

Proposed maximum levels for the addition of manganese 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 manganese to food supplements a maximum amount of 0.5 milligrams (mg) per recommended daily dose of a food supplement (Table 1).

Fortification of conventional foods with manganese should be avoided (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	0.5 mg
Conventional foods (per 100 g or 100 ml)	no addition

2 Rationale

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

For manganese, due to insufficient scientific data, the former Scientific Committee on Food (SCF) of the European Commission could not derive a UL. In the risk characterisation, the Committee indicated that the space between the effect levels identified in human and animal studies following oral manganese intakes and the estimated manganese intake from foods is small. Based on evidence of neurotoxicity of manganese and increased vulnerability of some population groups, the SCF concluded that, while there is no evidence for beneficial effects, there is an increased risk for adverse health effects of manganese intakes beyond those commonly ingested through liquid and solid foods may present a health risk (SCF, 2000).

The estimated value for an adequate intake of manganese derived by the D-A-CH Societies² is 2–5 mg per day for persons aged ten years and older (D-A-CH, 2019³; Table 2).

The European Food Safety Authority (EFSA) established an *Adequate Intake* (AI) for manganese of 3 mg per day for individuals 15 years of age and older (EFSA, 2013; 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.

² German-Austrian-Swiss Nutrition Societies

³ The D-A-CH estimated values for an adequate intake of manganese are based on a derivation from the year 2000.

Table 2: Dietary reference values

Age groups	Estimated values for an adequate intake (D-A-CH, 2015*)	Adequate Intake (AI) (EFSA, 2013)
	mg/day	
4 to < 7 years	1.5–2.0	1.0
7 to < 10 years	2.0–3.0	1.5 (7–10 years)
10 to < 15 years	2.0–5.0	2.0 (11–14 years)
≥ 15 years and adults**	2.0–5.0	3.0

* based on a derivation from the year 2000

** including pregnant and lactating women

2.2 Exposure⁴

Manganese intake was not recorded in the second National Food Consumption Survey (NFCS) II (MRI, 2008). However, the BfR has conducted an exposure estimate for manganese, based on the food consumption data of the NFCS II and the nutrient content data for manganese from the German Pilot Total Diet Study (Sachse et al., 2019). According to this exposure estimate, the median manganese intake of the German population aged 14 to 80 years ranges between 38.1 µg per kg body weight (bw) (= lower-bound²) and 42.6 µg per kg bw (= upper bound²), which corresponds to a median intake between 2.7 and 3.0 mg per day, taking into account a body weight of 70 kg. The estimated intake of the 5th percentile was thus between 16.4 and 19.9 µg per kg bw, corresponding to an intake between 1.1 and 1.4 mg per day for a body weight of 70 kg, and that of the 95th intake percentile between 78.6 and 83.2 µg per kg bw, corresponding to an intake between 5.5 and 5.8 mg per day for a body weight of 70 kg (Sachse et al., 2019).

In people living on a vegetarian diet, aged between 14 and 80 years, a median intake was estimated between 43.3 and 47.5 µg per kg bw, corresponding to between 3.0 and 3.3 mg per day for a body weight of 70 kg and in the 95th intake percentile, the estimate is between 100.8 and 106.4 µg per kg bw, corresponding to an intake between 7.1 and 7.5 mg per day for a body weight of 70 kg (Sachse et al., 2019).

All of these exposure estimates did not capture manganese intakes from consumption of food supplements or fortified foods (Sachse et al., 2019).

⁴ For manganese, the "lower bound" and the "upper bound" estimated values are provided. For the lower-bound estimates, a value of "0" was considered for manganese levels in foods below the detection limit. In the calculation of the "upper-bound" estimates, a value equal to the detection limit was considered for manganese levels in foods below the detection limit. The true estimated intake value for manganese lies between the "lower bound" and "upper bound" estimated values.

2.3 Aspects considered in the derivation of maximum levels for manganese

No UL for manganese could be derived from the SCF (2000) due to insufficient data. The procedure proposed by the BfR for deriving maximum levels for vitamins and minerals for food supplements and fortified foods is therefore not applicable in the case of manganese. The following aspects have been taken into account in deriving the maximum levels:

As part of the German Pilot Total Diet Study, the BfR estimated the manganese intake from usual food consumption of the German population 14 to 80 years of age (see Section 2.2) and conducted a comprehensive risk assessment based on the estimated intake values and the available relevant scientific literature (Sachse et al., 2019). Thereby, knowledge gaps relevant to risk assessment of oral manganese intakes were indicated. Furthermore, it was concluded that there is no evidence that dietary manganese intakes are associated with adverse health effects (one exception is manganese intake via drinking water, but this is not relevant given the manganese levels of drinking water available in Germany; another exception are food supplements - see below). Moreover, it was also concluded that adverse health effects of manganese intakes estimated by the BfR for the 14- to 80-year-old German population are very unlikely. Finally, it has been pointed out that the administration of manganese as a bolus and as a readily soluble salt, as in the case of food supplements, may affect the bioavailability and possibly also the toxicity of manganese, and therefore the use of manganese-containing food supplements could be associated with potential risks (especially in certain subpopulations) if intake levels, which are currently poorly defined, are exceeded (Sachse et al., 2019). In this context, it should be noted that the assessment by Sachse et al. (2019) was not intended to derive maximum levels for manganese in food supplements.

With regard to the special features of food supplements described above, it is also of relevance that EFSA in 2009 assessed the use of different manganese compounds as sources of manganese in food supplements and by that also referred to the assessment of the British *Expert Group on Vitamins and Minerals* (EVM, 2003). As a result of the assessment, the EFSA Panel concluded that there are no safety concerns with the intended use of the manganese compounds provided that the guidance values derived by the EVM⁵ for additional manganese intakes via food supplements and fortified foods are not exceeded, i.e. 4 mg per day for the general population and 0.5 mg per day for elderly persons (without further age definition) (EFSA, 2009; EVM 2003).

In view of this, the BfR considers the EFSA assessment from 2009 as an interim basis for the derivation of maximum levels for manganese.

2.3.1 Maximum levels for manganese in food supplements

In its assessment, EFSA did not indicate any safety concerns if the manganese intake resulting from the use of the different manganese salts in food supplements did not exceed the guidance value derived by the UK EVM for supplemental manganese intake of 4 mg per day for the general population and of 0.5 mg per day for elderly persons (EFSA 2009).

⁵ It should also be noted that the British EVM (2003), like the SCF (2000), was unable to derive a UL (referred to as "safe upper level" in the EVM) due to insufficient scientific data on manganese, and thus, subject to considerable scientific uncertainties, suggested only a "guidance value". In the case of manganese, the guidance value applies only to *supplemental* manganese intakes, i.e. intakes that are in addition to the usual diet. This comprises food supplements and fortified foods.

As different age-dependent dosages of manganese in food supplements for adults do not appear practicable, the BfR recommends to use the daily dose of 0.5 mg considered safe for elderly persons as the maximum level for food supplements. It should be noted that under these circumstances, there is no scope for another manganese-containing food supplement.

2.3.2 *Maximum levels for manganese in fortified foods*

In view of the considerable scientific uncertainties in relation with manganese and due to the fact that the maximum amount of 0.5 mg per day (for elderly persons), derived by the EVM for supplementary manganese intake and used here as a provisional guidance value, is already completely exhausted by food supplements, the BfR recommends that manganese should not be used to fortify conventional foods.

Further information on the BfR website on 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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