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For salt with potassium or sodium iodate, the simplified designation "iodised salt" is sufficient from a health perspective

Joint statement by the BfR and MRI

In brief

- Iodine is a naturally occurring trace element that is essential for human health. It is indispensable for the production of the thyroid hormones thyroxine and triiodothyronine, which are necessary for processes including normal growth, bone formation, brain and nervous system development, and metabolism.
- Overall, the natural iodine content of food in Germany is not sufficient to ensure an adequate iodine intake for the population. The use of iodised salt in food production and in private households therefore makes an important contribution to iodine supply.
- To date, only **iodates** are permitted for the production of iodised table salt in Germany, specifically as compounds with the minerals **sodium** or **potassium** (sodium and potassium iodate). Iodate and iodide are different chemical compounds of the element iodine.
- In this opinion, the German Federal Institute for Risk Assessment (BfR) and the Max Rubner-Institut (MRI) have investigated whether there is a health reason making it important for consumers to know which iodine compound is contained in iodised table salt: sodium or potassium iodate or iodide.
- According to the present scientific assessment by the BfR and MRI, there is no health reason necessitating that consumers know the exact iodine compound in iodised salt. The amount of potassium or sodium ingested through iodised salt is negligible compared to the amount of potassium or sodium ingested through a normal diet. Knowing the chemical compound (iodate or iodide) is also irrelevant for health reasons, as iodate which is ingested is almost completely converted into iodide in the body.
- In the opinion of the BfR and MRI, whether or not a salt contains iodine at all is more relevant to the purchase decision.

1 Subject of the assessment

Regulation (EU) No 1169/2011 on the provision of food information to consumers (Food Information Regulation) stipulates that ingredients must be listed in accordance with Article 18(2) of the Food Information Regulation with their specific designation, where applicable in accordance with the provisions of Article 17 and Annex VI.

If iodised table salt is added to a foodstuff, it is considered a compound ingredient under the Food Information Regulation, as it is produced from an iodine compound and a sodium or potassium compound. The individual components must therefore be indicated in accordance with Article 18(4) in conjunction with Annex VII Part E of the Food Information Regulation, for example "iodised salt (salt, potassium iodate)". Until the Food Information Regulation came into force, however, the indication "iodised salt" was sufficient.

In this opinion, the BfR and the MRI examined the question of whether there are population groups for whom knowledge of the specific iodine compound is important for health reasons.

2 Result

The BfR and the MRI conclude that, from a risk assessment perspective, simplified labelling with the sole indication "iodised salt" or "iodised table salt" does not lead to gaps in knowledge that would be relevant for health reasons, even in sensitive population groups.

In the case of iodised table salt – enriched with potassium or sodium iodate in accordance with legal requirements – the intake of the accompanying counterion (K^+, Na^+) is so low with normal salt consumption that it is insignificant compared to the intake of potassium or sodium from a normal diet.

If the corresponding iodide compounds, i.e. potassium and sodium iodide, are also approved in future, the BfR and the MRI do not believe that there are any particular population groups for whom it would be relevant for health reasons to know whether they are consuming iodine from table salt in the form of iodate or iodide compounds, as the small amounts of iodate consumed via salt are almost exclusively available to the body as iodide.

3 Rationale

3.1 Is it important for health reasons to know whether iodides or iodates are used in iodised salt?

Since 1981, only iodates (sodium and potassium iodate) have been approved for the production of iodised table salt in the Federal Republic of Germany. In other countries, sodium or potassium iodide are also used (WHO, 2004), a step currently under discussion in Germany (BfR, 2022).

The question of whether it is relevant for health reasons whether iodine from salt is absorbed in the form of iodide or iodate compounds was already investigated and answered in 2022 in a joint statement by the BfR and MRI (BfR, 2022).

The BfR and the MRI concluded that there are no nutritional, technological or toxicological data that speak against the use of iodides or iodates as food salt additives.

Iodate ingested through food is reduced to iodide in the body, making it more bioavailable. The small amounts of iodate ingested through salt are therefore almost exclusively available to the body as iodide. From the point of view of the BfR and the MRI, there are therefore no specific population groups for whom it would be relevant for health reasons to know whether they are consuming iodine from table salt in the form of iodate or iodide compounds, as the small amounts of iodate consumed via salt are almost exclusively available to the body as iodide.

3.2 Is it important for health reasons to know whether a potassium compound is used as an iodine additive in iodised table salt?

The extracellular potassium concentration in the human organism is strictly homeostatically regulated, with excess potassium being excreted via the kidneys (Domke, 2004; EFSA, 2016). In healthy people (without medically or drug-induced potassium excretion disorders), no negative health effects have been reported to date in connection with potassium intake through normal food (EFSA, 2005; EFSA Panel on Dietetic Products and Allergies, 2010, 2011a, b). However, there are certain population groups in which the homeostatic regulation of potassium is disturbed or restricted for other reasons. They are sensitive to excessive potassium intake and therefore have an increased risk of developing hyperkalaemia (potassium concentration in serum >5 millimoles (mmol) per litre (L)). These include, in particular, patients with renal insufficiency (CKD), heart failure, diabetes mellitus, adrenal insufficiency, but also infants, people aged 85 and over, people taking medication that affects potassium balance, and people who engage in extremely strenuous physical activity (EFSA, 2005; Desai, 2009). The pathophysiological mechanisms of hyperkalaemia are described in the literature (Hunter and Bailey, 2019).

In 2016, the German Nutrition Society (DGE) updated the reference values for potassium (DGE, 2016), basing its calculations on the prevention of high blood pressure and stroke. The estimated values for infants aged 0 to under 4 months are 400 milligrams (mg) per day and 600 mg per day for those aged 4 to under 12 months. For children and adolescents, the estimated values are derived from the values for adults. For 1 to under 4-year-olds, the estimated value is 1,100 mg per day, rising to 3,600 mg per day for 13 to under 15-year-olds. From 15 years of age onwards, as well as for adults and pregnant women, the estimated value is 4,000 mg per day. For breastfeeding women, the estimated value for an adequate potassium intake is 4,400 mg per day.

Potassium levels vary greatly between foods. Potassium-rich foods include raw bananas, which have a potassium concentration of 367 mg per 100 grams (g), and raw tomatoes, which have a potassium concentration of 235 mg per 100 g (Federal Food Code (BLS) 3.02). Foods low in potassium include cooked pasta (egg-free pasta) with a potassium concentration of 48 mg per 100 g and cooked bread dumplings with a potassium concentration of 36 mg per 100 g. Since potassium is water-soluble, cooked pasta has a significantly lower potassium concentration than raw pasta (200 mg potassium per 100 g) (Batista et al., 2021).

As part of a low-potassium diet for renal insufficiency, it is recommended that people consume no more than 2,000 to 2,500 mg of potassium per day and, to achieve this, specifically choose foods with a low to medium potassium concentration (Fulda, 2021; Hauner, 2010).

The current legal minimum and maximum amount of iodine in table salt is 15 to 25 mg iodine per kilogram (kg) of salt, i.e. an average of 20 mg iodine per kg of salt. Based on the molecular formula of KIO_3, iodine accounts for 59 % and potassium for 18 % of the molecular weight. For an iodine concentration of 20 mg per kg of table salt, approximately 34 mg of KIO_3 must therefore be added. According to a biomarker-based data analysis of the representative German Health Interview and Examination Survey for Adults (DEGS1) at the Robert Koch Institute (RKI), men consume 10 g of salt and women 8.4 g of salt per day (Remer and Thamm, 2015). Based on a salt consumption of 10 g per day, iodised salt enriched with KIO_3 would provide 61 micrograms (µg) (0.061 mg) of potassium per day.

The potassium intake from KIO_3-enriched iodised salt is more than 1,500 times lower than the potassium intake from a serving of cooked pasta (200 g), which can be considered low in potassium, based on a daily salt intake of 10 g.

From the perspective of the BfR and the MRI, there are therefore no specific population groups for whom it would be relevant for health reasons to know whether they are consuming iodine from table salt in the form of a potassium compound. Potassium intake from table salt enriched with KIO_3 is so negligible compared to potassium intake from other foods, including low-potassium foods, that it is irrelevant even in a recommended low-potassium diet.

3.3 Is it important for health reasons to know whether a sodium compound is used as an iodine additive in iodised table salt?

High sodium or salt intake is associated with high blood pressure (Gupta et al., 2023; Mills et al., 2020), and reducing sodium intake can lower blood pressure in people with hypertension (Filippini et al., 2021).

The American Heart Association recommends consuming no more than 2,300 mg of sodium per day, with no more than 1,500 mg per day being optimal, especially for people with high blood pressure (https://www.heart.org/en/health-topics/high-blood-pressure/changes-you-can-make-to-manage-high-blood-pressure/shaking-the-salt-habit-to-lower-high-blood-pressure).

In 2016, the DGE specified an estimated value for an adequate sodium intake of 1,500 mg per day for adults (DGE, 2016). The estimated values for infants aged 0 to under 4 months are 130 mg per day, and 200 mg per day for those aged 4 to under 12 months. For children aged 1 to under 4, the estimated value is 400 mg per day, rising to 1,400 mg per day for children aged 13 to under 15. From the age of 15 onwards, as well as for adults, pregnant women and breastfeeding women, the estimated value for an adequate intake is 1,500 mg per day.

In 2019, the European Food Safety Authority (EFSA) derived current reference values for sodium (EFSA, 2019). The panel considers 2,000 mg of sodium per day to be a safe and adequate intake for the general adult population in the EU. The same value applies to pregnant and breastfeeding women. For children aged 1 to 3 years, the value is 1,100 mg per day, for children aged 4 to 6 years it is 1,300 mg per day, for children aged 7 to 10 years it is 1,700 mg per day, and for children aged 11 to 17 years it is 2,000 mg per day. For infants aged 7 to 11 months, an adequate intake (AI) of 200 mg per day is recommended.

The DGE recommends a maximum daily intake of 6 g of table salt for adults (DGE, 2016), which corresponds to approximately 2,300 mg of sodium. According to a study by the RKI (DEGS1), the actual consumption of salt is closer to 8.4 g (women) and 10 g (men) per day (Remer and Thamm, 2015).

Based on the molecular formula of $NaIO_3$, iodine accounts for 64 % and sodium for 11.6 % of the molecular weight. For an iodine concentration of 20 mg per kg of table salt, approximately 31 mg of $NaIO_3$ must therefore be added. The sodium concentration would then be 3.6 mg sodium (from $NaIO_3$) per kg of salt. With a salt intake of 6 g, approximately 2,300 mg of sodium would be absorbed from sodium chloride and 0.022 mg (22 µg) from sodium iodate. With an intake of 10 g of salt per day, approximately 3,900 mg of sodium from sodium chloride and 0.036 mg (36 µg) of sodium from $NaIO_3$ would be consumed. This means that the sodium intake from sodium iodate is more than 100,000 times lower than that from salt (sodium chloride).

From the perspective of the BfR and the MRI, there are therefore no specific population groups for whom it would be relevant for health reasons to know whether they are consuming iodine from table salt in the form of a sodium compound. The sodium intake from $NaIO_3$ in table salt enriched with $NaIO_3$ is so low compared to the sodium intake from sodium chloride that it is irrelevant even for sensitive population groups, such as people with high blood pressure.

Furthermore, it should be noted that between January 2014 and September 2024 a search of the MINTEL database for salt products to which either potassium iodate or sodium iodate is added identified a total of 66 product names, none of which contained sodium iodate. However, the MINTEL database only includes new product launches, although products with new packaging and relaunches are also taken into account.

3.4 Further aspects

3.4.1 ALS decision of the 121st ALS meeting from 25 to 27 September 2023

In its 24 March 2022 judgement in Case C-533/20, the European Court of Justice (ECJ) ruled that Regulation (EU) No 1169/2011 (Food Information Regulation), in particular under consideration of Article 18(2), must be interpreted to mean that, in the case of foodstuffs to which a vitamin has been added, the list of ingredients of that food must include the name of the vitamin but not the name of the vitamin compound used. In the opinion of ALS and ALTS, this ruling is not transferable to the indication of minerals added for nutritional purposes in the list of ingredients (ALS, 2024) and provides the following rationale:

"The compounds listed in Annex II to Regulation (EC) No 1925/2006 are used to fortify foods with minerals. In contrast to vitamin compounds, the name of the compound in minerals always includes the name of the fortified substance, which is listed by name in the nutrition declaration. The indication of the name of the mineral compounds used in the list of ingredients has become established as the "customary name" and is to be regarded as generally accepted. Therefore, the indication of the mineral compound used as an ingredient does not result in less clear and less easily understandable information, but rather in accurate information within the meaning of Article 7(2) of the Food Information Regulation.

Unlike the names of vitamins, the indication of an element name does not represent the generic term for a group of compounds, but is the chemical name of an element that has different nutritional properties from the corresponding cation or anion of a mineral compound. The link with the counterion also provides consumers with additional information which, in particularly well-known or advertised contexts, significantly influences consumer decisions and thus, within the meaning of Article 3(1) of the Food Information Regulation*, provides consumers with a basis for making an informed choice. ALS and ALTS therefore consider that the compounds listed in Annex II to Regulation (EC) No 1925/2006 correspond to the specific names that must be listed in the list of ingredients in accordance with Article 18(2) of the* Food Information Regulation*. The mere mention of the enriched nutrients, e.g. in the form of "magnesium", "potassium", etc., in the list of ingredients is not a customary designation that sufficiently characterises the ingredient used. The opinion expressed above regarding the correct designation also applies to mineral compounds used as salt substitutes (e.g. potassium chloride) and to iodised table salt (e.g. potassium iodate).*

The BfR and the MRI fundamentally concur with the ALS decision. However, further aspects must be taken into account when labelling iodised salt. Even with simplified labelling, the term "iodised salt" would be used. This makes it clear that it is a compound (salt with iodine content), even if the exact iodine compound is not specified. Furthermore, until 2014, the simplified labelling "iodised salt" or "iodised table salt" had been common practice for many years and had thus established itself as a "customary designation". From the point of view of the BfR and the MRI, knowledge of the mineral compound used in other products, such as in food supplements, is important because it is generally consumed in larger quantities and therefore represents important additional information for consumers.

In the case of iodised salt, it is likely that knowledge of whether the salt contains iodine is the main factor influencing consumer decisions, particularly because simplified labelling had already been established and accepted for years prior to 2014. It can therefore be assumed that knowledge of the exact iodine compound does not constitute additional information that would significantly influence consumer decisions. This knowledge is also not relevant for health reasons.

Further information on iodised salt on the BfR website

FAQ: Iodine intake in Germany on the decline again – tips for a good iodine intake
https://www.bfr.bund.de/en/service/frequently-asked-questions/topic/iodine-intake-in-germany-on-the-decline-again-tips-for-a-good-iodine-intake/

BfR Opinion: Declining iodine intake in the population: model scenarios to improve iodine intake in children and adolescents
https://www.bfr.bund.de/cm/349/declining-iodine-intake-in-the-population-model-scenarios-to-improve-iodine-intake-in-children-and-adolescents.pdf

Information portal microco.info on iodine:
https://www.microco.info/minerals/iodine/

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About the MRI

The Max Rubner Institute (MRI), Federal Research Institute for Nutrition and Food, focuses its research on consumer health protection in the field of nutrition and food. It advises the Federal Ministry of Agriculture, Food and Regional Identity (BMLEH) in these areas. Important research priorities include the nutritional and health value of food, eating habits, and food safety and quality.

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