Declining iodine intake in the population: model scenarios to improve iodine intake in children and adolescents

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Iodine is an essential trace element that the body requires in order to produce thyroid hormones. These regulate many metabolic processes, and are responsible among other things for growth, bone formation and organ and brain development in children – even before birth.

Iodine must be consumed as part of the normal diet. Since soil iodine concentrations in Germany are low, domestic agricultural products contain very little of it. While saltwater fish and seafood contain a lot of iodine, their low consumption means they are only a minor source of intake. In Germany, the typical natural iodine concentrations in food are not high enough to ensure an adequate intake of iodine for the general population. As a result of a recommendation to use iodised table salt in the food industry, artisanal food retail and private households, iodine intake in the general population in Germany has improved since the mid-1980's. Iodine intake is still suboptimal, however, and is now on a downward trend. Furthermore, the volume of iodised table salt used in processed foods has also declined in recent years. In Germany, manufacturers can themselves decide whether or not to use iodised table salt in their foods. The amount of iodine that is added to the salt is regulated by law. As of this writing, this amount is 15–25 mg per kilogram of salt (mg/kg).

The National Reduction and Innovation Strategy (NRI) for sugar, fat and salt in ready-made products of the German Federal Ministry of Food and Agriculture (BMEL) aims to lower the concentrations of these ingredients in industrially processed and artisanal foods as part of a step-by-step process. The overall intention is to reduce the incidence of disease associated with being overweight or obese. However, the desirable reduction in salt consumption may at the same time lead to a reduced iodine intake via iodised table salt. This could be countered by increasing the concentration of iodine in iodised table salt.

Therefore, the German Federal Institute for Risk Assessment (BfR) used mathematical models to estimate if increasing the legal maximum concentration of iodine in table salt from 25 to 30 mg/kg would reduce the risk of insufficient iodine intake without also leading to intake values that exceed the tolerable daily upper intake level (UL). Long-term iodine intake in excess of the UL can produce adverse health effects.

The results for adults[1] for this scenario have already been published in BfR Opinion 005/2021, which was issued on 9 February 2021. This Opinion now presents the results for children and adolescents. The model scenarios show that even with a concentration of 30 mg of iodine per kg of salt, the risk of excessive iodine consumption is low at the current level of use of iodised salt. The risk of inadequate iodine intake would be slightly reduced by increasing the permitted iodine concentration in salt by 5 mg per kg, since the overall median iodine intake would increase somewhat. This also applies in the case of a successful reduction of salt consumption by 10%, as envisaged by the NRI. However, especially in the subpopulation of girls, this achieves only a slight reduction to the risk of inadequate iodine intake. Accordingly, simply increasing the iodine concentration in salt by 5 mg/kg is ineffective without simultaneously increasing the usage level of iodised salt in industrially processed or artisanal foods.

The BfR also investigated whether different iodine compounds are equally suitable for the enrichment of table salt. While only sodium or potassium iodate have been used in Germany to date, other countries also use the corresponding iodides. In the BfR's opinion, there are no

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[1] These also include adolescents aged 14 and over on the basis of the National Food Consumption Study II.

nutritional, technological or toxicological arguments for avoiding the use of iodides for enriching table salt here in Germany.

1 Subject of the assessment

In the light of data indicating a negative trend in renal iodine excretion in children and adolescents (Wave 2 of the 'Study on the Health of Children and Adolescents in Germany' (KiGGS Wave 2)) as well as a decline in the use of iodised salt in food production (report from Justus Liebig University (JLU) Giessen), the German Federal Ministry of Food and Agriculture (BMEL) asked the German Federal Institute for Risk Assessment (BfR) to assess whether, from a nutritional and toxicological point of view, an increase in the permitted concentration of iodine in salt from 25 to 30 mg per kg of salt would be both an appropriate measure and would not be associated with harmful effects to human health. The assessment was required to also account for potential effects on iodine intake resulting from the intended reduction in salt that has been initiated as part of the National Reduction and Innovation Strategy (NRI) for sugar, fat and salt in ready-made products.

The BMEL also asked the BfR and the Max Rubner Institute (MRI) to prepare a joint opinion on the question of whether all of the iodine compounds approved by Regulation (EC) No 1925/2006 are suitable for the iodisation of table salt, or if there are nutritional or technological reasons for approving only iodates or iodides for the iodisation of table salt. This question arose in light of the fact that, according to German national law to date, only sodium iodate and potassium iodate have been approved for the iodisation of table salt but not sodium iodide and potassium iodide.

2 Results

In terms of the benefits and risk of increasing the maximum iodine concentration in salt to 30 mg per kg, while simultaneously accounting for a reduction in salt by 10%, the BfR has already published an assessment of the situation for adolescents and adults in an opinion issued on 9 February 2021 (BfR Opinion no. 005/2021, issued 9 February 2021, hereafter 'BfR Opinion no. 005/2021'). In the present Opinion, the BfR discusses how the changes in the above-mentioned parameters affect iodine exposure of children (adolescents are also discussed again to an extent).

The BfR concludes that in children, as well as in adolescents and in adults, a successful reduction in salt consumption by 10% could still be compensated for by increasing the permitted iodine concentration in salt to a maximum of 30 mg per kg (that is, on average, 25 mg per kg in iodised salt products), since, despite the reduction in salt consumption, there would be a slight rise in median iodine intake. However, the existing prevalence of the occurrence of a risk of inadequate iodine intake, which is especially high in adults in the subpopulation of women of childbearing age and in children in the subpopulation of girls, would not be appreciably reduced. Accordingly, simply raising the iodine concentration in salt by 5 mg per kg is ineffective without simultaneously increasing the degree to which iodised salt is used in the production of industrially processed or artisanal foods. The BfR therefore recommends that measures should be adopted to promote the use of iodised table salt in the production of industrially processed and artisanal food products.

In relation to the risk of excessive iodine consumption, increasing the permitted iodine concentration in salt to 30 mg per kg can, assuming a current level of use of 29% iodised salt in industrially processed food, be considered as not harmful to health in both adults and children, even without any reduction in salt consumption and assuming the maximum level of 30 mg of iodine per kg of salt is indeed used.

Based on model scenarios, it was estimated that children, at an average iodine concentration of 25 mg per kg of salt and a simultaneous reduction in salt consumption by 10%, receive an adequate iodine intake if the level of iodised salt usage in all foods is at least 37% and more. On the other hand, this modelling also indicates that, given an unsuccessful reduction in salt consumption together with the maximum permitted iodine concentration in salt of 30 mg per kg, the age-specific *tolerable upper intake level* (UL) may be exceeded in some children, if the level of iodised salt usage is 50% and above across all foods. In adults, modelling under the corresponding conditions has shown that the UL may be exceeded with a level of iodised salt usage of and above 42%.

Overall, the BfR therefore concludes that increasing the maximum iodine concentration in salt from 25 to 30 mg per kg can be considered as appropriate and not harmful to health – both in the case of adults and children – if the level of usage of iodised salt would be at least 37% but would at the same time not substantially exceed 42%. As these model scenarios are based on a series of assumptions and simplifications, however, this means that these findings should be considered as establishing a general framework for iodised salt prophylaxis across all foods. This general framework certainly does not preclude situations where it can make sense to manufacture products from certain food groups (in an industrial or artisanal process) that contain iodised salt in a proportion higher than 42%.

As of this writing, for example, 47% of meats and sausages, 10% of bakery products and only 2% of milk and dairy produce are produced with iodised salt, resulting in a proportion of use of iodised salt of about 29% in processed foods to which salt is added.

From both the BfR's exposure assessments for children and adults made on the basis of the BfR MEAL study, whose concentration data include foods manufactured with iodised salt, and the model scenarios from the Max Rubner-Institute (MRI) on iodine intake in adolescents and adults based on the National Food Consumption Study II, it can be seen that, alongside meats and sausages, the food group of bread and bakery products is one of the most important pillars for iodised salt fortification in the context of iodine prophylaxis. Accordingly, achieving a targeted increase in the usage rate of iodised salt specifically in this food group is certainly advisable.

On the question of whether all of the iodine compounds approved by Regulation (EC) No 1925/2006 are suitable for the iodisation of table salt, or if there are nutritional or technological reasons for approving only iodates or iodides for the iodisation of table salt, both the MRI and the BfR conclude that there are no nutritional, technological or toxicological data that would argue against the use of iodides in the form of sodium or potassium iodide, or iodates in the form of sodium iodate or potassium iodate as table salt additives.

3   Rationale

3.1   Hazard potential for iodine insufficiency and oversupply

BfR Opinion no. 005/2021 has already addressed the hazard characterisation for iodine insufficiency and oversupply in children.

3.2   Exposure

3.2.1   Underlying data

In Germany, representative data on the iodine intake of children are provided by the nutrition study as KiGGS module (EsKiMo II) based on the German Nutrient Database (BLS) at the Robert Koch Institute (RKI) (Mensink et al., 2020), the KiESEL study ('Children's Nutrition Survey to Record Food Consumption') at the BfR and the EsKiMo II study, each of which are

now combined here with iodine concentration data from the BfR MEAL study ('Meals for Exposure Estimation and Analysis of Food') (Sarvan et al., 2017) and from the 'Study on the Health of Children' (KiGGS) Wave 2 at RKI (Hey and Thamm, 2019).

3.2.1.1 EsKiMo II combined with the German Nutrient Database (BLS) (RKI)

In the course of EsKiMo II, which ran from 2015 to 2017, 2,644 children and adolescents between the ages of 6 and 17 were asked about their consumption of food and their eating habits (Mensink et al., 2020). This cohort had already taken part in the second wave of the 'Study on the Health of Children and Adolescents in Germany' (KiGGS Wave 2) from the Robert Koch Institute. Food consumption in the 6- to 11-year-old age group was tracked with the help of their parents using weighing records conducted over four days. In the case of adolescents between 12 and 17 years of age, a modified *dietary history* method was used, so as to record their typical diet over the last four weeks. Personal interviews were conducted using the DISHES (*Dietary Interview Software for Health Examination*) software.

In addition, a computerised interview was also used to obtain more detailed information on eating habits in the form of a short questionnaire. Among other things, this questionnaire covered details relating to school meals, family mealtimes, use of dietary supplements and the consumption of certain kinds of foods. To identify nutrient intake, both methods were combined with the nutrient concentration data from the German Nutrient Database (BLS) 3.02 as provided by the Max Rubner Institute (MRI).

Exposure assessments made on the basis of EsKiMo II and the BLS are subsequently referred to here as 'EsKiMo II-BLS'. In EsKiMo I, the BLS was supplemented by the use of another database created by the RKI with additional types of foods that were not included in the BLS. This was necessary since the current BLS does not contain all types of food that were available on the market at the time and had been named by study participants. The BLS also does not distinguish between branded and unbranded products. However, information about branded products is important, for example in the context of manufacturer-specific enrichment quantities for vitamins and minerals. For EsKiMo II-BLS, the supplementary EsKiMo food nutritional value database was therefore updated by the RKI and expanded to include 626 new foods. As with the BLS, the scope of the additional database did not extend to the use of iodised salt.

In determining nutrient intake, intake via supplements was also taken into account. For this purpose, for 6- to 11-year-old children information on supplement intake was used from the weighing records and for 12- to 17-year-olds from the interview data (DISHES). In children and adolescents, the frequency of use for food supplements containing iodine was less than 1.5% (Mensink et al., 2020).

With only isolated exceptions, the values for iodine intake determined by the RKI in EsKiMo II-BLS do not include iodine from iodised salt, because: a) personal use of iodised salt and individual consumption of salt resulting from adding salt to food was not surveyed; and b) the iodine concentrations in food data held in the BLS 3.02 and the additional database do not account for potential preparation with iodised salt.

3.2.1.2 KiESEL

The BfR has conducted a nationwide, representative 'Children's Nutrition Survey to Record Food Consumption' (KiESEL study, Golsong et al., 2017) in Germany.

The KiESEL study recorded the food consumption of children from the age of six months up to and including five years of age. Some children celebrated their sixth birthday during the study period; these children were also assigned to the 5-year-old group. The surveys on food consumption were carried out by the BfR's KiESEL study team from 2014 until the end of

2017. A randomised procedure was used to select participants from a cross-sectional sample of KiGGS Wave 2.

The food intake of 1,008 children was documented by the families by means of a weighing record for three consecutive days and a weighing record on another single, independent day, allowing short-term and long-term exposure estimates. To ensure that consumption days were independent of one another, a gap of at least two weeks was maintained between the three-day nutrition record and the single-day nutrition record. This was supplemented by documenting a reduced estimate record for consumption at childcare facilities (Golsong et al., 2017; Schweter et al., 2015). A weighting factor was then applied to all consumption data, which compensates for differences in the group of test subjects compared with the base population in terms of various characteristics. These weighted data permit representative statements to be made about the respective age group in Germany. In the present Opinion, all values resulting from the KiESEL study (iodine intake levels, proportions and number (N)) are each specified with the respective weighting. For the present estimate of iodine exposure in children in Germany, the consumption data were split into the two age groups of '6 months to 2 years' and '3 to 5[2] years', so as to permit comparisons with the KiGGS data. Breastfed children were generally excluded from the evaluation. As a result, the evaluation encompasses consumption data from 941 children (weighted), corresponding to 952 observations from the random sample.

3.2.1.3 BfR MEAL Study

The BfR MEAL study was the first study to generate concentration data for desirable and undesirable substances in food that was representative of food consumption for the entire German population (Sarvan et al., 2017).

Iodine was investigated in the core module for the BfR MEAL study in all 356 foods on the MEAL food list. The MEAL food list covers a total of 94% of average consumption based on the KiESEL study, as well as 91% of average consumption based on the EsKiMo II study, and its data also account for rarely consumed foods that are known to have high concentrations of the substances under investigation, such as algae products, which contain an above-average concentration of iodine. The foods were purchased nationwide in Germany in four separate regions, with the choice of products accounting for the various purchasing patterns within the German population, as well as regional and seasonal specialities. The underlying information for this representative compilation of samples was generated from consumer studies as well as from market data. The foods were prepared in the MEAL study kitchen while simulating typical consumer approaches to preparation. The foods and meals were then pooled (grouped together) and homogenised.

For the investigation into iodine, a total of 840 pools were formed, consisting of 15 to 20 individual foods. The pools represent combinations of various purchasing regions (national, east, south, west and north), purchasing times (non-seasonal, season 1 and season 2) and cultivation/production types (non-specific, organic and conventional).

For the present evaluation of iodine data, the pools surveyed regionally were assigned individually per participant and averaged over seasonal distribution. To improve clarity, only values from conventionally produced food products have been accounted for in this assessment. Differences in iodine intake when utilising organic instead of conventionally produced food products are given in the Appendix to this Opinion.

The food pools analysed in the MEAL study also contain (in relation to their market share) industrially manufactured and artisanal food products (designated as 'commercial foods' in

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[2]   Children who celebrated their sixth birthday during the study period were also assigned to the 5-year-old group.

the following) that were produced with the use of <u>iodised salt</u>. However, <u>no iodised salt</u> was used in the preparation of the meals and products in the MEAL kitchen.

The iodine concentrations were weighted using the *upper bound* (UB) approach, i.e. concentration values for individual food pools beneath the limit of quantification were replaced by the values of the limit of quantification and values beneath the limit of detection were replaced by the limit of detection. There is only a marginal difference (see Appendix, tables 1 and 5) between results from the *upper bound* approach and the 'modified *lower bound*' approach (mLB: values beneath the limit of quantification are replaced with the limit of detection while '0' replaces values beneath the limit of detection).

3.2.1.4 BfR MEAL study combined with KiESEL and EsKiMo II

To obtain an estimate of average iodine exposure of children in Germany, the iodine concentrations analysed in the course of the BfR MEAL study in various food groups were correlated with consumption data from 952 weighted study participants aged between six months and five years from KiESEL (hereinafter 'KiESEL-MEAL') and 1,190 weighted study participants aged between 6 and 11 from EsKiMo II (hereinafter 'EsKiMo II-MEAL'). Salt consumption in the home was accounted for using a separate scenario and not by means of salt consumption data from KiESEL or EsKiMo II, since quantitative statements are associated with large uncertainties here. The intake of iodine from food supplements was not accounted for when calculating iodine intake on the basis of consumption data. In the KiESEL evaluation, a food supplement containing iodine was recorded for 0.7% of children and, in EsKiMo II, for less than 1.5% of children (Mensink et al., 2020) on one of the four recording days for the 6- to 11-year-old age group.

An estimate of iodine intake for adolescents aged 14 years and over has already been given in the context of BfR Opinion no. 005/2021, based on NVS II and the 'Study on the Health of Children and Adolescents in Germany' (KiGGS) Wave 2.

3.2.1.5 KiGGS Wave 2 (KiGGS 2)

Within the scope of KiGGS Wave 2 (hereinafter 'KiGGS 2'), the RKI compiled a comprehensive set of health data on children and adolescents living in Germany from 2014 to 2017 (Hey and Thamm, 2019).

The basis of calculation for assessing iodine status was provided by the concentrations of sodium and iodine in the spot urine samples of 3,396 study participants between 3 and 17 years of age. The concentration of both parameters was first standardised to the creatinine concentration in urine and then, by applying age-standardised creatinine excretion quantities per day for each study participant, these data were converted into excretion values for sodium and iodine on the day the sample was taken. Since the sodium- and iodine-specific excretion values are known from other studies, salt and iodine intakes could be estimated for study participants on the basis of the excretion quantities.

The iodine intake levels determined using this method reflect the total iodine intake of study participants on the day the urine sample was taken, enabling a realistic assessment of the average iodine status of the population[3] that <u>does not, however, differentiate by the respective iodine sources</u> (iodised salt, other food groups, food supplements and medicines).

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[3] This cannot be used to determine the iodine status of individual persons, since the respective daily iodine intake may be subject to strong fluctuations.

3.2.2 Iodine intake levels for children and adolescents in Germany as determined in the studies

Iodine intake levels in the percentiles of 5, 25, 50 (median), 75 and 95 (where available), as determined on the basis of representative studies with children and adolescents living in Germany, are shown in tabulated comparisons below (tables 1 and 2). To improve comparability between the exposure assessments from EsKiMo II-MEAL and the biomarker-based KiGGS 2 results, the age groups '6 to 8 years' and '9 to 11 years' have been supplemented by an additional age group comprising 7- to 10-year-old children.

For reasons of clarity, table 1 and table 2 present only the exposure assessments based on conventionally produced food products. A comparison between iodine intakes on the basis of organic versus conventionally produced food products is given in the Appendix, in tables 1, 4, 5 and 8. In each of these scenarios, the theoretical assumption is made that only food products from either conventional or organic production are consumed, insofar as the type of production could be distinguished. The data show that with conventionally produced foods, a median figure of 73.9 µg of iodine per day is achieved by the KiESEL children and a slightly higher figure of 88.2 µg of iodine per day is achieved by the EsKiMo children, compared with foods from organic production, with which the KiESEL children would have an iodine intake of 68.0 µg per day, with this figure being 80.8 µg of iodine per day for the EsKiMo children (UB approach, tables 1 and 5 in the Appendix).

Table 1 Iodine intake levels for boys in Germany, based on the various data surveys

Dataset	Source	Age (years)	N	Iodine intake for boys in µg per day				
				P5	P25	P50	P75	P95
EsKiMo II-BLS[a]; <u>without</u> iodised salt in commercial foods and without iodised salt at home	RKI Mensink et al. (2020)	6–8	606	29.6	n.d.	63.4	n.d.	157.4
		9–11		39.7	n.d.	68.6	n.d.	150.3
		12–14	626	38.2	n.d.	81.1	n.d.	159.8
		15–17		43.8	n.d.	93.9	n.d.	194.7
EsKiMo II-MEAL[b]; <u>with</u> iodised salt in commercial foods but without iodised salt at home	BfR Current assessment	6–8	305	55.0	75.5	93.4	111.7	141.5
		9–11	307	52.9	76.6	93.3	116.5	140.9
		7–10	407	55.7	77.5	95.6	115.7	145.7
KiESEL-MEAL[b], <u>with</u> iodised salt in commercial foods but without iodised salt at home	BfR Current assessment	0.5–2	179	41.4	58.9	72.3	93.7	132.5
		3–5	302	39.5	61.9	76.5	92.9	122.6
KiGGS 2 total iodine	RKI Hey and Thamm (2019)	3–6	428	n.d.	44.1	69.6	100.3	n.d.
		7–10	457	n.d.	53.3	75.9	116.2	n.d.
		11–13	392	n.d.	65.5	96.1	141.1	n.d.
		14–17	402	n.d.	76.1	112.0	149.3	n.d.
	Esche and Remer[c] (2019)	6–12	1586	n.d.	n.d.	78.9	107.2[d]	180.0[d]
		13–17	1251	n.d.	n.d.	96.6	126.7[d]	220.9[d]

[a]   Food supplements containing iodine were also surveyed (level of use <1.5%).

[b]   Conventional foods, UB approach.

[c]   In Esche and Remer (2019), iodine intakes were determined for boys and girls together, so identical values are used for both of these genders.

n.d.:   No data available.

[d]   The iodine intakes determined within P75 and P95 are not included in the 2817HS007 final report from Esche and Remer (2019). These details were made available to the BfR on request by the authors of the project report.

Table 2 Iodine intake levels for girls in Germany, based on the various data surveys

Dataset	Source	Age (years)	N	Iodine intake for girls in µg per day				
				P5	P25	P50	P75	P95
EsKiMo II-BLS[a]; <u>without</u> iodised salt in commercial foods and without iodised salt at home	RKI Mensink et al. (2020)	6–8	584	25.9	n.d.	58.0	n.d.	108.0
		9–11		34.3	n.d.	64.7	n.d.	124.0
		12–14	727	29.6	n.d.	64.0	n.d.	150.2
		15–17		32.0	n.d.	74.1	n.d.	133.4
EsKiMo II-MEAL[b]; <u>with</u> iodised salt in commercial foods but without iodised salt at home	BfR Current assessment	6–8	289	38.4	66.0	80.8	98.5	127.5
		9–11	290	54.1	73.0	88.0	107.5	135.2
		7–10	385	45.6	71.3	86.0	103.3	132.4
KiESEL-MEAL[b], <u>with</u> iodised salt in commercial foods but without iodised salt at home	BfR Current assessment	0.5–2	186	32.3	55.0	69.5	90.2	131.6
		3–5	286	42.5	61.8	73.9	88.5	116.8
KiGGS 2 total iodine	RKI Hey and Thamm (2019)	3–6	369	n.d.	39.9	62.5	81.0	n.d.
		7–10	415	n.d.	49.9	75.5	110.0	n.d.
		11–13	382	n.d.	53.2	84.2	123.8	n.d.
		14–17	478	n.d.	66.6	94.4	140.3	n.d.
	Esche and Remer[c] (2019)	6–12	1586	n.d.	n.d.	78.9	107.2[d]	180.0[d]
		13–17	1251	n.d.	n.d.	96.6	126.7[d]	220.9[d]

[a]   Food supplements containing iodine were also surveyed (level of use <1.5%).

[b]   Conventional foods, UB approach.

[c]   In Esche and Remer (2019), iodine intakes were determined for boys and girls together, so identical values are used for both of these genders.

n.d.:   No data available.

[d]   The iodine intakes determined within P75 and P95 are not included in the 2817HS007 final report from Esche and Remer (2019). These details were made available to the BfR on request by the authors of the project report.

As expected, on the basis of the EsKiMo II-BLS study (Mensink et al., 2020), in which no data on iodine from iodised salt were collected, a lower median intake level was recorded compared with the other surveys, in which data on iodine from iodised salt were partially collected (KiESEL-MEAL and EsKiMo II-MEAL) or collected overall via biomarker-based total

iodine intake (KiGGS 2) (Hey and Thamm, 2019). As a result of the low level of use (<1.5%), the intakes via food supplements containing iodine accounted for by EsKiMo II-BLS presumably have little effect on iodine intake in the lower consumption percentiles (Mensink et al., 2020).

The exposure assessment based on EsKiMo II-MEAL yields medians of (♀) 80.8 μg (6–8 years) and 88.0 μg (9–11 years) as well as of (♂) 93.4 μg (6–8 years) and 93.3 μg (9–11 years) of iodine per day: these median iodine intake levels are approximately 30% higher than the estimate based on EsKiMo II-BLS from the RKI. This result correlates well with the results for adolescents and adults, where the evaluations based on MEAL data also resulted in a roughly 30% higher iodine intake than the BLS-based calculations (BfR Opinion no. 005/2021). The higher estimates based on MEAL data can be ascribed to the fact that food pools assembled in accordance with market share and dietary habits were analysed in the MEAL study, and these pools included both industrially processed foods and artisanal products made with iodised salt. From the exposure assessment made on the basis of the MEAL data, this can also be seen in the fact that meats and sausages constitute a relevant source of iodine (figure 1), with an iodine contribution of 8% (KiESEL-MEAL) and 11% (EsKiMo II-MEAL). In EsKiMo II-BLS, in contrast, meats and sausages (without iodised salt) were not among the top-ranking sources of iodine (Mensink et al., 2020).
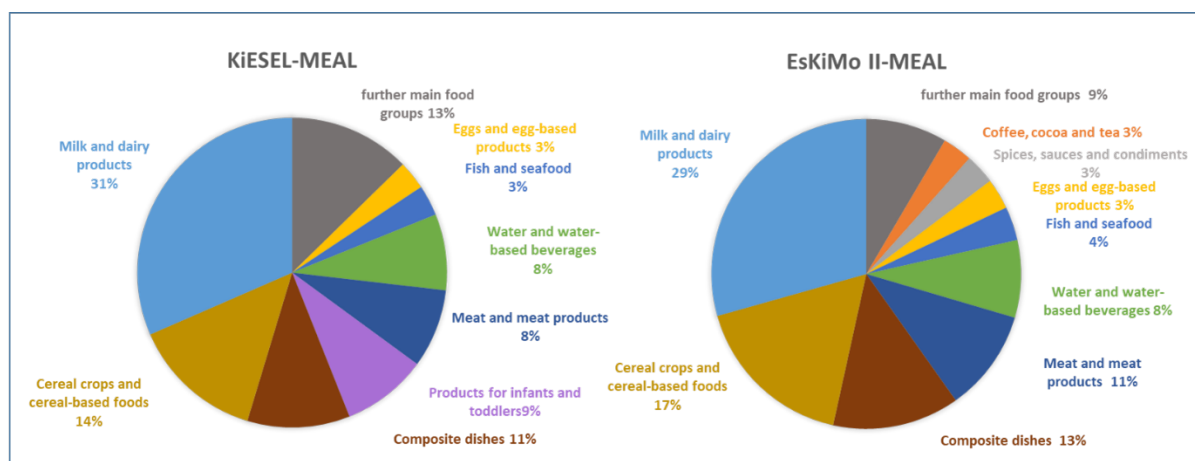

Figure 1 Share of food groups in average iodine intake, calculated via KiESEL-MEAL and EsKiMo II-MEAL (conventional, UB, without iodised salt at home)

In the exposure assessment based on MEAL concentration data, 'Cereals and cereal-based products' make the second-highest contribution to iodine intake, at 14% (KiESEL-MEAL) and 17% (EsKiMo II-MEAL), also because of the large quantities consumed (figure 1). A food group of this type is not listed in EsKiMo II-BLS, which makes a direct comparison difficult. However, bread in EsKiMo II-BLS contributes only 2% to 4% of iodine intake for the children, and the food groups such as 'Breakfast cereals', 'Cereals and rice' and 'Pasta products' (all without iodised salt) mentioned in the RKI report are not listed as relevant sources of iodine. Accordingly, the high contribution to iodine intake made by conventional 'Cereals and cereal-based products', as determined on the basis of the MEAL evaluation, appears to be largely the result of the iodised salt used to manufacture these products. In KiESEL-MEAL and EsKiMo II-MEAL, consumers of this food group exhibit a greater difference in iodine intake between products from conventional and organic production in comparison with the other food groups. When consuming foods primarily from organic production, consumers of 'Cereals and cereal-based products' have a median iodine intake that is approximately 40% lower from this food group than when using primarily conventional products (tables 4 and 8 in the Appendix). This result is supported by the 'Representative market survey on the use of io-

dised salt in artisanal and industrially processed foods' from Bissinger et al., which established that iodised table salt was not utilised in any of the organically certified bakery products investigated (Bissinger et al., 2018).

In all evaluations of the various consumption surveys, milk and dairy produce supply the largest proportion of a child's iodine intake. On the basis of KiESEL-MEAL and EsKiMo II-MEAL, this amounts to roughly 30% (figure 1), and between 17% and roughly 30% based on Es-KiMo II-BLS (Mensink et al., 2020). Since the contribution that is made by milk and dairy produce in EsKiMo II-BLS is also high, the iodine intake from dairy produce appears to stem largely from the iodine already present in unprocessed milk (natural iodine as well as additional iodine from animal feed as a result of using iodine as an animal feed additive). A slightly larger contribution is found based on the MEAL evaluation, although this can be explained by the presence of iodised salt – as used in cheese manufacturing, for example.

In addition, 'Products for infants and young children' are listed in the KiESEL-MEAL evaluation with a relevant iodine contribution of 9%. This can be explained by the fact that, as transposed from various pieces of EU legislation, the German Regulation on Dietary Food (Dietary Regulation) sets out minimum and maximum limits for the iodine that is added to infant starter and follow-on formula. In contrast, the addition of iodine compounds to baby food products is regulated differently, with only maximum values being applied that must not be exceeded.

The biomarker-based median daily iodine total intake levels from KiGGS 2 (Hey and Thamm, 2019) can be compared both with KiESEL-MEAL in the age group '3 to 5 years' and with the EsKiMo II-based (EsKiMo II-MEAL and EsKiMo II-BLS) data. However, here one should note that the age groupings do vary slightly between the various surveys, which results in a certain level of uncertainty in any comparisons. In the age group '7 to 10 years' additionally considered in EsKiMo II-MEAL, the iodine intake determined deviates only slightly from the iodine intakes in the age groups '6 to 8 years' and '9 to 11 years' in the same survey, however (excepting 6- to 8-year-old girls, where the iodine intake is slightly lower). Accordingly, while taking into account a certain level of uncertainty, a comparison of the 6- to 8-year-olds and 9- to 11-year-olds with the 7- to 10-year-old age group does appear to be justifiable.

In contrast to the evaluations made for adults on the basis of NVS II and DEGS1 (BfR Opinion no. 005/2021), the median total iodine intakes from KiGGS 2 are indeed higher than the BLS-based EsKiMo II evaluation from the RKI, but are below the calculated iodine intake levels on the basis of MEAL data (KiESEL-MEAL and EsKiMo II-MEAL), notwithstanding the fact that the use of iodised salt at home was not considered in the MEAL evaluation. This is not explained by the fact that the MEAL evaluation considers only conventional foods, which can result in a slight overestimate, because, when considering foods from organic production, the calculated median KiESEL-MEAL and EsKiMo II-MEAL values are still slightly higher than the values from KiGGS 2 (table 1 and table 2, table 1 and table 5 in the Appendix). The UB approach applied to the iodine concentration data also plays only a minor role, since the differences to the 'modified lower bound' approach (mLB) are only marginal (tables 1 and 5 in the Appendix). The drinking water used for preparing the ready-to-eat meals and beverages in the BfR MEAL study has a comparatively high concentration of iodine. In regions with lower concentrations of iodine in drinking water, the iodine intake for local populations can also be correspondingly lower.

The differences are most likely to result from methodological variations between the various survey instruments. While total iodine intake in KiGGS 2 was determined with a biomarker-based approach from iodine excreted in urine, iodine intakes in EsKiMo II-MEAL and KiE-SEL-MEAL were estimated on the basis of consumption surveys. Uncertainties can arise from both of these survey instruments. The determination of iodine from spot urine, for example, is subject to a high level of intra- and inter-individual variability (despite normalisation via

age-standardised 24-hour creatinine excretions to compensate for fluctuations in hydration status), since iodine intake can vary considerably within a single day or on separate days. Accordingly, this method is not suitable for determining an individual iodine status, although, despite these uncertainties, it is considered a good indicator for estimating average iodine intake at the level of the population (König et al., 2011). Common to almost all consumption surveys is the risk of *under-* or *over-*reporting. Even within the various consumption surveys (e.g. weighing records, DISHES, *24-hour recall*), each method has its pros and cons that may well vary in terms of their impacts on survey results. When using weighing records, for example, documenting 'out-of-home consumption' is associated with greater uncertainty, especially in the case of younger children (Straßburg, 2010). To minimise these uncertainties, a reduced estimate record was utilised in KiESEL for documenting consumption in childcare facilities.

In the 95th percentile, however, KiGGS 2 identified the highest iodine intakes in comparison to all other surveys, with values of 180.0 µg per day (6 to 12 years) and 220.9 µg per day (13 to 17 years). On the basis of EsKiMo II-MEAL, with iodised salt in commercially produced foods taken into account, 6- to 11-year-old children in the 95th percentile have iodine intake values of between 127.5 µg and 145.7 µg per day.

Since the KiGGS 2 data were collected on the basis of biomarkers, these reflect total iodine intake, with all sources of iodine taken into account, even if these individual iodine sources are not directly attributable. Accordingly, the higher iodine intakes in KiGGS 2 in the 95th percentile in comparison to the surveys based on the MEAL study may be an indication that other sources of iodine, such as food supplements, were being used in addition to customary, day-to-day foods. EsKiMo II-MEAL does not include the proportion of iodine intake that may result from the use of food supplements and medicines. By contrast, EsKiMo II-BLS does survey food supplements containing iodine, which could explain the higher iodine intakes in boys in the 95th percentile in EsKiMo II-BLS compared to EsKiMo II-MEAL (this effect was not observed in girls, however). According to the EsKiMo II-BLS report, the level of use of food supplements containing iodine in children and adolescents is less than 1.5% (Mensink et al., 2020), which is why the role of iodine intake via food supplements seems to be trivial in the average and lower consumption percentiles.

On the other hand, a higher level of use of iodised salt and/or food containing iodised salt by a subgroup of the study participants could also lead to higher iodine intake levels than for an average level of use, which would be reflected in the biomarker-based KiGGS 2 evaluation.

3.2.3   Iodised salt as a proportion of iodine intake in Germany

None of the national representative studies (EsKiMo II-BLS, EsKiMo II-MEAL, KiESEL-MEAL and KiGGS 2) permits the proportion of iodised salt as an iodine source in Germany to be determined directly. Iodine prophylaxis as an intervention depends critically on the degree of use of iodised salt – both in the households and in the industrial processing and artisanal production of foods – as well as on the concentration of iodine in iodised salt. Models were therefore used to calculate an estimate for the contribution of iodised salt to iodine intake in the children.

3.2.3.1 EsKiMo II-MEAL and KiESEL-MEAL

The food pools in the MEAL study already contain artisanal and industrially processed products made with iodised salt, according to their market share (BfR, 2021). For the preparation of foods in the MEAL study kitchen, however, no iodised table salt was used.

In the results based on the MEAL study, a key aspect that is missing is therefore the proportion of iodine intake resulting from the use of iodised salt at home. In accordance with the results from the NVS II and NEMONIT (National Nutrition Monitoring) consumption studies, the

use of iodised table salt in private households is roughly 76% (MRI, 2020), and 74% according to KiESEL. Here, the proportion of salt intake from cooking at home and adding salt to food is estimated at 10–11% of total salt intake (Mattes and Donnelly, 1991; Zimmermann, 2010). Since the median total salt intake of children and adolescents in Germany is estimated on the basis of sodium concentrations in urine at 5.0 to 9.4 g per day (boys) and 3.9 to 8.6 g per day (girls), depending on age (Hey and Thamm, 2019), the long-term use of iodised salt (with 20 mg iodine per kg) would result in roughly the following additional median iodine intakes per day at home (household use), when stratified by age: Girls: 3 to 6 years: 8 µg, 7 to 10 years: 12 µg, 11 to 13 years: 14 µg;
Boys: 3 to 6 years:11 µg, 7 to 10 years: 13 µg, 11 to 13 years: 17 µg.

In order to estimate total iodine intake, the iodine intake from iodised salt at home estimated with the help of KiGGS 2 was added - individually by age and by gender, for each participating child - to the the results of iodine intake without iodised salt at home based on the KiE-SEL-MEAL and EsKiMo II-MEAL evaluations. The individually estimated iodine intakes were then again consolidated into the age groups necessary for the comparisons (tables 2 and 6 in the Appendix). Since no total salt intake values were available for children between the ages of 0 to 2 years, no intake of iodine from iodised salt at home can be estimated for this group.

Although uncertainties relating to the comparison of two separate databases of concentrations can arise, the median salt-dependent iodine intake from commercial foods produced with iodised salt was calculated using the difference between the results given by EsKiMo II-MEAL and EsKiMo II-BLS from the RKI (Mensink et al., 2020). Since the EsKiMo II-BLS results, based on the BLS and the additional database, do not account for any commercial food products manufactured with iodised salt, the difference in iodine intake between both sets of results should reflect the salt-dependent iodine intake from artisanal and industrially processed food products.

Although data on food supplements containing iodine were surveyed in EsKiMo II-BLS (in contrast to EsKiMo II-MEAL), the low level of supplement use (<1.5%, Mensink et al., 2020) should have little impact on the median. The resulting calculated median iodine intake from the iodised salt used in these products is presented in table 3.

Table 3 also shows the calculation results based on an additional scenario, in which the daily use of iodised salt in the household is included, in order to estimate the cumulative potential total daily intake of iodine from iodised salt.

Table 3 Calculated median iodine intake from iodised salt from commercially manufactured foods using iodised salt. With and without the use of iodised salt at home. Based on EsKiMo II-MEAL and EsKiMo II-BLS

Age in years	Iodine intake from iodised salt without iodised salt at home		Iodine intake from iodised salt including use of iodised salt at home	
	Boys (P50)	**Girls (P50)**	**Boys (P50)**	**Girls (P50)**
	µg per day			
6–8	30.0	22.8	41.7	33.5
9–11	24.7	23.3	40.5	36.3
Total	27.4	23.1	41.1	34.9
	25.3		38.0	

3.2.3.2 KiGGS Wave 2

The intake levels for salt and iodine determined by KiGGS 2 in children (cross-sectional dataset of 6- to 12-year-olds; n = 1,586) and adolescents (cross-sectional dataset of 13- to 17-year-olds; n = 1,251), with complete datasets for spot urine values (sodium, iodine and creatine), BMI and age, were adjusted using a linear regression in terms of age, gender and BMI (Esche and Remer, 2019). By applying the regression formula, adjusted iodine intake levels were calculated as function of salt intake, whereby the intercept of salt intake produced an iodine intake of 41.9 μg (6 to 12 years) and 45.7 μg (13 to 17 years) per day, which is equivalent to the salt-independent proportion of total iodine intake from food. At the median of salt intake of 5.8 g (6 to 12 years) and 7.8 g (13 to 17 years) per day, the median of total iodine intake was 78.9 μg and 96.6 μg per day, respectively. By a simple subtraction of the salt-independent iodine intake from the median total iodine intake, a salt-dependent iodine intake value of 37.0 μg (6 to 12 years) and 50.9 μg (13 to 17 years) per day was determined, corresponding to 47% and 53% of median total iodine intake, respectively. Assuming that the average iodine concentration in iodised salt in Germany is 20 μg of iodine per gram of salt, then 37.0 μg of iodine corresponds to 1.9 g of salt and 50.9 μg of iodine to roughly 2.5 g of salt. In terms of median total salt intake, this corresponds to an iodised salt proportion of 32% (6 to 12 years) and 33% (13 to 17 years), respectively.

The median consumption of iodised salt and iodine from salt determined in KiGGS 2 reflects both the quantity of iodised salt used in the home and the iodised salt from commercial foods in the KiGGS 2 total population. However, the salt-dependent iodine intake determined using the KiGGS 2 data was published only for the median (Esche and Remer, 2019), since uncertainties arising due to the methodology, such as food supplement consumption, more strongly affect the calculations of higher intake percentiles.

While the results in the upper consumption percentiles do involve a greater degree of uncertainty than in the median, these must nonetheless be determined as part of the risk assessment. Accordingly, the salt-dependent iodine intake levels that were calculated per day for the P75 and P95 percentiles from KiGGS 2 were made available at the BfR's request by Dr Esche, Ms Hua and Prof. Remer.

Table 4 Total salt and total iodine intake from KiGGS 2, and proportions of iodine intake from iodised salt derived from these data (Esche and Remer, 2019)

	Age	P50 (median)	P75	P95
Total salt intake (g per day)	6–12 years	5.8	8.5*	13.7*
	13–17 years	7.8	11.9*	18.7*
Total iodine intake (µg per day)	6–12 years	78.9	107.2*	180.0*
	13–17 years	96.6	126.7*	220.9*
Iodine from iodised salt (µg per day)	6–12 years	37.0	50.4**	84.6**
	13–17 years	50.9	67.1**	117.1**
Iodine from food (µg per day) (independent of use of iodised salt)	6–12 years	41.9	56.8**	95.4**
	13–17 years	45.7	59.5**	103.8**

*   The total salt and total iodine intakes determined within P75 and P95 in Esche et al. (2019) are not included in the 2817HS007 final report (Esche and Remer, 2019). These details were made available to the BfR on request by the authors of the project report.

**   Calculated by BfR on the assumption that the iodine proportion from iodised salt is constant in all consumption percentiles (47% for 6- to 12-year-olds and 53% for 13- to 17-year-olds).

The respective iodine intakes from iodised salt in food were calculated for the higher consumption percentiles (P75 and P95), on the assumption that the iodine proportion from iodised salt is constant in all consumption percentiles. This introduces some uncertainty, since the actual proportion of iodine from iodised salt in P75 and P95 is unknown.

The median salt-dependent iodine intake levels that were modelled in the context of KiGGS 2 and the difference between EsKiMo II-MEAL and EsKiMo II-BLS for the 6- to 11- and 12-year-olds agree very well with one another, despite differences in the respective underlying datasets and survey instruments. A median salt-dependent iodine intake of 37 µg per day (6 to 12 years) was determined on the basis of KiGGS 2, and a median iodine intake of 38 µg per day was determined, based on the difference between EsKiMo II-MEAL and EsKiMo II-BLS (and including the use of iodised salt at home). Accordingly, the results also indicate that, despite the existing uncertainties in terms of the comparison of various databases of concentrations and survey instruments, the proportion of iodine intake that may result from food supplements containing iodine should have little impact on the median. In comparison with KiGGS 2, this proportion should have revealed itself as a lower value in the difference between EsKiMo II-MEAL and EsKiMo II-BLS, since EsKiMo II-MEAL iodine intake values do not account for food supplements. This result correlates well with the lower level of use of food supplements containing iodine in children and adolescents, namely less than 1.5% as per the EsKiMo II-BLS report (Mensink et al., 2020).

For the 13- to 17-year-olds, a median salt-dependent iodine intake of 50.9 µg per day was determined on the basis of KiGGS 2. A comparison with EsKiMo II-MEAL is not possible here, since, for the reasons mentioned in 3.2.1.4, this age group was not evaluated on the basis of the MEAL study.

Accordingly, iodised salt in Germany supplies roughly a third of the daily iodine intake recommended by the European Food Safety Authority (EFSA) for children (4 to 14 years: 90 to 120 µg per day) and adolescents (15 to 17 years: 130 µg per day) (EFSA, 2014). This result

also correlates well with the corresponding evaluations in adolescents and adults (BfR Opinion no. 005/2021).

3.3 Identification of risk groups

Health risks are associated both with very low and very high intakes of iodine. Accordingly, the data on iodine intake by children in Germany should be used to identify and characterise subpopulations that are exposed to the risks of iodine sufficiency or oversufficiency in terms of their iodine intake. To do so, iodine intake will be evaluated on the basis of suitable reference values, such as the *estimated average requirement* (EAR), estimates of values required to cover *adequate intake* (AI) and the *recommended dietary allowance* (RDA), as well as 'safe' upper intake levels (ULs – *tolerable upper intake levels*).

3.3.1 Risk groups for insufficient iodine intake

Reference values for the iodine intake by infants, young children, children and adolescents are given as between 40 and 200 µg per day by the DGE (D-A-CH, 2015), between 70 and 130 µg per day by EFSA (EFSA, 2014), and between 90 and 150 µg per day by the *Food and Nutrition Board* (FNB) of the former US *Institute of Medicine* (IOM, 2001) (table 5).

In contrast to the reference values by the DGE and EFSA, the reference value (RDA) by the FNB was derived from a physiological estimated average requirement (EAR), determined as 65 to 95 µg per day from the iodine metabolism of the thyroid gland in human studies (IOM, 2001).

Table 5 Dietary reference values for iodine (estimates, adequate intake, recommendations) and estimated average requirements for children and adolescents, as published by various organisations

Dietary reference value D-A-CH (2015)	Adequate intake (AI) (EFSA, 2014)	Recommended dietary allowance (RDA) (IOM, 2001)	Estimated average requirement (EAR) (IOM, 2001)
[µg/day]	[µg/day]	[µg/day]	[µg/day]
0 to <4 months: 40[a]			
4 to <12 months: 80	7 to 11 months: 70		
1 to <4 years: 100	1 to 3 years: 90	1 to 3 years: 90	1 to 3 years: 65
4 to <7 years: 120	4 to 6 years: 90	4 to 8 years: 90	4 to 8 years: 65
7 to <10 years: 140	7 to 10 years: 90	9 to 13 years: 120	9 to 13 years: 73
10 to <13 years: 180	11 to 14 years: 120	14 to 18 years: 150	14 to 18 years: 95
13 to <15 years: 200	15 to 17 years: 130		
15 to <19 years: 200	≥18 years: 150		

[a] This is an estimated value

Both the physiological requirement for nutrients and the nutrient intake itself are not fixed pa-

rameters within any given population, but are subject to their own distribution, which is assumed to be a normal distribution for the sake of simplification. Dietary reference values are chosen with the aim of covering 97% to 98% of the physiological requirements of the population. To obtain a recommended dietary allowance (RDA) for the nutrient, double the standard deviation is therefore added to the physiological estimated average requirement (EAR) for a nutrient, which theoretically equates to the median of the requirement distribution. If a lack of data means that the standard deviation cannot be calculated, it is set to a *default* value, namely 10% of the EAR.

Since the RDA therefore represents a very high physiological requirement (97–98th requirement percentile), most members of the population (97–98%) consuming the nutrient on a daily basis at the level of the RDA would actually consume more of the nutrient than they require in physiological terms. For this reason, the RDA has only limited suitability as a factor for assessing the nutrient status of a population. To identify groups at risk of having an inadequate iodine intake, the EAR *cut point* method from the FNB/IOM is therefore applied (IOM, 2006).

The EAR corresponds to the median physiological requirement for a nutrient in a population. If it is assumed that the intake of a nutrient occurs independently of physiological need for individual persons, an intake below the EAR can certainly cover requirements in cases where this individual's requirement also happens to be below the average requirement. Conversely, an intake above the EAR may fail to cover an individual requirement if this person happens to have a requirement that is even higher than the nutrient is actually consumed.

Accordingly, while an individual nutrient intake below the EAR is not proof of an insufficiency for a specific person, the percentage proportion of a population with a nutrient intake below the EAR can be considered as a means of estimating prevalence for the risk of an inadequate nutrient intake in the general population (IOM, 2006). The level of supply of a population with a considered nutrient is therefore estimated to be better, the lower the percentage of individuals is whose intake of the respective nutrient is below the EAR.

KiESEL-MEAL and EsKiMo II-MEAL were used to calculate the proportions of children exhibiting an iodine intake below the EAR (table 6). To do so, the age-specific EAR was assigned individually to each child within each age group. In addition, to calculate the estimated iodine intake with iodised salt being used at home, the respective estimate was also added for each child individually, by gender and age (see 3.2.3.1). Morover, for better comparability with the biomarker-based KiGGS 2 results (Hey and Thamm, 2019), the age groups '6 to 8 years' and '9 to 11 years' were supplemented by an additional age group comprising 7- to 10-year-old children.

Table 6 Proportion of boys and girls with an iodine intake below the EAR

Age in years	N				Proportion in % <EAR					
	BfR-MEAL		KiGGS 2		BfR-MEAL		KiGGS 2	BfR-MEAL		KiGGS 2
					Without iodised salt at home	With iodised salt at home	Total iodine	Without iodised salt at home	With iodised salt at home	Total iodine
	♀	♂	♀	♂	Girls			Boys		
1–2	154[a]	153[a]	n.d.	n.d.	44.6	n.d.	n.d.	36.8	n.d.	n.d.
3–5	286[a]	302[a]	*	*	33.8	20.8	*	29.6	17.5	*
3–6	*	*	369	428	*	*	53.7	*	*	46.5
6–8	289[b]	305[b]	*	*	24.8	13.8	*	14.3	4.8	*
9–11	290[b]	307[b]	*	*	25.4	11.6	*	21.3	10.3	*
7–10	385[b]	407[b]	415	457	22.6	10.8	44.8	14.8	6.8	40.9
11–13	* n.d.	* n.d.	382	392	* n.d.	* n.d.	43.8	* n.d.	* n.d.	30.5
14–17	* n.d.	* n.d.	478	402	* n.d.	* n.d.	50.3	* n.d.	* n.d.	37.7

[a]   KiESEL.

[b]   EsKiMo II.

n.d.:   No data available.

*   No corresponding age group available.

In the exposure assessment based on KiESEL-MEAL and EsKiMo II-MEAL (UB, conventional foods without iodised salt at home), age-stratified prevalence values for the risk of an inadequate intake were determined in girls as ranging between 22.6% and 44.6%, and in boys as ranging between 14.3% and 36.8% (table 6). For both genders, the use of foods from organic production (without iodised salt at home) increases the prevalence of the risk of inadequate iodine intake by roughly 6% to 8% (tables 3 and 7 in the Appendix), while the use of iodised salt with 20 mg of iodine per kg of salt at home can lower the prevalence by roughly 8% to 13% (conventional, UB) (table 6, tables 3 and 7 in the Appendix).

In KiGGS 2, 30.5% to 53.7% of participating boys and girls (3 to 17 years) were identified as exhibiting an iodine intake below the average requirement (Hey and Thamm, 2019) (table 6). Although this affects an average of 43.6% of boys and girls when considered together, this average of children not achieving the average estimated need was still 37% in the base survey (2003 to 2006) (Hey and Thamm, 2019). A comparison in the age group '7 to 10 years' shows that the prevalence figures determined on the basis of EsKiMo II-MEAL (without iodised salt at home) are roughly 22% to 26% lower than for the biomarker-based KiGGS 2 evaluations. A comparison between KiESEL-MEAL on the basis of the age group '3 to 5 years' with the biomarker-based KiGGS 2 results in 3- to 6-year-old children also produces prevalence values from consumption surveys that are roughly 17% to 20% lower. This divergence of prevalence values between the studies for the risk of an inadequate iodine intake can be explained by the deviating median iodine intake levels determined (table 1 and table

2), which, in turn, can be generally stated to have resulted from the methodological differences between the survey instruments, as has already been discussed in section 3.2.2.

The highest prevalence values for the risk of an inadequate iodine intake are found in the subpopulation of girls, both on the basis of KiGGS 2, and on the basis of KiESEL-MEAL and EsKiMo II-MEAL. However, in younger children between 1 and 6 years of age (note that KiGGS 2 only considers children aged 3 and up), the proportion of children with an iodine intake below the EAR is high for both girls and boys. In addition, the group of 14- to 17-year-old girls from KiGGS2 in particular exhibits a high prevalence for the risk of an inadequate iodine intake. When estimating iodine exposure in adults, women of childbearing age were identified as a risk group for inadequate iodine intake (BfR Opinion no. 005/2021).

In terms of the effects on the prevalence of the risk of inadequate iodine intake that are expected by changing the parameters of iodised salt prophylaxis, girls, women of childbearing age and children between 1 and 6 years of age are therefore the most important subpopulations in which these effects should be measured.

In addition, certain kinds of dietary choices, such as a vegetarian or vegan diet, may also be associated with an increased risk of an inadequate iodine intake. As a result of the inadequate available data on the foods consumed by vegans or vegetarians, however, these risk groups are unsuitable for modelling the effects that result from changing the parameters of an iodised salt prophylaxis.

3.3.2 Risk groups for excessive iodine intake

Tolerable upper daily intake amounts from all sources of iodine (*tolerable upper intake levels*, ULs) were derived for children and adolescents at 200 to 500 µg per day by EFSA (formerly *Scientific Committee on Food*) (SCF, 2002), and at 200 to 900 µg per day by the FNB at the former US IOM (IOM, 2001) (table 7). According to IOM, a UL for infants could not be derived, since no adequate data about adverse effects in this age group are available.

Table 7 Tolerable daily iodine intake levels for children and adolescents

Age [years]	UL (SCF, 2002) [µg/day]	Age [years]	UL (IOM, 2001) [µg/day]
1–3	200	1–3	200
4–6	250	4–8	300
7–10	300		
11–14	450	9–13	600
15–17	500	14–18	900

In the EsKiMo II-BLS consumption study, without accounting for iodised salt, an iodine intake of 150.3 to 194.7 µg per day in boys (6 to 17 years) and of 108.0 to 150.2 µg per day in girls (6 to 17 years) was determined in the 95th consumption percentile (table 1 and table 2). Since under current conditions (iodised salt concentration 15–25 mg/kg, usage level of iodised salt around 74–76% at home and around 29% in commercial food production), intakes of iodine from iodised salt in the 95th percentile are around 85 µg for children between 6 and 12 years of age and around 117 µg of iodine per day for children between 13 and 17 years of age (biomarker-based determination) (table 4), the respective, age-specific UL (250–500 µg iodine/day) in the 95th percentile is not exceeded when calculations are based on EsKiMo II-BLS (plus the proportion of iodine from iodised salt via the normal diet and with current usage levels of food supplements with iodine (<1.5%)).

Regarding the total iodine intakes determined by using biomarkers from KiGGS 2, the respective age-specific ULs are also not exceeded, with 180 µg (6- to 12-year-olds) and 220.9 µg (13- to 17-year-olds) iodine per day in the 95th percentile, respectively.

Based on KiESEL-MEAL and EsKiMo II-MEAL, the 95th percentile of iodine intake (UB, conventional foods), and the number and proportion of study participants was calculated that exceed the respective UL (table 8). To do so, the age-specific UL was assigned individually to each child within the age groups. In addition, the respective estimate for iodine intake via iodised salt at home was also added for each child individually, by gender and age, to calculate the estimated iodine intake including also the usage of iodised salt at home (see 3.2.3.1).

**Table 8 Iodine intake via food without and with the use of iodised salt at home
Based on KiESEL-MEAL and EsKiMo II-MEAL**

Iodine intake via food	N	Median (µg/day)	P95 (µg/day)	UL (SCF, 2002) (µg/day)	Iodine intake >UL (N)	Iodine intake >UL (%)
KiESEL-MEAL						
6 months–1 year <u>without</u> iodised salt at home	57	86.6	192.9	n.d.	n.d.	n.d.
1–2 years <u>without</u> iodised salt at home	308	69.5	118.7	200	2.4	0.8
3–5 years <u>without</u> iodised salt at home	588	75.0	121.3	200/250*	0.0	0.0
3–5 years <u>with</u> iodised salt at home	588	85.0	132.3	200/250*	0.0	0.0
EsKiMo II-MEAL						
6–8 years <u>without</u> iodised salt at home	594	86.4	134.1	250/300*	0.42	0.07
6–8 years <u>with</u> iodised salt at home	594	98.4	146.8	250/300*	0.42	0.07
9–11 years <u>without</u> iodised salt at home	596	91.9	138.1	300/450*	0.0	0.0
9–11 years <u>with</u> iodised salt at home	596	104.9	154.5	300/450*	0.0	0.0

n.d.:   A UL was not derived for this age group.

*   Within the age groups, the age-specific UL was assigned individually to each child.

In the 95th percentile of the iodine intakes determined from KiESEL-MEAL and EsKiMo II-MEAL, the respective, age-specific UL (also with the use of iodised salt at home, where corresponding data are available) is also not exceeded (table 8). Accordingly, only isolated participants were identified for whom the UL was exceeded. Among the 1- to 2-year-olds it was only 2.4 of 308 study participants (0.8%) (without iodised salt in the household, data on the use of iodised salt are not available), and among the 6- to 8-year-olds it was 0.42 of 594 participants (0.07%) (with and without use of iodised salt in the household) who exceeded the UL by consuming food (Table 8); the additional use of NEM was not taken into account.

Overall, for children and adolescents, just as in the case of adults (BfR Opinion no. 005/2021), the risk of exceeding the UL can therefore be considered as exceptionally low, given the contemporary circumstances of iodised salt prophylaxis.

3.4 Is an increase in the maximum permitted iodine concentration in salt from 25 mg to 30 mg per kg of salt both appropriate and not harmful to health, also considering a 10% reduction in salt consumption?

3.4.1 Target values for salt-dependent iodine intake in order to assess as 'appropriate' and 'not harmful to health'

The intake of a nutrient can be characterised as appropriate and 'not harmful to health' when the prevalence of the risk of an inadequate (insufficient or excessive) nutrient intake is low at both ends of the distribution. The figure defined as acceptable for the prevalence of the risk of an inadequate nutrient status is a health policy decision, however, which depends on the severity of the adverse health effects resulting from an intake that is too low or too high.

In the context of the EAR *cut point* method, the recommendation is made that a population can be considered as having an adequate nutrient status if the prevalence of the risk for an inadequate nutrient status is not more than 2% to 3% and if the risk of exceeding the UL is also acceptably low (IOM, 2006). For its part, the BfR considers the risk of excessive iodine intake to be acceptably low if the iodine intake in the 95th consumption percentile does not exceed the UL for the respective age group.

According to the biomarker-based data from KiGGS 2, the prevalence of the risk of an inadequate iodine intake in Germany for 3- to 17-year-old children is between 30.5% and 53.7% (table 6) (Hey and Thamm, 2019). The risk of an excessive iodine intake (exceeding the UL) from food alone can be characterised as negligible, according to the data based on KiESEL-MEAL and EsKiMo II-MEAL, which provide figures of between 0.07% and 0.8% of study participants (table 8). In the 95th percentile of the iodine intakes determined from KiESEL-MEAL and EsKiMo II-MEAL, the respective, age-specific UL (also while accounting for the use of iodised salt at home, where corresponding data are available) is not exceeded. Although the use of food supplements was not taken into account when calculating iodine intake in KiESEL-MEAL and EsKiMo II-MEAL, the respective, age-specific UL is also not exceeded on the basis of the biomarker-based KiGGS 2 evaluation in the 95th percentile of <u>total</u> iodine intake, i.e. while accounting for all sources of iodine. Accordingly, the current risk of excessive iodine intake for children and adolescents in Germany can still be considered as low overall, even when accounting for the current practice of using food supplements containing iodine.

Under current conditions of iodised salt prophylaxis, 47% (37 μg of iodine per day) and 53% (50.9 μg of iodine per day) of the median intake value from food for iodine come from iodised salt, for 6- to 12-year-old children and 13- to 17-year-old children, respectively (table 4) (Esche and Remer, 2019). The question arises as to how high the salt-dependent iodine intake needs to be to reduce the prevalence of the risk of an inadequate iodine status to between 2% and 3%. The prevalence of the risk of an inadequate iodine intake in a population is inversely proportional to the median iodine intake. Accordingly, the risk prevalence figures determined on the basis of KiESEL-MEAL and EsKiMo II-MEAL were compared with the corresponding median iodine intakes determined (UB, conventional, without iodised salt at home), and the inverse correlation was used to extrapolate the median iodine intake from food that correlates with a prevalence of the risk for an inadequate iodine status of 2.5%. Since only risk prevalence figures that are based on an identical EAR can be accounted for in this calculation, only the 1- to 8-year-old children were considered, for whom a uniform EAR of 65 μg per day had been determined (IOM, 2001). Based on the inverse correlation a median iodine intake from food of 96.9 μg per day could be extrapolated, which correlates with a prevalence of the risk for an inadequate iodine status of 2.5% (median iodine intake (y) = 98.6 + (−0.69) × risk prevalence (x)). The simplified modelling as a linear regression applied here is based on a number of simplifying assumptions, however. On the one hand, this presupposes that the distribution of iodine intake is similar in each age group and, on the

other hand, that the variance remains unchanged as iodine intakes rise, which is not necessarily the case in reality. Accordingly, the extrapolated assumed relationship between risk prevalence and median iodine intake presents only a rough approximation. Furthermore, the distribution of residuals in the regression cannot be clarified, as a result of the low number of data points (n = 8) and may not necessarily be a normal distribution.

Despite the stated uncertainties, the value determined of 96.9 µg of iodine per day is in the same order of magnitude as the intake reference value from EFSA, who specifies an *adequate intake* (AI) of 90 µg per day for 1- to 8-year-old children (EFSA, 2014). This result is therefore in good agreement with the values that were extrapolated for adolescents and adults using the same approach (BfR Opinion no. 005/2021), and which, at around 140 to 150 µg iodine per day, are also within the same range of the AI from EFSA (15 to 17 years: 130 µg per day; adults: 150 µg per day) (EFSA, 2014).

Children aged 8 and over could not be included in this regression analysis, since other EARs are used as a basis for this age group, compared with the 1- to 8-year-olds. There would not have been enough data points available for a separate analysis. Even with the data available from KiGGS 2, an estimate of this kind could not be performed as a result of the age groupings and the associated heterogeneous EARs. In analogy to the results for the younger children, adolescents and adults, EFSA's Adequate Intake was therefore also defined as a target value for the 9- to 13-year-old children.

According to the criteria of the EAR *cut point* method, iodine intakes for children and adults in Germany can be considered adequate if they achieve a median iodine intake from food that is within the range of the AI from EFSA.

In the case of the 6- to 12-year-old children, a median value of roughly 42 µg of the iodine that is consumed daily with food occurs naturally within food and is therefore salt-independent (Esche and Remer, 2019) (table 4). For 6- to 10-year-old children, EFSA specifies an adequate intake of 90 µg and for 11- to 12-year-olds of 120 µg per day (EFSA, 2014). Accordingly, 6- to 10-year-old children must obtain a further 48 µg of iodine per day and 11-to 12-year-olds another 78 µg of iodine per day from iodised salt in order to achieve the EFSA value.

In the case of the 13- to 17-year-old children, a median value of roughly 46 µg of the iodine that is consumed with food occurs naturally within food and is therefore salt-independent (Esche and Remer, 2019) (table 4). According to EFSA, the intake for 13- to 14-year-old children is considered adequate at 120 µg of iodine per day and for 15- to 17-year-olds at 130 µg per day. Accordingly, 13- to 17-year-olds must obtain a further 74 µg or 84 µg of iodine per day from iodised salt in order to achieve an iodine intake within the range of EFSA recommendations.

In consideration of the above, all measures can be considered appropriate in relation to 6- to 12-year-old children that increase the current salt-dependent median iodine intake of approximately 37 µg per day to a median of around 48 µg or 78 µg per day. For the 13- to 17-year-olds, the current salt-dependent median iodine intake of approximately 51 µg per day must be increased to roughly 74 and 84 µg per day.

3.4.2 Impact of increasing the iodine content in salt and reducing salt consumption on iodine intake

To be able to estimate the impact of increasing the iodine content in salt and reducing salt consumption on iodine intake, the current figure for iodine provided by iodised salt must be known. The levels of iodine intake from iodised salt under contemporaneous conditions were calculated using the biomarker-based exposure assessments in KiGGS 2 for children aged 6 and above (Esche and Remer, 2019) (section 3.2.3.2, table 4).

If 47% (37 µg) and 53% (50.9 µg) of iodine intake stems from iodised salt for 6- to 12-year-old and 13- to 17-year-old children, respectively, then a median daily figure of 1.9 g and 2.5 g of iodised salt is consumed, respectively, assuming an iodine concentration of 20 mg per kg of salt. This means iodised salt has a share of 32% and 33% of the median total salt intake, which amounts to 5.8 g (6- to 12-year-olds) and 7.8 g (13- to 17-year-olds) per day (Esche and Remer, 2019).

If, for the data across all consumption percentiles from KiGGS 2, it is assumed that the proportion of iodine from iodised salt is a constant 47% (6- to 12-year-olds) and 53% (13- to 17-year-olds), then 50.4 µg of iodine from 2.5 g of iodised salt (6- to 12-year-olds) and 67.1 µg of iodine from 3.4 g of iodised salt (13- to 17-year-olds) is consumed in the 75th consumption percentile, and 84.6 µg of iodine from 4.2 g of iodised salt (6- to 12-year-olds) and 117.1 µg of iodine from 5.9 g of iodised salt (13- to 17-year-olds) is consumed in the 95th consumption percentile (table 9).

Table 9 Total iodine intake, iodine intake from salt, iodine intake from food, total salt consumption and iodised salt consumption in the median, in the P75 and P95, and iodised salt as a percentage of salt consumption, based on KiGGS 2 (Esche and Remer, 2019)

6–12 years	Iodine$_{total}$ (µg/d)	Iodine$_{salt}$ (µg/d)	Iodine$_{food}$ (µg/d)	Salt$_{total}$ (g/d)	Iodised salt g/d	Iodised salt as a proportion of salt consumption in %
Iodine intake %		47.0	53.0			
P50	78.9	37.0	41.9	5.8	1.9	32
P75*	107.2	50.4	56.8	8.5**	2.5**	30**
P95*	180.0	84.6	95.4	13.7**	4.2**	31**
13–17 years	**Iodine$_{total}$ (µg/d)**	**Iodine$_{salt}$ (µg/d)**	**Iodine$_{food}$ (µg/d)**	**Salt$_{total.}$ (g/d)**	**Iodised salt g/d**	**Iodised salt as a proportion of salt consumption in %**
Iodine intake %		53.0	47.0			
P50	96.6	50.9	45.7	7.8	2.5	33
P75*	126.7	67.1	59.5	11.9	3.4**	28**
P95*	220.9	117.1	103.8	18.7	5.9**	31**

* The values in the percentiles P75 and P95 are not contained in the 2817HS007 final report from Esche and Remer (2019) but were made available personally by Dr Esche, Ms Hua and Prof. Remer.

** Values calculated using the figures provided by Dr Esche, Ms Hua and Prof. Remer.

Since salt-dependent iodine intake is the product of iodised salt consumption and the salt's iodine content, and since more salt, and therefore more iodised salt, is consumed in the high consumption percentiles, increasing the iodine content in salt has a stronger effect on iodine intake in the high consumption percentiles than in the median or lower consumption percentiles.

By using the intake of iodine from salt shown in table 9 in the percentiles of 50 (median), 75 and 95, the corresponding salt-dependent iodine intakes can be determined easily with iodine concentrations of 25 mg and 30 mg per kg of salt, and for both current salt consumption and for after a reduction in salt consumption by 10% (table 10).

Table 10 Calculation of salt-dependent iodine intake as a function of the iodine concentration in salt, in the median, the P75 and the P95, with and without accounting for a 10% reduction in salt consumption, by using data from KiGGS 2

	Expected iodine intake from iodised salt in µg per day					
6–12 years	With current salt consumption			After 10% reduction in salt consumption		
mg iodine/kg salt	**20**	**25**	**30**	**20**	**25**	**30**
Median	37.0	46.3	55.5	33.3	41.6	50.0
P75	50.4	63.0	75.6	45.4	56.7	68.0
P95	84.6	105.8	126.9	76.1	95.2	114.2
13–17 years	With current salt consumption			After 10% reduction in salt consumption		
mg iodine/kg salt	**20**	**25**	**30**	**20**	**25**	**30**
Median	50.9	63.6	76.4	45.8	57.3	68.7
P75	67.1	83.9	100.7	60.4	75.5	90.6
P95	117.1	146.4	175.7	105.4	131.7	158.1

Increasing the maximum permitted iodine concentration from 25 to 30 mg of iodine per kg of salt would probably result in products offered on the market having iodine concentrations in salt between 20 and 30 mg per kg (average of 25 mg/kg). Assuming that salt consumption and the use of iodised salt for the production of commercial foods both remain constant, this measure would be expected to increase median salt-dependent iodine intake by approx. 9 µg per day to 46.3 µg per day and by approx. 13 µg per day to 63.6 µg per day, for 6- to 12-year-olds and 13- to 17-year-olds, respectively (table 10).

The increased iodine intakes from iodised salt with an average concentration of 25 mg of iodine per kg of salt would increase the median total iodine intake of 78.9 µg per day to roughly 88 µg per day (6 to 12 years) and of 96.6 µg per day to approx. 109 µg per day (13 to 17 years). Even with salt consumption remaining constant, this shows that increasing iodine concentration by 5 mg per kg of salt would be unable to achieve a median value equal to the intake reference value from EFSA for children between 11 and 17 years of age. The 6- to 10-year-old group would roughly achieve the intake reference value under these conditions (AI for 1- to 10-year-olds: 90 µg per day; AI for 11- to 14-year-olds: 120 µg per day; AI for 15- to 17-year-olds: 130 µg per day) (EFSA, 2014).

If, at the same time that the iodine concentration in salt is increased, salt consumption is also successfully reduced by 10%, the expected increase in salt-dependent median iodine intake according to KiGGS 2 data is limited to 4.6 µg per day for 6- to 12-year-olds and 6.4 µg per day for 13- to 17-year-olds. Accordingly, even with a 10% reduction in salt consumption, the measure is expected to slightly increase the salt-dependent iodine intake in the overall population. However, the target value for iodine from salt (48 and 78 µg of iodine per day for 6- to 12-year-olds and 74 and 84 µg of iodine per day for 13- to 17-year-olds, see section 3.4.1) is not achieved in the median with an average concentration of 25 mg of iodine per kg salt with a simultaneous 10% reduction in salt consumption.

3.4.2.1 Impact on the prevalence for inadequate iodine intake

In girls, women of childbearing age and children aged 6 and under, a high proportion of individuals with an iodine intake below the EAR was identified (section 3.3.1). Accordingly, these groups are the most important subpopulations in which the effects on the prevalence of the risk of an inadequate intake of iodine expected – namely by increasing the concentration of iodine in salt and by reducing salt consumption by 10% – should be measured.

For the women of childbearing age subpopulation, the BfR had already noted that increasing the concentration of iodine in salt by 5 mg per kg while simultaneously reducing salt consumption by 10% would not significantly reduce the existing high prevalence for the risk of an inadequate iodine intake (BfR Opinion no. 005/2021).

In Esche and Remer (2019), the current iodine intake from iodised salt was not calculated for younger children under the age of 6, which means that the effects cannot be modelled for this group. As a basis, the age-stratified total salt and total iodine intakes, as well as the calculated percentage proportions of participating girls with an iodine intake below the EAR from the final report by Hey and Thamm (2019) have been used, since the proportion of study participants with an iodine intake below the EAR was not calculated in Esche and Remer (2019) because the latter work pursued a different objective.

Table 11 Median salt and iodine consumption, and prevalence of the risk for an inadequate iodine status in girls under current conditions (as per Hey and Thamm, 2019), and while accounting for an increase in the iodine concentration in salt to an average of 25 mg per kg, and a reduction in salt consumption by 10%, based on data from KiGGS 2

Girls from KiGGS 2	20 mg iodine per kg salt Without salt reduction			25 mg iodine per kg salt With 10% salt reduction		
Age	Median salt g/d	Median iodine µg/d	<EAR in %	Median salt g/d	Median* iodine µg/d	<EAR** in %
7–10	5.9	76	45	5.3	80*	42**
11–13	6.9	84	44	6.2	89*	41**
14–17	8.6	94	50	7.7	101*	47**

* The percentage iodine proportions from iodised salt were not determined for the age groups presented in the table. Accordingly, for the calculations of iodine intakes to be expected after increasing the salt iodine concentration and reducing salt consumption, it was assumed that the iodine proportions from iodised salt determined as per Esche and Remer (2019) for 6- to 12-year-olds are approximately applicable to 7- to 13-year-old girls, and that the proportions determined for 13- to 17-year-olds are similarly applicable to 14- to 17-year-old girls.

** The calculations of prevalence figures for the risk of an inadequate iodine intake for girls, as to be expected after increasing the salt iodine concentration and reducing salt consumption, were simplified by assuming that the resulting effects on iodine intake would be the same across all consumption percentiles. Since this is not necessarily always the case, this produces a degree of uncertainty.

Increasing the iodine concentration in salt also has only a negligible effect on the subpopulation of 7- to 17-year-old girls. After increasing the iodine concentration to an average of 25 mg per kg and considering a 10% reduction in salt consumption, the median iodine intake in this group does rise moderately by 4 to 7 µg per day, but the age-specific intake reference values of EFSA are not achieved in the median and the prevalence for the risk of an inadequate iodine status remains at the relatively high level of 41% to 47% (table 11).

As a general statement, it can be said that a reduction in salt consumption by 10% is still well compensated and median iodine intake does rises slightly if iodine concentration in salt is increased to a maximum of 30 mg per kg, i.e. a more likely average value of 25 mg per kg in

actual products. However, the existing prevalence of the risk of an iodine insufficiency, which is especially high in the subpopulation of girls, is only negligibly reduced. Accordingly, simply raising the iodine concentration in salt by 5 mg per kg does not fulfil the 'appropriate' criterion.

3.4.2.2 Impact on the risk of exceeding the UL

As of this writing, the risk that children and adolescents will exceed the respective, age-specific UL by their consumption of food is considered as negligible. In the KiGGS 2 study, a total iodine intake of 180.0 µg (6- to 12-year-olds) and 220.9 µg (13- to 17-year-olds) per day was determined in the P95, of which 84.6 µg and 117.1 µg can be ascribed to iodised salt, and 95.8 µg and 103.8 µg can be ascribed to other foods (table 4 and table 9). With an iodine concentration of 20 mg per kg in salt, this equates to a consumption of iodised salt of 4.2 or 5.9 g per day in the P95 (table 9). Assuming salt consumption and the usage rate of iodised salt in the production of food both remain constant, raising the iodine concentration in salt to 25 mg per kg would result in a salt-dependent iodine intake of 105.8 (6 to 12 years) and 146.4 (13 to 17 years) µg per day in the P95 and, if the maximum concentration of 30 mg per kg were to be achieved, this would result in a salt-dependent iodine intake of 126.9 and 175.7 µg per day in the P95 (table 10).

In assessing the risk of an excessive intake of iodine, a scenario is assumed in which the intended reduction in salt consumption is unsuccessful, since, even in this case, increasing the iodine concentration in salt to a maximum of 30 mg per kg must not be associated with harmful effects to health. Accordingly, the only iodine intake levels evaluated here are those that result from maximising the possible iodine concentration in iodised salt to 30 mg per kg of salt (table 10). In total, with the inherent iodine content from food of 95.4 or 103.8 µg per day in the P95 (Table 9), this would result in an iodine intake of 222.3 or 279,5 µg per day in the 95th consumption percentile in the case of the KiGGS 2 study, which would be about 30 to 230 µg or 170 to 220 µg below the respective age-specific UL (Table 12). In these values, the difference of 30 µg to the UL is derived from the 4- to 6-year-old age group, in which the 6-year-olds lie at the transition to the next-higher UL. The biomarker-based total iodine intake levels from KiGGS 2 account for all sources of iodine, and therefore the use of food supplements is already included.

Table 12 Calculation of potential total iodine intake in the P95 with current salt consumption and a maximum permitted iodine concentration of 30 mg per kg of salt, based on data from KiGGS 2

Age	Iodine intake from food in P95	Potential iodine intake with current salt consumption and 30 mg of iodine per kg of salt		UL (SCF, 2002)
		Iodine intake from iodised salt in P95	Total iodine intake in P95	
	μg per day			
6–12 years	95.4	126.9	222.3	250/300/450
13–17 years	103.8	175.7	279.5	450/500

In the scenarios from KiESEL-MEAL and EsKiMo II-MEAL (UB approach, conventional foods), iodine intake levels of 132.3 μg (3 to 5 years), 146.8 μg (6 to 8 years) and 154.5 μg (9 to 11 years) per day were determined in the 95th percentile while accounting for the potential use of iodised salt at home (table 8). This results in a distance of roughly 70 to 120 μg for the 3- to 5-year-olds, of roughly 100 to 150 μg for the 6- to 8-year-olds and of 150 to 300 μg for the 9- to 11-year-olds from the respective, age-specific UL – a gap that would be available for increasing the concentration of iodine in salt.

By applying the proportion of 47% salt-dependent iodine intake in the 6- to 12-year-olds as determined in KiGGS 2 (Esche and Remer, 2019) to the iodine intake levels determined in the P95 from EsKiMo II-MEAL[4], this produces an iodine proportion of 69 μg (6 to 8 years) and 73 μg (9 to 11 years) per day from salt, and of 78 μg and 82 μg of iodine per day from other foods. This equates to an iodised salt consumption of 3.5 g and 3.7 g per day if the iodine concentration is 20 mg per kg of salt. Increasing the iodine concentration in salt to 30 mg per kg would raise the salt-dependent iodine intake to 105 and 111 μg per day. In total, together with the iodine proportion from other foods, an iodine intake of 183 and 193 μg per day would be achieved in the P95 in the EsKiMo II-MEAL exposure assessment. In this case, the distance to the UL would still be roughly 70 to 120 μg (6 to 8 years) and 110 to 260 μg (9 to 11 years) per day, which would then be available for food supplements, for example (the iodine intake levels determined in EsKiMo II-MEAL do not account for the use of food supplements). With a level of use of food supplements containing iodine in children and adolescents below 1.5%, however (Mensink et al., 2020), only a small proportion of these subpopulations would obtain additional iodine via food supplements. Accordingly, the risk of exceeding the UL by increasing the iodine concentration in salt to 30 mg per kg can still be considered as low, also on the basis of EsKiMo II-MEAL and the biomarker-based iodine proportions from iodised salt, as long as the usage rate of 29% iodised salt for the production of commercial foods (Bissinger et al., 2018) remains constant.

At this juncture, however, the BfR notes that, in the MEAL studies, a proportion of 0.8% of KiESEL children between the ages of 1 and 2, and a proportion of 0.07% of EsKiMo II children between the ages of 6 and 8 already exceeds the UL, even without taking into account iodised salt at home and the use of food supplements containing iodine.

Overall, however, it becomes clear that increasing the iodine concentration in salt to 30 mg per kg with the current usage rate of 29% of iodised salt for the production of commercial foods (Bissinger et al., 2018) can be considered as not harmful to health.

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[4] KiESEL-MEAL could not be considered here, because no data on iodine intake from iodised salt are available for the younger children.

3.4.3 Determination of usage rates of iodised salt that are 'appropriate' and 'not harmful to health' after increasing the maximum iodine concentration to 30 mg per kg

The following section aims to calculate the range of usage rates of iodised salt that are 'appropriate' and 'not harmful to health' for children, based on KiGGS 2 data. In doing so, the iodine and iodised salt consumption levels will be applied as given in table 9.

The median salt-dependent iodine consumption of 37.0 µg (6- to 12-year-olds) and 50.9 µg (13- to 17-year-olds) per day was used to derive a proportion of 47% and 53% of iodine consumption, and a median iodised salt consumption of 1.9 and 2.5 g per day, which in turn equates to 32% and 33% of the median salt consumption of 5.8 and 7.8 g per day (Esche and Remer, 2019). As salt-dependent iodine consumption depends directly on the consumption of iodised salt, there is a linear relationship between salt-dependent iodine intake (y) and the proportion of iodised salt in salt consumed (x). In accordance with the levels and proportions as determined in KIGGS 2, the linear formula $y = f(x)$ can now be formulated for each desired iodine content in salt, which can be used to calculate the required proportion of iodised salt needed to achieve a specified target value for salt-dependent iodine intake.

However, this approach is associated with larger uncertainties and fluctuations in children than in adults, since the values for the inherent iodine proportions from food that are required for the calculations were determined on the basis of the broad-based age groups '6 to 12 years' and '13 to 17 years'. Based on these values, the target values, however, are oriented towards the respective, age-specific intake reference values – or ULs – in which the age groups have narrower definitions. Accordingly, the following estimates must be viewed as only very rough guide values.

The calculations of the proportions of iodised salt in salt consumed required for the 'appropriate' criterion were completed for the iodine concentration of 25 mg per kg salt while accounting for a 10% reduction in salt consumption.

The required iodine intake from iodised salt to achieve the intake reference values from EFSA is 48 µg per day for 6- to 10-year-olds and 78 µg per day for 11- to 12-year-olds, in the median (see section 3.4.1). Taking into account the above conditions (average iodine content 25 mg per kg, salt reduction of 10%), the increase in iodine intake per percent of iodised salt proportion in 6- to 12-year-olds (with a median total salt intake of 5.8 g per day) was $y = 1.305x$. Accordingly, a salt-related iodine intake of 48 µg is achieved at an iodised salt proportion of 37% and of 78 µg at an iodised salt proportion of 60%.

In the case of 13- to 14-year-olds, the required iodine intake from iodised salt to achieve the intake reference values from EFSA is 74 µg per day and 84 µg per day for 15- to 17-year-olds, in the median (see section 3.4.1). Taking into account the above conditions, the increase in iodine intake per percent of iodised salt proportion in 13- to 17-year-olds (with a median total salt intake of 7.8 g per day) was $y = 1.755x$. Accordingly, a salt-related iodine intake of 74 µg is achieved at an iodised salt proportion of 42% and of 84 µg at an iodized salt proportion of 48%.

The calculation of the maximum 'not harmful to health' iodised salt proportion in salt consumed was completed for the iodine concentration of 30 mg per kg salt, with salt consumption remaining unchanged.

In the 7- to 10-year-olds[5], the target value for salt-dependent iodine intake is 205 µg per day in the P95, since, when added to the figure for iodine consumption from other foods of around 95 µg per day (table 4 and table 9), this should not exceed the UL of 300 µg per day. For the 11- to 12-year-olds, for whom an iodine intake of 95 µg from other foods in the P95 is also used as a baseline, the target value is 355 µg of iodine per day at which the UL of 450 µg per day would not be exceeded. For the 6- to 12-year-olds, with a salt consumption of 13.7 g per day in the P95, applying the above-mentioned conditions produced a rise in iodine intake per percent of iodised salt proportion of y = 4.11x. Accordingly, a salt-dependent iodine intake of 205 µg in the P95 is achieved at an iodised salt proportion of 50% and of 355 µg at an iodised salt proportion of roughly 86%.

In the 13- to 17-year-olds, an iodine intake from other foods was calculated as roughly 104 µg per day in the P95 (table 4 and table 9). Based on this, the distance to the UL for 13- to 14-year-olds (UL: 450 µg per day) is 346 µg and 396 µg for the 15- to 17-year-olds (UL: 500 µg per day). For the 13- to 17-year-olds, with a salt consumption of 18.7 g per day in the P95, applying the above-mentioned conditions (maximum iodised salt concentration of 30 mg per kg; no salt reduction) produced a rise in iodine intake per percent of iodised salt proportion of y = 5.61x. Accordingly, a salt-dependent iodine intake of 346 µg in the P95 is achieved at an iodised salt proportion of roughly 62% and of 396 µg with an iodised salt proportion of roughly 71%.

Overall, while taking into account the applicable uncertainties and fluctuations, an increase in the maximum iodine concentration in salt from 25 to 30 mg per kg can be viewed as appropriate for children, even in the case of salt consumption being successfully reduced, if the usage rate of iodised salt across all food products is between 37% and 60%. However, some of the levels of use calculated for the individual age groups that are harmless to health are below the appropriate levels of use. The lowest value for a usage rate considered as not harmful to health under *worst-case* conditions (30 mg of iodine per kg salt, no salt reduction) was determined at 50% for 7- to 10-year-olds. In adults, the usage rate for iodised salt across all foods that is considered as not harmful to health is slightly lower, at 42% (BfR Opinion no. 005/2021). This should not be substantially exceeded.

In this context, regular monitoring of the iodine concentration in iodised salt products and the usage rate of iodised salt in industrially processed and artisanal food products is to be considered as advisable.

At this juncture, the BfR wishes to note that the calculations made here are based on a considerable number of assumptions and simplifications. The assessment findings should therefore be considered as establishing a general framework for iodised salt prophylaxis across all foods. This general framework certainly does not preclude situations where it may be advisable to manufacture products from certain food groups (in an industrial or artisanal process) that contain iodised salt in a proportion higher than 42%. As of this writing, for example, 47% of meats and sausages, 10% of bakery products and only 2% of milk and dairy produce are made with iodised salt, resulting in a proportion of 29% across the three food groups investigated (Bissinger et al., 2018).

Both from the exposure assessments made on the basis of KiESEL-MEAL and EsKiMo II-MEAL, which have accounted for iodised salt in commercial foods (figure 1), and from the MRI's model scenarios for adolescents and adults (MRI, 2020), it can be seen that, apart from meats and sausages, the food group of bread and bakery products is one of the most

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[5]　The 6-year-olds were not considered here, since their age-specific UL is oriented towards the '4 to 6 years' age group. The underlying inherent proportions of iodine from food used for the calculation were calculated using the '6 to 12 years' age group, however, which means that these are barely applicable to the 4- to 6-year-olds.

important pillars for iodised salt fortification in the context of iodine prophylaxis. Accordingly, achieving a targeted increase in the usage rate of iodised salt specifically in this food group is advisable.

3.5   Uncertainties

The *food list* used for the BfR MEAL study covers more than 90% of consumption but less than 100% and, within individual food groups, sometimes less than 90% of consumption from the EsKiMo II and KiESEL studies. A slight underestimate of exposure may therefore result from this gap.

The iodine concentration and intake data shown are based on the UB approach. The differences to the mLB approach in the concentration data have only a very small impact on the estimated iodine intake and the population (table 1 and table 5 in the Appendix). When interpreting all of the results as shown, however, it must be remembered that a slight overestimate of iodine concentrations and of iodine intake may be present when using the UB approach.

The drinking water used for preparing the meals and beverages in the BfR MEAL study has a comparatively high concentration of iodine. Although typically very nuanced, the regional variability in drinking water concentrations can only be partially accounted for by a TDS approach. However, in regions with lower concentrations in drinking water, one may assume a lower intake of iodine from food that is prepared with drinking water.

The scenarios 'Organic production' and 'Conventional production' are based on the iodine concentration data from the MEAL pools with conventional and organic foods. For the 251 foods for which no pools stratified by production type were available, values not specific to the production type were substituted from the corresponding foods. The potential bias and magnitude of effect of this substitution are not known.

Non-iodised salt was used when preparing the foods in the MEAL study kitchen. This leads to an underestimate of iodine concentrations in foods whose pools contain meals prepared with salt and, consequently, to an underestimate of iodine intake. However, this uncertainty is quantified and taken into account by the scenario 'Use of iodised salt at home'.

In contrast to the evaluations made for adults on the basis of NVS II and DEGS1, the median total iodine intakes from KiGGS 2 are indeed higher than the BLS-based EsKiMo II evaluation from the RKI, but are below the calculated iodine intake levels on the basis of MEAL data (KiESEL-MEAL and EsKiMo II-MEAL), notwithstanding the fact that the use of iodised salt at home was not considered in the MEAL evaluation. The differences in the iodine intake values determined are most likely to result from methodological differences between the various survey instruments. While total iodine intake in KiGGS 2 was determined with a biomarker-based approach from iodine excreted in urine, iodine intakes in EsKiMo II-MEAL and KiESEL-MEAL are estimates based on consumption surveys.

Uncertainties can arise from both of these survey instruments. The determination of iodine from spot urine, for example, is subject to a high level of intra- and inter-individual variability (despite normalisation via age-standardised 24-hour creatinine excretions to compensate for fluctuations in hydration status), since iodine intake can vary considerably within a single day or on separate days. Accordingly, this method is not suitable for determining an individual iodine status, although, despite these uncertainties, it is considered a good indicator for estimating average iodine intake at the level of the population. Common to almost all consumption surveys is the risk of *under*- or *over*-reporting. Even within the various consumption surveys (e.g. weighing records, DISHES, *24-hour recall*), each method has its pros and cons that may vary in terms of their impacts on survey results. When using weighing records, for

example, documenting 'out-of-home consumption' is associated with greater uncertainty, especially in the case of younger children. To minimise these uncertainties, a reduced estimate record was utilised in KiESEL for documenting consumption in childcare facilities.

Furthermore, here one should note that the age groupings vary slightly between the various surveys, which risks a certain level of uncertainty in any comparisons. However, comparability with the KiGGS 2 data has been simplified by the creation of an additional '7 to 10 years' age group within the scope of the EsKiMo II-MEAL evaluation.

Iodine intake tends to be overestimated in the model scenarios based on KiESEL-MEAL and EsKiMo II-MEAL, in which the use of iodised salt at home was accounted for, since the use of iodised salt at home was assumed for all study participants.

In order to calculate the level of salt-dependent iodine intake needed to reduce the prevalence for the risk of an inadequate iodine status to between 2% and 3%, the risk prevalence figures determined on the basis of KiESEL-MEAL and EsKiMo II-MEAL were compared with the corresponding median iodine intakes determined. The linear regression applied here is based on a number of simplifying assumptions, however. On the one hand, this presupposes that the distribution of iodine intake is similar in each age group and, on the other hand, that the variance remains unchanged as iodine intakes rise, which is not necessarily the case in reality. Accordingly, the extrapolated assumed relationship between risk prevalence and median iodine intake presents only a rough approximation. Furthermore, the distribution of residuals in the regression cannot be clarified, as a result of the low number of data points (n = 8), and may not necessarily be a normal distribution.

To calculate the iodine proportion from salt based on EsKiMo II-MEAL and EsKiMo II-BLS, the BLS-based iodine intake, in which no iodised salt is accounted for, was subtracted from the MEAL-based iodine intake. It should be noted that this methodology involves uncertainties when making direct comparisons between the respective iodine intake levels. While an identical underlying data set was used for consumption in both exposure assessments, different content data were used and separate methodological approaches were also applied when correlating the data. Nonetheless, the median salt-dependent iodine intake levels that were modelled in the context of KiGGS 2 and the difference between EsKiMo II-MEAL and EsKiMo II-BLS agree very well with one another.

As a basic rule, it must be remembered that the approach taken to modelling iodised salt usage does not allow personal behavioural patterns, such as brand loyalty or other habits, to be appropriately accounted for. Accordingly, consumers who stay true to their brand and only use iodised salt or prefer to buy products containing iodised salt may achieve very high individual iodine intake levels. The frequency of these kinds of behaviour could not be estimated in the models calculated, nor can it be extrapolated to address potential future cases where a UL is exceeded.

Calculations of usage rates for iodised salt that are appropriate and are unlikely to pose a risk of adverse effects to human health are based on a series of assumptions and simplifications. These include the assumption that the salt-dependent iodine intake and iodine concentration in salt is constant across all consumption percentiles. Iodised salt products on the market may also contain varying levels of iodine (15 to 25 mg per kg), which means that the median iodised salt consumption as calculated can only be an estimate. Calculations are also associated with larger uncertainties and fluctuations in children than in adults, since the values for the inherent iodine proportions from food that are required for the calculations have been determined on the basis of the broad-based age groups '6 to 12 years' and '13 to 17 years'. Based on these values, the target values, however, are oriented towards the respective, age-specific intake reference values – or ULs – in which the age groups have narrower definitions.

If the iodine concentration in salt is increased to a maximum of 30 mg per kg with a simultaneous 10% reduction in salt use, then the iodised salt usage rates considered as 'appropriate' and 'not harmful to health' should therefore be viewed as a general framework for iodised salt prophylaxis across all foods.

3.6 Suitability of iodate and iodide as table salt additives

In human development, iodine plays an important role in health as an essential trace element, and must be ingested together with our food. Within and as part of a food system, various iodine compounds such as iodides and iodates together with elemental iodine take part in oxidation and reduction reactions. As a result, for example, an iodide can oxidise to elemental iodine in the presence of oxygen or other oxidising agents. Elemental iodine sublimates easily and is quickly lost to the atmosphere from evaporation and diffusion. Accordingly, an iodate is generally considered as more stable than an iodide in food (BfR, 2004; Kaiho, 2014; West et al., 1995).

As a precaution against iodine deficiency in populations all over the world, table salt is enriched with potassium iodide or iodate. In areas with a hot, moist climate, the iodate is preferred on account of its greater stability (WHO, 2004). For historical reasons, potassium iodide is used in North America and a number of European countries, while most tropical countries use potassium iodate (WHO, 2004). Potassium iodide is used in many countries, as its availability was higher compared to potassium iodate and it was also more affordable (Chavasit et al., 2002). In the Federal Republic of Germany, only iodates (sodium and potassium iodate) have been approved for the production of iodised table salt since 1981. Potassium iodate exhibits greater stability during storage in comparison to potassium iodide. Use of the iodate was able to significantly improve the quality of iodised table salt together with its shelf life expiry date (Habermann et al., 1978). If potassium iodide is used as a salt additive, sodium carbonate, sodium bicarbonate, sodium thiosulphate or dextrose are also often added to increase the pH and stabilise the potassium iodide (Habermann et al., 1978; WHO, 2014). This should be considered prior to any potential approval of potassium iodide in Germany.

WHO estimates the loss of iodine during food production as 20%, followed by a further 20% during processing and food preparation (WHO, 2007). In the literature, however, there are only a few reliable studies to be found on the stability of iodide as an additive during food production and processing. In addition, very few studies have performed a comparison of the stability of iodide and iodate during food processing. Accordingly, no estimate can be made on the stability of the iodide, either in its own right or when compared with the stability of the iodate during food production processes. However, a study by Liu et al. does suggest that most of the iodate in iodised salt is reduced to the iodide during the cooking process (in this study, 86.8% ±14.5% of the iodate was converted to the iodide, with 9.6% ±6.2% also converted to molecular iodine) (Liu et al., 2017).

An example regarding meat processing shows that the use of the iodide or iodate as a salt additive has no negative effects on sensory perception, processing characteristics or the formation of nitrosamines (Wirth and Kühne, 1991). Another study determined that the addition of potassium iodide or potassium iodate had no influence on the quality of a range of foods, including meats, dairy produce, cereals and vegetable products (West et al., 1995). Accordingly, neither the use of the iodide nor the iodate in table salt should lead one to expect any significant impacts on food production processes.

Iodate is reduced to the iodide by reactions involving glutathione, both in the human digestive tract as well as in tissue and erythrocytes. Unlike the iodate, the iodide is absorbed directly

and is fully bioavailable (Blanco and Blanco, 2017). The small quantities of the iodate consumed with salt are therefore available to the body almost exclusively as the iodide (Bürgi et al., 2001).

In terms of health risks posed by the iodate, adverse effects have been observed at extremely high potassium iodate doses, which can potentially pass through the intestinal barrier (Bürgi et al., 2001). In case studies where individuals accidentally consumed excessively high doses of potassium iodate (8.4 to 24 g or 187 to 470 mg per kg of body weight) orally as an aqueous solution, symptoms reported included dizziness, vomiting, diarrhoea, severe disruptions to vision as well as renal failure (Singalavanija et al., 2000). In comparison, table salt enriched with potassium iodate at an iodine concentration of 20 mg per kg of salt (average concentration in Germany) contains 32 mg of potassium iodate per kg of salt. This means that an individual would consume roughly 0.3 mg of potassium iodate with a salt consumption of roughly 8 g per day, assuming the exclusive consumption of iodised table salt. The intake via salt would therefore be roughly 30,000 times lower than in the case studies mentioned above.

Most of the (typically older) toxicity studies available on the iodate in a range of animal species are inconsistent and do not meet the current standard for a valid assessment, since toxicokinetics are generally poorly accounted for. Overall, however, adverse effects were observed in these studies only at very high doses of the iodate (Bürgi et al., 2001), which would exceed any potential exposure to the iodate from enriched salt by several orders of magnitude (Bürgi et al., 2001). Data on the potential genotoxicity of the iodate are hard to come by. In a study by Poul et al., however, no damage to DNA was detected by means of a *comet assay* and cytokinesis-block micronucleus *assay*, up to a dose of 10 mM of potassium iodate (Poul et al., 2004).

In Germany, iodate has been used to enrich table salt for decades. To date, no valid data have been presented as evidence of adverse effects arising from the consumption of this salt. The same applies for the iodide as an additive, which has been used as part of iodised salt prophylaxis in many other countries for many years. The more direct bioavailability of iodide would argue for the use of this iodide as a salt additive. From the available data, no estimate can be made to what extent this will affect the iodine intake of the German population.

In summary, there are no nutritional, technological or toxicological data available as of this writing that would argue against the use of iodide or iodate as iodine compounds pursuant to Regulation (EC) No 1925/2006 as table salt additives in the concentration ranges as typically used for this purpose. The simultaneous use of the iodide and iodate in a single food product should be avoided, however. In such a situation, both compounds may react together to produce volatile elemental iodine, which negates the effect of enriching the salt in the first place.

Further information on the subject of iodine from the BfR website:

Opinion 'Proposed maximum levels for the addition of iodine to foods including food Supplements' (https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-iodine-to-foods-including-food-supplements.pdf)

Press release: 'Veganism: Vitamin B12 is well supplemented, iodine is a matter of concern' (https://www.bfr.bund.de/en/press_information/2020/28/veganism__vitamin_b12_is_well_supplemented__iodine_is_a_matter_of_concern-259482.html)

Press release 'Iodine, folic acid and pregnancy – practical advice' (https://www.bfr.bund.de/en/press_information/2022/07/iodine__folic_acid_and_pregnancy___practical_advice-291920.html)

FAQ 'Iodine intake in Germany on the decline again – advice for a healthy iodine intake' (in German) (https://www.bfr.bund.de/de/jodversorgung_in_deutschland_wieder_rueck-laeufig___tipps_fuer_eine_gute_jodversorgung-128626.html)

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Appendix

Concentration data

The iodine concentration data for the foods investigated in the MEAL study have already been listed in Appendix 1a to BfR Opinion no. 005/2021.

Exposure assessment methodology

For each child participating in the KiESEL and EsKiMo II studies, the long-term level of consumption was determined by calculating the average consumption across all consumption days for each food in the BfR MEAL study. For the exposure assessment, a food from the MEAL sample plan was assigned to each of these consumption events for which an assignment was possible, based on the respective food code from the consumption study. In this step, food processing factors were accounted for as necessary, in order to ensure that the consumption data and the concentration data were present in the same format (e.g. 'boiled'). Since the MEAL food list was not created on the basis of KiESEL or EsKiMo II data, no consumption could be assigned to some MEAL foods. A matching MEAL food was also unavailable for some consumption events. Notwithstanding these facts, assignments from the MEAL pools covered a total of 94% of average consumption based on the KiESEL study, as well as 91% of average consumption based on the EsKiMo II study.

Based on this assignment, the exposure was calculated for each assigned consumption event by multiplying the quantity consumed by the concentration from each pool from the MEAL results. In cases where more than one analytical result was available in a pool, the average of all results was used. Values below the limit of detection or quantification were replaced by the limit of detection/quantification (*upper bound* approach).

For the present Opinion, iodine concentrations evaluated were stratified without exception according to conventional or organic food production. As a result of pool stratification differences, however, more than one organic or conventional pool was created in the case of some foods (such as cauliflower, for example, which was sampled and stratified regionally, seasonally and also according to the production type). Some foods without stratification also exist (such as millet, for example) and some foods are not stratified by production type (such as carp, which have only regional stratification). To ensure that exposures could still be aggregated onto food groups or to be able to specify total exposure for each individual in the scenarios 'Total consumption with organic or conventional production', the following methodology was used:

1. Is a stratification available that is an exact match (e.g. only organic production)?
   If 'Yes', this pool was selected.
2. If 'No', a check was made to confirm additional seasonal sampling, i.e. whether a pool with organic production is present for both seasons.
   If 'Yes', the average concentration in both seasons was used.
3. If 'No', a check was made to confirm additional regional (but not seasonal) sampling.
   If 'Yes', the matching region (based on the federal state) was assigned to each individual consumer and the corresponding pool was selected (e.g. 'Region north with organic production').
4. If 'No', a check was made to confirm simultaneous sampling in season and region.
   If 'Yes', the average concentration of both seasons in the matching region was assigned to each individual consumer.

For foods that were not stratified by production type, the respective, non-stratified pool was selected and then a different pool was substituted, according to the same methodology.

Accordingly, both with general stratification according to organic or conventional production and in the aggregated exposure assessment, the same value is assigned if no stratification

by production type is available for a pool (251 foods). For this reason, differences in the exposure assessment result solely from differences in foods that have stratification by production type.

The exposure assessment was completed using the 'R' software package.

In the main document, iodine exposure was considered solely via products from conventional production. By way of comparison, the results of exposure via foods from organic production are listed in tables 1, 3, 4, 5, 7 and 8 here in the Appendix.

KiESEL in combination with the MEAL concentration database (KiESEL-MEAL)
Table 1 KiESEL-MEAL: iodine intake – by production type *

	N	Conventional production mLB (µg per day)			Conventional production UB (µg per day)			Organic production mLB (µg per day)			Organic production UB (µg per day)		
		Mean	P50	P95	Mean	P50	P95	Mean	P50	P95	Mean	P50	P95
Total	952	77.1	72.7	124.9	77.9	73.9	126.0	70.6	67.2	117.3	71.4	68.0	117.9
Female	471	74.6	71.4	119.9	75.4	72.1	120.4	68.6	66.2	115.0	69.5	67.2	116.0
Male	481	79.5	74.2	126.2	80.3	75.3	126.6	72.4	68.1	119.6	73.4	68.9	120.9
6 months– 2 years	364	77.4	69.6	132.2	78.1	71.1	132.9	68.3	64.3	127.8	69.1	64.9	128.2
3–5[a] years	588	76.8	74.1	120.3	77.8	75.0	121.3	71.9	69.5	114.6	72.9	70.0	115.5

*   With use of non-iodised table salt at home.

[a]   Children who celebrated their sixth birthday during the study period were also assigned to the 5-year-old group.

Table 2 KiESEL-MEAL: Estimated iodine intake when using iodised salt at home for 3- to 5-year-olds

	N	Conventional production UB					
		Mean µg per day	P5 µg per day	P25 µg per day	P50 µg per day	P75 µg per day	P95 µg per day
Total	588	87.3	50.4	71.8	85.0	100.4	132.3
Female	286	84.0	50.5	69.8	81.9	96.5	124.8
Male	302	90.4	50.5	72.9	87.5	103.9	133.6

Table 3 KiESEL-MEAL: Proportion of individuals with iodine intake <EAR or <RDA (%) – without and with use of iodised salt at home (20 mg iodine per kg salt)

| | Without iodised salt at home | | | | With iodised salt at home | | | | |
| | N | Iodine intake <EAR (%) | | Iodine intake <RDA (%) | | N | Iodine intake <EAR (%) | | Iodine intake <RDA (%) | |
		Con-ven-tional	Organic	Con-ven-tional	Organic		Con-ven-tional	Organic	Con-ven-tional	Organic
Total	952	32.7	40.6	70.8	77.9	588	19.1	23.2	60.0	67.4
Female	471	35.1	43.4	72.1	78.3	286	20.8	27.4	65.0	73.8
Male	481	30.3	37.8	69.5	77.5	302	17.5	19.3	55.4	61.4
1–2 years	308	40.7	50.9	74.8	89.1	n.d.	n.d.	n.d.	n.d.	n.d.
3–5[a] years	588	31.6	39.1	74.8	79.6	588	19.1	23.2	60.0	67.4

[a]   Children who celebrated their sixth birthday during the study period were also assigned to the 5-year-old group.

n.d.:   For this age group, no data on iodised salt consumption at home are available.

Table 4 KiESEL-MEAL: Iodine intake via food groups (consumers only) – by production type *

Food group	Number of consumers	Conventional production UB (µg per day)			Organic production UB (µg per day)		
		Mean (µg/d)	P50 (µg/d)	P95 (µg/d)	Mean (µg/d)	P50 (µg/d)	P95 (µg/d)
01 Cereal crops and cereal-based foods	940	10.0	8.9	23.6	6.4	5.2	17.4
02 Vegetables and vegetable produce	789	0.7	0.4	2.2	0.9	0.6	2.7
03 Roots or tubers containing starch and their products	723	0.9	0.7	2.4	1.3	0.5	5.9
04 Pulses, nuts, oil seeds and spices	202	0.1	0.1	0.6	0.1	0.1	0.4
05 Fruit and fruit produce	906	1.6	1.2	4.3	2.3	1.8	5.9
06 Meat and meat produce	820	7.1	5.3	20.6	7.0	5.1	19.8
07 Fish and seafood	279	9.1	6.6	25.7	9.1	6.6	25.7
08 Milk and dairy produce	899	26.9	23.9	62.5	25.6	22.2	59.3
09 Eggs and egg-based products	291	7.5	6.5	19.3	8.4	7.1	22.1
10 Sugar, confectionery and water-based sweet desserts	767	1.5	1.1	4.5	1.4	1.0	3.8
11 Animal and vegetable fats and oils	690	0.2	0.2	0.5	0.2	0.1	0.5
12 Fruit and vegetable juices and squashes	553	1.6	1.0	5.3	1.6	1.0	5.1
13 Water and water-based beverages	942	5.9	4.7	13.8	5.9	4.7	13.8
14 Coffee, cocoa and tea	507	4.4	2.5	12.7	4.3	2.5	12.6
15 Alcoholic beverages	10	0.3	0.2	0.5	0.3	0.2	0.5
16 Products for infants and toddlers	274	30.5	12.2	113.6	21.6	6.5	81.9
17 Vegan/vegetarian products	48	0.9	0.1	5.8	0.9	0.1	5.8
18 Composite dishes	841	8.9	6.9	23.6	8.5	6.5	22.0
19 Spices, sauces and condiments	675	2.4	1.5	7.6	2.4	1.5	7.6

*   With use of non-iodised table salt at home.

EsKiMo II in combination with the MEAL concentration database (EsKiMo II-MEAL)

Table 5: EsKiMo II-MEAL: iodine intake – by production type (µg per day) *

	N	Conventional production mLB (µg per day)			Conventional production UB (µg per day)			Organic production mLB (µg per day)			Organic production UB (µg per day)		
		Mean	P50	P95	Mean	P50	P95	Mean	P50	P95	Mean	P50	P95
Total	1190	90.2	87.0	133.6	91.5	88.2	135.0	83.2	80.1	129.0	84.5	80.8	130.4
Female	578	85.4	82.7	132.4	86.6	84.1	133.4	78.8	76.9	123.5	80.0	77.7	124.2
Male	612	94.7	91.4	139.1	96.0	93.4	141.5	87.5	84.1	133.6	88.8	86.1	134.9
6–8 years	594	87.8	85.1	132.9	89.0	86.4	134.1	80.8	77.6	127.1	82.0	79.1	128.0
9–11 years	596	92.6	89.4	137.0	93.9	91.9	138.1	85.7	82.8	130.1	87.1	84.5	131.1

*   With use of non-iodised table salt at home.

Table 6: EsKiMo II-MEAL: Estimated iodine intake when using iodised salt at home

	N	Conventional production UB					
		Mean µg per day	P5 µg per day	P25 µg per day	P50 µg per day	P75 µg per day	P95 µg per day
Total	1190	104.0	59.6	84.6	100.4	121.9	149.6
Female 6–8 years	289	92.8	48.9	75.5	91.5	109.4	136.2
Female 9–11 years	290	103.8	67.1	85.2	101.0	121.1	147.2
Male 6–8 years	305	107.9	66.9	88.3	105.1	124.7	154.5
Male 9–11 years	307	110.9	67.4	89.6	109.1	129.6	157.1

Table 7: EsKiMo II-MEAL: Proportion of individuals with iodine intake <EAR or <RDA (%) – without and with use of iodised salt (20 mg iodine per kg salt) at home

	Without iodised salt at home				With iodised salt at home			
	N	Iodine intake <EAR (%)		Iodine intake <RDA (%)		N	Iodine intake <EAR (%)		Iodine intake <RDA (%)	
		Con-ven-tional	Organic	Con-ven-tional	Organic		Con-ven-tional	Organic	Con-ven-tional	Organic
Total	1190	21.3	28.6	69.5	77.4	1190	10.1	15.7	51.8	63.3
Female	578	25.1	31.1	75.9	81.9	578	12.7	19.7	59.1	70.8
Male	612	17.8	26.3	63.5	73.1	612	7.6	11.9	44.9	56.2
6–8 years	594	19.4	26.1	56.6	66.0	594	9.2	16.0	36.0	49.7
9–11 years	596	23.3	31.1	82.4	88.7	596	11.0	15.4	67.5	76.9

Table 8: EsKiMo II-MEAL: Iodine intake via food groups (consumers only) – by production type *

Food group	Number of consumers	Conventional production UB (µg per day)			Organic production UB (µg per day)		
		Mean (µg/d)	P50 (µg/d)	P95 (µg/d)	Mean (µg/d)	P50 (µg/d)	P95 (µg/d)
01 Cereal crops and cereal-based foods	1190	14.9	13.6	31.0	9.0	7.6	20.6
02 Vegetables and vegetable produce	1002	1.0	0.6	3.1	1.3	0.8	4.0
03 Roots or tubers containing starch and their products	943	1.4	1.0	4.1	2.0	0.7	7.2
04 Pulses, nuts, oil seeds and spices	240	0.2	0.1	0.8	0.2	0.1	0.6
05 Fruit and fruit produce	1072	1.9	1.4	5.2	2.7	2.1	6.8
06 Meat and meat produce	1086	10.4	8.4	26.2	10.2	8.7	25.1
07 Fish and seafood	341	12.3	10.4	31.8	12.3	10.4	31.8
08 Milk and dairy produce	1169	28.9	26.8	61.4	27.0	24.8	56.5
09 Eggs and egg-based products	368	9.9	7.9	20.7	11.2	8.5	23.5
10 Sugar, confectionery and water-based sweet desserts	1054	2.6	1.8	7.8	2.4	1.8	6.8
11 Animal and vegetable fats and oils	932	0.3	0.2	0.8	0.3	0.2	0.7
12 Fruit and vegetable juices and squashes	668	1.7	1.0	5.0	1.6	1.0	4.8
13 Water and water-based beverages	1166	7.2	6.0	17.1	7.2	6.0	17.1
14 Coffee, cocoa and tea	683	5.5	3.2	16.9	5.4	3.2	16.9
15 Alcoholic beverages	17	0.8	0.7	1.5	0.8	0.7	1.5
16 Products for infants and toddlers	8	12.5	0.6	48.6	10.1	0.6	35.0
17 Vegan/vegetarian products	38	0.7	0.2	3.4	0.7	0.2	3.1
18 Composite dishes	1107	12.9	10.6	31.5	12.3	10.0	31.3
19 Spices, sauces and condiments	922	3.6	2.4	11.5	3.6	2.4	11.5

*   With use of non-iodised table salt at home.

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