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Ceramic crockery: BfR recommends lower release of lead and cadmium

Opinion No 043/2020 of the BfR dated 21 September 2020

Glazes and patterns on ceramic crockery - for example earthenware or china - sometimes contain heavy metals such as lead, cadmium or cobalt. These substances can be released from the ceramic. This process is known as 'element release'. The quantities passed into foodstuffs depend on a variety of factors: in addition to the quality of the glaze, they are also dependent on the temperature at which the ceramic was fired, on the manner of pattern application and on the foodstuff (e.g. acidic foodstuffs) and the duration of contact. The limits for the release of lead and cadmium are regulated by the European (Ceramic) Directive (84/500/EEC). This is currently being revised by the European Commission. No release limit is specified in the named directive for cobalt.

Current data from the German food monitoring authorities concerning the release of lead, cadmium and cobalt from ceramic plates show that high quantities can migrate into foodstuffs. In the view of the German Federal Institute for Risk Assessment (BfR), however, products used daily such as crockery should not contribute to heavy metal intake of consumers. For this reason, the BfR has derived the quantity of lead, cadmium and cobalt, respectively, which can be released without any health risks being anticipated. Herein, the BfR calls these quantities 'acceptable surface-related release'. To calculate these quantities, the Institute uses the available toxicological studies, in order to first determine a toxicologically based release value. In addition, the latest technology with respect to limits of detection was taken into account. Subsequently the BfR compared the acceptable release per unit area with the existing limits laid down in the Ceramic Directive. The result: The acceptable surface-related release newly derived by the BfR is up to 70 times (for cadmium) or 400 times (for lead) lower than the limits currently in force.

The acceptable surface-related release derived by the BfR would result in a significant reduction in the exposure of consumers to these heavy metals. The BfR therefore recommends that for risk assessment of heavy metal release from ceramics, significantly lower acceptable release limits should be used than those limits specified in the Directive 84/500/EEC. The BfR advises this in particular in view of the vulnerability of children, and recommends that manufacturers ensure low release of heavy metals, particularly in the case of ceramic crockery for children.

In the BfR's view, the (Ceramic) Directive (84/500/EEC) should, as part of the revision, be expanded at least by the element cobalt. In addition, the testing conditions stipulated in the Directive 84/500/EEC from the year 1984, in the BfR's view, barely correspond to the actual use of ceramic crockery. They do not, for example, take into account the effect of short-term contact, heating, heating in the microwave, hot-filling, or the use of crockery over several years. In the interests of a meaningful risk assessment, the BfR recommends using application-oriented test conditions for the release tests.

	BfR risk profile: Ceramic crockery: BfR recommends lower release of lead and cadmium Opinion no. 043/2020)				
A Affected persons	General population Children				
B Likelihood of health impairment with the applicable limits	Practically impossible	Unlikely	**Possible**	Likely	Certain
C Severity of health impairment with applicable limits	No impairment	Mild impairment [reversible/irreversible]	**Moderate impairment [reversible/irreversible]**	Severe impairment [reversible/irreversible]	
D Validity of available data [1]	High: The most important data are available and there are no contradictions	**Medium: Some important data are missing or contradictory**	Low: A large volume of important data is missing or contradictory		
E Controllability by the consumer [2]	Control not necessary	Controllable with precautionary measures	Controllable through avoidance	**Not controllable**	

Fields with a dark blue background indicate the properties of the risk assessed in this Opinion
(for more details, see the text of Opinion no. 043/2020 from the BfR dated 21 September 2020).

Explanations

The risk profile is intended to visualise the risk outlined in the BfR Opinion. The profile is not intended to be used to compare risks. The risk profile should only be read in conjunction with the corresponding Opinion.

Row D - Validity of available data
[1] - Hitherto there has been a lack of data from realistic test conditions. There is therefore a high degree of uncertainty regarding the data from the release tests. There is some uncertainty regarding the transferability of the measured release values for lead, cadmium and cobalt to health-based guidance values. However, the statement that the release of some of the plates tested is too high, in particular in relation to lead and cadmium, remains indisputable.

Row E - controllability by the consumer
[2] Details given in the row "Controllability by the consumer" are merely descriptive and not to be understood as a recommendation by the BfR. The BfR has given recommendations for action in its Opinion: 1. Adjustment of the limits in the (Ceramic) Directive (84/500/EEC) and expansion by the element cobalt. 2. Since coloured glazes and patterns often have the capability to release heavy metals and since the highest resulting exposure is to be expected in children, who are frequently the target group for such products (vulnerable consumer group), manufacturers of such ceramics should take particular precautionary measures in this regard. 3. Revision of the test conditions of the (Ceramic) Directive (84/500/EEC).

GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT (BfR)

1. Subject of the assessment

In 2016 and 2017, food monitoring authorities in the German federal states of North Rhine-Westphalia and Baden-Württemberg tested ceramic plates - particularly attractive to children due to their patterns - for potential release of elements into foodstuffs. The European Directive 84/500/EEC (Ceramic Directive) from 1984 concerning ceramic articles intended to come into contact with foodstuffs (EWG, 1984) is currently being revised (EC, 2017). The BfR has used this as an opportunity for assessing the release of lead, cadmium and cobalt from ceramic consumer articles according to the current toxicological knowledge.

Since the last Opinion of the BfR on this topic in 2004, (BfR, 2004) the health risks resulting from the intake of lead and cadmium have been re-assessed, among other things by the World Health Organisation (WHO). As a result, the provisional tolerable weekly intake for lead and cadmium valid at the time was retracted (JECFA, 2011). In addition, the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) once again concerned themselves with the toxicological assessment of lead and cadmium. On the basis of its own research results and data from food monitoring, the BfR felt prompted also to toxicologically assess the release of cobalt from ceramic food contact articles alongside the elements lead and cadmium regulated by the above-named Directive.

The Ceramic Directive specifies that the quantities of lead and cadmium released from ceramic articles from Categories 1 to 3 (Table 1) into a foodstuff(simulant) under predefined conditions must not exceed the following limits:

Table 1: Limits for the release of lead and cadmium from ceramic consumer articles in accordance with the Directive 84/500/EEC, based on the surface area of the relevant article and/or the volume of foodstuff (simulant)

Category	Description	Lead	Cadmium
1	Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm	0.8 mg/dm^2	0.07 mg/dm^2
2	All other articles which can be filled	4.0 mg/L	0.3 mg/L
3	Cooking ware; packaging and storage vessels having a capacity of more than three litres	1.5 mg/L	0.1 mg/L

2. Results

A total of 42 plates were tested for their lead and cadmium release and 31 plates were checked for their cobalt release. The test conditions were, in accordance with the European Ceramic Directive (84/500/EEC), 4% acetic acid and 24 h at 22 ± 2 °C.

On the basis of toxicological assessments and taking into consideration the analytical feasibility, the BfR has derived release values for lead, cadmium and cobalt from ceramic articles. With children in particular, the daily cadmium intake from other sources (foodstuffs, toys, house dust etc.) may reach or exceed the tolerable weekly intake (TWI) of 2.5 micrograms (µg) per kilogram (kg) body weight derived by EFSA. The daily intake of lead from these sources is also very close to the corresponding toxicological reference value of 0.5 (children) and 1.5 (adults) µg per kg body weight per day or may even exceed this - above all in children. Consequently, ceramic articles should not, in the BfR's view, make any additional contribution to daily lead or cadmium intake. Against this backdrop and taking into consideration the latest possibilities for chemical analysis, the release of lead and cadmium from ceramic articles should be not detectable, with a maximum limit of detection of 10 µg lead per kg foodstuff(simulant) or 5 µg cadmium per kg foodstuff(simulant). For cobalt, a toxicologically justified release of 20 µg per kg foodstuff(simulant) was derived. On the basis of these values, acceptable surface-related release quantities were derived for lead, cadmium and cobalt using three different approaches (conventional approach, exposure-related approach, technical feasibility). These are up to 70 times (for cadmium) and 400 times (lead) lower than the limits currently specified for flatware from Category 1 in Directive 84/500/EEC (for definition of categories, see Table 1) and would lead to a significant reduction in the potential exposure of consumers to these heavy metals.

Depending on the approach, the release from 24 - 64% (for lead), 26 - 31% (for cadmium) and 13 - 16% (for cobalt) of the plates tested exceeds the acceptable surface-related release values. The BfR therefore recommends, particularly in view of the vulnerability of children, that when assessing the release of ceramics, significantly lower acceptable release limits be used than the limits specified in the Directive 84/500/EEC, and that the Directive be expanded at least to include the element cobalt. However, the limits specified in Directive 84/500/EEC should always be viewed in combination with the current testing conditions (see above). These can be regarded as not particularly representative compared with the actual use of ceramic articles that come into contact with foodstuffs (short-term contact, heating, microwave). Consequently, in the BfR's view the Ceramic Directive should also be revised with respect to the testing conditions.

3. Rationale

3.1. Risk assessment

3.1.1. Hazard identification

Glazes and patterns on ceramics may contain heavy metals such as lead, cadmium and cobalt. On contact with foodstuffs, these substances may be released from the ceramic and ingested by humans. The intake of heavy metals may cause impairment to health. The amount of heavy metals passed from the ceramic into the foodstuff, as well as depending on the quality of the glaze, essentially also depend on the temperature at which the ceramic was fired, on the manner of pattern application, the type of foodstuff (e.g. acidic foodstuffs) and the duration of contact.

3.1.2. Hazard potential

3.1.2.1 Lead

Based on the latest knowledge, lead is not deemed genotoxic in a direct mode of action (EFSA, 2010). However, numerous studies (summarised e.g. in ECHA (2019)) on workers report a positive association between the lead concentration in blood and the occurrence of clastogenic effects such as an increased number of cells with micronuclei, an increased number of mutated T-cell receptors or a higher rate of DNA damage observed using the "comet assay". Whether lead actually caused the effects observed has not yet been conclusively proven. A weak indirect genotoxic effect through the formation of reactive oxygen species and reduction in the DNA repair activity is supposed (EFSA, 2010).

In rodents, the formation of tumours in a number of organs - in particular in the kidney, the lung, the prostate and the adrenal gland - and a promoting effect in the formation of kidney tumours was observed in the case of high exposure to lead compounds (EFSA, 2010).

In accordance with Regulation (EC) No. 1272/2008 (CLP Regulation), lead is classified as reprotoxic Category 1A ("May damage fertility. May damage the unborn child") and as Lact. ("May cause harm to breast-fed children."). Owing to this classification, in 2018 lead was, on the basis of the Regulation (EC) No. 1907/2006 (REACH Regulation), classified as a Substance of Very High Concern (SVHC)[1]. In addition, only restricted use is permitted of lead and its compounds[2].

In the "Scientific Opinion on Lead in Food", the EFSA Panel on Contaminants in the Food Chain (CONTAM) names cardiovascular effects and renal toxicity in adults as the most critical effects of lead relevant to health (EFSA, 2010). The starting point used for the risk assessment is the "Benchmark Dose Lower Confidence Limit" (BMDL). This BMDL

[1] https://echa.europa.eu/de/candidate-list-table
[2] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.028.273

constitutes the lower confidence limit of a “benchmark dose” (BMD) at which, for example in an animal test, a certain change would be observed compared with the control (e. g. 10% effect → $BMDL_{10}$). For the cardiovascular effects a $BMDL_{01}$ value (describes the lower confidence limit of the daily dose which would result in an average increase of 1% in blood pressure) of 1.5 µg/kg body weight (bw) per day was derived. For the renal toxicity, a $BMDL_{10}$ value (describes the lower confidence limit of the daily dose which would result in an average increase of 10% in the frequency of kidney damage) of 0.6 µg/kg bw per day was derived.

For children, the developmental neurotoxicity (brain development, impaired development of intelligence and concentration and also behavioural disorders) were assessed as the most critical toxicological end point, and a $BMDL_{01}$ value (describes the lower confidence limit of the daily dose which would result in an average reduction of the intelligence quotient by one point) of 0.5 µg/kg bw per day was calculated.

All BMDL values are based on epidemiological studies which associate the observed effects with the lead concentration in the human blood in each case. Since - based on the latest available knowledge - no threshold level exists for the effects described, no tolerable intake value has been derived by EFSA. Since lead can cross the placenta, prenatal damage through exposure of the unborn child is also possible (EFSA, 2010).

The daily dietary intake of lead of 1.10 - 3.10 µg/kg bw/day estimated by EFSA (2010) in the age group > 1 to 3 years already significantly exceeds the $BMDL_{01}$ value of 0.5 µg/kg bw/day derived by EFSA. However, more recent figures from France estimate the daily lead intake from foodstuffs in this age group to be 0.05 - 0.31 µg/kg bw/day, so as significantly lower (ANSES, 2016; Sirot et al., 2018). On the basis of the occurrence data from the German federal control plan (BÜp) and the monitoring from 2015, the BfR (2018) carried out a health risk assessment of the concentration of lead in baby formula and processed cereal-based foods for babies and toddlers (BfR, 2018). The BfR took the position that when establishing maximum concentrations for lead the ALARA principle should be applied, because no safe intake can be named for lead in respect of the developmentally neurotoxic effects in children. ALARA stands for “As Low As Reasonably Achievable” and means that the exposure to a substance should be reduced as far as reasonably achievable. Exposure through infant and toddler food should therefore essentially be reduced to the achievable minimum. There are additional sources of lead exposure known for children. For example, in its opinion no. 048/2009, the BfR referred to possible lead intake via toys (BfR, 2009).

The daily dietary lead intake of 0.36 - 2.43 µg/kg bw/day estimated by EFSA (2010) in the adult age group can also already exhaust or exceed the $BMDL_{01}$ of 1.5 µg/kg bw/day and/or the $BMDL_{10}$ of 0.6 µg/kg bw/day. However, more recent figures from Germany estimate the daily lead intake originating from foodstuffs in this age group to be 0.07 - 0.17 µg/kg bw/day, so as significantly lower (Kolbaum et al., 2019).

Release of lead from ceramics for food contact should not take place owing to the high exposure described from other sources that already exists in all age groups.

3.1.2.2 Cadmium

In accordance with the CLP Regulation, cadmium or some of his salts are among others classified as a Category 1B carcinogen (“May cause cancer.”), as a Category 2 mutagenic substance (“Suspected of causing genetic defects.”) and as reprotoxic in Category 1B (“May damage fertility. May damage the unborn child.”). Owing to this classification, in 2013 cadmium and subsequently also some of its compounds were classified as SVHC on the basis of the REACH Regulation[1]. In addition, only restricted use is permitted of cadmium and some of its compounds[3].

Cadmium is also renally toxic and contributes to demineralisation of the bones - directly or indirectly - via renal dysfunction. On the basis of renal toxicity in the case of long-term exposure, the CONTAM panel of the EFSA derived a TWI of 2.5 µg/kg bw/week for cadmium (EFSA, 2009).

Foodstuffs are the chief source of exposure for cadmium. The exposure is heavily influenced by the composition of the food and eating habits of consumers, as cadmium accumulates in cereal (products), vegetables, nuts and starchy roots (tubers). The highest concentrations have been detected in fish, seafood, seaweed, chocolate, mushrooms and oil seed. In a consumer information sheet on cadmium intake in the German population (BfR, 2009) the BfR comes to the conclusion that 58% of the TWI is reached primarily through vegetables and cereal products. Once again, EFSA confirmed in 2012 that the exposure in some children and adults who ingest a lot of cadmium (95th percentile of exposure) may exceed the TWI (EFSA, 2012). Smokers have higher exposure through tobacco, and children are additionally exposed through toys and house dust (BfR, 2009). In certain population groups (vegetarians, children, smokers) the TWI may be exceeded twofold. Infants and toddlers probably ingest only harmless amounts of cadmium through follow-on formula (BfR, 2018).

In order to reduce exposure via food, the maximum concentrations of cadmium in foodstuffs permitted in accordance with Regulation (EC) No. 1881/2006 have been lowered (EU, 2014). Release of cadmium from ceramics for food contact should not take place owing to the high exposure of consumers to other sources that already exists.

3.1.2.3 Cobalt

According to the CLP Regulation, cobalt is classified as skin sensitising, Category 1 (“May cause an allergic skin reaction.”) and as a respiratory sensitiser, Category 1 (“May cause allergy or asthma symptoms or breathing difficulties if inhaled.”). In September 2017, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) supported the proposal of classifying cobalt as a Category 2 mutagenic substance (“Suspected of causing genetic defects.”), as a Category 1B carcinogen (“May cause cancer.”) and as a Category 1B reprotoxic substance (“May damage fertility.”) (ECHA, 2016). Legal classification has taken place through the Regulation (EU) No. 2020/217. This Regulation enters into force on 9 September 2021. The compounds cobalt sulphate (CAS 10124-43-3), cobalt dichloride (CAS 7646-79-9), cobalt dinitrate (CAS 10141-05-6), cobalt carbonate (CAS 513-79-1) and cobalt diacetate (CAS 71-48-7) have already been classified as stated above in accordance with Regulation (EC) No. 1272/2008. In addition, these compounds are to be included in Annex XVII of the REACH Regulation (EC) 1907/2006 and their use is to be thereby restricted (ECHA, 2018). The specific migration limit (SML) for cobalt in the Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food is currently 0.05 mg/kg foodstuff(simulant).

Several harmful effects on humans have been described for the oral intake of cobalt; the most important here include cardiac effects (cardiomyopathies), effects on erythropoesis (polycythemia) and on the thyroid and the immune system (allergic dermatitis). Furthermore,

[3] https://echa.europa.eu/de/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2518

in animal studies neurological and reprotoxic effects and damage to the intestine and kidneys occurred (ATSDR, 2004; ECHA, 2016; Nielsen et al., 2013).

Derivation of a valid health limit for chronic exposure to cobalt is complicated by uncertainties regarding the toxicological data available. Among other things, there are no studies available concerning chronic oral cobalt intake; the available data comes from, in part, old toxicological (animal) studies which also do not comply with today's requirements, and in most cases no NOAEL (no observed adverse effect level) was determined.

As one of the most sensitive end points, many authors identified cobalt-induced cardiomyopathy. This occurred in the years 1961 - 64 in Leuven (Belgium), 1965/66 in Quebec (Canada), 1964 - 66 in Omaha (USA) and 1964 - 67 Minneapolis (USA) as a result of a technological addition of inorganic cobalt salts to beer (Anonymous, 1966; Anonymous, 1967; Alexander, 1968; Alexander, 1969; Alexander, 1972; Bonenfant et al., 1969; Kesteloot et al., 1968; Kesteloot et al., 1966; McDermott et al., 1966; Mercier und Patry, 1967; Morin, 1966; Morin und Daniel, 1967; Morin et al., 1971; Morin et al., 1967; Sullivan et al., 1969a; Sullivan et al., 1969b). Since the data were gathered as part of clinical treatments, none of the studies contain patients who were exposed to cobalt but did not show any adverse effects. With regard to the cobalt quantities ingested by the patients, the various studies were collectively evaluated for the first time by the Agency for Toxic Substances and Disease Registry (ATSDR, 1992). The following citations refer at least in part to this work: ATSDR (2004); EDQM (2013); EFSA (2009); Kim et al. (2006); Nielsen et al. (2013); Paustenbach et al. (2013); RIVM (2001).

The Dutch National Institute for Public Health and the Environment (RIVM, 2001) used these studies as a basis for deriving a tolerable daily intake (TDI) because they are, in the RIVM's view, the studies with the lowest LOAEL (lowest observed adverse effect level) of 0.04 mg/kg bw/day. From this, the RIVM derived - using a total uncertainty factor of 30 (3 for intraspecies differences due to the higher sensitivity of the test subjects and 10 for the extrapolation of LOAEL to the NOAEL) - a TDI of 1.4 µg cobalt/kg bw/day. After renewed evaluation of the original literature, it must however be stated that the data used have in some cases been cited and summarised in a contradictory manner concerning the quantity of beverages consumed and the ingested quantity of cobalt derived thereof.

The specified average ingested amount of 0.04 mg cobalt/kg bw/day to 0.14 mg cobalt/kg bw/day cannot be comprehended by the BfR on the basis of the original literature. The units of the consumption quantities specified in the original literature (ounces, glasses, pints, bottles) are ambiguous, and in some cases contradict each other. The consumers were heavy drinkers (occasionally up to 20 quarts/day stated (Morin et al., 1971), which corresponds to approx. 19 l/day (1 US liquid quart = 0.9464 l)). Since the volumes consumed were not measured but asked for, considerable error can be expected in the reported consumption quantities (Sullivan et al., 1969a). Similarly, the cobalt concentration of the beer actually consumed is not known.

Cobalt salts were added to the beer for foam stabilisation or for the prevention of excessive foaming when the bottle is opened (gushing) (Kesteloot et al., 1968; Segel und Lautenbach, 1964). This practice goes back to Danish studies (Thorne, 1958; Thorne und Helm, 1957) and patents based on this (Thorne, 1958) in which the optimum beer properties were obtained by adding 0.5 - 1.0 ppm cobalt. In the United States, the addition of cobalt salts to fermented malt drinks had, since 1963, been authorised up to a level of 1.2 ppm (21 C.F.R. § 121.1142, Oct. 25, 1963, 28 F.R. 11454) and from 1965 onwards up to 1.5 ppm (21 C.F.R. § 121.1142, Aug. 31, 1965, 30 F.R. 11171). In June 1966 (31 F.R. 9008) the removal of the authorisation was announced and in August (31 F.R. 10744) the authorisation for cobalt salts was withdrawn. It was estimated that in the intervening time, a considerable quantity of the beer brewed in the USA had cobalt salts added to it (Alexander, 1969; Alexander, 1972; Segel und Lautenbach, 1964). Similar rules applied in Canada (Anonymous, 1966). In the original literature cited above, predominantly cobalt concentrations of between 0.5 and 1.5 ppm are named; none of the authors had at their disposal precise details on the actual cobalt concentration of the beer consumed.

Since cardiomyopathy occurred in all patients described, it would be possible in a “worst case” consideration to estimate the lowest cobalt intake quantities which still have an adverse effect by linking the lowest reported consumed quantity to the lowest technologically useful cobalt concentration in the beer. According to the literature evaluation by the BfR, the lowest specified quantity drunk is between 1.5 l/day (40 - 60 oz, (McDermott et al., 1966)) and 1.8 l/day (6 glasses beer/day assuming 0.3 l/glass (Kesteloot et al., 1968)). With the lowest cobalt concentration assumed technologically useful of 0.5 mg/l this would result in the LOAEL being at 0.013 - 0.015 mg cobalt/kg bw/day (assumption: 60 kg bw). Using a total uncertainty factor of 6 (3 for intraspecies differences and 2 for the extrapolation from the LOAEL to a NOAEL) this would result in a TDI of 0.002 mg/kg bw/day.

Having said this, the cardiomyopathies occurred very rapidly after the cobalt intake and, after the ban on adding cobalt to beer and the associated removal of this individual exposure source, abated again very quickly in the surviving patients (Packer, 2016). Consequently one must speak of an acute, rather than a chronic, toxicity. In addition it cannot be ruled out that the cardiac effects were also caused by malnutrition of the patients or by pre-existing heart conditions resulting from the very high alcohol consumption, and/or that the sensitivity to this effect was enhanced (Nielsen et al., 2013; Paustenbach et al., 2013; RIVM, 2001). Packer (2016) discusses cobalt-induced hypothyroidism (and not a direct effect of cobalt on the heart) in malnourished beer drinkers as a cause of these cardiomyopathies. Owing to this and because of the described uncertainties in determining the actual cobalt quantity ingested, the BfR deems the studies unsuitable for deriving a TDI.

The majority of authorities see cobalt-induced polycythemia as the most sensitive parameter for deriving health-based guidance values (AFSSA, 2010; ATSDR, 2004; EFSA, 2009; Nielsen et al., 2013); this was observed with a LOAEL of 1 mg/kg bw/day in a subacute study of six healthy test subjects (Davis und Fields, 1958). In this study 150 mg cobalt chloride was administered orally on a daily basis. Over a period of 7 to 22 days, the erythrocyte count in the blood of the test subjects increased by 0.5 - 1.19 × 10^6 (mean value 0.96 × 10^6) cells/mm^3 (normal range for adults: 4.1 - 5.5 × 10^6 cells/mm^3 (Thomas und Thomas, 2005)). Within 9 to 15 days of adjusting the cobalt administration, the values returned to the normal range. The uncertainties regarding the overall toxicological data situation were assessed differently by the named authorities. The total uncertainty factor for the derivation of health-based guidance values is - depending on the authority and on the type of derived health-based guidance value - between 100 (ATSDR, 2004) and 3000 (Nielsen et al., 2013).

The ATSDR (2004) regarded the available data as being insufficient for assessing chronic exposure to cobalt. Hence they only derived a guidance value (Minimal Risk Level; MRL) for a mean exposure duration (≤ 365 days) and used, starting with the LOAEL of 1 mg/kg bw/day, the uncertainty factors 10 for intraspecies differences and 10 for extrapolation from the LOAEL to the NOAEL. This results in a subchronic MRL of 10 µg cobalt/kg bw/day.

As part of its assessment of cobalt compounds as additives in pet food, EFSA (2009) used the MRL from the ATSDR and estimated a maximum daily intake of 600 µg per person (60 kg, so 10 µg/kg bw/day) as protective with respect to the known threshold-dependent adverse effects.

The French agency for food safety (AFSSA, 2010) is of the view that an extrapolation could be performed from the subacute study in humans to chronic exposure in accordance with the guideline documents on REACH (ECHA, 2012) through an additional factor of 6. This produces - based on the subacute MRL from the ATSDR - a TDI of 1.6 µg cobalt/kg bw/day.

The Danish environmental protection authority (Nielsen et al., 2013), by contrast, calculated a TDI for chronic cobalt exposure with an uncertainty factor of 10 for intraspecies differences and an expanded uncertainty factor 300 for the extrapolation from the LOAEL to the NOAEL and also because of a lack of studies on chronic exposure and limited data availability concerning developmental toxicity and genotoxicity. Accordingly, a TDI of 0.33 µg cobalt/kg bw/day results.

Because of the uncertainties due to the data, the BfR regards a conservative derivation of cobalt release from ceramic food contact articles as appropriate. However, the evaluation of the uncertainties regarding the toxicological data situation as performed by the Danish environmental protection authority and resulting in a total uncertainty factor of 3000 (Nielsen et al., 2013) appears - in the BfR's view - to be too high, as an evaluation of the named uncertainties with uncertainty factors corresponding to current guidelines can be deemed sufficiently conservative. The MRL derived by the ATSDR (2004) to which the EFSA (2009) also refers, is based on a LOAEL from a 22-day study (Davis und Fields, 1958) and - corresponding to the estimate of the ATSDR and the opinion of the BfR - constitutes only an adequate level of protection for medium exposure (≤ 365 days). For the assessment of chronic exposure, the BfR regards the TDI of 1.6 µg cobalt/kg bw/day that has been derived by the AFSSA (2010) as most suitable.

The registration dossier according to the REACH Regulation for cobalt lists a subchronic study on Sprague Dawley rats. A summary of the study has also recently been published (Danzeisen et al., 2020). According to this summary, the study was performed in a GLP-compliant manner in accordance with the OECD Guideline 408. Each day a solution of cobalt dichloride hexahydrate or the vehicle (control) was administered to the animals by gavage. The doses were 0, 3, 10 or 30 mg/kg bw/day. Alongside the slightly reduced body weights, predominantly effects on the blood, in particular a dose-dependent increase in the haematocrit and the haemoglobin value and in the erythrocyte count, were observed. In addition, a dose-dependent increase in the bilirubin value occurred. The histopathological examination showed hyperplasia of the erythroid cells of the bone marrow in the medium and high dose groups. The NOAEL was 3 mg $CoCl_2(H_2O)_6$/kg bw/day. This corresponds to 0.74 mg cobalt/kg bw/day.

On the basis of the published data (Danzeisen et al., 2020) the BfR has - using benchmark dose modelling for increased haemoglobin and/or haematocrit values in the blood of the male rats - calculated averaged $BMDL_{05}$ values of 0.58 mg cobalt/kg body weight/day (Figure 1 and Figure 2). Using an uncertainty factor of 200 (10 for intraspecies and 10 for interspecies differences and 2 for extrapolation from sub-chronic to chronic exposure), the TDI would be 2.9 µg/kg bw/day. The fact that this TDI derived from the animal experiment virtually corresponds to the TDI from the human study of 1.6 µg/kg bw/day (see above), and that in addition it is likewise based on polycythemia as a critical toxicological effect, can be regarded as additional evidence for the use of the TDI from the human study. In addition, it shows that the uncertainty factors from the AFSSA (2010), which the BfR regards as suitable, were selected sufficiently conservatively.

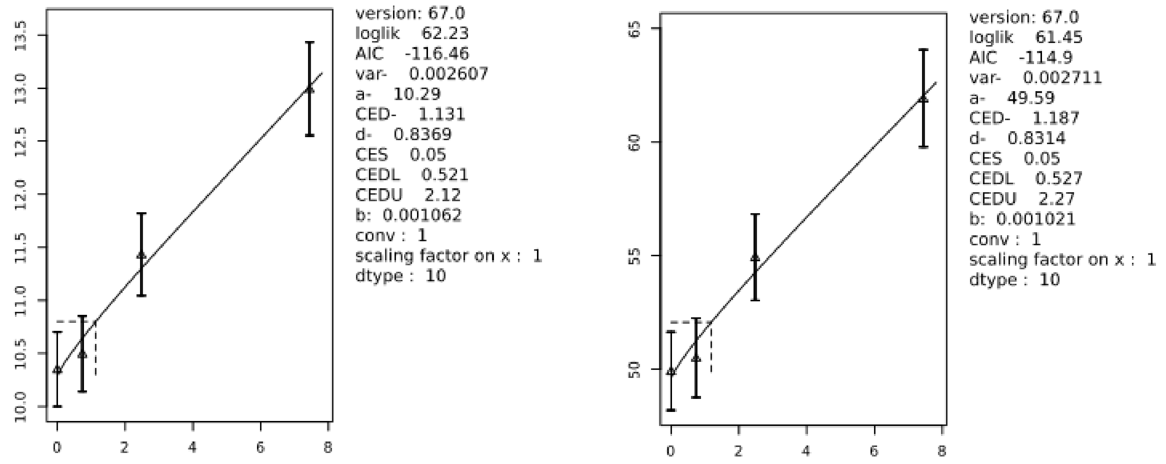

Figure 1: Modelling of the haemoglobin concentration (left) and of the haematocrit value (right) in the blood of male rats using the example of the "exponential model 3"; x-axis: dose in mg Co/kg bw/day; y-axis: haemoglobin in mmol/l (left) and/or haematocrit in % (right)

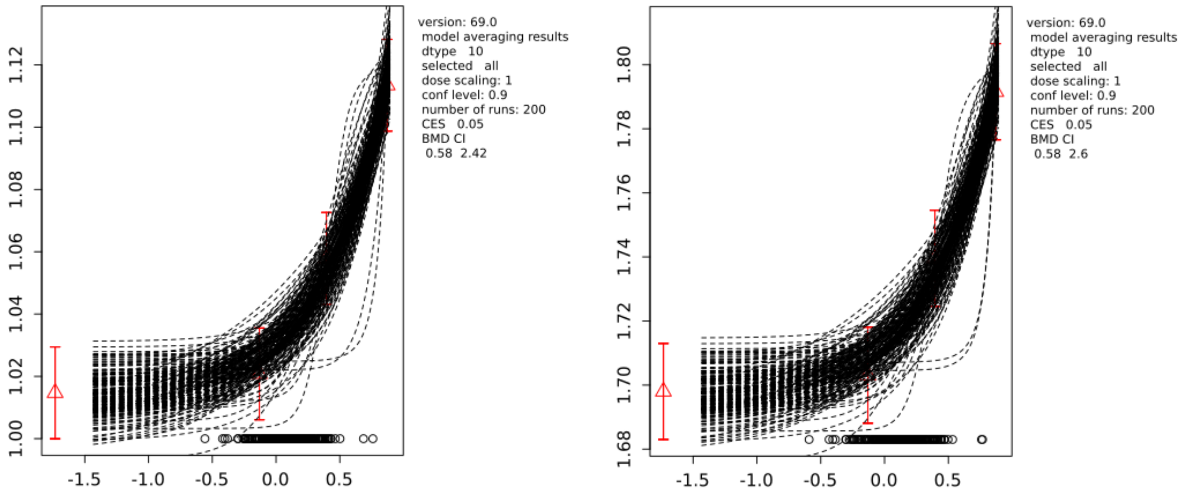

Figure 2: Modelling of the haemoglobin concentration (left) and of the haematocrit value (right) in the blood of male rats: Mean $BMDL_{05}$ values by means of "model averaging"; x-axis: dose in mg Co/kg bw/day; y-axis: haemoglobin in mmol/l (left) and/or haematocrit in % (right), in each case logarithmic scaling with base 10

In addition to its toxicological impact, cobalt is essential to the human body in its complexed form as a component of cobalamins. Cobalamins are also known as the Vitamin B_{12} group and synthesised by certain bacteria (O'Leary und Samman, 2010). They are coenzymes for methionine synthase and methylmalonyl-Coenzyme A mutase (Ströhle et al., 2019). These enzymes catalyse intermediate steps in the breakdown of certain fatty acids and amino acids. The succinyl-Coenzyme A formed in the process contributes to energy metabolism via the mitochondrial citric acid cycle. Over and above this, basic building blocks are generated for the synthesis of DNA bases. The DACH reference value issued jointly by the German Nutrition Society (DGE), the Austrian Nutrition Society (ÖGE) and the Swiss Nutrition Society (SSG/SSN) for the recommended daily dose in adults is 4 µg vitamin B_{12} (Ströhle et al., 2019). This corresponds to approximately 0.15 µg cobalt. A longer-term, significant Vitamin

B_{12} deficiency is associated with an increased risk of cardiovascular diseases, bone damage and pancytopenia (in particular anaemia) and, in pregnant women, with an increased risk of miscarriage as well as neural canal defects in the foetuses (O'Leary und Samman, 2010; Ströhle et al., 2019; Watanabe, 2007).

The Guideline from the European Council on Metals and Alloys (EDQM, 2013) reports daily intake values for cobalt of 0.18 µg/kg bw for adults and 0.31 µg/kg bw for children; these are based on the results of a Total Diet Study carried out by the French food safety authority ANSES in 2011 (ANSES, 2011). These correspond to 11 and 19%, respectively, of the TDI of 0.0016 mg/kg bw/day (1.6 µg/kg bw/day) used for deriving the release limit. Other studies (ATSDR, 2004; EFSA, 2009; Nielsen et al., 2013) show that the cobalt intake ranges between 3 and 15 µg/person/day, which corresponds to 0.05 - 0.25 µg Co/kg bw/day (adults, bw = 60 kg) and 0.25 - 1.25 µg Co/kg bw/day (toddlers, bw = 12 kg). The TDI would therefore already be largely exhausted in toddlers. However, more recent figures from France estimate the daily cobalt intake from foodstuffs in toddlers aged up to 36 months to be 0.06 - 0.51 µg/kg bw/day, so as somewhat lower (ANSES, 2016; Sirot et al., 2018). Depending on the place of residence, however, the drinking water can be a significant source of exposure, above all in mining regions (ATSDR, 2004).

In the following section, the BfR has - on the basis of the available data on toxicology and on the exposure of consumers from other sources - derived toxicologically acceptable values for the release of cobalt and also lead and cadmium from ceramic food contact articles.

3.1.2.4 Derivation of toxicologically acceptable release values

The currently valid Directive 84/500/EEC on ceramic articles intended to come into contact with foodstuffs sets down limits for the release of lead and cadmium (see Table 1). These values, to the best of the BfR's knowledge, were not established on the basis of toxicological data and a subsequent risk assessment but represent the best available technology regarding (element) release at the time of drawing up the legislation (1970s). These limits should, in the BfR's view, be adapted in line with current toxicological findings.

From a toxicological perspective, the BfR recommends that ceramics should not release any lead or cadmium (see sections 3.1.2.1 and 3.1.2.2). With the latest analytical technology, limits of detection in the ppt range (1 nanogram (ng) lead or cadmium per kg foodstuff (simulant)) are achieved. However, the sensitivity and accuracy of the determination method - and thereby the reliability of the assessment of a tested product - are essentially influenced by the contribution of the sample preparation (release) to the measurement uncertainty. Taking into account the customary equipment in analytical laboratories and the named influential factors on the stated result, the BfR recommends - in accordance with the *"discussion starting value"* (Beldì, 2016; Simoneau et al., 2017) proposed by the European Commission - that the migration of lead and cadmium from ceramics must not be detectable, with a limit of detection of 10 µg lead/kg foodstuff(simulant) or 5 µg cadmium/kg foodstuff(simulant).

In the case of cobalt, the European Council has, as part of the Technical Guideline on Metals and Alloys (EDQM, 2013), derived a specific release limit (SRL) based upon the TDI of 1.4 µg/kg bw derived by the RIVM (2001). Here, starting with an acceptable daily cobalt intake of 0.084 mg for a 60 kg adult, an allocation factor of 20% was used, so that an SRL of (rounded) 0.02 mg/kg foodstuff(simulant) for cobalt results (EDQM, 2013). The BfR likewise regards the application of an allocation factor of 20% of the acceptable daily intake as justified. This procedure is based on the considerations of the EU Commission concerning the application of allocation factors, and is used above all to sufficiently protect children since the TDI may in some cases already be exhausted through dietary intake. The BfR does not have any more recent data for deriving a TDI for cobalt. In view of the uncertainties in the available data concerning the toxicity of cobalt (ECHA, 2016), the BfR uses the conservative TDI of 1.6 µg cobalt/kg bw/day as a basis for its risk assessment. The release of cobalt from ceramic food contact materials should therefore not exceed the value of 0.02 mg/kg foodstuff(simulant) derived from this TDI (bw = 60 kg, allocation factor = 20%, consumed quantity = 1 kg foodstuff/day).

3.1.3. Exposure assessment

For the exposure assessment, the BfR uses the available data from the food monitoring authorities from the years 2016 and 2017 concerning the release of the elements lead, cadmium and cobalt from plates into the foodstuff simulant 4% acetic acid. In total, 42 heavily decorated plates, 35 of which are explicitly intended for use by children, were tested. 30 plates were tested by the German federal state of North Rhine-Westphalia (NRW), 11 plates by the German federal state of Baden-Württemberg (BW) and one plate by the BfR. The test was performed in accordance with the specifications of the Directive 84/500/EEC. The release of lead and cadmium was determined for all plates, and for 31 plates additional testing was performed for cobalt. The results show that in 7 plates the release of cadmium is above the current limit set in Directive 84/500/EEC.

Table 2: Release data from the food monitoring authorities and from the BfR regarding lead, cadmium and cobalt from ceramic plates in µg/dm²

Element	Number of measurements	Minimum	Median	Mean	90th percentile	95th percentile	Maximum
Lead	42	< 1	10.0	54.7	129	152	500
Cadmium	42	<0.2	1.1	24.0	105	142	170
Cobalt	31	< 1	2.0	18.1	85.0	114	133

The limits from the Ceramic Directive 84/500/EEC (see Table 1) are solely to be regarded in combination with the testing conditions stipulated therein. It should be noted that requirements that arise from the risk assessment perspective regarding the release of elements from ceramic relate to the content in the foodstuff, taking into account the usual assumptions on consumption quantities (1 kg foodstuff/day) and body weight (60 kg).Therefore, a comparison of the release values obtained experimentally in accordance with the specifications of the Ceramic Directive 84/500/EEC (4% acetic acid, 24 h, 22 ± 2 °C) with toxicologically derived thresholds must be regarded critically against this backdrop.

3.1.4. Risk characterisation

In order to assess the release values under consideration, in the BfR's view it is possible to use three different assessment approaches. The first two (conventional and exposure-related approach) are, from the BfR's point of view, to be preferred, since in these approaches the assessment is based on health-based guidance values.

3.1.4.1 Conventional approach

Frequently, foodstuffs are only in contact with ceramics for less than 24 hours. The intended use of the different ceramic food contact articles available on the market ranges from the preparation, serving and/or consumption and short-term storage to the cooking and baking of foods. Consequently, contact temperatures and -times may differ greatly. Hence, significantly higher temperatures than room temperature must also be taken into account (e. g. hot-filling, microwave heating, preparation in the oven). In addition, the release of metals at temperatures above 60 °C increases disproportionately in acidic media owing to the decomposition of the glass body (Beldì, 2016; Seth et al., 1973). On the other hand, scenarios with significantly longer contact times are conceivable (e.g. storage of long-life foodstuffs). Since there is currently no differentiated approach available for exposure-relevant release scenarios for ceramics, the BfR - as well as the Norwegian Scientific Committee for Food Safety (VKM) - uses the standardised testing conditions of 24 hours at room temperature with 4% acetic acid and the assumption of 5 square decimetres (dm²)/kg foodstuff arising from the Directive 84/500/EEC for the surface-volume ratio for flatware to estimate the release from the ceramic to the foodstuff (VKM, 2004).

In accordance with the specifications of the Ceramic Directive 84/500/EEC, the repeated use of food contact articles made from ceramic is also tested in the first release test. By contrast, for the testing of repeated use for food contact articles made from other materials, measurement in the third release test was established (EDQM, 2013; EU, 2011). This approach is also proposed by the European Reference Laboratory (EURL) for ceramics (Beldì, 2016). The data taken as a basis for the present assessment, however, were gathered in the first release test. In its tests, the EURL (Beldì, 2016) experimentally determined a connection between the first and the third release test. In order to assess the third release test (i.e. of repeated use) the BfR therefore proposes using, in a first approximation, the correlation determined experimentally by the EURL for assessment purposes. However, in the experiments by the EURL, the reduction in the quantity of released metal was dependent from test to test on the relevant article being investigated and on the released metal. Hence, the authors (Beldì, 2016) advise against using such a calculation factor. Nevertheless, in this Opinion - by way of an alternative - the average of the ratio between the third and first release test is set at 20% (migration results for lead, Table 8 from (Beldì, 2016) with 14 samples, non-rounded mean value 18.1%). In the BfR's view, the release of lead and cadmium from ceramics should not be detectable, with a limit of detection of 10 µg lead/kg foodstuff (simulant) or 5 µg cadmium/kg foodstuff (simulant). This applies both to the first and to the third release test. Consequently for lead and cadmium no conversion is performed between the release tests. From the assumptions described, the following values are calculated for an acceptable surface-related release (see Table 3):

Table 3. Derivation of acceptable surface-related release values - conventional approach, highlighted grey: values used for assessment

Element	Derived acceptable release in µg/kg foodstuff(-simulant)	Estimation of the acceptable concentration in the first release test in µg/kg*	Acceptable surface-related release in the first release test in µg/dm² (S/V = 5)
Lead	ND (10)	ND (10)	**ND (2)**
Cadmium	ND (5)	ND (5)	**ND (1)**
Cobalt	20	100	**20**

ND: not detectable (value smaller than the limit of detection), the number in brackets constitutes an acceptable limit of detection.
* Assumption: 3rd release test = 20% of the value from the 1st release test
S/V: Surface-Volume-Ratio

When using these assumptions, 27 of the 42 measured values (64%) for lead, 13 of the 42 measured values (31%) for cadmium and 5 of the 31 measured values (16%) for cobalt are above the derived acceptable surface-related release values.

3.1.4.2 Exposure-related approach

With this alternative approach to assessing the exposure, the BfR assumes a daily one-off dietary intake of a toddler from one and the same ceramic plate. The weight of the toddler is assumed as being 12 kg (EFSA, 2016), the surface area of the plate as being 3 dm². For the element lead, with an intake of 6 µg/day, the $BMDL_{01}$ value of 0.5 µg/kg bw/day for developmental neurological impairments in children is already exhausted. The maximum intake for cadmium, derived from the TWI of 2.5 µg/kg bw/week, is 4.3 µg/day (2.5 µg/kg bw/week x 12 kg bw / 7 days/week). For cobalt, a maximum intake of 19.2 µg/day results from the TDI of 1.6 µg/kg body weight and day. It is also assumed that the total quantity of heavy metals released in the third release test migrates into the food and is consumed. To convert the experimentally determined values from the first release test to the third release test, the above-named assumption (3rd release test = 1st release test * 20%) is applied (results in Table 4). In this approach, solely the exposure via ceramic food contact materials is considered and therefore no allocation factor is taken into account. In particular for lead and cadmium, the intake from other sources, such as foodstuffs, may already reach or exceed the relevant health-based guidance values.

Table 4. Derivation of acceptable surface-related release values - exposure-related approach, highlighted grey: values used for assessment

Element	Acceptable quantity in µg/day (= µg/plate)	Acceptable surface-related quantity in µg/dm² (3 dm²/plate)	Estimation of the acceptable surface-related release in µg/dm² in the first release test*
Lead	6	2	**10**
Cadmium	4.3	1.4	**7**
Cobalt	19.2	6.4	**32**

* Assumption: 3rd release test = 20% of the value from the first release test

When using these assumptions, 20 of the 42 measured values (48%) for lead, 12 of the 42 measured values (29%) for cadmium and 5 of the 31 measured values (16%) for cobalt are above the derived acceptable surface-related release values.

3.1.4.3 Technical feasibility

The results of the monitoring carried out in Germany in 2014 “Release of elements from food contact articles” (BVL, 2016) are taken as a starting point. The raw data available for flatware were evaluated separately by the BfR with respect to the issues being considered here, and the results summarised in the following table.

Table 5: Results from the 2014 monitoring on lead, cadmium and cobalt from non-fillable ceramic articles (flatware) in µg/dm²; < LOQ = below the limit of quantification

Element	Number of measurements	Minimum	Median	Mean	90th percentile	95th percentile	Maximum
Lead	122	<LOQ	15.8	89.0	70.7	119	2695
Cadmium	123	<LOQ	0.80	2.54	5.00	9.76	27.0
Cobalt	115	<LOQ	0.71	37.5	50.0	50.0	1514

The 95th percentile of the totality of the samples is considered technically feasible. For lead, this results in a value of 119 µg/dm², rounded 100 µg/dm², for cadmium 9.8 µg/dm², rounded 10 µg/dm² and for cobalt 50 µg/dm². In Table 6, for a better overview, the 90th and 95th percentile of the monitoring data and the acceptable surface-related release values derived from these by the BfR are displayed. It should be pointed out, however, that while there are a few samples with very high release, this contrasts with a large number of samples with, comparatively, significantly lower element release values. This is clearly apparent from the sharp rise in the values from the median via the 90th/95th percentile to the maximum and a big difference between the mean value and the median. It can therefore be assumed that for the overwhelming number of articles, a significantly lower release than the named values is also technically possible. For cobalt, it should also be noted that the 95th percentile corresponds to a measurement below the limit of quantification (LOQ) of a large number of the measured values which was corrected according to the “upper bound” approach to the LOQ of the measurements. The LOQ for these measurements is comparatively high (see median). It can therefore be assumed that the actual release is lower and therefore, overall, a lower release than 50 µg/dm² ought to be technically feasible.

Table 6. Derivation of surface-related release values - technical feasibility, highlighted grey: values used for assessment

Element	90th percentile [µg/dm²]	95th percentile [µg/dm²]	acceptable surface-related release in µg/dm² used for assessing the technical feasibility in the first release test
Lead	71	119	100
Cadmium	5.0	9.8	10
Cobalt	50	50	50

When evaluating the results using these criteria, 10 of the 42 measured values summarised in Table 2 for lead (24%), 11 of the 42 measured values for cadmium (26%) and 4 of the 31 measured values for cobalt (13%) show migration above the level of technical feasibility.

The assumptions concerning technical feasibility are supported by monitoring data from Poland in which, in the years 2010-2012, 83% of the samples displayed release values below 100 µg/dm² lead and 93% of the samples displayed release values below 10 µg/dm² cadmium in the first release test (Rebeniak et al., 2014).

In the BfR’s last Opinion on this matter in 2004 (BfR, 2004), test results from the years 1998 to 2001 were presented. Even then, flatware showed comparable release values: 87% of the release values for lead were below 50 µg/dm² and 84% of the release values for cadmium were below 5 µg/dm².

3.1.4.4 Risk characterisation summary of assessment approaches

The results of the assessment in accordance with the three above-mentioned assessment approaches are summarised in Table 7 and Table 8. The percentage of samples whose element release exceeds the derived acceptable release values is - across all assessment approaches - largest for lead. For the conventional and the exposure-related approach, more than and almost half of the samples, respectively, release too much lead. The level to which the value is exceeded in each case (Table 8) must also be viewed critically. For example the 95th percentile of the lead releases is up to 76 times (= 7600%) higher than the acceptable release value (conventional approach). Even the median reaches the - from a health perspective - acceptable release value (exposure-related approach) or exceeds it significantly (conventional approach).

In many cases (up to 31%) the cadmium release from the samples also exceeds the acceptable release values, in some cases very clearly. For example the 95th percentile of the cadmium releases is up to 142 times higher than the acceptable release value (conventional approach). By comparison, however, the median of the cadmium release is very low and only slightly exceeds the acceptable release values (conventional approach) or not at all (exposure-related approach).

Table 7. Comparison of the three approaches for risk assessment and proportion of samples with exceedance of the respective derived acceptable surface-related release values / total sample number

Element	**Conventional approach**		**Exposure-related approach**		**Technical feasibility approach**	
	Acceptable release value in µg/dm²	Number samples with exceedance	Acceptable release value in µg/dm²	Number samples with exceedance	Acceptable release value in µg/dm²	Number samples with exceedance
Lead	2	27 / 42 (64%)	10	20 / 42 (48%)	100	10 / 42 (24%)
Cadmium	1	13 / 42 (31%)	7	12 / 42 (29%)	10	11 / 42 (26%)
Cobalt	20	5 / 31 (16%)	32	5 / 31 (16%)	50	4 / 31 (13%)

Table 8. Comparison of the three approaches for risk assessment in terms of the respective acceptable surface-related release values, in relation to selected percentiles of the release values; values marked bold exceed the relevant acceptable surface-related release value

Element	**Measurement in µg/dm²**	**Conventional approach**	**Exposure-related approach**	**Technical feasibility approach**
		% of the acceptable release value	% of the acceptable release value	% of the acceptable release value
Lead		Acceptable release: 2 µg/dm²	Acceptable release: 10 µg/dm²	Acceptable release: 100 µg/dm²
Median	10.0	**500**	100	10
Mean	54.7	**2735**	**547**	55
95th percentile	152	**7600**	**1520**	**152**
Cadmium		Acceptable release: 1 µg/dm²	Acceptable release: 7 µg/dm²	Acceptable release: 10 µg/dm²
Median	1.1	**110**	16	11
Mean	24.0	**2400**	**343**	**240**
95th percentile	142	**14200**	**2029**	**1420**
Cobalt		Acceptable release: 20 µg/dm²	Acceptable release: 32 µg/dm²	Acceptable release: 50 µg/dm²
Median	2.0	10	6,2	4,0
Mean	18.1	91	57	36
95th percentile	114	**570**	**356**	**228**

The released amounts of cobalt exceed the acceptable release values for significantly fewer samples compared with lead and cadmium. Nevertheless the 95th percentile of the cobalt release is almost 6 times as high as the acceptable release (conventional approach). In particular against the backdrop of toddlers being a consumer group, which must be regarded particularly critically, the described release values for the highly decorated plates tested were in part significantly too high (compared with the health-based guidance values). If the intake values which are acceptable from a health perspective are exceeded long term (conventional and exposure-oriented approach) an increased risk of reversible and irreversible health impairment is possible. This seems particularly critical against the backdrop of the severity of the possible harmful effects (see Section 3.1.2). This is compounded by an already high exposure from other sources (e. g. foodstuffs), which may exhaust or exceed the health-based guidance values. Consequently, food contact materials made from ceramic ought, if possible, not to release any lead or cadmium into foodstuffs (conventional approach). On no account should, on a day-to-day basis, quantities of lead, cadmium and cobalt pass into foodstuffs, which are greater than those determined using the exposure-related approach, in particular when the foodstuffs are consumed by children. For the 95th percentile of the observed release (technical feasibility approach), if these happen to be the actual migration into food, an increased health risk is possible. In particular for lead, the corresponding value is more than one order of magnitude above the toxicologically derived, acceptable release values.

3.2. Other aspects / Uncertainty analysis

Compared with the results of the monitoring from 2014 (Table 5), when testing exclusively heavily decorated plates (risk-oriented sampling, see Table 2) an increased release of cadmium (mean value, 90th and 95th percentile, maximum value) is noticeable.

As already mentioned in Section 3.1.3, the usage conditions for ceramic products are varied. At the BfR, comparative tests were performed regarding the release of elements into simulants (4% acetic acid and 0.5% citric acid) and into a foodstuff (apple purée) (Kolar, 2017). A plate (surface area 2.77 dm²) belonging to a ceramic breakfast set for children was used for the release tests (contained in the data set of Table 2). The tests were performed following DIN EN 1388 (4% acetic acid; 24 hours at 22 °C) and the conditions of the Practical Guide of the European Council on Metals and Alloys for Hot Filling (0.5% citric acid solution; 2 hours at 70 °C) (EDQM, 2013). In addition, heating with a commercially available microwave (710 watts) was incorporated into the comparative release tests in order to determine the release of the elements into the simulant 0.5% citric acid solution and the foodstuff apple purée during heating to approx. 100 °C (3 minutes). In order to model consumer-typical, frequent use of the ceramic children's crockery, a total of 9 successive release experiments were performed. The results are depicted in Table 9.

When evaluating the data, it is noticeable that also with the 9th release experiment, in all cases quantities of cadmium are released, which with long-term daily intake can lead to an increased health risk (see "Exposure-related approach" in 3.1.4.2, acceptable release quantity 1.4 µg/dm²).

The comparison of the release under the conditions of hot filling (2 hours, 70 °C) into the simulant citric acid show, in comparison with the currently standardised testing conditions (24-hour test at 22 °C, simulant 4% acetic acid), higher release rates and a smaller reduction in the release rates on repeated use. The comparison of the experiments with 0.5% citric acid solution under hot filling conditions (2 hours, 70 °C) and the short-term experiments in the microwave shows similarly high release values for the plate tested. Additional comparative release experiments into the foodstuff apple purée were performed in the microwave. Since apple purée has a significantly higher pH than 0.5% citric acid solution, the elements release is lower. For cadmium, however, the release values are up to 7 times higher than the - from a health perspective - acceptable release quantity of 1.4 µg/dm^2 (see exposure-related approach in Section 3.1.4.2). With a long-term daily intake of such quantities of cadmium, an increased risk to health is possible.

Table 9. Results of the release tests on lead, cadmium and cobalt from a highly decorated plate during repeated testing

Test	Compartment dryer		Microwave	
	Release into 4% acetic acid* in µg/dm² 22 °C, 24 hours	Release into 0.5% citric acid** in µg/dm² 2 hours, 70 °C	Release into 0.5% citric acid*** in µg/dm² 3 mins to 100 °C	Release into apple purée**** in µg/dm² 3 mins to 100 °C
Lead				
1	3.5	5.3	5.3	0.42
2	1.1	5.5	3.2	0.14
3	0.6	5.2	2.6	0.11
4	0.8	3.1	2.4	0.13
5	0.5	2.7	1.6	0.08
6	0.5	1.9	1.4	0.07
7	0.7	1.1	1.3	0.08
8	0.3	1.2	1.0	0.05
9	0.4	1.1	0.9	0.09
Cadmium				
1	108	132	114	11
2	21	132	68	3
3	11	151	57	3
4	16	92	68	4
5	11	88	41	3
6	10	66	40	3
7	13	36	47	2
8	8	41	32	2
9	9	38	30	2
Cobalt				
1	133	165	137	10
2	18	97	64	4
3	7	91	47	3
4	11	65	44	4
5	5	64	24	3
6	5	56	22	3
7	6	27	20	2
8	4	33	17	2
9	4	30	15	2

* DIN EN 1388 4% acetic acid; 24 hours at 22 °C
** Release following the conditions of the Practical Guide of the European Council (2 hours at 70 °C with 0.5% citric acid solution)
*** Release in a commercially available microwave (710 watts; duration 3 minutes, start temperature room temperature; end temperature approx. 100 °C) with 0.5% citric acid solution
**** Release in a commercially available microwave (710 watts; duration 3 minutes, start temperature room temperature; end temperature approx. 100 °C) with apple purée (pH 3.41)

It can be assumed that the test for release under the currently defined testing conditions (4% acetic acid, 22 °C, 24 hours) underestimates the real release under the conditions of heating in the microwave. The BfR points out that these are initial, comparative data which provide indications of the release behaviour under different usage conditions. Further tests are needed in order to make general statements.

For food contact materials for repeat use made from metals/alloys it is usual, or for those made of plastic compulsory, to use the results from the third release test for assessment. The data assessed in this Opinion concerning release from ceramic articles was determined, in accordance with the Directive 84/500/EEC, in the first release test. In order to convert the data to a possible third release test, a factor of 0.2 is used as discussed in Beldì (2016). This procedure involves some uncertainty with regard to the individual article, as the factor, as described in Beldì (2016), is not always the same and the correlation is not always clear. For example, even within the 14 samples tested in Beldì (2016) in respect of their lead release, the factor varies between 0.35 and 0.06.

In light of the results and limitations described above regarding the release tests, the assessment of the measured release of lead, cadmium and cobalt on the basis of health-based guidance values involves some uncertainties. However, the statement that the release for some of the plates is too high, in particular in relation to lead and cadmium, remains indisputable.

3.3. Risk management options / Recommendations

The BfR recommends that when assessing the release of elements from ceramics in terms of health risks, significantly lower health-based guidance values than the limits specified in the Directive 84/500/EEC should be used. On the basis of the data gathered for ceramics as part of the Germany-wide monitoring (BVL, 2016), the BfR recommends expanding the Directive 84/500/EEC at least to include the element cobalt. For articles in Category 1 of the Directive 84/500/EEC (flat articles such as plates) the BfR has, by way of an example, derived toxicologically justified, surface-related release values of 2 and 10 µg lead/dm^2, 1 and 7 µg cadmium/dm^2 and 20 and 32 µg cobalt/dm^2 (conventional and exposure-related approaches respectively). In particular for lead and cadmium, the intake from other sources, such as foodstuffs, may already reach or exceed the respective health-based guidance value. Consequently, in the exposure-related approach, one might consider the application of allocation factors as a risk management measure.

In addition, in the BfR's view the Ceramic Directive should also be revised in respect of the test conditions. Hot applications such as baking, cooking, heating in the microwave and hot filling as well as the change in release during repeated use should be given greater consideration. There is the possibility that the conditions currently stipulated underestimate the potential element release at high temperatures. In addition, further research is required to characterise the links between repeated use and reduction in release. This applies both to foodstuffs and also to simulants used for testing purposes.

There should be technological endeavours to further reduce element release from ceramic materials, above all if the materials are to be used in the context of foodstuffs for children. Since coloured glazes and patterns often have the capability to release heavy metals and since the highest resulting exposure is to be expected in children, who are frequently the target group for such products (vulnerable consumer group), manufacturers of such ceramics should take particular precautionary measures in this regard.

Further information on the subject from the BfR website

Lead - Overview of all BfR publications on lead
https://www.bfr.bund.de/en/a-z_index/lead-129758.html

Cadmium - Overview of all BfR publications on cadmium
https://www.bfr.bund.de/en/a-z_index/cadmium-129752.html

Main topic: materials in contact with foodstuffs
https://www.bfr.bund.de/en/health_assessment_of_food_contact_materials-528.html

BfR "Opinions app"

4. References

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