

Proposed maximum levels for the addition of sodium 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 not to use sodium for nutritional purposes in food supplements and not to fortify conventional foods with sodium (Table 1).

However, the addition of sodium to special foods such as carbohydrate-electrolyte solutions may be useful from a nutritional point of view to compensate for significant losses, e.g. due to increased sweat losses after intense physical activity. Such products should contain a sodium concentration of 1,150 milligrams per litre (mg/L), recommended by the European Food Safety Authority (EFSA) (Table 1) and - as a prerequisite for a nutrition claim - fulfil the requirements stipulated in Regulation (EU) No 432/2012.

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	no addition*
Conventional foods (per 100 g)	no addition*
Special foods to compensate for increased sodium losses (per L)	1,150 mg (minimum level: 460 mg)

* for nutritional purposes

2 Rationale

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

EFSA (2005) was unable to derive a UL for sodium on the scientific data available (Table 2). However, it was pointed out that there is a high level of evidence that the amount of table salt (sodium chloride) currently consumed in Europe increases the risk of high blood pressure in the population and that high blood pressure is associated with the development of cardiovascular and kidney diseases (EFSA, 2005). For this reason, the D-A-CH Societies², among others, recommended limiting the consumption of table salt to 6 g (corresponding to 2.4 g sodium) per day (D-A-CH, 2015).

For sodium, an estimated value for adequate intake was derived, which is 1500 mg/day for adolescents aged 15 years and older and for adults (D-A-CH, 2015; 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

Table 2: Dietary reference values (estimated values for an adequate intake) and UL

Age groups	Dietary Reference Values		UL
	(D-A-CH, 2016)	(EFSA, 2019)	(EFSA, 2005)
mg/day			
Adolescents from 15 years and adults	1,500	2,000	-

2.2 Exposure

According to the second National Food Consumption Survey (NFCS II), the median sodium intake of male and female persons aged 14 to 18 years was 3,300 and 2,310 mg/day, respectively, and in men and women > 18 years it ranged from 2,940 to 3,415 mg/day and from 2,220 to 2,460 mg/day, respectively. The 95th consumption percentiles of the 14- to 18-year-olds were at 5,980 mg/day (m) and 4,430 mg/day (f), respectively. In males and females > 18 years, the 95th percentiles ranged from 4,770 to 6,750 mg/day and from 3,640 to 4,130 mg/day, respectively (MRI, 2008).

2.3 Aspects considered in the derivation of maximum levels for food supplements

Taking into account the supply situation of the German population as well as the health risks associated with a high intake of sodium or sodium chloride, there is no reason in favour of the addition of sodium to food supplements for nutritional purposes.

2.4 Aspects considered in the derivation of maximum levels for fortified foods

To the knowledge of the BfR, sodium has so far not been used in Germany to fortify conventional foods. However, beverages manufactured for the purpose of rehydration after intense physical exercise can be found on the market as so-called "isotonic beverages".

Both, the former Scientific Committee on Food (SCF) of the European Commission (SCF, 2001) and the EFSA NDA Panel (EFSA, 2015), acknowledged the importance of fluid (and carbohydrate) intake and the role of sodium in maintaining physical performance during endurance exercise and in rehydration after intense exercise, and have formulated compositional requirements for carbohydrate-electrolyte solutions: Thus, sodium concentrations between 20 and 50 millimoles per liter (mmol/L), equivalent to 460 and 1,150 mg/L, were considered appropriate for increasing the absorption of carbohydrates and fluids in the small intestine and for maintaining the extracellular fluid volume (EFSA, 2015).

Furthermore, EFSA (EFSA, 2011a) assessed the substantiation of health claims for carbohydrate-electrolyte solutions, and two health claims were approved by the European Commission in 2012 under Article 13 (1): to maintain endurance performance during prolonged endurance training and to improve the absorption of fluids during physical activity. Accordingly, in order to be eligible to bear one of the two claims, beverages must comply with the following conditions in addition to the above-mentioned sodium concentration requirements: Carbohydrate-electrolyte solutions should contain 80-350 kilocalories per liter (kcal/L) from carbohydrates, and at least 75 % of the energy should be derived from carbohydrates that have a significant blood sugar raising effect, such as glucose, glucose polymers and sucrose. Moreover, these beverages should also have an osmolality of 200-330 Milliosmol per kilogram (mOsm/kg) water.

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

Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. <https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=CELEX:02012R0432-20170822&from=EN>, last accessed 1 March 2021.

D-A-CH (2016). German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society (eds.). Dietary Reference Values. Complete revision of the chapters on sodium, chloride and potassium in the 2nd version of the 2nd updated edition 2016, German Nutrition Society, Bonn.

EFSA (2005). European Food Safety Authority. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Sodium (Request N° EFSA-Q-2003-018) (adopted on 21 April 2005). The EFSA Journal. 209: 1-26. <https://www.efsa.europa.eu/de/efsajournal/pub/209>, last accessed 1 March 2021.

EFSA (2011). EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to carbohydrate-electrolyte solutions and reduction in rated perceived exertion/effort during exercise (ID 460, 466, 467, 468), enhancement of water absorption during exercise (ID 314, 315, 316, 317, 319, 322, 325, 332, 408, 465, 473, 1168, 1574, 1593, 1618, 4302, 4309), and maintenance of endurance performance (ID 466, 469) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal. 9: 2211 [29 pp]. <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2211/epdf>, last accessed 1 March 2021.

EFSA (2015). Scientific and technical assistance on food intended for sportspeople. EFSA supporting publication: EN-871. 32 pp. <https://www.efsa.europa.eu/de/supporting/pub/871e>, last accessed 1 March 2021.

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Castenmiller J, de Henauw S, Hirsch-Ernst K-I, Kearney J, Knutsen HK, Maciuk A, Mangelsdorf I, McArdle HJ, Pelaez C, Pentieva K, Siani A, Thies F, Tsabouri S, Vinceti M, Aggett

P, Fairweather-Tait S, Martin A, Przyrembel H, Ciccolallo L, de Sesmaisons-Lecarre A, Martinez SV, Martino L and Naska A (2019). Scientific Opinion on the dietary reference values for sodium. EFSA Journal 17: 5778, 191 pp.

MRI (2008). Max Rubner Institute. National Nutrition Survey II, Results Report, Part 2. Max Rubner-Institut, Federal Research Institute of Nutrition and Food.

SCF (2001). Report of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen (Adopted by the SCF on 22/6/2000, corrected by the SCF on 28/2/2001). SCF/CS/NUT/SPORT/5 Final (corrected), 28 February 2001 https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out64_en.pdf, last accessed 1 March 2021.

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.

This text version is a translation of the original German text which is the only legally binding version.