Proposed maximum levels for the addition of potassium 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 a maximum amount of 500 milligrams (mg) per recommended daily dose of an individual food supplement for the addition of potassium to food supplements (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum level
Food supplements (per recommended daily dose of an individual product)	500 mg

For the fortification of conventional foods with potassium, the derivation procedure proposed by BfR resulted in maximum levels that would have to be classified as non-significant according to Regulation (EU) No. 1169/2011, and thus products would not be allowed to carry a claim according to the Regulation (EC) No. 1924/2006 currently in force. Against this background, the BfR proposes the following options for setting maximum levels for the addition of potassium to conventional foods:

Option 1: As an exception, non-significant maximum levels could be accepted, e.g. depending on the level of safety aimed for: 120 or 240 mg/100 g or 32 or 64 mg/100 ml of food.

Option 2: The use of significant amounts of potassium (≥ 300 mg/100 g or ≥ 150 mg/100 ml) for fortification of conventional foods could be restricted to selected food groups.

Option 3: Potassium could be excluded from fortification of foods for nutritional purposes. In this case, the total residual amount of 2,000 mg/day available for food supplements and conventional foods could be allocated to the category of food supplements alone.

The possibility of using potassium for technological purposes, including as a substitute for table salt, would remain unaffected by each of the proposed options.

2 Rationale

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

[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.

The European Food Safety Authority (EFSA) could not derive a UL for potassium on the basis of the available data (EFSA, 2005). However, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) concluded that the risk of adverse health effects from excessive dietary potassium intakes (at daily intakes of up to 5,000–6,000 mg or 129–154 millimol (mmol) in adults) is low in the healthy general population because potassium concentrations in the organism are normally strictly homeostatically regulated (Lehnhardt and Kemper, 2011 cited in: EFSA, 2016).

However, hyperkalaemia can occur in individuals whose homeostatic regulation is disturbed, e.g. in impaired renal function, or when extremely high amounts of potassium are ingested via supplements or parenterally and intracellular potassium is released from the cells into the blood, e. g. in metabolic acidosis, hypoxia or severe tissue damage (EFSA, 2005 and 2016).

In 2003, the British Expert Group on Vitamins and Minerals (EVM) proposed 3,700 mg/day, a level at which no obvious adverse health effects have been observed so far, as a guidance upper level (GUL) for potassium intake via supplements, but EVM pointed out that certain potassium preparations, even below this dose, may be associated with minor gastrointestinal lesions. The EVM recommended that potassium compounds used for technological purposes should also be included in the GUL (FSA, 2003).

In a recent meta-analysis examining the effects of potassium supplementation on heart rate, the authors concluded that supplementation of 2,000 to 3,000 mg of potassium per day for two to 24 weeks in healthy individuals does not affect heart rate, but based on the available scientific data no conclusions could be drawn about possible long-term effects (Gijsbers et al., 2016). In addition, Cappuccio et al. (2016) reported on the basis of a systematic review, in which they included 20 – predominantly controlled – studies, that no negative effects on renal function were observed with potassium supplementation in doses between 860 and 5,500 mg/day for 2 to 24 weeks in "relatively healthy" individuals, some of them with mild hypertension but normal renal function. However, in some studies, adverse gastrointestinal effects were reported. It should be noted that the studies predominantly used potassium doses of or below 3,000 mg/day and their duration was in most cases only two to six weeks; only one of the studies was conducted for a total of 24 weeks.

Case reports described adverse effects on cardiac function in otherwise healthy adults after use of potassium supplements at doses between 5,000 and 7,000 mg/day (128–179 mmol) (EFSA, 2005 and 2016).

In summary, based on current knowledge, supplementation of healthy adults with no more than 3,000 mg of potassium per day does not appear to result in adverse health effects.

The BfR recommends using the amount of 3,000 mg/day as a reference value for the derivation of maximum levels. Taking into account the reference body weight of 70 kg for adults, as defined by EFSA (EFSA, 2012), this would result in an intake of 43 mg potassium per kg body weight (bw). For the age group of 15- to 17-year-olds (or 14- to < 18-year-olds), for whom EFSA considers a reference body weight of 61.3 kg to be appropriate, a somewhat lower orientation value of about 2,600 mg/day is derived for supplemental potassium intake.

The D-A-CH Societies[2] have derived estimated values for an adequate intake for potassium, which are at 4,000 mg/day for adolescents aged 15 years and older and adults, and at 4,000 and 4,400 mg/day, respectively, during pregnancy and lactation. For children between 1 and

[2] German-Austrian-Swiss Nutrition Societies

14 years of age, estimated values between 1,100 and 3,600 mg/day have been derived, depending on age (D-A-CH, 2016; Table 2).

EFSA has derived an *Adequate Intake (*AI) of 3,500 mg/day for individuals ≥ 15 years of age based on the observed associations between potassium and blood pressure as well as the risk for stroke. This value also applies to pregnant women, while 4,000 mg/day was set for lactating women. For children aged 1-14 years, age-dependent AI values of between 800 and 2,700 mg/day were set (EFSA, 2016; Table 2).

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

Age groups	Dietary reference values		UL (EFSA, 2005)
	(D-A-CH, 2016)	(EFSA, 2016)	
	mg/day		
4 to < 7 years	1,300	1.100	-
7 to < 10 years	2,000	1,800 (7–10 years)	-
10 to < 13 years	2,900	2,700 (11–14 years)	-
13 to < 15 years	3,600		-
15 to < 19 years	4,000	3,500 (15–17 years)	-
Adults ≥ 19 years	4,000	3,500	-
Pregnant women	4,000	3,500	-
Lactating women	4,400	4,000	-

2.2 Exposure

2.2.1 Adults

According to the second National Food Consumption Survey (NFCS II), the median potassium intake of adult men and women (19 to 80 years) ranged from 3,374 to 3,807 mg and from 2,825 to 3,254 mg per day, respectively, depending on age. The 95th percentiles of dietary intake were between 5,231 and 6,980 mg and between 4,687 and 5,327 mg per day, respectively. Adolescents aged 14 to 18 years had a median dietary intake of 3,490 mg (male) and 2,810 mg (female) potassium per day; the 95th percentiles of intake in this age group were at 6,230 mg (male) and 5,160 mg (female) per day, respectively (MRI, 2008).

In order to assess the supply of potassium more reliably, spontaneous urine samples were collected in the first wave of the German Health Interview and Examination Survey (DEGS1), in which potassium and creatinine concentrations were measured. The median daily potassium intakes derived from spontaneous urine excretion ranged from 2,801 to 3,528 mg and from 2,228 to 3,286 mg per day in men and women aged 19 to 79 years, respectively. Thus, the values determined via renal excretion compare well with the intakes determined in the NFCS II (using Diet-History interviews) (DGE, 2016).

It should, however, be noted that spontaneous urine excretion is less reliable than the determination of potassium excretion from 24-hour urine. Furthermore, it must be taken into account that less than 100 % of the dietary potassium is absorbed and excreted via urine

(EFSA, 2016); rather about 10 % is excreted via faeces and sweat. The intake amounts estimated on the basis of urine excretion thus underestimate the actual dietary intake of potassium by about 10 %.

The intake of potassium in children was determined in the EsKiMo study (nutrition module of KiGGS[3]) conducted by the Robert Koch Institute (RKI) in 2006. According to this study, boys and girls aged 6 to 11 years had a median daily potassium intake of between 2,200 and 2,300 and between 2,100 and 2,300 mg, respectively; the 95th percentiles (P95) of potassium intake were at 3,400 to 3,600 mg and 3,000 to 3,500 mg/day, respectively. Among older children (12 to 17 years), the median (P95) intakes were between 3,300 and 3,900 (5,600–7,300) mg and between 2,800 and 3,200 (5,300–5,900) mg/day, respectively (Mensink et al., 2007).

The median intake of children aged 6 to 11 years are thus in the range of the D-A-CH reference value derived for this age group (7 to < 10 years: 2,000 mg/day), while the median intakes of older children are to some degree below the D-A-CH reference values (10 to < 13 years: 2,900 mg/day; 13 to < 15 years: 3,600 mg/day).

2.3 Aspects considered in the derivation of maximum levels for potassium

- In healthy people (without medically or drug-induced disorders of potassium excretion), no adverse health effects have been reported so far in relation with potassium intakes from the usual diet. Therefore, the dietary intake of potassium can be disregarded in the derivation of maximum levels.

- According to the results of the NFCS II, food supplements with potassium have so far not made a relevant contribution to the intake of this nutrient (Römer and Heuer, 2017).

- Potassium is an accompanying cation in a number of compounds that are added to foods for technological purposes. In addition, potassium compounds are permitted as a substitute for table salt (see Annex 3 DiätV).

- In the Netherlands, the impact of replacing 20, 50 or 100% of sodium chloride in processed foods with potassium chloride was modeled and increases in the median intake of potassium (approximately 3,330 mg/day) of 450 to 730 mg/day were calculated (van Buren et al., 2016).

Possible risk groups for high potassium intakes:

- Individuals at increased risk for adverse health effects from high (supplemental) potassium intakes comprise those with pre-existing hyperkalemia as well as those with impaired renal function, insulin deficiency or diabetes mellitus, heart disease, and in general older individuals with increasingly impaired renal function.
  Against this background, the former US Institute of Medicine (IOM) advised individuals taking medications such as ACE inhibitors in cardiovascular disease and individuals using angiotensin receptor blockers or potassium-sparing diuretics not to consume potassium supplements and to consume lower amounts of dietary potassium than recommended for the healthy population (IOM, 2004).

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

- In the German Health Interview and Examination Survey 2008–2011 (DEGS1), representative data on the prevalence of renal dysfunction were collected for the first time. According to this study, 2.3 % of the population studied (N=7,115) aged between 18 and 79 years had an impaired glomerular filtration rate (eGFR[4]). In terms of the German population, this corresponds to about 1.5 million people. The data indicate a strong age dependency: While renal dysfunction is extremely rare in persons under 50 years of age, it affects one in eight persons in the age group 70–79 years, and it can be assumed that the prevalence is even higher in the over–80s. Important predictors of impairment of renal function are diabetes mellitus and arterial hypertension (Girndt et al., 2016).
  According to DEGS1, only about 28 % of subjects with eGFR are aware of their renal function impairment, and only about two-thirds of these individuals reported that they were under medical treatment for this reason (Girndt et al., 2016).

Taking into account that

a) a number of potassium compounds are used both in food reformulation (salt substitutes) and for other technological purposes;
b) according to DEGS1, only about 1/3 of those with renal dysfunction are aware of this disorder, and
c) a relatively high proportion of the population (elderly people, people with diabetes mellitus and heart diseases) must be considered as a risk group for adverse health effects of high potassium intakes,

the BfR is of the opinion that potassium used for technological purposes should be included in the orientation value suggested for tolerable additional intake of potassium. This was also recommended by the EVM (FSA, 2003).

Taking into account the above cited model calculations by van Buren et al. (2016), an amount of 600 mg of potassium per day should be "earmarked" for use for technological purposes. Based on an orientation value of 2,600 mg/day (for 15- to 17-year-olds), proposed for supplemental potassium intake (over and above normal dietary intake), after deduction of 600 mg of potassium for technological purposes, a total residual amount of 2,000 mg/day would be available for the addition to food supplements and fortification of conventional foods.

If the total residual amount is allocated equally to food supplements and conventional foodstuffs, 1.000 mg/day is available for the addition to food supplements and other foods.

2.3.1 Maximum levels for potassium in food supplements

Taking into account an uncertainty factor of 2, in view of a possible multiple exposure by use of more than one potassium-containing food supplement per day and gaps of data (there are no experimentally determined data on potassium requirements and no UL for potassium could be derived on the basis of existing data), a maximum level of 500 mg per recommended daily dose of a food supplement (1,000 mg/day : 2 = 500 mg per daily dose of a food supplement) is recommended.

2.3.2 Maximum levels for potassium in fortified foods

If the residual amount available for fortified foods of 1,000 mg/day is assigned to the estimated daily energy intake from fortified foods and under the assumption that 15 to 30 % of

[4] GFR < 60 ml/min/1.73 m^2

the daily energy intake comes from fortified foods, the resulting maximum age-dependent levels of potassium would range between 71 and 333 mg/100 kcal (Table 3).

Table 3: Daily energy intake (P95) of the population and potassium levels assuming that 15 % or 30 % of the energy intake comes from fortified foods

Age groups	Energy intake*	Fortification of 15 % of the energy intake		Fortification of 30 % of the energy intake	
		15 % of daily energy intake	Potassium**	30 % of daily energy intake	Potassium**
	kcal/day	*kcal*	*mg/100 kcal*	*kcal*	*mg/100 kcal*
4 to 6 years	2,000	300	333	600	167
7 to 9 years	2,400	360	278	720	139
10 to 11 years	2,550	383	261	765	131
12 years	3,900	585	171	1,170	85.5
13 to < 15 years	3,900	585	171	1,170	85.5
15 to < 17 years	4,700	705	142	1,410	71
Adults	3,500	525	190	1,050	95

* Data for children up to the age of 17 from EsKiMo and for adults from NFCS II

** Allocation of the residual amount of 1,000 mg/day to 100 kcal portions

In order to ensure that none of the age groups exceeds the respective age-specific guidance value, the lowest of the potassium levels resulting from the calculation are proposed as maximum levels, i.e. 71 mg/100 kcal under the assumption that 30 % of the daily energy intake is fortified with potassium, and 142 mg/100 kcal under the assumption that only 15 % of the daily energy intake is fortified with potassium (Table 3).

2.3.2.1 Conversion of energy-based maximum levels into maximum amounts per 100 g of solid foods or 100 ml of beverages

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

Taking into account the average energy densities used for the calculation, the following table provides weight- and volume-based maximum levels for the addition of potassium to conventional foods (Table 4).

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

Potassium per 100 kcal	Potassium per 100 g or ml	
	Solid foods (energy density: 170 kcal/100 g)	**Beverages** (energy density: 45 kcal/100 ml)
71 mg*	120 mg	32 mg

142 mg**	240 mg	64 mg

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

** assuming that 15 % of the energy intake comes from fortified foods

If one considers as an additional criterion for setting maximum levels that the amounts added to a food product should be a significant amount in order that a claim may be made on the product in accordance with Regulation (EC) No 1924/2006[5], then according to Regulation (EU) No 1169/2011, the product must contain at least 15 % of the respective nutrient reference value for nutrition labelling (NRV) per 100 g in the case of solid foods and at least 7.5 % of the respective reference value per 100 ml in the case of beverages.

For potassium, the NRV is 2,000 mg; 15 % of this amount corresponds to 300 mg, and 7.5 % corresponds to 150 mg. Thus, in any case, the weight- and volume-based maximum levels calculated in Table 4 are below amounts considered as significant, and therefore no claims would be allowed on foods containing these amounts.

If potassium is nevertheless to be permitted for fortification of conventional foods, it would have to be decided whether non-significant levels (see Table 4) should be accepted for this purpose, by way of exception, or whether the addition of significant amounts (≥ 300 mg/100 g or ≥ 150 mg/100 ml) should be restricted to selected food groups.

Finally, it would also be possible that potassium be exempted from an addition to foods for nutritional purposes and that the entire residual amount of 2,000 mg/day be allocated to the category of food supplements only.

This would not affect the possibility of using potassium for technological purposes, including as a substitute for table salt.

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

3 References

Bechthold A (2014). Dietary energy density and body weight. Ernährungs Umschau international. 1: M14-23.

[5] Conditions for a product to be allowed to carry a claim "source of..." or "rich in...", according to EU Regulation 1924/2006 (Health Claim Regulation: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0009:0025:DE:PDF)

Cappuccio FP, Buchanan LA, Ji C, Siani A, Miller MA (2016). Systematic review and meta-analysis of randomised controlled trials on the effects of potassium supplements on serum potassium and creatinine. BMJ Open. 6: e011716.

D-A-CH (2016). German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society. Dietary Reference Values. 2nd version of the 2nd updated edition 2016, German Society for Nutrition, Bonn.

DGE (2016). 13th DGE nutrition report. Deutsche Gesellschaft für Ernährung e. V. (ed.). Bonn, 2016.

EFSA (2005). 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 Potassium. EFSA Journal. 193: 1-19. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/opinionon ulpotassium1%2C7.pdf, last accessed 04 March 2021.

EFSA (2012). EFSA Scientific Committee; Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal.10: 2579.

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies) (2016). Scientific opinion on dietary reference values for potassium. EFSA Journal. 14: 4592.

FSA (2003) Food Standards Agency. Expert Group on Vitamins and Minerals. Safe Upper Levels for Vitamins and Minerals. Report of the Expert Group on Vitamins and Minerals. May 2003. https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf, last accessed 04 March 2021.

Girndt M, Trocchi P, Scheidt-Nave C, Markau S, Stang A (2016). The prevalence of renal failure-results from the German Health Interview and Examination Survey for Adults, 2008-2011 (DEGS1). Dtsch Arztebl Int. 113: 85-91.

Gijsbers L, Mölenberg FJ, Bakker SJ, Geleijnse JM (2016). Potassium supplementation and heart rate: a meta-analysis of randomized controlled trials. Nutr Metab Cardiovasc Dis. 26: 674-82.

IOM (2004). Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. The National Academies. https://www.nap.edu/read/10925/chapter/1, last accessed 04 March 2021.

Mensink GBM, Heseker H, Richter A, Stahl A, Vohmann C (2007). Nutritional study as KiGGS Module (EsKiMo). Robert Koch Institute and University of Paderborn, 2007.

Mensink GB, Klenow S, Schlaud M. Supply situation of the German population with selected nutrients based on the results of the Study on Adult Health in Germany (DEGS): potassium. in German Nutrition Society (ed.), 13th Nutrition Report 2016. Bonn: 2016. pp. 57–59.

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

Regulation (EU) No 1169/2011 of the European Parliament and of the council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No

1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&from=DE, last accessed 04 March 2021.

Römer K, Heuer T (2017). Multiple use of dietary supplements (NVS II). Report of the Max Rubner Institute from 12.05.2017.

Schusdziarra V, Kellner M, Mittermeier J, Hausmann M, Erdmann J (2010). Energy intake, food quantity, and frequency of consumption of main and snack meals in normal-weight individuals. Aktuel Ernahrungsmed. 35: 29-41.

van Buren L, Dötsch-Klerk M, Seewi G, Newson RS (2016). Dietary Impact of Adding Potassium Chloride to Foods as a Sodium Reduction Technique. Nutrients. 8: 235.

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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