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Declining iodine intake in the population: model scenarios to improve iodine intake

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lodine is an essential trace element that is especially important for the production of thyroid hormones. In the body, thyroid hormones play a central role in orchestrating a wide range of metabolic processes, and are necessary for functional areas such as normal growth, bone formation, the development of the brain and energy metabolism.

lodine must be consumed as part of the normal diet. Iodine concentrations in soil are low, so agricultural products contain very little of the element. Sea fish and seafood, on the other hand, contain a lot of iodine, but do not contribute significantly to the iodine supply due to their comparatively low consumption frequency. Overall, the natural iodine content of our food is currently insufficient to ensure adequate iodine intake for the population in Germany. The recommended use of iodised table salt in the food industry, artisanal food retail and private households since the mid-1980s has improved the iodine supply of the German population. The use of iodine as an animal feed additive also had the effect of improving the situation, since it led to higher concentrations of iodine in milk and dairy produce. However, current data taken from national representative health surveys show that iodine intake in the population remains suboptimal, and reveal a declining trend. At the same time, the results of a recent market survey conducted by the University of Giessen indicate that there has been a decline in the use of iodised table salt in the production of processed foods in recent years.

In Germany, manufacturers can themselves decide whether or not they use iodised table salt in their food products. The amount of iodine that may be added to salt is legally regulated. It is currently 15 to 25 mg per kilogram (mg/kg).

The National Reduction and Innovation Strategy for sugar, fat and salt in ready-made products (NRI) of the German Federal Ministry of Food and Agriculture (BMEL) aims to lower the concentrations of sugar, fat and salt in industrially processed finished products and artisanal foods as part of a step-by-step process occurring over the next few years. The aim of this strategy is to contribute to the reduction of the incidence of overweight and obesity and the diseases that often accompany them. While a low-salt diet is a positive development, this can simultaneously lead to a reduction in iodine intake from iodised table salt. The situation could be compensated for by increasing the concentration of iodine in iodised table salt.

Therefore, the German Federal Institute for Risk Assessment (BfR) has estimated on the basis of model calculations whether increasing the legal maximum amount of iodine in table salt from 25 to 30 mg/kg would reduce the risk of insufficient iodine uptake without simultaneously leading to an exceedance of the still tolerable daily maximum intake (Tolerable Upper Intake Level, UL). Long-term iodine intake levels in excess of the UL can produce adverse health effects.

The model scenarios, which have focused to date on adolescents and adults, show that increasing the iodine concentration in salt by 5 mg/kg - taking into account a successful tenpercent reduction in salt consumption in the context of the NRI – would to some extent increase the median iodine intake in the general population. However, especially in women of childbearing age, the incidence of risk for inadequate iodine intake would only slightly be reduced. Accordingly, simply increasing the iodine concentration in salt by 5 mg/mg is not appropriate without simultaneously increasing the degree to which iodised salt is used in the production of industrially processed or artisanal foods.



1 Subject of the assessment

In light of data indicating a negative trend in renal iodine excretion in children and adolescents (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 BfR assessed whether an increase in the permitted concentration of iodine in salt from 25 to 30 mg per kg of salt would be an appropriate measure from a nutritional and toxicological perspective. The assessment also intended to account for potential effects on iodine intake from the reductions in salt initiated as part of the National Reduction and Innovation Strategy (NRI) for sugar, fat and salt in readymade products.

In the following, the BfR presents its assessment in terms of the utility and the risk of increasing the maximum iodine concentration in salt to 30 mg/kg.

2 Results

In its Opinion, the BfR concludes that a successful reduction in salt consumption by 10% could be compensated for by increasing the iodine concentration in salt to a maximum of 30 mg/kg (or 25 mg/kg on average), as this would—despite a reduction in salt consumption— slightly increase the median iodine intake. The existing prevalence for the occurrence of a risk of inadequate iodine intake, which is especially high (40% to 50%) in the subpopulation of women of childbearing age, would not be substantially reduced, however. Accordingly, simply raising the iodine concentration in salt by 5 mg/mg is not appropriate without simultaneously increasing the degree to which iodised salt is used in the production of industrially processed or artisanal foods. In the BfR's view, measures should therefore be adopted to promote the use of iodised table salt in the production of industrially processed and artisanal food products.

In terms of safety, increasing the maximum iodine concentration in salt to 30 mg/kg at the contemporary rate of usage of iodised salt (29%) for the production of commercial foods can be regarded as 'safe' even without any reduction in salt consumption. If the maximum iodine content of 30 mg/kg salt is exhausted, then the model scenarios in which a rate of usage of 50% iodised salt has been modelled would predict the tolerable upper intake level (UL) to be exceeded by young men in cases where food supplements containing iodine were consumed simultaneously. If an 80% use of iodised salt is modelled, the UL would be exceeded in young men even in the absence of food supplement use. In the worst-case scenario where iodised salt is used to 100%, the UL would be exceeded by 1.5% of women and 11.2% of men.

Overall, the BfR concludes that an increase in the maximum iodine content in salt from 25 to 30 mg/kg can be considered as appropriate, if the degree of usage of iodised salt across all foods would be at least 36% but would not substantially exceed 42%.

3 Rationale

3.1 Hazard potential for iodine insufficiency and oversufficiency

According to the *World Health Organisation* (WHO), the supply status of a population can be determined from the median concentration of iodine measured in spot urine samples (WHO, 2007a). On this view, an iodine concentration in urine of 100 to 199 micrograms per litre



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(μ g/l) is indicative of an adequate iodine status. An iodine concentration in urine of 50 to 99 μ g/l indicates a mild iodine deficiency, 20 to 49 μ g/l a moderate and < 20 μ g/l indicates a serious iodine deficiency. For pregnant women, an iodine concentration in urine of < 150 μ g/l is considered inadequate because of their greater requirement for iodine. According to WHO, while breastfeeding women have the same requirement as pregnant women, they are considered to have an adequate status with an iodine concentration in urine of > 100 μ g/l, because iodine is also excreted into breast milk.

According to WHO, health risks resulting from an excessive intake of iodine can occur if the median concentration of iodine in urine exceeds 300 µg/l (WHO, 2007a).

Health risks are present in the case of both iodine insufficiency and oversufficiency. In various studies a U-shaped correlation between the excretion of iodine in urine and a number of thyroid parameters has been observed, such as thyroglobulin in children (Farebrother et al., 2019; Zimmermann et al., 2013) and pregnant women (Shi et al., 2015). Thyroglobulin is a sensitive biomarker for the iodine status of population groups (Andersson and Herter-Aeberli, 2019) and is produced exclusively by the thyroid gland. Thyroglobulin plays an important role in the synthesis of the thyroid hormones triiodothyronine (T3) and thyroxine (T4), and is also secreted into circulating blood together with the release of the thyroid hormones (Ma and Skeaff, 2014). There is a significant correlation between higher levels of thyroglobulin and excessive or deficient iodine intake, goitre, thyroid nodules or hypothyroidism (Du et al., 2017). Moreover, U-shaped correlations have been discovered between the urinary iodine excretion and goitre prevalence (Liu et al., 2010), and the risk of an autoimmune disease targeting the thyroid (Wang et al., 2019).

3.1.1 lodine deficiency

Enlargement of the thyroid gland (known as 'goitre') is the classic symptom of iodine insufficiency and a physiological response by the body to adjust chronic iodine deficiency (Andersson and Herter-Aeberli, 2019; Zimmermann, 2014). These goitres can develop both in children and adults (WHO, 2007a). If a goitre persists over a long period of time, 'hot nodules' can then form, which produce an excessive amount of hormone, regardless of the body's needs (functional autonomy) (Domke A., 2004; Zimmermann, 2014). These hot nodules that result from a permanent iodine insufficiency may then increase the risk for triggering hyperthyroidism in the event of an excessive iodine intake (D-A-CH, 2015). In addition, chronic iodine deficiency can lead to hypothyroidism in both adults and children, a condition that is associated with reduced hormone synthesis. Hypothyroidism can be associated with a wide range of symptoms, including fatigue, weakness, reduced mental and physical performance, a reduced basal metabolic rate with weight gain, a slow heart rate, dry and pale skin, brittle nails, apathy, problems concentrating, loss of appetite, constipation and depressive mood swings (Domke A., 2004).

During pregnancy in particular, iodine deficiency can have a number of adverse health effects, depending on its severity. The consequences of especially severe intrauterine iodine deficiency have been known for a long time, which for example can lead to cretinism or increase the risk of a miscarriage or stillbirth (Zimmermann, 2012; Zimmermann and Aeberli, 2010). Several studies suggest that even mild to moderate intrauterine iodine deficiency may elevate the risk for reductions in cognitive performance. Observational studies have reported a lower verbal IQ and reduced reading performance in children of mothers with mild to moderate iodine deficiency when compared with mothers having an adequate iodine status (Bath et al., 2013; Hynes et al., 2013; Levie et al., 2019; Markhus et al., 2018). Iodine supplementation during pregnancy increases urinary iodine excretion of pregnant women (Ittermann et al., 2019; Jeon, 2011). However, there are indications, that in terms of the cognitive abilities of children, iodine supplementation before or during early pregnancy in particular is capable



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of achieving a positive effect (Bougma et al., 2013; Zimmermann, 2012), whereas later supplementation appears to be ineffective in this context (Gowachirapant et al., 2017). This could be explained by the fact that foetal brain development is especially sensitive to an inadequate supply of iodine during the first trimester (Levie et al., 2019). Since the foetal thyroid does not mature until the 18th to 20th week of pregnancy, the foetus is entirely dependent on the placental transfer of T4 from the mother during this time (Korevaar et al., 2017). Accordingly, ensuring an adequate iodine status for pregnant women during this phase appears to be particularly important in relation to the cognitive abilities of their children.

A recent systematic review and meta-analysis examining the effects of iodine supplementation on thyroid function and neuronal development in the children of pregnant women with a slight to moderate iodine deficiency was unable to produce any clear-cut results in terms of cognitive effects. The authors suspect that the inconsistencies in the evidence for slight to moderate iodine deficiency could be explained by differences between the studies in terms of the mother's iodine status before pregnancy, the dose and format of the iodine given, the point in time of supplementation and the cognitive tests used (Dineva et al., 2020).

3.1.2 Oversupply

In areas with sufficient iodine supply, individuals with a healthy thyroid can generally tolerate iodine intakes of up to $1,000 \ \mu g$ per day without exhibiting clinical symptoms. This is because a healthy thyroid is capable of adapting to a wide range of iodine intake levels in order to regulate the synthesis and release of thyroid hormones (Zimmermann, 2014).

Germany suffered from a persistent state of iodine deficiency until the 1980s; as a result, older people in particular are likely to be affected by a functional autonomy of the thyroid gland (Domke A., 2004).

In individuals with a functional autonomy, however, iodine intake at a level of 500 µg or more per day can increase the risk for iodine-induced hyperthyroidism (Domke A., 2004). Individuals with Graves' type immunothyroidism may also develop iodine-induced hyperthyroidism in addition to their immunologically induced hyperthyroidism, if iodine intake levels are too high (Leung and Braverman, 2014). The symptoms of iodine-induced hyperthyroidism are almost always transient, and include weight loss, tachycardia, muscular weakness and warm skin. However, iodine-induced hyperthyroidism can become dangerous if it occurs in the context of existing heart disease (Zimmermann, 2014).

In individuals with a healthy thyroid, an excessive iodine intake can lead to a temporary blockade of thyroid hormone synthesis as a result of a natural adaptation mechanism (Wolff-Chaikoff effect) (Burgi, 2010). With the consequent downregulation of the sodium-iodide symporter (NIS) within the time-frame of a few days, an 'escape phenomenon' occurs that frees the thyroid from the Wolff-Chaikoff effect and normal hormone synthesis can resume (Burgi, 2010; Pearce et al., 2016). With certain underlying conditions, the escape phenomenon may be disrupted and the downregulation of hormone synthesis then remains in place—leading to iodine-induced hypothyroidism (Burgi, 2010). A risk of iodine-induced hypothyroid-ism following excessive iodine intake is elevated with the following conditions in particular: (i) radioiodine treatment for Graves' disease; (ii) partial thyroidectomy for non-malignant nod-ules; and (iii) existence of autoimmune thyroidits such as Hashimoto's disease (Burgi, 2010). The general symptoms produced by hypothyroidism have already been mentioned above.

In the case of foetal development, the escape mechanism from the Wolff-Chaikoff effect does not fully mature until the 36th week of pregnancy. As a result, foetal hypothyroidism can develop in association with a very high intake of iodine on the part of the mother, even if the mother's thyroid function is normal (euthyroid) (Pearce et al., 2016).



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In China, a cross-sectional study of 7,190 pregnant women (fourth to eighth week of pregnancy) from a region with excellent sources of iodine demonstrated that a concentration of iodine in urine from 250 to 500 mg/l was associated with a 1.72x (1.13–2.61) higher risk of subclinical hypothyroidism (Shi et al., 2015). From a concentration of iodine in urine of \geq 500 mg/l, a 2.17x (1.13–4.19) higher risk of subclinical hypothyroidism and a 2.85x (1.40–5.81) higher risk of isolated maternal hypothyroxinaemia was found. Isolated maternal hypothyroxinaemia is a special form of hypothyroidism that can also be caused by iodine deficiency during pregnancy.

Tolerable upper intake level (UL)

After considering two small dose-response studies conducted with 32 and 10 participants, respectively, who received various active doses ranging from 1,700 to 4,500 µg of iodine per day for a duration of 14 days, the European Food Safety Authority (EFSA) identified a lowest observed adverse effect level (LOAEL) of 1,700 µg (EFSA, 2002). An increase in serum TSH was observed in both studies from this dose upwards. While EFSA notes that these increases are not clinically important, it suggests that they could be used as indicators for an existing risk of induced hypothyroidism. EFSA also stated that, although both studies were of a short duration and with few participants, the results had in fact been substantiated by a five-year study in which approximately 1,800 µg iodine was administered per day and during which no clinically relevant thyroid pathologies were observed. After the application of an uncertainty factor of 3, EFSA therefore specified a UL of 600 µg per day for adults. EFSA also considered this to be an acceptable level of intake for pregnant and breastfeeding women. For children aged between 1 and 17, a UL of 200 to 500 µg per day was derived. However, EFSA also noted that in countries with a history of jodine deficiency, an intake of 500 µg per day in adults should not be exceeded, in order to avoid the potential occurrence of hyperthyroidism (EFSA, 2002).

The derivation of a UL by the *Institute of Medicine* (IOM) was based on the same two studies that were used by EFSA. Unlike EFSA, however, the IOM used an uncertainty factor of 1.5, which is why a UL of 1,100 μ g per day for adults was derived (IOM, 2001).

Germany follows the EFSA UL, including the recommendation for countries with a long-term undersupply of iodine, since functional autonomy of the thyroid is still likely to be encountered in older people as a result of insufficient sources of iodine in the past in Germany. Accordingly, the German Nutrition Society (DGE) has also stated that it views a UL of 500 µg per day as an appropriate value for adults (D-A-CH, 2015).

3.2 Exposure

3.2.1 Underlying data

In Germany, representative data on iodine intake by adults are available from the National Food Consumption Study II (NVS II) at the Max Rubner Institute (MRI), the exposure assessment made on the basis of iodine concentration data from the BfR MEAL study at the German Federal Institute for Risk Assessment (the BfR MEAL study is a total diet study), and from the German Health Interview and Examination Survey for Adults (DEGS1) at the Robert Koch Institute (RKI).

NVS II (combined with the German Nutrient Database (BLS)):

In the course of NVS II, which ran from 2005 to 2007, 19,329 men and women between the ages of 14 and 80 were asked about their consumption of food and their eating habits. This involved collecting data on typical patterns of consumption over a period of four weeks with the help of a diet history interview (DHI), while current food consumption was surveyed on



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two independent days by using 24-hour recall. To determine nutrient intake, the results from both methods were calculated using nutrient concentration data taken from the German Nutrient Database (BLS version II.4/3.01/3.02). The nutrient intake data that resulted from the diet history interview were published in the NVS II Results Report Part 2 (MRI, 2008) and the nutrient intake values that resulted from the two 24-hour recalls were published in the DGE's 12th Nutrition Report (DGE, 2012).

With only isolated exceptions, the figures for iodine intake determined as part of NVS II <u>do</u> <u>not include iodine from iodised salt</u>, 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 German Nutrient Database (BLS) v. 3.01/02 do not account for potential preparation with iodised salt. However, the use of iodised salt was modelled as part of NVS II (see 3.2.3).

BfR MEAL study – NVS II:

The BfR MEAL study was the first study to generate concentration data for desirable and undesirable substances in food 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. Based on the 24-hour recalls conducted as part of NVS II, the MEAL food list covers at least 90% of the average food intake of various age groups within the German population, while also accounting for foods consumed rarely that are known to have high concentrations of undesirable substances. 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. Subsequently, the foods and meals were pooled (grouped together) before then being homogenised. For the investigation of iodine, a total of 840 pools were formed, consisting of 15-20 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). The 356 foodstuffs were assigned to 19 food groups.

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 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.

To obtain an estimate of average iodine exposure for adolescents and adults in Germany, the iodine concentrations analysed in the course of the BfR MEAL study in various food groups were correlated with consumption data from the 24-hour recalls from 13,926 NVS II study participants.

DEGS1:

Within the scope of DEGS1, the RKI compiled a comprehensive set of health data on the adult population living in Germany between 2008 and 2011. Spot urine samples were also taken from almost all study participants.

The basis of calculation for assessing iodine status was provided by the concentrations of sodium and iodine in the spot urine samples of 7,238 study participants. The concentration of both parameters was first standardised to the creatinine concentration in urine and then, by



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applying age-standardised creatinine excretion quantities per day for all study participants, these data were converted into excretion figures for sodium and iodine on the day the sample was taken. Since the sodium- and iodine-specific excretion balances 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 (Johner et al., 2016; Remer and Thamm, 2015) reflect the total iodine intake of the study participants on the day the urine sample was collected, enabling a realistic assessment of the iodine status of the population¹, but no differentiation according to the respective iodine sources (iodised salt, other food groups, food supplements, pharmaceuticals).

3.2.2 Iodine intake levels for adults in Germany as determined in the studies

lodine intake levels in the percentiles of 25, 50 (median), 75 and 95, as determined on the basis of representative studies in adults living in Germany, are shown in tabulated comparisons below (Table 1 and Table 2). As expected, the studies in which iodine from iodised salt was not (NVS II) (DGE, 2012; MRI, 2008, 2011) or only partially (BfR MEAL study) accounted for produced results with lower intake levels than the data from DEGS1 (Johner et al., 2016; Remer and Thamm, 2015), in which total iodine intake was determined on the basis of endogenous biomarkers.

| Underlying data | Source | Men (µg per day) | | | | |
|--|--------------------|------------------|-----|--------|------|--------|
| | | Ν | P25 | Median | P75 | P95 |
| NVS II DHI (BLS II.4; without iodised salt) | MRI, 2008 | 7,093 | 78 | 99 | 127 | 184 |
| NVS II DHI (BLS 3.01 mod.; without iodised salt) | MRI, 2011 | 7,093 | 85 | 110 | 140 | 216 |
| NVS II 24-hour recalls (BLS 3.02; without io- dised salt) | DGE, 2012 | 6,160 | 70* | 86 | 106* | 147* |
| BfR MEAL study (conventional**) | BfR | 6,257 | 88 | 115 | 149 | 218 |
| BfR MEAL study (organic**) | BfR | 6,257 | 84 | 110 | 142 | 207 |
| DEGS1 total iodine | Remer et al., 2015 | 3,355 | 85 | 126 | 184 | 372*** |

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

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

| Underlying data | Source | Women (µg per day) | | | | |
|--|--------------------|--------------------|-----|--------|-----|--------|
| | | N | P25 | Median | P75 | P95 |
| NVS II DHI (BLS II.4; without iodised salt) | MRI, 2008 | 8,278 | 70 | 92 | 119 | 174 |
| NVS II DHI (BLS 3.0 mod.; without iodised salt) | MRI, 2011 | 8,278 | 72 | 91 | 117 | 171 |
| NVS II 24-hour recalls (BLS 3.02; without io- dised salt) | DGE, 2012 | 7,593 | 62* | 75 | 92* | 129* |
| BfR MEAL study (conventional**) | BfR | 7,669 | 76 | 99 | 125 | 176 |
| BfR MEAL study (organic**) | BfR | 7,669 | 72 | 95 | 120 | 169 |
| DEGS1 total iodine | Remer et al., 2015 | 3,648 | 82 | 125 | 193 | 372*** |

* The DGE's 12th Nutrition Report (DGE, 2012) calculates only the medians and the respective confidence interval for nutrient intakes. The percentiles specified in the table were provided by the MRI at the request of the BfR.

** Various intake scenarios have been calculated in the exposure assessment based on the MEAL data. The present risk assessment is based primarily on the results of the so called upper bound scenarios, in which the limit of detection was utilised as the iodine concentration for all foods in which an iodine concentration below the limit of detection was determined. In each case, the results are shown as determined by using the concentration data from the conventionally manufactured foods and organic food products. The use of iodised salt in the household is not included in the data.

¹ This cannot be used to determine the iodine status of individual persons, since the respective daily iodine intake may be subject to fluctuations.



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*** The iodine intake determined in the P95 in DEGS1 was determined using the DEGS1 total population and is not included in Remer et al., 2015. These details were made available to the BfR upon request to the authors of the project report.

The results of NVS II for iodine intake from food enable the detection of methodological differences between the survey instruments used. Accordingly, higher median iodine intake levels from foods are calculated with the consumption data from the diet history interviews ((\mathcal{S}) 99/110 and (\mathcal{Q}) 92/91 µg iodine per day) than with the consumption data from the 24-hour recalls ((\mathcal{S}) 86 and (\mathcal{Q}) 75 µg iodine per day). The strengths and weaknesses of the respective survey instruments, and the differences in the results from NVS II have been discussed by the MRI, although not in the specific context of iodine intake (Eisinger-Watzl et al., 2015; Strassburg et al., 2019).

The exposure assessment, in which the iodine concentration data from the BfR MEAL study were combined with consumption data from the NVS II 24-hour recalls, provides median intake levels for iodine ((Ω) 99/95 (conventional/organic) and (\mathcal{E}) 115/110 (conventional/organic) µg iodine per day) roughly 30% higher than the NVS II calculations based on the 24hour recalls. From this, it can be seen that slightly higher iodine intakes are achieved with conventionally produced foods than with organically produced foods. The approximately 30 % higher iodine intakes determined on the basis of the content data of the MEAL study compared to the iodine intakes determined in the NVS II on the basis of the BLS can be attributed to the fact, that in the MEAL study food pools compiled according to market shares and consumption habits were analysed, which also contained industrially and artisanal products made with iodised salt. This is also shown in the exposure estimate based on the MEAL data, among other things, by the fact that, when using organically produced products as well as conventionally produced foods, the meat and sausage products with an iodine contribution of 15% and 13% were identified as the second or third most important source of iodine (figure 1). In NVS II, in contrast, meat and sausage goods (without jodised salt) were not among the top-ranking sources of iodine (MRI, 2008). This means that the food selections made in the BfR MEAL study accurately reflect the results of a representative market survey from the University of Giessen, according to which 48% of meat and sausage goods are produced using iodised salt (Bissinger et al., 2018).

The biomarker-based median total iodine intake levels from DEGS1 exceed (with (Q) 125 and (d) 126 µg per day) the iodine intake levels determined from consumption and concentration data by 10–67% (depending on underlying data set and gender). Since the DEGS1 data correspond to total iodine intake, they best reflect the actual iodine status of adults living in Germany. What is notable about these data, however, is that the intake level in the 95th percentile (372 µg iodine per day) is roughly triple the median intake level, while in the evaluations of iodine intake on the basis of food consumption, the intake levels in the 95th percentiles only amount to 1.7x to 1.9x of the median intake levels. There are at least two factors that can explain this difference. Firstly, the proportion of iodine that is ingested from food supplements (and potentially also from medicines) is not included in the intake estimates based on NVS II (which utilise BLS and MEAL data). Secondly, a higher rate of usage of iodised salt and/or foods rich in iodine can lead to higher iodine intake levels for a specific subgroup of study participants than is normally achieved with an average rate of usage.

While the DEGS1 data cannot be used to draw direct conclusions about individual sources of iodine, the ratio of the median to the P95 not only indicates that other sources of iodine apart from food, such as food supplements, must be present, but also suggests that exposure calculations based on food consumption and content data tend to underestimate the actual iodine intake in the high intake percentiles. Both factors are particularly relevant when assessing health risks that could result from excessive intake levels.



3.2.3 Iodised salt as a proportion of iodine intake in Germany

None of the national representative studies (NVS II, BfR MEAL study, DEGS1) allows a direct determination of the contribution of iodised salt to the iodine supply in Germany. Since iodine prophylaxis as an intervention depends critically on the degree of use of iodised salt in the household, on the manufacture of industrial and artisanal food products, as well as on the iodine concentration in iodised salt, mathematical models were applied in the context of all three studies to estimate the contribution made by iodised salt to the iodine supply.

NVS II:

To estimate the iodine consumption from iodised salt, an additional iodine variable was integrated into the BLS as part of the NVS II evaluation, in that for all recipes and mixtures (pooled foods) that contain table salt as an ingredient, production with iodised salt was assumed. With the exception of cheese and a number of pasta products/baked goods, all foods containing salt were "enriched" accordingly with iodine (MRI, 2008; MRI, 2011). In this simulated enrichment of all mixtures and recipes with iodised table salt (equivalent to iodised salt usage of 100%), a median iodine intake of (\bigcirc) 185/219 and (\bigcirc) 233/290 µg per day, and an intake in the P95 of (\bigcirc) 310/367 and (\bigcirc) 412/522 µg per day was modelled. In the 100% iodised salt scenario, however, the actual iodine intake in the general population is likely to be overestimated (MRI, 2008; MRI, 2011).

In 2011, working on the basis of BLS 3.01 and accounting for corrections to iodine concentrations in herbal, fruit and peppermint teas (= BLS 3.01 modified), the MRI modelled iodine intake <u>considering iodised salt</u> for the scenarios 'without iodised salt' and '30%, 80% and 100% usage rate for iodised salt' in the mixtures and recipes in the BLS (MRI, 2011). By deducting the iodine intake levels without iodised salt from the iodine intake levels in the three iodised salt scenarios, the modelled iodine intake from iodised salt could be calculated for all study participants. The respective intake percentiles for <u>salt-dependent iodine intake</u> are tabulated for all scenarios in Table 3.

| Intake from iodine from iodised salt | | | Men (µg per day) | | | | Women (µg per day) | | | |
|--------------------------------------|-----------|-----|------------------|-----|-----|-----|--------------------|-----|-----|--|
| Underlying data | Source* | P25 | Median | P75 | P95 | P25 | Median | P75 | P95 | |
| NVS II DHI (30% iodised salt) | MRI, 2011 | 39 | 51 | 68 | 101 | 27 | 35 | 46 | 66 | |
| NVS II DHI (80% iodised salt) | MRI, 2011 | 106 | 139 | 185 | 277 | 74 | 97 | 125 | 182 | |
| NVS II DHI (100% iodised salt) | MRI, 2011 | 134 | 176 | 233 | 348 | 93 | 122 | 157 | 230 | |

* In the 'MRI, 2011' source, the iodine intake levels from all foods for all scenarios are specified, but figures for separate iodine intake levels from iodised salt are not given. However, the BfR does have a copy of the SPSS tables used as the basis of the MRI report, with the iodine intake data from all study participants in all MRI scenarios. These tables were used to calculate the separate iodine intake from iodised salt for each scenario.

All models used to estimate the iodine intake from iodised salt as part of NVS II were calculated using the consumption data from the diet history interviews. The consumption data from 24-hour recalls have not been used for modelling purposes to date.

BfR MEAL study:

The food pools in the MEAL study already contain artisanal and industrially manufactured products made with iodised salt, according to their market share. For the preparation of foods in the MEAL study kitchen, however, no iodised table salt was used, so as to be able to represent the intake from natural sources and industrial processing separately from the use of iodised salt in the home.



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lodised salt is used at home by around 84% of the population in Germany (Scriba et al., 2007). To account for this additional source of iodine intake, an extra scenario 'with iodised salt in the household' is considered. 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). Total salt intake in Germany on the basis of sodium concentrations in urine is estimated at 8.4 and 10 g per day (median for women and men, respectively) (Johner et al., 2016; Remer and Thamm, 2015). Accordingly, women and men using iodised salt (with 20 mg of iodine/kg) at home consume an additional (median) quantity of 18 and 21 μ g of iodine per day, respectively. In the 'with iodised salt in the household' scenario, this produces median iodine intake levels of (\mathcal{P}) 117/113 and (\mathcal{J}) 136/131 μ g per day (UB, conventional/organic foods).

The salt-dependent iodine consumption from commercial foods manufactured using iodised salt in the results based on the MEAL data can be estimated using a comparison with the BLS-based intake estimate, which is also combined with the 24h recalls of the NVS II (DGE, 2012). Since the BLS-based results 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 manufactured food products. The calculated iodine intake from the iodised salt used in these products is presented in table 4 in scenarios 1 and 3 ('BfR MEAL study (UB, conventional, without iodised salt in the household)' and 'BfR MEAL study (UB, organic, without iodised salt in the household)').

Table 4 also calculates an additional scenario in each case (scenarios 2 and 4), in which the daily use of iodised salt in the household (\bigcirc : 18 and \bigcirc : 21 µg per day) is cumulated, in order to estimate the potential total daily intake level from iodised salt.

| Table 4: Calculated ic | dine intake froi | n iodised sal | t, based on t | he BfR MEAL | study and 24 | I-hour recalls |
|------------------------|------------------|---------------|---------------|-------------|--------------|----------------|
| from NVS II | | | | | | |
| | | | | | | |

| Salt-dependent iodine intake with and without iodised salt in the household | N | len (µg p | er day | () | Women (µg per day) | | | |
|--|-----|-----------|--------|-----|--------------------|--------|-----|-----|
| Underlying data | P25 | Median | P75 | P95 | P25 | Median | P75 | P95 |
| 1. BfR MEAL study (UB, conventional, without io- dised salt in the household) | 18 | 29 | 46 | 71 | 14 | 24 | 34 | 47 |
| 2. BfR MEAL study (UB, conventional, with io- dised salt in the household) | 39 | 50 | 67 | 92 | 32 | 42 | 52 | 65 |
| 3. BfR MEAL study (UB, organic, without iodised salt in the household) | 13 | 24 | 39 | 61 | 10 | 20 | 28 | 41 |
| 4. BfR MEAL study (UB, organic, with iodised salt in the household) | 34 | 45 | 60 | 82 | 28 | 38 | 46 | 59 |

With and without accounting for the use of iodised salt in the household (\bigcirc : 18 and \bigcirc : 21 µg per day)

UB: Upper bound

DEGS1:

The intake levels for salt and iodine identified in DEGS1 for 6,738 study participants with complete datasets for spot urine values (sodium, iodine and creatinine), as well as BMI and age, were adjusted using a linear regression based on age, gender and BMI (Esche et al., 2019). By applying the regression formula, adjusted iodine intake levels were calculated as function of salt intake, yielding an iodine intake of 73.7 μ g per day at the zero point of salt intake, which corresponds to the salt-independent fraction of total iodine intake from food. At the median of salt intake of 9.3 g per day, the median of total iodine intake was 126.2 μ g per day. By simply subtracting the salt-independent iodine intake from the median total iodine intake, a salt-dependent iodine intake. Assuming the average iodine concentration in iodised



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salt in Germany to be 20 μ g of iodine per gram of salt, then 52.5 μ g of iodine corresponds to 2.6 g of iodised salt or 28% iodised salt in terms of median total salt intake. The median consumption of 2.6 g of iodised salt (52.5 μ g of iodine from salt) determined in DEGS1 reflects the iodised salt quantity used in the home as well as the iodised salt from commercial food products in the DEGS1 total population (women and men). However, the salt-dependent iodine intake determined using the DEGS1 data was published only for the median (Esche et al., 2019), since uncertainties arising due to the methodol-ogy—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 at 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 DEGS1 were made available at the BfR's request by Dr Esche and Prof. Remer.

Table 5 Total salt and total iodine intake from DEGS1, and proportions of iodine intake from iodised salt derived from these data

| P50 (median) | P75 | P95 |
|--------------|-------------------------|--|
| 9.3 | 13.7 | 22.5 |
| 126.2* | 188.2 | 372.3 |
| 52.5** | 79.0*** | 156.4*** |
| 73.7** | 109.2*** | 215.9*** |
| | 9.3 126.2* 52.5** | 9.3 13.7 126.2* 188.2 52.5** 79.0*** |

* Median as per *predicted values*, deviates slightly from the original data according to Johner et al. (Johner et al., 2015). ** Derived from *predicted values* according to Esche et al. (Esche et al., 2019)

*** Basis of calculation: median proportion of iodine intake from iodised salt according to Esche et al. (Esche et al., 2019) in percent (42%) and original DEGS1 measurement data according to Johner et al. (Johner et al., 2015 and Johner et al., 2016)

The median iodine intake levels that were modelled in the context of the three studies (and while accounting for the 30% iodised salt usage scenarios from NVS II) agree well with one another despite differences in the respective underlying datasets and survey instruments (Figure 1). With a relatively high probability, it can therefore be assumed that the median daily intake for men from iodised salt is roughly 50 μ g, and between 35 and 50 μ g for women. As a result, iodised salt in Germany delivers roughly a third of the daily level of iodine intake recommended by the European Food Safety Authority (EFSA) for adults, which is 150 μ g per day (EFSA, 2014).

In the upper consumption percentiles (P75 and P95), the modelling from the BLS- and MEAL-based estimates also results in a comparable salt-dependent iodine intake, although the modelling from the DEGS1 data is distinguished by significantly higher salt-dependent iodine intake levels. As already mentioned in section 3.2.2, it must also be assumed here that the salt-dependent iodine intake levels derived from DEGS1 in the high percentiles can probably be ascribed not merely to higher personal use of iodised salt, but also being skewed by other iodine sources (such as food supplements, for example, and potentially medicines).



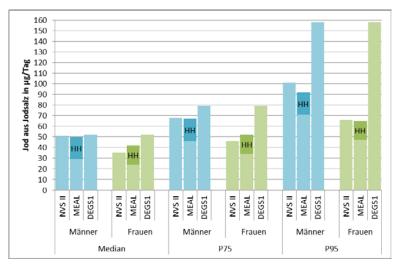


Figure 1: Salt-dependent iodine intake in the percentiles 50 (median), 75 and 95.

Modelled using the data from NVS II (BLS with 30% iodised salt usage), the BfR MEAL study (UB, conventional food + iodised salt in the household (HH)) and DEGS1. HH (dark shading) corresponds to the estimated proportion of iodised salt from the use of salt in the household in the MEAL exposure assessment. Proportions of iodine intake from iodised salt from DEGS1 were calculated only for the total population, which is why identical values have been used for men ("Männer") and women ("Frauen").

3.3 Identification of risk groups

Health risks are associated both with too low and too high intakes of iodine. Accordingly, the data on iodine intake by adults in Germany should be used to identify and characterise sub-populations that are at risk of iodine sufficiency or oversupply in terms of their iodine intake. To do so, iodine intake is evaluated on the basis of suitable reference values, such as the estimated average requirement (EAR), estimated values required to cover adequate intake (AI) and the recommended dietary allowance (RDA), as well as 'safe' upper intake levels (UL – tolerable upper intake level).

3.3.1 Risk groups for insufficient iodine intake

Reference values for the iodine intake of adolescents and adults are available from the DGE (180–200 µg per day), EFSA (130–150 µg per day) and the Food and Nutrition Board (FNB) of the US Institute of Medicine (IOM) (150 µg per day). For pregnant and breastfeeding women, recommended daily allowances from the three organisations are 220 to 290 µg (Table 6). In contrast to the reference values from the DGE and EFSA, the reference value (RDA) developed by the FNB was derived from a physiological estimated average requirement (EAR), determined as 95 µg per day from the iodine metabolism of the thyroid gland in human studies. The recommended dietary allowances for pregnant and breastfeeding women were increased to account for the iodine needs of the foetus or infant (IOM, 2001).

| sumated average requirements for addrescents and addres, as published by various organisations | | | | | | | | | |
|--|---|--------------------------------------|--|---|--|--|--|--|--|
| Age [years] | Estimated value for intake (D-A-CH, 2015) | Adequate intake (Al) (EFSA, 2014) | Recommended die- tary allowance (RDA) (IOM, 2001) | Estimated average requirement (EAR) (IOM, 2001) | | | | | |
| | [µg/day] | [µg/day] | [µg/day] | [µg/day] | | | | | |
| 14 to 17 | 200 | 130 | 150 | 95 | | | | | |
| 18 to 50 | 200 | 150 | 150 | 95 | | | | | |
| >51 | 180 | 150 | 150 | 95 | | | | | |
| Pregnant women | 230 | 200 | 220 | 160 | | | | | |
| Breastfeed- ing women | 260 | 200 | 290 | 209 | | | | | |

Table 6: Reference intake values for iodine (estimated values, adequate intake, recommendations) and estimated average requirements for adolescents and adults, as published by various organisations



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Both the physiological requirement for nutrients and nutrient intake itself are not fixed parameters within any given population but are subject in each case to a specific distribution, which is assumed to be a normal distribution for the sake of simplification. Dietary allowance reference values are chosen with the aim of covering 97–98% of the physiological requirements of the population. The physiological estimated average requirement (EAR) for a nutrient, which theoretically equates to the median of the requirement distribution, is therefore supplemented by adding double the standard deviation to obtain a recommended dietary allowance (RDA) for the nutrient. 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 higher than that met by consumption of the nutrient.

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 population (IOM, 2006). The supply level of a population with a nutrient under consideration is therefore estimated to be better, the lower the percentage of individuals is, whose intake of the respective nutrient is below the EAR.

To determine the percentage proportion of adolescents and adults exhibiting an iodine intake below the EAR, the results of the exposure assessment on the basis of the BfR MEAL study were applied, since these results also permit an estimate to be made of the influence of the consumption of organic products and the use of iodised salt in the household on iodine status (BfR MEAL study). The evaluation was completed using several age and gender groups, which were grouped together in accordance with the ranges used in DEGS1, as a result of the comparability of the results from DEGS1. Since the group of 14- to 17-year-old adolescents is not included in DEGS1, biomarker-based data on iodine status from the study on the health of children in Germany (KiGGS Wave 2) (Hey and Thamm, 2019) were used for this group as a means of comparison with the exposure on the basis of the BfR MEAL study.

According to the calculations made based on the BfR MEAL study (scenario UB – conventional foods), 45% of women and 31% of men have an iodine intake less than the estimated average requirement (Table 7 and Table 8). For both genders, the use of organically produced foods increases the prevalence of a risk of inadequate iodine intake by roughly 5%, whereas the use of iodised salt (with 20 mg of iodine per kg of salt) in the household can reduce this prevalence by 16–20%.

In DEGS1, a percentage share of 30% of study participants was identified for both genders with an iodine intake below the estimated average requirement (Johner et al., 2016; Remer and Thamm, 2015). As a result, the prevalence of the risk for an inadequate iodine intake of 31% for men, as determined in the exposure assessment on the basis of the BfR MEAL





study, is broadly in agreement with the results from DEGS1, while in contrast, the prevalence of 45% determined for women overestimates the prevalence for the risk of an inadequate iodine intake.

An evaluation of the proportion of individuals with an iodine intake below the EAR by age group shows, in the case of both studies, a decline in prevalence for the risk of an inadequate iodine intake with increasing age, which is significantly more pronounced in the case of women than in men (Figure 2, Table 7 and Table 8).

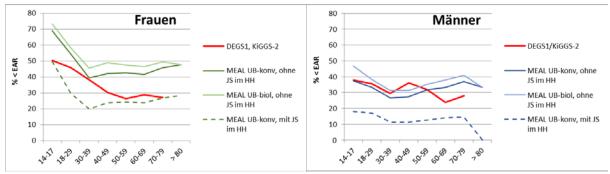


Figure 2: Percentage share of persons with an iodine intake below the EAR.

Stratified by age and gender (women ("Frauen") and men ("Männer")) from the DEGS1/KiGGS2 studies (solid red line) and exposure assessments based on the data from the BfR MEAL study.

MEAL scenarios: UB conventional foods without iodised salt use in the household (solid line – \bigcirc dark green, \eth dark blue), UB conventional foods with iodised salt use in the household (dashed line – \bigcirc dark green, \eth dark blue), and UB organic foods without iodised salt use in the household (solid line – \bigcirc light green, \eth light blue)

In the exposure assessment on the basis of the BfR MEAL study (UB, conventional foods without iodised salt in the household), age-stratified prevalences for the risk of an inadequate intake were determined in men, ranging between 26.5% (30–39 years) and 37.3% (14–17 years), and in DEGS1/KiGGS2 between 23.9% (60–69 years) and 37.7% (14–17 years). In women, the prevalences determined on the basis of the BfR MEAL study lie between 39.4% (30–39 years) and 68.8% (14–17 years), while the prevalences determined in DEGS1/KiGGS2 lie between 26.3% (50–59 years) and 50.3% (14–17 years) (Table 7 and Table 8).

Table 7: Proportion of men with an iodine intake under the EAR

| Men | | BfR MEA (UB, conv | | BfR MEA (UB, org | DEGS1/ KiGGS2* | |
|--------|------|------------------------------------|---------------------------------|------------------------------------|---------------------------------|-------------------|
| Age | N** | Without io- dised salt in HH | With io- dised salt in HH | Without io- dised salt in HH | With io- dised salt in HH | Total io- dine |
| 14-17* | 375 | 37.3 | 18.1 | 46.7 | 25.3 | 37.7* |
| 18-29 | 1117 | 33.3 | 17.1 | 38.1 | 21.5 | 35.5 |
| 30-39 | 1044 | 26.5 | 11.5 | 31.3 | 13.4 | 29.5 |
| 40-49 | 1321 | 27.4 | 11.4 | 31.3 | 12.1 | 36.2 |
| 50-59 | 971 | 31.7 | 12.7 | 35.3 | 15.3 | 31.8 |
| 60-69 | 947 | 33.3 | 14.0 | 37.9 | 17.4 | 23.9 |
| 70-79 | 558 | 36.9 | 14.7 | 40.9 | 17.7 | 28.1 |
| > 80 | 12 | 33.3 | 0.0 | 33.3 | 16.7 | n.d. |
| Total | 6897 | 31 | 14 | 36 | 17 | 30 |



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| Women | | | BfR MEAL study (UB, conventional) | | BfR MEAL study (UB, organic) | |
|--------|------|------------------------------------|--------------------------------------|------------------------------------|---------------------------------|-----------------|
| Age | N** | Without io- dised salt in HH | With io- dised salt in HH | Without io- dised salt in HH | With io- dised salt in HH | Total iodine |
| 14-17* | 369 | 68.8 | 49.6 | 73.4 | 58.3 | 50.3* |
| 18-29 | 1066 | 54.4 | 29.7 | 58.2 | 36.6 | 45.9 |
| 30-39 | 1034 | 39.4 | 19.9 | 45.6 | 23.4 | 38.4 |
| 40-49 | 1289 | 42.1 | 23.9 | 48.9 | 28.7 | 30.4 |
| 50-59 | 987 | 42.7 | 24.3 | 47.4 | 27.1 | 26.3 |
| 60-69 | 995 | 41.7 | 23.8 | 46.5 | 25.4 | 28.9 |
| 70-79 | 730 | 45.9 | 26.8 | 49.3 | 28.8 | 27 |
| > 80 | 21 | 47.6 | 28.6 | 47.6 | 28.6 | n.d. |
| Total | 7029 | 45 | 26 | 50 | 30 | 30 |

Table 8: Proportion of women with an iodine intake under the EAR

* The biomarker-based proportions with an intake under the EAR in the age group 14–17 years were taken from Wave 2 report on the child health study in Germany (Hey and Thamm, 2019).

** The numbers of persons in the individual age groups represent only the age groups from NVS II.

The results of the model scenarios on the use of iodised salt in the household (HH) are highlighted.

To estimate the actual prevalence of the risk of an inadequate intake of iodine, the biomarker-based results from DEGS1 and KiGGS2 are authoritative in comparison to the results from consumption studies such as NVS II (BLS- and MEAL-based). In both types of studies, however, the highest prevalence for the risk of an inadequate intake of iodine was found for women aged 14 to 39. This is also an age group in which the vast majority of pregnant and breastfeeding women are expected to be found, since roughly 95% of births occurred in this age group, according to the Federal Statistical Office (Federal Statistical Office, 2018). In terms of the effects on the prevalence of the risk of an inadequate intake of iodine that are expected by changing the parameters of iodised salt prophylaxis, women of childbearing age therefore represent the most important subpopulation in which these effects should be measured.

The trajectory and magnitude of the effects that result from changing the parameters of iodised salt prophylaxis can be modelled using consumption studies, however—irrespective of the differences in the specific, determined values for age- and gender-stratified prevalences for the risk of an inadequate intake of iodine as present in both types of studies.

Alongside these stratifications by age and gender, certain kinds of dietary choices—such as a vegetarian or vegan diet—are also associated with an increased risk of an inadequate intake of iodine. The consumption data from the 24-hour recalls from NVS II, which were used in the BfR MEAL study, include 212 individuals (1.5%) who stated that they followed a vegetarian diet. The median iodine intake for this group was 100 and 91 μ g/day for conventional and organic foods, respectively, and therefore 10% below the intake levels for non-vegetarians and for the overall population, for whom a median iodine intake was determined that amounted to 107 and 102 μ g/day, respectively (UB scenario, not stratified by gender) (BfR MEAL study). Since the proportion of vegetarians in NVS II is very low (1.5%), however, and this group also contains fish-consuming "pesco vegetarians", the exposure assessment completed on the basis of NVS II and BfR MEAL data cannot be used to generate any valid statements about the iodine status of persons who follow a vegetarian diet.

Nor can the NVS II data be used to make any statements about the iodine intake of those following a vegan diet, since the consumption data only contain isolated details about vegan individuals (proportion 0.1%). However, the BfR does have access to initial findings from the



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cross-sectional study 'Risks and benefits of a vegan diet' (RBVD study). In this study, the 36 vegans consumed a median value of 80 μ g of iodine per day and therefore significantly less iodine from food than the 36 omnivores in the study, who consumed 120 μ g of iodine per day. In addition, iodine excretion below 20 μ g/l in urine was found for a third of the vegans in the study, which means that these individuals fulfil the WHO criterion (WHO, 2007a) for severe iodine deficiency (Weikert et al., 2020).

As a result of the inadequate available data on the foods consumed by persons following a vegan or vegetarian diet, these risk groups are not suitable 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 adolescents and adults at 450–600 μ g per day by EFSA (EFSA, 2002) and at 900–1,100 μ g per day by the FNB at the US IOM (IOM, 2001). No separate ULs were derived for pregnant and breastfeeding women (Table 9).

| Age [years] | UL (EFSA, 2002) | Countries with historical deficiencies (EFSA, 2002) | UL (FNB/IOM, 2001) |
|--------------------------|--------------------|---|-----------------------|
| [J =] | [µg/day] | [µg/day] | [µg/day] |
| 14 | 450 | | 900 |
| 15-17 | 500 | | 900 |
| 18 | 600 | 500 | 900 |
| > 19 | 600 | 500 | 1.100 |
| Pregnant women | 600 | | 1.100 |
| Breastfeed- ing women | 600 | | 1.100 |

Table 9: Tolerable upper daily iodine intake levels (ULs) for adolescents and adults

In the representative German consumption studies, and without accounting for iodised salt, an iodine intake of 147–218 μ g per day in men and of 129–174 μ g per day in women was determined in the 95th consumption percentile (Table 1 and Table 2). Assuming contemporary conditions (iodised salt concentration 15–25 mg/kg, degree of use of iodised salt around 84% in the household and around 29% in commercial food production), men in the 95th consumption percentile would have an intake of around 100 μ g of iodine per day and women an intake of around 65 μ g of iodine per day from iodised salt (Table 3 and Table 4). A daily intake level of 500 μ g of iodine per day via the normal diet is therefore not exceeded in Germany. Accordingly, the exposure assessment based on the data from the BfR MEAL study (in an analysis independent of the use of conventional or organic foods) identified only two of 13,926 study participants (0.015%) with an intake level higher than 500 μ g of iodine from food (UB scenarios without accounting for iodised salt in the household) (BfR MEAL study).

Mathematical models applied by the MRI using the maximum level of iodine in table salt currently permitted (25 mg/kg) also showed that with 100% usage of iodised salt, around 6% of the male and around 1% of the female population would exceed the UL of 500 μ g/day from food (MRI, 2011).

However, users of food supplements containing iodine have a much higher risk of exceeding the UL of 500 μ g per day than individuals who do not use food supplements. From the 493 users of iodine food supplements from NVS II in the exposure assessment based on the



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MEAL study, 5 users (without iodised salt in the household, 1%) and 6 users (with iodised salt in the household, 1.3%) were identified with intake levels exceeding 500 μ g of iodine per day, due to the consumption of food supplements. Compared with individuals not using food supplements, users of iodine food supplements have an iodine intake level from both sources that is higher by 84 μ g per day in the median and by 134 μ g per day in the P95 (calculated by subtracting the iodine intake with and without food supplements by users of food supplements from Table 10).

lodine intake from food supplements was also determined in the core analyses made in NVS II, which found that users of food supplements have an iodine intake of 100 μ g in the median and 200 μ g in the P95 solely from these supplements (MRI, 2008). Accordingly, users of food supplements are the subpopulation whose risk of exceeding the UL of 500 μ g per day is most likely to be elevated by measures leading to an increase in iodine intake from iodised salt.

Table 10: Aggregated iodine intake for users of iodine food supplements, and iodine intake via foods for users of food supplements and non-users

| | | Conventional production UB | | | | | |
|---|--------|----------------------------|---------------|---|-------------------------------|-------------------------------|--|
| | Ν | Median (µg/d) | P95 (µg/d) | lodine in- take <ear(%)< th=""><th>lodine in- take >UL (n)</th><th>lodine in- take >UL (%)</th></ear(%)<> | lodine in- take >UL (n) | lodine in- take >UL (%) | |
| Users of iodine supplements – io- dine intake via foods and food sup- plements – – plus iodised salt in the household – | 493 | 190 210 | 340 361 | 2.4 0.8 | 5 6 | 1.0 1.3 | |
| Users of iodine supplements – io- dine intake only via foods – | 493 | 116 | 206 | 29.8 | 0 | 0 | |
| Non-users of iodine supplements – iodine intake via foods – | 13433* | 106 | 199 | 38.6 | 2 | 0.016* | |

From MEAL (UB conventional foods without iodised salt in the household)

* Non-users of food supplements are considered here, although the prevalence stated in the text of 0.015% relates to the iodine intake from foods in the total population of 13,926 study participants.

3.4 Is an increase in the maximum permitted iodine concentration in salt from 25 mg to 30 mg per kg of salt appropriate and 'safe' if a 10% reduction in salt consumption is assumed?

3.4.1 Target values for salt-dependent iodine intake in order to assess 'appropriate' and 'safe'

The intake of a nutrient can be characterised as appropriate and 'safe' when the prevalence of the risk of an inadequate 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.



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According to the data from DEGS1, the prevalence of the risk of an insufficient intake of iodine in Germany for all adults is 30%, and is between 40% and 50% for women of childbearing age (Table 7 and Table 8). In addition, according to the data based on the BfR MEAL study, the figure of 0.015% of study participants with an excessive iodine intake from food alone can be described as negligible (see section 3.3.2). However, the risk of exceeding the UL rises in the case of food supplement use to roughly 1–1.3%.

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 2–3% 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 of 500 μ g per day.

Under the present conditions for iodised salt prophylaxis, the median value for the dietary iodine intake originating from iodised salt is 42% (52.5 μ g per day) (Esche et al., 2019). The question arises as to how high the salt-dependent iodine intake needs to be in order to reduce the prevalence for the risk of an inadequate iodine status to 2–3%.

The prevalence for the risk of an inadequate iodine intake in a population is lower, the higher the median iodine intake is. By taking this inverse correlation between prevalence and median iodine intake, which was determined in the exposure assessment of the BfR MEAL study for the age- and gender-based groups in NVS II (UB conventional foods with and without iodised salt in the household) (Table 7 and Table 8), it was possible to extrapolate the median iodine intake from foods correlating to a prevalence of the risk for an inadequate iodine status of 2.5% as being around 140 μ g per day for women and around 150 μ g per day for men (Figure 3). Both values are close to the recommended daily intake from EFSA of 150 μ g per day. According to the criteria of the EAR cut-point method, this means adults in Germany can be considered to have an adequate status if they achieve a median iodine intake from food that is within the range of the EFSA recommended dietary allowance.

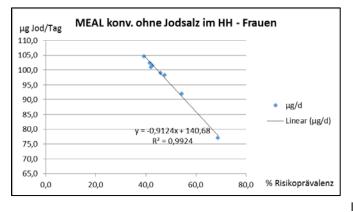


Figure 3: Correlation between the median iodine intake of the age groups and the prevalence of the risk of an inadequate iodine intake, from the exposure assessment with MEAL concentration data and NVS II consumption data

The example shows the correlation curve for female age groups from the scenario 'UB – conventional foods without iodised salt in the household'. Comparable calculations for women and men were conducted with the scenario 'UB – conventional foods without and with iodised salt'. By applying the corresponding formulae, a risk prevalence of 2.5% resulted in median intake levels of 138/140 μ g per day for women and 150/152 μ g per day for men.

Just under 75 μ g of the iodine that is consumed daily together with food is originally sourced from the food itself and is salt-independent (Esche et al., 2019). The iodised salt prophylaxis should therefore be designed to ensure that adults in Germany consume an extra 75 μ g of iodine per day from iodised salt. Accordingly, measures suitable for increasing salt-dependent iodine intake from its current median value of approx. 50 μ g per day by approx. 25 μ g per day or increasing the proportion of salt-dependent iodine intake by 50% should be considered as appropriate.



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

If 42% (52.5 μ g) of iodine intake originates from iodised salt, then a median daily value of 2.6 g of iodised salt with an iodine content of 20 mg/kg is consumed. This means iodised salt has a share of 28% of the median total salt intake, which amounts to 9.3 g per day (Esche et al., 2019). If it is assumed that the iodine proportion from iodised salt is a constant 42% across all consumption percentiles for the data from DEGS1, then 79 μ g of iodine is consumed from 4 g of iodised salt in the 75th consumption percentile and 156.4 μ g of iodine is consumed from 7.8 g of iodised salt in the 95th consumption percentile (Table 11).

| Table 11: Percentage proportion of iodine intake from salt and percentage proportion of iodised salt i | n |
|--|---|
| salt consumption, as per DEGS1 (Esche et al., 2019) | |

| | lodine _{total} µg/d | lodine _{salt} µg/d | lodine _{food} µg/d Salt _{total} g/d | | lodised salt g/d | % |
|------|---------------------------------|-----------------------------|--|--------|---------------------|------|
| P50 | 126.2 | 52.5 | 73.2 | 9.3 | 2.6 | 28 |
| P75* | 188.2 | 79.0 | 109.2 | 13.7** | 4.0** | 29** |
| P95* | 372.3 | 156.4 | 215.9 | 22.5** | 7.8** | 35** |
| % | 100 | 42 | 58 | 100 | | |

* The values in the percentiles P75 and P95 are not contained in Esche et al. 2019 but were made available personally by Dr Esche and Prof. Remer.

** Values calculated using the figures provided by Esche and Remer

With a constant proportion of salt-dependent iodine intake, a rising percentage of iodised salt in salt consumption is identifiable in the higher consumption percentiles, which reaches 35% in the 95th percentile. However, it should be noted that the total iodine intake was determined in DEGS1 and the consumption of iodine-rich food supplements is reflected most strongly in the high consumption percentiles of the DEGS1 iodine intake values. Since this is virtually absent in the lower consumption percentiles, the assessment of the measures intended to affect the prevalence of the risk for an inadequate iodine intake assumes that all iodine originates in food and ignores any potential influence from food supplements.

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 at the median or in lower consumption percentiles. By using the iodised salt intake shown in Table 11 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 after a reduction in salt consumption by 10% (Table 12).

Table 12: 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 DEGS1

| | | Expected iodine intake from iodised salt in μ g per day | | | | | | | | |
|----------------------|---|---|-------|----------|-------|-------|--|--|--|--|
| | With current salt consumption After 10% reduction in salt consumption | | | | | | | | | |
| mg iodine/kg of salt | 20 | 25 | 30 | 20 25 30 | | | | | | |
| Median | 52.5 | 65.6 | 78.8 | 47.3 | 59.1 | 70.9 | | | | |
| P75 | 79.0 | 98.8 | 118.6 | 71.1 | 88.9 | 106.7 | | | | |
| P95 | 156.4 | 195.5 | 234.5 | 140.7 | 175.9 | 211.1 | | | | |



Impact on the prevalence for inadequate iodine intake:

Increasing the maximum permitted iodine concentration from 25 to 30 mg of iodine per kg of salt will probably result in products offered on the market having iodine concentrations in salt between 20 and 30 mg/kg (average of 25 mg/kg). Assuming that salt consumption and the use of iodised salt for the production of commercial food both remain constant, it is to be expected that this measure will increase salt-dependent iodine intake by 13 μ g per day, to a median of 65.6 μ g per day (Table 12). Salt-dependent iodine intake will rise in the P75 by approx. 20 μ g to 98.8 μ g per day, and by 39 μ g to 195 μ g per day in the P95. If the maximum iodine concentration of 30 mg/kg is utilised to the full, the models calculated by the MRI using the diet history interviews from NVS II, and assuming a usage rate of 30%, show a median higher iodine intake of 8 μ g per day for women and 11 μ g per day for men (MRI, 2020). Even with salt consumption remaining constant and with the iodine concentration being maximised, this shows that increasing iodine content by 5 mg/kg salt would not be sufficient to ensure a 'reliable' iodine status for the population.

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 iodine intake according to DEGS1 data is limited to 6.6 μ g per day in the median, approx. 10 μ g per day in the P75 and roughly 20 μ g per day in the P95. 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. The intended iodine contribution from salt of around 75 μ g per day will not be achieved, however.

Increasing the iodine concentration in salt also has only a minor effect on the subpopulation of women of childbearing age (aged between 14 and 39). After increasing the iodine concentration by an average of 25 mg/kg and reducing salt consumption by 10%, the median iodine intake in this age group also rises slightly, but the prevalence of the risk of an inadequate iodine status remains unchanged at 35–46% (Table 13). For the mathematical models as calculated by the MRI, no details are available on the proportion of individuals with an iodine intake below the EAR. However, the MRI models also show a comparatively low median iodine intake for young women aged 24 and under (table 14). Even if salt were to be enriched by 30 mg of iodine per kg, young women would be brought within the range of recommended iodine intake only with a usage rate of 80% (MRI, 2020).

Table 13: Median iodine consumption and prevalence of the risk for an inadequate iodine status in women of childbearing age (39 and under) under current conditions, and while accounting for an increase in salt iodine concentration to 25 mg/kg and a reduction in salt consumption by 10%, according to data from DEGS1

| DEGS1 | | 20 mg/kg | | 25 mg/kg | | | | |
|--------|---|--------------|-----------------------|-------------------------|---------------------------|---------------------------|--|--|
| DECOT | Witho | ut salt redu | ction | With 10% salt reduction | | | | |
| Female | Median salt g/d Median iodine µg/d | | <ear in %</ear | Median salt g/d | Median* iodine µg/d | <ear** in %</ear** | | |
| 14-17 | 8.6 | 94.4 | 50 | 7.7 | 101.4* | 46 | | |
| 18-29 | 7.4 | 99.5 | 46 | 6.7 | 104.3* | 44 | | |
| 30–39 | 8.2 | 114.4 | 38 | 7.4 | 120.9 | 35 | | |

* The calculations of iodine intakes expected after increasing the iodine concentration in salt and reducing salt consumption are based on the iodised salt proportions from the final report (2817HS007) as specifically determined for adolescents and young adults from DEGS1 and KiGGS2 (Esche and Remer, 2019).

** The prevalence to be expected for an inadequate iodine status in the age group of women of childbearing age has been extrapolated from the correlation formula that describes an inverse relationship between the median iodine intake levels for the female age groups and the prevalence for the risk of an inadequate iodine status for the DEGS1 study.



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As mentioned, almost all pregnant and breastfeeding women are to be found in the group 'women of childbearing age aged 39 and under'. For both groups, no representative assessment of iodine intake can be made, because only a few pregnant and breastfeeding women were included in the study population for NVS II. Higher recommended dietary allowances exist for pregnant and breastfeeding women (Table 6), however, than for other women. It can therefore be assumed that, within these subgroups, the prevalence for an inadequate iodine intake is even higher than for women of childbearing age in general. In Germany, iodine food supplements are recommended for pregnant women (BfR, 2014). Indeed, pregnant and breastfeeding women represent 2.2% and 2.8%, respectively, of the 493 users of iodine food supplements accounted for in the exposure assessment made on the basis of the BfR MEAL study. These are significantly higher percentages than for non-food supplement users (0.3% and 0.4%, respectively). However, only 18% of pregnant women and 26% of breastfeeding women from the NVS II 24-hour recalls actually use iodine food supplements. Due to the low number of pregnant and breastfeeding women in NVS II, these figures can only give an indication of the frequency of use of iodine food supplements within this subpopulation.

As a general statement, it can be said that a reduction in salt consumption by 10% is well compensated for by increasing the iodine concentration in salt to a maximum of 30 mg/kg (average of 25 mg/kg in actual products). However, the existing prevalence of the risk of an iodine insufficiency in the 'women of childbearing age' group is especially high and is only negligibly reduced. The 'appropriate' criterion is therefore not fulfilled.

Impact on the risk of exceeding the UL:

As of this writing, the risk of exceeding the UL of 500 μ g of iodine per day through the consumption of food is negligible. In the DEGS1 study, a total iodine intake of 372.3 μ g per day was determined in the P95, of which 156.4 μ g can be ascribed to iodised salt and 215.9 μ g from other foodstuffs (Table 11). With an iodine concentration of 20 mg/kg in salt, this equates to a consumption of iodised salt of 7.8 g per day. 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/kg would result in a salt-dependent iodine consumption of 195 μ g per day and, if the maximum concentration of 30 mg/kg were to be utilised, a salt-dependent iodine consumption of 234.5 μ g per day (Table 12).

In assessing the risk of an excessive intake of iodine, it is assumed that the intended reduction in salt consumption is unsuccessful, since, even in this case, increasing the iodine concentration in salt to max. 30 mg/kg must nevertheless be 'safe'. Accordingly, the only iodine intake levels evaluated here are those that result from maximising the possible iodine concentration to 30 mg/kg in salt. If the above figure is added to the inherent iodine proportion from food of 216 µg per day (215.9 from Table 11 rounded up), an iodine intake of 450.5 µg per day in the 95th consumption percentile is derived from the DEGS1 study in this case—a figure only 50 µg below the UL. This difference could be exceeded easily by the additional use of food supplements containing iodine. At this point, it must be noted that the use of food supplements is already contained in the iodine intake levels that were determined as part of DEGS1. However, the BfR does not have any data on the proportion of food supplement users in the DEGS1 study population. For the assessment, the following therefore applies the P95 consumption quantities determined in the consumption studies.

In the scenarios for the MEAL-based exposure assessment (UB – conv./org.), iodine intake levels of 169–218 μ g per day were determined in the 95th percentile (Table 1 and Table 2), which would be increased to 187–239 μ g per day by the use of iodised salt in the household (\bigcirc : 18 and \bigcirc : 21 μ g per day, see section 3.2.3). If these iodine intake levels are standardised and rounded to 240 μ g per day, this would give a distance of 260 μ g to the UL, which would



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be available for increasing the iodine concentration in salt on the one hand and for the use of food supplements on the other.

By applying the proportion of 42% of salt-dependent iodine intake as determined in DEGS1 to the roughly 240 μ g per day that was determined in the P95 for the MEAL-based scenarios, this produces an iodine proportion of 101 μ g per day from salt and of 139 μ g of iodine per day from other food. This equates to an iodised salt consumption of 5 g per day if the iodine concentration is 20 mg/kg salt. Increasing the iodine concentration in salt to 30 mg/kg would raise the salt-dependent iodine intake to 151 μ g per day. In total, together with the iodine proportion from other foods, an iodine intake of 290 μ g per day would be achieved in the P95 in the MEAL-based exposure assessment. In this case, the distance to the UL would still be 210 μ g per day. Since an additional iodine intake of 134 μ g per day was found in the MEAL-based scenarios for food supplement users in the P95 (calculated by subtracting iodine intake of 200 μ g per day (MRI, 2008) from food supplements in NVS II, the risk of exceeding the UL by increasing the iodine concentration in salt to 30 mg/kg can still be considered as low, 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 a proportion of 1.0% to 1.2% of food supplement users who exceed the UL has already been calculated in the MEAL scenarios. In parallel to an increase of the iodine concentration in salt, the BfR therefore refers to its proposed maximum concentrations of iodine in food supplements of 100 μ g for the general population and 150 μ g for pregnant women per daily dose (Weissenborn, 2018).

By using data from NVS II (diet history interviews) and a modified version of BLS 3.01, the MRI has modelled the impact of the usage rate of iodised salt on iodine intake for the maximum iodine concentration in salt of 30 mg/kg salt (Table 14, Figure 4). In these calculations, the iodine intake was modelled for iodised salt proportions of 30%, 50%, 80% and 100%. From these scenarios, it can be seen that with a proportion of 30% iodised salt and salt consumption remaining constant, median intake values can be achieved of 175 μ g per day for men and 137 μ g per day for women. In the 95th consumption percentile, men in this scenario would consume 312 μ g per day and women 233 μ g per day from food. Both of these intake values are near the figure of 290 μ g per day that is also estimated for the P95 from the results of the BfR MEAL study for an iodine concentration of 30 mg/kg salt. With an iodised salt proportion of 30%, the NVS II modelling results can therefore also be applied to show that the risk of exceeding the UL by increasing the iodine concentration salt to 30 mg/kg is appreciably low.

However, the risk of achieving an iodine intake above the UL in the P95 rises significantly from an iodised salt proportion of 80% in young men and an iodised salt proportion of 100% for all men (Figure 4). While only 1.5% of women would consume more than 500 μ g of iodine from food on a daily basis in the 100% iodised salt usage scenario, this would be true for 11.2% of men—and the young men subgroup would be expected to have the highest proportion of persons exceeding the UL, at 19.3%.

If iodine consumption from food supplements is also accounted for in the P95 (134 μ g per day as determined in the MEAL exposure assessment and 200 μ g per day as determined in NVS II (MRI, 2008)), the UL would be expected to be exceeded in the P95 in men with an iodised salt proportion of already 50%.

Overall, it becomes clear that increasing the iodine concentration in salt to 30 mg/kg with the current usage rate of 29% of iodised salt for the production of commercial foods (Bissinger et

Aged 51 to 64

Aged 65 to 80

1840

1562

92

83



al., 2018) can be considered as 'safe'. As usage rates for iodised salt increase, however, the risk of an iodine intake above the UL also rises, especially for the young men subgroup.

| on the basis of die | et history inte | erviews from N | IVS II and BLS (| MRI, 2020) | • | C C/ | | | |
|---------------------------|-----------------|----------------|------------------|--|------|-------|--|--|--|
| lodine intake (µg/day) | n | | Usage | Usage rate of iodised table salt (30 mg/kg) | | | | | |
| (median) | | 0 % | 30 % | 50 % | 80 % | 100 % | | | |
| Men, total | 7093 | 110 | 175 | 218 | 283 | 326 | | | |
| Aged 14 to 18 | 712 | 112 | 178 | 220 | 284 | 327 | | | |
| Aged 19 to 24 | 510 | 113 | 188 | 235 | 302 | 348 | | | |
| Aged 25 to 34 | 690 | 118 | 184 | 233 | 305 | 350 | | | |
| Aged 35 to 50 | 2079 | 113 | 179 | 225 | 290 | 334 | | | |
| Aged 51 to 64 | 1633 | 104 | 169 | 212 | 275 | 317 | | | |
| Aged 65 to 80 | 1469 | 100 | 159 | 199 | 257 | 297 | | | |
| | | | | | | | | | |
| Women, total | 8278 | 91 | 137 | 168 | 214 | 244 | | | |
| Aged 14 to 18 | 700 | 83 | 127 | 154 | 200 | 228 | | | |
| Aged 19 to 24 | 510 | 86 | 128 | 153 | 192 | 220 | | | |
| Aged 25 to 34 | 972 | 97 | 142 | 172 | 218 | 249 | | | |
| Aged 35 to 50 | 2694 | 97 | 145 | 176 | 222 | 253 | | | |

139

128

171

159

219

205

249

234

Table 14 lodine intake (μ g/day), accounting for various usage rates of iodised table salt (30 mg iodine/kg) on the basis of diet history interviews from NVS II and BLS (MRI, 2020)

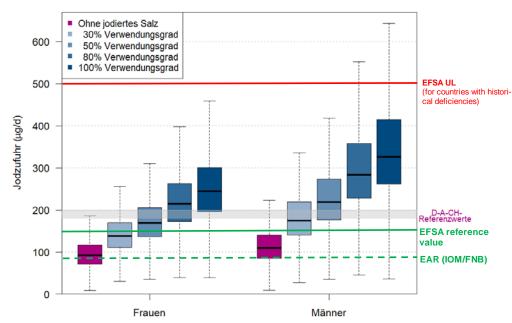


Figure 4:Distribution of iodine intake (µg/day), accounting for various usage rates of iodised table salt (30 mg iodine/kg) – based on NVS II diet history interviews/BLS modified according to MRI, 2020.



3.4.3 Determination of 'appropriate' and 'safe' usage rates of iodised salt after increasing the maximum iodine concentration to 30 mg/kg

In the mathematical models calculated by the MRI using data from NVS II (diet history interviews), with the maximum iodine concentration in salt of 30 mg/kg salt and with unchanged salt consumption for the usage rate of 30%, median intake levels resulted that converged on the EFSA recommendation of 150 μ g/day in women (with 137 μ g per day) and actually exceeded this value in men (with 175 μ g per day). In addition, it was also shown that the benefit from higher enrichment of salt with iodine is less for women than for men, since women eat less meat, sausage products and bread, whose iodine concentration rises significantly when salt is enriched (MRI, 2020). However, it must also be remembered that the iodine concentrations of iodised salt products on the market would tend to average out at around 25 mg/kg, and that health policy efforts are being undertaken to reduce the consumption of salt in the general population.

In the following section the range of 'appropriate' and 'safe' usage rates of iodised salt, which can be roughly estimated between 30 and 50% based on the NVS II scenarios (MRI, 2020), shall be verified using DEGS1 data. In doing so, iodine and iodised salt consumption levels will be applied as given in Table 11.

The median salt-related iodine consumption of 52.5 μ g per day resulted in a share of 42% in iodine consumption and a median iodised salt consumption of 2.6 g per day, which corresponds in turn to 28% of the median salt consumption of 9.3 g per day. 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 consumption (x). Knowing the amounts and ratios determined in DEGS1, the simple linear equation y = f(x) can now be formulated for any desired iodine content in salt. This formula can be used to calculate the required proportion of iodised salt needed to achieve a specified target value for salt-dependent iodine intake.

The calculation of the proportion of iodised salt in salt consumption required for the 'appropriate' criterion was completed for the iodine concentration of 25 mg/kg salt while accounting for a 10% reduction in salt consumption. The target value for salt-dependent iodine intake is 75 μ g per day in the median, so that in total, with the iodine contained in other foods (just under 75 μ g per day, Table 5), the EFSA recommended dietary allowance of 150 μ g per day can be achieved. For this condition, there was an increase in iodine intake per percent of iodine salt proportion of y = 2.0925x, according to which a salt-related iodine intake of 75 μ g is achieved in the median with an iodised salt proportion of 36% of the salt consumption.

The calculation of the maximum 'safe' iodised salt proportion in salt consumption was completed for the iodine concentration of 30 mg/kg salt, with salt consumption remaining unchanged. The target value for salt-dependent iodine intake is 284 μ g per day in the P95, since in sum with iodine consumption from other foods of about 216 μ g per day, the UL of 500 μ g per day should not be exceeded (Table 5). No additional assumptions were made for food supplements, since these are already included in the iodine intake levels from DEGS1. For this condition, there was an increase in iodine intake per percent of iodised salt proportion of y = 6.75x, with which a salt-dependent iodine intake of 284 μ g in the P95 is achieved with an iodised salt proportion of 42% of salt consumption.

In summary, an increase in the maximum iodine content in salt from 25 to 30 mg/kg can be viewed as 'appropriate' and 'safe', even in the case of salt consumption being reduced successfully, if the usage rate of iodised salt across all food products is at least 36% but does not significantly exceed 42%. In this context, regular monitoring of the iodine concentration in



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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 notes that the assessments completed here are based on a series of assumptions and simplifications that have been taken from different studies. 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, 48% of meat and sausage products, 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 assessment made on the basis of the BfR MEAL study, whose concentration data include foods manufactured with iodised salt, and from the model scenarios from the MRI's NVS II (MRI, 2020), it can be seen that, apart from meat and sausage products, especially the food group of bread and baked goods, are among the most important food carriers for iodised salt prophylaxis. Accordingly, achieving a targeted increase in the usage rate of iodised salt in this food group is certainly advisable. As to the degree to which this impacts iodine intake for groups following special diets, this can be determined only by the application of fine-tuned mathematical models that are based on representative consumption studies.

3.4.4 Uncertainties

The data from the NVS II are the most current and representative data available on consumption patterns in the adult German population. These data were collected some time ago, however, in 2005/2006. The data of the DEGS study were also already collected in 2008-2011. Potential changes in consumption or in urinary iodine excretion resulting from consumption have not been accounted for in the present analysis. The participants providing consumption data in NVS II and iodine urine concentration samples in DEGS are also not the same individuals. Since both study populations are representative of the composition of the adult population in Germany, however, the data should be comparable with one another.

Iodine intake from salt was modelled using three studies, which are based on different datasets and survey instruments. The biomarker-based DEGS data, for example, contain the total iodine intake, including the use of food supplements and medicines. In the NVS II model scenarios from MRI, however, the salt-dependent iodine intake at the higher usage rates is overestimated in comparison with the current situation, since the salt was hypothetically iodised in almost all foods. Iodine intake also tends to be overestimated in the model scenarios based on the MEAL data, in which the use of iodised salt in the household was estimated, since the use of iodised salt was assumed for all study participants in NVS II.

To calculate the iodine proportion from salt in the exposure assessment based on the MEAL data, the NVS II-based iodine intake from the 24-hour recalls, in which no iodised salt was accounted for (DGE, 2012), 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. This leads to differences, especially in the P95. In addition, 14-year-olds were excluded from the MRI calculation based on the 24-hour recalls. Overall, despite the differences in the respective datasets and survey instruments, the median iodine intake levels determined in each case are in fact in general agreement with one another.



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As a basic rule, it must be kept in mind 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.

In addition, the subgroup of vegetarians in NVS II (n = 215) is not suitable for the purpose of conducting more in-depth investigations—not least because this subgroup also includes pescatarians. Since this latter group also consumes fish, their iodine intake is probably higher than those who do not eat fish. Probably, this leads to an overestimation of iodine intake on the part of vegetarians who do not consume any fish or fish products. Likewise, the subgroup of pregnant and breastfeeding women in NVS II is also too small to generate any valid statements about the use of iodine food supplements.

Calculating the appropriateness and 'safe' usage rate for iodised salt is based on a series of assumptions and simplifications. These include assumptions that the salt-dependent iodine intake is 42% across all consumption percentiles and that the iodine concentration in salt is 20 mg/kg. However, since iodised salt products on the market may contain varying amounts of iodine (15–25 mg/kg), the calculated median iodised salt consumption of 2.6 g per day is also merely an estimate. If the iodine concentration in salt is increased to a maximum of 30 mg/kg, then the conditions determined as being 'appropriate' (36% usage rate for iodised salt) and 'safe' (usage rate of iodised salt not significantly over 42%) should therefore be considered as a general framework for iodised salt prophylaxis across all foods.

3.5 Other aspects

In many countries, the iodine status of pregnant women is inadequate according to WHO criteria (a median urine iodine concentration (UIC) of <150 μ g/l is considered inadequate for pregnant women) (IGN, 2017; WHO, 2007b). In Switzerland too, this risk group also exhibits a slight deficiency according to WHO, despite a nationally funded iodine prophylaxis using iodised salt.

As in Germany, Switzerland also pursues a policy of voluntary iodisation of salt and usage of iodised table salt (Andersson and Herter-Aeberli, 2019). As part of efforts to improve the total intake of iodine in the Swiss population, the concentration of iodine in salt was raised from 20 to 25 mg/kg in January 2014. In 2015, a national cross-sectional study was conducted in order to investigate the impact of this increase on the iodine status of schoolchildren (6 to 12 vears of age), women of childbearing age and pregnant women (Andersson and Herter-Aeberli, 2019). Following the increase of iodine concentration in table salt, a slight increase in urinary iodine excretion was observed in schoolchildren and women of childbearing age, although the latter group still failed to achieve an adequate iodine status in accordance with WHO criteria. Schoolchildren exhibited an adequate iodine status both before and after the increase. For the subgroup of pregnant women, which had had an adequate iodine status according to WHO before the iodine concentration in salt was raised (median UIC 162 µg/l), this group's median urine iodine concentration actually declined after the increase to a level that must be interpreted as inadequate (median UIC 140 µg/l). Compared with the 2009 survey, the pregnant women investigated in 2015 exhibited a decline in urine iodine concentration especially at the lower end of the distribution in the 25th guartile of 16 µg/l (from 81 to 65 $\mu q/l$). In the 75th percentile, however, the urine iodine concentration rose by 12 $\mu q/l$ (from 302 to 314 µg/l).

Based on the available data, the underlying reasons for this trend in the pregnant women investigated—namely that the increase did not lead to an improvement in iodine status in the



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bottom UIC quartile—can only be surmised. Pregnant women may well have eating habits that differ to those found in the general population. This could lead to a preference for types of products (e.g. organic produce) that are rarely manufactured with iodised salt. Voluntary iodised salt prophylaxis involving a relatively low coverage of products enriched with iodised salt seems to be a less suitable way of reaching certain population groups who have special dietary habits. Other targeted measures could therefore be appropriate in this case.

The results of the Swiss survey have also been published in an article (Andersson et al., 2020). In their conclusions, the authors state that merely increasing the concentration of iodine in salt may not lead to an improved iodine intake in women if the use of iodised salt is not widespread for processed food products.

Further information on the subject of iodine from the BfR website

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

Questions and answers on iodine intake and the prevention of iodine deficiency<u>https://www.bfr.bund.de/de/jodversorgung_in_deutschland_wieder_rueck-</u> laeufig__tipps_fuer_eine_gute_jodversorgung-128626.html



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Appendix 1

lodine exposure in Germany on the basis of content data from the BfR MEAL study

1. Underlying data

(1) Consumption data

The data set for consumption by adolescents and adults was taken from the National Food Consumption Study II (NVS II) published by the Max Rubner Institute (MRI). NVS II is the current representative study for food consumption in the German population. The study, which surveyed about 20,000 individuals aged between 14 and 80 on their eating habits using three separate survey methods (dietary history, 24-hour recall and weighing protocol), was conducted between 2005 and 2006 throughout Germany (Krems et al. 2006, MRI 2008).

The consumption analyses are based on the data from the two independent 24-hour recalls from NVS II, which were surveyed in a computer-aided interview using 'EPIC-SOFT'. Data was evaluated from 13,926 people for whom both interviews were available. Due to the presence of consumption data for individual days, the 24-hour recall method is suitable for use in exposure assessments considering both acute and chronic health risks. The 24-hour recalls are coded with reference to the German Nutrient Database (BLS).

(2) Content data

The iodine content data were collected in the BfR MEAL study designed by the BfR, which is the first total diet study conducted in Germany. The 'MEAL' acronym describes the methodology: meals for the exposure assessment and analysis of foods (foods = 'Lebensmittel' in German). Initiated in 2015, the BfR MEAL study is one of the most comprehensive total diet studies conducted worldwide (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. Based on the 24-hour recalls conducted as part of NVS II, the MEAL food list covers at least 90% of the average food intake of various age groups within the German population, while also accounting for foods consumed rarely that are known to have high concentrations of undesirable substances. 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 pooled (grouped together) before then being homogenised.

For the investigation into iodine, a total of 840 pools were formed in this way, consisting of 15–20 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). The 356 foodstuffs can be assigned to 19 food groups (table 1).



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| Table 1: Iodine sam | pling — | overview |
|---------------------|---------|----------|
|---------------------|---------|----------|

| Food group | Nun | nber |
|---|------|-------|
| Food group | Food | Pools |
| 01 Cereals and cereal-based products | 40 | 97 |
| 02 Vegetables and vegetable products | 33 | 151 |
| 03 Roots or tubers containing starch and their products | 8 | 26 |
| 04 Pulses, nuts, oil seeds and spices | 20 | 24 |
| 05 Fruit and fruit products | 22 | 64 |
| 06 Meat and meat products | 35 | 101 |
| 07 Fish and seafood | 30 | 39 |
| 08 Milk and dairy products | 23 | 37 |
| 09 Eggs and egg-based products | 2 | 10 |
| 10 Sugar, confectionery and water-based sweet desserts | 15 | 18 |
| 11 Animal and vegetable fats and oils | 8 | 13 |
| 12 Fruit and vegetable juices and squashes | 10 | 12 |
| 13 Water and water-based beverages | 6 | 12 |
| 14 Coffee, cocoa and tea | 9 | 12 |
| 15 Alcoholic beverages | 8 | 11 |
| 16 Products for infants and toddlers | 11 | 15 |
| 17 Vegan/vegetarian products | 7 | 8 |
| 18 Composite meals | 53 | 171 |
| 19 Spices, sauces and condiments | 16 | 19 |
| Total: | 356 | 840 |

As an example, the food 'Apple, raw' belongs to the food group '05 Fruit and fruit products'. 'Apple, raw' itself consists of ten pools, with examples including 'Apple, national, season 1, organic', 'Apple, national, season 2, organic' and 'Apple, region east, season 1, conventional'. Each of these apple pools consists of 15 apples of various varieties, purchased in different stores.

The pool samples from the BfR MEAL study were analysed using inductive coupled plasma mass spectrometry (ICP-MS) by an external accredited laboratory. Depending on the specific matrix, the limits of detection (LODs) were 0.01, 0.002 and 0.0003 mg/kg and the limits of quantification (LOQs) were 0.03, 0.006 and 0.001 mg/kg.



lodine content in food groups

The individual results available for each of the 840 pools were determined using a modified lower bound (mLB) approach (if result <LOQ, then value = LOD; if result <LOD, then value = 0) and an upper bound (UB) approach (if result <LOQ, then value = LOQ; if result <LOD, then value = LOD). In 8 of the 19 food groups, there were no differences or only marginal differences between the results from the two approaches. In the food groups 'Pulses, nuts, oil seeds and spices', 'Animal and vegetable fats and oils', 'Fruit and vegetable juices and squashes', 'Water and water-based beverages' and 'Products for infants and toddlers', a larger number of individual samples had concentrations below the analytical limits. As a consequence, results for the UB approach are higher in comparison to the mLB approach in these food groups (table 2). The following tables largely present the iodine concentration data from the UB approach. In addition, the slight overestimate of intake values that results from this is presented in table 6 and discussed in the 'Uncertainty analysis' section.

Table 2 presents the distribution of average values from foods within the food groups (n = 19). These average values for foods were calculated from the 1–10 average pool values in each food group. As a result of the significantly higher concentrations of iodine found in algae and salt compared with other foods, these are presented separately from their food groups.

When interpreting the concentration data, it should be remembered that non-iodised table salt was used for preparation work in the MEAL study kitchen: accordingly, the specified concentrations refer to natural iodine concentrations or could result from the use of iodised salt in industrially processed ready-to-eat foods. It should also be noted that the drinking water used in the MEAL study kitchen for preparing ready-to-eat meals and beverages has a relatively high concentration of iodine, namely 0.018 mg/kg (median). The national drinking water samples also taken in the course of the BfR MEAL study (n = 29) had a lower iodine concentration of 0.004 mg/kg (median). This value is within the range of a drinking water study conducted in Germany, which revealed iodine concentrations of 0.001 to 0.009 mg/kg (Bittermann and Großklaus 1999). The effect of the higher iodine concentration in the MEAL drinking water is especially pronounced for water-based foods such as tea or coffee.

The food group with the highest iodine concentration (median UB) is 'Eggs and egg-based products' (0.497 mg/kg). This food group includes fried and boiled chicken eggs with comparable iodine concentrations (see minimum and maximum). The 'Fish and seafood' group has a concentration of roughly half this value (0.230 mg/kg). This food group has a wide range of iodine concentrations, with 'Carp' having the lowest value and 'Atlantic cod' having the highest iodine concentration. Slightly lower iodine concentrations are found in 'Meat and meat produce' (0.165 mg/kg), with a maximum for 'Raw sausage for slicing (poultry)', and in 'Milk and dairy produce' (0.132 mg/kg), with a maximum for 'Sheep's cheese'.

The lowest iodine concentrations are found in 'Fruit and fruit produce' and beverages ('Fruit and vegetable juices and squashes', 'Water and water-based beverages' and 'Alcoholic beverages').



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Table 2: Iodine content in food groups (mg/kg)*

| | | | mLB | | | UB | | Food with highest content (maximum) within the food |
|---|--------------|-------------------|--------------------|--------------------|-------------------|--------------------|--------------------|---|
| Food group | No. of foods | Median (mg/kg) | Minimum (mg/kg) | Maximum (mg/kg) | Median (mg/kg) | Minimum (mg/kg) | Maximum (mg/kg) | group |
| 01 Cereals and cereal-based products | 40 | 0.049 | 0.000 | 0.307 | 0.049 | 0.002 | 0.307 | Cheesecake |
| 02a Vegetables and vegetable products – without algae | 32 | 0.030 | 0.002 | 0.148 | 0.030 | 0.005 | 0.148 | Kale |
| 02b Algae | 1 | 14.175 | 14.175 | 14.175 | 14.175 | 14.175 | 14.175 | - |
| 03 Roots or tubers containing starch and their products | 8 | 0.020 | 0.000 | 0.075 | 0.023 | 0.003 | 0.075 | Mashed potato, potato puree |
| 04 Pulses, nuts, oil seeds and spices | 20 | 0.010 | 0.000 | 0.239 | 0.018 | 0.010 | 0.239 | Dried spices |
| 05 Fruit and fruit products | 22 | 0.008 | 0.001 | 0.075 | 0.008 | 0.003 | 0.075 | Fruit preserves |
| 06 Meat and meat products | 35 | 0.165 | 0.015 | 0.455 | 0.165 | 0.015 | 0.455 | Raw sausage for slicing (poultry) |
| 07 Fish and seafood | 30 | 0.230 | 0.017 | 1.900 | 0.230 | 0.017 | 1.900 | Atlantic cod |
| 08 Milk and dairy products | 23 | 0.135 | 0.012 | 0.645 | 0.135 | 0.012 | 0.645 | Sheep's cheese |
| 09 Eggs and egg-based products | 2 | 0.497 | 0.475 | 0.519 | 0.497 | 0.475 | 0.519 | Fried (chicken) eggs |
| 10 Sugar, confectionery and water-based sweet desserts | 15 | 0.036 | 0.000 | 0.220 | 0.036 | 0.010 | 0.220 | Milk chocolate AND chocolate with other fillings |
| 11 Animal and vegetable fats and oils | 8 | 0.003 | 0.000 | 0.021 | 0.015 | 0.010 | 0.034 | Butter |
| 12 Fruit and vegetable juices and squashes | 10 | 0.002 | 0.000 | 0.021 | 0.006 | 0.002 | 0.021 | Apple fruit juice |
| 13 Water and water-based beverages | 6 | 0.001 | 0.000 | 0.018 | 0.004 | 0.002 | 0.018 | Drinking water from MEAL study kitchen |
| 14 Coffee, cocoa and tea | 9 | 0.017 | 0.011 | 1.400 | 0.017 | 0.011 | 1.400 | Powdered beverages containing cocoa (powder) |
| 15 Alcoholic beverages | 8 | 0.005 | 0.002 | 0.008 | 0.007 | 0.006 | 0.009 | Red wine |
| 16 Products for infants and toddlers | 11 | 0.021 | 0.002 | 0.830 | 0.031 | 0.006 | 0.830 | Infant formula (powder) |
| 17 Vegan/vegetarian products | 7 | 0.022 | 0.013 | 0.115 | 0.022 | 0.013 | 0.115 | Soy protein extrudate |
| 18 Composite meals | 53 | 0.100 | 0.019 | 0.402 | 0.100 | 0.019 | 0.402 | Omelette/scrambled egg |
| 19a Spices, sauces and condiments – without salt | 15 | 0.130 | 0.016 | 0.280 | 0.130 | 0.016 | 0.280 | Light sauces AND light sauces with ham |
| 19b Salt | 1 | 20.20 | 20.20 | 20.20 | 20.20 | 20.20 | 20.20 | _ |

* Use of non-iodised table salt in the MEAL study kitchen



Iodine content in foods

Table 3 shows the 15 foods with the highest content of iodine (average UB) in descending order.

Table 3: Foods with the highest concentrations of iodine in descending order (mg/kg)*

| Food | No. of pools | Average UB (mg/kg) |
|--|-----------------|-----------------------|
| Salt | 1 | 20.20 |
| Algae | 1 | 14.18 |
| Atlantic cod | 1 | 1.90 |
| Molluscs | 1 | 1.68 |
| Powdered beverages containing co- coa | 1 | 1.40 |
| Cod liver | 1 | 1.33 |
| Infant formula (powder) | 2 | 0.83 |
| Sheep's cheese | 1 | 0.65 |
| Fish fillet, gratinated | 1 | 0.64 |
| Ready-made milk porridge (powder) | 1 | 0.57 |
| Rollmop herring | 1 | 0.55 |
| Fried (chicken) eggs | 5 | 0.52 |
| Fish sticks | 1 | 0.50 |
| Boiled (chicken) egg | 5 | 0.47 |
| Raw sausage for slicing (poultry) | 1 | 0.46 |

* Use of non-iodised table salt in the MEAL study kitchen

'Salt' has the highest iodine concentration, at 20.20 mg/kg. The second-highest iodine concentration is 'Algae' with 14.18 mg/kg. This pool consists of 20 sub-samples of various types of algae (including nori, wakame and kombu) in a ready-to-eat condition. The pool contains fresh as well as dried and rehydrated algae.

Seven of the 15 foods with the highest concentrations belong to the food group 'Fish and seafood'. 'Atlantic cod' has the highest iodine concentration, at 1.9 mg/kg. The pool consists of 20 subsamples from various stores (in accordance with market share), both fresh and frozen, and prepared with standard household methods (breaded and not breaded, steamed, fried, baked or boiled). The 'Molluscs' group also has a high iodine concentration (1.68 mg/kg). This pool consists mostly of blue mussels, as well as a few individual samples of scallops and oysters.

Alongside representatives of the 'Fish and seafood' group, 'Sheep's cheese' (0.65 mg/kg) as well as 'Fried (chicken) eggs', 'Boiled (chicken) eggs' (0.52 and 0.47 mg/kg) and 'Raw sausage for slicing (poultry)' (0.46 mg/kg) are some other foods with high iodine concentrations.

When interpreting the iodine concentrations listed in table 3 for 'Powdered beverages containing cocoa (powder)', 'Infant formula (powder)' and 'Ready-made milk porridge (powder)', it must be remembered that these concentration data relate specifically to the powder. The iodine content of the rehydrated, ready-to-eat food is lower and depends on individual portioning.



Impact of production type

For 105 of the 356 foods, specific pools were put together depending on the type of production used (conventional/organic). Based on these pools, table 4 presents the iodine concentration of 16 of the 19 food groups, stratified by type of production.

For conventionally produced foods, 1–8 pools per food group were available (n = 285 pools). For organically produced foods, 1–2 pools per food group were available (n = 146 pools). Analogous to the procedure already described, the mean values of the conventionally or organically produced pools of each food group (n = 105) were averaged. On the basis of these food averages, the median and range are presented in each case for the food groups (n = 16) (table 4).

The most significant difference is seen with 'Products for infants and toddlers', with a content that is six times higher in conventionally produced products compared with organically produced products (median UB: 0.113 versus 0.020 mg/kg). A noticeable difference is also apparent in the food group 'Cereals and cereal products'. In this group, the iodine content for conventionally produced products is twice as high as the figure for organic products (0.052 versus 0.027 mg/kg). Conventionally produced 'Vegan/vegetarian products' also have an average iodine concentration that is double the value for organic products (0.047 versus 0.022 mg/kg)—this comparison relates to two 'Tofu' pools.

In contrast, conventionally produced 'Fruit and fruit products' exhibit a significantly lower iodine concentration than the organically produced samples (0.006 versus 0.024 mg/kg).



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Table 4: Iodine content in food groups – by production type (mg/kg)*

| | · · | Conven | tional produc | ction UB | | | Orgai | nic production | on UB | |
|---|--------------|-----------------|-------------------|--------------------|--------------------|--------------|-----------------|-------------------|--------------------|--------------------|
| Food group | No. of foods | No. of pools | Median (mg/kg) | Minimum (mg/kg) | Maximum (mg/kg) | No. of foods | No. of pools | Median (mg/kg) | Minimum (mg/kg) | Maximum (mg/kg) |
| 01 Cereals and cereal-based products | 15 | 33 | 0.052 | 0.002 | 0.233 | 15 | 15 | 0.027 | 0.002 | 0.140 |
| 02 Vegetables and vegetable products | 13 | 47 | 0.015 | 0.006 | 0.059 | 13 | 20 | 0.016 | 0.004 | 0.066 |
| 03 Roots or tubers containing starch and their products | 4 | 14 | 0.023 | 0.002 | 0.045 | 4 | 8 | 0.017 | 0.003 | 0.115 |
| 04 Pulses, nuts, oil seeds and spices | 4 | 4 | 0.041 | 0.013 | 0.360 | 4 | 4 | 0.029 | 0.015 | 0.119 |
| 05 Fruit and fruit products | 7 | 24 | 0.006 | 0.002 | 0.043 | 7 | 12 | 0.024 | 0.004 | 0.083 |
| 06 Meat and meat products | 12 | 40 | 0.121 | 0.010 | 0.370 | 12 | 16 | 0.103 | 0.004 | 0.380 |
| 08 Milk and dairy products | 7 | 7 | 0.145 | 0.010 | 0.187 | 7 | 14 | 0.128 | 0.075 | 0.175 |
| 09 Eggs and egg-based products | 2 | 8 | 0.486 | 0.467 | 0.505 | 2 | 2 | 0.540 | 0.505 | 0.574 |
| 10 Sugar, confectionery and water-based sweet desserts | 3 | 3 | 0.030 | 0.020 | 0.283 | 3 | 3 | 0.030 | 0.030 | 0.158 |
| 11 Animal and vegetable fats and oils | 4 | 4 | 0.020 | 0.010 | 0.034 | 4 | 5 | 0.010 | 0.010 | 0.034 |
| 12 Fruit and vegetable juices and squashes | 2 | 2 | 0.014 | 0.006 | 0.021 | 2 | 2 | 0.013 | 0.006 | 0.020 |
| 13 Water and water-based beverages | 0 | 0 | - | - | - | 0 | 0 | _ | _ | - |
| 14 Coffee, cocoa and tea | 3 | 3 | 0.015 | 0.011 | 0.018 | 3 | 3 | 0.014 | 0.012 | 0.016 |
| 15 Alcoholic beverages | 3 | 3 | 0.006 | 0.006 | 0.008 | 3 | 3 | 0.009 | 0.007 | 0.011 |
| 16 Products for infants and toddlers | 4 | 4 | 0.113 | 0.006 | 0.965 | 4 | 4 | 0.020 | 0.006 | 0.695 |
| 17 Vegan/vegetarian products | 1 | 1 | 0.047 | 0.047 | 0.047 | 1 | 1 | 0.022 | 0.022 | 0.022 |
| 18 Composite meals | 21 | 88 | 0.095 | 0.011 | 0.400 | 21 | 34 | 0.085 | 0.006 | 0.410 |
| 19 Spices, sauces and condiments | 0 | 0 | — | _ | - | 0 | 0 | - | _ | - |
| Total: | 105 | 285 | | - | | 105 | 146 | | _ | |

* Use of non-iodised table salt in the MEAL study kitchen



Table 5 offers an overview of the iodine concentrations of food in the three food groups where the production type has the most significant impact.

Table 5: Iodine concentrations for food in the food groups 'Cereals and cereal products', 'Fruit and fruit produce' and 'Products for infants and toddlers' – by production type (mg/kg)*

| | Conventi | onal production | Organ | ic production |
|---|-----------------|-----------------------|-----------------|-----------------------|
| Food (group) | No. of pools | Average UB (mg/kg) | No. of pools | Average UB (mg/kg) |
| 01 Cereals and cereal-based products ($n = 15$) | 33 | | 15 | |
| Pancakes with egg/waffles with fresh egg | 4 | 0.233 | 1 | 0.140 |
| Fruit muesli | 1 | 0.030 | 1 | 0.030 |
| Rye bread with ingredients | 4 | 0.049 | 1 | 0.052 |
| Rye breads | 4 | 0.052 | 1 | 0.022 |
| Oatmeal | 1 | 0.010 | 1 | 0.020 |
| Pretzel products | 4 | 0.059 | 1 | 0.002 |
| Puffed mixed cereal waffles | 1 | 0.010 | 1 | 0.010 |
| Rice | 1 | 0.111 | 1 | 0.088 |
| Rice waffles | 1 | 0.079 | 1 | 0.065 |
| Muesli with chocolate | 1 | 0.074 | 1 | 0.035 |
| Other muesli | 1 | 0.030 | 1 | 0.030 |
| Pasta, egg-free | 1 | 0.002 | 1 | 0.002 |
| Pasta, with egg | 1 | 0.061 | 1 | 0.027 |
| Wholegrain bread/wholegrain rolls | 4 | 0.033 | 1 | 0.011 |
| White breads/rolls | 4 | 0.091 | 1 | 0.018 |
| 05 Fruit and fruit products ($n = 7$) | 24 | | 12 | |
| Apple, raw | 8 | 0.027 | 2 | 0.034 |
| Apple, processed/apple puree | 8 | 0.028 | 2 | 0.083 |
| Banana, raw | 1 | 0.006 | 1 | 0.006 |
| Pear, raw | 2 | 0.002 | 2 | 0.004 |
| Kiwi, raw | 2 | 0.043 | 2 | 0.035 |
| Orange/mandarin orange/clementine, raw | 1 | 0.006 | 1 | 0.007 |
| Grapes, raw | 2 | 0.004 | 2 | 0.024 |
| 16 Products for infants and toddlers $(n = 4)$ | 4 | | 4 | |
| Cereal porridge (powder) | 1 | 0.150 | 1 | 0.014 |
| Fruit porridge (ready-to-eat) | 1 | 0.006 | 1 | 0.006 |
| Baby/junior ready meals (ready-to-eat) | 1 | 0.076 | 1 | 0.026 |
| Infant milk products (powder) | 1 | 0.965 | 1 | 0.695 |

* Use of non-iodised table salt in the MEAL study kitchen

The higher iodine content in conventionally produced 'Cereals and cereal products' is particularly noticeable with the foods 'Rye breads', 'Wholegrain breads/rolls' and 'White breads/rolls' (factor of 2.4–5.1). This difference is in line with the findings of the market survey conducted by the University of Giessen, which showed that none of the organically certified products surveyed in the bread product group had been prepared using iodised salt (Bissinger et al. 2018). The BfR MEAL study also shows that conventionally produced 'Pasta, with egg' and 'Muesli with chocolate' products have iodine concentrations roughly double those of the respective organic products.

In the 'Fruit and fruit produce' group, the conventionally produced foods 'Apple, processed/apple puree' and 'Grapes' exhibit significantly lower iodine concentrations than the organically produced products.

The difference between conventional and organically produced 'Products for infants and intoddlers' stems from the significantly higher iodine concentration in conventionally produced



'Cereal porridge (powder)'. Conventionally produced 'Infant milk products (powder)' also exhibits a higher iodine concentration than the organic pool. The difference found in the 'Baby/junior ready meals' may arise as a result of the composition of the pools. While 6 of the 15 individual samples in the conventional pool contained fish, fish was absent from all of the individual samples in the organic pool.

As a general point to remember when interpreting the differences, these should be interpreted statistically as average differences from 15–20 subsamples and can therefore be influenced by concentrations below the limit of detection or quantification.

2. Exposure assessment

For each person participating in the 24-hour recalls, the long-term level of consumption was determined by calculating the average consumption across both 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, based on the BLS code from the 24-hour recalls. At 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'). This assignment process permits an identification of the matching consumption events for each MEAL pool.

Based on this assignment, the exposure was calculated for each 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 selected. Values below the limit of detection or quantification were replaced by the limit of detection/quantification (upper bound approach).

For the present Opinion, only the differences between conventional and organic production were considered. 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). Stratification is also absent for some foods (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.
- 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, a different pool was substituted, according to a similar methodology:

- 1. Does a pool without stratification exist? If 'Yes', this pool was selected.
- If 'No', do seasonal pools exist? If 'Yes', the average concentration in both seasons was used.
- If 'No', do regional pools exist?
 If 'Yes', the matching regional pool was assigned to each individual consumer.
- If 'No', do regional and seasonal pools exist?
 If 'Yes', the average concentration of both matching regional seasons was assigned to each individual consumer.

The difference here to the first procedure is that non-specificity was applied to the production type in this second procedure. Both for stratification by organic and by conventional production, this procedure therefore assigns an identical value in the aggregated exposure assessment: as a result, 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.

Total iodine intake based on all respondents

As described above, determining the total intake of all respondents for all participants in the 24-hour recalls involved totalling the iodine intake values from separate foods at an individual level.

Table 6 presents the average, median and 95th percentile for the resulting intake. The iodine intake estimated on the basis of UB concentration data is marginally higher compared with the mLB approach. For example, the average total iodine intake (median, conventional production) in the UB scenario (107 μ g/d) is 3 μ g/d higher than in the mLB scenario (104 μ g/d). The tables below therefore present only the iodine intake estimated on the basis of the UB approach. When interpreting the results, it should be remembered that the effect described can lead to a slight overestimate of the iodine intake.

The scenarios 'Organic production' and 'Conventional production' are based on the iodine concentration data from the conventional and organically produced MEAL pools. For the 251 foods for which no pools stratified by production type were available, an identical, non-productionspecific value for the corresponding food was substituted in both scenarios, according to the methodology described above.



Table 6: Iodine intake – by production type $(\mu g/d)^*$

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| | | Conventional mL | | duction | Conver | ntional pro UB | duction | Orga | anic produ mLB | ction | Orga | anic produ UB | ction |
|----------------|-------|--------------------|------------------|---------------|---------------|-------------------|---------------|---------------|-------------------|---------------|---------------|------------------|---------------|
| | N | Av. (µg/d) | Median (µg/d) | P95 (µg/d) | Av. (µg/d) | Median (µg/d) | P95 (µg/d) | Av. (µg/d) | Median (µg/d) | P95 (µg/d) | Av. (µg/d) | Median (µg/d) | P95 (µg/d) |
| Total | 13926 | 111 | 104 | 196 | 114 | 107 | 199 | 106 | 100 | 188 | 108 | 102 | 190 |
| Female | 7029 | 103 | 97 | 174 | 104 | 99 | 176 | 98 | 93 | 168 | 100 | 95 | 169 |
| Male | 6897 | 120 | 112 | 214 | 124 | 115 | 218 | 115 | 108 | 204 | 118 | 110 | 207 |
| Aged 14 to 18 | 937 | 98 | 89 | 189 | 101 | 92 | 192 | 91 | 82 | 182 | 93 | 85 | 185 |
| Aged 19 to 64 | 10332 | 113 | 106 | 198 | 116 | 109 | 202 | 108 | 101 | 189 | 110 | 103 | 191 |
| Aged 65 to 80 | 2657 | 109 | 102 | 190 | 111 | 104 | 193 | 106 | 98 | 184 | 107 | 100 | 185 |
| Vegetarian | 212 | 103 | 98 | 178 | 105 | 100 | 179 | 97 | 89 | 180 | 99 | 91 | 183 |
| Non-vegetarian | 13714 | 111 | 104 | 196 | 114 | 107 | 199 | 107 | 100 | 188 | 109 | 102 | 190 |

* With use of non-iodised table salt in the household



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The average iodine intake (median UB) is 107 μ g/d (conventional production) and 102 μ g/d (organic production). The 95th percentile of iodine intake is 199 μ g/d (conventional production) and 190 μ g/d (organic production). Iodine intake is slightly lower in the 'Organic production' scenario. This difference could be underestimated, since only 105 of the 356 foods were sampled when stratified by production type.

With an average of 99 μ g/d, women have a lower iodine intake than men, whose average is 115 μ g/d. Adolescents (aged 14 to 18) have an average iodine intake of 92 μ g/d, which is lower than the 109 μ g/d for adults. Vegetarian participants in NVS II (n = 215) have an average of 100 μ g/d, which is a slightly lower iodine intake than non-vegetarian consumers, whose figure is 107 μ g/d (all values: median UB, conventional production). The subgroup of NVS II vegetarians also includes pescatarians, whose iodine intake as a result of consuming fish is probably higher than that of vegetarians who do not consume any fish or fish products.

The differences described here are within a comparable range for the 'Organic production' scenario.

When interpreting these results, it must be remembered that non-iodised salt was used when preparing the foods in the MEAL study kitchen. In terms of the consumption data, salt that was used for adding salt to foods in the household was also not accounted for in the exposure assessment. If iodised salt is used in the household, this would therefore result in a higher iodine intake. This would affect roughly 84% of the population in Germany (Großklaus 2017). 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). Total salt intake in Germany on the basis of spot urine tests is estimated at 8.4 and 10 g per day (median for women and men, respectively) (Johner et al. 2015). Based on these assumptions, women and men who use iodised salt (with 20 μ g iodine/kg) in the home would consume an additional 18 and 21 μ g of iodine/d on average. When aggregated with the iodine intake estimated on the basis of the BfR MEAL study (see table 6), this produces an average iodine intake (median, conventional production UB) of 117 μ g/d (women) and 136 μ g/d (men) if iodised salt is used in the household.

On the other hand, it must be remembered that the drinking water used in the BfR MEAL study for the preparation of the ready-to-eat meals and beverages has a comparatively high concentration of iodine. In regions with lower concentrations in drinking water, the iodine intake for the population will be correspondingly less.

Tables 7a and 7b present the proportion of individuals with a lower iodine intake than the estimated average requirement (EAR) of 95 μ g/d and the recommended dietary allowance (RDA) of 150 μ g/d. Table 7a shows these proportions on the basis of iodine concentration data from the BfR MEAL study, i.e. with the use of non-iodised table salt in the home. In contrast, table 7b shows the proportions for the assumption that iodised salt is used in the home. For this table, 18 and 21 μ g iodine/d were added to the individual iodine intakes for women and men, respectively.



Table 7a: Proportion of individuals with iodine intake <EAR or <RDA (%) – with use of non-iodised table salt in the household

| | | lodine intak | ke <ear (%)<="" th=""><th>lodine intak</th><th>e <rda (%)<="" th=""></rda></th></ear> | lodine intak | e <rda (%)<="" th=""></rda> |
|----------------|-------|-------------------------|---|-------------------------|-----------------------------|
| | Ν | Conventional production | Organic pro- duction | Conventional production | Organic pro- duction |
| Total | 13926 | 38 | 43 | 82 | 85 |
| Female | 7029 | 45 | 50 | 88 | 90 |
| Male | 6897 | 31 | 36 | 76 | 79 |
| Aged 14 to 18 | 937 | 53 | 59 | 86 | 89 |
| Aged 19 to 64 | 10332 | 37 | 41 | 81 | 84 |
| Aged 65 to 80 | 2657 | 40 | 44 | 85 | 87 |
| Vegetarian | 212 | 45 | 51 | 87 | 90 |
| Non-vegetarian | 13714 | 38 | 43 | 82 | 85 |

When non-iodised table salt is used, 38% (conventional production) and 43% (organic production) of individuals exhibit an iodine intake below the EAR. With a proportion of 82% (conventional production) and 85% (organic production), a majority of individuals do not achieve the level of the RDA. Similarly to the iodine intake values, a smaller proportion of women, adolescents and vegetarians achieve the reference values—regardless of the scenario (table 7a).

Table 7b: Proportion of individuals with iodine intake <EAR or <RDA (%) – with use of iodised salt (20 μ g iodine/kg) in the household

| | | lodine intak | e <ear (%)<="" th=""><th>lodine intak</th><th>e <rda (%)<="" th=""></rda></th></ear> | lodine intak | e <rda (%)<="" th=""></rda> |
|----------------|-------|-------------------------|--|-------------------------|-----------------------------|
| | N | Conventional production | Organic pro- duction | Conventional production | Organic pro- duction |
| Total | 13926 | 20 | 23 | 71 | 75 |
| Female | 7029 | 26 | 30 | 79 | 83 |
| Male | 6897 | 14 | 17 | 62 | 67 |
| Aged 14 to 18 | 937 | 34 | 41 | 78 | 83 |
| Aged 19 to 64 | 10332 | 19 | 22 | 69 | 74 |
| Aged 65 to 80 | 2657 | 20 | 22 | 74 | 77 |
| Vegetarian | 212 | 27 | 30 | 76 | 80 |
| Non-vegetarian | 13714 | 20 | 23 | 71 | 75 |



When iodised table salt is used, 20% (conventional production) and 23% (organic production) of individuals exhibit an iodine intake below the EAR—a proportion only roughly half the previous figure. Despite this, a majority of individuals—the proportions being 71% (conventional production) and 75% (organic production)—do not achieve the level of the RDA (table 7b). An iodine intake above the upper level (UL) of 500 μ g/d is present in the case of two individuals, both with the use of non-iodised salt and with the use of iodised salt—regardless of the scenario.

lodine intake via food groups

Table 8 presents the iodine intake via the individual food groups on the basis of the consumers of these food groups.

| | Conver | ntional pro UB | duction | Organ | ic product | ion UB |
|---|---------------|-------------------|---------------|---------------|------------------|---------------|
| Food group | Av. (µg/d) | Median (µg/d) | P95 (µg/d) | Αν. (μg/d) | Median (µg/d) | P95 (µg/d) |
| 01 Cereals and cereal-based products | 17.1 | 13.0 | 45.9 | 10.6 | 6.0 | 34.6 |
| 02 Vegetables and vegetable products | 2.4 | 1.6 | 6.8 | 2.5 | 1.7 | 7.4 |
| 03 Roots or tubers containing starch and their products | 2.2 | 1.4 | 6.6 | 2.5 | 0.7 | 12.7 |
| 04 Pulses, nuts, oil seeds and spices | 0.4 | 0.1 | 1.4 | 0.3 | 0.1 | 1.1 |
| 05 Fruit and fruit products | 3.4 | 2.0 | 11.1 | 4.4 | 3.3 | 13.8 |
| 06 Meat and meat products | 16.4 | 12.7 | 43.2 | 17.8 | 14.2 | 45.2 |
| 07 Fish and seafood | 24.9 | 11.2 | 78.7 | 25.3 | 11.6 | 79.2 |
| 08 Milk and dairy products | 28.2 | 20.7 | 80.4 | 26.5 | 19.1 | 76.2 |
| 09 Eggs and egg-based products | 20.5 | 13.8 | 41.4 | 23.1 | 15.5 | 46.5 |
| 10 Sugar, confectionery and water-based sweet desserts | 3.2 | 1.1 | 14.1 | 2.8 | 1.1 | 11.0 |
| 11 Animal and vegetable fats and oils | 0.7 | 0.5 | 1.8 | 0.6 | 0.4 | 1.7 |
| 12 Fruit and vegetable juices and squashes | 2.1 | 1.1 | 7.4 | 2.1 | 1.1 | 7.3 |
| 13 Water and water-based beverages | 10.2 | 8.0 | 26.4 | 10.2 | 8.0 | 26.4 |
| 14 Coffee, cocoa and tea | 11.0 | 9.3 | 25.6 | 11.1 | 9.3 | 25.9 |
| 15 Alcoholic beverages | 3.0 | 2.0 | 9.0 | 4.8 | 2.8 | 14.5 |
| 17 Vegan/vegetarian products | 2.6 | 1.2 | 10.6 | 2.3 | 0.9 | 10.5 |
| 18 Composite meals | 18.7 | 14.4 | 49.5 | 17.5 | 13.0 | 46.8 |
| 19 Spices, sauces and condiments | 5.5 | 3.8 | 16.6 | 5.5 | 3.8 | 16.6 |

Table 8: Iodine intake via food groups (consumers only) – by production type (µg/d)*

* With use of non-iodised table salt in the household

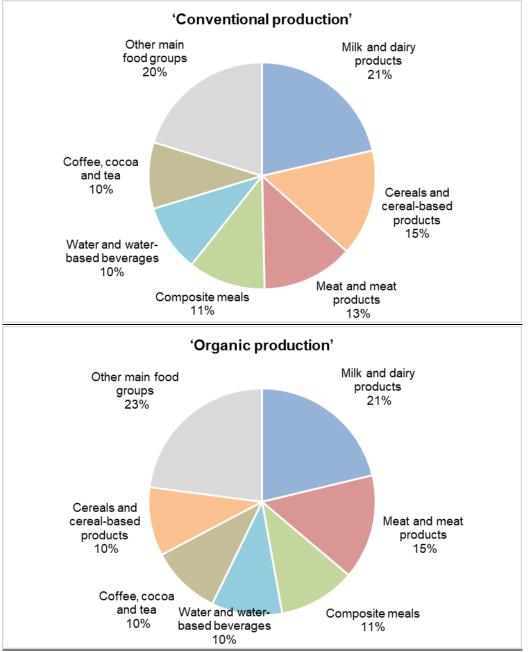
The greatest contribution to iodine intake is from 'Milk and dairy products'. The daily average intakes from this food group are 20.7 μ g of iodine (conventional production) and 19.1 μ g of iodine (organic production) (median UB). The iodine intake obtained from 'Composite meals', 'Eggs and egg-based products', 'Cereals and cereal-based products', 'Meat and meat products' and 'Fish and seafood' is 8.0–14.4 μ g/d (conventional production, median UB) and therefore within the average range. Beverages are consumed in large quantities and therefore also contribute to iodine intake. As explained above, the iodine intake from beverages made with drinking water is lower in regions with lower concentrations of iodine in the drinking water. The remaining food groups contribute a low iodine intake of 0.1–3.8 μ g/d (conventional production, median UB).



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Figure 1 shows the percentage proportions of iodine intake contributed by food groups, based on all respondents. In both scenarios, 'Milk and dairy products' makes the greatest contribution to iodine intake, at 21%. While 'Cereals and cereal-based products' is second-placed (15%) for 'conventional production', this same food group takes sixth place (10%) for 'organic production', on account of the lower iodine concentration, especially in breads and rolls. High proportions of iodine intake (10–15%) are also accounted for by 'Meat and meat products', 'Composite meals' and beverages—regardless of the scenario.

Figure 1: Proportions of food groups contributing to average iodine intake (all respondents) – by production type (%)*



* With use of non-iodised table salt in the household



lodine intake via foods

Table 9 shows the foods with the highest proportional share of average iodine intake.

Table 9: Foods with the highest share of average iodine intake (all respondents) – by production type $(\%)^*$

| | Conventional production | | Organic production |
|--------------|-------------------------------|--------------|-------------------------------|
| Share (%) | Food | Share (%) | Food |
| 8.9 | Cow's milk | 9.3 | Cow's milk |
| 6.2 | Mineral water | 6.5 | Mineral water |
| 3.7 | White breads/rolls | 3.3 | Yoghurt-based products/drinks |
| 3.7 | Yoghurt-based products/drinks | 3.1 | Instant coffee (beverage) |
| 3.0 | Instant coffee (beverage) | 2.9 | Coffee (beverage) |
| 2.6 | Coffee (beverage) | 2.7 | Drinking water |
| 2.6 | Drinking water | 2.5 | Apple, raw |
| 2.2 | Raw sausage for slicing | 2.4 | Boiled (chicken) egg |
| 2.1 | Boiled (chicken) egg | 2.4 | Raw sausage for slicing |
| 1.9 | Apple, raw | 2.0 | Boiled pork |

* With use of non-iodised table salt in the household

In both scenarios, 'Cow's milk' makes the greatest contribution to iodine intake (8.9% and 9.3%), followed by 'Mineral water' (6.2% and 6.5%). While 'White breads/rolls' (3.3%) are thirdplaced with 'conventional production', these foods are not among the top ten for 'organic production', as a result of the lower iodine concentration. Other foods in both scenarios that contribute significantly to iodine intake based on all respondents are 'Yoghurt-based products/drinks', 'Drinking water' (and water-based beverages), 'Boiled (chicken) egg', 'Raw sausage for slicing' and 'Apple, raw'.

Comparison of the top and bottom exposure quintiles

Based on the subdivision of the sample into quintiles dependent on the individual exposures, a comparison is to be made between the individuals with the lowest iodine intake (bottom quintile) and the individuals with the highest iodine intake (top quintile).

Table 10 presents the personal attributes of individuals in the bottom and top exposure quintiles. If personal attributes from the total population are compared (column 2), the proportion of women is seen to be slightly higher (63%) and significantly lower (34%) in the bottom and top quintiles, respectively, than in the total population (55%). In contrast, the proportion of men is lower (37%) and significantly higher (66%) in the bottom and top quintiles, respectively, than in the total population (45%). Age-group stratification reveals the clearest difference for the adolescent age group. In the top quintile, the proportion for this group is only roughly half that of the total population (5% versus 9%) (all values: conventional production).

The proportions are within the same range for the 'organic production' scenario.



| | | Conventiona | I production | Organic p | roduction |
|--------------------|-------|----------------------|--------------|----------------------|--------------|
| | Total | Bottom quin- tile | Top quintile | Bottom quin- tile | Top quintile |
| N | 13926 | 2828 | 2830 | 3299 | 2335 |
| Female (%) | 55 | 63 | 34 | 62 | 33 |
| Male (%) | 45 | 37 | 66 | 38 | 67 |
| Aged 14 to 18 (%) | 9 | 11 | 5 | 12 | 5 |
| Aged 19 to 64 (%) | 73 | 69 | 79 | 70 | 79 |
| Aged 65 to 80 (%) | 18 | 19 | 16 | 19 | 17 |
| Vegetarian (%) | 2 | 2 | 1 | 2 | 1 |
| Non-vegetarian (%) | 98 | 98 | 99 | 98 | 99 |

Table 10: Personal attributes of individuals in the bottom and top exposure quintiles (%)*

* With use of non-iodised table salt in the household

Table 11 presents the proportion of food groups contributing to average iodine intake for individuals in the top and the bottom exposure quintiles.

Table 11: Proportions of food groups contributing to average iodine intake (all respondents) – bottom and top exposure quintiles $(\%)^*$

| Food mount | | al production %) | Organic pro | oduction (%) |
|---|--------------------|---------------------|--------------------|-----------------|
| Food group | Bottom quintile | Top quintile | Bottom quintile | Top quintile |
| 01 Cereals and cereal-based products | 16 | 14 | 9 | 9 |
| 02 Vegetables and vegetable products | 2 | 1 | 2 | 1 |
| 03 Roots or tubers containing starch and their products | 2 | 1 | 2 | 1 |
| 04 Pulses, nuts, oil seeds and spices | 0 | 0 | 0 | 0 |
| 05 Fruit and fruit products | 3 | 2 | 4 | 3 |
| 06 Meat and meat products | 14 | 12 | 16 | 13 |
| 07 Fish and seafood | 1 | 7 | 1 | 8 |
| 08 Milk and dairy products | 15 | 28 | 16 | 28 |
| 09 Eggs and egg-based products | 2 | 4 | 2 | 6 |
| 10 Sugar, confectionery and water-based sweet desserts | 2 | 2 | 2 | 2 |
| 11 Animal and vegetable fats and oils | 1 | 0 | 1 | 0 |
| 12 Fruit and vegetable juices and squashes | 1 | 1 | 1 | 0 |
| 13 Water and water-based beverages | 14 | 6 | 14 | 6 |
| 14 Coffee, cocoa and tea | 12 | 6 | 13 | 7 |
| 15 Alcoholic beverages | 2 | 1 | 2 | 2 |
| 17 Vegan/vegetarian products | 0 | 0 | 0 | 0 |
| 18 Composite meals | 10 | 11 | 11 | 11 |
| 19 Spices, sauces and condiments | 4 | 2 | 4 | 2 |

* With use of non-iodised table salt in the household



While table 10 does not show a difference between the top and bottom percentiles in the percentage proportion of vegetarians, looking instead at the food groups (table 11) reveals a comparatively greater impact from the food groups made up of animal-based products on the total intake of individuals with high iodine intake levels (top quintile) compared with low iodine intake levels (bottom quintile). In the 'conventional production' scenario, the impact of the food group 'Fish and seafood' ranges from 1% in the bottom quintile to 7% in the top quintile. In the food group 'Milk and dairy products', this difference is 15% to 28%, and 2% to 4% for 'Eggs and egg-based products'. In contrast, the food group 'Meat and meat products' shows slightly higher proportions in the bottom quintile (14%) when compared with the top quintile (12%).

In the 'conventional production' scenario, bottom quintile, 'Cereals and cereal-based products', 'Milk and dairy products', 'Meat and meat products' and beverages make the highest contribution overall to iodine intake, with 12–16%. In the top quintile, in contrast, 'Milk and dairy products' makes the greatest contribution to iodine intake by a wide margin, at 28%. 'Fish and seafood' also contributes a significantly higher proportion (7% versus 1%) in the top quintile, while drinking water and water-based beverages show lower proportions (6% versus 14% and 12%). In the 'organic production' scenario, comparable differences can be seen between the top and bottom exposure quintiles.

Iodine intake for consumers of iodine supplements

Table 12 presents the aggregated iodine intake from food and iodine supplements for consumers of iodine supplements from NVS II (3.5%). Individuals are considered to be consumers of iodine supplements if they consumed supplements containing iodine on at least one of the 24-hour recall survey days (Heuer et al. 2012). All calculations are made on the basis of the 'conventional production' scenario.

| | | Conventional production UB | | | | | |
|---|-------|----------------------------|---------------|--|--|-----------------------------|--|
| | N | Median (µg/d) | P95 (µg/d) | lodine intake <ear (%)</ear | lodine intake <rda (%)</rda | lodine intake >UL (n) | |
| Consumers of iodine supplements – iodine in- take via foods with use of iodised salt (with 20 µg iodine/kg) in the household and supple- ments – | 493 | 210 | 361 | 0.8 | 13.0 | 6 | |
| Consumers of iodine supplements – iodine in- take via foods* and supplements – | 493 | 190 | 340 | 2.4 | 22.5 | 5 | |
| Consumers of iodine supplements – iodine in- take only via foods* – | 493 | 116 | 206 | 29.8 | 77.3 | 0 | |
| Non-consumers of iodine supplements – io- dine intake only via foods* – | 13433 | 106 | 199 | 38.6 | 82.1 | 2 | |

Table 12: Aggregated iodine intake for consumers of iodine food supplements, and iodine intake via foods for consumers of food supplements and non-consumers of food supplements

* With use of non-iodised table salt in the household

Consumers of iodine supplements who also use iodised salt in the household consume a median of 210 μ g of iodine per day. In this scenario, only four individuals (0.8%) do not achieve the EAR, while six individuals exceed the UL.



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For consumers of iodine supplements, iodine intake from foods and iodine supplements is higher in the median by 84 μ g/d than for non-consumers of iodine supplements (190 versus 106 μ g/d). Only a very low proportion of consumers of iodine supplements fail to achieve the EAR (2.4%). The proportion of consumers of iodine supplements who are below the RDA is also significantly lower than for non-consumers of iodine supplements (23% versus 82%). For five consumers of iodine supplements, the aggregated iodine intake lies above the UL.

A comparison of iodine intake achieved solely via foods reveals a slightly higher iodine intake for consumers of iodine supplements than for non-consumers of these supplements (median 116 versus 106 μ g/d).

Appendix I provides details of specific risk groups (pregnant women, breastfeeding women and women of childbearing age) as proportions of the consumers of iodine supplements from NVS II.

Comparison of iodine intake with the literature

The median iodine intake estimated in the present work on the basis of the iodine concentration data from the BfR MEAL study is comparable with the iodine intake estimated from the iodine concentration in 24-hour urine from the 'Study on adult health' (DEGS I) (Johner et al. 2016). The proportion of individuals with an iodine intake under the EAR is also comparable. Even greater agreement can be found with the scenario 'Use of iodised salt in the household', which modelled the use of iodised salt when preparing food and when adding salt to food in households (table 13). For a detailed comparison with the iodine intake estimated based on the iodine concentration data from 24-hour urine in DEGS I, a presentation was completed based on the iodine intake estimated using the iodine concentration data from the BfR MEAL study, stratified according to the DEGS I age groups (see appendices IIa and b).

The median iodine intake estimated in the present work on the basis of the iodine concentration data from the BfR MEAL study is also comparable with the results of a model calculated from the BLS iodine concentration data (MRI 2011). The consumption data from both calculation methods is taken from NVS II, although the present work uses the 24-hour recall data and the MRI paper uses the DISHES data. The median iodine intake for the present work is roughly within the range of the BLS scenario 'Without iodised salt', while the iodine intake from the scenario 'Use of iodised salt in the household' in the present work lies between the BLS scenarios 'Without iodised salt' (table 13).



| | BfR MEAL study/NVS | II 24-hour recalls (this |
|--|---------------------|--|
| | Men (aged 14 to 80) | Women (aged 14 to 80) |
| Ν | 6257 | 7669 |
| Median (µg/d) | 115 | 99 |
| Median (µg/d) – scenario 'Use of iodised salt in the household' | 136 | 117 |
| lodine intake <ear (%)<="" td=""><td>31</td><td>45</td></ear> | 31 | 45 |
| lodine intake <ear 'use="" (%)="" household'<="" in="" iodised="" of="" salt="" scenario="" td="" the="" –=""><td>14</td><td>26</td></ear> | 14 | 26 |
| | | dine intake (24-hour er et al. 2016) |
| | Men (aged 18 to 79) | Women (aged 18 to 79) |
| Ν | 3355 | 3623 |
| Median (µg/d) | 126 | 125 |
| lodine intake <ear (%)<="" td=""><td>24 - 36</td><td>26 - 46</td></ear> | 24 - 36 | 26 - 46 |
| | BLS/NVS II DIS | HES (MRI 2011) |
| | Men (aged 14 to 80) | Women (aged 14 to 80) |
| Ν | 7093 | 8287 |
| Median (µg/d) – scenario 'Without iodised salt' | 110 | 91 |
| Median (µg/d) – scenario '30% iodised salť | 164 | 129 |

Table 13: Iodine intake for the German population

A comparison of the median iodine intake estimated in the present work on the basis of iodine concentration data from the BfR MEAL study with the results of other total diet studies (TDS) reveals a wide range of values, which is probably also dependent on the variation in iodine enrichment regulations for food at national level. While the iodine intake for the population of Ireland (121 μ g/d (median)) (Mc Nulty et al. 2017) is slightly higher than that in Germany (median: 107 μ g/d), the estimated iodine intake for the US population is significantly higher still, at 216 μ g/d (median) (Abt et al. 2018). However, the urine iodine concentrations for both populations are within the range of the iodine intake estimated from the TDS data (Mc Nulty et al. 2017, Juan et al. 2016).

Uncertainty analysis

Data from NVS II are the most current and representative data available on consumption patterns in the German population. These data were collected some time ago, however, in 2005/2006. Possible changes in consumption have not been accounted for in the present analysis.

In the case of foods that are eaten only rarely, the survey period of twice a single day for the repeated 24-hour recalls is unable to accurately represent intra-individual variability in dietary habits and consumption may be underestimated.

The food list used for the BfR MEAL study covers more than 90% of consumption—but less than 100%. A slight underestimate of exposure may therefore result from this gap.

The iodine concentration and intake data shown are based on the UB approach. In 5 of the 19 food groups, there were differences between the concentration data in the mLB and UB approaches (see table 1). These differences have only a very small impact on the estimated iodine intake in the population (see table 6). When interpreting all of the results as shown, © BfR, page 52 of 59



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however, it must be remembered that a slight overestimate of iodine concentrations and of iodine intake—especially for the stated food groups—may be present when using the UB approach.

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. In addition, the salt used when adding salt to food was not reliably surveyed by the 24-hour recalls and was therefore not accounted for in the exposure assessment. This leads to a further underestimate of the iodine intake. However, this uncertainty is both accounted for and quantified by the scenario 'Use of iodised salt in the household'.

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 conventional and organically produced MEAL pools. 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.

The subgroup of vegetarians in NVS II is not representative (n = 215). Furthermore, this subgroup also includes pescatarians. Since this latter group also consumes fish, their iodine intake is probably higher than for vegetarians who do not eat fish. In all probability, this leads to an overestimate of iodine intake on the part of vegetarians who do not consume any fish.



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| | | Total | Consumers of iodine supplements | Non- consumers of iodine supplements |
|---------------------------|---|-------|---------------------------------|--|
| Total | Ν | 13926 | 493 | 13433 |
| Pregnant women | n | 62 | 11 | 51 |
| | % | 0.45 | 2.23 | 0.38 |
| Breastfeeding women | n | 54 | 14 | 40 |
| | % | 0.39 | 2.84 | 0.30 |
| Women of childbearing age | n | 2660 | 92 | 2568 |
| | % | 19.10 | 18.66 | 19.12 |

Appendix I: Consumers of iodine supplements in NVS II: pregnant women, breastfeeding women and women of childbearing age

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<u>Appendix IIa:</u> Iodine intake and proportion of individuals with iodine intake <EAR – with use of non-iodised table salt in the household (DEGS I age groups)

| | | Conventional production UB | | | | | | Organic production UB | | | | | | |
|---------------|------|----------------------------|------------|------------------|------------|------------|---|-----------------------|------------|------------------|------------|------------|---|--|
| | Ν | Av. (µg/d) | P25 (µg/d) | Median (µg/d) | P75 (µg/d) | P95 (µg/d) | lodine in- take <ear (%)</ear | Av. (µg/d) | P25 (µg/d) | Median (µg/d) | P75 (µg/d) | P95 (µg/d) | lodine in- take <ear (%)</ear | |
| Female, total | 7029 | 104 | 76 | 99 | 125 | 176 | 45 | 100 | 72 | 95 | 120 | 169 | 50 | |
| Male, total | 6897 | 124 | 88 | 115 | 149 | 218 | 31 | 118 | 84 | 110 | 142 | 207 | 36 | |
| Female (ages) | | | | | | | | | | | | | | |
| 14-17 | 369 | 84 | 58 | 77 | 103 | 156 | 69 | 77 | 53 | 71 | 96 | 146 | 73 | |
| 18-29 | 1066 | 97 | 73 | 92 | 118 | 166 | 54 | 91 | 67 | 88 | 110 | 156 | 58 | |
| 30-39 | 1034 | 111 | 82 | 105 | 132 | 179 | 39 | 105 | 78 | 99 | 127 | 174 | 46 | |
| 40-49 | 1289 | 107 | 78 | 101 | 127 | 178 | 42 | 102 | 74 | 96 | 123 | 172 | 49 | |
| 50-59 | 987 | 106 | 78 | 102 | 125 | 177 | 43 | 101 | 74 | 97 | 120 | 172 | 47 | |
| 60-69 | 995 | 108 | 78 | 102 | 129 | 176 | 42 | 104 | 77 | 98 | 124 | 169 | 47 | |
| 70-79 | 730 | 105 | 75 | 99 | 125 | 186 | 46 | 101 | 73 | 96 | 121 | 177 | 49 | |
| 80 | 21 | 114 | 86 | 98 | 116 | 328 | 48 | 112 | 84 | 99 | 117 | 323 | 48 | |
| Male (ages) | | | | | | | | | | | | | | |
| 14-17 | 375 | 116 | 82 | 107 | 138 | 217 | 37 | 106 | 74 | 97 | 130 | 203 | 47 | |
| 18-29 | 1117 | 124 | 84 | 115 | 152 | 229 | 33 | 116 | 80 | 109 | 142 | 216 | 38 | |
| 30-39 | 1044 | 127 | 93 | 119 | 153 | 218 | 27 | 120 | 88 | 114 | 144 | 207 | 31 | |
| 40-49 | 1321 | 129 | 92 | 121 | 154 | 222 | 27 | 123 | 89 | 116 | 149 | 213 | 31 | |
| 50-59 | 971 | 121 | 88 | 115 | 146 | 202 | 32 | 117 | 84 | 109 | 141 | 196 | 35 | |
| 60-69 | 947 | 121 | 87 | 113 | 144 | 215 | 33 | 116 | 83 | 108 | 137 | 209 | 38 | |
| 70-79 | 558 | 116 | 84 | 107 | 136 | 204 | 37 | 112 | 80 | 104 | 133 | 194 | 41 | |
| 80 | 12 | 117 | 88 | 117 | 139 | 171 | 33 | 113 | 88 | 117 | 137 | 166 | 33 | |
| | | | | | | | | | | | | | | |

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<u>Appendix IIb:</u> Iodine intake and proportion of individuals with iodine intake <EAR – with use of iodised salt (20 µg iodine/kg) in the household – female +18 µg iodine/d and male +21 µg iodine/d (DEGS I age groups)

| | N | | Conventional production UB | | | | | | Organic production UB | | | | | | |
|--------|------|------------|----------------------------|------------------|------------|------------|---|------------|-----------------------|------------------|------------|------------|---|--|--|
| | | Av. (µg/d) | P25 (µg/d) | Median (µg/d) | P75 (µg/d) | P95 (µg/d) | lodine in- take <ear (%)</ear | Av. (µg/d) | P25 (µg/d) | Median (µg/d) | P75 (µg/d) | P95 (µg/d) | lodine in- take <ear (%)</ear | | |
| Female | 7029 | 122 | 94 | 117 | 143 | 194 | 26 | 118 | 90 | 113 | 138 | 187 | 30 | | |
| Male | 6897 | 145 | 109 | 136 | 170 | 239 | 14 | 139 | 105 | 131 | 163 | 228 | 17 | | |
| Female | | | | | | | | | | | | | | | |
| 14-17 | 369 | 102 | 76 | 95 | 121 | 174 | 50 | 95 | 71 | 89 | 114 | 164 | 58 | | |
| 18-29 | 1066 | 115 | 91 | 110 | 136 | 184 | 30 | 109 | 85 | 106 | 128 | 174 | 37 | | |
| 30-39 | 1034 | 129 | 100 | 123 | 150 | 197 | 20 | 123 | 96 | 117 | 145 | 192 | 23 | | |
| 40-49 | 1289 | 125 | 96 | 119 | 145 | 196 | 24 | 120 | 92 | 114 | 141 | 190 | 29 | | |
| 50-59 | 987 | 124 | 96 | 120 | 143 | 195 | 24 | 119 | 92 | 115 | 138 | 190 | 27 | | |
| 60-69 | 995 | 126 | 96 | 120 | 147 | 194 | 24 | 122 | 95 | 116 | 142 | 187 | 25 | | |
| 70-79 | 730 | 123 | 93 | 117 | 143 | 204 | 27 | 119 | 91 | 114 | 139 | 195 | 29 | | |
| 80 | 21 | 132 | 104 | 116 | 134 | 346 | 29 | 130 | 102 | 117 | 135 | 341 | 29 | | |
| Male | | | | | | | | | | | | | | | |
| 14-17 | 375 | 137 | 103 | 128 | 159 | 238 | 18 | 127 | 95 | 118 | 151 | 224 | 25 | | |
| 18-29 | 1117 | 145 | 105 | 136 | 173 | 250 | 17 | 137 | 101 | 130 | 163 | 237 | 21 | | |
| 30-39 | 1044 | 148 | 114 | 140 | 174 | 239 | 11 | 141 | 109 | 135 | 165 | 228 | 13 | | |
| 40-49 | 1321 | 150 | 113 | 142 | 175 | 243 | 11 | 144 | 110 | 137 | 170 | 234 | 12 | | |
| 50-59 | 971 | 142 | 109 | 136 | 167 | 223 | 13 | 138 | 105 | 130 | 162 | 217 | 15 | | |
| 60-69 | 947 | 142 | 108 | 134 | 165 | 236 | 14 | 137 | 104 | 129 | 158 | 230 | 17 | | |
| 70-79 | 558 | 137 | 105 | 128 | 157 | 225 | 15 | 133 | 101 | 125 | 154 | 215 | 18 | | |
| 80 | 12 | 138 | 109 | 138 | 160 | 192 | 0 | 134 | 109 | 138 | 158 | 187 | 17 | | |
| | | | | | | | | | | | | | | | |



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