA also referred in its 2012 assessment to new case reports providing evidence that the intake of high-dose calcium-containing food supplements (containing calcium in the form of calcium carbonate) may increase the risk of CAS/MAS syndrome (calcium alkali syndrome/milk alkali syndrome). CAS/MAS syndrome is typically characterised by increased serum calcium and creatinine concentrations, calcification in the kidney and resulting kidney damage. However, according to EFSA, no dose-response relationship could be established based on data from case reports (EFSA, 2012).

In 2011, the Food and Nutrition Board (FNB) of the US-Institute of Medicine (IOM) concluded, based on available case reports, that supplemental calcium intake in the form of calcium carbonate at a dose of 3,000 mg per day could be problematic, particularly in individuals with impaired renal function (FNB, 2011).
The FNB derived a UL of 3,000 mg per day for healthy children and adolescents 9–18 years of age and a UL of 2,500 mg per day for adults aged 19–50 years. In contrast, for older adults 51 years and older, a lower UL of 2,000 mg per day was established. The value of 2,000 mg per day corresponded to a total daily intake of calcium that was considered by the panel to be the Lowest Observed Adverse Effect Level ((lowest experimental dose at which an adverse health effect was observed; LOAEL) for an increased incidence of the occurrence of kidney stones in older adults (FNB, 2011).

Table 1: Dietary reference values (recommended intake) and UL

<table>
<tr><th rowspan="2">Age groups</th><th colspan="2">Dietary Reference Values</th><th rowspan="2">UL
(EFSA, 2012)</th></tr>
<tr><th>(D-A-CH, 2018*)</th><th>(EFSA, 2015)</th></tr>
<tr><td></td><td colspan="2">mg/day</td><td></td></tr>
<tr><td>1 to < 4 years</td><td>600</td><td>450</td><td rowspan="5">Not defined</td></tr>
<tr><td>4 to < 7 years</td><td>750</td><td rowspan="2">800 (4–10 years)</td></tr>
<tr><td>7 to < 10 years</td><td>900</td></tr>
<tr><td>10 to < 13 years</td><td>1,100</td><td rowspan="2">1,150 (11–17 years)</td></tr>
<tr><td>13 to < 19 years</td><td>1,200</td></tr>
<tr><td rowspan="2">≥ 19 years including pregnant and lactating women</td><td rowspan="2">1,000**</td><td>1,000 (18–24 years)</td><td rowspan="2">2,500</td></tr>
<tr><td>950 (≥ 25 years)</td></tr>
</table>

* last revision in 2013

** pregnant and lactating women < 19 years: 1200 mg/day

In 2013, the D-A-CH Societies[2] derived dietary reference values for calcium of 600 to 750 mg per day for 1- to 6-year-old children and of 900 to 1,100 mg per day for 7- to 12-year-old children. For 13- to 18-year-olds, the recommended intake is 1,200 mg per day; for adults 19 years and older, 1,000 mg per day (D-A-CH, 2018; Table 2).

[2] German-Austrian-Swiss Nutrition Societies

The European Food Safety Authority (EFSA) derived a Population Reference Intake (PRI) of 450 mg per day for children aged 1–3 years, 800 mg for children aged 4–10 years, 1,150 mg per day for children and adolescents aged 11–17 years, 1,000 mg for young adults (18–24 years) and 950 mg for adults 25 years and older (EFSA, 2015; Table 2).

2.2 Exposure

The results of the second National Food Consumption Survey (NFCS II) show that the median calcium intake in male adolescents and adults aged 14–80 years (n=7,093) was 1,052 mg per day and in female adolescents and adults (n=8,278) 964 mg per day (MRI, 2008; Table 3).

Table 3: Calcium intake at the 5th, 25th, 50th, 75th and 95th percentiles (P) of male and female adults based on NFCS II (MRI, 2008).

Population groups	N	P5	P25	P50	P75	P95
		mg/day				
Men	7,093	526	808	1,052	1,379	2,061
Women	8,278	507	755	964	1,208	1,734

After stratification for age and sex, the median calcium intakes of men were above or in the range of the D-A-CH reference value of 1,000–1,200 mg per day in all age groups, with the exception of the group of 65- to 80-year-old men. Among women, only the median intakes of the 14- to 18-year-olds and 65- to 80-year-olds were below the D-A-CH reference value of 1,200 mg per day and 1,000 mg per day, respectively. In the 95th percentile, calcium intake values decreased with increasing age and ranged from 1,669 mg to 2,176 mg per day in men and from 1,553 to 1,784 mg per day in women (Table 4).

Overall, the NFCS II data show that in adolescents and adults, the median intakes are roughly at or above the intake recommendations for calcium in almost all age groups, with the exception of female adolescents of 14–18 years and of the 65- to 80-year-olds.

In view of the importance of calcium for bone health, median intakes of a population group that are significantly below the intake recommendations are to be regarded as crucial with regard to health. On the other hand, it should be noted that the 95th percentiles of calcium intake in the NFCS-II study already exhausted 87% (2,176 mg per day) of the adult UL value of 2,500 mg per day in male adolescents aged 14–18 years and 97 % (2,422 mg per day) in male adults aged 19–24 years.

Table 4: Calcium intake in mg per day in adolescents and adults taking into account gender and age based on NVS II (MRI, 2008).

Men	n	P10	P25	P50	P75	P90	P95	Dietary Reference value
Age in years					**mg/day**			
14–18	712	730	932	1,194	1,548	1,870	2,176	1,200
19–24	510	688	877	1,179	1,503	2,048	2,422	1,000
25–34	690	675	862	1,134	1,492	1,942	2,226	1,000
35–50	2,079	663	845	1,088	1,398	1,716	2,109	1,000
51–64	1,633	588	762	989	1,294	1,642	1,908	1,000
65–80	1,469	557	707	909	1,171	1,451	1,669	1,000
Total	*7,093*	*630*	*808*	*1,052*	*1,379*	*1,735*	*2,061*	
Women	**n**	**P10**	**P25**	**P50**	**P75**	**P90**	**P95**	**Dietary Reference value**
Age in years					**mg/day**			
14–18	700	567	738	969	1,226	1,517	1,784	1,200
19–24	510	573	769	985	1,222	1,515	1,756	1,000
25–34	972	619	794	1,002	1,262	1,534	1,804	1,000
35–50	2,694	620	799	1,014	1,264	1,559	1,815	1,000
51–64	1,840	598	760	954	1,189	1,477	1,700	1,000
65–80	1,562	543	686	873	1,087	1,344	1,553	1,000
Total	*8,278*	*588*	*755*	*964*	*1,208*	*1,502*	*1,734*	

2.2.1 Calcium intake in children and adolescents (up to 17 years)

According to the EsKiMo study (Nutrition module in KiGGS[3]) (2007), the median intake of 6- to 11-year-old boys was between 820 mg and 908 mg and that of 6- to 11-year-old girls between 716 mg and 871 mg of calcium per day. The 95th percentile of intake of 6- to 11-year-old boys consumed between 1,312 mg and 1,425 mg and girls of the same age between 1,294 mg and 1,429 mg per day. In 12- to 17-year-old boys and girls, median intakes ranged from 1,192–1,525 mg and 1,073–1,260 mg per day, respectively, and the 95th percentiles of intakes ranged from 2,309–2,895 mg and 1,998–2,530 mg/day, respectively (Mensink et al., 2007; Table 5).

The median intakes of children and adolescents thus met the dietary reference values derived for the respective age groups (Table 2).

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

Table 5: Calcium intake of children and adolescents in Germany

Age groups	P5	P50 (median)	P95
		mg/day	
Boys			
6 years	416.2	820.0	1,312.4
7-9 years	490.5	887.4	1,483.5
10-11 years	476.2	908.0	1,424.9
12 years	721.3	1,192.2	2,308.7
13-14 years	619.0	1,317.0	2,456.2
15-17 years	765.0	1,524.8	2,895.0
Girls			
6 years	360.8	716.0	1,294.0
7-9 years	409.0	824.1	1,303.2
10-11 years	401.8	871.2	1,428.7
12 years	525.6	1,073.4	1,998.2
13-14 years	696.0	1,204.4	1,947.7
15-17 years	668.0	1,259.5	2,353.1

* EsKiMo study (Mensink et al., 2007), based on nutrient database BLS, version II.3

2.2.2 Main sources of calcium intake for adults

According to the Max Rubner Institute, the main sources of calcium intake in the population aged 14–80 years are milk, dairy products and cheese (about 40 %) followed by non-alcoholic beverages (about 25 %) (MRI, 2008).

2.2.3 Main sources of calcium intake for children and adolescents

In the EsKiMo study (2007), dairy products, cheese and cottage cheese were the main sources of daily calcium intake (42–50 %) for children and adolescents, followed by water as a beverage (13–23 %) and confectionery with a proportion of 7–9 % (Mensink et al., 2007; Table 6).

Table 6: The six main sources of daily calcium intake of children and adolescents in Germany, stratified by gender and age groups, EsKiMo study (Mensink et al., 2007)

Girls 6-11 years	%	Calcium in mg	Boys 6-11 years	%	Calcium in mg
Dairy products*	34	285	Dairy products	36	330
Water as a drink	14	116	Cheese and cottage cheese	14	124
Cheese and cottage cheese	14	116	Water as a drink	13	116
Confectionery	8	67	Confectionery	9	78
Juices	5	41	Juices	4	39

Bread	3	29	Cereals	4	32
Girls 12-17 years	**%**	**Calcium in mg**	**Boys 12-17 years**	**%**	**Calcium in mg**
Dairy products	27	346	Dairy products	30	441
Water as a drink	23	287	Water as a drink	20	302
Cheese and cottage cheese	15	191	Cheese and cottage cheese	14	206
Confectionery	7	88	Confectionery	7	105
Juices	6	76	Juices	6	82
Other vegetables	3	43	Lemonades	3	45

* Number of recorded products: 27

2.3 Aspects considered in the derivation of maximum levels for calcium

2.3.1 Maximum levels for of calcium in food supplements

Applying the procedure proposed by the BfR (2004b) for calculating the residual amount of a mineral that would be available for food supplements and fortified foods would result in a residual amount of 78 mg per day for calcium. This residual amount was calculated from the difference between the UL for adults (2,500 mg per day) and the highest percentile of nutrient intake from the usual diet (2,422 mg per day, 95th percentile for male adults aged 19-24 years)[4]. Even if the entire remaining amount of 78 mg per day available for supplemental calcium intake was added to a single food supplement, this amount would no longer make a significant contribution to daily calcium intake (less than 10 % of the reference value of 800 mg for calcium according to the Nutrition Labelling Regulation (Regulation (EU) No 1169/2011).

Although it can be concluded on the basis of the median intakes that most population groups included in the NFCS-II study achieved satisfactory intakes of calcium, it should be noted that a proportion of female adolescents aged 14–18 years and a certain proportion of the elderly aged 65–80 years had lower calcium intakes (Section 2.2.1, Table 4). In view of the fact that, for calcium, certain groups of people may exceed the maximum tolerable daily intake, but that, on the other hand, calcium is of particular importance for bone health, it is proposed to target the maximum amount of calcium to those parts of the population with low calcium intakes. Based on the data of the NFCS II, an additional intake of calcium would significantly improve intakes in these parts of the population.
For example, with an additional intake of 500 mg per day, as recommended by the BfR in 2004 (BfR, 2004b), the 10th percentile of intake of all age groups from 14 years would meet the intake recommendations for clacium. On the other hand, calcium intake in the 95th percentile of male adolescents and adults (age groups 14–18 and 25–50 years) and also in the 90th percentile of males in the 19–24 age group would then exceed the UL derived by EFSA for adults of 2,500 mg/day, but would still be below 3,000 mg per day.

It should be noted that since the BfR's comprehensive assessment of calcium in 2004 (BfR, 2004b), studies have been published indicating possible health risks associated with the use

[4] UL_{adults} - $P95_{diet\ (NFCS\ II)\ of\ 19\text{- to }24\text{-year-olds}\ ♂}$ = residual amount → 2,500 mg/day – 2,422 mg/day = 78 mg/day

of calcium supplements, particularly high-dosed supplements. For example, an increased incidence of cardiovascular events (myocardial infarctions, strokes) was observed in a randomised controlled trial of postmenopausal women taking either a placebo or a calcium supplement in a dosage of 1,000 mg per day over a period of five years (Bolland et al., 2008). Other studies (meta-analysis taking into account eleven randomised controlled trials, Bolland et al., 2010[5]; study on the Heidelberg cohort of the EPIC *(European Prospective Investigation into Cancer and Nutrition*) study, Li et al., 2012) also point to an increase in the risk of myocardial infarction in relation with calcium supplement intake. Overall, however, the data on a possible association between calcium intake (especially via supplements) and the risk of cardiovascular events is inconsistent. In particular, systematic studies are often lacking with respect to supplement doses below 1,000 mg per day, and observational studies often lack clear information on the supplement dosage or total calcium intake and on the duration of supplementation. In the context of the re-evaluation of the ULs for calcium in 2012, EFSA also took into account, among other things, the above-mentioned studies by Bolland et al. and Li et al. and concluded that a total intake of calcium of up to 2,500 to 3,000 mg per day from food (including supplements) was not associated with an increased risk of cardiovascular risks in adults (EFSA, 2012).

In a recent prospective study published after the re-evaluation of the UL for calcium, 388,229 men and women were assessed with regard to calcium intake from the usual diet and from supplements at baseline, and the number of deaths from cardiovascular diseases (CVD) in total as well as from heart disease, and cerebrovascular disease was recorded throughout a follow-up period of 12 years in average. This study provided evidence for an increased CVD-related risk of death in men associated with the use of high-dose calcium supplements, particularly products with a daily dose above 1,000 mg per day. It should be noted that no information is available on the duration of supplement use. Neither in women nor in men was an association found between CVD-related deaths and the intake of calcium via the usual diet (Xiao et al., 2013).

Bristow et al. reported in 2015 that intake of a given amount of calcium as a supplement or via fortified fruit juice resulted in an acutely long-lasting increase in blood serum calcium concentrations as well as higher peak concentrations than the intake of a comparable amount of calcium via a serving of (non-calcium fortified) dairy products (Bristow et al., 2015).
As an explanation for a possible increase of the risk of cardiovascular events with calcium intake via supplements compared to the usual diet, it has been postulated that higher calcium concentrations could be obtained from supplement intake (corresponding to a bolus intake) and that regularly acutely or persistently elevated calcium levels in the blood could promote vascular calcification processes and other effects, such as an enhancement of blood clotting (Reid et al., 2017).

In a randomised controlled trial with patients in whom at least one lesion that could be considered a possible precancerous lesion had previously been identified during coloscopies, these patients received a calcium supplement in a dosage of 1,200 mg per day for 3–5 years. Not during the supplementation period, but during the follow-up period (6–10 years after commencing the supplementation), there was an increased incidence of sessile serrated adenomas or polyps (SSA/Ps) in the group that had received a calcium supplement compared to the placebo group (Crockett et al., 2019). Sessile serrated adenomas or polyps are considered relevant precursors of colon carcinoma.

[5] With regard to the meta-analysis by Bolland et al. (2010), it should be noted that most of the individual studies considered supplements with dosages ≥ 1,000 mg/day.

In view of the uncertainties described regarding possible adverse health effects of a long-term intake of calcium via (high-dose) supplements and due to the lack of establishment of dose-response relationships for any effects to date, the maximum amount of 500 mg per day, currently recommended by the BfR for a total daily intake of calcium via food supplements for persons aged 15 years and older, is to be regarded as provisional and should not be exceeded without medical consultation. In order to avoid exceeding this maximum amount, the BfR recommends that in the case of food supplements containing more than 250 mg calcium per daily recommended dose, a note should be issued advising against the consumption of other food supplements containing calcium.

2.3.2 Maximum levels for fortified foods subject to the condition that only certain foods (food categories) are fortified with calcium

Since the proposed maximum amount of 500 mg per daily dose of a food supplement for persons aged 15 years and older allows for UL exceedances of male adolescents and men in the age groups 14–50 years who achieve high calcium intakes from the usual diet, there is actually no scope for additional calcium intakes via fortified foods according to the general concept of the BfR for deriving maximum levels for food supplements and fortified foods (BfR, 2004b). However, it should also be noted that a proportion of female adolescents aged 14–18 years and a certain proportion of older people aged 65–80 years have low calcium intakes.

At the population level, about two thirds of the calcium intake of adults, children and adolescents in Germany comes from the consumption of only a small number of food groups (about 40–50 % from milk and milk products including cheese, and about 25 % from non-alcoholic beverages in adolescents and adults (NFCS II) and 13–23 % from water in children (EsKiMo study), see Section 2.3; Table 6).

Accordingly, it should be borne in mind that, in the long term, population groups following a particular diet (e.g. vegan) or not consuming milk or dairy products for other reasons, without covering their calcium requirements from other relevant sources, may be at increased risk of calcium insufficiency.
Calcium fortification, which should be limited to a few food groups, would be an opportunity for these population groups to increase their calcium intake. In the view of the BfR, foods that can replace milk or milk products (cottage cheese, yoghurt, semi-hard cheese, soft cheese) are suitable food groups for calcium fortification and should contain calcium in similar concentrations as natural dairy food "counterpart". For example, plant-based beverages such as oat, almond or soy beverages could be fortified with approximately 120 mg/100 ml calcium, corresponding to the level contained in cows' milk. These foods can be expected to be consumed as substitutes for foods with naturally high calcium contents (milk and milk products) and thus are not likely to lead to additional calcium intakes in persons consuming milk/products.

In view of the use of calcium in food supplements (with a maximum amount of 500 mg per daily intake from food supplements for persons aged 15 years and older), from the BfR's point of view any fortification of foods with calcium should be limited to a few food groups that are consumed as a substitute for conventional foods with a naturally high calcium content, such as substitute products for milk or milk products.

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

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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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