

22 September 2025

Metal kitchen utensils: Do substances transfer into food?

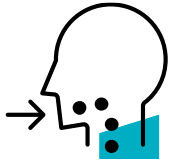
Results from regional authorities give no cause for concern

In brief

- In many kitchens, uncoated and enamelled metal items such as pots, pans and cutlery come into daily contact with food. Small amounts of elements from the materials can transfer into food and thus be ingested by humans.
- There are currently no legal limit values in the EU for the release of elements from uncoated and enamelled metal items into food. However, there is a technical guide from the Council of Europe on metals and alloys and a technical standard for enamelled items in contact with food.
- In 2022, 194 metal items, both uncoated and enamelled, were examined as part of a nationwide monitoring programme. The regional authorities of the German federal states ("Laender") investigated which elements can be transferred from the materials into food in which amounts.
- The German Federal Institute for Risk Assessment (BfR) evaluated the results of this study and assessed whether the amounts released could pose health risks. To this end, the daily intake amounts were estimated based on the element release measurements. These were then compared with health-based guidance values (HBGV) or toxicological reference values.
- Most of the items examined released only very small amounts of the elements in question. It is the opinion of the BfR that these products are therefore suitable for contact with food.
- However, some items contributed substantially to people's daily intake of certain elements, especially when other sources such as food were also taken into account. The BfR recommends that manufacturers of such items improve materials and production processes in order to further reduce the release of elements into food.

- Only a few items released elements to a degree that could exceed the derived HBGV or toxicological reference values and thus increase the risk of the occurrence of health impairments. From a toxicological point of view, these items are not suitable for contact with food.

How do substances from metal kitchen utensils enter the body?



The intake of substances from metal food contact materials occurs **orally** via food. During the preparation, storage, or consumption of food, small amounts of elements from uncoated or enamelled items such as pots, pans, baking trays, crockery, or cutlery can migrate into the food.

Is there a health-based guidance value?



Yes, there are health-based guidance **values** (HBGV) for most elements that can be released from the materials. They describe the amount of a substance that, when ingested, is not expected to pose any health risks to consumers.

For some elements, no HBGV could be derived, either because the data available was not sufficiently conclusive or because, based on current knowledge, there is no intake amount for the element in question that does not pose a health risk.

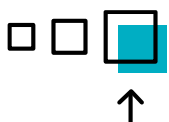
There are currently **no uniform legal limit values** for metal food contact materials, but there is a technical guide from the Council of Europe on metals and alloys and a technical standard for enamelled items in contact with food.

Is there a health risk?



Most of the items examined released only very small amounts of elements. In the BfR's view, these products are therefore suitable for contact with food. However, for individual items, the derived health guidelines were exceeded under the assumed conditions of use. In these cases, there may be an increased health risk for consumers.

What is the quality of the data?



The quality of the data is **high**. A total of 194 uncoated or enamelled metal objects were examined by the regional authorities of the German federal states ("Laender"). In the BfR's opinion, the established selection procedure for the samples results in a sample that is representative of the market as a whole. Nevertheless, items with higher element releases than those described here could also be on the market.

For most elements, especially those for which release has been frequently observed, the toxicological data is good. For some elements, however, there is only incomplete data or studies of low significance.

How can the health risk be reduced?



The government can continue to monitor and assess the quality of marketed products through regional authorities of the German federal states and regular monitoring programmes.



Most of the items examined released only very small amounts of metals.
Manufacturers of items with excessive element releases should review and improve their raw materials and production processes to reduce health risks to consumers.



Consumers should follow the manufacturer's instructions for use, cleaning, and treatment of the items before first use.

1 Introduction

Uncoated and enamelled metal items intended to come into contact with food are ubiquitous in the kitchen and include pots, pans, baking trays, and cutlery. If elements are released from these objects, they can migrate into food and be ingested. Currently, there are no harmonised legal limit values in the EU for the release of elements from these metal items. However, there are recommendations from the European Directorate for the Quality of Medicines for the release from uncoated metal food contact materials (EDQM, 2024) and the standard DIN EN ISO 4531:2022 for enamelled items for contact with food.

In 2022, the German regional authorities of the German federal states ("Laender") investigated the release of elements from metal food contact materials as part of the monitoring programme. The release of 21 different elements from a total of 194 uncoated or enamelled metal objects was investigated.

The German Federal Institute for Risk Assessment (BfR) used the results of the monitoring programme as an opportunity for health risk assessment of the potential intake of the released elements through food. To this end, the estimated daily intake of the elements from the released amounts was compared with the health-based guidance values (HBGV) or toxicological reference values derived from current studies.

A comparison of the release quantities with the maximum values from the above-mentioned standard and the technical guide provided by the Council of Europe showed that the vast majority of uncoated and enamelled metal items release only small amounts of elements. The

risk assessment based on the exposure assessment carried out showed that these items are suitable for food contact. However, with regard to overall exposure, taking into account possible additional sources of intake (such as food), the BfR considers that some objects contribute too much to the daily intake of certain elements. The BfR recommends that manufacturers of these products review their raw materials and manufacturing processes in order to further reduce element release. Only a few items showed element releases that could exceed the derived HBGV or toxicological reference values and thus increase the risk of the occurrence of health impairments. From a toxicological point of view, these items are not suitable for contact with food.

2 Subject of the assessment

In 2022, regional authorities from ten German federal states ("Laender") investigated uncoated and enamelled metal kitchen items with regard to the possible release of elements into food. Currently, there are no legal limit values in the EU for the release of elements from metal food contact materials or enamelled food contact materials. However, according to legal requirements, food contact materials must comply with current technical standards and must not release substances into food in amounts that could pose a health risk to consumers. In its recently updated technical guide on metals and alloys in food contact, the Council of Europe has derived specific release limits (SRLs) for a large number of elements as an interpretation of this general legal provision (EDQM, 2024). For enamelled metal items, the recently revised standard DIN EN ISO 4531:2022 applies, which contains release limits for enamelled items in contact with food (DIN EN ISO, 2022).

The German Federal Institute for Risk Assessment (BfR) has taken the monitoring results as an opportunity to assess the release of the 21 analysed elements from metallic food contact materials in accordance with the latest toxicological findings.

3 Result

To assess the proper manufacture of uncoated metal items, the element releases in the third consecutive migration test were compared with the SRLs of the Council of Europe technical guide on metals and alloys in food contact published in 2024 (EDQM, 2024). 99.1% of the 115 samples tested demonstrated compliance with these assessment values in the third migration test. Only one sample (cast iron pan) was conspicuous and showed increased releases of iron and cobalt. Element releases in the third migrant are used for the assessment of multi-use items (such as cutlery, pans, cups, etc.), as it more realistically reflects the long-term, repeated release of substances than the first migrant.

The limit values for element release specified in DIN EN ISO 4531:2022 were used to assess the proper manufacture of enamelled products. Here, the release quantities from 53.2% of the 79 samples tested in the third migrant were below all respective limit values.

It should be noted that, out of a total of 194 samples, 24 samples exceeded the respective limit value for the release of a single element and 14 samples exceeded the respective limit values for the release of several elements. Aluminium release exceeded the limit value most frequently (33 samples). The high overall number of samples (80.4%) that demonstrate compliance with all release limits clearly shows that it is possible to manufacture such

products with low element releases. Manufacturers of products with excessive element releases should review and adjust their raw materials and production processes accordingly in order to further reduce element releases.

An exposure assessment was carried out based on the element releases from the respective metal objects in the third migration. For a risk assessment, exposure to the released elements was then compared with the respective tolerable daily intake (TDI) or comparable health-based guidance values (HBGV). If the intake of the elements from sources other than food contact materials already almost or completely exhausts the respective HBGV, additional allocation factors were included in the consideration. No HBGV could be derived for arsenic, beryllium, lead and thallium. For beryllium and thallium, this was due to insufficient data and for arsenic and lead the reason was that, according to the current state of research, no intake level without adverse health effects is known for these elements. In the EU, the ALARA principle ("As Low As Reasonably Achievable") is to be applied for risk management in such cases. In the event of an unavoidable release of these elements from food contact materials, resulting intake levels were identified that should not be exceeded under any circumstances.

In 186 of 194 samples tested, the element releases did not result in any exceedance of an HBGV or toxicological reference value. In the BfR's opinion, the remaining 8 items should not be used for contact with food. However, when allocation factors were applied, the calculated exposure values for 39 samples (20.1%) exceeded the assigned HBGV for one or more elements or the values considered to be the maximum unavoidable exposure to arsenic or lead. In most of these samples, the occurrence of exceedances occurred for only a single element, while in 11 samples (5.7%), several elements were affected. Since the use of these objects can contribute significantly to the overall intake of some elements, the BfR believes that manufacturers should revise their raw material qualities and manufacturing processes so that exposure from these food contact materials is below the allocated HBGV for all elements and below an exposure contribution of 0.003 mg lead/person/day and 0.00036 mg arsenic/person/day.

However, the vast majority of uncoated and enamelled metallic materials showed low to very low element release and are suitable for food contact.

4 Rationale

4.1 Risk assessment

4.1.1 Hazard identification

Metal kitchenware, especially enamelled kitchenware, may contain a variety of different elements due to the manufacturing process, including heavy metals such as lead, cadmium and cobalt. When in contact with food, these elements may be released from the metal objects and transferred to the food. Excessive intake of such elements by humans may result in an increased risk of the occurrence of health impairments. The type and amount of elements released depend on various factors, including the composition of the contact material and the material quality of the items, the temperature and type of use, the type of food (e.g. acidic, liquid or solid food) and the duration of contact between the metal object and the food.

4.1.2 Hazard characterisation

In order to determine the amounts in which elements can be released from such metal objects during use, release tests were carried out for 21 different elements. The results of the release tests show that most of the consumer goods tested release only small amounts of elements or even that the element releases were below the limit of quantification or detection. Nevertheless, in order to provide a comprehensive picture, the toxicological properties of all tested elements are presented below, regardless of the extent of release. In addition, exposure to these elements from other sources, such as food, is taken into account. If intake from such sources already largely or completely exhausts the respective HBGV or toxicological reference value, additional allocation factors are included in the assessment. There are a wide variety of approaches to the use of allocation factors worldwide (Greene et al, 2025). In this opinion, an allocation factor of 10% was used if the respective HBGV was more than 50% exhausted by intake from other sources, and 20% if the exhaustion was more than 10%. If other sources of intake are known but the intake from these sources is less than 10% of the HBGV, no allocation factor was used. For arsenic, lead and thallium, for which no HBGV could be derived for various reasons, an allocation factor of 10% of the respective toxicological reference value was used.

4.1.2.1 Aluminium

According to the current state of research, aluminium is neither genotoxic nor carcinogenic (COT, 2013; EFSA, 2008). However, it is neurotoxic, nephrotoxic and toxic to reproduction (SCCS, 2014). Developmental neurotoxicity is considered the most critical endpoint (EFSA, 2008). Aluminium is poorly absorbed after oral intake, usually less than 1% (BfR, 2019). It is distributed throughout all tissues, with accumulation occurring particularly in the bones (COT, 2013; EFSA, 2008; JECFA, 2012). Due to its accumulation behaviour and the adverse effects described, the European Food Safety Authority (EFSA) derived a tolerable weekly intake (TWI) of 1 mg/kg body weight (bw)/week instead of a tolerable daily intake (TDI) for aluminium (EFSA, 2008). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has derived a provisional TWI (PTWI) of 2 mg/kg bw/week (JECFA, 2012).

The main sources of exposure to aluminium are food and drinking water. EFSA estimates the average weekly aluminium intake for an adult to be 0.2 to 1.5 mg/kg bw/week (EFSA, 2008). Dermal intake of aluminium from cosmetic products such as antiperspirants contributes little to overall exposure to aluminium (BfR, 2023). Since intake of aluminium via food can already exhaust the EFSA TWI of 1 mg/kg bw/week, the release of aluminium from food contact materials should be kept to a minimum. An allocation factor of 10% is considered appropriate for the contribution from food contact materials, in line with Regulation (EU) No 10/2011. The release of aluminium from food contact materials should be as low as possible, but in the BfR's opinion, an oral intake of 6 mg/week of aluminium from food contact materials should not be exceeded for a person weighing 60 kg.

4.1.2.2 Antimony

EFSA has assessed antimony as non-genotoxic (EFSA, 2004). However, antimony trioxide is classified as a possible carcinogen (Carc. 2) in accordance with the Regulation on Classification, Labelling and Packaging (CLP Regulation). The World Health Organisation (WHO) derived a TDI from an oral subchronic animal study with antimony trioxide (Poon et al., 1998). The NOAEL

("no observed adverse effect level") of 6 mg/kg body weight was used to derive the TDI of 6 µg/kg bw/day (WHO, 2003; WHO, 2022; Lynch et al., 1999).

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) estimates the average daily intake of antimony through food to be 0.03 µg/kg bw/day for adults and 0.04 µg/kg bw/day for children (ANSES, 2011). Accordingly, dietary exposure is well below the TDI, and the application of an allocation factor for the contribution from food contact materials is not necessary. In the BfR's view, an oral intake of 0.36 mg antimony/day from food contact materials should not be exceeded for a person weighing 60 kg.

4.1.2.3 Arsenic

According to the current state of research, arsenic and inorganic arsenic compounds are carcinogenic and toxic to reproduction (EFSA, 2024 a; IARC, 2012; the BfR, 2015). They also induce DNA damage, in particular clastogenic and aneugene effects (EFSA, 2024 a). As there is no trigger threshold for genotoxic-carcinogenic effects, the "margin of exposure" approach is used for risk assessment. This involves calculating the margin between the daily intake and a toxicological reference point. EFSA used the "benchmark dose lower confidence limit" (BMDL) based on an epidemiological study on skin cancer as a reference point (EFSA, 2024 a). This BMDL represents the lower confidence limit of what is known as a benchmark dose (BMD), meaning the dose at which a certain change would be observed compared to the control. For the study mentioned, EFSA 2024 derived a BMDL₀₅ of 0.06 µg inorganic arsenic/kg bw/day (EFSA, 2024 a). Due to its genotoxic and carcinogenic effects, arsenic intake should be as low as possible.

Arsenic is mainly ingested through food and is found in particular in rice and other grains. For rice (products), Regulation (EU) 2023/915 sets maximum levels between 0.03 and 0.30 mg inorganic arsenic/kg fresh weight. For fruit juices and baby food, the maximum levels are between 0.01 and 0.02 mg/kg. According to EFSA (2021), the average dietary exposure to arsenic for adults is between 0.03 and 0.15 µg/kg bw/day. In its opinion, EFSA did not make any recommendations as to what margin of exposure would be sufficiently safe. In any case, exposure through food already leads to very low margins of exposure. In general, arsenic intake should be as low as possible. The release of arsenic from food contact materials should therefore be as low as technically possible, and food contact materials should not contribute significantly to arsenic exposure in the opinion of the BfR. As part of a pragmatic approach in cases of unavoidable arsenic exposure from food contact materials, these should not exceed 10% of the above-mentioned BMDL₀₅ (corresponding to an intake of 0.36 µg/day for a person weighing 60 kg).

4.1.2.4 Barium

Barium can cause cardiovascular effects after oral intake, but the most sensitive endpoints are nephropathies (Kravchenko et al., 2014; EU-FORA, 2022). The BfR considers the TDI of 0.2 mg barium/kg bw/day derived by the Agency for Toxic Substances and Disease Registry (ATSDR) and recognised by the Scientific Committee on Health and Environmental Risks (SCHER) to be appropriate for risk assessment (ATSDR, 2007; SCHER, 2012). The derivation was based on a chronic study in mice (reference point: BMDL₀₅ for nephrotoxic effects).

The intake of barium from food is negligible in adults at 7.5 to 9 µg/kg bw/day (Health Canada, 2005), so no allocation factor is applied here. In the BfR's opinion, a daily oral intake of 12 mg barium/day from food contact materials should not be exceeded for a person weighing 60 kg.

4.1.2.5 Beryllium

Beryllium occurs in some metals and alloys in the form of impurities, but rarely as an alloy component. There is little data on the toxicity of beryllium when ingested orally; most studies have been conducted to determine its inhalative toxicity. Although the WHO (2009) attempted to derive a TDI, the BfR considers the derivation of a TDI for beryllium to be inappropriate due to insufficient data and is therefore unable to derive a tolerable daily intake (TDI).

4.1.2.6 Lead

Lead is classified as toxic to reproduction (Repr. 1A) in accordance with the CLP Regulation and is therefore identified as a substance of very high concern. The EFSA CONTAM Panel identifies cardiovascular effects and renal toxicity in adults and developmental neurotoxicity in children as the most critical health effects of lead (EFSA CONTAM, 2010). Based on current knowledge, there is no threshold for the effects described. Therefore, EFSA has not established a tolerable daily intake (TDI) value for lead. A BMDL₀₁ value of 1.5 µg/kg bw/day has been established for cardiovascular effects, a BMDL₁₀ value for renal toxicity of 0.6 µg/kg bw/day and a BMDL₀₁ value for developmental neurotoxicity in children and adolescents (endpoint: reduction in intelligence quotient) of 0.5 µg/kg bw/day derived. The BfR considers the lowest value, the BMDL₀₁ for developmental neurotoxicity of 0.5 µg/kg bw/day, to be a suitable reference point for risk assessment.

Human exposure to lead occurs mainly through food, such as cereal products, and drinking water. In adults, the average daily intake of lead through food is 0.36 to 1.24 µg/kg bw/day, and in children it is even higher, at 0.80 to 3.10 µg/kg bw/day (EFSA CONTAM, 2010). This dietary intake is already well above the BMDL₀₁ value of 0.5 µg/kg bw/day derived by EFSA. However, more recent figures from Germany estimate the daily dietary lead intake of adults to be significantly lower, at 0.07 to 0.17 µg/kg bw/day (Kolbaum et al., 2019). Nevertheless, this still results in very low margins of exposure. In general, lead intake should be as low as possible. The release of lead from food contact materials should therefore be as low as technically possible, and food contact materials should not contribute significantly to lead exposure in the opinion of the BfR. However, this contribution should not exceed 10% of the above-mentioned BMDL₀₁ under any circumstances. Unavoidable lead exposure from food contact materials should not exceed a daily oral intake of 3 µg lead/day for a person weighing 60 kg.

4.1.2.7 Cadmium

In accordance with the CLP Regulation, cadmium is classified as carcinogenic, probably toxic for reproduction and probably mutagenic (Carc. 1B, Repr. 2, Muta. 2)-. Cadmium and some of its compounds are identified as substances of very high concern and may only be used in a restricted manner under the REACH Regulation (ECHA, 2016 a). EFSA found no evidence that cadmium acts as a carcinogen after oral intake (EFSA, 2009). The most critical effect of long-term exposure to cadmium is considered to be renal toxicity. Based on this endpoint, the EFSA's CONTAM Panel derived a TWI of 2.5 µg/kg bw/week for cadmium (EFSA, 2009).

The main source of exposure to cadmium is food such as grain, vegetable and starchy roots (BfR, 2009). EFSA estimated the average weekly dietary intake of cadmium to be 2.04 µg/kg bw/week (EFSA, 2012 a). As this average dietary exposure already accounts for a large proportion of the TWI, an allocation factor of 10% is applied to cadmium exposure from food

contact materials. The release of cadmium from food contact materials should be as low as possible, but should not exceed a tolerable oral intake of 0.015 mg cadmium/week from food contact materials for a 60 kg person.

4.1.2.8 Chromium

Chromium occurs naturally mainly as chromium(III). In food, which typically has a slightly acidic pH value, higher oxidised chromium compounds such as chromium(VI) compounds are unstable and decompose into chromium(III) compounds. The EFSA CONTAM Panel therefore decided to consider all chromium values in food as chromium(III). It derived a TDI of 0.3 mg/kg bw/day for chromium from the lowest NOAEL in an animal study on chronic oral toxicity (EFSA CONTAM, 2014).

The average dietary intake of chromium is estimated by the German, Austrian and Swiss Society for Nutrition to be between 61 and 84 µg/day (D-A-CH, 2019; BfR, 2021). For children, EFSA estimates the average intake of chromium to be between 54.3 and 83.4 µg/day (EFSA CONTAM, 2014). According to this, dietary exposure is well below the TDI and the application of an allocation factor is not necessary. From the BfR's point of view, a daily oral intake of chromium from food contact materials should not exceed 18 mg/day for a person weighing 60 kg.

4.1.2.9 Cobalt

Cobalt is classified in the CLP Regulation as carcinogenic, toxic to reproduction and probably mutagenic (Carc. 1B, Repr. 1B, Muta. 2) (ECHA, 2016 b). In view of the lack of recent studies on the chronic toxicity of cobalt, the BfR bases its risk assessment on the conservative TDI of the French Food Safety Agency (AFFSA). This is based on a subacute human study following oral cobalt intake, with the haematological endpoint of cobalt-induced polycythaemia (Davis et al., 1958). From this study, the AFFSA derived a TDI of 1.6 µg cobalt/kg bw/day (AFFSA, 2010). More recent animal data also support this value (Danzeisen et al., 2020). The Netherlands National Institute for Public Health and the Environment (RIVM) previously derived a TDI of 1.4 µg/kg bw/day from several studies on the consumption of alcoholic beverages containing cobalt salt, with cardiomyopathy as the endpoint (RIVM, 2001). The BfR does not follow this derivation due to various contradictions in the original literature, but instead uses the AFFSA TDI of 1.6 µg cobalt/kg bw/day (BfR, 2020).

According to EFSA, the daily intake of cobalt is between 0.005 and 0.029 mg cobalt/day (EFSA, 2012 b). Since half of the TDI may already be exhausted by other sources, the BfR considers it justified to apply an allocation factor of 20% of the acceptable daily intake for the contribution from metal food contact materials.

For the establishment of a specific release limit (SRL) for cobalt from uncoated metal objects, the Council of Europe set an SRL of (rounded) 0.02 mg/kg food (simulant) for cobalt in its technical guide on Metals and Alloys (EDQM, 2024). Since cobalt oxide is necessary for the production and function of enamel, DIN EN ISO 4531:2022 specifies a significantly higher SRL for cobalt of 0.1 mg/kg food (simulant) for enamelled food contact items. Based on the (conservative) standard assumption of 60 kg body weight and 1 kg food consumption/day, the TDI would thus already be exhausted. However, from the BfR's point of view, a daily oral cobalt intake of 0.02 mg/day from food contact materials should not be exceeded for a person weighing 60 kg, taking into account the 20% allocation.

4.1.2.10 Iron

Iron is ubiquitous in the environment and in the human body, for example in haemoglobin as a component of red blood cells. Both an undersupply and an oversupply of iron can lead to health impairments. Chronically excessive iron intake can be associated with organ damage, for example to the liver or the intestine. This has been observed in individuals with impaired iron absorption or in people who have taken daily food supplements containing iron in the range of 100 to 1000 mg for over 15 years. In 2024, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was unable to derive an upper limit for daily iron intake based on this data, but found that, according to studies, supplementation of up to 25 mg of iron per day does not lead to adverse effects in humans. Together with the background intake, EFSA calculated a safe level of intake for iron at 40 mg/day for adults (EFSA NDA 2024).

According to the National Consumption Study II, the average daily iron intake for men and women aged 14–80 is 15.2 mg/day and 12.3 mg/day, respectively (MRI, 2022). Iron is a necessary component of many metal food contact materials. Since the safe intake level for iron is thought to be well below a problematic intake level and only about one-third of this is absorbed from food, no allocation factor is used here. For a person weighing 60 kg, the BfR recommends that a daily oral intake of 40 mg/day of iron from food contact materials should not be exceeded.

4.1.2.11 Copper

Similar to iron, copper is also an essential trace element for humans, and both a deficiency and excessive exposure to copper can have adverse health effects. Increased copper retention in the liver is considered an early indicator of potentially harmful effects from chronically excessive copper intake (EFSA, 2023). EFSA has set an acceptable daily intake (ADI) of 0.07 mg/kg bw/day (EFSA, 2023).

According to EFSA, dietary copper exposure for adults is 0.015 to 0.022 mg/kg bw/day (equivalent to 0.9 to 1.32 mg/day for a 60 kg person) (EFSA, 2023). This is consistent with previous EFSA data on average copper intake in eight EU German federal states ("Laender"), which ranged from 1.27 to 1.67 mg/day for men and 1.15 to 1.44 mg/day for women (EFSA, 2015). As a considerable proportion of the ADI is already consumed through food, the BfR considers an allocation factor of 20% to be appropriate. According to the BfR, a person weighing 60 kg should not exceed a daily oral intake of 0.84 mg/day of copper from food contact materials.

4.1.2.12 Lithium

Since lithium is used therapeutically, most toxicological studies on lithium are based on clinical investigations of patients treated with lithium (EU-FORA, 2022). The most commonly observed adverse effects include kidney damage and hypothyroidism (McKnight et al., 2012). Lithium salts are used to treat mental disorders. The US Environmental Protection Agency (EPA) uses the lower limit of the therapeutic serum lithium concentration range as the LOAEL (lowest-observed-adverse-effect-level) to derive a preliminary chronic reference dose (RfD). This corresponds to an oral lithium intake of approximately 2.1 mg Li/kg bw/day. With an uncertainty factor of 1000 (10 for extrapolation from a LOAEL to a NOAEL, 10 for intraspecies differences and 10 to account for inadequacies in the database), this results in an RfD of 0.002 mg/kg bw/day (EPA, 2008). However, no TDI for lithium could be derived from this study. Overall, the BfR has no new reliable toxicological data on lithium, so it continues to follow the

TDI of 0.008 mg/kg bw/day derived by the RIVM in 1991 (RIVM, 1991), in line with the Council of Europe technical guide on metals and alloys.

The lithium exposure of the population through the environment and food intake can vary considerably depending on the region (Iordache et al., 2024). The average daily intake of lithium in adults has been estimated at 48.2 µg/day in France (ANSES, 2011), 17 µg/day in England (Ysart et al., 1999) and 18.5 µg/day in Italy (Filippini et al., 2020). Lithium is a necessary matrix element for the production of enamels. Since other exposure to lithium is significantly below the TDI, it is considered acceptable for the risk assessment of exposure through food contact materials to use the TDI without applying an allocation factor. From the BfR's point of view, a daily oral intake of lithium from food contact materials should not exceed 0.48 mg/day for a person weighing 60 kg.

4.1.2.13 Manganese

Human and animal studies show that neurotoxicity is the most critical effect of excessive manganese intake (EFSA NDA, 2023; Kern et al., 2010). The French ANSES uses 55 µg/kg bw/day as a toxicological reference value, derived from a rat study with a LOAEL of 25 mg/kg bw/day, using neurological effects as the endpoint (ANSES, 2018; Valcke et al., 2018). However, according to the EFSA opinion on manganese from 2023, many studies are insufficient to show a clear dose-effect relationship for manganese toxicity and to derive a tolerable upper limit for daily manganese intake. Nevertheless, EFSA determined a safe level of intake at which it can be assumed with sufficient certainty that no harmful effects will occur. This value is 8 mg/day for adults (EFSA NDA, 2023).

The main source of manganese intake is food, with grain-based foods, fruit, vegetables and nuts in particular containing high levels of manganese. According to EFSA, the average daily intake of manganese is between 2.60 and 5.25 mg/day for men and between 2.20 and 4.69 mg/day for women (EFSA NDA, 2023). These values are consistent with earlier studies, such as the French Total Diet Study, which found that the average exposure for adults was 2.16 mg/day (ANSES, 2011), and the UK Total Diet Study, which found the mean daily intake for adults to be 62 µg/kg bw/day (approx. 3.7 mg/day for 60 kg bw) (FSA, 2014). Since daily intake from food already accounts for a significant proportion of the safe intake, an allocation factor of 20% is applied to intake from food contact materials. From the BfR's point of view, taking into account the 20% allocation, an oral intake of 1.6 mg manganese/day from food contact materials should not be exceeded for a person weighing 60 kg.

4.1.2.14 Molybdenum

Various observational studies have linked excessive molybdenum intake to joint pain and arthritis-like symptoms, but there are no reliable chronic studies in humans that can be used for risk assessment (Hosokawa et al., 1994; Vyskocil et al., 1999). The Scientific Committee on Food (SCF) set the tolerable upper intake level (UL) for molybdenum at 0.6 mg/day (SCF, 2000; EFSA, 2024 b). This value was based on a study of reproductive toxicity in rats, in which the NOAEL was 0.9 mg/kg bw/day (uncertainty factor: 100) (Fungwe et al., 1990).

According to ANSES, the average daily molybdenum intake for adults is 93.9 µg/day and, according to EFSA, 58 µg/day in Germany (ANSES, 2011; EFSA, 2013). Since a significant proportion of the UL is already exhausted by other sources of exposure, an allocation factor of 20% is used for the intake of molybdenum from food contact materials. From the BfR's

point of view, a daily oral intake of 0.12 mg molybdenum/day from food contact materials should not be exceeded for a person weighing 60 kg, taking into account the 20% allocation.

4.1.2.15 Nickel

Elemental nickel is classified as a probable carcinogen (Carc. 2) in the CLP Regulation. A large number of soluble nickel compounds are also classified as toxic to reproduction (Repr. 1B), carcinogenic by inhalation (Carc. 1A) and probably mutagenic (Muta. 2). Nickel and its compounds are a common trigger of contact allergies. Around 15% of the German population is sensitised to nickel (BfR, 2012; Ahlström et al., 2019). Chronic oral exposure to nickel can lead to the occurrence of various organ damage (especially to the liver and kidneys) as well as damage to the nervous and immune systems. In its latest re-evaluation, EFSA derived a TDI of 13 µg/kg bw/day, which the BfR uses as the basis for its risk assessment (EFSA CONTAM, 2020). Reproductive toxicity (loss of embryos after implantation) was identified as the most sensitive endpoint after chronic oral exposure in a study on rats. While the WHO derived a TDI of 12 µg/kg bw/day in its 2017 "Guidelines for Drinking-water Quality" based on a study on the triggering of allergies in already sensitised people through the intake of nickel with drinking water, it has also been following the EFSA TDI since 2022 (WHO, 2017; WHO, 2022).

The main exposure to nickel is through food. The average dietary exposure to nickel calculated by EFSA is in a range between 2.90 and 3.41 µg/kg bw/day (0.174 mg/day to 0.204 mg/day) for adults (EFSA CONTAM, 2020). In view of possible toxicological effects and the fact that a significant proportion of the TDI is already exhausted by other sources of exposure, consumer exposure to nickel from food contact materials should be as low as possible, but should not exceed 20% of the TDI. From the BfR's point of view, a daily oral intake of 0.156 mg nickel/day from food contact materials should not be exceeded for a person weighing 60 kg, taking into account the 20% allocation.

4.1.2.16 Selenium

Selenium is an essential trace element for the human body, but chronically elevated selenium intake can cause toxic effects, which are often summarised under the collective term 'selenosis'. These include structural damage and loss of hair and nails, as well as neurological disorders (ATSDR, 2003; Fairweather-Tait et al., 2011). A LOAEL value for alopecia as an early sign of selenium toxicity was derived from a large randomised controlled trial in humans and is 330 µg/day (Lippman et al., 2009). Applying an uncertainty factor of 1.3, the EFSA NDA Panel derived a tolerable upper intake level of 0.255 mg/day for the European population (EFSA NDA, 2023).

The main source of selenium intake is food, particularly dairy and meat products, fish and cereal products. The average daily intake for adults is between 42.7 and 65.6 µg/day for men and between 35.8 and 50.5 µg/day for women (EFSA NDA, 2023). Since daily selenium intake from food already accounts for a significant proportion of the tolerable total daily intake, an allocation factor of 20% is applied to intake from food contact materials. In the BfR's view, a daily oral intake of 0.051 mg selenium/day from food contact materials should not be exceeded for a person weighing 60 kg, taking into account the 20% allocation.

4.1.2.17 Silver

As part of its biocide assessment, the ECHA derived an acceptable daily intake (ADI) for silver of 0.9 µg/kg bw/day (EFSA and ECHA, 2021; ECHA, 2021). This was calculated from a NOAEL

value of 9 mg silver-zinc zeolite/kg bw/day (uncertainty factor 100 for inter- and intra-species differences and a further factor of 100 for conversion from silver-zinc zeolite to free silver ions), which was determined in a study on rats and is based on the pigmentation of internal organs (Takizawa et al., 1992). It should be noted that this ADI can be considered very conservative, as pigmentation of internal organs does not necessarily represent an adverse effect. In addition, the ADI is partly at odds with observations in humans: according to ANSES calculations, the average intake (see below) is already up to three times higher than the ADI without resulting in pigmentation of internal organs.

Silver can be ingested through drinking water or food, where it is also approved as a food additive. ANSES estimates the average daily intake of silver for adults to be 1.29 to 2.65 µg/kg bw/day (ANSES, 2011). Formally, an allocation factor of 10% would therefore be appropriate. However, due to the very conservative ADI chosen as described above and the fact that the resulting intake is still considered to be very low compared to other intakes, the BfR considers an allocation factor of 20% for the intake of silver from food contact materials to be appropriate. In the BfR's view, a daily oral intake of 0.0108 mg silver/day from food contact materials should not be exceeded for a person weighing 60 kg, taking into account the 20% allocation.

4.1.2.18 Thallium

Thallium is rapidly and efficiently absorbed, with excretion occurring mainly via the kidneys (EPA, 2009). Chronic exposure to thallium typically causes neurological disorders of both a sensory and motor nature, as well as hair loss (EU-FORA, 2022; Cvjetko et al., 2010). The concentration of thallium in urine is considered a reliable indicator of thallium exposure. Exposure to 10 µg of soluble thallium compounds leads to a thallium concentration of approximately 5 µg/l urine (WHO, 1996). The WHO classifies this daily intake as unlikely to have harmful effects on human health. However, it concluded that, due to uncertainties regarding the dose-effect relationship, it cannot derive a health-based limit value (WHO, 1996). The US EPA also came to this conclusion (EPA, 2009, 2012). It proposes a "provisional screening value" that could be useful in certain cases. The value is 10 ng/kg bw/day and is based on a subchronic study in rats in which alopecia occurred. As the uncertainty in the data from the animal experiment is very high, it seems appropriate to rely on epidemiological data. Based on an epidemiological study, the German Federal Environment Agency (UBA) has determined a significantly lower value for oral thallium exposure of 10 µg/person/day, at which no adverse health impairments are expected (Brockhaus et al., 1981; UBA, 2011). The BfR recommends that the total intake of thallium from all sources should not exceed 10 µg/person/day (BfR, 2004). Due to uncertainties in the underlying data, the specified value should not be regarded as a HBGV. This value is used as an aid to identify an intake level that should not be exceeded due to the release of thallium from food contact materials.

Although dietary intake of thallium is low, it can be as high as 2 to 5 µg/day in adults (Sherlock et al., 1986; FSA, 2014). Since dietary intake already accounts for a significant proportion of the maximum total intake and due to uncertainties in the data, an allocation factor of 10% is used for exposure to thallium from food contact materials. This approach is in line with the Council of Europe's recommendations on release limits for thallium from uncoated metal objects. From the BfR's point of view, taking into account the 10% allocation, a daily oral intake of 0.001 mg thallium/day from food contact materials should not be exceeded for a person weighing 60 kg.

4.1.2.19 Vanadium

Vanadium is not mutagenic, but can cause numerical and structural chromosome damage. These effects are attributable to indirect mechanisms with a threshold (ATSDR, 2012; EFSA, 2004). In animal studies, damage to the kidneys, spleen and lungs has been observed as a result of chronic vanadium exposure (EFSA, 2004; RAC, 2020). Clinical experience in humans is limited to studies with a small number of volunteers, in which gastrointestinal disorders were observed as the most sensitive endpoint. The lowest dose of a vanadium compound reported to cause such an effect was approximately 0.2 mg/kg bw/day (Dimond et al., 1963; EFSA, 2004). A 1997 study involving 12 weeks of oral exposure of patients to vanadium, in which haematological and blood pressure effects were investigated, led to the determination of a NOAEL of 0.12 mg/kg bw/day (Fawcett et al., 1997). This NOAEL was used by both the Agency for Toxic Substances and Disease Registry (ATSDR, 2012) and the International Council for Harmonisation (ICH) to calculate HBGV (Laupheimer et al., 2025). The ICH derived a permitted daily exposure (PDE) of 120 µg/day (ICH, 2022). This value is supported by the results of a recent subchronic study in rats and mice, in which changes in blood count were identified as the most sensitive effect (NTP, 2023). The BfR uses this value to identify a maximum intake level that should not be exceeded through the release of vanadium from food contact materials.

Vanadium can be ingested through drinking water and food and is found in significant amounts in seafood and mushrooms, for example. Estimates of total dietary intake of vanadium in humans range from 10 to 60 µg/day (ICH, 2022). In the ANSES Total Diet Study, the average daily intake of vanadium in adults was estimated at 52 µg/day (ANSES, 2011). Since dietary intake already accounts for a significant proportion of the maximum total intake, an allocation factor of 20% is used for exposure to vanadium from food contact materials. In the BfR's view, a daily oral intake of 0.024 mg vanadium/day from food contact materials should not be exceeded for a person weighing 60 kg, taking into account the 20% allocation.

4.1.2.20 Zinc

Zinc is an essential trace element and an important component of many metalloenzymes. Zinc and copper impair each other's intake, so, in the gastrointestinal tract, increased intake of one can lead to reduced intake of the other. Reduced copper absorption is considered a sensitive parameter for increased zinc absorption. This endpoint was used by the UK Expert Group on Vitamins and Minerals (EVM) and the SCF to derive a safe upper limit for zinc intake of 25 mg/day (EVM, 2003; SCF, 2003). This tolerable upper intake level for total daily zinc intake was reconfirmed by EFSA in 2024 (EFSA, 2024 b).

The main source of zinc intake is food, especially bread, meat and dairy products. According to the National Consumption Study II, the average daily zinc intake (including supplements) for men and women aged 14–80 is 12.3 mg/day and 9.5 mg/day, respectively (MRI, 2022). Since dietary intake already accounts for a substantial proportion of the safe upper limit for zinc intake, an allocation factor of 20% is used for exposure to zinc from food contact materials. From the BfR's point of view, a daily oral intake of 5 mg zinc/day from food contact materials should not be exceeded for a person weighing 60 kg, taking into account the 20% allocation.

4.1.2.21 Tin

The absorption of tin and its inorganic compounds is very low. Oral intake of high amounts of tin can lead to gastrointestinal complaints, which is why there are legal maximum levels

(Regulation (EU) 2023/915) for tin concentrations in canned food and canned beverages of 200 and 100 mg/kg, respectively. According to the WHO, there is no evidence of chronic tin toxicity in humans, so it was not considered necessary to set a guideline value for drinking water (WHO, 2022). The oral toxicity of tin was investigated in a 28-day study on rats back in 2010, and no harmful effects were found even at the highest daily dose of 1000 mg/kg bw (ECHA, 2023). However, as tin was administered in powder form, this study is not representative of human exposure via food, where tin is usually present in ionic form. In a subchronic study conducted in 1973 with tin(II) chloride in rats, effects such as growth inhibition, reduced food efficiency, mild anaemia and histological changes in the liver were observed at concentrations of 0.3% tin chloride in the feed. The NOAEL was converted (cf. EFSA, 2012 c) to 81 mg/kg bw/day (de Groot et al., 1973).

The RIVM derived a TDI for chronic tin exposure from a NOAEL value in a study on rats (RIVM, 2009). The slight increase in tin accumulation in the bones and the decrease in feed efficiency were identified as the most sensitive endpoints. The TDI of 0.2 mg/kg bw/day was derived from the NOAEL of 20 mg/kg bw/day and the application of an uncertainty factor of 100 (10 for inter- and 10 for intra-species variation). This TDI is also used here for the risk assessment.

ANSES estimates the average daily dietary intake of tin for adults to be 3.9 µg/kg bw/day (ANSES, 2011). According to this, dietary exposure is well below the TDI and the application of an allocation factor is not necessary. In the BfR's view, a daily oral intake of 12 mg tin/day from food contact materials should not be exceeded for a person weighing 60 kg.

4.1.2.22 Summary and health-based guidance values (HBGV)

Based on existing toxicological studies and corresponding assessments by other authorities, the BfR has derived HBGV or toxicological reference values for 20 of the 21 elements examined. In addition, allocation factors were defined where necessary to describe the maximum proportion of the respective HBGV or toxicological reference values that can be utilised through exposure via food contact materials from the BfR's perspective. Under the assumption of a person with a body weight of 60 kg, daily and weekly maximum tolerable intake levels were then calculated. The results are summarised in Table 1 and 2.

Table 1: Health-based guidance values (HBGV) and derived maximum tolerable intake levels for the 17 elements investigated. The BfR recommends that the exposure contributions from food contact materials (FCM) listed in the last column should not be exceeded.

Element	Type of HBGV	Source	HBGV in mg/kg bw/day or *week	Maximum tolerable intake in mg per person (60 kg) and day or *week	Allocation factor (AF)	Recommended maximum intake from FCM in mg/person/day or *week
Aluminium	TWI	EFSA (2008)	*1	*60	10%	*6
Antimony	TDI	WHO (2003)	0.006	0.36	-	
Barium	TDI	SCHER (2012)	0.2	12	-	
Cadmium	TWI	EFSA CONTAM (2012)	*0.0025	*0.15	10%	*0.015
Chromium	TDI	EFSA CONTAM (2014)	0.3	18	-	
Cobalt	TDI	EFSA (2012)	0.0016	0.1	20%	0.02
Iron	Safe level of intake	EFSA NDA (2024)	-	40	-	
Copper	ADI	EFSA (2022)	0.07	4.2	20%	0.84
Lithium	TDI	RIVM (1991)	0.008	0.48	-	
Manganese	Safe level of intake	EFSA NDA (2023)	-	8	20%	1.6
Molybdenum	UL	SCF (2006)	-	0.6	20%	0.12
Nickel	TDI	EFSA CONTAM (2020)	0.013	0.78	20%	0.156
Selenium	UL	EFSA NDA (2023)	-	0.255	20%	0.051
Silver	ADI	ECHA (2021)	0.0009	0.054	20%	0.0108
Vanadium	PDE	ICH (2022)	0.002	0.12	20%	0.024
Zinc	UL	SCF (2003)	-	25	20%	5
Tin	TDI	RIVM (2009)	0.2	12	-	

Table 2: Toxicological reference or guidance values used for guidance for the elements investigated for which no HBGV could be derived. In the BfR's opinion, the release of these elements from food contact materials (FCMs) should be as low as possible and should not contribute significantly to exposure. For unavoidable exposure from FCM, the maximum daily intake levels specified in the table should not be exceeded. Due to insufficient data, neither an HBGV nor a toxicological reference value could be derived for beryllium.

Element	Toxicological reference value	Source	Toxicological reference value in mg/kg BW/day	Toxicological reference value in mg per person (60 kg) per day	Allocation factor (AF)	Maximum unavoidable exposure via FCM in mg/person/day
Arsenic	BMDL ₀₅	EFSA (2024)	0.00006	0.0036	10%	0.00036
Beryllium	-		-	-	-	
Lead	BMDL ₀₁	EFSA (2010)	0.0005	0.03	10%	0.003
Thallium	Maximum exposure	WHO (1996)	-	0.01	10%	0.001

4.1.3 Element release and technical assessment

For the following exposure assessment, the BfR uses the available monitoring data from the regional authorities of the German federal states ("Laender") on the release of elements from metal objects intended to come into contact with food from 2022. Release tests were carried out in food simulants under various test conditions.

The summarised results of the release tests and the specific release limit values (SRLs) of the Council of Europe and DIN EN ISO 4531:2022 are shown in Table 3. These limit values serve as compliance criteria for the technical suitability assessment of food contact materials. The measured element releases were also compared with these limit values. For the risk assessment, however, the derived HBGV or toxicological reference values are used.

The release tests for uncoated items were carried out in artificial tap water and in 0.5% citric acid (at 40 °C/70 °C/100 °C), based on the prescribed test conditions of the Council of Europe recommendations. Based on the DIN EN ISO 4531:2022 standard, enamelled objects were tested in 3% acetic acid in hot contact for 2 hours (70 °C or 95 °C) and in 4% acetic acid at room temperature for 24 hours. The temperature was selected according to the type of use of the respective object. For example, an uncoated saucepan was tested at 100 °C, a coffee spoon at 70 °C, and an apple slicer at 40 °C. In the case of enamelled items, for example, a dessert plate was tested at 70 °C and an oven dish at 95 °C. To reflect repeated use, three consecutive migrations were carried out and the results of the third migration were used for assessment.

A total of 194 items were examined, 115 of which were uncoated and 79 enamelled. The elemental release of 21 different elements was examined. The elements copper, cobalt and zinc were examined in all samples. The elements aluminium, antimony, barium, cadmium, lead, chromium, iron, lithium and nickel were examined in the vast majority (over 75%) of the samples, and the elements arsenic, beryllium, manganese, molybdenum, selenium, silver, thallium, vanadium and tin were examined in less than 75% of the samples. The elements tested were determined by the analytical equipment available in the testing laboratories.

As described above, release tests were carried out for each element in two food simulants. For the following evaluations, the higher measured release value was used in each case to ensure a conservative, "worst-case" estimate of element release.

The majority of the samples tested showed release values below the respective SRLs. 99.1% of the uncoated samples demonstrated compliance with all SRLs, while this was only true for 53.2% of the enamelled samples. Overall, at least one SRL value was exceeded in 38 of the 194 samples analysed, with 37 of these 38 samples being enamelled. In 24 of the 38 samples, the release of a single element exceeded the respective release limit value, and in 14 samples, the release of several elements exceeded the respective release limit value. Aluminium is the element that shows release quantities above the SRL in most samples. In the new version of DIN EN ISO 4531:2022, the limit value for aluminium was lowered to 1 mg/kg food simulant; in the previous version from 2018, the SRL for aluminium was still 5 mg/kg food simulant. Accordingly, the new limit value of 1 mg/kg was exceeded in 33 samples, compared to 2 samples that would have exceeded the previous SRL of 5 mg/kg.

Table 3: Element release quantities in mg/kg simulant from the uncoated and enamelled kitchen items examined and comparison with the specific release limits (SRL) according to Council of Europe technical Guide on metals and alloys in food contact for uncoated metal items ^a and according to standard DIN EN ISO 4531:2022 for enamelled metal items ^b.

Element	Sample type	Number of samples	Mean value	Median	Maximum	90th percentile	SRL	Samples > SRL
Aluminium	uncoated	115	0.0305	0.012	0.681	0.05	5	0
	enamelled	73	1.86	0.871	43.0	3.426	1	33
Antimony	uncoated	110	0.000818	0.0005	0.00318	0.0015	0.04	0
	enamelled	70	0.00609	0.0015	0.077	0.0138	0.04	1
Arsenic	uncoated	92	0.000253	0.00015	0.00158	0.0005	0.002	0
	enamelled	46	0.000347	0.000379	0.002	0.0005	0.002	0
Barium	uncoated	100	0.0139	0.009	0.033	0.033	1.2	0
	enamelled	79	0.685	0.025	18.3	1.05	1.2	6
Beryllium	uncoated	37	0.000755	0.0003	0.003	0.0025	0.01	0
	enamelled	25	0.00021	0.0003	0.0003	0.0003	/	0
Lead	uncoated	104	0.000417	0.0003	0.00573	0.001	0.01	0
	enamelled	70	0.0760	0.000539	4.62	0.0146	0.01	7
Cadmium	uncoated	111	0.000219	0.00015	0.0044	0.0005	0.005	0
	enamelled	62	0.0123	0.000247	0.721	0.00190	0.005	3
Chromium	uncoated	115	0.0162	0.005	0.348	0.0399	1	0
	enamelled	74	0.114	0.0015	7.74	0.0323	1	1
Cobalt	uncoated	115	0.00227	0.00045	0.143	0.0025	0.02	1
	enamelled	79	0.0552	0.00355	1.55	0.0854	0.1	5
Iron	uncoated	100	25.5	0.15	2490	1.10	40	1
	enamelled	77	157	0.050	12000	0.50	/	0
Copper	uncoated	115	0.0306	0.0055	0.15	0.15	4	0
	enamelled	79	0.107	0.016	0.888	0.50	4	0
Lithium	uncoated	107	0.00151	0.00075	0.013	0.005	0.048	0

Element	Sample type	Number of samples	Mean value	Median	Maximum	90th percentile	SRL	Samples > SRL
Manganese	enamelled	69	0.0824	0.0085	2.37	0.0973	0.48	4
	uncoated	72	0.105	0.0125	4.9	0.114	0.55	1
	enamelled	56	1.65	0.025	84.8	0.5	0.55	2
Molybdenum	uncoated	52	0.00153	0.0005	0.0133	0.00485	0.12	0
	enamelled	35	0.00130	0.00015	0.009	0.004	0.12	0
Nickel	uncoated	112	0.00282	0.00105	0.032	0.00556	0.14	0
	enamelled	66	0.0176	0.00199	0.507	0.0361	0.14	2
Selenium	uncoated	23	0.00294	0.00375	0.00375	0.00375	/	0
	enamelled	30	0.00244	0.0015	0.0104	0.005	/	0
Silver	uncoated	19	0.00301	0.0025	0.006	0.0055	0.08	0
	enamelled	17	0.000804	0.000487	0.0015	0.0015	0.08	0
Thallium	uncoated	54	0.000053	0.000025	0.00015	0.00015	0.001	0
	enamelled	39	0.000204	0.000025	0.0005	0.0005	/	0
Vanadium	uncoated	52	0.00142	0.0009	0.02	0.0025	0.01	1
	enamelled	35	0.0128	0.00075	0.413	0.00194	0.01	1
Zinc	uncoated	115	0.0559	0.0225	2.29	0.150	5	0
	enamelled	79	0.110	0.035	1.23	0.50	5	0
Tin	uncoated	42	0.00794	0.003	0.03	0.0240	100	0
	enamelled	32	0.00231	0.00015	0.0279	0.0105	/	0

^a Food simulants used: artificial tap water and 0.5% citric acid, depending on the type of use of the item, tested at 40 °C/70 °C/100 °C for 30 minutes or 2 hours. The higher release value was used for each item.

^b Food simulants used: 3% acetic acid in hot contact for 2 hours (70 °C or 95 °C) and in 4% acetic acid at room temperature for 24 hours. The higher release value was used for each item.

Overall, it can be seen that – apart from aluminium release from enamelled samples – the technical requirements are met by the vast majority of the items examined for all elements. In the case of individual items, some of which significantly exceed one or more SRLs, the BfR believes that manufacturers should review the quality of their raw materials and manufacturing processes or exclude the use of these products, particularly for hot acidic food.

4.1.4 Exposure assessment and risk characterisation

In order to estimate the actual exposure to the elements examined through food consumed that has come into contact with metal kitchenware, the following consumption quantities were assumed: For items with large capacities of more than 1 litre (cooking pots, roasting pans, baking trays, etc.), it was assumed that an adult consumes 1 kg of food per day that has come into contact with these items. For items with smaller capacities (cups, cocktail shakers) or enveloping volumes (cutlery, whisks, pizza cutters, etc.) than 1 litre, it was assumed that the total volume of food simulant used for the test corresponds to the daily consumption amount, as the food that comes into contact with these items in the household usually has a significantly smaller volume than 1 litre. The daily or weekly intake for the respective elements

was then compared with the HBGV or toxicological reference values for a 60 kg adult specified in section 4.1.2 (see also Table 1). Where deemed necessary, an allocation factor (Table 1) was also taken into account. The results are shown in Figure 1.

Calculation example 1:

An enamelled pot showed aluminium release in 3% acetic acid (2 hours at 95 °C) and 4% acetic acid (24 hours at 22 °C) of 3.04 and 8.27 mg/kg simulant, respectively, in the third migration test. The simulant volume was 750 ml. The higher release value from the determination in 4% acetic acid for 24 hours at 22 °C was used for the calculation. Based on the assumptions described above, the following weekly exposure was obtained:

$$Exposure = 8,27 \frac{mg}{kg} * 0,75 \frac{kg}{day} / 60 kg BW * 7 \frac{days}{week} = 0,724 \frac{mg}{kg BW * week}$$

These values correspond to an exceedance of the SRL for aluminium from enamel (1 mg/kg) and the allocated 10% of the tolerable weekly intake (TWI) for aluminium (HBGV = 1 mg/kg BW/week) – but not an exceedance of the HBGV itself.

Calculation example 2:

An enamelled baking tray showed a cobalt release in 3% acetic acid (2 hours at 95 °C) and 4% acetic acid (24 hours at 22 °C) of 0.35 mg/kg simulant or < limit of quantification (0.004 mg/kg simulant). The simulant volume was 1410 ml. The higher release value from the determination in 3% acetic acid for 2 hours at 95 °C was used for the calculation. Based on the assumptions described above, the following daily exposure was calculated:

$$Exposure = 0,35 \frac{mg}{kg} * 1 \frac{kg}{day} / 60 kg BW = 0,0058 \frac{mg}{kg BW * day}$$

These values result in both an exceedance of the SRL for cobalt (0.1 mg/kg) and the tolerable daily intake (TDI) for cobalt (HBGV = 0.0016 mg/kg BW/day, 0.1 mg/day for a person weighing 60 kg).

Overall, the release of elements from the vast majority of the samples tested does not result in the derived HBGV being exceeded, even when allocation factors are taken into account. The calculated margins of exposure were (far) greater than 1 for arsenic in all samples and for lead in the vast majority of samples. The calculated exposure exceeds one or more HBGVs in a total of 8 (out of 194) samples or corresponds to a margin of exposure for lead of less than 1. These 8 samples consist of seven enamelled kitchen items and one without coating. In the BfR's opinion, these items are not suitable for contact with food.

Cobalt is a special case. The release of cobalt from 5 samples (4 of which are enamelled) leads to an exceedance of the HBGV of 0.1 mg/day (for a person weighing 60 kg). In the BfR's view, these items are not suitable for daily use in contact with food. The release of cobalt from a further 6 samples resulted in the allocated HBGV of 0.02 mg/day being exceeded, but not in the HBGV itself being exceeded. From a toxicological point of view, the contribution of these items to the overall exposure to cobalt is assessed as too high. However, cobalt oxide cannot be entirely omitted as an adhesion promoter for the manufacture and function of enamelled surfaces. The ALARA principle ("As Low As Reasonably Achievable") applies accordingly to the use of cobalt in food contact materials made of enamel. The large number of enamelled items

whose cobalt release did not result in the exceedance of allocated HBGV for cobalt shows that this is technically possible.

Taking into account the allocations of 10-20% for elements that are also subject to significant exposure from other sources, 39 samples exceeded the allocated HBGV or the value considered to be the maximum exposure contribution for lead (0.003 mg/person/day) or arsenic (0.00036 mg/person/day) even in the case of unavoidable release. The elements for which exceedances occurred in most samples are aluminium, arsenic, lead and cobalt. In 28 of 39 samples, exceedances occurred for a single element, while in 11 samples (5.7% of all samples), several elements were affected. These 11 samples consist of ten enamelled kitchen items and one without coating. As the use of these items contributes significantly to the overall intake of some elements, the BfR believes that manufacturers should revise their raw material qualities and manufacturing processes so that exposure from these food contact materials is below the allocated HBGV for all elements and below an exposure contribution of 0.003 mg lead/person/day and 0.00036 mg arsenic/person/day.

As expected, the occurrence of increased element release tends to occur when testing in acidic simulants and at elevated temperatures – i.e. for items such as pots, roasting pans and oven trays. For elements for which the SRL value was frequently exceeded, there is also a tendency for the respective HBGV/toxicological reference value or the allocated share thereof to be exceeded more frequently.

In summary, the risk assessment based on the exposure assessment showed that the vast majority of enamelled or uncoated metal food contact materials are suitable for food contact. However, with regard to overall exposure, taking into account possible additional sources of intake (such as food), the BfR considers that some items contribute too much to the daily intake of certain elements. The BfR recommends that manufacturers of these items review their raw materials and manufacturing processes in order to further reduce element release. Only a few objects showed element releases that could exceed the derived HBGV or toxicological reference values and thus increase the risk of the occurrence of health impairments. From a toxicological point of view, these objects are not suitable for contact with food.

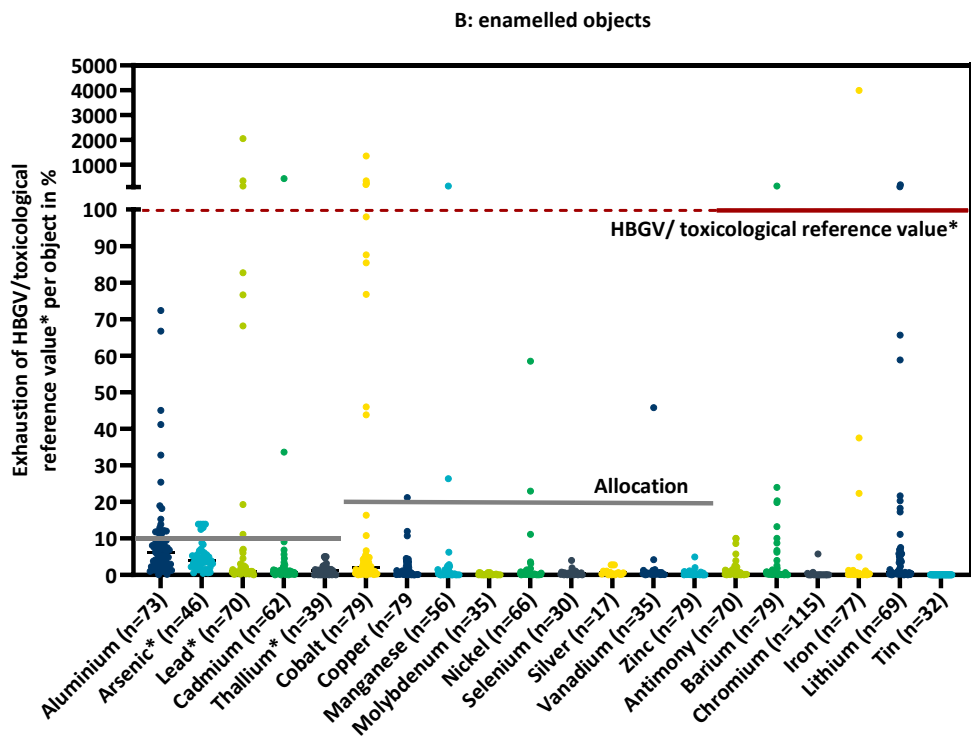
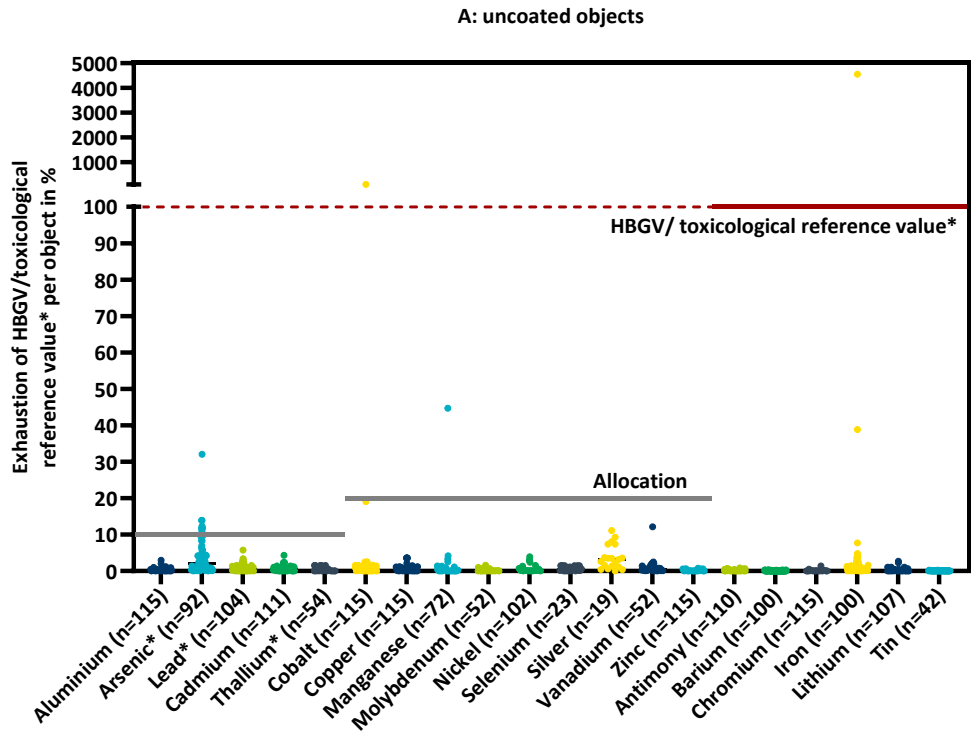


Figure 1: Comparison of the amounts in which elements were released from (A) uncoated and (B) enamelled metal items with the health-based guidance values (HBGV, red line) derived from toxicological studies with allocation factors (grey lines at 10% or 20% of the HBGV). * No HBGV could be derived for the elements arsenic, lead and thallium, so exposure for these three elements is shown in comparison to the respective toxicological reference value (grey line at 10%: exposure contribution that should not be exceeded, even for unavoidable releases from food contact). Neither an HBGV nor a toxicological reference value could be derived for beryllium, therefore beryllium is not shown here.

4.1.5 Consideration of uncertainties

In the present assessment, there is uncertainty both when it comes to the toxicological derivation of HBGV or toxicological reference value and in the analytical determination of element release and exposure assessment.

In terms of toxicology, uncertainties are mainly due to incomplete data or low-quality studies. An attempt was made to address these uncertainties by reviewing the studies for their suitability and selecting the study with the lowest NOAEL or BMDL from all suitable studies for each element, as well as by using appropriate assessment and uncertainty factors. Experience has shown that this approach usually results in a conservative HBGV or toxicological reference values.

Food simulants and test conditions designed to describe the most unfavourable realistic use case were used to determine element releases. Conversely, this also means that there are uses (i.e. certain food, contact times and temperatures) in which significantly lower amounts of elements are transferred than in the tests carried out. Given the variety of uses for most kitchen items, this tends to lead to an overestimation of the average regular release quantities.

Conservative assumptions were used to estimate exposure from element releases from individual items. Contrary to these assumptions, however, it can be assumed that only a few of the items examined are used daily and throughout a person's lifetime. Therefore, the actual exposure from a particular item is generally lower than the values calculated here. A good picture of exposure can be obtained by looking at the total number of items examined.

An overall assessment of the uncertainties shows that the present assessment was conducted conservatively and, in particular, that the actual exposure from the use of the examined items was likely overestimated rather than underestimated. However, individual items with particularly high element release can contribute substantially to exposure even if they are not used on a daily basis.

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