

Information

Rationale for the test values of the evaluation criteria for enamels and ceramic materials that come into contact with drinking water (enamel/ceramic evaluation criteria)

1 Preface

Enamel and ceramics are materials used for products that come into contact with drinking water, e.g. drinking water heaters or large shut-off valves. The hygienic suitability of enamels and ceramic materials is verified on the basis of the "Evaluation criteria for enamels und ceramic materials that come into contact with drinking water".

Enamel is a glass-like material; it is inorganic and has a predominantly oxide structure. In addition, other oxides (of Zr, Cu, Zn, Ba Ca, usually 0.5 – 1.0%) are used to improve the enamelling properties.

Ceramic is an inorganic and non-metallic material. A distinction is drawn between different technical ceramics (see: Evaluation Criteria for Enamels and Ceramic Materials).

When enamelled products or products with ceramic parts are used as intended, the release of elements may not lead to an exceedance of the limit values of the German Drinking Water Ordinance in distributed drinking water. For elements for which the Drinking Water Ordinance does not specify limit values, the guideline values of the WHO or the UBA must be respected. The test values are defined as percentages of the limit or guideline values in order to take into account other possible sources of release. The percentages differ for the various elements. The release should be as low as possible, in keeping with the minimization obligation (Sections 6 (3) and 17 (2) No. 3 of the German Drinking Water Ordinance (TrinkwV). Therefore the test value for enamel and ceramic materials is normally limited to 10 % of the limit or guideline value. For prohibited constituents (lead and cadmium) which may be contained in the product as impurities, the test value contribution is limited to 5 %. Cobalt, manganese and aluminium are important components of enamels. For cobalt no further pathways of release into drinking water are known, so that the test value for cobalt can be set at 90 % of the guideline value. Likewise, no further pathways of release into drinking water are known for lanthanum, so that the test value for it is also set at 90 %. In the case of manganese and aluminium, no releases from other materials used in the distribution of drinking water are expected. For this reason, the test values for manganese and aluminium can be set at 50 % of the respective limit values of the German Drinking Water Ordinance (TrinkwV). The 50 % principle also applies to cerium, titanium and zirconium, because no other relevant release pathways into drinking water are known for these elements. Based on the test results submitted to the German Environment Agency so far, it assumes that the migration of hafnium and tungsten from ceramic materials does not lead to concentrations in drinking water above 0.1 g/l. Therefore, a test value of 0.1 µg/l is set for these substances. Values are also set at this level if no further toxicological information is available for the substance concerned. The test values are summarised in Table 1 and

Table 2 below.

Table 1 Test values (PW) for various elements

Element	Source of the test value	Contribution of test value to limit value/guideline	Test value [µg/l]
Aluminium	German Drinking Water Ordinance	50 %	100
Barium	WHO	10 %	70
Bismuth	UBA		0.1
Lead	German Drinking Water Ordinance	5 %	0.5
Boron	German Drinking Water Ordinance	10 %	100
Cadmium	German Drinking Water Ordinance	5 %	0.15
Chromium ¹	German Drinking Water Ordinance	10 %	5.0
Cerium	UBA	50 %	20.0
Hafnium	UBA		0.1
Cobalt ²	UBA	90 %	9.0
Copper	German Drinking Water Ordinance	10 %	200
Lanthanum	UBA	90%	2.7
Manganese	German Drinking Water Ordinance	50 %	25.0
Molybdenum	WHO	10 %	7.0
Nickel	German Drinking Water Ordinance	10 %	2.0
Strontium	UBA	10 %	210
Titan	UBA	50 %	70
Tungsten	UBA		0.1
Yttrium	UBA	10%	3.5
Zirconium	UBA	50 %	5.0

¹ The limit in the Drinking Water Regulation currently applies for chromium at 50 µg/l. It has been discussed to reduce the limit.

² Preliminary criteria for cobalt (due to submitted toxicological data the criteria could change)

Table 2 Test values (PW) for PAHs

Polycyclic aromatic hydrocarbons	Source of the test value	Contribution of test value to limit value/guideline	Test value [$\mu\text{g/l}$]
Benzo-(b)-fluoranthene	German Drinking Water Ordinance	10 %	Sum of the 4 PAHs 0.01.
Benzo-(k)-fluoranthene			
Benzo-(ghi)-perylene			
Indeno-(1,2,3-cd)-pyrene			
Benzo-(a)-pyrene	German Drinking Water Ordinance	10 %	0.001

2 Rationales

As explained above, the test values are percentages of the limit values of the German Drinking Water Ordinance (TrinkwV) or, alternatively, of the guideline values of the WHO or the UBA. The rationales for the decisions about the individual substances listed in Table 1 and

Table 2 are provided below.

For toxicological assessment the UBA researched reviews and assessments from other institutes and, based on this, specific data and literature relevant for the assessment goal. The toxicity data proved to be highly heterogeneous for some substances. On the one hand there are assessments (Co, Sr and Ti) by other institutions but these may not necessarily be reliable (Ti). Where such assessments were not available (Zr and Ce), the data were usually inadequate for justifying health-related maximum values or guideline values for drinking water. Therefore, the values determined here, in some cases for orientation purposes (but determined nevertheless), contain not only extrapolation factors but also safety factors to compensate assessment uncertainties (no safety factor has been included for Zr because, with the necessary total factor of 10,000, no reliable tolerable drinking water concentration can be justified).

The values determined in this way or already available in terms of tolerable doses for humans (e.g. in $\mu\text{g/kg}\cdot\text{d}$) were converted using the standard conventions for the German Drinking Water Ordinance (TrinkwV) (70 kg body weight, 2 litres of drinking water consumption per day and 10 % exhaustion of the tolerable intake via drinking water) to a tolerable drinking water concentration ($\mu\text{g/l}$) and are shown with the respective percentages in Table 1 and

Table 2 as test values.

The test values and rationales for the various substances are set out below:

Aluminium (Al, CAS No: 7429-90-5)

The German Drinking Water Ordinance, the Guidelines for Drinking Water Quality (WHO, 2011) and the Drinking Water Directive (RL 98/83/EC) set a limit value of 200 µg/l for aluminium.

The resulting test value for aluminium as part of the enamel/ceramics evaluation criteria is 100 µg/l, representing a 50 % exhaustion of the drinking water limit value (Table 1).

Literature:

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

RL 98/83/EG: Richtlinie 98/83/EG des Rates vom 3. November 1998 über die Qualität von Wasser für den menschlichen Gebrauch (ABl. L 330/32 vom 5.12.1998)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

WHO (2010): Aluminium in drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality, http://www.who.int/water_sanitation_health/dwq/chemicals/aluminium/en/

WHO (2011): Guidelines for drinking-water quality – 4th edition, World Health Organization, CH-Geneva; http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf

Barium (Ba, CAS No: 7440-39-3)

The blood pressure increasing effect and kidney effects after exposure to high doses of barium are known from acute, sub-chronic and chronic animal experiment studies. Schroeder and Mitchener (1975a, b) exposed Long-Evans rats and Charles River CD mice to 0 and 5 ppm barium in their drinking water in a life-long experiment. A LOAEL of 5 ppm (0.61 mg Ba/kg·d) for renal glomerular damage in the male rats and a NOAEL of 5 ppm (1.2 mg Ba/kg·d) of comparably exposed CD mice were identified. Perry et al. (1983, 1985, 1989) exposed female Long-Evans rats to 0, 1, 10 and 100 ppm Ba in the drinking water over a period of 1, 4 and 16 months; during this time, the animals received feed with a low mineral content. The study produced a LOAEL of 0.82 mg Ba/kg·d and a NOAEL of 0.17 mg Ba/kg·d for blood pressure increase as the critical effect after 16 months exposure. IRIS (2003) reported a LOAEL of 75 mg Ba/kg·d and a NOAEL of 45 mg Ba/kg·d for renal effects as critical end point from a 2-year drinking water study by the NTP (1994) with F344/N rats.

There is only limited data on reproduction and development toxicity, and these data indicate that these end points appear to be less relevant for barium. In carcinogenicity studies with animals, barium that was administered orally did not prove to be carcinogenic.

Based on a retrospective epidemiological study (Brenniman et al., 1981, Brenniman and Levy, 1984), the WHO (1996, 2004) derived a drinking water guideline value of 700 µg Ba/l. Mean drinking water concentrations of 7.3 mg Ba/l (range 2–10 mg Ba/l) caused no significant changes in blood pressure or in the occurrence of cardiovascular disease or kidney disease in 1175 adults from the population of West Dundee/Illinois (age > 18 years), compared to a control group that drank drinking water with a mean barium concentration of 0.1 mg/l. In addition, a sub-group of persons who lived in both communities for more than 10 years was investigated in more detail. With a NOAEL of 7.3 mg/l and a safety factor of 10 to take into account highly sensitive sub-groups, a drinking water guideline value for barium of (rounded) 0.7 mg/l can be derived.

In a clinical volunteer study by Wones et al. (1990) adults (average age 39.5 years) were administered barium chloride in varying concentrations with the drinking water (1.5 l/d) over a total period of 10 weeks. In the first two weeks no barium was added to the drinking water, in the following four weeks 5 ppm Ba (0.11 mg/kg·d) was added and in the last four weeks 10 ppm Ba (0.21 mg/kg·d) was added. The authors observed no cardiovascular changes or changes to clinical-chemical parameters; differences in Ca serum levels were assessed as not relevant. The NOAEL from this study would be 0.21 mg/kg·d.

The basis for the derivation of a human toxicology based value are the epidemiological study by Brenniman et al. (1981), Brenniman and Levy (1984) and the investigations by Wones et al. (1990). According to Brenniman et al. (1981) and Brenniman and Levy (1984) based on a NOAEL of 7.3 mg Ba/l a body intake (rounded) of 0.21 mg/kg·d can be calculated ($\text{NOAEL} = 7.3 \text{ mg/l} \times 2 \text{ litres drinking water/d} \times 1/70 \text{ kg body weight} = 0.209 \text{ mg/kg·d}$). A body dose of (rounded) 0.21 mg/kg·d also results from the drinking water study by Wones et al. (1990) on adult volunteers, based on a NOAEL of 10 mg Ba/l for the end point cardiovascular effects, supporting the NOAEL from the epidemiological study.

A NOAEL of 0.21 mg/kg·d only contains the percentage consumed via drinking water and not the intake via food. In their study, Wones et al. (1990) estimated the intake of barium through the diet as 0.011 mg/kg·d. In its "Environmental Health Criteria" for barium (EHC Report 107), the WHO (1990) gives a range of 0.3 to 1.77 mg/d or 0.004 to 0.025 mg/kg·d for dietary intake. Assuming that the above-mentioned study populations had an average daily barium intake via other food equal to the dose of 0.0145 mg/kg·d estimated by the WHO (1990), a NOAEL of 0.225 mg Ba/kg·d results. Uptake of barium by inhalation is seen as negligible.

With a safety factor of 3 for intra-species variation, this results in a TDI of 0.075 mg/kg·d based on a NOAEL of 0.225 mg/kg·d. Assuming a body weight of 70 kg, 2 litres of drinking water/d, 50% exhaustion of the tolerable body intake (the standard assumption of 10 % does not appear justified in light of the above deliberations concerning other foodstuffs), a human toxicology-based guideline value of (calculated) 1.31 mg/l or rounded 1.0 mg/l is obtained for barium based on a TDI of 0.07 mg/kg·d.

Barium is no longer addressed in the German Drinking Water Ordinance of 2001 (TrinkwV). A limit value of 1.0 mg/l was laid down in the old drinking water ordinance of 1990.

The resulting test value for barium as part of the enamel/ceramics evaluation criteria is **70 µg/l**, representing a 10 % exhaustion of the above-mentioned WHO guideline value (WHO 1996, 2004) (Table 1).

Literature:

Brenniman, G.R.; Kojola, W.H.; Levy, P.S.; Carnow, B.W.; Namekata, T. (1981): High barium levels in public drinking water and its association with elevated blood pressure. Arch. Environ. Health 36(1), 28 – 32

Brenniman, G.R.; Levy, P.S. (1984): Epidemiological study of barium in Illinois drinking water supplies. In: Advances in modern toxicology, Calabrese, EJ, ed. Princeton, NJ: Princeton, Scientific Publications, 231 – 249

IRIS (2003): Barium and Compounds (CASRN 7440-39-3); <http://www.epa.gov/iris/subst/0010.htm>

NTP (1994): Technical report on the toxicology and carcinogenesis studies of barium chloride dihydrate (CAS No. 10326-27-9) in F344/N rats and B6C3F1 mice (drinking water studies). NTP TR 432. National Toxicology Program, Research Triangle Park, NC. NIH Pub. No. 94-3163. NTIS Pub. PB94-214178

Perry, H.M.; Kopp, S.J.; Erlanger, M.W. et al. (1983): Cardiovascular effects of chronic barium ingestion. In: Trace substances in environmental health, XVII, Hemphill, D.D., ed., Proc. Univ. Missouri's 17th Ann. Conf. on Trace Substances in Environmental Health. University of Missouri Press, Columbia, MO., 155 – 164

Perry, H.M.; Perry, E.F.; Erlanger, M.W. et al. (1985): Barium-induced hypertension. In: Inorganic substances in drinking water and cardiovascular disease. Ch. XX. Adv. Mod. Environ. Toxicol. 9, 221 – 279

Perry, H.M.Jr.; Koop, S.J.; Perry, E.F. et al. (1989): Hypertension and associated cardiovascular abnormalities induced by chronic barium feeding. *J. Toxicol. Environ. Health* 28(3), 373 – 388

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

Schroeder, H.; Mitchener, M. (1975a): Life-term studies in rats: effects of aluminium, barium, beryllium and tungsten. *J. Nutr.* 105, 421 – 427

Schroeder, H.; Mitchener, M. (1975b): Life-term effects of mercury, methyl mercury and nine other trace metals on mice. *J. Nutr.* 105, 452 – 458

TrinkwV (1990): Verordnung über Trinkwasser und über Wasser für Lebensmittelbetriebe (Trinkwasserverordnung – TrinkwV) i. d. F.d. Bek. vom 5. Dez. 1990 (BGBl. I S. 2612)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

Wones, R.G.; Stadler, B.L.; Frohman, L.A. (1990): Lack of effect of drinking water barium on cardiovascular factors. *Environ. Health Perspect.* 85, 355 – 359

WHO (1990): Environmental Health Criteria 107: Barium. International Programme on Chemical Safety (IPCS); World Health Organization, CH-Geneva

WHO (1996): Guidelines for drinking-water quality. Vol. 2 – Health Criteria and Other Supporting Information, 2nd edition, International Programme on Chemical Safety; World Health Organization, CH-Geneva

WHO (2004): Barium in Drinking-water, Background document for development of WHO Guidelines for Drinking-water Quality, http://www.who.int/water_sanitation_health/publications/barium/en/

Bismuth (Bi, CAS No: 7440-69-9)

Based on the test results submitted to the German Environment Agency so far, it expects that bismuth does not migrate from ceramic materials into drinking water in concentrations above 0.1 µg/l. Therefore, a test value of **0.1 µg/l** (Table 1) was set for inclusion in the evaluation criteria for enamel and ceramic materials. This value would also be set for a substance for which no further toxicological information is available.

Boron (B, CAS No: 7440-42-8)

The German Drinking Water Ordinance specifies a limit value of 1 mg/l for boron; this value was adopted from the EC Drinking Water Directive (RL 98/83/EC).

The resulting test value for boron as part of the enamel/ceramics evaluation criteria is **100 µg/l**, representing a 10 % exhaustion of the drinking water limit value (Table 1).

Literature:

Allen, B.C.; Strong, P.L.; Price, C.J.; Hubbard, S.A.; Daston, G.P. (1996): Benchmark dose analysis of developmental toxicity in rats exposed to boric acid. *Fundam. Appl. Toxicol.* 32, 194 – 204

Dieter, H.H. (2003): Bedeutung und Bewertung von Bor im Trinkwasser. S. 299 – 305 in: Grohmann, A.; Hässelbarth, U.; Schwerdtfeger, W.K. (Hrsg.): Die Trinkwasserverordnung. Einführung und Erläuterung für Wasserversorgungsunternehmen und Überwachungsbehörden. 4., neu bearbeitete Auflage, Erich Schmidt Verlag Berlin

Price, C.J.; Strong, P.L.; Marr, M.C.; Myers, C.B.; Murray, F.J. (1996a): Developmental toxicity NOAEL and postnatal recovery in rats fed boric acid during gestation. *Fundam. Appl. Toxicol.* 32, 79 – 193

Price, C.J.; Marr, M.C.; Myers, C.B.; Seely, J.C.; Heindel, J.J.; Schwetz, B.A. (1996b): The developmental toxicity of boric acid. *Fundam. Appl. Toxicol.* 34, 176 – 187

RL 98/83/EG: Richtlinie 98/83/EG des Rates vom 3. November 1998 über die Qualität von Wasser für den menschlichen Gebrauch (ABl. L 330/32 vom 5.12.1998)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

WHO (1996): Guidelines for drinking-water quality. Health criteria and other supporting information. Monograph Vol. 2, 2nd edition. International Programme on Chemical Safety. World Health Organization, CH-Geneva

WHO (1998): Addendum to Volume 1: Guidelines for drinking-water quality. International Programme on Chemical Safety. World Health Organization, CH-Geneva

Cadmium (Cd, CAS No: 7440-43-9)

A limit value of 3 µg/l was established for Germany through the first Ordinance of 3 May 2011 to amend the Drinking Water Ordinance (German Drinking Water Ordinance (TrinkwV).

The resulting test value for cadmium as part of the enamel/ceramics evaluation criteria is **0.15 µg/l**, representing a 5 % exhaustion of the drinking water limit value (Table 1).

Literature:

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

RL 98/83/EG: Richtlinie 98/83/EG des Rates vom 3. November 1998 über die Qualität von Wasser für den menschlichen Gebrauch (ABl. L 330/32 vom 5.12.1998)

RL 2008/105/EG: Richtlinie 2008/105/EG des Europäischen Parlaments und des Rates vom 16. Dezember 2008 über Umweltqualitätsnormen im Bereich der Wasserpolitik und zur Änderung und anschließenden Aufhebung der Richtlinien des Rates 82/176/EWG, 83/513/EWG, 84/156/EWG, 84/491/EWG und 86/280/EWG sowie zur Änderung der Richtlinie 2000/60/EG (ABl. L 348 vom 24.12.2008, S. 84)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

WHO (1993): Guidelines for drinking-water quality. Volume1: Recommendations; 2nd edition. World Health Organization, CH-Geneva

WHO (2011): Guidelines for drinking-water quality – 4th edition. World Health Organization, CH-Geneva; http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf

Chromium (Cr, CAS No: 7440-47-3)

The German Drinking Water Ordinance, the Guidelines for Drinking Water Quality (WHO, 2011) and the Drinking Water Directive (RL 98/83/EC) stipulate a limit value of 50 µg/l for chromium.

The resulting test value for chromium as part of the enamel/ceramics evaluation criteria is **5.0 µg/l**, representing a 10 % exhaustion of the drinking water limit value (Table 1).

Literature:

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

RL 98/83/EG: Richtlinie 98/83/EG des Rates vom 3. November 1998 über die Qualität von Wasser für den menschlichen Gebrauch (ABl. L 330/32 vom 5.12.1998)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

WHO (2011): Guidelines for drinking-water quality – 4th edition. World Health Organization, CH-Geneva; http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf

Cerium (Ce, CAS No: 7440-45-1)

There is a Toxicological Review by the U.S.-EPA from 2009 on the topic of "Cerium Oxides and Cerium Compounds" (CAS-No. 1306-38-3). This regards the data relating to oral intake as inadequate for deriving a reference dose (RfD) for oral exposure or for assessing the carcinogenic potential ("inadequate information to assess the carcinogenic potential").

Due to the lack of long-term animal testing studies available, the U.S.-EPA (2009) has identified effects on the heart tissue (increase in collagen) and the haemoglobin-oxygen affinity as possible relevant health effects. This is also based on a study by Cheng et al. (2000) on Wistar rats that received oral doses (without further details) of 0.1, 1.1 or 11.4 mg Ce/kg·d as Ce-chloride for a period of up to 105 days. In this study, 11.4 mg Ce/kg·d generated a slight increase in the haemoglobin level in the erythrocytes after 40 days, with an even greater increase after 80 days (U.S.-EPA 2009: "The highest dose, 20 mg/kg-day, produced a slight increase of haemoglobin content in the erythrocytes after 40 days of treatment, with an even greater increase in haemoglobin content after 80 days"). At a dose of 0.1 mg Ce/kg·d and after 105 days there were no significant changes. No NOAEL or LOAEL could be determined from the further available studies due to magnesium-deficient diets, inadequate examination depth or insufficient dose groups (U.S.-EPA, 2009).

Based on the study by Cheng et al. (2000), a dose of 1.1 mg Ce/kg·d as a NOAEL and a factor of 10 respectively for duration extrapolation, interspecies extrapolation and extrapolation to sensitive population groups, and after conversion to a drinking water concentration, a tolerable value of (38.5 or) rounded to 40 µg/l can be calculated.

The resulting test value for cerium as part of the enamel/ceramics evaluation criteria is **20.0 µg/l**, representing a 50 % exhaustion of the tolerable concentration (Table 1).

Literature:

U.S.-EPA (2009): Toxicological Review of Cerium Oxide and Cerium Compounds (CAS No. 1306-38-3). In Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-08/002F, www.epa.gov/iris

Cheng Y. et al. (2000): Orally administered cerium chloride induces the conformational changes of rat hemoglobin, the hydrolysis of 2,3-DPG and the oxidation of heme-Fe(II), leading to changes of oxygen affinity. Chem Biol Interact 125(3): 191 – 208.

Cobalt (Co, CAS No: 7440-48-4)

Important end points after sub-chronic and chronic oral exposure to cobalt are reproduction-toxic effects, disorders of the immune system, cardiomyopathy, thyroid effects and nonspecific effects (reduced body weights trend). Cardiac effects were shown to be important end points in humans and in laboratory animals. After an intake of 0.04 to 0.14 mg Co/kg·d as Co(II)-sulphate in beer among heavy drinkers over several years, cardiomyopathy (some cases were fatal), liver damage, cyanosis and gastrointestinal complaints were established. A "tolerable resorbed dose" (TRD value) via long-term oral intake was not formally derived by Hassauer and Schneider (2001) due to the poor quality of the data. Derivation based on human cardio-toxicity data is difficult because there are some confounding factors to be considered when looking at beer drinkers (low-protein diets, prior cardiac damage) and the effect doses among the drinkers were lower than for patients who were administered cobalt to cure anaemia and who did not display these effects. The assessment-relevant animal studies showed testis toxicity after subchronic oral exposure to be the most sensitive end point, but only one dose was administered in these studies.

Based on the human study by Paley et al. (1958) Hassauer and Schneider (2001) proposed a (preliminary) TRD value for short-term oral intake of 1.4 µg Co/kg·d for the most sensitive end point thyroid effects, based on a lowest observed adverse effect level (LOAEL) of 0.54 mg Co/kg·d.

The overall extrapolation factor (EF_{ges}) of 100 accounts for extrapolation from an observed LOAEL to an estimated NOAEL and the protection of sensitive groups of persons with a factor of 10 in each case. The resorption was assumed to be 25 %.

As an orientation point for tolerable long-term exposure, a resorbed body dose in the range of 0.7 to 1.4 µg Co/kg·d was proposed for long-term oral exposure; supported by inadequate evidence, this proposal was based on the data for short-term oral intake (thyroid effects in humans) and taking into account proposals made by experts during a consensus discussion which envisaged partially a direct adoption of the TRD value for short-term exposure and partially the use of a further extrapolation factor (Hassauer und Schneider, 2001). Assuming a resorption rate of 25 %, this corresponds to an administered dose of 2.8 to 5.6 µg Co/kg·d. The (lower) body dose of 0.7 µg Co/kg·d therefore contains an additional safety factor of 2 to also cover long-term exposure.

With the orientative body dose of 2.8 µg Co/kg·d and the usual assumptions (70 kg body weight, 2 litres of drinking water/d, 10 % exhaustion via drinking water), the human-toxicology-based tolerable value for cobalt would be 9.8 µg/l, rounded to 10 µg/l.

The resulting test value for cobalt as part of the enamel/ceramics evaluation criteria is **9.0 µg/l**, representing a 90 % exhaustion of the tolerable concentration (Table 1).

Literature:

Hassauer, M.; Schneider, K. (2001): Kobalt. Kennziffer D 561 in: „Gefährdungsabschätzung von Umweltschadstoffen – Toxikologische Basisdaten und ihre Bewertung“, Hrsg., Eikmann, Th.; Heinrich, U.; Heinzow, B.; Konietzka, R.; S. 1- 42, 5. Erg. Lfg. 10/01; Erich Schmidt Verlag, Berlin

Paley, K.R.; Sobel, E.S.; Yalow, RS (1958): Effect of oral and intravenous cobaltous chloride on thyroid function. J. Clin. Endocrin. Metabol. 18, 850 - 859; zit. in Hassauer & Schneider (2001)

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

Copper (Cu, CAS No: 7440-50-8)

The German Drinking Water Ordinance, the Guidelines for Drinking Water Quality (WHO, 2011) and the Drinking Water Directive (RL 98/83/EC) stipulate a limit value of 2 mg/l for copper.

The resulting test value for copper as part of the enamel/ceramics evaluation criteria is **200 µg/l**, representing a 10 % exhaustion of the drinking water limit value (Table 1).

Literature:

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

RL 98/83/EG: Richtlinie 98/83/EG des Rates vom 3. November 1998 über die Qualität von Wasser für den menschlichen Gebrauch (ABl. L 330/32 vom 5.12.1998)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

WHO (1996): Guidelines for drinking-water quality. Health criteria and other supporting information. Monograph Vol. 2, 2nd ed.; International Programme on Chemical Safety (IPCS), World Health Organization, CH-Geneva

WHO (1998): Environmental Health Criteria 200: Copper. International Programme on Chemical Safety, World Health Organization, CH-Geneva

WHO (2011): Guidelines for drinking-water quality – 4th edition. World Health Organization, CH-Geneva; http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf

Hafnium (Hf, CAS No: 7782-41-4)

Based on the test results submitted to the German Environment Agency so far, it expects that hafnium does not migrate from ceramic materials into drinking water in concentrations above 0.1 µg/l. Therefore, a test value of **0.1 µg/l** (Table 1) was set for inclusion in the evaluation criteria for enamel and ceramic materials. This value would also be set for a substance for which no further toxicological information is available.

Lanthanum (La, CAS No: 7439-91-0)

The toxicological data on lanthanum are incomplete. There are no chronic studies on the behaviour of lanthanum in humans and test animals. In a 60-day study from 2012 with mice, Cheng et al. observed histopathological changes of the liver, kidney and heart at a concentration of 20 mg/kg bw (Jie Cheng et al., 2012). Lanthanum was administered daily “intragastrically” in the form of dissolved lanthanum chloride. For conversion to a tolerable daily dose in humans the following extrapolation factors must be applied:

- 10 for extrapolation from an LOAEL to a NOAEL
- 10 for mouse/human interspecies variability
- 10 for intraspecies variability between humans
- 10 for extrapolation from subchronic to chronic

This results in a total extrapolation factor of 10,000. Hence, a tolerable level for humans is calculated by dividing 20 mg/kg of body weight by 10,000 = 0.002 mg/kg bw. Due to the uncommon exposure duration and the specific method of administration (intragastric) in the underlying study, this derivation involves relevant uncertainties, as also indicated by the very high total exposure factor. To roughly calculate a health-based maximum acceptable drinking water concentration on this basis, an average body weight of 70 kg, consumption of 2 litres of drinking water per day and allocation of 10% of the TDI to the drinking water route are assumed. This gives the following calculation:

$$\text{Concentration in drinking water} = \frac{0.002 \frac{\text{mg}}{\text{kg}} * 70 \text{ kg} * 0.1}{2 \text{ l}} = 0.007 \text{ mg/l} = 7.0 \text{ µg/l}.$$

In a 30-day study from 2014 by the same working group, a lanthanum concentration of 2 mg/kg already induced initial changes in leucocyte composition (Jie Cheng et al., 2014). These changes were concentration-dependent within a range between 2 and 20 mg/kg bw. While this study can, strictly speaking, be considered subchronic it is only a little longer than a study that would be called subacute, which lasts a maximum of 28 days. Because of its short duration, extrapolation to lifetime exposure seems to be even less feasible in the case of this study; however, its result additionally underlines the uncertainty of the derivation described above. Also, subacute studies are not usually used to assess lifetime risks (Konietzka, Rainer et al., 2014). As the duration of the study by Cheng et al. from 2014 is more that of a subacute study than a subchronic one, it is taken into account here but not used as lead study.

Another aspect in the assessment of lanthanum is its use in medicines, as lanthanum carbonate. Thus, the use of medications containing lanthanum carbonate during pregnancy is counter-indicated (Rote Liste, 2015). Likewise, they are not recommended for children and adolescents, since “no data on the safety and efficacy of Fosrenol in children and adolescents are available” (Fachinformation Fosrenol, 2015).

Furthermore, judging by the principles defined by the German Environment Agency, after consultation of the Drinking Water Commission, in its Recommendation concerning health assessment of partly or non-assessable substances in drinking water (referred to briefly as GOW³ concept), concentrations above 3 µg/l can be tolerated if at least a chronic oral study is available (UBA, 2003). As mentioned above, this is not the case here. Therefore, in view of the rough derivation described above and its inherent uncertainties, also with regard to the important asset drinking water, we recommend compliance with a lanthanum concentration in drinking water of less than 3 µg/l for lifetime exposure.

The resulting test value for lanthanum as part of the enamel/ceramics evaluation criteria is **2.7 µg/l**, representing a 90% exhaustion of the above-mentioned health-based orientation value (Table 1).

Literature:

Jie Cheng et al. (2012): Organ Histopathological Changes and its Function Damage in Mice Following Long-term Exposure to Lanthanides Chloride. *Biol Trace Elem Res.* 145:361–368

Jie Cheng et al. (2014): Immune Dysfunction and Liver Damage of Mice Following Exposure to Lanthanoids. *Environ Toxicol.* 29(1):64-73

Konietzka, Rainer; Schneider, Klaus & Ritter, Leonard (2014): Extrapolation Factors and Safety Factors in Toxicology. In: Reichl, Franz-Xaver & Schwenk, Michael (Eds.) *Regulatory Toxicology*, Springer Berlin Heidelberg, 431-438

Rote Liste (2015): Eintrag 81 150, Fosrenol

Fachinformation Fosrenol (2015), Shire Pharmaceutical Contracts Ltd., Basingstoke, UK, available on the internet at: www.shire.de/documents/FI-Fosrenol-Kautabletten.pdf, accessed on 23.07.15

UBA, 2003. Bewertung der Anwesenheit teil- oder nicht bewertbarer Stoffe im Trinkwasser aus gesundheitlicher Sicht - Empfehlung des Umweltbundesamtes nach Anhörung der Trinkwasserkommission beim Umweltbundesamt. *Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz* 46, 249-251

Lead (Pb, CAS No: 7439-92-1)

The German Drinking Water Ordinance, the Guidelines for Drinking Water Quality (WHO, 2011) and the Drinking Water Directive (RL 98/83/EC) stipulate a maximum value of 10 µg/l for lead.

The resulting test value for lead as part of the enamel/ceramics evaluation criteria is **0.5 µg/l**, representing a 5 % exhaustion of the drinking water limit value (Table 1).

Literature:

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

RL 98/83/EG: Richtlinie 98/83/EG des Rates vom 3. November 1998 über die Qualität von Wasser für den menschlichen Gebrauch (ABl. L 330/32 vom 5.12.1998)

³ GOW = Gesundheitlicher Orientierungswert (health-based orientation value)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

WHO (2011): Guidelines for drinking-water quality – 4th edition, World Health Organization, CH-Geneva; http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf

Manganese (Mn, CAS No: 7439-96-5)

The German Drinking Water Ordinance (TrinkwV), the Guidelines for Drinking Water Quality (WHO, 2011a) and the Drinking Water Directive (RL 98/83/EC) stipulate a limit value of 50 µg/l for manganese.

The resulting test value for manganese as part of the enamel/ceramics evaluation criteria is **25 µg/l**, representing a 50 % exhaustion of the drinking water limit value (Table 1).

Literature:

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

RL 98/83/EG: Richtlinie 98/83/EG des Rates vom 3. November 1998 über die Qualität von Wasser für den menschlichen Gebrauch (ABl. L 330/32 vom 5.12.1998)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

WHO (2011a): Guidelines for drinking-water quality – 4th edition. World Health Organization, CH-Geneva; http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf

WHO (2011b): Manganese in Drinking-water, Background document for development of WHO Guidelines for Drinking-water Quality, http://www.who.int/water_sanitation_health/dwq/chemicals/manganese/en/

Molybdenum (Mo, CAS No: 7439-98-7)

Molybdenum is a metal essential for health and it is a component of several enzymes. According to Tsongas et al. (1980) the molybdenum intake via food is 120 – 240 µg/d, the mean value is 180 µg/d. In an FDA study from 1984, daily molybdenum intakes of between 74 and 126 µg for older children and adults were reported (Pennington and Jones, 1987). Based on the FDA study, the U.S.-National Research Council (NRC, 1989) recommended daily molybdenum intakes of between 15 and 40 µg/d (2.5 – 4.45 µg Mo/kg•d) for small children, of between 25 and 150 µg/d (1.95 – 5.36 µg Mo/kg•d) for children and of between 75 and 250 µg/d (1.5 – 3.6 µg Mo/kg•d) for teenagers and adults. According to Seeger (1990) between 1.7 and 8 µg Mo/kg•d is consumed via the normal diet.

The degree of resorption in the gastrointestinal tract depends on the species and is affected by the chemical compound form. Molybdenum (VI) is easily absorbed if taken orally; the degree of resorption is higher among non-ruminants than ruminants. In contrast, the tetravalent Mo (IV) is not easily resorbed. Humans resorb around 30 – 70 % of the molybdenum consumed via the diet. After resorption, molybdenum manifests quickly in the blood and most organs; the highest concentrations were found in the liver, kidneys and bones. Obviously, molybdenum is not able to bioaccumulate in human tissue.

Molybdenum has complex interactions with copper and sulphate that are not yet fully understood. Experimental animals placed on a copper-deficient diet are generally more sensitive to the toxic effects of molybdenum. Molybdenum-loaded animals excrete renally a higher amount of a copper-molybdenum complex in which the copper can no longer be used.

In this way, secondary copper deficiency occurs (Anke, 1989). In rats, doses of 2 to 6 mg Mo/kg•d of ammonium tetrathiomolybdate administered orally led to a reduced ability to absorb copper, reduced efficiency of ceruloplasmin as a copper transport protein in plasma and a reduction in the copper content of the liver (Davis, 1984).

The WHO (2011) derived a health-based value of 70 µg/l. However, this value is based on a questionable 2-year study involving persons exposed to molybdenum via drinking water (Chappell et al., 1979), which resulted in a NOAEL of 0.2 mg/l. Because molybdenum is considered an essential element, the WHO reduced the usual intra-species factor to 3 to arrive at a health-based value of (rounded) 70 µg/l. As molybdenum is only found in very low concentrations in drinking water, the WHO (2011) does not believe it is necessary to set a formal drinking water guideline value.

Reproduction-toxic effects after exposure to Mo were observed in experiments with mice (LOAEL = 1.5 mg Mo/kg•d; Schroeder and Mitchener, 1971), Long-Evans rats (dose range 0.1 – 14 mg/kg•d, NOAEL = 2 mg/kg•d; Jeter and Davis, 1954), Sprague-Dawley rats (NOAEL = 0.9 mg/kg•d; Fungwe et al., 1990) and Holstein calves (dose range 4.1 – 7.8 mg/kg•d, LOAEL 4.1 mg/kg•d Thomas and Moss, 1951).

Long-term higher oral intake of molybdenum in humans has been associated with both higher (Kovalsky et al., 1961) and lower (U.S. EPA, 1979) uric acid levels in blood and cannot therefore be evaluated in health terms on the basis of these human data. According to the U.S.-Institute of Medicine (IoM, 2001) it is also debatable whether an intake of molybdenum of up to 2 mg a day per person could disrupt the copper metabolism in people with normal copper intakes. The data from Turnlund and Keyes (2000) contradict this.

There is no data available about the carcinogenicity of molybdenum if taken orally. The U.S. Institute of Medicine (IoM 2001) derived a health-related tolerable value based on the above-mentioned reproduction-toxic effects. The starting point is the LOAEL in Sprague-Dawley (SD) rats and in mice of approx. 1.5 mg/kg•d in both species and the NOAEL of 0.9 mg/kg•d in the SD rats. To transfer this NOAEL to humans, the IoM (2001) uses an extrapolation factor (EF) of 10 for inter-species differences between humans and animals (in this case: SD rats) and an intra-species EF of 3, because it assumes that there are no significant differences in the uptake and excretion of molybdenum within the human population, if copper deficiency (daily intake less than 0.5 mg Cu a day per person) can be excluded or prevented.

Under these preconditions, the life-long tolerable intake of molybdenum for humans is set at $\text{NOAEL}/30 = \text{TDI} = 30 \mu\text{g/kg}\cdot\text{d}$ (IoM, 2001). The corresponding concentration in drinking water is 100 µg Mo/l based on the usual exposure assumptions.

If one prefers to follow the option that also securely protects copper-deficient persons against excessive molybdenum intakes, an intra-species extrapolation factor of 10 would have to be applied to the above NOAEL from the animal study together with the inter-species factor, resulting in a total EF of 100. Based on this very conservative risk assessment, the life-long tolerable intake would be $\text{NOAEL}/100 = \text{TDI} = 10 \mu\text{g Mo/kg}\cdot\text{d}$. The human-toxicology- based value in drinking water would then be 35 µg molybdenum per litre.

The value derived by the WHO (2011) lies between the result of the IoM (2001) and the above-mentioned conservative assessment and as mean estimate is used here for justification of the test value.

The resulting test value for molybdenum as part of the enamel/ceramics evaluation criteria is **7.0 µg/l**, representing a 10 % exhaustion of the WHO drinking water value (Table 1).

Literature:

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- IoM (2001): Molybdenum. Chapter 11 in: Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium and Zinc. Institute of Medicine – Food and Nutrition Board/Panel on Micronutrients, National Academy Press, Washington DC, 420 – 441
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- WHO (2011): Molybdenum in Drinking-water, Background document for development of WHO Guidelines for Drinking-water Quality, http://www.who.int/water_sanitation_health/dwq/chemicals/molibdenum/en/

Nickel (Ni, CAS No: 7440-02-0)

The German Drinking Water Ordinance and the Drinking Water Directive (RL 98/83/EC) define a limit value of 20 µg/l.

The resulting test value for nickel as part of the enamel/ceramics evaluation criteria is **2.0 µg/l**, representing a 10 % exhaustion of the drinking water limit value (Table 1).

Literature:

P-SC-EMB (2013): Technical Guide on Metals and alloys used in food contact materials, Committee of Experts on packaging materials for food and pharmaceutical products, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, PA/PH/EMB (13) 9

RL 98/83/EG: Richtlinie 98/83/EG des Rates vom 3. November 1998 über die Qualität von Wasser für den menschlichen Gebrauch (ABl. L 330/32 vom 5.12.1998)

TrinkwV (2001): Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (Trinkwasserverordnung – TrinkwV) vom 21. Mai 2001 (BGBl. I S. 959), zuletzt geändert durch Artikel 1 der Verordnung vom 3. Mai 2011 (BGBl. I S. 748)

WHO (2011): Guidelines for drinking-water quality – 4th edition. World Health Organization, CH-Geneva; http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf

Polycyclic aromatic hydrocarbons

The German Drinking Water Ordinance and the Drinking Water Directive (RL 98/83/EG) both stipulate a limit value of 0.1 µg/l for the sum of the four substances benzo(b)fluoranthene (CAS no.: 205-99-2), benzo(k)fluoranthene (CAS no.: 207-08-9), benzo(ghi)perylene (CAS no.: 191-24-2) and indeno(1,2,3-cd)pyrene (CAS no.: 193-39-5).

The resulting test value for polycyclic aromatic hydrocarbons as part of the enamel/ceramics evaluation criteria is 0.01 µg/l, representing a 10 % exhaustion of the limit value for drinking water.

For benzo(a)pyrene, the German Drinking Water Ordinance and the Drinking Water Directive both stipulate a limit value of **0.01 µg/l** (

Table 2).

The resulting test value for benzo(a)pyrene as part of the enamel/ceramics evaluation criteria is **0.001 µg/l**, representing a 10 % exhaustion of the limit value for drinking water (

Table 2).

Strontium (Sr, CAS No: 7440-24-6)

(In light of the fact that the radioactive isotope ⁹⁰Sr is only formed during nuclear fission, it is not relevant for the matter at issue here.)

The U.S.-EPA has determined a reference dose of 0.6 mg/kg•d for “stable” Sr from a study of juvenile or adult rats (20-day feed study with SrCO₃, NOAEL: 190 mg/kg bw•d). This value includes a total factor of 300, with a factor of 10 respectively for species-to-species extrapolation, for incomplete data (including a lack of data on developmental and reproduction toxicity) and for uncertainty due to the use of data for the strontium carbonate in a risk assessment that is meant to also cover other strontium salts. To take sensitive population groups into account, a factor of 3 was included; a factor of 10 was deemed too high because the critical study was carried out on young animals. Longer-term studies did not lead to a lower NOAEL (IRIS, 1996). The U.S.-EPA set a drinking water guideline value of 4 mg/l (HSDB, 2004) for “stable” Sr.

Using the reference dose by the U.S.-EPA of 0.6 mg/kg•d and the parameters usually applied in Germany, a tolerable drinking water value of 2.1 mg/l is calculated for Sr.

The resulting test value for strontium as part of the enamel/ceramics evaluation criteria is **210 µg/l**, representing a 10 % exhaustion of the drinking water value (Table 1).

Literature:

ATSDR (2004): Agency for Toxic Substances and Disease Registry, Toxicological Profile for strontium, 2004

IRIS (1996): Integrated Risk Information System, <http://www.epa.gov/iris/subst/0550.htm>

HSDB, Hazardous Substances Data Bank: <http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~uijpDe:1>

Titanium (Ti, CAS No: 7440-32-6)

Kerger (2008) presents a reference dose for oral exposure of 4 mg/kg•d that the author says is listed in a "2004 EPA Region 9 PRG table". No reference to a key study or a justification was given, and nothing was found in the Internet (EPA website).

Alternatively, the WHO (1982) reports in its "Environmental Health Criteria" on titanium (Volume 24) about a study of reproduction toxicity (Schroeder und Mitchener, 1971) in which the only tested concentration (5 mg Ti/l as soluble salt in drinking water) led to effects on the number of survivors in the third generation and the gender ratio (for a water consumption of the rats of 0.046 l/d for ♂ and 0.038 l/d for ♀ and body weights of ♂ 0.523 and ♀ 0.338, 5 mg/l correspond to a body dose of ♂ 0.44 mg/kg•d or ♀ 0.56 mg/kg•d; average across both sexes: 0.5 mg/kg•d). This study lacks validity as the basis for evaluation but it does provide an indication of a clearly more sensitive end point than the one that may have been used to derive the above-mentioned reference dose. (If the value from Schroeder and Mitchener, 1971, was transferred to humans via LOAEL → NOAEL, inter-species and intra-species extrapolation, the resulting value would be smaller by several orders than the above-mentioned reference dose.)

The reference dose of the U.S.-EPA (Kerger, 2008) contains relevant uncertainties. It lacks a justification and possibly neglects to take all relevant toxicological end points into consideration. Also, there are indications of genotoxic effects (DNA changes in offspring after subcutaneous administration of titanium dioxide, Shimizu et al., 2009). Therefore, for this problem, an additional safety factor of 100 should be included in this reference dose. With the resulting value (40 µg/kg•d) and after conversion, the tolerable drinking water concentration is 140 µg/l.

The resulting test value for titanium as part of the enamel/ceramics evaluation criteria is **70 µg/l**, representing a 50 % exhaustion of the above-mentioned drinking water concentration (Table 1).

Literature:

Kerger B.P. (2008): Technical Memorandum. Toxicity Criteria for Titanium and Compounds, and for Tungsten and Compounds. <http://ndep.nv.gov/bmi/docs/ndep techmemotitaniumtungsten.pdf>

Schroeder H.A. und Mitchener M. (1971): Toxic effects of trace elements on the reproduction of mice and rats. Arch. env. Health, 23: 102 - 106

Shimizu M. et al. (2009): Maternal exposure to nanoparticulate titanium dioxide during the prenatal period alters gene expression related to brain development in the mouse. Particle and Fibre Toxicology 6: 20 – 27

Tungsten (W, CAS No: 7440-33-7)

Based on the test results submitted to the German Environment Agency so far, it expects that tungsten does not migrate from ceramic materials into drinking water in concentrations above 0.1 µg/l. Therefore, a test value of **0.1 µg/l** (Table 1) was set as part of the enamel/ceramics evaluation criteria. This value would also be set for a substance for which no further toxicological information is available.

Yttrium (Y, CAS No: 7440-65-5)

The toxic effects of Yttrium (Y) and its compounds have not yet been studied satisfactorily. Also, some published studies are available only in Chinese or Russian with an English-language summary.

When yttrium chloride was administered orally to male Wistar rats at single doses of 100 or 1000 mg/kg, 92 to slightly more than 98 % of the dose was found in feces. The authors conclude that gastrointestinal absorption is low under the conditions of their study (Nakamura, Y. et al., 1991). Y accumulates relatively quickly in e.g. teeth and bones and can cross the placenta (Zhang, W. D. et al., 1988).

Y injected intravenously (as YCl_3) in rats was found in blood plasma in colloidal material composed of proteins and minerals, which was then taken up by phagocytic cells in the liver and spleen. At a dose of 1 mg/rat, the liver Y was cleared with a half-time of 144 days. Glutamic oxaloacetic transaminase (SGOT) and alanine aminotransferase (ALT) activity in blood plasma were increased at this dose, indicating acute hepatic injury. Calcium was significantly increased in the liver and spleen (10- and 100-fold) and slightly increased in the lung and kidney (1.5-fold) (Hirano, S. et al., 1993).

YCl_3 showed no mutagenic effect in *Salmonella typhimurium* strains TA 1537 and TA 2637 at concentrations of up to 10,000 $\mu\text{mol}/\text{plate}$ (Ogawa H.I. et al., 1987). A micronucleus study using human lymphocytes cultured in vitro showed a concentration-dependent significant increase in micronucleus frequency by treatment with yttrium chloride (Yang, H. et al., 1998). This result cannot, however, be evaluated, since the published study is available only in Chinese with an English-language abstract.

Y administered by gavage to Wistar rats of both sexes for 28 days at doses of 0, 40, 200 or 1000 mg $YCl_3/\text{kg}/\text{d}$ accumulated in the kidney, femur, liver and spleen in a dose-dependent manner. Iron concentrations in the liver, kidney and spleen, and barium and strontium concentrations in the femur were decreased, likewise dose-dependently. At doses higher than 200 mg/kg, a decrease in serum cholinesterase activity was observed in females. At 1000 mg/kg, hyperkeratosis in the forestomach and eosinophilic leucocyte infiltration in the submucosa of the stomach were found, as were erosion and dilatation of the gastric gland in males and swelling of the glandular stomach epithelium in females (Ogawa, Y. et al, 1994).

In a neurobehavioural development study from 2015, Sprague-Dawley rats were exposed by gavage to 0, 5, 15 or 45 mg/kg daily of yttrium nitrate from gestation day (GD) 6 to post-natal day (PND) 21. Body weight and food consumption were monitored weekly. Neurobehaviour was assessed by developmental landmarks and reflexes, motor activity, heat sensitivity, coordination and balance (Rota-rod test) and cognitive tests. Additionally, brain weights were measured on PNDs 21 and 70. Both male and female rat pups showed a significant increase in body weight over a limited period of time (PND 21 to PND 35); body weight continued to increase thereafter but at a non-significant rate. Except for the group exposed to 5 mg/kg/d, the duration of female forelimb grip strength and ambulation were decreased on PND 13. Yttrium nitrate exposure did not affect measures of individual behavioural development or pre-weaning and post-weaning behaviour. The authors conclude from their study that exposure to doses of yttrium nitrate of up to 45 mg/kg/d has no adverse effects on neurobehavioural outcomes during the early stages of development in rats (Li C.X. et al., 2015).

To set a guideline value for drinking water, an oral toxicity study in rodents with a duration of at least 90 days must be available at a minimum. In addition, information should be available on genotoxicity and toxicokinetics. A 90-day study is not available and the few available findings on genotoxicity are inconsistent, to say the least. Therefore, a guideline value for drinking water cannot be derived; instead, a test value is set on the basis of the following plausibility considerations:

Conversion of a recommended occupational exposure limit of 1 mg/m³ (Health Council of the Netherlands, 2000 and GESTIS Substance Database, 2016) would have to take into account a respiration rate of 10 m³ for light work over the daily working time as well as exposure over seven days per week instead of five (gives $\approx$ 7 mg/d). Assuming further 100% absorption both via the respiratory tract and via the intestinal tract, a tolerable body dose of 0.1 mg/kg/d would result for a body weight of 70 kg. This value does not yet account for the higher sensitivity of the general population compared to that of workers.

If the NOAEL of 200 mg/kg/d from the 28-day study (Ogawa, Y. et al., 1994) is taken as the basis and a factor of 20 is assumed for duration extrapolation (subacute – chronic), another factor totalling 100 is necessary for extrapolation regarding intra- and interspecies variability. The NOAEL from the animal study would then correspond to a human equivalent dose of 0.1 mg/kg/d.

This dose would presumably be too high, given the much-cited occupational exposure limit, because the missing extrapolation to the sensitive general population and the lower oral absorption in comparison to inhalation would probably not fully offset each other. However, the above dose corresponds to that stated by Xiaofei Li et al. (Li, X. et al., 2013) and, based on the results of the study by Chen Xi Li et al. (Li C.X. et al., 2015), would also sufficiently protect against suspected adverse effects on neurobehavioural development (for data extrapolation from Sprague-Dawley rats to humans, significantly lower factors have to be applied here, since exposure already occurred during a sensitive period, i.e. pregnancy, and a group considered especially sensitive, i.e. unborn and nursed offspring, was exposed).

Based on this assumed human equivalent dose of 0.1 mg/kg/d and applying the usual data (70 kg body weight, consumption of 2 litres of drinking water per day, 10% exhaustion of a tolerable dose received solely via drinking water), a drinking water concentration of 0.35 mg/l would result. This derivation contains relevant uncertainties.

In view of the insufficient and (regarding genotoxicity) inconsistent data, and given the regulatory-toxicological plausibility considerations undertaken here, it is recommended to limit, as a precautionary measure, migrations of yttrium into drinking water to only a tenth of the drinking water concentration derived above and assessed as involving relevant uncertainties, i.e. to 35 µg/l.

The resulting test value for yttrium as part of the enamel/ceramics evaluation criteria is **3.5 µg/l**, representing a 10% exhaustion of the above-mentioned concentration in drinking water (Table 1).

Literature:

Li, X., Chen, Zhib., Chen, Zhiq., Zhang, Y., 2013: A human health risk assessment of rare earth elements in soil and vegetables from a mining area in Fujian Province, Southeast China, *Chemosphere* 93, 1240–1246

Health Council of the Netherlands, Committee on Updating of Occupational Exposure Limits, 2000: Yttrium and yttrium compounds, Health-based Reassessment of Administrative Occupational Exposure Limits, Committee on Updating of Occupational, 2000/15OSH/017

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Nakamura, Y., Tsumura-Hasegawa, Y., Tonogai, Y., Kanamoto, M., Tsuboi, N., Murakami, K., Ito, Y., 1991: Excretion of Dysprosium, Europium, Ytterbium and Yttrium in the Rat after Oral Administration, *Eisei Kagaku* 37 (5), 418 – 425 (in Japanese)

Zhang, W. D., Li, F. Q., Zhang, X. Y., und Chen, Y., 1988: Effects of Traces of Rare Earth Elements on the Protozoan *Blepharisma* and on Mice, *Biological Trace Element Research* 17, 81 - 90

Hirano, S., Kodama, N., Shibata, K., Suzuki, K. T., 1993: Metabolism and Toxicity of Intravenously Injected Yttrium Chloride in Rats, *Toxicology and Applied Pharmacology* 121, 2, 224-232

Ogawa, H. I., Tsuruta, S., Niyitani, Y., Mind, H., Sakata, K. und Kato, Y., 1987: Mutagenicity of metal salts in combination with 9-aminoacridine in *Salmonella typhimurium*, *Jpn. J. Genet.* 62, pp. 159-162

Yang, H., Ji Q., Zhang X., 1998: Studies on effects of yttrium chloride and praseodymium chloride on frequency of micro-nucleus in human blood lymphocytes, *Zhonghua Yufang Yixue Zazhi* 32 (3), 156-158 (in Chinese)

Ogawa, Y., Suzuki, S., Naito, K., Saito, M., Kamata, E., Hirose, A., Kaneko, T., Chiba, M., Inaba, Y., Kurokawa, Y., 1994: Studies on the biological effects of yttrium. Effects of repeated oral administration tests in rats. In Japanese. *Jpn J Toxicol Environ Health*, 40, 374-82, English-language abstract, cited in: Health Council of the Netherlands: Committee on Updating of Occupational Exposure Limits. Yttrium and yttrium compounds; Health-based Reassessment of Administrative Occupational Exposure Limits. The Hague: Health Council of the Netherlands, 2000; 2000/15OSH/017.

Li C. X., Ma C., Fang H. Q., Zhi Y., Yu Z., Xu H. B. und Jia X. D., 2015: Neurobehavioral Assessment of Rats Exposed to Yttrium Nitrate during Development, *Biomed Environ Sci*, 28 (4), 281-290

Zirconium (Zr, CAS No: 7440-67-7)

(Natural zirconium usually comprises 51.4 % of the isotope ^{90}Zr , 17.5 % of the isotope ^{94}Zr , 17.1 % of the isotope ^{92}Zr , 11.2 % of the isotope ^{91}Zr and 2.8 % of the radioactive isotope ^{96}Zr , half-life 3.6×10^{17} years.)

The following oral toxicity studies are cited in the rationale for the (preliminary) maximum workplace concentration (MAK value) for Zr and its compounds (MAK, 1998):

Harrison et al. (1951): 10 rats per gender were administered a daily dose of approx. 4 g Zr/kg BW in the form of $3\text{ZrO}_2 \cdot \text{CO}_2 \cdot \text{H}_2\text{O}$ in a standard diet for 17 weeks. In terms of growth rate, blood and urine changes, and mortality, there were no adverse effects.

Schroeder et al. (1968): After life-long administration of 5 mg Zr/l drinking water as Zr sulphate, the lifespan of treated mice was shorter than that of those that had not been treated. This was seen as an indication of slight toxicity. The overall daily intake was 0.9 mg/kg BW via drinking water and 0.4 mg/kg BW via feed (concentration measured in the feed: $2.66 \mu\text{g Zr/g}$).

Schroeder et al. (1970): Exposure of Long-Evans rats to 5 ppm of Zr sulphate via drinking water had no impact on the survival rate, however there was a significantly increased incidence of glycosuria (measured in non-fasting 18 month old animals: 23 % in 90 controls, 52 % in 56 of the Zr group; significantly increased compared to the controls according to chi-square analysis, $P < 0.01$).

The administration of Zr below the skin (injection in CBA/J mice, implantation in Fisher rats) led to tumours (benign chondromas, subcutaneous tumours that are histologically similar to human malign fibrohistiocytomas) where the Zr was administered (MAK, 1998). Other carcinogenicity tests (one i.v. and two p.o.) were negative (MAK, 1998).

These data are insufficient for defining a drinking water guideline value. Alternatively, the studies by Schroeder et al. (1968, 1970) with a value for total intake (drinking water and feed) of $1.3 \text{ mg/kg} \cdot \text{d}$ (Schroeder et al., 1968) can be used as the LOAEL. With a factor of 10, each, for extrapolation to a NOAEL (as an alternative to calculating a benchmark as is

recommendable when there is no NOAEL), for species-to-species extrapolation and to account for sensitive population groups, a NOAEL could be derived for (sensitive) persons (1.3 µg/kg•d).

Wünschmann et al. (2003) determined an average daily Zr intake (geom. mean) of 19.4 µg/d ± 318 % (0.5-270 µg/d) on the basis of food samples from the Nysa region (Federal Republic of Germany, The Czech Republic and Poland) for 23 breast-feeding (non-smoking) test persons; this figure was around 60 % lower than the intake quantity estimated by Binder (2000).

(According to measurements of atmospheric depositions in the Nysa region, the loads there are similar to those in other moderately loaded regions in Central Europe.) With an assumed female body weight (in the study by Wünschmann et al. the body weight was queried but no information on this was provided in the report) of 60 kg, the assumed Zr intake via the diet is around 0.32 µg/kg•d. This is around 25 % of the NOAEL of 1.3 µg/kg•d determined above for (sensitive) people. Based on this, it is possible to deviate from the initially stated default assumption of 10 % exhaustion of the tolerable doses via drinking water and an exhaustion that is twice as high can be tolerated. Factoring in the other common factors, a value of (9.1 or), rounded, 10 µg/l is calculated for orientation. This value contains relevant uncertainties in terms of the type of study (only one concentration tested), the lack of a NOAEL and the examination depth (were all relevant toxicological end points examined?). The possible local carcinogenicity (injection or implantation below the skin, MAK, 1998) is not considered relevant here.

The resulting test value for zirconium as part of the enamel/ceramics evaluation criteria is **5.0 µg/l**, representing a 50 % exhaustion of the drinking water value (Table 1).

Literature:

Binder, H. (Hrsg., 2000): Lexikon der chemischen Elemente, S. Hirzel Verlag Stuttgart, Leipzig.

Harrison J.W.E. et al. (1951): The acute, chronic and topical toxicity of zirconium carbonate. J Pharmacol Exp Ther 102: 179 - 183

Schroeder, H.A. et al. (1968): Zirconium, Niobium, Antimony and Fluorine in Mice: Effects on growth, survival and tissue levels. J. Nutrition 95: 95 - 101

Schroeder, H.A. et al. (1970): Zirconium, Niobium, Antimony, Vanadium and Lead in Rats: Life term studies. J. Nutrition 100: 59 - 68.

MAK, (1998): Zirkonium und seine Verbindungen, 27. Lieferung

Wünschmann, S. et al. (2003): Transfer von Elementen in die Muttermilch, Internationales Hochschulinstitut Zittau Lehrstuhl Umweltverfahrenstechnik, Fachgruppe Human- und Ökotoxikologie, Forschungsbericht StSch 4258, im Auftrag des Bundesamtes für Strahlenschutz, Hrsg. 2005

3 Ingredients without test values

Calcium (Ca, CAS No: 7440-70-2), Magnesium (Mg, CAS No: 7439-95-4)

Calcium and magnesium are ingredients of natural drinking water. Both are essential for human health. A recommended daily intake for adults lies between 1,000 and 1,300 mg for calcium and 250 and 400 mg for magnesium (WHO, 2009). As a supply source, drinking water only plays a subordinate role. Migration from enamels or ceramic materials into drinking water is therefore not relevant for health, and no restriction is required for these parameters.

Literature:

WHO (2009): Calcium and Magnesium in Drinking-water, Public health significance, http://www.who.int/water_sanitation_health/publications/publication_9789241563550/en/

Iron (Fe, CAS No.: 7439-89-6)

Any iron released from enamels or ceramic materials will not contribute to the limit value for iron in drinking water (200 µg/l under the German Drinking Water Ordinance (TrinkwV) being exceeded. Setting a restriction is therefore considered unnecessary.

Fluorine (F, CAS No: 7782-41-4)

Enamels or ceramic materials could release fluorine as fluoride into drinking water. Such release of fluoride would not lead to the limit value for fluoride in the drinking water being exceeded (1.5 mg/l under the German Drinking Water Ordinance (TrinkwV). Setting a restriction is therefore considered unnecessary.

Potassium (K, CAS No: 7440-09-7)

Potassium is an ingredient of natural drinking water. It is essential for human health. There is no evidence of a risk to health by drinking water containing potassium (WHO, 2009). A limitation of the migration of potassium from enamels or ceramic materials in drinking water is therefore considered unnecessary.

Literature:

WHO (2009): Potassium in drinking-water, Background document for development of WHO Guidelines for Drinking-water Quality, http://www.who.int/water_sanitation_health/gdwqrevision/potassium/en/

Lithium (Li, CAS No: 7439-93-2)

Lithium has been inadequately examined from a toxicological point of view. In connection with other lithium compounds, the European Food Safety Authority (EFSA) recommends for lithium salts that come into contact with food a "specific migration limit" (SML) of 0.6 mg/kg (EFSA, 2008). Migration from enamels or ceramic materials in drinking water reaches at a maximum 50 % of this quantity per litre. Setting a restriction is therefore considered unnecessary.

Literature:

EFSA (2008): Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) on a 20th list of substances for food contact materials. *The EFSA Journal* (2008) 816-821, 1-20. <http://www.efsa.europa.eu/en/efsajournal/pub/816.htm>

Sodium (Na, CAS No: 7440-23-5)

Sodium has a limit value of 200 mg/l in the German Drinking Water Ordinance. The possible release of sodium from enamels or a ceramic material will not be anywhere near this concentration. For this reason, setting a restriction for the parameter sodium is considered unnecessary.

Phosphorus (P, CAS No: 7723-14-0 (red)/ 12185-10-3 (white))

Enamels and ceramic material could release phosphorus as phosphates into drinking water. Phosphate is an approved treatment chemical for drinking water and, accordingly, may be added to treat drinking water up to a concentration of 6.7 mg/l. The expected release from enamels and ceramic materials is much lower in comparison. Setting a restriction is therefore considered unnecessary.

Silicon (Si, CAS No: 7440-21-3)

Silicon is a main component in enamel and occurs in it in the form of non-crystalline (amorphous) silicon dioxide. Silicon dioxide is very poorly water-soluble. Amorphous silicon dioxide has a substantially better solubility than crystalline silicon dioxide (quartz). Guidelines for drinking water or tolerable maximum quantities after oral intake are not known. According to the EFSA the estimated typical dietary intake is 20-50 mg/d, corresponding to 0.3 - 0.8 mg/kg for a person weighing 60 kg, and these intakes are unlikely to cause adverse effect (EFSA, 2004). It is not expected that the release of silicon from enamels and ceramic materials can make a significant contribution here, which is why a restriction is considered unnecessary.

Literature:

EFSA (2004): Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Silicon, The EFSA Journal (2004) 60, 1-11.
<http://www.efsa.europa.eu/en/efsajournal/pub/60.htm>

Titanium dioxide (TiO₂, CAS-No.: 13463-67-7)

Titanium dioxide is deemed inert, i.e. it is insoluble in water and organic solvents; and is therefore only slightly systemically toxic (local effects after inhalation do not need to be examined here).

In a carcinogenicity study, Fischer 344 rats and B6C3F₁ mice (50 per gender) were administered 0, 25,000 or 50,000 mg of TiO₂/kg via their food for a period of 103 weeks (NCI, 1979). An increased occurrence of C-cell adenoma in the thyroid was observed in the high-dose group of female rats (controls 1/48, lower dose 0/47, high dose 6/44), but this increase was not significant statistically (P = 0.043 for the comparison of the high-dose group with the control group, Bonferroni criterion: P = 0.025). The U.S. National Cancer Institute (NCI 1979) does not see a substance-related effect. The number of tumours in the exposed B6C3F₁ mice was not significantly higher than in the control groups. The administration of the TiO₂ had no relevant effect on the mean body weights of the rats or mice. Apart from white faeces, there were no clinical signs judged to be related to the administration of the TiO₂. The survival of the rats and the male mice at the end of the test was not affected, the mortality of the female mice was dose-related (NCI, 1979).

Over 130 weeks, Fischer 344 rats were fed diets containing 0, 1, 2 or 5 % TiO₂ coated mica. This showed no toxicological (survival rate, body weight increase, haematological or clinical-chemical parameters, histopathology) or carcinogenic effects (Bernard et al. 1990).

In 1969 the JECFA deemed TiO₂ to be so insignificantly toxic that the derivation of an "acceptable daily intake" (ADI value) was thought unnecessary (JECFA, 1969). Other institutes concurred after the presentation of new data (EFSA, 2004, U.S.-EPA, 2005). No test value for TiO₂ is proposed for the problem at issue here because it cannot be assumed that TiO₂ migrated from enamel can even get close to reaching toxicological concentrations.

Literature:

Bernard, B. K.; Osherooff, M. R.; Hofmann, A.; Mennear, J. H. (1990): Toxicology and Carcinogenesis Studies of Dietary Titanium Dioxide-Coated MICA in Male and Female Fischer 344 Rats. Journal of Toxicology and Environmental Health, 29: 417 - 429

EFSA, European Food Safety Authority, (2004): Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a Request from the Commission Related to the Safety in use of Rutile Titanium Dioxide as an Alternative to the Presently Permitted Anatase Form, The EFSA Journal 163: 1 - 12

JECFA, Joint FAO/WHO Expert Committee on Food Additives, (1969): Thirtieth Report of the FAO Nutrition Meetings Report Series, WHO Technical Report Series, FAS 70.36/NMRS 46A-JECFA 13/55 to titanium dioxide (INS 171)

NCI, National Cancer Institute, (1979): Technical Report Series No. 97, Bioassay of Titanium Dioxide for Possible Carcinogenicity

U.S.-EPA, U.S.-Environmental Protection Agency, (2005): Office of Prevention, Pesticides and Toxic Substances, Action Memorandum: Inert Ingredient Tolerance Reassessment - Titanium Dioxide, June 28, 2005

Zinc (Zn, CAS No: 7440-66-6)

Zinc has no limit value in the German Drinking Water Ordinance. However, there is a WHO guideline for zinc of 3 mg/l that is based on effects on sensory quality of drinking water. Compared to this value, any concentrations in drinking water caused by zinc released from enamels and ceramic materials is very low. For this reason, setting a restriction for the parameter zinc is considered unnecessary.

Tin (Sn, CAS No: 7440-31-5)

The WHO "Expert Committee on Food Additives" derived a "Provisional tolerable weekly intake" (PTWI) of 14 mg/kg body weight (2 mg/kg•d) based on acute gastrointestinal irritation; this would correspond to 200 mg/kg in the diet (JECFA, 1989). Due to the low toxicity of the (inorganic) tin, the WHO does not define a drinking water guideline (WHO, 2004). It is not expected that the release of tin from enamels and ceramic materials can make a significant contribution here. Setting a restriction is therefore considered unnecessary.

Literature:

JECFA (1989) Toxicological evaluation of certain food additives and contaminants. Joint FAO/WHO, Expert Committee on Food Additives. Cambridge, Cambridge University Press, pp. 329–336 (WHO Food Additives Series No. 24).

WHO (2004): Inorganic Tin in Drinking-water, Background document for development of WHO Guidelines for Drinking-water Quality.