Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) regarding criteria for the estimation of concentrations for the discussion of proposals for migration limits of certain heavy metals and other elements from ceramic articles intended to come into contact with foodstuffs

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Abstract

Directive 84/500/EEC and its amendments establish the requirements for the commercialisation of ceramic articles intended to come into contact with foodstuffs, in order to guarantee that they do not constitute a risk for consumers and to establish the maximum limits of migration for cadmium and lead.

In this respect, in the light of developments in scientific knowledge, it is advisable to review the lead and cadmium limits and the test conditions. Therefore, the European Commission is assessing the amendment of said Directive.

The Scientific Committee has assessed a proposal regarding criteria for the estimation of concentrations for the discussion of proposals for migration limits of certain heavy metals and other elements from ceramic articles intended to come into contact with foodstuffs.

It has assessed whether the criteria used in the preparation of the proposal are adequate, considering them to be acceptable except in two cases, for which it has put forward the application of alternative criteria.

Key words

Ceramic materials, heavy metals, migration.

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1. Introduction

Ceramic materials intended to come into contact with foodstuffs are regulated throughout the European Union by Regulation (EC) No 1935/2004 of the European Parliament and of the Council, of 27 October 2004, on materials and articles intended to come into contact with food (EU, 2004), and particularly by Directive 84/500/EEC, of 15 October 1984, on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs (EU, 1984).

Directive 84/500/EEC and its amendments were transposed to the Spanish legal system by Royal Decree 891/2006, of 21 July, approving the technical and sanitary regulations applicable to ceramic articles intended to come into contact with foodstuffs, which was recently modified by Royal Decree 1631/2011, of 14 November (Real Decreto, 2006, 2011).

These provisions establish the requirements for the commercialisation of ceramic articles intended to come into contact with foodstuffs, in order to guarantee that they do not constitute a risk for consumers. In particular, maximum migration limits are established for cadmium and lead.

In the light of developments in scientific knowledge, it is advisable to review the lead and cadmium limits established in 1984, and the test conditions. Consequently, the European Commission is assessing the amendment of Directive 84/500/EEC and the inclusion of migration limits for other heavy metals and other elements which may be present in ceramic articles in high quantities or which may constitute a toxicological risk for the consumer.

The European Commission has established priorities for the establishment of maximum limits for the migration of heavy metals and other elements from ceramic materials according to the potential risk they represent.

The Spanish Agency for Food Safety and Nutrition (AESAN) has put forward a proposal, which provides a baseline for the establishment of migration limits for different heavy metals and other elements which may be present in ceramic articles and which belong to the first three priority groups of the European Commission. The proposal is based on different toxicological documentary sources and establishes a series of baseline concentrations for the discussion regarding the maximum migration limits. In addition, this proposal refers to articles to be filled included in category 2 as established by Royal Decree 891/2006.

These concentrations are not a proposal of maximum limits as such, but offer a baseline on which to base an application to the Scientific Committee to assess whether the criteria used in the preparation of the proposals of the different elements are adequate, as regards their discussion in an eventual amendment of the Directive regarding ceramic articles intended to come into contact with foodstuffs, and whether analytical methods are available to permit the control of compliance of the proposed baseline levels.

2. Estimations made for the proposal of baseline concentrations

In preparing the proposal for baseline concentrations of heavy metals and other elements provided by the AESAN, it has been assumed that a 60 kg adult may eat and drink 1 kg per day of food which has been in contact with ceramic articles.

The proposal has considered the exposure of population to these heavy metals and other elements through other sources. In addition, certain criteria are established for preparing the baseline concentration proposal:

1. When exposure to these elements from other sources is known and is significant but below the Tolerable Daily Intake (TDI), the remaining portion of the TDI is taken as the baseline concentration proposal.
2. When exposure to these elements from other sources is above the TDI, a 10% utilization of the TDI is allowed.
3. However, if the exposure through other sources is more than 2 times the TDI, a 5% utilization of the exposure is taken, as long as it is below the TDI.

On this basis, the AESAN has provided the Scientific Committee with the baseline concentration proposal for the discussion on maximum migration limits as summarised in Table 1. The Scientific Committee has assessed whether the criteria used in their preparation are adequate, without dismissing the fact that there may be other methods of estimation that are also acceptable. In addition, the values resulting from the application of these criteria should not be considered as a proposal for maximum migration limits but rather as a baseline for discussion, in which other factors such as their applicability and other specific safety considerations should be taken into account for each element.

Table 1. Proposal of baseline concentrations for discussion on maximum migration limits of heavy metals and other elements from ceramic articles intended to come into contact with foodstuffss

Element	Symbol	µg/kg foodstuff
Arsenic	As	18
Cadmium	Cd	5
Cobalt	Co	45
Copper	Cu	1,000
Manganese	Mn	550
Mercury	Hg	9.6
Nickel	Ni	125
Lead	Pb	10
Selenium	Se	24
Thallium	Tl	0.4

3. Assessment of the proposals of baseline concentrations

3.1 Assessment of the criteria for the proposal of baseline concentrations

The first two criteria used to prepare the proposal of baseline concentrations are considered adequate (section 2). With respect to the third criteria, in the event that the exposure is more than 2 times the TDI, the application of the criteria initially proposed would imply that the TDI is exceeded excessively. Therefore, in this case, when the exposure through other sources is more than 2 times the TDI, the proposed concentration of 5% of the exposure is considered to be more adequate, provided this quantity does not exceed 10% of the TDI, in which case the proposed value of 10% would be taken.

3.2 Arsenic

3.2.1 Proposal

The European Food Safety Authority (EFSA) has used a $BMDL_{01}$ (confidence limit less than 5% of the daily dose which produces an increase of 1% in the appearance of lung, skin and bladder cancer, and skin lesions with respect to the controls, derived from the adjustment of a mathematical model to the experimental data) of arsenic of 0.3-8 µg per kg body weight and day (EFSA, 2009a). Taking the most conservative limit, this is equivalent to a daily intake limit of 18 µg in a 60 kg person.

Exposure to arsenic through other sources, including foodstuffs, is up to 1.22 µg per kg body weight and day (EFSA, 2009a) and, therefore, the value of 0.3 µg is considered to be sufficiently conservative, thus obtaining a baseline concentration for the discussion of the maximum migration limit of arsenic from ceramic articles of 18 µg/kg of food.

3.2.2 Assessment of the proposal

When there is no established an Acceptable Daily Intake (ADI) but a value is available for the $BMDL_{01,}$ the lowest value in the range established for the $BMDL_{01}$ is used as the baseline concentration for the discussion of the maximum migration limit. This procedure does not exactly follow the criteria given in section 2. Given a daily intake of As of 73.2 µg/day, and therefore more than 2 times the TDI, and applying the third criteria, the estimated value would be 4 µg/kg. However, the limit of 18 µg/kg is considered to be sufficient, as the $BMDL_{01}$ is far more demanding than the TDI. Moreover, in this case, there is a very wide range for the $BMDL_{01}$ (0.3-8 µg/kg) and the lower value has been taken. The $BMDL_{01}$ is considered to be a highly demanding and suitably conservative parameter. The criteria used for preparing the proposal are acceptable.

3.3 Cadmium

3.3.1 Proposal

EFSA has established a Tolerable Weekly Intake (TWI) of cadmium of 2.5 µg per kg body weight (EFSA, 2009b, 2011). This is equivalent to a TDI of 21.4 µg in a 60 kg person.

Exposure to cadmium through food ranges between 2.04 and 3.66 µg/kg body weight per week (EFSA, 2012). As this exposure is somewhat higher than the TWI and applying the criteria established in section 2 for proposing a baseline concentration for the discussion of the maximum migration limit of cadmium from ceramic articles, this should be defined at 10% of the TDI: 2 µg/kg of food. However,

considering that the limit established for some bottled water is 5 µg/l (EU, 1998), and that more restrictive values may be difficult to meet, a value of 5 µg/kg of food is obtained as the limit value for discussion.

3.3.2 Assessment of the proposal

The criteria used for preparing the proposal are acceptable. The resultant value is the limit in bottled drinking water (5 µg/l), the intake of which is much higher than that of foodstuff in contact with ceramic articles.

3.4 Cobalt

3.4.1 Proposal

The RIVM *(Rijksinstituut voor Volksgezondheid in Milieu)* in The Netherlands has established a TDI of cobalt of 1.4 µg per kg body weight (RIVM, 2001) based on an assessment by Vermeire et al. (1991). This is equivalent to a TDI of 84 µg in a 60 kg person.

Exposure to cobalt through other sources, including food, is 39 µg/day according to data from a total diet study carried out in the United Kingdom (VKM, 2007). As this value is less than the TDI, the difference between the TDI and this value is taken as the proposal for a baseline concentration for the discussion of the maximum migration limit of cobalt from ceramic articles: 45 µg/kg of food.

3.4.2 Assessment of the proposal

The use of the intake value of 39 µg/day (VKM, 2007) in the proposal appears to be acceptable. If this intake is considered, and applying the first criteria (intake<TDI), the concentration proposal is the difference (84-39=45 µg/kg). The criteria used for preparing the proposal are acceptable.

3.5 Copper

3.5.1 Proposal

The Scientific Committee on Food has estimated a tolerable upper intake level of 5 mg per day (SCF, 2003). In turn, the World Health Organisation (WHO, 2003) has considered a TUIL (Tolerable Upper Intake Level) of 10 mg/day based on a report from the Institute of Medicine (IOM, 2001). Given that, in the establishment of the value of 5 mg, safety factors have been considered, the value of 5 mg is considered to be sufficient.

Exposure to copper through sources such as water may often be more than 1 mg/day and may reach 4 mg in Scandinavia (VKM, 2007). As this value is less than the TDI, the difference between the TDI and this value is taken as the proposal for a baseline concentration for the discussion of the maximum migration limit of copper from ceramic articles: 1 mg/kg of food.

3.5.2 Assessment of the proposal

The criteria used for preparing the proposal are acceptable. The first criteria mentioned in section 2 (intake<TDI) is applied and, therefore, the concentration proposal is the difference between the TDI and the intake.

3.6 Manganese

3.6.1 Proposal

The WHO has considered that a level of approximately 4 mg is safe (WHO, 2008).

According to the WHO (2008), the daily intake of manganese is approximately 11 mg. In the absence of other toxicological data, the WHO has assumed the value of 4 mg as the TDI based on this intake and a safety factor of 3.

As this exposure is more than 2 times the TDI, and applying the criteria established in section 2 for proposing a baseline concentration for the discussion of the maximum migration limit of manganese from ceramic articles, this is defined at 5% of the exposure: 550 µg/kg of food.

3.6.2 Assessment of the proposal

The application of the third criteria, initially mentioned in section 2, gives a value of 550 µg/kg of food (5% of the exposure and the TDI is not exceeded). However, the use of the alternative criteria listed in section 3.1 is thought to be suitable. In this case, it would apply assuming a maximum 10% of the TDI (400 µg/day). Therefore, with these criteria, a baseline value of 400 µg/kg of food is obtained for the discussion.

3.7 Mercury

3.7.1 Proposal

EFSA (2004) assumes the Provisional Tolerable Weekly Intake (PTWI) of mercury to be 1.6 µg per kg body weight and week, proposed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2003). This is equivalent to a TDI of 96 µg in a 60 kg person.

Exposure to mercury through different sources, including food, is 1.5 µg per kg body weight (EFSA, 2004). As this exposure is similar to the PTWI and applying the criteria established in section 2 for proposing a baseline concentration for the discussion of the maximum migration limit of mercury from ceramic articles, this would be defined at 10% of the TWI: 9.6 µg/kg of food.

3.7.2 Assessment of the proposal

The criteria used for preparing the proposal are acceptable.

3.8 Nickel

3.8.1 Proposal

The WHO has proposed a TDI of nickel of 12 µg per kg body weight derived from a LOAEL (Lowest Observed Adverse Effect Level) (WHO, 2008) and the EFSA has not established a reference value (EFSA, 2005). The WHO proposal is equivalent to a TDI of 720 µg in a 60 kg person.

Exposure to nickel through different sources, including food, is 2,500 µg per day in the worst case, although normally exposure is close to or below the TDI (VKM, 2007). As this exposure is more than 2 times the TDI, and applying the criteria established in section 2 for proposing a baseline concentration for the discussion of the maximum migration limit of nickel from ceramic articles, this would be defined at 5% of the exposure: 125 µg/kg of food.

3.8.2 Assessment of the proposal

Given that the daily intake is not known precisely and may vary considerably, the alternative criteria given in section 3.1 appears more reasonable, thus assuming 10% of the TDI (72 µg/day) as a maximum, and obtaining a baseline concentration for the discussion of 72 µg/kg of food.

3.9 Lead

3.9.1 Proposal

EFSA has considered that it is not possible to establish a tolerable weekly intake of lead but has calculated a $BMDL_{01}$ of lead with a lower level of 0.5 µg per kg body weight and day (EFSA, 2010). This implies that 1% of the population could be adversely affected at this level. As there is no available NOAEL (No Observable Adverse Effect Level) and that the $BMDL_{01}$ is considered suitably conservative, a value of 30 µg per day for a 60 kg person is taken as the substitute for the TDI.

Exposure to lead through food is up to 2.43 µg per kg body weight and day (146 µg per day in a 60 kg person) (EFSA, 2010). As this exposure is more than 2 times the $BMDL_{01}$, and applying the criteria established in section 2 for proposing a baseline concentration for the discussion of the maximum migration limit of lead from ceramic articles, this would be defined at 5% of the exposure: 7.3 µg/kg of food. However, considering that the limit established for bottled water is 10 µg/l (up to 2014) (EU, 1998) and that the intake of bottled water is far higher than that of foods in contact with ceramic articles, the limit of 10 µg/kg of food is proposed.

3.9.2 Assessment of the proposal

The criteria used for preparing the proposal are acceptable.

3.10 Selenium

3.10.1 Proposal

The WHO has proposed a NOAEL of selenium of 4 µg per kg body weight and day (WHO, 2008). With this NOAEL, it is possible to obtain a TDI of 240 µg for a 60 kg person without applying a safety factor, given that the NOAEL is observed in humans and that the WHO does not use it.

Given that exposure to selenium through other sources is frequent, a baseline concentration is proposed for the discussion of the maximum migration limit of selenium from ceramic articles of 10% of the TDI: 24 µg/kg of food.

3.10.2 Assessment of the proposal

The criteria used for preparing the proposal are acceptable.

3.11 Thallium

3.11.1 Proposal

The U.S. Environmental Protection Agency (EPA) has specified a RfD (Reference Dose) of 0.00007 mg per kg body weight and day (EPA, 2003). The EPA proposal is equivalent to a RfD of 0.004 mg per day in a 60 kg person. The RfD is obtained from a NOAEL of 0.20 mg per kg body weight and day obtained in

a subchronic study in rats and applying an uncertainty factor of 3,000 (10 to extrapolate the data from a subchronic study to a chronic study, 10 to consider the variability between species, 10 to consider interspecies variability and 3 to consider the lack of data as regards chronic and reproductive toxicity).

Given that the RfD is derived from a NOAEL, the baseline concentration for the discussion of the maximum migration limit of thallium from ceramic articles is defined at 10% of the RfD: 0.4 µg/kg of food.

3.11.2 Assessment of the proposal

The criteria used for preparing the proposal are acceptable.

3.12 Control methods and final consideration

Methods with adequate sensitivity are currently available for detecting the baseline concentrations proposed for the discussion of the maximum migration limit. The assessment of the proposals has only been carried out with respect to whether the criteria used in their preparation are adequate, considering that these concentrations are not a proposal for maximum limits as such but a baseline for their discussion, and without dismissing the fact that there may be other possible methods of estimation that are also acceptable. The values resulting from the application of these criteria must not be taken as a proposal of maximum migration limits from ceramic articles, but as a baseline for their discussion, in which other factors and specific criteria for each element may also be considered.

References

EFSA (2004). European Food Safety Authority. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to mercury and methylmercury in food. *The EFSA Journal*, 34, pp: 1-14.

EFSA (2005). European Food Safety Authority. 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 Nickel. *The EFSA Journal*, 146, pp: 1-21.

EFSA (2009a). European Food Safety Authority. Scientific Opinion on Arsenic in Food. EFSA Panel on Contaminants in the Food Chain (CONTAM). *The EFSA Journal*, 7 (10), pp: 1.351.

EFSA (2009b). European Food Safety Authority. Scientific Opinion on Cadmium in Food. EFSA Panel on Contaminants in the Food Chain (CONTAM). *The EFSA Journal*, 980, pp: 1-139.

EFSA (2010). European Food Safety Authority. Scientific Opinion on Lead in Food. EFSA Panel on Contaminants in the Food Chain (CONTAM). *The EFSA Journal*, 8 (4), pp: 1.570.

EFSA (2011). European Food Safety Authority. Statement on tolerable weekly intake for cadmium. EFSA Panel on Contaminants in the Food Chain (CONTAM). *The EFSA Journal*, 9 (2), pp: 1.975.

EFSA (2012) European Food Safety Authority. Cadmium dietary exposure in the European population. *The EFSA Journal*, 10 (1), pp: 2.551.

EPA (2003). U.S. Environmental Protection Agency. Thallium (I) soluble salts; CASRN various. Available at: http://www.epa.gov/iris/subst/1012.htm [accessed: 28-3-12].

EU (1984). Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs. OJ L 277, 20 October 1984, pp: 12–16.

EU (1998). Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5 December 1998, pp: 32–54.

EU (2004). Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on

materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13 November 2004, pp: 4–17.

IOM (2001). Institute of Medicine. Dietary reference intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium and zinc. A report of the Panel on Micronutrients, Subcommittees on Upper Reference Levels of Nutrients and of Interpretation and Use of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. Food and Nutrition Board, Institute of Medicine. Washington, DC, National Academy Press. Available at: http://www.nap.edu/openbook.php?isbn=0309072794 [accessed: 21-3-12].

JECFA (2003). Joint FAO/WHO Expert Committee on Food Additives. Methylmercury. Evaluation of Certain Food Additives and Contaminants. WHO Technical Report Series No 922.

Real Decreto (2006). Real Decreto 891/2006, de 21 de julio, por el que se aprueban las normas técnico-sanitarias aplicables a los objetos de cerámica para uso alimentario.

Real Decreto (2011). Real Decreto 1631/2011, de 14 de noviembre, por el que se modifica el Real Decreto 891/2006, de 21 de julio, por el que se aprueban las normas técnico-sanitarias aplicables a los objetos de cerámica para uso alimentario.

RIVM (2001). Rijksinstituut voor Volksgezondheid en Milieu. Reevaluation of human toxicological maximum permissible risk levels. RIVM Report 711701 025. Available at: http://www.rivm.nl/bibliotheek/rapporten/711701025.pdf [accessed: 14-3-12].

SCF (2003). Scientific Committee on Food. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Copper. SCF/CS/NUT/UPPLEV/57 Final. Available at: http://ec.europa.eu/food/fs/sc/scf/out176_en.pdf [accessed: 21-3-12.

VKM (2007). Norwegian Scientific Committee for Food Safety. Risk assessment of health hazards from nickel, cobalt, zinc, iron, copper and manganese migrated from ceramic articles. Available at: http://vkm.no/dav/ebc8d55983.pdf [accessed: 26-3-12].

Vermeire, T.G., van Apeldoo, M.E., de Fouw, J.C. and Janssen, P.J.C.M. (1991). Voorstel voor de humaan-toxicologische onderbouwing van C-(toetsings) waarden. Rapportnr. 725201005.

WHO (2003).World Health Organization. Copper in Drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/copper.pdf [accessed: 21-3-12].

WHO (2008). World Health Organization. Guidelines for drinking-water quality [electronic resource]: incorporating 1st and 2nd addenda, Vol.1, Recommendations. Available at: http://www.who.int/water_sanitation_health/dwq/fulltext.pdf [accessed: 14-3-12].