Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

lead and its compounds in articles intended for consumer use

ECHA/RAC/RES-O-0000003487-67-04/F

Adopted

10 December 2013

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Opinion of the Committee for Risk Assessment

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	***Lead and its compounds***
EC No.:	231-100-4
CAS No.:	7439-92-1

This document presents the opinion adopted by RAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

Sweden has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***21 March 2013***. Interested parties were invited to submit comments and contributions by ***21 September 2013***.

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: ***Frank Jensen***

Co-rapporteur, appointed by RAC: ***Helmut Greim***

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on 10 December 2013.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted ***by simple majority*** of all members having the right to vote. Any minority position(s) including their grounds are made available in a separate document, published at the same time as the opinion.

OPINION

RAC has formulated its opinion on the proposed restriction based on: information related to the identified risk; the options identified to reduce the risk as documented in the Annex XV report and information submitted by interested parties as well as other available information as recorded in the Background Document (BD).

RAC considers that the proposed restriction on Lead and its compounds in articles intended for consumer use is the most appropriate Community-wide measure to address the identified risks in terms of the effectiveness in reducing such risks, provided that the conditions are modified.

RAC proposes that the conditions of the restriction should consider the following elements:

Lead and its compounds, (CAS No. 7439-92-1, EC No. 231-100-4)

1. Shall not be placed on the market or used in articles, or accessible parts of articles, which are supplied to the general public and which can be placed in the mouth by children if the concentration of lead (expressed as metal) in that article, or part of article, is equal to or greater than 0.05% by weight.
2. For the purposes of paragraph 1, an article or part of article can be placed in the mouth by children if it is smaller than 5 cm in one dimension or has detachable or protruding parts of that size.
3. Paragraph 1 does not apply if an article, or a part of an article, is not accessible by children during normal or reasonably foreseeable conditions of use.

   European Standard EN71-1, as adopted by the European Committee for Standardisation (CEN), shall be used, where appropriate, as the method to determine "accessible parts" of articles.
4. Paragraph 1 does not apply when it can be demonstrated that the rate of lead release from an article or any part of an article, whether coated or not coated[1], does not exceed 0.05 µg/cm^2 per hour (0.05 µg/g per hour).

[1] The coating should be sufficient to ensure the rate of lead migration from any mouthed parts will not exceed the relevant limit for a period of at least 2 years of normal or reasonably foreseeable conditions of use of the article.

5. By way of derogation, paragraph 1 shall not apply to[2]:

   (i) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC[3]

   (ii) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/87[4]), unless they have been treated with lead or its compound or mixtures containing these substances;

   (iii) enamels, defined as having vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500°C;

   (iv) keys and locks, including padlocks, and musical instruments[5];

   (v) articles comprising brass alloys if the concentration of lead in the brass alloy does not exceed 0.5% by weight of lead (expressed as metal);

   (vi) the tip of writing instruments;

   (vii) articles covered by European Union legislation specifically regulating lead content or migration.

6. By way of derogation paragraph 1 shall not apply to articles placed on the market for the first time before ….(12 months after entry into force)[5]

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[2] Subsection (i), (ii) and (iii) are taken from the entry 63 in REACH, Annex XVII, since RAC considers there are reasons to exempt them from articles covered by this proposal, even though it is recognised that articles containing these materials may pose a risk (see pg. 17 of the Justification).

[3] Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass OJ L 326 29.12.1969, p 36.

[4] Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff. OJ L 256, 7.9.1987, p 1–675.

[5] Keys and padlocks, some musical instruments and second hand articles are considered by RAC to pose a risk; however the DS chose to propose an exemption for these articles in their original proposal.

JUSTIFICATION FOR THE OPINION OF RAC

IDENTIFIED HAZARD AND RISK

The restriction proposal is targeted towards lead exposure from lead-containing articles intended for consumer use, which can be placed in the mouth by children and are not regulated by other EU legislation. RAC finds that this targeting is justified by the data on lead content in different consumer articles, and parts thereof, as presented in the Annex XV Restriction Report.

Lead is harmful both to human health and to the environment. The specific health effects of lead of importance for the proposal are related to the neurotoxic/neurodevelopmental properties of lead, especially impairment of the development of children's central nervous system. No threshold has been scientifically established for this effect; lead causes IQ deficits in children at blood-lead levels lower than 10 µg/L. The highest tolerable exposure level (BMDL (01)) has been determined by EFSA (2013)[6] to be 12 µg/L (corresponding to a daily intake of 0.5 µg/kg bw per day). Based on this value, RAC in the previous opinion on lead and lead compounds in jewellery[7], established a maximum exposure value of 0.05 µg/kg bw per day for lead. The current average blood lead levels in European children are 15–20 µg/L in Western Europe, while higher levels (30–50 µg/L) have been measured in Central and Eastern Europe[8]. Since these levels are higher than the highest tolerable exposure level, and since no threshold for the neuro-developmental effects has been established, all additional exposure must be avoided as far as possible.

Children are targeted in the present proposal as a sub-group of the population due to their particular sensitivity to the toxic effects of lead during brain development. The targeting is based on toxicity data and on the exposure assessment carried out for this proposal; it relates to the potential for exposure and not to whether the consumer articles were intended for children or not. The primary group at risk is children between 6 and 36 months of age; not only are they especially sensitive to the effects of lead but they also are the group most likely to be exposed to articles containing lead due to their mouthing behaviour. However, as EFSA could not exclude children up to the age of 7 being at risk from current food and environmental exposures, it also cannot be excluded that a risk to them from mouthing consumer articles also exists. Small children, who are actively exploring their environment, are at increased risk of exposure as they frequently place any kind of object in their mouth to suck and chew on. Studies have shown that children spend approximately 20 minutes on average per day sucking and chewing on objects (besides toys and objects that are intended for that purpose e.g. teething rings), of which approximately 22% of the mouthing events relate to potentially lead-containing articles covered by the present restriction proposal and which are not regulated by other EU legislation.

Lead is already restricted in several product groups, including paints (residential and others), electrical equipment, toys, food contact materials, packaging, and more recently in jewellery. Lead and lead compounds, such as carbonates and sulphates in paints, are however still used in the manufacturing of articles both inside and outside the EU and

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6 EFSA (2013) Scientific Opinion on Lead in Food. EFSA Journal 8(4). 1570 (replaces EFSA's opinion of 2010, which is no longer available).

7 Committee for Risk Assessment Opinion, Lead and lead compounds in jewellery, ECHA/RAC/ RES-O-0000001304-85-03/F.

8 See page 5: Blood levels.

contained in metal parts, pigments, painted surfaces and to some extent also as stabilisers in polymers. These are the uses that are targeted in the proposal.

Considering the weight of evidence as described above, RAC considers that the proposed restriction is justified.

Information on hazard(s), emissions and exposures

(i) Hazard

RAC agrees with the assessment by the Dossier Submitter (DS) that neurotoxicity, specifically neurobehavioral and neuro-developmental effects from repeated lead exposure, are the key effects that this restriction is aimed at protecting against. Small children will be particularly sensitive to this hazard, given that their central nervous system is still under development. In children, an elevated blood lead level is inversely associated with a reduced Intelligence Quotient (IQ) score and reduced cognitive functions up to at least seven years of age. There is some evidence that this subsequently leads to a reduced adult grey matter volume, especially of the prefrontal cortex (EFSA 2013). No threshold for the relevant neurotoxicity has been identified in humans according to JECFA (2010)[9] and EFSA (2013).

In line with EFSA, RAC has previously established a maximum exposure value for children of 0.05 µg/kg bw per day for exposure to lead. This exposure potentially increases the blood lead level by 1.2 ug/L and is equivalent to an IQ reduction of 0.1 point.

(ii) Exposure

Blood levels (background exposure)

Human exposure to lead has decreased significantly since the 1970's due to different policies such as the ban on lead in petrol[10], waste related restrictions and restrictions in e.g. toys and food packaging materials.

However, the decrease in blood lead concentrations seems to have recently levelled off. According to EFSA (2013), WHO (2009)[11], CDC (2012)[12] and Skerfving et al. (2011)[13], blood lead levels in European children have reached a steady state at 10-50 µg/L. These blood levels, as well as the background exposure to lead from food and environmental sources (between 1.3 and 6.4 µg/kg bw per day as reported by EFSA for children under the age group of 3 years), exceeds the established maximum exposure with respect to the neurodevelopmental effects of lead (1.2 µg/L, corresponding to 0.05 µg/kg bw per day). This indicates that any additional exposure should be avoided wherever possible. Also EFSA

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9 JECFA, FAO/WHO Expert Committee on Food Additives, 2010. Summary report of the seventy-third meeting of JECFA.

10 Directive 98/70/EC prohibited the marketing of leaded petrol, entering into force in 2000; many EU countries had banned leaded petrol from the mid 1980's onward.

11 WHO, 2009. Blood Lead Levels in Children-ENHIS Fact Sheet 4.5, World Health Organisation, Europe.

12 CDC, 2012. Lead in Drinking Water and Human Blood Lead Levels in the United States. Morbidity and Mortality Weekly Report Supplement. Vol. 61.

13 Skerfving, S. et al., 2011. Public health impact of long-term, low-level mixed element exposure in susceptible population strata (PHIME Report) - Integrated Project within the EU 6th Framework Programme for Research & Technological Development.

(2013) recommended that 'work should continue to reduce exposure to lead from both dietary and non-dietary sources'.

Lead content of articles

Published and unpublished test reports, as described in section B.9. of the Background Document (BD), as well as new testing conducted by the DS, show that lead can be present in different materials where it will give the article a certain function, such as a given colour or mechanical properties during the manufacturing process. The most common uses are as metallic lead e.g. for adding weight, as an additive (or impurities) in metal alloys, as pigments or as stabilisers in polymers. However there are also several article groups where the use of lead can be regarded as unintentional.

The concentration of lead in the identified categories (e.g. clothes, shoes, accessories, interior decorations, articles for sports and leisure, stationary and keys) of consumer articles is normally in the range between hundreds of ppm to 40,000 ppm (4%), with an average above 10,000 ppm (1%). Some articles like fishing sinkers and curtain weights contain more than 70% lead. More details are available in Section 9.3.1, Appendix 3 and Appendix 4 in the BD.

A summary of all test results, both from the literature and the DS' own testing, can be found in B.9.3.1 and Appendices 3 and 4 of the BD. The average number of articles containing lead that could potentially be mouthed by children was found to be 13% and the average lead content about 11,000 ppm (1.1%).

For the purpose of further risk assessment it is assumed that 10% of articles contain lead and articles containing lead have a content of 1% as proposed by the DS so as not to overestimate the lead exposure. This is supported by the RAC. Test results for articles with a content of less than 500 ppm (0.05%) were regarded by the DS as being essentially lead-free, as the lead content related to the maximum exposure level should not exceed 0.05% according to the DS' proposal; these articles are therefore regarded as lead free in the calculations for the market share and average lead content.

Lead migration limit based on the maximum lead exposure of 0.050 µg/kg body weight

Migration rate studies detailed in the Background Document and other relevant information received during the stakeholder consultation, confirm that there is a migration of lead ions from both metallic (i.e. brass alloys) and polymeric materials, although the number of reports is very limited and most reports did not cover situations that were comparable to exposure via mouthing (i.e. migration in saliva). During public consultation, the migration of lead from polymers was questioned by some stakeholders, but test results from 16 samples of lead containing polymer materials (see Background Document Appendix 4) indicate that migration does take place[14].

As with the lead in jewellery restriction, RAC recognised that a migration limit would be the most appropriate measure to cover the potential for exposure to the consumer articles covered in the present restriction proposal. However, very limited data is available on migration and on the relationship between the migration rate and the lead content of

[14] Six of them showed migration rates that exceeded the toys directive limit value of 90 mg Pb/kg (value is currently under revision).

materials. Nevertheless, considering an exposure scenario in which a child of 10kg body weight mouths an article (or part thereof) with a surface area of 10 cm^2 and a weight of 10g for 60 minutes, a migration rate of 0.05 µg pb per cm^2 per hour (or 0.05 µg pb/g per hour) can be estimated, which in principle is applicable for all the materials under consideration. This migration rate cannot be directly linked to a content limit, given the lack of data, but RAC considers a concentration limit of 0.05% to be protective for all materials concerned, in line with the DS proposal and the lead in jewellery restriction. In the latter, the concentration limit of 0.05% was considered protective for both metallic and non-metallic materials.

Mouthing times

In the Background Document, published mouthing times are reported from four studies (Juberg et al., 2001)[15]; DTI, (2002)[16]; RIVM/Groot, (1998)[17]; Greene, (2002)[18]/Babich et al., (2004)[19] for items/objects considered most representative for the articles intended to be restricted, i.e. items *not* including pacifiers, teethers, toys, fingers, etc. Based on these data, the DS has chosen the following mouthing times for realistic and reasonable worst case scenarios for these so-called "other objects":

Table 1: Summary of realistic and reasonable worst case mouthing time for mouthing "other objects" in young children (Table 25 of the background document).

Age (Months)	Realistic Mouthing time (min)	Reasonable Worst case Mouthing Time (min)
6–12	20	80
12–24	20	65
24–36	15	120

Previously, the same studies formed the basis for the mouthing times established by ECHA in their assessment on DINP and DIDP in toys and childcare articles, which was supported by RAC[20]. However, for the DINP and DIDP assessment the mouthing times relevant to

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15 Juberg, D.R., Alfano, K., Coughlin, R.J., Thompson, K.M., 2001, An Observational Study of Object Mouthing by Young Children, Pediatrics 107 (1) 135-142.

16 DTI (Department of Trade and Industry), 2002. Research into the mouthing behaviour of children up to 5 years old – Report to the Consumer and Competition Policy Directorate. http://www.berr.gov.uk/files/file21800.pdf

17 RIVM (National Institute of Public Health and Environmental Protection, Netherlands), 1998. Phthalate release from soft PVC baby toys, Report from the Dutch Consensus Group. Bilthoven, The Netherlands: RIVM Report 31 3320 002. http://www.rivm.nl/bibliotheek/rapporten/613320002

18 Greene, M.A. 2002, Mouthing times among young children from observational data. U.S. Consumer Product Safety Commission, Bethesda, MD.

19 Babich MA, Chen SB, Greene MA, Kiss CT, Porter WK, Smith TP, Wind ML, Zamula WW (2004). Risk assessment of oral exposure to diisononyl phthalate from children's products. *Regul Toxicol Pharmacol* **40**:151-67.

20 ECHA (2013). " Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006" available from http://echa.europa.eu/documents/10162/13579/201308_echa_review_dinp_didp_final_report_en.pdf

items/objects representing toys and childcare articles were assessed. These articles types are not relevant for this restriction, so a different mouthing time can be expected.

Considering some limitations and uncertainties in the available data from the relevant studies, RAC concluded that 20 min is a **realistic daily mouthing time** for articles that potentially contain lead for all three age categories.

However, RAC is of the opinion that the realistic worst case mouthing times for 'other articles' as proposed by the DS, especially the 120 min for 24-36 months old children, are likely to be overestimates because only data from one study were used and these data were rather skewed.

Based on an assessment of the relevant studies in the Background Document and some additional data found for two of the studies (RIVM 1998 and Greene 2002 – see background document), RAC concluded that a **realistic worst case mouthing time** of 1 hour would be more representative for all three age categories. This value is consistent with the mouthing time used in the lead in jewellery opinion.

Lead in alloys

During the public consultation, the European Copper Institute presented new migration rate studies based on work by the Chilenian Mining & Metallurgy Research Center. To support their request for a derogation for brass alloys containing lead, migration rates of 3 alloys with different lead content were determined in mucin. Based on their analysis (which assumed a 20 min mouthing time), a content limit of 1.7% was proposed by the consultee. Evaluation of these studies by RAC indicated that the methodology, including the use of standard discs of material, was plausible. The results are given in the following Table:

Table 2: Lead migration data of 3 samples of alloys of different lead contents normalized to 1 hour incubation (mouthing) time and 1 cm^2 surface area (2^{nd} column). The 3^{rd} column indicates the lead concentration, which leads to a migration of 0.05 µg/cm^2 per hour.

Sample	Pb content % (average)	Migration rates µg/cm^2 per hr	Pb content % leading to 0.05 µg/cm^2 per hr
M57	0.1-0.2 (0.15)	0.041	0.18
Z45	1.7-2.2 (1.95)	0.173	0.56
Z33	3.1-3.5 (3.3)	0.243	0.68

Since the average lead concentration in the 3 alloy samples, which releases 0.05 µg/cm^2 per hr (4^{th} column), was 0.47%, the RAC proposes a maximum Pb content in such material of 0.5%. The RAC considered it appropriate to use a 1 hour mouthing time (reasonable worst case mouthing time) for this evaluation, as with the calculation of the 'general' limit value of 0.05%, and did not agree with the industry's proposal to use a mouthing time of 20 min (realistic mouthing time), which would result in a concentration limit of about 1.5%.

(iii) Risk characterisation and conclusion

The RAC supports the risk assessment of EFSA (2013), in which a benchmark dose level (BMDL (01)) of 0.5 µg Pb/kg bw per day, was derived as a dose descriptor for the potential adverse effects of lead in children. This corresponded to a change in blood level of 12 µg Pb/L and an IQ loss of 1 point. RAC supports the EFSA assessment that a Margin of Exposure (MoE) of 10 or greater in relation to the BMDL (01) level should be considered sufficient to ensure no appreciable risk. This exposure of 0.05 µg/kg bw per day is equivalent to an IQ reduction of 0.1 point and is equivalent to a migration of 0.05 µg/cm2 per hr, and potentially increases the blood lead level by 1.2 ug/L.

EFSA (2013) observed that children in the age group of 1 - 3 years have mean background lead exposures of between 1.3 and 6.4 µg/kg bw per day (e.g. from the diet and background environmental exposure). Clearly, this already exceeds the BMDL(01) level of 0.5 µg Pb/kg bw per day, and therefore any additional lead exposure would on average be expected to further increase a child's typical exposure above the dose descriptor level.

RAC considers that chronic exposure to children as a result of children's mouthing behaviour is the most relevant to justify this restriction. To limit the additional exposure of children to lead from consumer articles targeted in the current restriction proposal as much as possible, RAC considers a lead concentration limit of 0.05% for these articles, irrespective of the material, to be sufficiently protective. When children would mouth these articles (or parts thereof) for 1 hr, the IQ impact would in that case be limited to a reduction of 0.1 point. The proposed restriction would also cover risks presented after a single exposure from swallowing lead containing articles. A similar approach was taken by RAC for the lead in jewellery restriction.

The migration data submitted for brass alloys justify a limit value of 0.5% in these materials.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

RAC considers a Community-wide restriction to be appropriate.

Placing on the market of lead in articles that can be mouthed by children (e.g. clothes (typically metallic and plastic parts), shoes, accessories, interior decorations, articles for sports and leisure, and stationery) occurs across the EU. As this concern is not limited geographically or nationally, and as the same articles will in many cases be available on the market in several Member States, Community-wide action is justified.

In addition, no threshold has been found for the harmful effect of lead on the central nervous system, and with a view to background exposure from diet and other environmental sources, any relevant lead exposure should in principle be avoided. Generally, there are no specific national risk management measures to avoid lead exposure to children mouthing relevant articles, and so adequate measures to minimise such exposures should be implemented on a community-wide basis.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

The possibility to use other legislative measures than a restriction in Annex XVII of REACH has been considered and discussed in the proposal; none of these has proven to be sufficient, effective and efficient enough to lower the lead exposure from articles.

Four restriction options have been discussed in detail in section E.2 of the BD:

1. Restriction of lead content in articles and part of articles that are sold to the general public and that can be mouthed by children.

2. Restriction of lead migration from articles and part of articles that are sold to the general public and that can be mouthed by children.

3. Restriction of lead content in (all accessible parts of) clothes, accessories and shoes.

4. Restriction of lead migration in all articles and part of articles that are sold to the general public.

The **overall assessment of** the restriction options is summarised in the table 3 below.

Table 3 (table 64 in the BD): Overview over the assessed restriction options.

	Option 1 (proposed) **Restriction on lead content in articles that can be mouthed.**	**Option 2** **Restriction on lead migration in articles that can be mouthed.**	**Option 3** **Restriction on lead content in clothes, accessories and shoes.**	**Option 4** **Restriction based on lead migration in all articles.**
Effectiveness	**++**	**++**	**+**	**++**
Risk reduction capacity	++	++	(+)	++(+)
Costs	++	++	++(+)	++
Proportionality	++	++	+	+
Practicality	**++**	**+**	**++**	**+**
Implementability and manageability	++	+	+++	(+)
Enforceability	++	+	++	+
Monitorability	**++**	**+**	**++**	**+**
OVERALL ASSESSMENT	**++**	**+(+)**	**+**	**+**

(+) Criterion barely met
+ Criterion partly met
++ Criterion met
+++ Criterion met with excellence

The restriction options assessed in the Background Document differ from each other as regards the scope and whether on the one hand lead content or on the other, the migration of lead is restricted. All restriction options apply to entire articles as well as to parts of articles, provided that these parts are protruding, detachable or by other means accessible to be placed in the mouth by children, following the definition of accessibility as laid down in the European standard EN 71-1.

Overall, the scope 'can be placed in the mouth by children' has been found sufficiently practical by RAC, while any wider scope would be impractical. The limited scope of option 3 'clothes, accessories and shoes' is clear, unambiguous and therefore the most practical alternative; however, as regards to effectiveness, it is clear that the limited scope does not yield the same level of risk reduction. To gain the maximum possible risk reduction, it is necessary to involve all articles that potentially contribute to the risk given that lead has no threshold with regard to neuro-developmental effects.

As in its opinion in lead in jewellery, RAC is of the opinion that the most appropriate option would be to set a limit for the migration of lead under the conditions found when children

might place lead-containing articles in their mouths (RMO 2). A targeted restriction option linked directly to lead migration from a given surface area or a given weight of an article would cover the potential for exposure. However, as also mentioned in the RAC opinion on lead in jewellery and described by the DS in the current proposal, RAC considers that practical as well as methodological problems with such a targeted restriction linked to lead migration currently exist, including the greater cost of monitoring enforcement and compliance than an alternative option based on the content of lead in the articles in question. The FORUM also shared this opinion.

RAC therefore concludes that the proposed restriction based on lead content is appropriate (see also effectiveness).

In line with the DS proposal and consistent with the opinion on lead in jewellery, RAC proposed that the concentration limit should be 0.05 % Pb for articles produced from all types of materials, except those made from brass where a content limit of 0.5% is proposed.

Effectiveness in reducing the identified risks

(i) Effectiveness

Risk Reduction capacity

To achieve the maximum possible reduction in the risks posed by lead, it is necessary to address a wide range of articles that contribute to that risk, such as bags, childcare articles, clothing, furniture handles, key rings, key chains, wallets and writing instruments, i.e. where the articles are not already covered by other EU legislation (e.g. toys, jewellery, electrical and electronic equipment, batteries and accumulators, plastic materials and food contact articles). Therefore, this proposal seeks to cover the remaining risks posed by lead containing articles that can be mouthed by children.

Several article types, such as the tip of writing instruments (see derogation section for more explanation), have been considered in terms of derogations. The restriction proposed by the DS exempted keys, locks and padlocks as well as musical instruments.

The DS calculated that the total exposure of children to lead from consumer articles in the baseline scenario is approximately *474* g Pb per year. The DS has further estimated that exposure from all articles other than keys is approximately *398* g Pb/year. This exposure will be reduced by the proposed restriction by 97.5% to approximately *10* g Pb per year. Adding back in the exposure of lead from keys, which will remain also after the restriction, the total remaining exposure is approximately *86* g Pb per year. This is 18% of the initial exposure, or conversely a risk reduction of 82%. In addition, the restriction would prevent any potential increase in the use of raw materials containing lead in articles.

RAC is of the opinion that the above figures are largely based on estimates and therefore associated with uncertainties; it should therefore primarily be seen as indicative. Nevertheless, even taking these uncertainties into account, the above figure is high enough to give some certainty that this restriction significantly reduces the risk. RAC therefore concludes that the proposed restriction is appropriate as regards risk reduction capacity, particularly taking into account that blood levels in children generally are higher than the established maximum exposure level in any case and any additional exposure must be avoided.

Proportionality

As previously stated, RAC considers the concept of 'not accessible by children during normal or reasonably foreseeable conditions of use' (which is clearly described in the ECHA guidance on Substances in Articles combined with use of EN 71-1 and the size considerations in the EC guideline for phthalates[21]) as appropriate to define the articles covered by this restriction, if combined with the relevant derogations.

The proposed restriction applies to entire articles as well as to accessible parts of articles, provided that these parts are protruding, detachable or by other means accessible to be placed in the mouth by children, following the definition of accessibility as laid down in the European standard EN 71-1. This means that internal parts of a complex article are not within the scope.

Inclusion of the derogation for other EU legislation regulating lead content would further target the proposal and ensure that there are no overlaps with existing legal requirements.

Content vs. migration:

RAC is of the opinion that the restriction would be more proportional if it contained a migration limit in addition to the content limit and has therefore proposed such an element.

The preferred proposal from the DS targets lead content, whereas the actual risk emanates from lead migration. The relationship between content and migration has been questioned, in particular whether it is linear or not, for example in the opinion of RAC and SEAC on lead in jewellery. In their original proposal for that restriction, the French CA (2010) suggested a migration limit, based on the premise that there is no correlation between the lead content of an article and the quantity of lead which can migrate from the same article. This premise was based on a survey made by the Danish EPA (2008). However, when RAC re-evaluated that survey, an association was found (although rather uncertain) between lead migration and lead content for the metallic parts of jewellery. RAC also concluded that in the absence of data that the same association could be used for non-metallic parts and therefore the same concentration limit could be used in order to ensure the same level of protection.

In the RAC opinion on lead in jewellery it was concluded that due to a lack of validated methods for measuring migration which mimics mouthing, RAC considered that a restriction based on content was more practicable for implementation and enforcement. The committees consequently found a content restriction more appropriate than a restriction based on migration, and this was also reflected in the final restriction adopted in Commission Regulation 836/2012.

Even though a validated method for measuring migration which mimics mouthing is still lacking, RAC considers that there have been developments within industry that would allow such a migration limit, in the way RAC has proposed it, to play a part in the conditions of the restriction. Specifically, the data used in determining the higher content limit from brass alloys illustrates these developments. The test used was based on ASTM 5517 'extractability of metals from art materials', amongst others, but used with artificial saliva and a

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[21] Guideline on the interpretation of the concept "which can be placed in the mouth" as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006 ((accessible on (http://echa.europa.eu/documents/10162/13645/guideline_interpretation_concept_mouth_en.pdf)

standardised shape and surface treatment of the material with a known lead content, and therefore allowed the determination of lead migration in way that is repeatable and comparable. According to industry this test results in highly repeatable data sets with small observed coefficient of variation (CV) (< 20%) and shows consistent time-dependent release data. The data collected by industry, allowing a lower migration rate from certain articles to be established to the satisfaction of RAC, could be used as an example of how compliance with the proposed migration limit could be demonstrated.

Despite such developments, there would be substantial benefits in agreeing a standardised test method, for example by CEN, where the issues mentioned above could be independently validated.

Derogations

(a) Derogations proposed by the Dossier Submitter

Derogations were initially proposed for keys, locks, padlocks, musical instruments and second hand articles mainly based on socio-economic grounds including the lack of suitable alternatives and because of enforcement issues. RAC agrees with the DS assessment that in the case of keys, padlocks, some musical instruments and second-hand articles that these can potentially be mouthed by children and thus pose a potential risk.

The derogation for musical instruments is no longer considered necessary by the DS as they are considered unlikely to be accessible to children and would thus not be regarded to fall within the scope of the proposed restriction. RAC can agree to this analysis for instruments in general; however certain special smaller instruments like harmonicas and smaller flutes could be foreseen to be mouthed but the DS chose to exempt instruments as a whole, in the original proposal. Toy instruments would be covered under the relevant toys legislation.

The Dossier Submitter also proposed to derogate articles already regulated under existing Community legislation. This legislation would include the following legislation regulating articles because of their lead content:

(a) the restriction in entry 63 of Annex XVII of REACH[22];

(b) Directive 2009/48/EC on the safety of toys[23];

(c) Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (the RoHS Directive[24]);

Electrical and electronic articles, such as bulbs, light sources etc., and relevant child care article.

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22 OJ L 252, 19.9.2012, p 4.

23 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.6.2009, p.1.

24 Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 37, 13.2.2003, p. 19.

(d) Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC[25];

(e) Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food[26]; Kitchen utensils, including child care articles, intended for food contact, including crystal glass for beverages Food wrapping or containers

(g). (f) Directive 94/62/EC on packaging and packaging waste;[27]Restriction on lead in jewellery articles.

(b) Issues raised through the Public Consultation process

Industry has indicated a number of cases where risk or socio-economic considerations need to be assessed (e.g. for brass alloys, certain parts of writing instruments, curtain weights etc.).

As previously stated (see lead in alloys section), in relation to the lead migration from brass alloys, industry submitted 2 studies on the migration of lead from alloys that contain different concentrations of these metals. This has been assessed as justifying a different content limit from other lead containing substrates.

In addition, other comments on the scope of the restriction were raised during the public consultation due to their "non-accessibility" by children under normal and foreseeable conditions of use[28] (e.g. diving weights, fishing sinkers etc.).

When assessing the issues identified from either the original proposal or those received during the public consultation, RAC considered the possibility of mouthing taking place, focussing in particular on the size of the article/article groups and their accessibility (can children come in contact with the articles or would a child be prevented from mouthing due to coverings or other preventive measures). RAC has also looked at the possibility for children to come into contact with the articles during normal or reasonably foreseeable conditions of use, since the articles as such are not intended for use by children (e.g. they are not toys). The outcome of these considerations are given below.

Some of the article groups have a generic character:

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25 Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC, OJ L 266, 26.9.2006, p. 1.

26 OJ L 12, 15.1.2011, p.1.

27 OJ L 365, 31.12.94, p10

28 According to the Guidance on Substances in Articles, normal conditions of use means the conditions associated with the main function of an article. Reasonably foreseeable conditions of use mean conditions of use that can be anticipated as likely to occur because of the function and appearance of the article (even though they are not normal conditions of use). For example when a small child does not know the function of an article but uses it for any purpose he associates with it such as biting or licking it.

Articles made of recycled materials:

Such articles have the same risk profile as new articles and are therefore not considered as being different than new articles. Therefore they pose the same risk as articles made of new (not recycled) materials if these articles are within the scope of the restriction.

Outdoor articles:

In considering the probabilities, the technicalities and the reasonable worst case scenario for what a child will be likely to mouth both indoors and outdoors, it is considered that there is a higher probability of exposure via mouthing to children from consumer articles primarily intended for indoor use. However, children may have an opportunity to mouth some articles that are primarily intended for outdoor use, e.g. garden hoses which may be lying on the ground after use. With other outdoor articles, for safety and hygiene reasons, they do not appear to have the same risk of being mouthed, e.g. certain garden tools.

It is not possible therefore to conclude, based on the information in the dossier, that there is a risk in general for outdoor articles, primarily intended for outdoor use. However, notwithstanding this RAC notes that any additional exposure to lead should be avoided.

Coated articles:

In this case it needs to be specified what the 'coating' is comprised of, as the potential risk depends on the effectiveness of the coating in preventing migration of lead. In this respect RAC refers to the proposed migration limit of 0.05 µg/cm^2 per hr (0.05 µg/g per hr) as a suitable way of dealing with this issue. If the migration of lead from the coated article is below the migration limit value, it would then fall outside of the scope of the restriction. Any coating would have to be substantial enough to last for a reasonable length of time to be effective in preventing migration of lead if it were to be mouthed. It is therefore proposed to add a similar condition to that used in the restriction on nickel (entry 27(1)(c)).

Crystal glass, non-synthetic or reconstructed precious and semi-precious stones and enamels:

In the case of the exemptions given in the lead in jewellery restriction for these articles, RAC notes that these exemptions were given as there is expected to be very low migration from these materials. This view is supported by data supplied in the Public Consultation where, for instance, an average migration value of lead from crystal of 0.007 µg/h/cm^2 was quoted, which is 100 times lower than the value indicated for metallic material in the BD. Although this could also be seen as being covered by the migration limit, as for coated articles, the difficulties in determining if the articles should be covered under the lead in jewellery restriction or the proposed restriction for lead in consumer articles leads RAC to believe that a specific exemption would be justified.

Articles out of scope of the proposed restriction

The following articles are considered out of scope of the proposed restriction, following examination by RAC, in line with the previous argumentation (e.g. possibility to be mouthed by children), and considering the restriction is intended to protect mainly 6 – 36 month old children:

- **Diving weights**. Even though diving weights are accessible and possibly mouthable (smaller weights could have one side less than 5 cm in length), RAC considers normal or reasonably foreseeable conditions of use do not exist due to the danger

the child would be exposed to in handling such very heavy articles, and therefore they would be suitably stored to prevent small children coming into contact with these articles. Another type of diving weight consists of pouches filled with small pellets made of lead and in many cases closed by velcro tape. These pouches could be foreseen to be played with by smaller children, but RAC considers normal or reasonably foreseeable conditions of use do not exist due to the danger the child not just of the weight but also of swallowing such small pellets, and therefore the pouches would be suitably stored. In addition it is assumed that the coating (the pouch) would prevent direct contact with the lead pellets.

- **Ammunition**. It is assumed that ammunition is kept out of reach for children due to Member States implementation of existing EU legislation related to the safe-keeping of such articles. Normal and reasonably foreseeable conditions of use would not occur as the other hazards of ammunition would necessitate such articles being securely stored away from children. If ammunition cartridges are sold as jewellery they are covered by the relevant entry in Annex XVII of REACH.

- **Fishing sinkers and weights**. Like diving weights it is assumed there would be no normal and reasonably foreseeable conditions of use that would mean fishing gear is accessible to children. It is assumed that they are put out of reach for children for safety reasons, such as the proximity of fishing hooks to these articles and a possible choking hazard.

- **Fixed furnishing**. The mouthability of fixed furnishing, e.g. cupboards, by children is not possible as it is assumed that the part of fixed furniture is of a size that makes them too big for mouthing.

- **Screws and nails**. These articles are usually embedded in the articles they are used to secure. Individual loose nails and screws are considered to be kept out of children's reach due to their size (can easily be swallowed) and for other safety reasons, e.g. sharpness.

- **Internal hinge mechanisms**. These are considered out of scope since they are not accessible according to the EN 71.

Articles in scope of the restriction

A list of articles that were raised during the public consultation and that are considered as being within the scope is given below:

- **Outdoor and indoor shoes**. The soles of shoes are accessible and mouthable by a child.

- **Curtain weights**. Free hanging curtain weights are considered to be accessible, mouthable and within the range of a child so foreseeable misuse may occur. If the curtain weights are covered with a coating (see above) that prevents lead migration, then this fulfils the condition that if migration can be demonstrated to be below the limit then the curtain weights are exempted from the restriction. In addition, if curtain weights are enclosed in the curtain it should be considered on a case-by-case basis if normal or foreseeable use occurs.

- **Garden hoses**. These articles are considered to be mouthable and accessible. The question about foreseeable use is also answered positively, since in some cases there

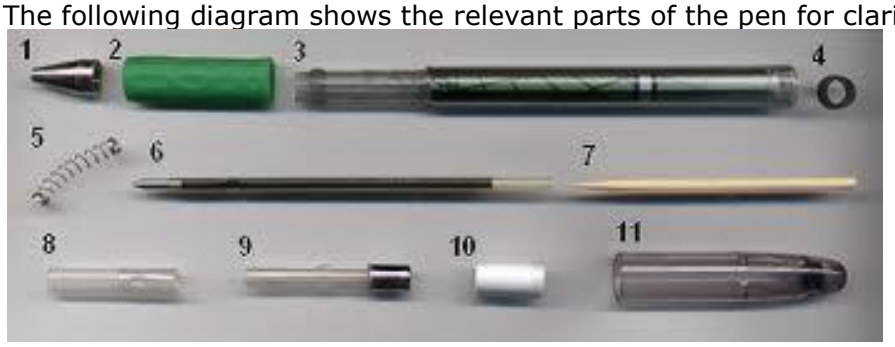
will be a garden hose lying on the ground (e.g. for filling bathing basins) and it therefore could be mouthed.

- **Writing instruments**.

  The tip of a ball point pen

  RAC considers the very tip of a ball point pen (the part where the ink comes out) to be so small, that there is a very low potential for exposure and therefore this could be exempted.

  The following diagram shows the relevant parts of the pen for clarification:



  Remainder of the pen

  Except for the tip, the surface area for the rest of the writing instrument (such as the nose and clip) is much larger and these parts of the article are therefore considered to be within scope.

- **Spectacle frames**. As with curtain weights, accessibility to the part of the frames where migrating can occur is dependent on whether there is a suitable coating or not. If there is no such protection the spectacle frames will be within the scope since it is mouthable, normal or foreseeable use can be foreseen.

- **Keys and padlocks**. Even though RAC considers these articles to be mouthable and thus pose a risk,the DS proposed them to be exempted.

Practicality, incl. enforceability

Practicality (including enforceability) and monitorability

For metallic parts, the analysis of lead content can usually be made in a non-destructive way using X-ray fluorescence (XRF) devices; only occasionally would a destructive standard wet chemical analysis need to be performed. Many items can be tested in a short time; only the articles containing lead above the limit value would require migration testing. RAC has noted the FORUM's advice on methods of analysis and sampling and a summary of this will be included in the BD.

As some materials might show low migration levels RAC considers that the restriction proposal may allow industry to market articles exceeding the concentration limit of 0.05% lead provided that the actual migration does not exceed the proposed migration limit.

However, RAC recognises that further work has to be done to specify how the testing for content as well as for migration should be performed and emphasises that reliable methods to determine migration rates from articles especially at lead concentrations below 1% need to be established, as previously suggested.

Monitorability

See above.

BASIS FOR THE OPINION

The Background Document, providing supporting infirmation, gives the detailed grounds for the opinions.

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by Sweden include the explicit exemption of crystal glass, precious stones and enamels, the tip of writing instruments and a higher limit for brass alloys. In addition, articles covered by European Union legislation specifically regulating lead content have been proposed to be exempted.

The basis for these changes is the information received during the public consultation, leading to consideration of further exemptions, and the advice of the Forum for Exchange of Information on Enforcement.