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

Draft

11 December 2013

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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 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 opinion adopted by 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 SEAC

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***.

OPINION

SEAC has 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 considers that the proposed restriction on ***lead and its compounds*** is the most appropriate EU 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 proposes 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)

1. Shall not be placed on the market 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 an 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 by children.

4. By way of derogation, paragraph 1 shall not apply to:

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

   (ii) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/87[2]), unless they have been treated with lead or its compound or mixtures containing these substances;

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

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

   (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; (see Annex III)

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

[1] 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.

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

or migration.

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

JUSTIFICATION FOR THE OPINION OF SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

SEAC considers that action on a community wide basis is justified, the need to act on a Community 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 good;

2. Regulating lead in consumer articles that can be placed in the mouth through Community wide action ensures that producers of such articles in different Member States are treated in an equitable manner;

3. Acting at Community 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

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, their proportionality, their practicality and their monitorability. Overall, the options 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 are proposed by SEAC to further limit the costs.

SEAC notes 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. USA) to manage the risks posed by the presence of lead in articles - has not been presented in the proposal. It is regrettable that the Dossier Submitter did not include that option in their analysis. SEAC has thus not been afforded the opportunity to assess the socioeconomic impacts of this as a possible alternative practical option and hence SEACs conclusions are bounded by the assessment scope considered in the dossier.

SEAC agrees 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, proportionality to the risks

1. 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 notes that some lead compounds are included in REACH Annex XIV and more lead compounds might be included in the future. Uses of the substances 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 may 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 notes that if it was taken into account, the cost of implementing the restriction could be lower but then the exposure of children to lead from articles would also be lower and as such, the benefits as well.

2. Scope of the proposed restriction

2.1 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.

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[3] 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. SEAC notes that the EN 71-1 does refer to the accessibility of parts, and not specifically to articles as defined in this restriction proposal. Furthermore, 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). Due to these inconsistencies, there might be some problems in using the EN 71-1 standard for this purpose. However, overall these inconsistencies appear to be minor and SEAC considers the use of the EN 71-1 appropriate.

[3] 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.

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

2.2 Derogations

SEAC notes 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.

It should be 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 Public Consultation. This approach does not guarantee that all relevant lead contained article categories that might be faced with unjustifiable socio-economic consequences due to this restriction proposal have been detected and analysed in SEACs evaluation performed for this restriction proposal despite the 6 month Public Consultation period. This is especially an issue as the scope of the restriction as proposed is necessarily so broad to ensure no additional lead uptake by children. SEAC sees this as a potentially serious issue in defining the scope of this restriction proposal and consequently of the SEA performed.

(a) Derogations proposed by the Dossier Submitter

Derogations were initially proposed for keys, locks, musical instruments and second hand articles mainly based on socio-economic grounds including lack of suitable alternatives and for enforcement issues.

Considering the derogation for keys, locks and padlocks proposed by the Dossier Submitter, 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 question the inclusion of the exemption.

The Dossier Submitter has proposed that the derogation for musical instruments is no longer considered necessary as they are unlikely to be accessible to children. Comments in the Public Consultation question this within the context of the definition of accessibility. Although SEAC considers that there may indeed be grounds for agreeing with the Public Consultation comments, there is nevertheless insufficient information on alternatives and possible socioeconomic impacts to include musical instruments within the scope of the restriction.

Furthermore, the Dossier Submitter proposes a general exemption for second hand market articles. Although RAC has indicated there is no difference in risk from second hand articles, SEAC agrees 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 considers an exemption for used articles placed on the market before xx.xx.xxxx (12 months after entry into force of the restriction) as being appropriate taking into account the realistic practical side of the issue.

(b) Issues raised through the Public Consultation process

Following the outcome of the Public Consultation, industry has indicated a number of proposals for derogation, based on risk or socio-economic 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 sees no reason to diverge 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 is 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 has 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 agrees that these cases should also be derogated.

With regard to the nose piece of writing instruments, RAC has not indicated that these are out of scope of the restriction. Since SEAC has not been presented with sufficient evidence to assess this issue, it is unable to make any recommendations. For the moment, therefore, no exemption of the nose piece of writing instruments is proposed.

2.3 Recycled materials

Articles produced from recycled materials are included in the scope of the proposed restriction. SEAC notes that a separate analysis of impacts expected to the recycling sector has not been carried out by the Dossier Submitter. Although some information 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.

3. Costs

For companies 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.

3.1 Substitution costs

SEAC has scrutinised the assessment of costs by the Dossier Submitter. The Dossier Submitter proposes 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 the method based on substitution costs for parts of articles that contain lead. With this method the substitution costs have been estimated at 12 (5.2-18) M€ per year. However, 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) in order 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 guidelines were used along with the relevant guidance related to entry 52 of Annex XVII of REACH as a basis (see section 2.2.) and the derogations and exemptions that were asked for are listed under scope as presented in section 2.2. 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 considered to be in scope in accordance with the definition of mouthing.

The cost estimation in this opinion is based on this set of articles. The total number of articles included in the analysis is around 20 000 million.

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, 2002) with the available statistical information in the PRODCOM database, so as to provide a proxy of the volume of kinds of articles that are mouthed and which might contain lead. SEAC is 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 guidelines that have been deemed to be applicable for this proposal.

2. The mouthing behaviour observed in the DTI study has been established only for those articles that were available to children at the time of the study. Although the list of articles that can be mouthed, according to the DTI study, is extensive it is questionable whether or not the mouthing times can be extrapolated to all consumer articles.

3. The estimation of number of articles per PRODCOM category is based on assumptions regarding a specific relationship between monetary value and weight, for which there is no empirical evidence or other support.

SEAC has reviewed the articles evaluated by the Dossier Submitter and has tried to identify where mouthing seems to be applicable on the basis of the EN-71 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 has been used as the basis for the cost estimation underlying this opinion and is presented in Annex I to this opinion.

SEAC would like to point that the list provided in Annex I is indicative. It is the rapporteurs interpretation of the application of EN-71 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 criteria indicated in the section on scope of this restriction proposal.

Given the above mentioned limitations and interpretations, SEAC is unable to confirm that the approach taken by the Dossier Submitter gives an accurate estimate for the number of articles that could be affected by the proposed restriction and also cannot provide bounds on the degree of uncertainty in the analysis.

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 in the BD. 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 purchased certain articles, 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 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 is 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 23). The information on testing can be found in chapter B 9.3.1 of the BD with additional information in appendices 3 and 4. The weights that the Dossier Submitter has assigned to these studies are apparently based on whether or not articles are independently chosen, representative for the EU market, whether the sampling process is adequately described, and 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. Moreover, SEAC wishes to underline the following shortcomings with the studies used to provide the market shares, with the consequence that the 10% assumption for articles containing lead cannot be confirmed as valid:

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 and that they cover a wide price range and are available in shops of any size. However SEAC cannot establish that the sample is representative and generalisable 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 compared to the variety of articles that are in scope is rather small which makes SEAC question whether the value of 10% can be applied to the whole range of consumer articles. In other words the heterogeneity of the articles in scope (all consumer articles) makes the applicability of the 10% found by the Dossier Submitter questionable.

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 is again unable to verify the validity of the estimate. Although the assumption is subsequently used in the cost calculations, SEAC again has concerns regarding the representativeness and generalisability of the samples.

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), 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 agrees the prices reported and the assumptions and information on substitution seem 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 claims 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[4])

3.2 Costs associated with product redesign, materials reformulation and alloy refinement

The Dossier Submitter did not assess costs associated with product redesign, materials reformulation and refinement of alloys in their proposal. It did take this into account to some extent by basing the higher bound prices on the industry feedback on expected substitution costs for functional lead and by discussing the economic feasibility of alternatives (chapter C). SEAC agrees that there might be costs associated with re-engineering articles etc. due to the need to use new materials in order to be compliant.

Pigments
The Dossier Submitter presents 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.
This information was confirmed on the Public Consultation where information was provided that some lead containing pigments were no longer in use in consumer articles and 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 been achieved. 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 and 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.

As a follow up of questions to industry on the impact of the brass derogation, industry indicated that extra costs will be endured in the order of 6 M€/year when the listed exemptions under point five of the opinion are recognized. The reason additional costs will

[4] http://www.vinylplus.eu/uploads/Progress_Report_2012/VinylPlus_ProgressReport_2012.pdf

incur is that reducing the maximum lead limit to 0.5 % means that copper alloys, which contain lead for technical reasons, can't be used for the current applications in consumer products and have to be substituted by other copper alloys (or other materials offering acceptable performance). Consequently larger amount of copper will have to melted. Additional cost are then 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.

SEAC takes the information from the cupper sector into account in the analytical scope by including these costs in the break even analysis.

3.3 Testing costs for lead content

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 has concluded that the analysis provided by the Dossier submitter does 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

The suggestion made in the Public Consultation that 65% of testing is done via XRF and 35% via destructive testing has been taken into account in the estimation carried out by SEAC. Subsequently the suggestion that a percentage of articles that undergo XRF testing still need to undergo destructive testing has also been taken into account. In the analysis carried out by SEAC it has been assumed that 15% of the XRF tested articles will undergo follow-up destructive testing.

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. This was apparently confirmed in the consultation with stakeholders whilst preparing the proposal (as documented in Appendix 15 of the BD). Further evidence of this can be found in the AFIRM [5] guidelines, which recommend [6] 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 testing cost estimation made by the Dossier Submitter and further elaborated by SEAC is 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:

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

[5] Apparel and footwear industry group: http://www.afirm-group.com/
[6] http://www.afirm-group.com/rsl-guidance/

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 does not agree with the approach set out by the Dossier Submitter as it implies that a priori knowledge on the share of articles that contain lead exists. This does 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[7] 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 proposes 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 test due to the proposed restriction is expected to be very limited.

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 articles are performed. Furthermore, it is known that articles can consist of multiple components for which separate testing might be needed. SEAC agrees 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 is based on the cost of tests for XRF testing known to the Dossier Submitter in the context of their own duties as a CA. This was a price range of about 20-40 € per analysis using XRF screening. Consequently the Dossier Submitter has based its values on the costs of testing on the

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

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 euro per test,

The Dossier Submitter assumes all testing is done using XRF screening. The Dossier Submitter claims that most of the larger retailers and most enforcement agencies have this equipment. It is however not likely that all testing will be performed using this method as the equipment is rather expensive. Therefore, some testing will be performed using wet-tests, which are destructive.

Average price per article

The Dossier Submitter uses 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) 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 6.95 euro[8].

Table 1 gives an overview of the derivation of the testing costs.

	unit		low number of xrf test, low value of destructive test	medium number of xrf test, medium value of destructive test	high number of xrf test, high value of destructive test
Number of articles assumed to contain lead (10% of total articles in scope)	nr	a	2012222159	2012222159	2012222159
share of articles tested		b	0,0001	0,0001	0,0001
Number of articles tested		c = a*b	201222	201222	201222
number of xrf tests per article		d	1	3	6
cost per test	€	e	5	5	5
average cost per article	€	f = d*e	5	15	30
share of articles that are tested with XRF		g = 65%	0,65	0,65	0,65
cost of XRF testing	€	h = f*g*c	653972	1961917	3923833

[8] based on 20 411726 027 articles with an overall value of 142 237 401 935

cost per destructive test	€	i	30	60	90
number of tests per article		j	1	3	6
average cost per article	€	k = i*j	30	180	540
rate of destructive testing		l = 35%	0,35	0,35	0,35
cost of destructive testing	€	m = c*k*l	2112833	12677000	38030999
% follow up test for xrf tested articles		n = 15%	0,15	0,15	0,15
cost of follow-up tests		o = c*g*i*n	588575	1177150	1765725
value of article	€	p	6,95	6,95	6,95
loss of value of tested article	€	q = c*l*p+ c*g*n*p	625826	625826	625826
total testing costs	€	r=h+m+ o+q	**3 981 207**	**16 441 892**	**44 346 383**

Overall the assumptions made by the Dossier Submitter and the following adjustments to the approach on the basis of information submitted via the Public Consultation on testing costs for companies seem to be plausible: the price of testing is based on values which have been confirmed during the Public Consultation. The testing regimes were confirmed by the stakeholder consultation and follow the recommendation set within the framework of the CPSIA. 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 considers 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 16.4 M€ (4.0 M€ - 44.3 M€).

3.4 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. These 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.

3.5 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 (table 1). 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). Finally, in order to incorporate the possible high reformulation/refinement of recycling material costs in the copper sector, , an extra scenario to the previous three scenarios is presented. These scenarios are shown in Annex II.

3.6 Conclusion on costs

Substitution cost
Overall, SEAC supports 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 utilize 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 M€ (range 5.2 M€ - 18.4 M€) per year.

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 can only provide some speculative implications on the testing costs of this restriction.

The estimate derived for testing cost is 16.4 M€ (range 4.0 M€ - 44.3 M€) per year.

Other Costs
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 has received information from industry that if the brass derogation is granted, costs would however be limited to 6 M€/year. SEAC has incorporated these costs into the break-even scenarios, based partly on estimates given during the Public Consultation.

Overall conclusion
SEAC supports the general methodological approach to the modelling of the costs, as described as above. However, due to the shortcoming in data and assumptions made, SEAC cannot assume that the cost assessment represents an accurate portrayal of the costs of the restriction. At best, the cost assessment may provide an order of magnitude estimate, but even that is highly uncertain.

Some cost 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 34.2 M€ 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.

4. 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 regards 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.

4.1 Benefits estimation presented in the Background Document

The assessment of benefits as presented by the Dossier Submitter does 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 might be relevant as well (Pichery et al, 2011)[9], (Gould 2009)[10].

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.

Although RAC estimated that the total exposure to children aged between 6 and 36 months from lead in consumer articles (assuming a 20 minute mouthing time) could be as much as 250[11] g/year (equating to a total IQ loss of 22,000[12] units per year), SEAC cannot use this for the purposes of estimating the annual benefits of this restriction proposal. RAC's estimation is based on extrapolation of hypothetical individual exposures aggregated using a hypothetically relevant population, such that this does not provide a realistic baseline for use in socioeconomic impact assessment.

Moreover, due to the lack of information on actual exposures in the population, suitable for use in benefits assessment, SEAC proposes 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 has been 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

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

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

[11] The total exposure has been calculated using estimations on mouthing time (20 min), migration rate (0.7 µg/cm^2/h/%), surface area (10 cm^2), lead content (1%), proportion of articles in scope of the restriction (22%), proportion of articles that contain lead (10%) and number of children of 0.5-3 years of age (13437880).
1/3 h * 0.7 µg/cm^2/h/% * 10 cm^2 * 1% * 22% * 10% * 13 437 880 = 251.8 g

[12] Based on total exposure, daily intake factor (1.08 µg/kg bw per day), conversion from day to year (*365), body weight per child (11.57 kg) and a factor to account for yearly intake (2,5), IQ loss estimate becomes (3518000000 / (1.08*365*11.57))/2.5= 22083 IQ points.

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 use 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).

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 8000 €.

The Dossier Submitter has based its analysis of the value of IQ losses on the analysis of Grosse (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 8000€, with a lower and upper bound of resp. 2400€ - 25000€ that correspond to 0.3-1.5% wage premiums in lifetime earnings according to previous studies.

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 (22% 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 (22% of 3728 minutes) 820 minutes per day (or 3.47 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 (2.2 % of 3728 minutes) 82 minutes per day (or 0.348 minutes per child). The number of minutes of mouthing articles containing lead per child per year is thus estimated at [0.348 x 365=] 126.85 minutes. It should be noted that this is the time spent mouthing the total number of such item which are already in circulation, rather than the additional items that come into circulation each year (which is the appropriate comparator to make with the 'break even' level.

However, it is not possible to estimate the mouthing time for the additional articles that come into circulation each year, without making some assumptions about what proportion of the total articles in circulation is made of up the additional articles items that come into circulation each year. In order to simplify the analysis, it is furthermore assumed that for any new articles item added to the circulation each year, an old articles items is removed from circulation, and that the lifetime of an item of an articles is 3 years (i.e. the items in circulation will be completely renewed every 3 years).

On this basis then, the number of minutes of mouthing articles containing lead per child per year for additional articles items that come into circulation per year is estimated at 42.3 minutes (2537 seconds) or 6.95 s 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.

Break-even scenario	Break-even point based on Central estimate of costs and benefits.
Number of IQ points lost to balance costs of 34.2 M€.	4279[13]
Lead intake per day (based on 11.57 kg bw/child) corresponding to the IQ points given above.	60395 µg[14]
Mouthing time of lead in articles necessary per day for each and every child in Europe to reach the exposure given above.	5.8 sec per day[15]

The break-even analysis (Full break even analysis in Annex II) shows that the costs are balanced if every child in Europe would mouth the lead in articles containing lead for minutes per year (given that the articles contain 1% lead).

It should be noted however that this assumes an equal distribution of lead intake across every child. As such it does not distinguish between clinically appreciable (in terms of IQ impact of at least 0.1 IQ point) lead intake and clinically meaningless lead intake. In order to assess the break-even level in terms of clinically appreciable IQ impacts, it would be necessary to convert the break-even level mouthing time to the relevant mouthing exposure times that would generate clinically appreciable IQ impacts of 0.1 IQ points.

In accordance with RAC's analysis, for a 1% average lead content, the daily 'default' mouthing time necessary to produce a 0.1 IQ point deficit is 5 minutes. Accordingly, the number of relevant children in the EU population which would have to mouth the lead in lead containing articles for the 5 minutes every day of the year required to produce a clinically appreciable IQ impact of 0.1 IQ point is around 223,000 children. This is around 1.65% of the population of children (or about 1 in every 60 children).

However, taking into account that lead is a non-threshold substance, and the level of the

[13] Number of IQ points to break even = total cost per year divided by the value of IQ point (8000 €); 34229076 €/8000 €/IQ point = 4279 IQ point. It must be noted that the cost estimate is subject to remarkable uncertainties, specifically relating to testing costs.
[14] Lead intake per day = Number of IQ points to break even (4279)* daily lead intake factor (1.08) * body weight per child (11.57 kg) = 60395 µg
[15] The mouthing hours required for daily lead intake calculated in = lead intake per child per day (45819) / migration factor for 1% lead content and 10 cm2 (7) =8628.
Daily mouthing time = Mouthing hours required for daily lead intake, converted to seconds, divided by Number of children in relevant age group = 8628*3600/ (13437000/2,5) = 5.8 seconds.

background exposure, also clinical non-meaningful IQ impacts may be relevant on society level. Furthermore children that daily mouth leaded consumer articles for more than 5 minutes have a higher loss of IQ points.

5. Proportionality

In the assessment of costs the Dossier Submitter has 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 on the benefit side have not been able to be established adequately, though a break-even analysis was undertaken based on the available parameters used to develop the cost assessment. The following summarises the estimations done after RAC's and 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 15.2 M€ and 68.7 M€ with a central estimate of 34.2 M€.
- the number of relevant children in the EU population which would have to mouth the lead in lead containing articles for the 5 minutes every day of the year required to produce a clinically appreciable IQ impact of 0.1 IQ point is around 223,000 children. This is around 1.65% of the population of children (or about 1 in every 60 children).

The associations between lead and different measures of cognitive abilities are typically described in terms of the effect of lead on IQ and earnings. It is estimated that the value of one lost IQ point is around 8,000 € (with a range between 2400 € and 25,000 € used for sensitivity analysis).

Based on, albeit highly uncertain, estimates of actual mouthing times for articles containing lead for a sample of children in the UK, it would appear that actual mouthing durations may exceed those that would be required to achieve the 'break even' level of mouthing duration per year. However, a sensitivity analysis on the 'break even' level of mouthing duration indicates that when more conservative parameters for the cost of the restriction and the value of a lost IQ point are used, the actual mouthing duration (based on a sample of UK children) does not surpass the estimated break-even durations.

It should be noted other effects than solely loss of IQ points is likely impacts of lead exposure to children, e.g. impaired school performance, distractibility, short attention span, impulsivity, perseveration and increased activity. Although linked, these impacts are not all covered by life income impacts which are the basis for the actual analysis of proportionality. Furthermore, the assessment of benefits does not include other potential benefits of reducing lead exposure. These include non-cognitive functioning and other health and non-health related endpoints.

It should be underlined that the estimations carried out in this analysis come with a high degree of uncertainty and are based on a number of unverifiable assumptions.

Having considered uncertainties SEAC concludes that the restriction is justified from the point of view of proportionality of costs and benefits.

Practicality, incl. enforceability

Content vs. migration

SEAC notes that RAC prefers 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 regards that the two-way approach (content limit unless it can be shown that migration does not exceed a given value) would in appropriate circumstances be a good option, as it would reduce any unnecessary cost on industry when lead is present but not available for exposure.

However, while there have been some developments regarding the test methods for the determination of migration, taking into account that a standard test method mimicking mouthing conditions is not yet available and also bearing the conclusions made in the context of the restriction proposal concerning lead in jewellery in mind, SEAC considers that a restriction based on content is more practical for implementation and enforcement than a restriction based on lead migration. Moreover, SEAC notes that the FORUM has raised the enforceability of the migration limit as an issue. Therefore, SEAC considers content to be the preferable property to be restricted.

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 agrees to propose a derogation accepting a higher limit for brass alloys.

Therefore SEAC recommends that the restriction should be based on content (w/w), and SEAC recognises that the values recommended by RAC of 0.05 % (and 0.5% for brass alloys) are practical and a less costly method to implement than a migration test.

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 agrees with the Dossier Submitter conclusion.

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

Monitorability

The SEAC rapporteurs consider that monitoring is possible and that major monitoring costs are not anticipated.

BASIS FOR THE OPINION

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 nose piece of pens and a higher limit for brass alloys. In addition, articles covered by European Union legislation specifically regulating lead content have been proposed to be exempted.

The basis for these changes is information received during the Public Consultation, 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 evaluation of the Dossier submitter

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

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
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	In

PRCCODE	Description	In scope
	(excluding knitted or crocheted and for industrial and occupational wear)	
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
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
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.

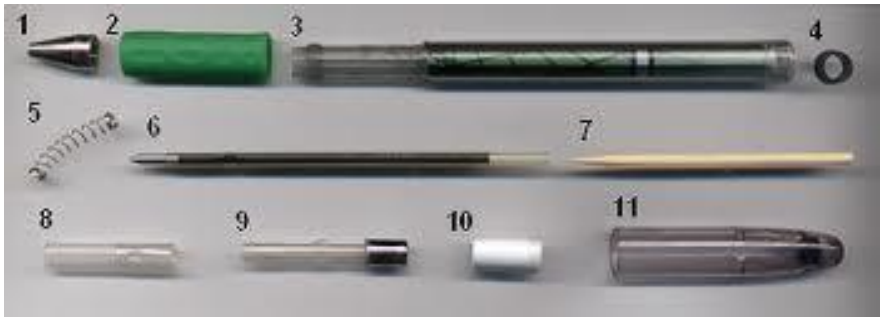
PRCCODE	Description	
25721130	Base metal padlocks	x
25721350	Base metal keys presented separately (including roughly cast, forged or stamped blanks, skeleton keys)	x
25721230	Base metal cylinder locks used for doors of buildings	x
25721250	Base metal locks used for doors of buildings (excluding cylinder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

Break even calculation of lead in articles starting from four different calculations of costs					
	unit		low cost -High IQ value, low dos repsonse	Central estimate	high cost - low IQ value-low dose/response
Total cost for one year, €	€	a	15 141 179	34 229 075	68 760 778
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	606	4279	28650
Daily lead intake pr IQ-point loss	µgram	d	1.08	1.08	1.22
Contribution of each years exposure to IQ	factor	e=	1.0	1.0	1.0
One day lead intake pr IQ loss	µgram	f=e*d	1.08	1.22	1.22
Lead intake pr kg bw pr day required to equal cost	µgram	g=c*f	654	5220	34953
Lead intake (pr child (11.57 kg) pr day) required to equal cost	µgram	h=g*10	7 568	60 395	404 411
Migration rate for 1 % lead content	µg/cm^2	j	0.7	0.7	0.1
Migration rate for 3 cm2	µg/cm^2	k=j*3	2.1	2.1	0.2
Migration rate for 1% lead content, 10 cm2	µg	l=k*10	7.0	7.0	0.8
mouthing hours to result in required microgram lead intake (daily)	hours/	m=i/l	1 081	8 628	505 513
Number of children per age group EU (0.5-3 years age)		n	5 375 152	5 375 152	5 375 152
Secondsper day required to reach break even / per European child		p=m*3600/n	0.7	5.8	338.6
minutes per year			4	35	2 060
second per day			0.72	5.78	338.57

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