

Proposed maximum levels for the addition of iron 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 iron a maximum level of 6 milligrams (mg) per daily recommended dose of a food supplement (Table 1). In addition, it is recommended that a warning label be affixed to iron-containing food supplements indicating that adult men, postmenopausal women and pregnant women should only supplement iron after medical consultation.

Table 1: Proposed maximum levels

Food category	Maximum level
Food supplements (per daily recommended dose of an individual product)	6 mg

In the view of the BfR, there are the following options for the addition of iron to conventional foods:

Option 1: no addition of iron

Option 2: Restrict the addition to the food group 'breakfast cereals' and set a maximum level in line with the current fortification practice in Germany, both in terms of iron content and iron compounds used.

2 Rationale

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

Based on the available data, the European Food Safety Authority (EFSA) was unable to derive dose-response data on the disease risks discussed in relation with high iron intakes or body stores (i.e. cardiovascular diseases, cancer and type 2 diabetes mellitus) and thus no UL has been derived for iron (EFSA, 2004; Table 2).

The D-A-CH Societies² have derived a dietary reference value of 12 mg (m) or 15 mg (f) per day for adolescents between 15 and 18 years of age. For males over 18 years of age and for females over 50 years of age, the recommended intake is 10 mg/day and for females between 18 and 50 years of age, 15 mg/day. For pregnant and lactating women, who have an

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 SD-A-CH societies

increased iron requirement, the D-A-CH societies recommend 30 and 20 mg/day, respectively (D-A-CH, 2015; Table 2).

Table 2: Dietary Reference Values (Recommended Intake) and UL

Age groups	Recommended Intake (D-A-CH, 2015)	UL (EFSA, 2004)
	mg/day	
Children		
1 to under 4 years	8	-
4 to under 7 years	8	-
7 to under 10 years	10	-
10 to under 13 years	12 (m) 15 (f*)	-
13 to under 15 years	12 (m) 15 (f*)	-
Adolescents and Adults		
15 to under 19 years	12 (m) 15 (f*)	-
19 to under 25 years	10 (m) 15 (f*)	-
25 to under 51 years	10 (m) 15 (f*)	-
51 to under 65 years	10	-
65 years and older	10	-
Pregnant women	30	-
Lactating women**	20	-

* women who are not menstruating and not pregnant or breastfeeding: 10 mg/day

** This information applies to all women after childbirth (breastfeeding or not) to compensate for losses during pregnancy.

2.2 Exposure

According to the second National Food Consumption Survey (NFCS II), the median iron intake reported for men aged 14 to 18 years was 15 mg/day and for older men (> 18 years) between 13 and 15 mg/day. The median intake for women aged 14 to 18 years was 11 mg/day and for women aged 18 to 50 and over 50 years between 11 and 12 mg/day. The 95th percentile of 14- to 18-year-old males was 26.5 mg/day and that of males over 18 years between 21 and 28 mg/day. The 95th percentile of 14- to 18-year-old females was 21 mg/day and of females over 18 years, 18 and 20 mg/day (MRI, 2008).

According to the data of the EsKiMo study (nutrition module in KiGGS³), the median iron intake in children aged 6 to 11 years was between 9.8 and 11.1 mg/day (boys) and between 8.6 and 10.4 mg/day (girls), and the 95th percentiles were between 16.4 and 19.2 mg/day (boys) and between 14.1 and 16.4 mg/day (girls). At ages 12 to 14 years, the median intake of boys was 14.4 to 17.3 mg/day and of girls 13.5 to 13.9 mg/day; the 95th percentiles of boys and girls in this age group were between 25.8 and 28.7 mg and between 24.9 and 23.6 mg per day, respectively (Mensink et al., 2007).

³ German Health Interview and Examination Survey for Children and Adolescents

2.3 Aspects considered in the derivation of maximum levels

With the exception of menstruating girls and women between 14 and 50 years of age, adequate iron intakes at or above the D-A-CH dietary reference values are achieved in Germany through the usual diet.

Populations at increased health risk of high iron intakes/stores:

- In particular, healthy adult men, postmenopausal women and people with hereditary or secondary haemochromatosis, whose proportion in the population is high⁴, are considered to be risk groups for adverse health effects of high iron intakes/stores. The above populations should supplement iron only after diagnosed deficiency and under medical supervision. The same is recommended for pregnant women, for whom a medical check of the iron status is also important with a view to a possible undersupply.
- A new evaluation of the NFCS II data by the Max Rubner Institute (MRI) on the (multiple) intake of food supplements showed that just under 20 % of supplement users used iron-containing supplements. The intake of iron was predominantly via one product. The use of two products containing iron was reported by around 3% of supplement users, while the use of three products only occurred in rare cases (Römer and Heuer, 2017). However, it should be taken into account that the data reported by the participants of the NFCS II on the supplements used as well as the nutrient content data of the MRI supplement database originate from the years 2005 to 2007. A change in the intake behaviour of the population and the nutrient composition of the supplements over the past ten years cannot be ruled out (Römer and Heuer, 2017).
- The former *Institute of Medicine* (IoM) of the USA had defined a LOAEL (Lowest Observed Adverse Effect Level) of 60 mg/day for adolescents 14 years and older and adults and of 40 mg/day for children under 14 years of age, which was based on the risk of adverse gastrointestinal effects of iron supplements. Applying an uncertainty factor of 1 to this LOAEL, a UL of 40 mg/day was derived for children between 4 and 13 years and of 45 mg/day for all age groups above 14 years including pregnant and lactating women (FNB, 2002).

From the point of view of the BfR, this UL may be provisionally used for the derivation of maximum levels for iron in food supplements for women between 14 and 50 years of age, since these women (in contrast to postmenopausal women) have higher iron requirements and their median intake does not meet the dietary reference value. If one follows the derivation procedure proposed by the BfR⁵, a 'residual amount_{FS}' of 12.5 mg/day results for the addition of iron to food supplements.

2.3.1 Maximum levels for iron in food supplements

Based on the 'residual amount_{FS}' of 12.5 mg/day and taking into account an uncertainty factor of 2 for possible multiple exposure to iron-containing food supplements, the maximum amount of iron per daily dose of an individual food supplement is 6 mg.

⁴ In Germany, the frequency is estimated at 0.2-0.6% (homozygous carriers) to 8-12% (heterozygous carriers).

⁵ Subtracting the 95th percentile of iron intake by women (20 mg/day) from the UL of the IoM (45 mg/day) and dividing the residual amount between food supplements and fortified foods (45 - 20 = 25/2) results in a residual amount of 12.5 mg/day available for the addition to food supplements.

The above-mentioned population groups (healthy adult men, postmenopausal women and people with hereditary or secondary haemochromatosis), who are at increased risk of adverse health effects from additional iron intake, should only take iron after diagnosed iron deficiency and medical consultation. Therefore, it is recommended that a warning label should be applied on these products in order that risk groups be informed accordingly.

2.3.2 Maximum levels for iron in fortified foods

In view of the long-term health risks discussed in relation with iron, the BfR has taken the view, for many years already, that iron should not be used to fortify conventional foods (BfR, 2004b).

If fortification of conventional foods with iron is nevertheless to be permitted, the BfR proposes that this be limited to breakfast cereals, which are the most frequently iron-fortified food group in Germany (approx. 90 % of iron-fortified foods) (Verbraucherzentrale Hessen, 2010).

Breakfast cereals are predominantly marketed to children and adolescents and are also consumed in greater quantities by them than by adults: According to the NFCS II, the 95th percentiles of consumption of cereal products⁶ by males and females ≥ 14 to 80 years were 117 and 102 g/day, respectively. However, the food group "cereal products" in the NFCS II includes breakfast cereals and muesli as well as, for example, cereals and flours, rice, pasta and others such as bulgur and millet (MRI, 2008). According to the EsKiMo study, which specifically recorded the consumption of "breakfast cereals", the 95th consumption percentiles of 6- to 11-year-old boys and girls ranged from 80 to 100 and from 44 to 67 g/day, respectively. Among 12- to 17-year-old boys and girls, consumption ranged from 86 to 114 and from 66 to 93 g/day, respectively (Mensink et al., 2007).

Taking into account the high consumption levels (P95) of breakfast cereals identified in children and adolescents, it is proposed to set a maximum level for iron fortification of this product group that roughly corresponds to the current fortification practice: In a master's thesis from 2007 on the "Economic and health significance of fortifying breakfast cereals with vitamins and minerals with regard to children and adolescents as a consumer group", an average iron content of 7.6 mg/100 g was identified in fortified cereals on the German market; the 75th percentile was at 11.75 mg/100 g (Büsch 2007). Even though these data are already ten years old, they roughly confirm the applications for derogation or general authorisation for the manufacture and/or marketing of iron-enriched breakfast cereals submitted to the BfR for assessment in recent years.

In breakfast cereals, iron is mainly added in the form of iron pyrophosphate, NaFeEDTA or elemental iron, which is chemically largely inert. Compared to soluble iron compounds, these iron compounds have good technological properties which do not cause any undesirable "off flavour" or discolouration. However, the bioavailability can vary greatly depending on the production method and physicochemical properties (e.g. particle size) and is generally low compared to that of water-soluble iron compounds such as ferrous sulphate or fumarate (BfR, 2004b). Under safety considerations, however, a low bioavailability of the iron compounds used for fortification is to be regarded as positive.

⁶ Defined in NFCS II as "e.g. cereals and flours, rice, cereals (processed), muesli (dry), pasta, miscellaneous (bulgur, millet)" (MRI, 2008).

In summary, it is proposed to limit the addition of iron to foods to breakfast cereals and to set a maximum level for this in line with the current fortification practice in Germany, both in terms of iron content and compounds used.

Further information on the BfR website on the subject of iron

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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