



Risk assessment of health hazards from lead and other heavy metals migrated from ceramic articles

Assessed by: The Panel on Food Additives, Flavourings, Processing Aids, Materials in contact with food and Cosmetics

Date: 19 October 2004

Summary:

The Norwegian Scientific Committee for Food Safety [Vitenskapskomiteen for mattrygghet (VKM)] was commissioned by the Norwegian Food Safety Authority [Mattilsynet] to assess potential health hazards linked to the intake of heavy metals such as lead, cadmium and barium from ceramic articles. The question was assessed by the Panel on Food Additives, Flavourings, Processing Aids, Materials in contact with Food and Cosmetics. A survey conducted by the Norwegian Food Control Authority [Næringsmiddeltilsynet] in Oslo in 2003 provided the basis for commissioning the risk assessment, as several ceramic articles tested had indicated lead migration levels over the migration limit. Exposure from all three heavy metals has been assessed in relation to the provisional tolerable weekly intake (PTWI) for lead and cadmium set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and the tolerable daily intake (TDI) for barium based on the WHO's guideline value for barium levels in drinking water. The exposure calculations carried out were based on the assumption that the amount of liquid consumed from ceramic articles was 1 litre per day, and exposure to other sources was taken into account. The estimated intakes therefore indicate a "worst-case" scenario for heavy metal migration from ceramic articles.

Lead migration at the levels measured in the survey could lead to an estimated intake exceeding the PTWI of 25 µg/kg body weight several times over. The intake is 120 times higher than PTWI from the ceramic article releasing the highest amount (30 mg/l lead). This level of intake could represent a risk of lead poisoning. Migration at the current limit for lead (4.0 mg/l for hollow products < 3 l) would give a weekly intake of 400 µg/kg body weight for a person weighing 70 kg. This is 16 times PTWI.

Corresponding calculations for cadmium indicate that migration at the levels measured in the survey could lead to an intake far exceeding the PTWI of 7 µg/kg body weight. For the ceramic article with the highest migration level (0.23 mg/l cadmium) the estimated intake would be approximately three times the PTWI. Migration at the current limit for cadmium (0.3 mg/l for hollow products < 3 l) would give a weekly intake of 30 µg/kg body weight for a person weighing 70 kg. This is more than four times the PTWI. The results from the exposure calculations carried out in the risk assessment indicate that the migration limits for lead and cadmium in the current regulations are too high to assure safe products in terms of safeguarding the public's health.

In the case of barium, the exposure calculations in the risk assessment indicate that 11 of the ceramic articles tested would exceed the TDI of 0.05 mg/kg body weight. The estimated daily intake from the article with the highest migration (80 mg/l barium) is equivalent to 1.14 mg/kg body weight for a person weighing 70 kg. This is 22 times the TDI, which indicates a need to lower the intake of barium from ceramic articles.

Compared with previous surveys of industrially manufactured ceramic articles, the conclusion could be drawn that the problem of heavy metal migration from ceramic articles is predominantly linked to hand-crafted articles made by potters. This is also reflected in the high levels of lead migration found in imported Greek ceramic articles associated with the recently reported cases of lead poisoning in Sweden.

1. Terms of reference

In its letter of 26 January 2004 the Norwegian Food Safety Authority asked the Norwegian Scientific Committee for Food Safety (VKM) to assess potential health hazards linked to the intake of lead (Pb) and other heavy metals, such as cadmium (Cd) and barium (Ba), from ceramic articles. Based on the results of a survey conducted by the Norwegian Food Control Authority in Oslo in 2003 (1) which investigated the migration of metals from ceramic articles, the Norwegian Food Safety Authority wanted VKM to assess migration levels, exposure and existing limits for migration of heavy metals from ceramic articles with regard to the tolerable daily intake levels for the metals in question. Exposure levels from ceramic articles were requested examined in context with other known sources of intake of the above-mentioned heavy metals.

2. Background

Lead has been used since ancient times and its toxic effect is well-known (2). Even though classic cases of lead poisoning are rare nowadays, several incidents of lead poisoning caused by lead migration from ceramic articles have recently been reported. In Norway, a healthy 54-year-old woman suffered lead poisoning in 2000 after having drunk wine, which had been kept in a Greek pottery jug for several days (3). In Sweden, two cases of lead poisoning have been reported in 2004 after drinking juice kept in ceramic articles. First, a person suffered serious lead poisoning in January after having drunk juice kept in a ceramic jug bought in Greece (4). Then in May, high levels of lead were discovered in the blood of members of a family who had also drunk juice from a similar ceramic jug (5).

Lead is added to the glaze in order to lower the baking temperature and make ceramic articles more visually attractive. If ceramic articles are baked at the wrong temperature, the glazing will not have the desired sealing properties and lead can leak into food and drink with a low pH (6). To ensure that ceramic articles under normal or foreseeable conditions of use do not transfer their constituents to food in quantities which could endanger human health, migration limits have been established for migration levels of lead and cadmium (which are used in glazing pigments) in the legislation (7).

Table 2.1 Migration limits for lead and cadmium from ceramic articles

	Lead	Cadmium
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
Cooking ware, packaging and storage vessels having a capacity of more than three litres	1.5 mg/l	0.1 mg/l
All other articles (hollow products) which can be filled and having a capacity of less than three litres	4.0 mg/l	0.3 mg/l

Common for all the articles causing these poisoning incidents was the fact that all of them showed migration of lead exceeding the migration limit. In the most serious case in Sweden, it was found that the migration from the ceramic jug was as high as 500 mg lead/l.

Norway and the other Nordic countries have only established limits for the migration of lead and cadmium from ceramic articles. These regulations have been harmonized within the whole European Economic Area (8). In the Netherlands, a migration limit also has been set for barium at 1 mg/kg foodstuffs in glass and so-called glass ceramics. These kinds of products do not conform to the usual definition of ceramic articles.

Cadmium and barium are other heavy metals, which are used in pigments to colour the glaze used for ceramic articles. No cases of poisoning from migration of these heavy metals have been reported.

3. Toxicology

Lead (Pb)

Lead is accumulated in the body in a variety of tissues and organs and can give many different toxic effects in large enough doses. The main effects of long-term exposure to low doses of lead are on the nervous system. Small children, and foetuses in particular, are most vulnerable, and exposure to lead could result in reduced cognitive and motoric development. These effects of lead are well documented and have also been confirmed through epidemiological studies (9). Based on the effects on children and foetuses, the PTWI for lead was set to 25 µg/kg body weight in 1986 by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In 1993 and 2000, JECFA confirmed this PTWI value and extended it to apply to all ages (10, 11). The European Food Safety Authority (EFSA)'s Scientific Panel on Contaminants in the Food Chain has recently issued an revised opinion in 2004 in which they conclude that lead contamination of food is regarded as a public health problem because new data could indicate that mental and cognitive development in foetuses and small children might be inhibited even by quantities of lead previously thought to be safe (12).

Cadmium (Cd)

Cadmium is absorbed gastrointestinally by the same mechanism as other divalent metals and accumulates primarily in the kidneys and the liver. The absorption rate of cadmium can increase significantly if a person is iron deficient. The metal is excreted from the body very slowly (biological half-life is between 10 – 30 years) and is accumulated with age, in practice throughout life. The largest concentration can accumulate in the renal cortex. Kidney damage with proteinuria is the primary effect of cadmium exposure and possibly accompanied by

disturbances in the calcium and vitamin D metabolism, which could lead to loss of bone mass and osteoporosis. Long-term effects have also been observed in the liver, as well as in haematopoietic, immuno- and cardiovascular organs, and furthermore in the skeleton. The effects of cadmium are well documented (13). The International Agency for Research on Cancer (IARC) has also classified cadmium as a human carcinogen, although this applies predominantly to inhalation. The PTWI has been set by the JECFA to 7 µg/kg body weight (14). Cadmium was re-evaluated by the JECFA in 2003 (15). More recent epidemiological studies have indicated that low-grade exposure at the PTWI level is linked to an increased prevalence of minor renal changes. The long-term significance of these changes is uncertain, and JECFA has therefore retained the previous PTWI of 7 µg/kg body weight.

Barium (Ba)

Barium can disturb the cellular transportation of potassium and intake of high doses of soluble barium can induce hypokalemia, which could lead to cramps and muscular paralysis as well as arrhythmia. Barium can also induce vasoconstriction. Incidents of food-borne barium poisoning have been reported, as well as a number of cases of suicide or suicide attempts. Insoluble barium sulphate is used as an x-ray contrast agent and cannot be absorbed gastrointestinally.

Less toxicological data is available for barium than for lead and cadmium, and has not been evaluated by either JECFA or EU. WHO has proposed a guideline value for barium in drinking water of 0.7 mg/l, based on an epidemiological study in which no effect on blood pressure or the prevalence of cardiovascular disease was found from exposure to drinking water containing up to 7.3 mg barium/l, and by using an uncertainty factor of 10 for inter-individual variation (16). In so-called ecological studies of populations previously exposed to barium in drinking water, higher risks of cardiovascular disease or death have been observed. In a clinical study, in which 11 men were given barium in doses of up to 10 mg/l, no indications of any adverse health effects were found. However, these studies are difficult to interpret because of several confounding factors, or because of a small number of subjects included.

However, this guideline value based on the epidemiological study is close to a guideline value derived from the results of a study in which barium was given in drinking water to rats for up to 16 months, and in which higher blood pressure was observed at the highest doses. Based on the results from this animal study a TDI of 51 µg/kg body weight was established by employing an uncertainty factor of 10 (10 for variation between humans and 1 for extrapolation from rats to humans, since it has been shown that humans are not more sensitive than rats). By allocating 20% of the TDI to drinking water, a guideline value of 0.3 mg/l in drinking water was set by WHO.

A TDI of 51 µg/kg body weight will correspond to a tolerable daily intake of 3.57 mg barium for an adult weighing 70 kg.

4. Analytical results

Sampling

In 2003, the Norwegian Food Control Authority in Oslo conducted a survey on the migration of metals from ceramic articles commissioned by the Norwegian Food Safety Authority (1). The survey consisted of 648 individual ceramic articles intended to come into direct contact with foodstuffs. The articles were for the most part made by Norwegian potters and not manufactured industrially. Of these, 631 were hollow products and 17 were flatware (less than 25 mm deep). 41 hollow products intended for drinks were tested for lead migration from the rim (2 cm from the top edge). The Norwegian Food Safety Authority asked the Norwegian Scientific Committee for Food Safety to assess the health risks associated with the levels of heavy metal migration found in this survey.

Migration test

A standard method compliant with the EEC Council Directive of 15 October 1984 laying down basic rules for determining the migration of lead and cadmium (7, 8) was used for determining the levels of metal migration. In this migration test the object is first washed, thereafter the surface is exposed to 4% acetic acid at room temperature for a period of 24 hours. Hollow objects are filled with acetic acid, the same are flatware, but the volume of liquid must be noted and the effective area exposed calculated. Testing of migration from the rim is performed by placing the cup or mug upside down in 2 cm of acid. The amount of lead which is leaked by hollow objects is calculated per litre, whereas migration from flatware and rims are calculated in mg soluble metal per dm². The detection limits from hollow products were set at 0.1 mg/l for lead, 0.01 mg/l for cadmium and 0.3 mg/l for the other metals in the survey. For flatware and rims, the detection limits vary somewhat according to the shape and size of the object (1).

Migration of lead from ceramic articles

Hollow products (< 3 l)

In the survey conducted in 2003 (1), quantifiable quantities of lead (> 0.1 mg/l) were measured in 144 of the 631 examined articles (22.8%). 19 articles transferred more lead than the migration limit of 4 mg/l, of which eight articles transferred more than 10 mg/l. The highest quantity found was 30 mg Pb/l.

The average quantity of lead in samples above the detection limit was 1.9 mg/l.

Flatware

None of the 17 flatware tested transferred quantifiable quantities of lead.

Rims

28 of 41 articles released lead from the rim, although none exceeded the migration limit (0.8 mg/dm²). Five articles released > 0.2 mg/dm², and the highest value measured here was 0.47 mg/dm².

The Swedish National Food Administration [*Livsmedelsverket*] has analyzed a variety of Greek ceramic cups, mugs and jugs with regard to the cases of poisoning in Sweden in 2004. Migration levels from 8.4 to as high as 2000 mg Pb/l were measured (4, 17).

Migration of cadmium from ceramic articles

Hollow products (< 3 l)

Quantifiable amounts of cadmium (> 0.01 mg/l) were found in 12 of the 631 examined articles (1.9%). None of the articles transferred more cadmium than the migration limit of 0.3 mg/l. The highest quantity measured was 0.23 mg Cd/l.

The average quantity of cadmium in samples above the detection limit was 0.06 mg Cd/l.

Flatware

None of the 17 flatware tested transferred quantifiable amounts of cadmium.

Rims

No quantifiable amounts of cadmium were measured from the rim of the 41 tested hollow products.

Migration of barium from ceramic articles

Hollow products (< 3 l)

77 hollow products were analyzed for barium content. Barium was measured in concentrations above the detection limit (>0.3 mg Ba/l) in 52 hollow products (67%). Of these, 34 articles transferred more than 2.0 mg Ba/l, of which 12 products transferred more than 20 mg Ba/l. The highest concentrations measured were 75 and 80 mg Ba/l.

The average quantity of barium in samples above the detection limit was 21.3 mg Ba/l.

Flatware

Traces of barium were measured in one of the two tested flatware. The quantity was 9.3 mg Ba/dm².

Rims

The barium content in samples taken from the rims of 14 articles was analysed. Quantifiable amounts were measured in three cups and one beaker, with levels varying between 0.14 – 9.0 mg Ba/dm².

5. Exposure assessments

The migration test's relevance to the exposure estimates

In the Norwegian Food Safety Authority's document "Migration of lead and cadmium from ceramics – note for discussion of safety and regulatory limits" (18), the relevance of the migration test used in the survey for determining migration of metals to foodstuffs and beverages, is discussed. Migration is a function of time, as short exposure periods give significantly lower levels of migration than exposure for 24 hours. In many cases, beverages would not be in contact with ceramic articles for as long as 24 hours. On the other hand, the contact period could be significantly longer, for example, for jars used for storage of jam and juice, which could entail significantly higher levels of migration. Liquids could in some cases

have a significantly higher temperature, which could also increase migration (2-10 times). In so far as using 4% acetic acid as a test simulatant, this confers comparable migration as when using citric acid and lactic acid, and ought therefore to be deemed realistic. Repeated exposures could well lead to lower levels of migration, although this need not be the case. The standard test is thus not representative of a “worst case” scenario. In some cases, migration will be overestimated and in others underestimated.

For evaluation of migration from other plastic materials and articles in contact with foodstuffs, a migration to 1 kg or 1 dm³ of foodstuff/simulant from 6 dm² of packaging material is used in EU. For simplicity’s sake, it is assumed in the exposure calculations adopted in this evaluation that ceramic articles release the quantity per litre from 5 dm², and the consumption is set at 1 litre per 24 hours.

Lead

Exposure from ceramic articles

The Norwegian Food Safety Authority has estimated the intake of lead. These data are based on lead exposure from the beaker and cup with the highest respective migration of lead, 30 mg/l (beaker) and 5.7 mg/l (cup), and migration at the migration limit, 4 mg/l. A daily intake from these hollow objects of 1 l/day is assumed.

In the table below, the estimated intake of lead is given for a person who drinks 1 litre of liquid daily (50% of the standard intake of 2 l (16) from the specific cup/beaker). The estimated intake provides a certain level of insight as to what a “worst-case” scenario for lead migration from these kinds of products can entail in terms of exposure.

Table 5.1 The estimated intake of lead by an adult (70 kg) drinking one litre of liquid from a ceramic article every day. The intake is monitored over seven days to facilitate comparison with the PTWI (25 µg/kg body weight/week). The ratio between intake and PTWI is specified.

Article	Contents mg/l	Consumption l/week	Intake of lead (µg/kg body weight/week)	Ratio between the intake and the PTWI
Beaker	30	7	3000	120
Cup	5.7	7	570	23
<i>Migration limit for ceramic articles</i>	4	7	400	16

The table shows that the levels found in the survey could result in people having an intake of lead exceeding the PTWI many times over. Ceramic articles transferring quantities of lead under the assumed conditions (daily intake of 1 l from the article in question) at the current migration limit would also give an intake far above the PTWI for lead.

Exposure from other sources

The population’s dietary exposure levels to lead are on the whole considered to be very low in relation to the PTWI. The estimated average intake in the population is approximately 8% of the PTWI while the 95 percentile is estimated to be around 30% (19). Some exposure to lead is also via inhalation, although this is very low following the reduction in lead levels in petrol.

Assessment of exposure from ceramic articles

In the exposure calculations, it is assumed that 50% of the standard liquid intake originates from ceramic articles with migration at a specific level. Exposure up to the migration limit for all articles together will give a substantial overestimate, since most articles as shown in the survey have a lower migration and even do not release detectable amounts of lead. On the other hand, in a “worst-case” scenario some people could be ingesting vast quantities of liquid daily from the same article – as demonstrated by the cases of poisoning. The PTWI is intended to guard against lead exposure from all sources.

Given that exposure from foodstuffs and other sources amounts to maximum 50% of the PTWI for the 95 percentile and based on the assumption that 50% of the PTWI could originate from ceramic articles and using an exposure to 1 litre of the liquid per day, the migration of lead into the liquid could maximum amount to 0.125 mg lead/l.

Conclusion

The exposure assessment shows that the levels determined in the survey could result in people receiving an intake of lead exceeding the PTWI of 25 µg/kg body weight several times over. The highest level of lead migration measured in the survey was 30 mg/l. This would result in an intake which is 120 times higher than the PTWI and could represent a risk of poisoning.

The current limit of 4 mg/l for migration of lead from ceramic articles (hollow products < 3 litres) would give a weekly intake of 400 µg/kg body weight for a person weighing 70 kg. This is 16 times the PTWI, a fact that indicates that the current migration limit is too high. A calculation example shows that if the migration limit was to be adjusted to 0.125 mg lead/l, exposure from ceramic articles could at most be 50% of the PTWI.

Cadmium***Exposure from ceramic articles***

In the same way as for lead, cadmium exposure from beakers and cups can be estimated at different migration levels. The Norwegian Food Safety Authority has estimated these intakes based on the highest cadmium migration level determined in the survey (0.23 mg/l) and migration at the limit for cadmium (0.3 mg/l). It is assumed an intake from these hollow objects of 1 l/day.

In the table below, the estimated intake of cadmium is given for a person who drinks 1 litre of liquid daily from a specific cup/beaker. The estimated intake provides a certain level of insight as to what a “worst-case” scenario for cadmium migration from these kinds of products can entail in terms of exposure.

Table 5.2 The estimated intake of cadmium by an adult (70 kg) drinking one litre of liquid from a ceramic article every day. The intake is monitored over seven days to facilitate comparison with the PTWI (7 µg/kg body weight/week). The ratio between intake and PTWI is specified.

Article	Contents mg/l	Consumption l/week	Intake of cadmium (µg/kg body weight/week)	Ratio between the intake and the PTWI
Beaker	0.23	7	23	3.3
<i>Migration limit for ceramic articles</i>	0.3	7	30	4.3

The table shows that ceramic articles transferring cadmium at levels similar to the current migration limit and at the levels measured in the survey could exceed the PTWI for cadmium significantly.

Exposure from other sources

The population's cadmium exposure level is already relatively high compared to the PTWI. Population clusters along the Norwegian coast and in inland parts of Norway have an average higher intake of cadmium than the population in general. Persons with a specific high intake (the 95 percentile) from the coastal population have an intake at 43% of PTWI (3 µg/kg body weight/week), while the corresponding high intake in the inland population is 49% (3,4 µg/kg body weight/week) (based on Part B of the Fish and Game Study and supporting data from NORKOST 1997) (19, 20). Cigarette smoke is a main source of cadmium exposure and contributions from foodstuffs will be of little significance in relation to these levels (13).

Assessment of exposure from ceramic articles

In the exposure calculations, it is assumed that 50% of the standard liquid intake originates from ceramic articles with migration at a specific level. Exposure up to the migration limit for all articles together will give a substantial overestimate, since most articles as shown in the survey, have a lower migration and even do not release detectable amounts of cadmium. On the other hand, in a "worst-case" scenario some people could be ingesting vast quantities of liquid daily from the same article – as demonstrated by the cases of poisoning. The PTWI is intended to guard against cadmium exposure from all sources.

More recent epidemiological studies have indicated that low-grade exposure at the PTWI level is linked to an increased prevalence of minor renal changes (15). The long-term significance of these changes is uncertain. Even though the exposure in Norway lies well below the PTWI, these new data give grounds for concern to ensure that the Norwegian population's exposure to cadmium does not increase further.

Given that exposure from foodstuffs and other sources amounts to maximum 50% of the PTWI for the 95 percentile and assuming that the remaining 50% of the PTWI could originate from ceramic articles and using an exposure to 1 litre of liquid per day, the migration of cadmium into the liquid could be maximum 0.035 mg cadmium/l. If only 15% of the PTWI could originate from ceramic article, this would be equivalent to a migration limit of 0.01 mg cadmium/l.

Conclusion

The exposure assessment show that the levels determined in the survey could result in people receiving an intake of cadmium which exceeds the PTWI of 7 µg/kg body weight considerably. The highest level of cadmium migration measured in the survey was 0.23 mg/l. This would result in an intake that is 3 times higher than the PTWI.

The current limit of 0.3 mg/l for migration of cadmium from ceramic articles (hollow products < 3 litres) would give a weekly intake of 30 µg/kg body weight for a person weighing 70 kg. This is more than four times as high as the PTWI – a fact that indicates that the current migration limit is too high. A calculation example shows that if the migration limit was adjusted to 0.035 or 0.01 mg cadmium/l, the exposure from ceramic articles would at most be 50% or 15%, respectively, of the PTWI.

Barium

Exposure from ceramic articles

The highest barium value found in ceramic articles was 80 mg/l. It is assumed an intake from ceramic articles of 1 l/day. The estimated daily intake from a ceramic article releasing this quantity of barium would amount to 80 mg, or 1.14 mg/kg body weight for a person weighing 70 kg. Based on a TDI of 0.05 mg/kg body weight calculated from an animal experiment, the estimated intake would exceed the TDI 22 times over. The average barium quantity above the detection limit was 21.3 mg/l, which would give an estimated daily intake of 0.3 mg/kg body weight, which exceeds the TDI around 6 times.

Exposure from other sources

Normal barium intake levels from foodstuffs and beverages have been estimated to be more than 1 mg/day for adults, i.e. around 50% of the TDI level of 0.05 mg/kg body weight.

Barium levels contained in drinking water are reported to be somewhere between < 5 to 600 µg/l in Canada, whereas in the Netherlands 83% was under 50 µg/l and the highest concentration was 200 µg/l (16).

Conclusion

The intake estimates above show that 11 of the examined articles would exceed the TDI of 0.05 mg/kg body weight, under assumption of a consumption of 1 l/day.

Barium intake levels from foodstuffs and beverages have been estimated to be around 50% of the TDI. A calculation example shows that a migration limit of 1.75 barium/l would give a maximum intake of barium from ceramic articles of around 50% of the TDI.

6. Uncertainties in the exposure data

Sampling/analysis

A total of 648 household ceramic articles intended to come into contact with foodstuffs were tested (631 hollow products and 17 flatware) from over 100 potters located in all parts of Norway. All articles were analyzed for both lead and cadmium, while 79 articles were also analyzed for barium.

The selection of samples is deemed representative of the potential levels of heavy metals present in ceramic articles made by Norwegian artists and potters, although only random samples were taken and only one analysis was performed of each object. Uncertainty always remains as to how representative an analysis of a selection of crafted hand-made individual articles can actually be (for example, the quantity of heavy metals in an article is expected to vary between bakings). The articles included in this survey, however, have been analyzed using a standard method compliant with the EEC Council Directive of 15 October 1984 laying down basic rules for determining the migration of lead and cadmium (7, 8), and the analyses were performed at a laboratory with experience within these kinds of analyses going back to the 1980s. In general, some uncertainty will be attached to the analysis results which verge on the detection limit for the different metals in the method used, but this is of little significance for the exposure estimates, which were done in this risk assessment.

Exposure assessment/food consumption data

In the exposure calculations, it is assumed that a person is drinking one litre of liquid from the same article each day over a period of time. In making such an assumption some uncertainty is attached to the exposure estimates in the risk assessment. For example, some individuals could drink quantities of liquid even much higher than 1 l/day from the same object.

The two food consumption surveys, Norkost and part B of the Fish and Game Study, used in the exposure calculations for lead and cadmium will also be flawed with some uncertainty, which is described in more detail in the respective studies (19, 20).

7. Conclusion

In the exposure calculations, it is assumed that a person is drinking one litre of liquid from the same article each day over a period of time, and exposure to other sources of the heavy metals is taken into account. The estimated intake levels therefore show how high heavy metal migration from ceramic products in the worst case might be.

The exposure assessments show that migration levels measured in the survey could result in an intake of lead exceeding the PTWI of 25 µg/kg body weight (11) many times over. The highest migration of lead determined in the survey was 30 mg/l. This would result in an intake which is 120 times higher than the PTWI, and could represent a risk of poisoning. Corresponding calculations for cadmium indicate that migration at the levels measured in the survey could lead to an intake far exceeding the PTWI of 7 µg/kg body weight (14). The highest migration of cadmium determined in the survey was 0.23 mg/l. This would result in an intake which is around three times higher than the PTWI.

Migration at the current limit for lead (4.0 mg/l for hollow products < 3 l) would give a weekly intake of 400 µg/kg body weight for a person weighing 70 kg. This is 16 times PTWI. A calculation example shows that if the migration limit was adjusted to 0.125 mg lead/l, exposure from ceramic articles could at most be 50% of the PTWI. Migration at the current limit for cadmium (0.3 mg/l for hollow products < 3 l) would give a weekly intake of 30 µg/kg body weight for a person weighing 70 kg. This is more than four times as high as the PTWI. A calculation example shows that if the migration limit was adjusted to 0.035 or 0.01 mg cadmium/l, the exposure from ceramic articles would at most be 50% or 15%, respectively, of the PTWI.

The results from the risk assessment indicate that the current migration limits for lead and cadmium are too high to assure safe products in terms of safeguarding the public's health.

In the same way as for lead and cadmium, the risk assessment contains an exposure assessment for the measured levels of barium transferred from ceramic articles. The exposure calculations in the risk assessment show that for 11 of the examined ceramic articles the TDI for barium of 0.05 mg/kg body weight (16) would be exceeded, under the assumption that the consumption of liquid amounts to one litre per day. The intake of barium from foodstuffs and beverages is estimated to be around 50% of the TDI. A calculation example shows that a migration limit of 1.75 barium/litre in the worst case could result in an intake of barium from ceramic articles of around 50% of the TDI. This indicates a potential need to limit the intake of barium from ceramic articles.

In a survey from 2001 commissioned by the former Norwegian Food Control Authority (now the Norwegian Food Safety Authority), migration of quantifiable amounts of lead was found in 20 out of 165 ceramic articles (21). One of the products showed a migration level of around 3 mg lead/l. In the same survey, it was found that only one out of a total of 165 ceramic articles released cadmium in detectable quantities. The concentration of cadmium in this solution amounted to 0.17 mg/l. The 2001 survey was primarily conducted on industrially manufactured articles from 18 different countries from all over the world, with an emphasis on products from Asia.

The analytical results which form the basis for this risk assessment are of ceramic articles made by artists and potters. Compared to the results from the 2001 survey, there are indications that the problem of heavy metal migration from ceramic articles is predominantly linked to hand-crafted articles made by potters and not industrially manufactured ceramics. This is further illustrated by the lead levels determined in the Swedish analysis results carried out on imported Greek hand-crafted pottery in 2004 (4, 17).

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