Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

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

ECHA/SEAC/RES-O-0000003487-67-05/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 10 December 2013) and SEAC's opinion (adopted 13 March 2014)

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

10 December 2013

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

13 March 2014

ECHA/SEAC/RES-O-0000003487-67-05/F

Opinion of the Committee for Risk Assessment

And

Opinion of the Committee for Socio-economic Analysis

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 and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 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 opinions adopted by RAC and SEAC. 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 a simple majority*** of all members having the right to vote.

The minority position, including its grounds, is made available in a separate document which has been published at the same time as the opinion.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: ***Georgious BOUSTRAS***

Co-rapporteur, appointed by SEAC: ***Johanna KIISKI***

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***11 December 2013.***

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

The draft opinion was published at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***17 December 2013***. Interested parties were invited to submit comments on the draft opinion by ***14 February 2014***.

The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **13 March 2014**.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by a simple majority*** of all members having the right to vote***.***

The minority position, including its grounds, is made available in a separate document which has been published at the same time as the opinion.

OPINION

THE OPINION OF RAC

RAC 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.

RAC considered that the proposed restriction on **lead and its compounds** in articles intended for consumer use was the most appropriate Union wide measure to address the identified risks in terms of the effectiveness in reducing such risks, provided that the conditions are modified.

RAC proposed 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).

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), unless they have been

---

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.

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 p. 18 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.

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[4];

(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]

THE OPINION OF SEAC

SEAC formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considered that the proposed restriction on ***lead and its compounds*** was the most appropriate Union wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope and/or conditions are modified.

SEAC proposed that the conditions of the restriction should include the following elements:

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

Paragraphs 1-6 as described in the opinion of RAC

7. Paragraph 1 shall apply from {date corresponding to 12 months after the Commission Regulation amending Annex XVII to REACH regulation enters into force}

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

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD AND RISK

Justification for the opinion of RAC

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 found that this 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[5] (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 neurodevelopmental 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 opinion; 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 contained in metal parts, pigments, painted surfaces and to some extent also as stabilisers

---

5 Bench Mark Dose Level

6 European Food Safety Agency (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 7: Blood levels.

in polymers. These are the uses that are targeted in the proposal.

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

Information on hazard(s), emissions and exposures

(i) Hazard

RAC agreed with the assessment by the Dossier Submitter that neurotoxicity, specifically neurobehavioral and neurodevelopmental 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 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 µg/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 (2013) recommended that 'work should continue to reduce exposure to lead from both dietary and non-dietary sources'.

---

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.

Lead content of articles

Published and unpublished test reports, as described in section B.9. of the Background Document, as well as new testing conducted by the Dossier Submitter, 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.

A summary of all test results, both from the literature and the Dossier Submitter's own testing, can be found in B.9.3.1 and Appendices 3 and 4 of the Background Document. The average number of articles containing lead that could potentially be mouthed by children was calculated by the Dossier Submitter 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 Dossier Submitter so as not to overestimate the lead exposure. This is supported by RAC. Test results for articles with a content of less than 500 ppm (0.05%) were regarded by the Dossier Submitter as being essentially lead-free, as the lead content related to the maximum exposure level should not exceed 0.05%; 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 0.05 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[15], RAC recognised that a migration limit would be the most appropriate measure to cover the potential for exposure to the consumer articles included 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 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)

---

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

[15] Background Document to the opinions on the Annex XV dossier proposing restrictions on Lead and its compounds in jewellery (2011) (http://echa.europa.eu/documents/10162/c9388bba-2660-4c0e-946b-c3bbe5539940)

can be estimated. This is in principle 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 Dossier Submitter's 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)[16]; DTI, (2002)[17]; RIVM/Groot, (1998)[18]; Greene, (2002)[19]/Babich et al., (2004)[20] 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 Dossier Submitter 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.

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

Source: Table B 17 of the Background Document

Previously, the same studies formed the basis for the mouthing times established by ECHA in their assessment on diisononylphthalate (DINP) and diisodecylphthalate (DIDP) in toys and childcare articles, which was supported by RAC[21]. However, for the DINP and DIDP assessment the mouthing times relevant to 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

16 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.

17 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).

18 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

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

20 Babich MA, Chen SB, Greene MA, Kiss CT, Porter WK, Smith TP, Wind ML, Zamula WW,20040. Risk assessment of oral exposure to diisononyl phthalate from children's products. *Regul Toxicol Pharmacol* 40:151-67.

21 ECHA, 2013. " Evaluation of new scientific evidence concerning DINP (Diisononyl' phthalate) and DIDP (Diisodecyl' phthalate) 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)

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 Dossier Submitter, 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). 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 three 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 Table 2.

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 $\mu g/cm^2$ per hour.

Sample	Pb content % (average)	Migration rates $\mu g/cm^2$ per hr	Pb content % leading to 0.05 $\mu g/cm^2$ 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%
Average	1.6-2.0 (1.8)	0.152	0.47%

Source, table E 11 of the Background Document

Since the average lead concentration in the 3 alloy samples, which releases 0.05 $\mu g/cm^2$ per hr (4^{th} column), was 0.47%, the RAC proposed 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

RAC supported 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/cm^2 per hr, and potentially increases the level of lead in blood by 1.2 μg/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 considered that chronic exposure of children as a result of their mouthing behaviour is most relevant to justify this restriction. To limit additional exposure of children to lead from consumer articles as targeted in the current restriction proposal as much as possible, RAC agreed a lead concentration limit of 0.05% for these articles to be sufficiently protective, irrespective of the material,. Should children 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 aforementioned lead in jewellery restriction.

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

JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION WIDE BASIS

Justification for the opinion of RAC

RAC considered a Union 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, Union 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 Union wide basis.

Justification for the opinion of SEAC

SEAC considered that action on a Union-wide basis is justified. The need to act on a Union wide basis originates from the need to avoid different legislations in the Member States with the risk of creating unequal market conditions:

1. The proposed restriction would avoid the potentially distorting effects that possible national restrictions to control risks from lead in consumer articles may have on the free circulation of goods;

2. Regulating lead in consumer articles that can be placed in the mouth by children through Union wide action ensures that producers of such articles in different

Member States are treated in an equitable manner;

3. Acting at Union wide level would ensure a 'level playing field' among all producers and importers of the concerned articles.

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

Justification for the opinion of RAC and SEAC

Four restriction options were discussed in detail in section E.2 of the Background Document:

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 given below in table 3.

Table 3: 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	**++**	**+(+)**	**+**	**+**

Source: Table E21 of the Background Document

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

Justification for the opinion of RAC

The possibility to use other legislative measures than a restriction in Annex XVII of the REACH Regulation 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 such articles.

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' was found to be sufficiently practical by RAC, while any wider scope would be more complicated and 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 neurodevelopmental effects.

As in its opinion in lead in jewellery, RAC noted 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 (Option 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 Dossier Submitter in the current proposal, RAC considered 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 for Exchange of Information on Enforcement (Forum) also shared this opinion.

RAC therefore concludes that the proposed restriction based on lead content is appropriate.

In line with the Dossier Submitter's 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.

Justification for the opinion of SEAC

A restriction under REACH is the only viable regulatory option that can be applied to articles imported from third countries. The other EU level risk management options under REACH and CLP – classification and labelling, or identification as SVHC and the subsequent authorisation procedure – are either not applicable to articles or can only be applied to articles produced in the EU. Other EU wide measures are not considered appropriate for a long-term management of a chronic exposure from consumers' articles.

Four restriction options have been assessed by the Dossier Submitter with respect to their effectiveness, proportionality, practicality and monitorability (Table 3). Overall, the Option of restricting lead content in articles and parts of articles that are sold to the general public and that can be mouthed by children was concluded as the most appropriate solution in terms of proportionality. However, exemptions for certain product groups were proposed by SEAC to further limit the costs.

SEAC noted that an assessment of a restriction on the lead content of children's products only - which has been the scope of some previous efforts in other countries (e.g. the USA) to manage the risks posed by the presence of lead in articles - had not been presented in the proposal by the Dossier Submitter. SEAC had thus not been afforded the opportunity to assess the socioeconomic impacts of this as a possible alternative practical option and hence SEAC's conclusions were bounded by the assessment scope considered in the dossier. It is also noted that such an option is likely to allow a number of articles that potentially contain lead to remain available to children to mouth and thus adversely affect the risk reduction capacity of the proposal (as assessed by RAC).

SEAC agreed that the proposed restriction (modified as indicated) is the preferable restriction option amongst those considered by the dossier submitter.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

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 Dossier Submitter did not exclude keys, locks and padlocks as well as musical instruments.

The Dossier Submitter calculated that the total exposure of children to lead from consumer articles in the baseline scenario is approximately *474* g Pb per year. The Dossier Submitter 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 to that 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 was of the opinion that the above figures, being largely based on estimates are therefore associated with some uncertainties and should be seen as indicative. Nevertheless, even taking these uncertainties into account, the above figure is high enough to conclude 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 that any additional exposure must be avoided.

Justification for the opinion of SEAC

Baseline

Lead is primarily present in metal alloys, and in pigments/dyes and stabilisers for plastics, and because of these uses, lead has been found in various common articles such as clothes,

fashion accessories and shoes, furniture and interior decoration objects, keys and key rings, stationery, and others.

SEAC noted that some lead compounds are included in REACH Annex XIV and more lead compounds might be included in the future. Uses of these substances so included will be subject to an authorisation requirement leading to the progressive replacement of those lead compounds in EU produced articles. As a result articles would be either manufactured using alternative lead or lead-free compounds. Therefore, some substitution by lead-free compounds could be expected outside of the current restriction, and as a consequence, the number of articles containing lead may be lower. Imported articles containing lead will not be affected by authorisation requirements and remain on the European market. Moreover, it may take a long time until the authorisation procedure is effective in reducing the risk caused by lead in EU manufactured consumer articles.

Substitution due to authorisation has not been accounted for in this restriction but SEAC noted that if it was taken into account, the cost of implementing the restriction could be lower. However, if the effect of substitution was taken into account also the benefits would also be lower from the reduced exposure of children to lead from articles.

Scope of the proposed restriction

Concepts of placing in the mouth, accessibility and normal or foreseeable use

The scope of this restriction is defined as articles intended for consumer use containing lead (not regulated by other EU legislation) that can be placed by children in their mouth. Articles covered by EU specific legislation, under which lead is already restricted, and articles typically not accessible to children during normal or reasonably foreseeable conditions of use, are excluded from the scope of this restriction. SEAC noted that there are different views regarding the clarity of the scope of this restriction. Any lack of clarity will potentially give rise to problems with its practical implementation.

According to advice from the Forum, the concept of "accessible by children during normal or reasonably foreseeable conditions of use" provided in the ECHA Guidance on Substances in Articles combined with the use of EN 71-1 and the EC guideline of phthalates[22] is considered sufficient to define the range of items that can be included within scope of the proposed restriction.

Use of the European Standard EN 71-1 (section 8.10) is proposed to define the term accessibility. This European Standard could facilitate the judgement of whether articles fall in or out of the scope of the proposed restriction. However, it is noted that the EN 71-1 does not specify the exact target group of children in their definition of accessibility, where the restriction has a very clear target group of children (<36 months). Nevertheless, the general principles of this standard are considered to be appropriate by SEAC for the context of this restriction proposal and its scope. Further guidance on how to use EN-71 and the Guidance on substances in articles in terms of this restriction would be helpful.

SEAC would like to point out that the list provided in Annex I is indicative. It is SEAC's interpretation of the application of EN 71-1 to the articles analysed by the Dossier Submitter for the purposes of defining the analytical scope of the cost assessment. It is not in any way a definite list of articles relevant for the legal scope of this restriction. Any decision on whether an individual article falls within the scope of this restriction should be based on the

[22] 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 contains the criteria of size dimension of (parts of) articles that need to be met for children to be able to place the article in their mouth.

criteria given in the section on scope of this restriction proposal and should not be based on the indicative list given in Annex I. It should be noted that there are potentially some differences between the legal scope as defined in the restriction proposal and the restriction scope assessed in the socioeconomic analysis of the Dossier Submitter. The analytical conclusions here below are therefore bounded accordingly.

Section B2 of the Background Document presents indicative lists of articles that can be considered within and outside the scope of the proposed restriction.

Derogations

Justification for the opinion of RAC

RAC conclusions on the risk aspects of the proposed derogations

(a) Derogations proposed by the Dossier Submitter

Keys, locks, padlocks, musical instruments and second hand articles were not included mainly based on socioeconomic grounds including the lack of suitable alternatives and because of enforcement issues. RAC agrees with the Dossier submitter's 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 Dossier Submitter 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 Dossier Submitter 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 Union legislation. This legislation would include the following legislation regulating articles because of their lead content:

(i) The restriction in entry 63 of Annex XVII of REACH[23];

(ii) Directive 2009/48/EC on the safety of toys[24];

(iii) Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (the RoHS Directive[25]);

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

(iv) Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC[26];

[23] OJ L 252, 19.9.2012, p 4.
[24] OJ L 170, 30.6.2009, p.1.
[25] OJ L 37, 13.2.2003, p. 19.
[26] OJ L 266, 26.9.2006, p. 1.

(v) Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food[27]; Kitchen utensils, including child care articles, intended for food contact, including crystal glass for beverages Food wrapping or containers

(vi) Directive 94/62/EC on packaging and packaging waste;[28]

(vii) Restriction on lead in jewellery articles.

(b) Issues raised through the public consultation

Industry has indicated a number of cases where risk or socioeconomic 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 two 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[29] (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:

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 mouth some articles that are primarily intended for outdoor use, e.g. garden hoses which may be lying on the ground. Other

---

27 OJ L 12, 15.1.2011, p.1.

28 OJ L 365, 31.12.94, p10

29 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.

outdoor articles, (e.g. certain garden tools for safety and hygiene reasons), do not appear to have the same risk of being mouthed.

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 referred 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 noted 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 Background Document. 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 the scope of the proposed restriction

The following articles are considered out of the 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 considered 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 considered normal or reasonably foreseeable conditions of use do not exist due to the danger to 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 was 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 was 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 were 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 were considered out of scope since they are not accessible according to the EN71-1.

Articles in the scope of the restriction

A list of articles that were raised during the public consultation and that were 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 were 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 were 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 considered 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 diagram in Annex 4 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 the 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 considered these articles to be mouthable and thus pose a risk, the Dossier Submitter did not include these to their proposal.

Justification for the opinion of SEAC

SEAC conclusions on the socioeconomic aspects of the proposed derogations

SEAC noted that the scope of this restriction is framed by the concepts of *placed in the mouth by children*, where there is the necessity to have one dimension of less than 5 cm, and *accessibility to children during normal or reasonably foreseeable conditions of use*. Inaccessible parts of articles can also not be taken into the month. Articles or parts of articles should be considered inaccessible if, during normal or reasonably foreseeable conditions of use by children, they cannot be reached e.g. internal cabling etc.

SEAC noted that the derogations of the restriction have been defined based on an assessment of all the relevant article types within the original Annex XV proposal and on the information received in the 1st public consultation on the Annex XV report and the 2nd on the SEAC draft opinion.

(a) Derogations proposed by the Dossier Submitter

The Dossier Submitter did not include keys, locks, musical instruments and second hand articles in the scope mainly based on socioeconomic grounds including lack of suitable alternatives and for enforcement issues.

Considering keys, locks and padlocks RAC has indicated a potential risk from keys and padlocks. However, SEAC has not been provided with sufficient information on the availability of alternatives and possible socioeconomic impacts to evaluate the issue. The public consultation on the SEAC draft opinion did not yield more specific socioeconomic information but did confirm an overall support of the responding parties for not including these items. The responses also highlighted that lead free keys - made from harder materials - deteriorate faster, and result in a shorter life time of the lock.

The Dossier Submitter had proposed that the derogation for musical instruments was no longer considered necessary as they are unlikely to be accessible to children and would thus not be regarded to fall within the scope of the proposed restriction. Comments in the public consultation questioned this within the context of the definition of accessibility. Although SEAC considered that there may indeed be grounds for agreeing with the public consultation comments, the Dossier Submitter chose to exempt musical instruments as a whole, in the original proposal, and in addition there was insufficient information on alternatives and possible socioeconomic impacts to include musical instruments within the scope of the restriction.

The Dossier Submitter proposed a general exemption for second hand market articles. Although RAC has indicated there is no difference in risk from second hand articles, SEAC agreed with the Dossier Submitter's proposal to exempt such articles, as the restriction would likely have significant consequences for the second hand market and pose insurmountable challenges in terms of enforcement (although no formal assessment of this was undertaken in the dossier, the Forum has raised this as an enforceability issue). SEAC considered an exemption for used articles placed on the market before the date 12 months after entry into force of the restriction as being appropriate taking into account the considerations above.

(b) Issues raised through the public consultation process

Following the outcome of the public consultation on both the Annex XV report and the SEAC draft opinion, industry indicated a number of proposals for derogations, based on risk or socioeconomic considerations:

(i) Crystal glass, enamels, and precious and semiprecious stones.

RAC has proposed a specific exemption for these article types due to the low migration from them. In addition, during the public consultation it has been suggested that a similar approach to crystal glass, precious and semi-precious stones, and enamels should be followed as in the lead in jewellery restriction based on a similar justification. SEAC has not been presented with any evidence to support a divergence from its previous assessment in the lead in jewellery restriction and furthermore notes that granting of the requested exemptions and thereby aligning the proposed restriction with E-63 provisions would avoid problems of enforceability for the relevant "borderline" items (which are anyway very limited in number).

(ii) Other possible derogations

RAC has considered the risks associated with a number of additional proposed cases for derogation and was of the opinion that the following should not be included in the scope of the restriction: diving weights, ammunition, fishing sinkers and weights, fixed furnishing, screws and internal hinge mechanisms. This assessment is based on the possibility for mouthing taking place, focussing on the size of the article/article groups and the accessibility (can children get in contact with the articles or are they not possible for a child to mouth due to coatings or other preventive measures). In addition, based on risk considerations RAC has agreed a conditional derogation for brass based on a higher lead content. RAC has also proposed that with regard to writing instruments the tip (containing the ball of a ball point pen) should be exempted due to the very small size and thus low potential for exposure). Given RAC's conclusions on the risks associated with these cases, SEAC had no reason to question the derogations.

In addition, other comments on the scope of the restriction have been made regarding specific article types already restricted under other EU measures due to their lead content (e.g. digital watches, lead batteries). SEAC agreed that these cases should also be derogated.

With regard to the nose piece of writing instruments, RAC had not indicated that these are out of scope of the restriction. Some comments in the public consultation on the SEAC draft opinion supported the exemption for the nose piece of writing instruments, particularly regarding 'luxury' pens, and provided some qualitative justification for this position. However, SEAC could not agree to support a derogation based on the information provided.

Additional exemptions were requested in the public consultation on the SEAC draft opinion for frames and sunglasses, however, RAC had already indicated there was a risk from these articles and SEAC could not agree that a derogation was warranted based on the limited information submitted.

(iii) Recycled materials

Articles produced from recycled materials are included in the scope of the proposed restriction. SEAC noted that a separate analysis of impacts expected to the recycling sector has not been carried out by the Dossier Submitter. Although some information on the PVC related issues has been submitted during the public consultation, this has been insufficient in order to generate any meaningful general conclusions. Nevertheless the information from the public consultation indicated that in the case of recycled PVC containing lead, this is

mainly recycled into construction material which is outside the scope of the restriction. Therefore, significant costs to the parties involved in recycling PVC affected by the proposed restriction are not expected.

Proportionality to the risks

Justification for the opinion of RAC

As previously stated, RAC considered 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[30]) 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 was 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 Dossier Submitter targets lead content, whereas the actual risk originates 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 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 considered that there have been developments within industry that would

[30] 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)

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 standardised shape and surface treatment of the material with a known lead content. This therefore allowed the determination of lead migration in a 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.

Justification for the opinion of SEAC

In the assessment of costs the Dossier Submitter had only been able to take into account some of the costs resulting from the substitution of lead and testing costs. The avoided losses in IQ of the children spared from exposure to lead had also not been established adequately in relation to the benefits. Therefore a break-even analysis was undertaken based on the available parameters used to develop the cost assessment.

Costs

For companies that manufacture or put on the market articles that do not yet meet the lead content limit proposed in this restriction, the costs to comply with this proposal consist of substitution costs, cost associated with product redesign/materials reformulation and refinement, as well as costs associated with increased testing and administrative burdens.

Substitution costs

SEAC has scrutinised the assessment of costs by the Dossier Submitter. The Dossier Submitter proposed two different methods for the calculation of substitution costs in the Background Document, one method that is based on the total value of the article and one method that is based on the substitution of lead in those parts of articles that contain lead. The latter approach is based on a methodologically sound cost assessment technique. Therefore, SEAC has based its opinion on this method. With this method the substitution costs have been estimated at €11.8 million (€5.2-€18.4) million per year. It should be noted that there are significant uncertainties in some of the assumptions used, as well as incomplete accounting for all costs associated with the restriction. As such there is considerable uncertainty about both the magnitude and direction of error in the estimate of costs.

The estimation of substitution costs in the method based on substitution of lead in those parts of the article that contain lead is based on the following factors:

- Selection of article categories/ types included in scope
- Number of relevant articles per category
- Number of parts containing lead per category (Assumption 1)
- Weights of parts containing lead per category (Assumption 2)
- The share of total articles that are assumed to contain lead (Assumption 3)
- The percentage content of lead in articles (Assumption 4)
- Additional cost per tonne of lead in relevant applications

SEAC has analysed the reliability and suitability of these key parameters:

Selection of article categories/types included in scope

The Dossier Submitter has made a selection of articles based on the scope of the proposal as it was proposed in the Annex XV report. On the basis of that scope the Dossier Submitter has made an evaluation of the articles in the PRODCOM (PRODuction COMmunautaire) database and included those articles in the cost calculation.

During the development of the opinion the wording of scope was modified a) to better define what mouthing is and b) to react to requests for exemptions that were put forward in the public consultation. For the definition of mouthing the EN-71-1 guidelines were used along with the relevant guidance related to entry 52 of Annex XVII of REACH as a basis and the derogations and exemptions that were asked for are listed under scope as presented in the previous section. Annex 1 to this opinion indicates to what extent this has impacted the selection of articles as proposed by the Dossier Submitter e.g. it lists the articles selected by the Dossier Submitter that are considered to be in scope with SEAC's view in accordance with the definition of mouthing further developed in the opinion.

The cost estimation in this opinion was based on this set of articles. The total number of articles included in the analysis is around 20 billion.

Number of relevant articles per category (PRODCOM selection)

The Dossier Submitter has attempted to use the PRODCOM database to quantify the number of mouthable articles on the market that might contain lead in either metal parts, pigments, painted surfaces and to some extent polymers. The PRODCOM database contains statistics on production of manufactured goods together with related external trade data. The Dossier Submitter has sought to match the categories of articles mouthed by children in a study of children's mouthing behaviours (Department of Trade and Industry-DTI, 2002) with the available statistical information in the PRODCOM database, so as to provide an estimation of the volume of articles which might contain lead that would need to be substituted due to the introduction of the proposed restriction. SEAC was of the view that this approach has significant limitations, including:

1. The relevance for mouthing can be questioned for a number of articles: although many of the articles could potentially contain lead, it is questionable whether or not some of the articles can be mouthed according to the EN-71-1 guidelines that have been deemed to be applicable for this proposal.

2. The mouthing behaviour observed in DTI (2002) has been established only for those articles that were available to children at the time of the study. It should be noted, however, that DTI (2002) is supported in this regard by the three other studies considered in the opinion of RAC.

3. The estimation of number of articles per PRODCOM category is in some categories based on assumptions regarding a specific relationship between monetary value and weight (representing 11% of the estimate on the number of articles under the reduced scope). 89% of the articles were directly identified from the PRODCOM statistics.

SEAC has reviewed the articles evaluated by the Dossier Submitter and tried to identify where mouthing seemed to be applicable on the basis of the EN-71-1 guidelines using the criteria of dimensions, availability and reasonably foreseeable use for those articles selected by the Dossier Submitter which are in scope of this restriction proposal.

SEAC has made an interpretation on the categories that could be considered to be affected by the proposed restriction. This selection is presented in Annex 1 to this opinion and has been used as the basis for the cost estimation underlying this opinion.

Noting the above mentioned limitations and interpretations SEAC regarded that the proposal taken by the Dossier Submitter gives an as accurate as possible estimate for the number of articles that could be affected by the proposed restriction.

Assumption 1: number of parts per article

To further quantify the amount of lead to be substituted in articles that are relevant for this proposal the Dossier Submitter has, where relevant for the product category of PRODCOM, estimated the number of parts of articles that could contain lead. The Dossier Submitter has described what parts of the articles have been counted per product category and documented this in appendices 8 and 9 of the Background Document. The methodology used and the values that are derived seem plausible: e.g. the number of buttons and zippers in the textile categories is appropriate and accords with expectations from casual observation. It seems therefore reasonable to use these results in the cost calculation.

Assumption 2: weights of parts per articles

To quantify the total amount of lead to be replaced the Dossier Submitter has examined certain articles (some purchased for the purpose of testing, some old and some from the office inventory), separated those parts of articles that could potentially contain lead and weighed them. The Dossier Submitter has reported the weight per part of articles that they found in appendices 8 and 9 of the Background Document. It is unclear whether the coverage of articles sampled encompasses all of the relevant population.

Assumption 3: proportion of relevant articles on the market assumed to contain lead

With the previous 2 assumptions, the Dossier Submitter has derived the total volume of articles in the scope of this proposal. However only a certain percentage of these articles contain lead. This market share of articles that are suspected to contain lead was assumed to be 10%. This percentage is a weighted average that is based on testing by the Dossier Submitter and on reported test results from other sources (see table B 16 of the Background Document). The information on testing can be found in chapter B.9.3.1 of the Background Document with additional information in appendices 3 and 4. The weights that the Dossier Submitter has assigned to these studies are based on whether or not articles are independently chosen, representative for the EU market, whether the sampling process is adequately described, the total number of articles reported, and whether test results on lead concentration are available. SEAC has been unable to establish that the weights do indeed reflect these criteria or are analytically meaningful. SEAC accepted the value of 10% but noted the following:

1. The sample sizes are small which makes extrapolation of the findings to the entire range of consumer articles in scope of the proposal problematic.

2. The Dossier Submitter claims to have taken care to test articles from different market segments (company size, shop size, shop location, internet stores, and country of purchase and price range). For example the articles that are reported to contain lead (testfakta 2012, testfakta 2011) are available on the EU market , they cover a wide price range and are available in shops of any size. However SEAC could not establish that the sample is representative and generalizable to the population since the surveys appear to be based on a non-probability sampling approach.

3. SEAC finds that the variety of articles that were tested makes the applicability of the 10% found by the Dossier Submitter questionable.

It should be further noted, that the Dossier Submitter found the average market share was 13% (recalculated by SEAC and presented in the Background Document at 11.3%) but the lower 10% value was used not to overestimate exposure. This "rounded value" is based on

the currently best available data. In addition, the 10% figure of articles containing lead was supported by RAC.

Assumption 4: lead content

The lead content in consumer articles within the scope of this restriction was assumed by the Dossier Submitter to be 1%. This is again a weighted average of values found in literature and in values found in tests performed by the Dossier Submitter. SEAC was again unable to verify the validity of the estimate. Although the assumption is subsequently used in the cost calculations, SEAC accepted the 1% value but would like to raise the same points as under Assumption 3 as to the validity of the value. It should be noted that this average lead content value was supported by RAC.

Cost per tonne of lead replaced in relevant applications

The costs per tonne that are used to derive the total cost of substitution are based on the TemaNord study (TemaNord, 1995[31]), recent prices of alternatives to metallic lead, lead pigments and lead stabilizers, and on recent stakeholder consultations.

For metallic lead the cost per kg to substitute lead is based on information from the stakeholder consultation and the prices per tonne of alternative metals is derived from the London Metal Exchange. The Dossier Submitter has assumed a 1:1 ratio of substitution in those applications where lead has no function in the alloy and has used more recent information from the stakeholder consultation to assess the cost of substituting functional lead in alloys.

SEAC agreed the prices reported and the assumptions and that information on substitution seemed to be applicable for this proposal.

The cost per kg lead to be substituted in pigments is based on the TemaNord report (TemaNord 1995). The Dossier Submitter claimed that these prices can still be used as it is likely that due to technological development and industrial experience substitution costs have decreased since that study was published. The inclusion of lead based pigments in Annex XIV (for professional use) is likely to stimulate further substitution of lead based pigments with lead free alternatives and hence make alternatives more feasible in the (near) future.

The cost per kg lead to be substituted in stabilizers is also based mainly on the information in the TemaNord study. As there are on-going industry initiatives (Vinyl 2010) it is likely that lead free alternatives for plastic will become more available and hence less costly. These assumptions are confirmed by the Vinyl Plus own reporting (Vinyl Plus, 2012[32]).

Costs associated with product redesign, materials reformulation and alloy refinement

The Dossier Submitter did not explicitly assess the costs associated with product redesign, materials reformulation and refinement of alloys in their proposal. SEAC agreed that there might be costs associated with re-engineering articles etc. due to the need to use new materials in order to be compliant.

---

31 TemaNord (The Nordic Council of Ministers), 1995. Opportunities and Costs of substituting Lead. Experiences of the Nordic countries on selected lead based products: fishing sinker, lead shot, pigments in plastic and stabilizers in plastic. TemaNord Report 1995:565.

32 http://www.vinylplus.eu/uploads/Progress_Report_2012/VinylPlus_ProgressReport_2012.pdf

Pigments

The Dossier Submitter presented a (non-exhaustive) list of possible alternatives. During the stakeholder consultation for preparing the proposal the Dossier Submitter was informed that a) there are no consumer articles where lead is still needed and b) no major adjustments had to be done to change from lead stabilisers to lead free stabilisers.

It was confirmed in the public consultation that some lead containing pigments were no longer in use in consumer articles. In addition, SEAC was provided with a list of alternatives for lead containing pigments that are suitable for consumer articles.

Plastics

Through the Vinyl Plus Programme, major achievements to replace lead in stabilisers have already taken place. Furthermore, on the basis of comments received during the public consultation, re-engineering is not considered to be necessary as the lead containing recycled raw material will no longer be used; it has been indicated that this material will rather be used in construction materials and will not be used for (mouthable) consumer articles.

Metals

Re-engineering, reformulation and refinement might be an issue for some of the alloys, especially for those alloys where lead constitutes a functional addition to the metal. During the public consultation, information on several applications was provided that copper alloys used in consumer articles that are mouthable have a lead content above 1-2% by weight and where the presence of lead fulfils a technical function. The reason for additional costs to incur is that reducing the maximum lead concentration limit to 0.5% means that lead in copper alloys has to be substituted by other lead free copper alloys (or other materials offering acceptable performance). Consequently larger amounts of copper will have to be melted. Additional costs are foreseen due to the operating cost of the smelter, increased material and processing costs at the semi-fabricator's site and the impact on scrap recycling.

As a follow up of questions to industry on the impact on costs associated with re-engineering, reformulation and refinement if the concentration limit for brass alloys was 0.5%, industry indicated that those costs on would be in the order of €6.3 million/year. These costs would be considerably higher without the derogation suggested in paragraph 5 of the opinion.

SEAC took the information from the copper sector into account by including these costs in the break even analysis. SEAC however noted that since the analytical scope was narrowed during the discussion of the proposal, and the estimation of these additional costs is based on the original scope, €6.3 million/year is an overestimate of the actual cost. This reduction needs to be taken into account. Furthermore the costs are not fully additional to the costs already accounted for and it may be that consumer articles are not recycled into metal waste scrap. SEAC estimated that due to the reduced scope the amount of metallic lead that needs to be substituted is reduced by 55%[33] compared to the amount that needs to be substituted using the original scope. Assuming linearity of the effects, SEAC estimated that the total cost in this category should be €2.8 million/year. In order to deal with these estimates, SEAC proposed that the lower value (€2.8 million/year) was taken into the lower end scenario and the higher end estimation of industry (€6.3 million/year) in the high end

[33] See annex 4 for more details.

scenario. The normal average of these two (€4.6 million/year) is taken in the mid scenario.

Testing costs for lead content

For those manufacturers, importers, distributers and wholesalers which are not in full control of their supply chain, testing may be the only option to ensure due diligence that they are in compliance with the proposed restriction.

It is expected that large well-known retailers may be particularly proactive in ensuring conformity and may choose to test their products, or update their procurement requirements and contractual arrangements. This was confirmed in the consultation with stakeholders whilst preparing the proposal (as documented in Appendix 15 of the Background Document). Further evidence of this can be found in the AFIRM[34] guidelines, which recommend[35] buying metal parts, pigments, plastics etc. from known suppliers that are certified lead-free. In other cases, testing may be undertaken further upstream by wholesalers and distributors.

The total cost for testing as calculated by the Dossier Submitter was obtained by multiplying:

- the number of articles assumed to contain lead after implementation by
- the share of articles to be tested, and
- the average cost per test.

Following comments from the public consultation, as well as its own deliberations, SEAC concluded that the analysis provided by the Dossier Submitter did not take into account certain important elements, including:

1. Testing needs to be carried out on all articles in scope (not just those assumed to contain lead) since it is not known a-priori which articles contain lead and which do not.

2. The number of tests per article may be higher; more than one test is needed to estimate and verify the actual lead content of an article.

3. When a test for lead content gives a positive result, additional testing needs to be done which usually is done via destructive testing.

4. The lost value of damaged tested articles needs to be taken into account.

In the analysis carried out by SEAC it was assumed that 10% of all tested articles will undergo follow-up testing which will be carried out using destructive methods.

The testing cost estimation made by the Dossier Submitter and further elaborated by SEAC was intended to account for new testing triggered by the proposed restriction.

SEAC has assessed the following parameters used in the analysis by the Dossier Submitter:

---

[34] Apparel and footwear industry group: http://www.afirm-group.com/

[35] http://www.afirm-group.com/rsl-guidance/

Number of articles assumed to require testing for lead after implementation

According to the dossier submitter, the number of articles to be tested is based on both the total amount of articles and the proportion of articles that are assumed to contain lead.

The derivation of the number of articles from the PRODCOM database has been described in the section under substitution costs. In the calculation made by the Dossier Submitter, the proportion of the articles on the market that are assumed to contain lead is discussed under the substitution costs. The proportion of articles assumed to contain lead after implementation of the proposed restriction has been estimated at 1-3% by the Dossier Submitter. SEAC did not agree with the approach set out by the Dossier Submitter as it implied that a priori knowledge on the share of articles that contain lead exists. This did not seem to be logical as it is compliance with the restriction (and hence the share of articles that contain lead) that is determined through testing of articles in scope.

Share of articles to be tested

The testing rate of 0.1%-1% had been suggested during the public consultation whilst preparing the dossier. However, according to the Dossier Submitter, it was also indicated during the consultation that this testing regime might be an overestimate as in reality far fewer items per batch might be tested.

Within the framework of the US Consumer Product Safety Improvement Act[36] of 2008, recommendations have been made on the testing and certification requirements. As regards the frequency of testing, a recommendation is made *inter alia* to test articles for their lead content with a testing rate of 1 out of 10000 articles. Follow up questions to industry have confirmed that this value is not unreasonable to use and SEAC proposed to use this latter value.

However, there is no information that tests would be carried out only for the purpose of ensuring compliance with the proposed restriction. The producer of the different materials in articles would know which ingredients are used and therefore tests are not required. For downstream users of materials, including producers of articles, testing would in practice usually be done either to ensure functionality or in relation to compliance in a combination with testing for other materials, e.g. cadmium.

Furthermore, some lead compounds are listed on the candidate list maintained according to Article 59 of REACH, and suppliers of articles have to know whether the actual article contains these compounds and thereby lead following the presence of these compounds.

Therefore the number of additional tests due to the proposed restriction is expected to be very limited.

During the public consultation on the Annex XV dossier, industry brought forward a testing approach in which 65% of the articles would be tested using X-ray fluorescence (XRF) testing and that the remaining 35% would require destructive testing. SEAC has adopted these figures in the calculation of testing costs.

Number of tests per article

The approach as developed by the Dossier Submitter took into account only one test per article. Information provided by industry on request of the rapporteurs indicated that several tests per article are performed. Furthermore, it is known that articles can consist of

36 http://cs.cpsc.gov/ConceptDemo/SearchCPSC.aspx?query=http://www.cpsc.gov/library/foia/foia10/brief/102testing.pdf&OldURL=true&autodisplay=true

multiple components for which separate testing might be needed. SEAC agreed to this and has applied a higher number of tests per article (three tests in the central case).

Average cost per test

The prices have been based on both a literature search and on prices reported to the Dossier Submitter, for example, as part of the stakeholder consultation whilst preparing the dossier. SEAC has further assessed the testing cost based on comments submitted during the public consultation of the Annex XV dossier.

The average cost per test used in the calculations by the Dossier Submitter was based on the cost of tests known to the Dossier Submitter in the context of their own duties as a Competent Authority. This was a price range of about €20-40 per analysis. Consequently the Dossier Submitter has based its values on the costs of testing on the prices offered to them. Following comments from the public consultation the prices for XRF testing have in the assessment by SEAC been adjusted downwards to €5 per test.

Based on information in the Annex XV dossier the cost of one wet chemical test has been estimated to be in the range of €30 to €60. The cost for any subsequent tests after the first one is typically lower than that of the first one, and a price equalling 40 % of the price of the first test has been used in the estimation by SEAC.

Average price per article

The Dossier Submitter used an average price per article that is based on the value of all articles and the volume of articles. This is not likely to be a correct estimate; in reality the original scope of the proposal is very broad and the prices will vary within that scope to the extent that it is questionable to use such a measure. With the refined scope (based on a narrower range of articles subject to EN-71-1) using such an approach can be deemed proportionate. On the basis of the refined scope the average price per article is estimated to be around €4.34[37].

An overview of the derivation of the testing costs is given the table E 9 of the Background Document.

Overall the assumptions made by the Dossier Submitter, given the adjustments to the approach on the basis of information submitted via the public consultation, seem to be plausible. It is worth noting that the cost of obtaining information on lead content of articles is not known and it can therefore not be compared to the costs of testing. It is however likely that a number of companies will shift to lead free articles on the basis that the costs of shifting supplier can be lower as the costs of testing.

It is not clear how closely the information on testing regime reflects the actual situation in the different sectors affected by the proposed restriction, and it is suspected that the actual rate might in many cases be lower. However, SEAC considered the information generalizable enough to be used to derive an approximation for costs associated with additional testing. Using the abovementioned assumptions the total testing cost is estimated to be €8.2 million (€3.7 million - €18.2 million).

[37] based on 20 416 098 689 articles with an overall value of €88 578 844 575

Enforcement costs

The introduction of the new restriction is likely to require resources spent on training staff, advertising the new regulations to industry, updating guidance documents where necessary, and so on. These are unlikely to be large relative to compliance costs. There will also be costs associated with on-going enforcement activities through desk work, site inspections etc. All these costs are likely to be met out of existing enforcement budgets. SEAC has not been able to assess the costs associated with any additional or displaced enforcement efforts since no assessment was undertaken by the dossier submitter, and hence is unable to make any conclusions in this respect.

Reliability of the cost analysis

Inherent in the adoption of the assumptions in the costs analysis is a degree of uncertainty. In an effort to manage this risk, a sensitivity analysis has been undertaken to account for uncertainties in the testing cost regime. In addition, in order to account for the uncertainties regarding the estimation of substitution costs, SEAC has drafted three further scenarios (lower bound, central estimate and upper bound). The possible high reformulation/refinement of recycling material costs in the copper sector were incorporated to all three scenarios. These scenarios are shown in Annex 2.

Conclusion on costs

Substitution cost

Overall, SEAC supported the general methodological approach based on the substitution of lead in those parts of articles that contain lead, but wishes to point out that the data and assumptions necessary to validly utilise the approach are in many cases inadequate or lacking and hence SEAC considers the cost estimates highly uncertain.

The estimate derived for substitution cost is €11.8 million (range €5.2 million - €18.4 million) per year.

Costs of product redesign, materials reformulation and alloy refinement

Costs associated with reformulation/refinement of recycling material in the copper sector, as well as administrative burden have been identified during the public consultation as being potentially very large relative to the costs of substitution and testing above. SEAC proposed that the lower value (€2.8 million/year) is taken into the lower end scenario and the higher end estimation of industry (€6.3 million/year) in the high end scenario. The normal average of these two (€4.6 million/year) is taken in the mid scenario.

Testing costs

On the basis of the above outlined approach to estimation of testing costs, given the uncertainties and lack of information on their impact on the cost calculations, SEAC has only provided an educated estimate of the testing costs of this restriction.

The estimate derived for testing cost is €8.2 million (range €3.7 million - €18.2 million) per year.

Overall conclusion

SEAC supported the general methodological approach to the modelling of the costs, as described as above.

There is some uncertainty in the cost as several factors have not been quantified (costs

associated with product redesign and reformulation and enforcement). The cost estimate derived for the proposed restriction on the basis of the dossier submitters approach is €24.6 million per year and accounts for substitution costs, testing costs for additional testing and refinement costs in the copper sector. Incorporation of other cost elements highlighted during the public consultation could result in much higher total costs, as indicated in the break-even analysis.

SEAC agreed to the costing method and accepts the values as an order of magnitude estimate of the compliance costs. A summary of the costs is given in the table 4.

Table 4: Overview of the annual estimated compliance costs for the proposed restriction

	€ (million)/year		
Type of Costs	Central	Min	Max
Substitution costs	11.8	5.4	18.4
Product redesign, materials reformulation and alloy refinement	4.6	2.8	6.3
Testing costs	8.2	3.7	18.2
Total	**24.6**	**11.7**	**42.9**

Benefits

SEAC notes that the Dossier Submitter considered it was not possible to establish a full quantitative assessment of the impacts of the restriction, in particular with regard to the health consequences.

Within the current restriction proposal the end-points of concern are the cognitive abilities of children such as memory, verbal and spatial reasoning, planning, learning and the comprehension and use of language. Normally these abilities are tested with the use of IQ tests.

Benefits estimation presented in the Background Document

The assessment of benefits as presented by the Dossier Submitter only included the benefits referred to above and did not include other potential benefits of reducing lead exposure. These may include non-cognitive functioning and other health impacts and non-health related endpoints. Recent scientific evidence suggests that these impacts such as: impaired school performance, distractibility, short attention span, impulsivity, perseveration and increased activity might be relevant as well (Pichery et al, 2011)[38], (Gould 2009)[39]. Since the benefits originally significantly overweighed the costs, the Dossier Submitter did not find it appropriate to further assess and quantify additional benefits. For example, there is some evidence that the socioeconomic benefits related to a reduction in ADHD prevalence (in small children, caused by lead) is of the same order of magnitude as the benefits related

[38] Pichery et al., 2011. Childhood lead exposure in France: benefit estimation and partial cost-benefit analysis of lead hazard control, Environmental Health, , 10:44

[39] Gould, 2009. Childhood lead poisoning: conservative estimates of the Social and Economic Benefits of lead hazard control, Environmental health perspectives volume 117, number 7.

to reduced losses in IQ[40]. However, aggregating these effects could lead to double counting.

The assumptions on the content of lead in articles and on the proportion of articles that contain lead are already discussed under the costs. The same conclusions of SEAC on these assumptions apply.

SEAC proposed to follow the 'break even' approach used in the assessment of the Lead in Jewellery restriction in order to consider the proportionality of the restriction. The following parameters are used:

Migration rate

A migration rate of 0.7 µg/cm^2 per hour was assumed by RAC in its calculations of risk reduction capacity and in the calculation of the relevant lead content limit. RAC used the migration rate derived in its opinion on lead in jewellery. 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. 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 the methodology, including using standard discs of material, was plausible. Hence, a lower value of migration of 0.08 µg/cm^2 per hour is proposed to be used in the sensitivity analysis.

Daily intake factor of lead / Exposure to lead

The Dossier Submitter and RAC used a daily intake factor of 0.5 µg/kg bw per day as the intake factor for loss of 1 IQ point. The factor is based on the work done by EFSA (2013). Whilst this intake factor is appropriate for deriving a risk assessment based limit value for the restriction, it requires adjustment for the purposes of socioeconomic impact assessment. In accordance with the procedure outlined in the lead in jewellery restriction, SEAC use a daily intake factor for loss of 1 IQ point of 1.22 µg/kg bw per day (range 1.08 - 1.23 µg/kg bw per day).

The exposure value of 1.22 µg/kg bw per day is a median value calculated using the IEUBK model (as in the lead in jewellery restriction) using a 1.1 µg/kg bw/day lower bound daily dietary intake for an average child consumer of 1-3 years. These parameters are based on EFSA (2013).

Significance of IQ loss

Lead exposure has been extensively studied in children and its negative impact on the developing nervous system is well documented, using IQ as an indicator for neurodevelopmental status. It is not possible to identify a threshold for exposure below which lead would not affect the developing brain. SEAC noted that according to the EFSA (2013) opinion there is a continuous relationship between lead blood levels and the IQ loss. Although small changes in IQ following exposure to lead may not be identifiable in single individuals the exposure-response relationship per se is well established and a valid impact estimate for socioeconomic analysis as IQ is positively correlated to productivity and life-time income.

---

[40] Matrix Insight Ltd., 2012. Impact assessment study on the health costs due to children's exposure to lead via toys and on the benefits resulting from reducing such exposure, Final report. Delivered to the European Commission DG Enterprise and Industry.

During the public consultations of the Annex XV restriction report and the SEAC draft opinion, an industry stakeholder expressed concerns that small fractions of IQ points are below the limit of discrimination of IQ tests, which it claimed to be 3-5 IQ points. The stakeholder therefore claimed that these small fractions cannot be considered to be a measurable adverse effect for an individual. SEAC considered this contribution but concluded that the approach of the Dossier Submitter was acceptable. Furthermore, it is noted that a stakeholder suggested that the approach based on the "Population disease burden" of the WHO (2010) would be an alternative method to estimate low level improvements on IQ.

Monetary value of IQ point loss

The Dossier Submitter estimated the value for IQ loss by basing the value on future earnings excluding household production (although IQ income value where household production is included is used for sensitivity discussions). The loss of 1 IQ point has been set to correspond to a reduction of €8,000.

The Dossier Submitter has based its analysis of the value of IQ losses on the analysis of Grosse (2003) who estimated the present value of lifetime earnings for infants. The values are presented in euros in 2011 prices. A 1% wage premium used in the central estimate corresponds to a reductions in lifetime earning per IQ point of €8,000, with a lower and upper bound of respectively €2,400 - €25,000 that correspond to 0.3-1.5% wage premiums in lifetime earnings according to previous studies.

Given the uncertainty regarding the distribution of lead intake of children from lead in consumer articles, and hence the likelihood of short duration mouthing times for such articles, it was necessary for SEAC to consider whether and how to value fractional IQ defects arising from neurotoxicological effects which are below the benchmark response of 1 IQ point identified by EFSA (2013). Whilst SEAC recognised that there are differing views regarding the meaningfulness and validity of including such fractional IQ changes in impact assessment, it was assumed for illustrative purposes that such changes can be represented by scaling them in a linear manner with a constant valuation factor, based on a value of €8,000 per IQ point.

Benchmark

The total number of articles items mouthed relevant for the scope of this proposal was thus 356 out of 1665 items in the 'other objects' category (21.38% of items). Assuming that the total amount of time spent mouthing an object is proportionate to the frequency that the item is mouthed, then the total amount of time spent mouthing articles items by the 236 children is estimated to be (21.38% of 3728 minutes) 797 minutes per day (or 3.38 minutes per child).

Since it is estimated that only 10% of articles contain lead, then the total amount of time spent by the 236 children mouthing articles items containing lead is estimated to be (2.138% of 3728 minutes) 79.7 minutes per day (or 0.338 minutes per child). The number of minutes of mouthing articles containing lead per child per year is thus estimated at [0.338 x 365=] 123 minutes.

On this basis then, the number of seconds of mouthing articles containing lead per child is estimated at 20.3 seconds per day.

Break-even analysis

To look at the proportionality of the proposal, SEAC has calculated the break-even level based on the central substitution cost scenario and the relationship between lead exposure and IQ loss supported by RAC.

Table 5: Break even analysis

Break-even scenario	Break-even point based on Central estimate of costs and benefits (rounded values)
Number of IQ points lost to balance costs of €24.6 million.	3100[41]
Lead intake per day (based on 11.57 kg bw/child) corresponding to the IQ points given above.	43000 µg[42]
Mouthing time of lead in articles necessary per day for each and every child in Europe to reach the exposure given above.	4.2 sec per day[43]

Source: Table F 7 of the Background Document

The break-even analysis (full break even analysis in Annex II) shows that the costs are balanced if every child in Europe would mouth articles containing lead for 4.2 seconds per day (given that the articles contain 1% lead) (Table 5).

The following summarises the estimations done after SEAC's modifications of the cost calculations as well as the break-even benefits calculations:

- The compliance costs of the restriction (substitution and testing costs) per year are between €11.7 million and €42.9 million with a central estimate of €24.6 million.
- The estimated mouthing time for children between the ages of 6 months and 3 years is 20.3 seconds per day.
- The realistic mouthing time of lead in articles necessary per day for each and every child in Europe to break even is 4.2 sec per day.

A sensitivity analysis on the 'break even' level of mouthing duration has also been undertaken (see Annex 2). It should be noted that using the more conservative but less realistic parameters for the cost of the restriction and the value of a lost IQ point, the actual mouthing duration (20.3 seconds per day) does not surpass the estimated break-even duration. However, SEAC emphasised that these break-even calculations do not take benefits other than IQ-effects into account (see Section on 'benefits estimation above (pg. 32) and that taking into account that lead is a non-threshold substance, and the level of the background exposure, any additional lead exposure may have IQ impacts relevant on society level.

---

[41] Number of IQ points to break even = total cost per year divided by the value of IQ point (€8,000); 24587000 €/8000 €/IQ point = 3073 IQ point. It must be noted that the cost estimate is subject to remarkable uncertainties, specifically relating to testing costs.

[42] Lead intake per day = Number of IQ points to break even (3073)* daily lead intake factor (1.22) * body weight per child (11.57 kg) = 43382 µg

[43] The mouthing hours required for daily lead intake calculated in = lead intake per child per day (43382) / migration factor for 1% lead content and 10 cm2 (7) =6197. Daily mouthing time = Mouthing hours required for daily lead intake, converted to seconds, divided by Number of children in relevant age group = 6197*3600/ (13437880/2,5) = 4.15 seconds.

Based on the estimates of actual mouthing times for articles containing lead it would appear that actual mouthing durations (based on four studies) may exceed those that would be required to achieve the 'break even' level of mouthing duration per year. Having considered the relevant uncertainties and that there is no threshold for effects from lead, SEAC concluded that the restriction is justified from the point of view of proportionality of costs and benefits. However, SEAC noted that under certain assumptions (e.g. different cost estimates or the valuation of the fractional IQ points) this conclusion might not hold.

Practicality, incl. enforceability

Justification for the opinion of RAC

Practicality (including enforceability) and monitorability

For metallic parts, the analysis of lead content can usually be made in a non-destructive way using 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 had noted the Forum's advice on methods of analysis and sampling and a summary of this will be included in the Background Document.

As some materials might show low migration levels RAC considered 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 recognised 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.

Justification for the opinion of SEAC

Content vs. migration

SEAC noted that RAC preferred to include a limit value based on migration. Industry has also indicated that should the restriction be based on migration then many of the costs related to re-engineering could be avoided. SEAC regarded that the two-way approach (content limit unless it can be shown that migration does not exceed a given value) would be a good option, as it would reduce any unnecessary cost on industry when lead is present but not available for exposure.

SEAC noted that there have been developments in migration testing, such as the testing used to provide data used in determining the higher content limit from brass alloys. Furthermore, SEAC recognised there would be substantial benefits in agreeing a standardised test method, for example by CEN, where the issues mentioned above could be independently validated. Furthermore, SEAC noted that the Forum has raised the enforceability of the migration limit as an issue.

Industry has provided data related to the migration of lead from brass alloys using a standardised test on discs of metal incubated in synthetic saliva. RAC has accepted the data as valid in terms of a higher content limit for lead in brass and SEAC has agreed to this derogation. In the public consultation on the SEAC draft opinion there were several comments supporting the introduction of a migration limit as an option for industry, indicating the cost of testing is low, including for SMEs.

Therefore SEAC recommended that the restriction should be based on content (w/w), with

an option for market operators to demonstrate, using appropriate justification, that due to a low migration a particular article can be placed on the market.

Implementability

According to the Background Document, alternative materials seem to exist for the applications in scope, usually at comparable prices. Many companies exporting worldwide seem to already have substituted lead in their products to meet the limit value of 0.01 % of the Consumer Product Safety Improvement Act of the US and the 0.03% value in the Canadian Consumer Product Safety Regulation.

The proposed restriction suggests a transition period to facilitate implementation. The effects of transition periods of 6 months, 12 months and 18 months have been compared in the Background Document. Following this assessment, the Dossier Submitter has concluded that a transition period of 12 months (i) is considered reasonable for the market to adjust and adopt the requirements of the proposed restriction, (ii) would also facilitate the handling of existing stocks and give time for their depletion. SEAC agreed with the Dossier Submitter's conclusion.

Overall, SEAC regarded the restriction to be practical and enforceable.

Monitorability

Justification for the opinion of RAC

See the section above on 'Practicality (including enforceability) and monitorability'.

Justification for the opinion of SEAC

SEAC considers that monitoring is possible and that major monitoring costs are not anticipated.

BASIS FOR THE OPINION

Justification for the opinion of RAC

The Background Document, providing supporting information, 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 restriction limit for articles comprising 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.

Justification for the opinion of SEAC

The Background Document, provided as a supportive document, gives the detailed grounds

for the opinions.

The main changes introduced in the restrictions as suggested in this opinion compared to the restrictions proposed in the Annex XV restriction dossier submitted by Sweden include explicitly exempting crystal glass, precious stones and enamels, the tips of pens and a higher restriction limit for articles comprising brass alloys. In addition, second hand market articles and articles covered by European Union legislation specifically regulating lead content have been proposed to be exempted.

The basis for these changes is information received during the public consultations, such as additional issues that lead to consideration of further exemptions and the advice of the Forum for Exchange of Information on Enforcement.

Annex 1 - articles included in the analytical scope based on an evaluation of the Dossier submitter's own analysis

Table 7.1 Clothing categories, available for consumers/children (PRODCOM)

Note: some categories contain articles potentially both in and out of scope - in these cases the whole category has been evaluated as out of scope to avoid overestimating the costs and benefits e.g. PRCCODE 1521210 where sachels may be in scope but trunks and suitcases are out of scope – the whole category is out of scope.

PRCCODE	Description	In scope
14131110	Men's or boys' overcoats, car-coats, capes, cloaks and similar articles, of knitted or crocheted textiles (excluding jackets and blazers, anoraks, wind-cheaters and wind-jackets)	In
14131120	Men's or boys' anoraks, ski-jackets, wind-cheaters, wind-jackets and similar articles, of knitted or crocheted textiles (excluding jackets and blazers)	In
14131230	Men's or boys' jackets and blazers, of knitted or crocheted textiles	In
14131260	Men's or boys' suits and ensembles, of knitted or crocheted textiles	In
14131270	Men's or boys' trousers, breeches, shorts, bib and brace overalls, of knitted or crocheted textiles	In
14131310	Women's or girls' overcoats, car-coats, capes, cloaks and similar articles, of knitted or crocheted textiles (excluding jackets and blazers)	In
14131320	Women's or girls' anoraks, ski-jackets, wind-cheaters, wind-jackets and similar articles, of knitted or crocheted textiles (excluding jackets and blazers)	In
14131430	Women's or girls' jackets and blazers, of knitted or crocheted textiles	In
14131460	Women's or girls' suits and ensembles, of knitted or crocheted textiles	In
14131470	Women's or girls' dresses, of knitted or crocheted textiles	In
14131480	Women's or girls' skirts and divided skirts, of knitted or crocheted textiles	In
14131490	Women's or girls' trousers, breeches, shorts, bib and brace overalls, of knitted or crocheted textiles	In
14132110	Men's or boys' raincoats	In
14132120	Men's or boys' overcoats, car-coats, capes, etc.	In
14132130	Men's or boys' anoraks, ski-jackets, wind-jackets and similar articles (excluding jackets and blazers, knitted or crocheted, impregnated, coated, covered, laminated or rubberized)	In
14132210	Men's or boys' suits (excluding knitted or crocheted)	In
14132220	Men's or boys' ensembles (excluding knitted or crocheted)	In
14132300	Men's or boys' jackets and blazers (excluding knitted or crocheted)	In
14132442	Men's or boys' trousers and breeches, of denim (excluding for industrial or occupational wear)	In
14132444	Men's or boys' trousers, breeches and shorts, of wool or fine animal hair (excluding knitted or crocheted, for industrial or occupational wear)	In

PRCCODE	Description	In scope
14132445	Men's or boys' trousers and breeches, of man-made fibres (excluding knitted or crocheted, for industrial or occupational wear)	In
14132448	Men's or boys' trousers and breeches, of cotton (excluding denim, knitted or crocheted)	In
14132449	Men's or boys' trousers, breeches, shorts and bib and brace overalls (excluding of wool, cotton and man-made fibres, knitted or crocheted)	In
14132455	Men's or boys' bib and brace overalls (excluding knitted or crocheted, for industrial or occupational wear)	In
14132460	Men's or boys' shorts, of cotton or man-made fibres (excluding knitted or crocheted)	In
14133110	Woman's or girls' raincoats	In
14133120	Woman's or girls' overcoats, etc.	In
14133130	Women's or girls' anoraks, ski-jackets, wind-jackets and similar articles (excluding jackets and blazers, knitted or crocheted, impregnated, coated, covered, laminated or rubberized)	In
14133210	Women's or girls' suits (excluding knitted or crocheted)	In
14133220	Women's or girls' ensembles (excluding knitted or crocheted)	In
14133330	Women's or girls' jackets and blazers (excluding knitted or crocheted)	In
14133470	Women's or girls' dresses (excluding knitted or crocheted)	In
14133480	Women's or girls' skirts and divided skirts (excluding knitted or crocheted)	In
14133542	Women's or girls' trousers and breeches, of denim (excluding for industrial or occupational wear)	In
14133548	Women's or girls' trousers and breeches, of cotton (excluding denim, for industrial or occupational wear)	In
14133549	Women's or girls' trousers and breeches, of wool or fine animal hair or man-made fibres (excluding knitted or crocheted and for industrial and occupational wear)	In
14133551	Women's or girls' bib and brace overalls, of cotton (excluding knitted or crocheted, for industrial or occupational wear)	In
14133561	Women's or girls' shorts, of cotton (excluding knitted and crocheted)	In
14133563	Women's or girls' bib and brace overalls, of textiles (excluding cotton, knitted or crocheted, for industrial or occupational wear) and women's or girls' shorts, of wool or fine animal hair (excluding knitted or crocheted)	In
14133565	Women's or girls' shorts, of man-made fibres (excluding knitted or crocheted)	In
14133569	Women's or girls' trousers, breeches, bib and brace overalls, of textiles (excluding cotton, wool or fine animal hair, man-made fibres, knitted or crocheted)	In
14141230	Men's or boys' nightshirts and pyjamas, of knitted or crocheted textiles	In
14141310	Women's or girls' blouses, shirts and shirt-blouses, of knitted or crocheted textiles	In
14141430	Women's or girls' nighties and pyjamas, of knitted or crocheted textiles	In
14142100	Men's or boys' shirts (excluding knitted or crocheted)	In

PRCCODE	Description	In scope
14142230	Men's or boys' nightshirts and pyjamas (excluding knitted or crocheted)	In
14142300	Women's or girls' blouses, shirts and shirt-blouses (excluding knitted or crocheted)	In
14142430	Women's or girls' nightdresses and pyjamas (excluding knitted or crocheted)	In
14142570	Braces, suspenders, garters and similar articles and parts thereof	In
14191100	Babies' garments and clothing accessories, knitted or crocheted including vests, rompers, underpants, stretch-suits, napkins, gloves or mittens or mitts, outerwear (for children of height <= 86 cm)	In
14191210	Track-suits, of knitted or crocheted textiles	In
14191230	Ski-suits, of knitted or crocheted textiles	In
14191300	Gloves, mittens and mitts, of knitted or crocheted textiles	In
14192100	Babies' clothing and accessories, of textiles, not knitted or crocheted (for children of height <= 86 cm) including vests, rompers, underpants, stretch-suits, napkins, gloves, mittens and outerwear	In
14192210	Other men's or boys' apparel n.e.c., including waistcoats, tracksuits and jogging suits (excluding ski-suits, knitted or crocheted)	In
14192220	Other women's or girls' apparel n.e.c., including waistcoats, tracksuits and jogging suits (excluding ski-suits, knitted or crocheted)	In
14192230	Ski-suits (excluding of knitted or crocheted textiles)	In
14192370	Gloves, mittens and mitts (excluding knitted or crocheted)	In
14192395	Parts of garments or of clothing accessories, of textiles (excluding bras, girdles and corsets, braces, suspenders and garters, knitted or crocheted)	In
14193175	Gloves, mittens and mitts, of leather or composition leather (excluding for sport, protective for all trades)	In
14193180	Belts and bandoliers, of leather or composition leather	In
14391031	Men's or boys' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of wool or fine animal hair (excluding jerseys and pullovers containing <=50% of wool and weighing <=600g)	In
14391032	Women's or girls' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of wool or fine animal hair (excluding jerseys and pullovers containing <=50% of wool and weighing <=600g)	In
14391033	Jerseys and pullovers, containing <= 50% by weight of wool and weighing <= 600 g per article	In
14391061	Men's or boys' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of cotton (excluding lightweight fine knit roll, polo or turtle neck jumpers and pullovers)	In
14391062	Women's or girls' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of cotton (excluding lightweight fine knit roll, polo or turtle neck jumpers and pullovers)	In
14391071	Men's or boys' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of man-made fibres (excluding lightweight fine knit roll, polo or turtle neck jumpers and pullovers)	In

PRCCODE	Description	In scope
14391072	Women's or girls' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of man-made fibres (excluding lightweight fine knit roll, polo or turtle neck jumpers and pullovers)	In
14391090	Jerseys, pullovers, sweatshirts, waistcoats and cardigans, of textile materials (excluding those of wool or fine animal hair, cotton, man-made fibres)	In

PRCCODE	Description	
14143000	T-shirts, singlets and vests, knitted or crocheted	In

Table 7.2 Categories of accessories (PRODCOM)

PRCCODE	Description	
14193180	Belts and bandoliers, of leather or composition leather	In
14193190	Clothing accessories of leather or composition leather (excluding gloves, mittens and mitts, belts and bandoliers)	In
15121210	Trunks, suitcases, vanity-cases, briefcases, school satchels and similar containers of leather, composition leather, patent leather, plastics, textile materials, aluminium or other materials	Out
15121220	Handbags of leather, composition leather, patent leather, plastic sheeting, textile materials or other materials (including those without a handle)	In
15121230	Articles normally carried in pocket or handbag	In
15121250	Cases and containers, n.e.c.	Out
15121270	Travel sets for personal toilet; sewing; or shoe or clothes cleaning (excluding manicure sets)	Out
25711350	Manicure or pedicure sets and instruments (including nail files)	Out
25931800	Sewing, knitting needles, bodkins... of iron or steel, for use in the hand	Out
25992927	Iron or steel snuff boxes, cigarette cases, cosmetic and powder boxes and cases, and similar pocket articles	Out
32504250	Sunglasses	In
32504290	Spectacles, goggles and the like, corrective, protective or other (excluding sunglasses)	In
32504350	Plastic frames and mountings for spectacles, goggles or the like	In
32504390	Non plastic frames and mountings for spectacles, goggles and the like	In
32992130	Umbrellas, sun umbrellas, walking-stick umbrellas, garden umbrellas and similar umbrellas (excluding umbrella cases)	Out
32992150	Walking-sticks, seat-sticks, whips, riding-crops and the like	Out

Code 14193190 was accounted for in both Clothes and Accessories categories in the submitted report.

Table 7.3 Shoes (PRODCOM)

PRCCODE	Description	
15201100	Waterproof footwear, with uppers in rubber or plastics (excluding incorporating a protective metal toecap)	Out
15201210	Sandals with rubber or plastic outer soles and uppers (including thong-type sandals, flip flops)	Out
15201231	Town footwear with rubber or plastic uppers	Out
15201237	Slippers and other indoor footwear with rubber or plastic outer soles and plastic uppers (including bedroom and dancing slippers, mules)	In
15201330	Footwear with a wooden base and leather uppers (including clogs) (excluding with an inner sole or a protective metal toe-cap)	Out
15201351	Men's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)	Out
15201352	Women's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)	Out
15201353	Children's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)	In
15201361	Men's sandals with leather uppers (including thong type sandals, flip flops)	In
15201362	Women's sandals with leather uppers (including thong type sandals, flip flops)	In
15201363	Children's sandals with leather uppers (including thong type sandals, flip flops)	In
15201370	Slippers and other indoor footwear with rubber, plastic or leather outer soles and leather uppers (including dancing and bedroom slippers, mules)	In
15201380	Footwear with wood, cork or other outer soles and leather uppers (excluding outer soles of rubber, plastics or leather)	Out
15201444	Slippers and other indoor footwear (including dancing and bedroom slippers, mules)	In
15201445	Footwear with rubber, plastic or leather outer soles and textile uppers (excluding slippers and other indoor footwear, sports footwear)	Out
15201446	Footwear with textile uppers (excluding slippers and other indoor footwear as well as footwear with outer soles of rubber, plastics, leather or composition leather)	Out
15202100	Sports footwear with rubber or plastic outer soles and textile uppers (including tennis shoes, basketball shoes, gym shoes, training shoes and the like)	Out
15202900	Other sports footwear, except snow-ski footwear and skating boots	Out
15203200	Wooden footwear, miscellaneous special footwear and other footwear n.e.c.	out

Shoes for professional use are not included.

Table7. 4 Stationery (PRODCOM)

PRCCODE	Description	
22197321	Erasers, of vulcanized rubber	In
25711330	Paper knives, letter openers, erasing knives, pencil sharpeners and their blades (including packet type pencil sharpeners) (excluding pencil sharpening machines)	Out
25992370	Office articles such as letter clips, letter corners... of base metal	In
32991210	Ball-point pens	In
32991230	Felt-tipped and other porous-tipped pens and markers	In
32991250	Propelling or sliding pencils	In
32991330	Indian ink drawing pens	In
32991350	Fountain pens, stylograph pens and other pens (excluding Indian ink drawing pens)	In
32991510	Pencils and crayons with leads encased in a rigid sheath (excluding pencils for medicinal, cosmetic or toilet uses)	In

Several paper categories are excluded due no expectance and no test results indicating a content of lead in relevant concentrations for the proposal.

Table 7.5 Interior decorations (PRODCOM)

PRCCODE	Description	
13921660	Furnishing articles including furniture and cushion covers as well as cushion covers, etc. for car seats (excluding blankets, travelling rugs, bed linen, table linen, toilet linen, kitchen linen, curtains, blinds, valances and bedspreads)	Out
16291420	Wooden frames for paintings, photographs, mirrors or similar objects	Out
22292340	Household articles and toilet articles, of plastics (excl. tableware, kitchenware, baths, shower-baths, washbasins, bidets, lavatory pans, seats and covers, flushing cisterns and similar sanitary ware)	In
22292620	Statuettes and other ornamental articles of plastic (including photograph, picture and similar frames)	Out
23411150	Household and toilet articles, n.e.c., of porcelain or china	Out
23411330	Statuettes and other ornamental articles, of porcelain or china	Out
23411350	Ceramic statuettes and other ornamental articles	Out
25992400	Statuettes, frames, mirrors and other ornaments of base metal	Out
25992982	Bells, gongs, etc., non-electric, of base metal	Out

32995130	Articles for Christmas festivities (excluding electric garlands, natural Christmas trees, Christmas tree stands, candles, statuettes, statues and the like used for decorating places of worship)	Out
32995150	Festive, carnival or other entertainment articles, n.e.c.	In
32995500	Artificial flowers, foliage and fruit and parts thereof	In
32995980	Globes, printed (excluding relief globes)	Out
31001170	Upholstered seats with metal frames (excluding swivel seats, medical, surgical, dental or veterinary seats, barbers or similar chairs, for motor vehicles, for aircraft)	Out
31001190	Non-upholstered seats with metal frames (excluding medical, surgical, dental or veterinary seats, barbers or similar chairs, swivel seats)	Out
31001210	Seats convertible into beds (excluding garden seats or camping equipment)	Out
31001230	Seats of cane, osier, bamboo or similar materials	Out
31001250	Upholstered seats with wooden frames (including three piece suites) (excluding swivel seats)	Out
31001290	Non-upholstered seats with wooden frames (excluding swivel seats)	Out
31001300	Other seats, of HS 9401, nec	Out
31021000	Kitchen furniture	Out
31091100	Metal furniture (excluding office, medical, surgical, dental or veterinary furniture; barbers' chairs - cases and cabinets specially designed for hi-fi systems, videos or televisions)	Out
31091230	Wooden bedroom furniture (excluding builders' fittings for cupboards to be built into walls, mattress supports, lamps and lighting fittings, floor standing mirrors, seats)	Out
31091250	Wooden furniture for the dining-room and living-room (excluding floor standing mirrors, seats)	Out
31091300	Other wooden furniture (excluding bedroom, dining-, living-room, kitchen office, shop, medical, surgical, dental/veterinary furniture, cases and cabinets designed for hi-fi, videos and televisions)	Out
31091430	Furniture of plastics (excluding medical, surgical, dental or veterinary furniture - cases and cabinets specially designed for hi-fi systems, videos and televisions)	Out
31091450	Furniture of materials other than metal, wood or plastic (excluding seats, cases and cabinets specially designed for hi-fi systems, videos and televisions)	Out

Table 7.6 Sports and leisure (PRODCOM)

Items such are out but buttons and zippers should be lead free

PRCCODE	Description	
13922270	Pneumatic mattresses and other camping goods (excluding caravan awnings, tents, sleeping bags)	Out
13922430	Sleeping bags	Out
15121100	Saddlery and harness for any animal made from any material (including traces, leads, knee pads, muzzles, saddle cloths, saddle bags, dog coats and the like)	Out
32301131	Skis, for winter sports	Out
32301137	Ski-bindings, ski brakes and ski poles	Out
32301150	Ice skates and roller skates, including skating boots with skates attached; parts and accessories therefor	Out
32301200	Snow-ski footwear	Out
32301510	Leather sports gloves, mittens and mitts	In
32301530	Golf clubs and other golf equipment (including golf balls)	Out
32301550	Articles and equipment for table-tennis (including bats, balls and nets)	Out
32301560	Tennis, badminton or similar rackets, whether or not strung	Out
32301580	Balls (excluding golf balls, table-tennis balls, medicine balls and punch balls)	Out
32301590	Other articles and equipment for sport and open-air games, nec	Out
32301600	Fishing rods, other line fishing tackle; articles for hunting or fishing nec	Out
32404210	Articles and accessories for billiards (excluding mechanical counters, time meters and cue racks)	Out

Table 7.7 Childcare articles (PRODCOM)

PRCCODE	Description	
30924030	Baby carriages	In
30924050	Parts of baby carriages	In

Most of the child care articles are included in other subcategories, mainly as part of other statistical codes in the subcategory Interior decorations. Childcare articles may also be reported in statistics for categories not relevant for this proposal like electrical articles or articles in contact with food

Table 7.8 Keys and locks (PRODCOM)

Whole category was out of scope as it was referred to being out of scope during public consultation.

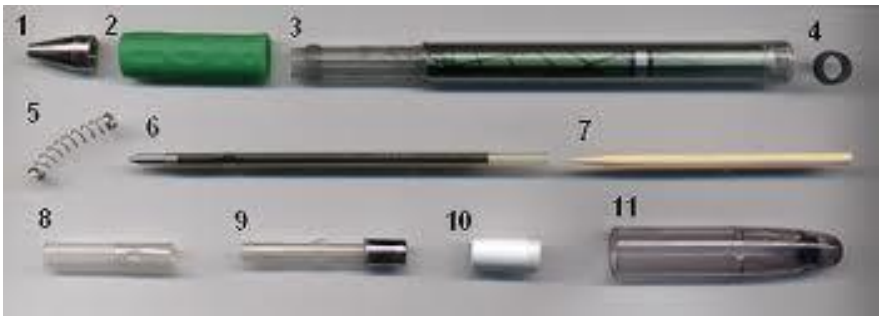
PRCCODE	Description	
25721130	Base metal padlocks	x
25721350	Base metal keys presented separately (including roughly cast, forged or stamped blanks, skeleton keys)	x
25721230	Base metal cylinder locks used for doors of buildings	x
25721250	Base metal locks used for doors of buildings (excluding cylinder locks)	x
25721270	Base metal locks (excluding padlocks, motor vehicle locks, furniture locks and locks used for doors of buildings)	x

Annex 2 – Full break-even analysis

	unit		low cost -High IQ value, low dose/response	Central estimate	high cost - low IQ value-low dose/response
Total cost for one year, €	€	a	11 693 000	24 587 000	42 885 000
Value of loss of one IQ point, €	€	b	25 000	8 000	2 400
Number of IQ to be lost to break even	points	c=a/b	468	3 073	17 869
Daily lead intake pr IQ-point loss	µg/kg bw/day	d	1,08	1,22	1,22
Contribution of each years exposure to IQ	factor	e	1	1	1
One day lead intake pr IQ loss	µg/kg bw/day	f=e*d	1.08	1.22	1.22
Lead intake pr kg bw pr day required to equal cost	µg/kg bw/day	g=c*f	505	3750	21800
Lead intake (pr child (11.57 kg) pr day) required to equal cost	µg/day	h=g*11.57	5 844	43 382	252 225
Migration rate for 1 % lead content	µg/cm2/h	j	0.7	0.7	0.1
Migration rate for 1% lead content, 10 cm2	µg/h	l=j*10	7	7	0.8
Mouthing hours to result in required microgram lead intake (daily)	h/day	m=h/l	835	6197	315281
Number of children per age group EU (0.5-3 years age)		n	5 375 152	5 375 152	5 375 152
Seconds per day required to reach break-even / per European child	s/day	p=m*3600/n	0.56	4.15	211.16

Annex 3 – elements of a pen

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



Element number 6 is the tip of a pen

Annex 4: Calculation of re-engineering costs due to refined scope

Industry submitted comments on re-engineering costs, a cost factor that was not accounted for in the original dossier. ECI reports additional costs of €6.3 million/year for the copper sector if the limit value for brass alloys is set at 0.5% Pb. SEAC agrees to take these costs into account.

The costs associated with product redesign, materials reformulation and alloy refinement are categorized as:

a) operating costs at the smelter,

b) increased material and processing costs at the semi-fabricator´s site, and

c) impact on scrap recycling

A further analysis of these costs is that the figures need to be readjusted in order to account for the reduction in scope.

Of these costs, category (b) is – at least partly – already accounted for in the substitution costs above. The additional costs associated with product redesign etc. are therefore likely to be lower than €6.3 million and €8.1 million, respectively. If the costs in category b) are already fully covered in the substitution cost assessment, the costs associated with product redesign etc. are €2 million and €3 million, respectively. Category (c) is collected scrap from used articles. Consumer articles within the scope of the restriction proposal do not take part in this kind of recycling procedure in the EU, as e.g. metals in packaging materials, vehicles or EEE do. Category (c) is thus not a relevant flow in this case. If cost categories (b) and (c) are excluded, the costs associated with product redesign etc. are around €1 million per year. Furthermore, the new scope assessed by SEAC (Annex 1 in the Draft opinion) implies far less lead metal to be substituted than the original submission from the Swedish CA, which was the basis for the assessment by the industry. With the new scope the total amount of metal supplied to the manufacturing of articles is reduced by 55%, calculated as follows:

With the revised method of estimating the substitution costs (based on amount of lead to be substituted), The Dossier Submitter estimated the quantity of metallic lead to be substituted to be 326 tons. With the revised scope, the quantity of metallic to be substituted was reduced to 147 ton which is 45% of 326, this means a 55% reduction of metallic lead to be substituted.

Consequently, the assessment of the additional costs associated with product redesign etc. of €6.3 million/year (if the limit value is set 0.5% Pb) is likely to be an overestimation. There are three reasons for this: (1) the costs are not fully additional to the substitution costs already accounted for, (2) consumer articles are not recycled as metal waste scrap in the EU and (3) the scope has been significantly reduced.

Consequently the cost for redesign are actually 45 % of €6.3 million = €2.8 million

In order to deal with these estimates, SEAC proposes that the lower value (€2.8 million/year) is taken into the lower end scenario and the higher end estimation of industry (€6.3 million/year) in the high end scenario. The normal average of these two (€4.6 million/year) is taken in the mid scenario.