Proposed maximum levels for the addition of iodine 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 level of 100 micrograms (µg) of iodine per daily recommended dose of an individual food supplement. In view of the increased iodine requirements of pregnant and lactating women, a maximum level of 150 µg iodine per recommended daily dose of a food supplement is recommended for these groups.

In Germany, fortification of salt with iodine is recommended for iodine prophylaxis purposes (regulated maximum level: 25 mg per kg table salt). There is, however, no scope for further iodine fortification of other conventional foods, which is therefore not recommended (Table 1).

Table 1: Proposed maximum levels

Food category	Maximum levels
Food supplements (per daily recommended dose of an individual product)	100 µg
Food supplements for pregnant and lactating women (per daily recommended dose of an individual product)	150 µg
Table salt (per 100 g)	2500 µg*
Fortified conventional foods (per 100 g)	No addition

* Based on model calculations carried out by the BfR in 2020, it has been shown that an increase in the current maximum amount of iodine in salt from 25 to 30 mg per kg would also be without health risk at the current level of use of iodised salt in processed foods.

2 Rationale

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

The former Scientific Committee on Food (SCF) of the European Commission derived a UL for iodine of 600 micrograms per day (µg/day) for adults, of 500 µg/day for adolescents aged 15 to 17 years, and of between 200 and 450 µg/day for 1- to 14-year-old children (SCF, 2002; Table 2).

The D-A-CH Societies[2] derived dietary reference values (DRV) for iodine of 100 to 120 µg/day for 1- to 6-year-old children and of 140 to 180 µg/day for 7- to 12-year-old children.

[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

For 13- to 50-year-olds, the DRV is 200 µg/day, and for older age groups (≥ 51 years), an intake of 180 µg/day is recommended. For pregnant and lactating women, DRVs of 230 µg/day and 260 µg/day, respectively, were derived (D-A-CH, 2015; Table 2).

The European Food Safety Authority (EFSA) set an *Adequate Intake* (AI) of 90 µg/day for 1- to 10-year-old children, 120 µg for 11- to 14-year-old children, 130 µg/day for adolescents (15 to 17 years), and 150 µg/day for adults (18 years and older). For pregnant and lactating women, an AI of 200 µg/day was defined (EFSA, 2014; Table 2).

Table 2: Dietary reference values and UL

Age groups	Dietary reference values		UL
	(D-A-CH, 2015)	(EFSA, 2014)	(SCF, 2002)
	µg/day		
1 to 3 years	100	90	200
4 to 6 years	120	90	250
7 to 9 years	140	90	300
10 years	180	90	300
11 to 12 years	180	120	450
13 to 14 years	200	120	450
15 to 17 years	200	130	500
18 to 50 years	200	150	600*
51 to 64 years	180	150	600*
65 years and older	180	150	600*
Pregnant women	230	200	600*
Lactating women	260	200	600*

* In Germany, due to the long-standing iodine deficiency and the resulting increased risk of undetected functional autonomies of the thyroid gland (especially in older persons who were affected by iodine deficiency for a long time), a UL of 500 µg/day has been set for adults (D-A-CH, 2015).

2.2 Exposure

In Germany, iodised table salt is recommended within the framework of iodine deficiency prophylaxis for use in households, restaurants, communal catering and in food processing. However, the actual use level of iodised table salt is not known. A representative market survey on the use of iodised salt conducted by the University of Giessen on behalf of the German Federal Ministry of Food and Agriculture (BMEL) indicates that 29 % of crafted and industrially processed meat, bread, and dairy products with added salt are manufactured with iodised salt (Bissinger et al., 2018).

Up to now, model calculations of the Max Rubner Institute (MRI) on the intake of iodine were based on a theoretical use level of iodised salt in foodstuffs of 0 %, 30 %, 80 % and 100 % (MRI, 2011). The iodine intake was calculated on the basis of consumption data from the *Diet History Interviews* (DISHES) conducted in the second National Food Consumption Survey (NFCS II) and the German Food Composition and Nutrient Data Base (BLS) 3.01, which, compared to BLS version II.4, includes an update of the iodine contents, in particular, of milk, yoghurt and tap water. The modelling took into account the regulated maximum level of 25 mg iodine per kg of salt.

Assuming a 30 % use level of iodised salt, the calculated median iodine intake for 14- to 18-year-old adolescents was 167 µg (m) and 119 µg (f) per day, respectively. At this level of iodised salt use, the median of 19- to 80-year-old men and women would reach 149 to 175 µg/day and 120 to 137 µg/day, respectively (MRI, 2011; Table 3). The 95th percentile of adolescents aged 14 to 18 years would take up 297 µg (m) and 223 µg (f) per day, respectively. The 19- to 34-year-old males would under these conditions take up 322 to 377 µg/day and the 35- to 80-year-old males 246 to 299 µg/day. The 95th percentile of women 19 to 34 years of age would take up 222 to 239 µg of iodine daily, while women 35 to 80 years of age would consume 195 to 232 µg daily (MRI, 2011; Table 3).

Assuming an 80 % use level of iodised salt, the calculated median iodine intake for 14- to 18-year-old adolescents was 255 µg (m) and 180 µg (f) per day, respectively. At this level of use, the median intake of 19- to 80-year-old men and women would reach 231 to 273 µg and 174 to 201 µg daily, respectively (MRI, 2011; Table 3). At this level of use of iodised salt, the 95th percentile of 14- to 18-year-old adolescents would take up 458 µg (m) and 339 µg (f) per day, respectively, and that of 19- to 80-year-old men and women would reach 378 to 549 µg and 290 to 333 µg/day, respectively (MRI, 2011; Table 3).

In the case of a 100 % usage level of iodised salt, the calculated median iodine intake for 14- to 18-year-old adolescents was 291 µg (m) and 205 µg (w) per day, respectively. At this level of use, the median intake of 19- to 80-year-old men and women would reach 264 to 313 µg and 197 to 227 µg daily, respectively (MRI, 2011; Table 3). At this level of use, the 95th percentile of 14- to 18-year-old adolescents would take up 521 µg (m) and 382 µg (f) of iodized salt per day. The 95th percentile of 19- to 50-year-old men and women would take up 539 to 626 µg and 372 to 382 µg/day, respectively, and the 95th percentile of 51- to 80-year-old men and women would reach 432 to 486 µg and 330 to 375 µg/day, respectively, at this level of iodised salt use (MRI, 2011; Table 3).

Table 3: Iodine intake in adolescents and adults taking into account the theoretical levels of use of iodised table salt, on the basis of data from NFCS II and BLS 3.01*

Age in years	0 % iodised salt		30 % iodised salt		80 % iodised salt		100 % iodised salt	
	P50	P95	P50	P95	P50	P95	P50	P95
	µg/day							
Men	110	216	164	295	253	454	290	522
14-18	112	221	167	297	255	458	291	521
19-24	113	256	175	377	273	549	308	626
25-34	118	242	172	322	273	480	313	547
35-50	113	216	169	299	261	465	298	539
51-64	104	193	158	272	247	418	282	486
65-80	100	182	149	246	231	378	264	432
Women	91	171	129	222	194	325	219	367
14-18	83	161	119	223	180	339	205	382
19-24	86	189	121	239	174	333	197	382
25-34	97	174	133	222	197	329	223	375
35-50	97	180	137	232	201	332	227	372
51-64	92	170	131	224	198	331	224	375

65-80	83	148	120	195	184	290	209	330

* modified from MRI (2011).

Additional model calculations, conducted by MRI and BfR, that took into account a possible salt reduction and an increase in the iodine content of salt from 25 µg to 30 µg per kg of salt, are addressed in BfR Opinion No. 005/2021, titled 'Declining iodine intake in the population: model scenarios for improving iodine intake' and in the MRI report, titled 'Model scenarios for iodine intake in Germany', both dated February 9, 2021.

In addition, the German Health Interview and Examination Survey (DEGS) estimated the iodine intake of adults on the basis of iodine urinary excretion. Based on this, the median intake of men and women of 18 to 79 years was estimated to be between 115 and 146 µg per day and 98 and 139 µg per day, respectively. The 95th percentile of idone intake of men and women, not stratified by age, was estimated to be at 324 µg and 405 µg/day, respectively (Johner et al., 2015).

For children, no model calculations are available with regard to different theoretical levels of use of iodised salt. In the consumption study to determine the food intake of infants and young children (VELS study), the consumption of table salt could not be quantified and the use of iodised salt has thus not been taken into account. According to this study, the median iodine intake of 1- to 4-year-old children was between 24 and 29 µg per day and between 40 and 67 µg per day at the 90th percentile (VELS, 2003; Table 4).

According to the EsKiMo study (nutrition module in KiGGS[3]), in which the use of iodised salt was also not taken into account, 6- to 14-year-old boys and girls had a median intake of between 72 and 101 µg and between 71 and 90 µg iodine per day, respectively. The 95th percentile of 6- to 14-year-old boys and girls was at 136 to 180 µg of iodine and 114 to 185 µg of iodine per day, respectively (Mensink et al., 2007; Table 4).

Table 4: Iodine intake of German children and adolescents without consideration of the use of iodised salt

Age in years	**Iodine intake (VELS-Study) µg/day**			
	Median (P50)		**P90**	
	m	**f**	**m**	**f**
1	29	27	61	64
2	27	24	67	45
3	26	24	58	40
4	28	27	49	47
Age in years	**Iodine intake (EsKiMo Study) µg/day**			
	Median (P50)		**P95**	
	m	**f**	**m**	**f**
6	72	71	136	114
7 - 9	80	74	138	151
10 - 11	79	78	172	156
12	96	86	180	185
13 - 14	101	90	171	144
15 - 17	122	94	223	205

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

For children and adolescents, iodine intake levels based on iodine excretion in urine are available from KiGGS Wave 2. According to this, boys (3 to 17 years) had a median intake of 88.2 µg iodine and girls of the same age of 76.7 µg iodine per day (RKI, 2019).

2.3 Aspects considered in deriving maximum levels for food supplements

The current use level of iodised salt in the food industry and in households is not known. The estimated iodine intake at a theoretical 30 % use level appears to come close to the estimated iodine intake based on data from the DEGS study on urinary excretion of iodine as well as the use level revealed in the market survey of the University of Giessen (Johner et al., 2016; Bissinger et al., 2018).

Based on a 30 % use level of iodised salt, the 95th percentile of iodine intake in adults (19-80 years) does not exceed an amount of 377 µg/day (19- to 24-year-old males). This leaves a difference of just over 200 µg to the UL of 600 µg/day. Among 15-year-old children, with a UL of 500 µg per day, a maximum of 297 µg/day of iodine is taken up with a 30 % use level of iodised salt, leaving a difference of about 200 µg here as well. Similarly, the group of older adults does not take up more than 300 µg/day, so that even compared to the UL of 500 µg/day, applicable in Germany, which refers in particular to the vulnerable group of the elderly, a difference of at least 200 µg remains.

For food supplements, taking into account an uncertainty factor of 2 in view of a possible multiple exposure to iodine-containing food supplements, a maximum level of 100 µg iodine per recommended daily dose per food supplement is thus recommended for all age groups from 15 years onwards.

With regard to the increased iodine requirements of pregnant and lactating women (D-A-CH, 2015), a maximum level of 150 µg iodine per daily recommended dose of an individual food supplement is proposed for products targeted to these groups.

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

In Germany, iodine fortification of salt is recommended for iodine prophylaxis purposes, with a current maximum level of 25 mg per kg table salt. There is no scope, however, for the addition of iodine to other conventional foods, which is therefore not recommended.

On the basis of model calculations carried out by BfR in 2020, it was shown that an increase of the current maximum level of iodine in salt from 25 to 30 mg per kg would be of no risk to health at the current level of iodised salt use in processed foods (BfR Opinion No. 005/2021 of February 9, 2021 "Declining iodine intake in the population: model scenarios for improving iodine intake").

Further information on the BfR website on iodine

A-Z index to iodine: https://www.bfr.bund.de/en/a-z_index/iodine-129903.html

Topic page on the assessment of vitamins and minerals in foods:
https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html

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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