Committee for Socio-economic Analysis (SEAC)

Response to comments on the SEAC draft Opinion on the Annex XV dossier proposing restrictions on Lead and its compounds

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Lead and its compounds
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Comments on the SEAC draft opinion and specific questions

Specific questions:

Question 1: Would it be helpful to introduce a migration limit (see below) to ensure an alternative manner of compliance to the restriction? Would there be any issues for industry, including SMEs and importers, and is there evidence on the availability of a test methodology, costs, or commercial testing facilities, that migration limit could be complied with?

x. "The content limit restriction 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 , does not exceed 0.05 µg/cm2 per hr (0.05 µg/g per hr)."

Question 2: SEAC is still considering an exemption for the noses of writing instruments. It would welcome socio-economic and other information to either justify a derogation or to concur that this use should be restricted.

Question 3: RAC and SEAC have maintained exemptions for keys, locks, padlocks and musical instruments in the restriction opinion as had been proposed by the Dossier Submitter. SEAC welcomes substantiated socio-economic and other information to understand if the derogations are justified or if they should be reconsidered. Such information could relate to the availability and possible additional costs of alternatives, (i.e. lead free keys, locks, padlocks or musical instruments).

Ref.	Date / Country / Organisation / MSCA	Comments and answers to questions
87	**Date / Time:** 2013/12/23 13:42 **Type:** Individual **Name confidential:** False	**Comment:** Good to see that true to form, Europe chooses to come up with something different to USA (0.01% total lead in all articles intended for children under 12 years) so global companies and SME's selling into these markets will have different scopes and different requirements to consider for different products. Whilst an alignment of legislation with our major trading partner would help business and protect children it would of course be a bit too easy and might even suggest the European institutions would not need quite so much funding and personnel to perform their tasks.
		Answer1: Depends if the intention is to restrict lead at all times or protect health of children. If it is the latter then if it can be shown that lead does not migrate from a material when children put it in their mouths or swallow a part so no exposure, then of course it would be helpful. Noted that EN71/1 may be used to determine accessiblity but that a migration rate will be given in the new law to ensure toy companies and those using toy requirements cannot use EN71/3 to demonstrate compliance with the proposed new lead law. Because that would really be helpful and save companies money I trust I will be vigourously prevented by EU regulators.
		SEAC Rapporteurs response Thank you for your comment. We appreciate the work done by the Dossier Submitter regarding the definition of the scope. Please note that toys are out of scope of the proposed restriction because they are already covered by European Union legislation (Toys Safety Directive, 2009/48/EC) specifically regulating lead content or migration.

88	**Date / Time:** 2013/12/30 12:32 **Organisation:** National Authority **Type:** BehalfOfAnOrganisation **Country:** Austria **Name confidential:** False	**Answer1:** It has to be noticed that introducing two parallel concepts for limiting lead in regulated articles forces national enforcement authorities (NEAs) to perform parallel compliance checks (and the related laboratory tests) based an any of the limit value concept stipulated in the restriction regulation prior to a final conclusion on the compliance status of the official sample taken. This is valid unless a clear hierarchy for the limit value concepts is defined. As a consequence the SEAC draft opinion poses considerably more burden of proof and more resource demands on NEAs. Once a migration limit value concept is included into the restriction, it has to be ensured that technical details of this concept have to be made available. For this purpose a concept and description needs to be ensured that is at least comparable to current best available technique for determination of migration in the area of toys or food contact materials/articles.
		SEAC Rapporteurs response Thank you for your comment. The feasibility of the migration limit will be considered in the light of the available technical and socio-economic evidence. Should both a content limit and a migration limit be proposed as restriction limits, then they will be recommended as two complementary tests, meaning that companies should comply with the content rule unless they can demonstrate that actual migration falls below the limit ("tiered two-way approach") and thereby poses no health risk.
89	**Date / Time:** 2014/01/16 01:18 **Type:** Individual **Name confidential:** False	**Comment:** Lead free alloys (max 0,1% Pb) are available in the market. From the ethical side I do not see any reason why still using Pb in the alloys when a technical solution is available (CW 724R-DW for example, 511L etc...). Also consider the Low lead law in the USA. For this market the lead free materials are already used... (drinking water applications). Economical: sone companies already invested in producing products from these lead free alloys. Confirming further use of lead contaning alloys is negative towards these companies who invest in clean materials and products. Production with lead free products is growing in USA and Asia 7 China,

		because of the Low Lwad Law in USA. By keeping high concentrations of Pb in the material in EU, the EU gets behind in technology and hygienic performance.Many products and applications can be done in lead free alloys.
		SEAC Rapporteurs response Thank you for your comment and the general support for phasing out lead. The technical and economic feasibility of lead free alloys has been reflected in the draft opinion and discussed in more details in the Background Document (in particular in the section C on alternatives).
90	**Date / Time:** 2014/02/04 15:26 **Organisation:** International NGO **Type:** BehalfOfAnOrganisation **Country:** Belgium **Name confidential:** **True**	**Comment:** **[...]** submitted arguments during the 1st public consultation outlining as to why ammunition should be out of scope from the proposed Restriction. We would like to take the opportunity to kindly ask that we receive confirmation that ammunition will formally be excluded from the final text of the proposed restriction
		SEAC Rapporteurs response Thank you for your comment. Ammunition was not included in the analysis carried out in view of the current restriction proposal and is excluded from the scope of the proposed restriction.
91	**Date / Time:** 2014/02/07 03:36 **Organisation:** Industry	**Comment:** **[...]** fully supports the SEAC´s draft opinion on the proposed restriction on lead and its compounds under the REACH Regulation.

	or trade association **Type:** BehalfOfAnOrganisation **Country:** Japan **Name confidential:** **True**	Above all, the opinion proposes to exempt "articles covered by European Union legislation specifically regulating lead content or migration" from the new restriction under REACH, and it will avoid possible confusion (including SMEs) in the implementation of the restriction of lead, especially for the products which have been covered by the RoHS Directive 2011/65/EU. Thank you very much for your due consideration on our previous comments. **SEAC Rapporteurs response** Thank you for your support.
92	**Date / Time:** 2014/02/07 10:10 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation **Country:** Belgium **Name confidential:** False	**Comment:** Comments for Optical frames and Sunglasses Compliance Cost. CALCULATION OF COMPLIANCE COSTS C =(p2-p1) q2 (p2-p1): increased cost between the “baseline” scenario (p1) and the “restriction” scenario (p2) q2 : number of units placed on the market in the “restriction” scenario The number of optical frames and sunglasses placed on the market during 2012 was 1.400.000.000 pairs (source: Global Trade ATLAS). For this reason the Cost of Compliance will be great, and effect millions of consumers, given that the market is global all items produced must comply the EC regulations. Comments concerning RAC Opinion adopted 10 December 2013 Articles in scope of the restriction •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. Comments: 1. Why Spectacle frames and not Sunglasses as well? This indicates a basic misunderstanding of

		the matter due to the fact that sunglasses represents ⅔ of the total production and the 2 items can be considered absolutely similar in use by the consumer and in the manufacturing processes. 2. To what “weights” are they referring? 3. It is not correct that “accessibility to migration” is solely dependent on the presence (or lack thereof) of a coating – design plays a large role. 4. It is already the case that Lead free metal alloys, plastics and paints must yet be used to manufacture optical frames and sunglasses. 5. For technical or cosmetic reasons almost all frames and sunglasses are protected with an organic coating: the small percentage that is not, could most often be manufactured with rolled gold or titanium. 6. If Spectacle Frames and Sunglasses would be listed among Articles in scope of the restriction in any extent, manufacturers will be forced to exhibit compliance certificates even if the product is lead-free and is protected with an organic coating: this would create a Compliance Cost that would seem to be disproportionate given that the restriction is addressed to avoid any possible risk of mouthing by small children. 7. Only a small percentage of frames and sunglasses are luxury goods, most of them are daily use consumer goods and increased costs will affect commerce negatively. 8. For metallurgical reasons, Lead-Pb can only be used until 0,1% or 0,2% in alloys for specific applications, namely the production of screws and internal hinge mechanisms, the reason being that lathe performances are improved because the breaking of metal chips is enhanced. In the case restriction, the producers will use an alternative alloy without Pb to manufacture the screws and some mechanism of the spring hinges: this would lead to a reduction of energy efficiency and of the tools lifetime by a certain extent which also add to cost without a perceived hazard. 9. Mouthing and direct skin contact of internal screws and hinge mechanisms of spectacle frames and sunglasses is not possible without disassembly. Given that: - the restriction is addressed only to articles which children have access to in their daily lives, as only these articles can be considered to pose a risk to the children: it has been estimated that 95% of optical frames and sunglasses, corresponding to the largest volume of items, are not available for mouthing (rest_lead_bd_db010957-56_tc_en page 240) - any restriction could generate enforcement and implementation (testing) costs.

		- any restriction involving optical frames and sunglasses generates a huge Compliance Cost. - Eyeglass and sunglass frames may not pose other risks to human health or the environment. the Regulatory matters for frames group ask: 1. to use always the wording: Eyeglass and sunglass frames 2. to delete Spectacle frames from the list of Articles in scope of the restriction. 3. to include Eyeglass and sunglass frames in the list of articles not intended to be accessible to children during normal or reasonably foreseeable conditions of use 4. to avoid any possibility of wrong interpretation of the restriction by using a sentence such as the following: Eyeglass and sunglass frames are exempted from the restriction, as they are coated articles, and any possible exposure to Lead for small children would not occur during normal or reasonably foreseeable use.
		Answer1: A migration restriction is not applicable for the following reasons: o The high uncertainty of the migration processes: after 20 years of standardization work concerning Ni migration, the uncertainty of the method in force(EN 1811)is 75%. o Measure a migration of 0.05 [µg/cm2/hr] is technically impossible; moreover the release is not linear. o The assumption that there is a linear relation between content and migration is untrue due to the fact that a metal alloy is like a team: the behaviour of each player is affected by the others, than the same content of Pb in different alloys does not mean that the migration will be the same. o The assumption that the migration restriction it will likely be more accurate than a content restriction is purely theoretical and not applicable. o Develop the testing method will be too expensive.
		SEAC Rapporteurs response Thank you for your comments, especially regarding migration limits The RAC opinion- which is not included in the frame of this public consultation-has addressed the risk

		aspects of spectacle frames (which to our understanding covers all types of glasses) in link to the issue of coating. As noted, spectacle frames are considered as items within the scope of the proposed restriction unless migration is sufficiently limited by coating. It should be noted, that Information received by other stakeholders during the earlier public consultation (e.g. ECI, 2013), claimed that due to nickel content spectacles are-in principle-coated. Furthermore, it is not clear from this comment whether brass alloys are mainly used for this application, but if that be the case then the proposed exemption (under 4(iv) would also be applicable for this type of articles.
93	**Date/Time:** 2014/02/10 11:49 **Type:** Individual **Name confidential:** False	**Comment:** In terms of enforcement and analytical testing expenditure the proposal of a limit based upon lead content in consumer articles is the best solution.
		Answer1: From a toxicological point of view it is the migrated concentration of the metal that is important. The introduction of a limit for lead based upon migration would not be concerned with skin contact or ingestion, but with mouth contact. Presently there is no European standard for lead migration from consumer articles, due to mouth contact. Analytical methods that are currently quoted for the determination of lead migration are based upon EN 71-3 or variations upon, which simulate the migration of lead after the article has been swallowed. Although it could be argued these methods represent the worst case scenario, they do not accurately simulate mouth contact and thus incorrectly estimate the lead migration. The SEAC draft opinion report does not consider in this respect the economic consequences to manufactures that export articles to countries such as China and USA where methods based upon EN71-3 for lead migration are currently applied. In such cases where the article does not exceed the European restriction proposal limit of 0.05% lead, the article can still fail the limit set for the EN71-3 migration test and consequently cannot be placed on the market. Additionally to the migration method issue insufficient consideration has been given in this report on how to address the problem of coated articles. The method quoted in this report EN 12472 was developed to simulate the wear and corrosion over a period of two years of normal use, of coated nickel containing articles. It is important to realize that this method as is stated in the introduction to

		the standard is to be considered as a pragmatic approach to simulate a complex interaction of various factors. There is absolutely no evidence that this method can be applied to simulate the wear and corrosion of lead containing consumer articles. Any future restriction proposal based upon lead migration will need to carefully consider how to deal with the issue of coated articles. In conclusion it should be considered to develop a European standard for lead migration with mouth contact and an associated wear and corrosion standard. A mandate from the European commission on CEN would be the appropriate way to start this development process. Due to the extra financial burden that migration testing would impose on manufacturers, exception regulations should be considered for lead containing consumer articles, that are shown to have a lead migrate significantly below 0.05 µg/cm2 per hr (0.05 µg/g per hr). Due to the complex nature of migration tests, the range of consumer articles proposed for this restriction and the issue of coated articles, the time required to develop these European standards and the associated financial expenditure should not be underestimated.
		SEAC Rapporteurs response Thank you for your comment and deliberation on migration methods, which will be carefully considered. The issue of migration testing (technical and socio economic aspects) will be further discussed with SEAC in the March Plenary meeting and be reflected in the final SEAC opinion and the Background Document.
94	**Date / Time:** 2014/02/10 15:01 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation **Country:** France	**Comment:** Project for the restriction of the use of lead and its compounds in items for consumers Submission to the Socio-Economic Analysis Committee (SEAC) of the European Chemicals Agency (ECHA) produced by The National Jewellery-making, Gold Jewellery-making and Silversmiths, Gift Makers and Decorative Arts Industries Trade Association (BOCI) The French Association of Watchmaking and Microtechnology (CFHM) The Federation of Handmade and Mixed Crystal and Glass-making Industries (FCVMM) The French Watchmaking Federation (FH) The Union of Jewellery and Watch Retailers (UBH)

	Name confidential: False	& The French Union of Jewellery, Silverware, Gems and Pearls (UFBJOP) With the support of the Francéclat Committee, the French Watchmaking, Jewellery, Silverware and Tableware Committee Within the scope of the report presented by Sweden to the European Chemical Agency (ECHA) regarding a proposal to restrict the use of lead and its compounds in items for consumers, the above-mentioned organisations are presenting their viewpoint of the preliminary opinion of the Socio-Economic Analysis Committee (SEAC), considering the consequences such a restriction would have on the manufacture and trade of their products. We are in agreement with the SEAC about the necessity to specify that items already covered by specific regulations limiting the presence of lead do not fall within the field of application of the future restriction. In effect, the jewellery and watchmaking sectors have, since 2012, been subject to a restriction of the use of lead and its compounds in items of jewellery and in the external components of watches (regulation n°836/2012/CE). For the watchmaking sector, this regulation, which came into effect in October 2013, clashed with an existing directive limiting the quantity of lead in quartz watches: directive n°2011/65/CE known as RoHS. The interference between these two regulations was a source of confusion and divergent interpretations for industry professionals, particularly in the case of relations between subcontractors and contracting parties. It made their application particularly difficult, notably because of the lack of coherence as these two regulations set the regulatory limits and had different exemptions. Considering the above, any text providing a restriction must systematically indicate that items already subject to a specific regulation do not fall within the field of application of said restriction project. Furthermore, the restriction project proposes to exempt crystal, enamels and precious stones, which is the case in regulation n°836/2012/CE, exempting all use of these materials. This proposal demonstrates the pertinence of the arguments highlighted during the preparation of the restriction specific to the jewellery and watchmaking sectors and particularly the existence of significant socio-economic issues associated with a weak even non-existent risk. The internal components of watches which are exempt within the scope of regulation n°836/2012/CE have not been explicitly mentioned in the list of exemptions proposed by the SEAC and the RAC because of the field of application of the restriction, which only concerns the accessible parts of the

		items. This field of application limited to accessible parts of the items seems perfectly aligned with the objective of this regulation project, to protect children from the risk of lead poisoning through sucking an item containing lead. As the risk highlighted within the scope of this project is the same as the risk which motivated the establishment of the restriction limiting the amount of lead in jewellery and watchmaking items, we would have preferred that this notion of accessibility had been as clearly defined in the restriction specific to our sectors and are therefore totally in favour of this approach, which reduces the legal risks associated with the interpretation of this notion. To conclude, we are in agreement with the proposed project of the SEAC and insist on the need to specify, as is the case in this project, the exemption of items already subject to regulations restricting the use of lead, out of concern for clarity, coherence and legal safety. We are also satisfied that the available information concerning crystal, precious stones and enamel led to the same conclusion as during the preparation of regulation n°836/2012/CE, meaning a weak even non-existent risk and a significant socio-economic impact. Furthermore, the proposed field of application which only covers the accessible parts of the items, seems consistent with the objective of the restriction.
		SEAC Rapporteurs response Thank you for your comment and the support.

95	**Date / Time:** 2014/02/10 15:01 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation **Country:** Germany **Name confidential:** False	**Comment:** We acknowledge and recognize the importance of this regulation and in general agree with the risk approach taken. While we do insist that writing instruments should be exempted for reasons detailed previously, if they are not, then we fully support the proposed exemptions and particularly the exemption of the ball pen tips, because of their small size and because of the non-availability of alternative materials with low lead content ensuring acceptable quality of the component necessary. The data supporting this exemption have already been given in the first stage of the consultation. It is important however to bear in mind that the implementation of this new regulation will generate important costs for the writing instruments industry.
		Answer1: A migration limit approach is a helpful alternative manner of compliance: We agree that a restriction based on the total lead content is surely simpler and more practical than a restriction based on a migration limit. However the content based approach also has downsides with risks of very high costs for the development of new materials or of significantly higher manufacturing costs because of a too low lead content into the raw material. Therefore the migration limit approach would be a helpful alternative method. The Toy industry is used since years to dealing with heavy metals migration measurements within the scope of the EN71-3 standard and based on this experience the alternative should be reasonably implementable. The migration approach, i.e. the demonstration that migration does not exceed a given value, is appropriate as regards nosecones when they are coated, which most of them are. The migration limit would be a helpful alternative as it would reduce unnecessary costs on industry when lead is present but not available for exposure. The migration limit approach requires identifying how to perform a reliable and repeatable test to measure the migration from articles or part of them. Specifically for the nose cone we should test single components, since the internal components of a pen could unduly alter the results and artificially influence the migration values. The industry together with the RAC experts and the metal raw material

		manufacturing industry should be ready to create a working group to identify the most appropriate method to measure the lead migration from metallic parts to artificial saliva. Test of normalized disc (coated or uncoated) in artificial saliva (similar to the one already used in other standards, see for instance DIN 53160-1:) could be sustained by our industry. The proposed migration limit of 0.05 µg/cm2 per hr (0.05 µg/g per hr) is suitable.
		Answer2: Social argument: low exposure As was set forth by the RAC report regarding tips (the part where the ink comes out), nosecones are also small, so that there is a very low potential for exposure and therefore they should be exempted as well. The surface area of a metallic nosecone is much smaller than the 10 cm^2 assumed. According to downstream user information, it typically has a surface area of 3 cm^2. Also, the probability of mouthing the nosecone of a pen is small. Finally, the nosecone is often coated. Economy: uneven playing field if metallic nosecones are not exempted The European Writing Instruments industry is deeply concerned about the loss in competitiveness against imported products from Asia, which would be unfairly generated by the implementation of the restriction of lead inside the raw material, if pens, or at least nosecones, were not exempted. Pens in the low price segment do not have a metallic nosecone. Only medium and high quality pens include a metallic nosecone. This means that on the one hand, the probability of mouthing a pen with a metallic nosecone is low. On the other hand, the manufacturing costs will be highly increased if the lead content is limited. Latest knowledge shows that the machinability can be decreased by about 50% for Pb-free raw materials in comparison with brasses with about 3% of lead. Metallic nosecones, as a major element influencing the perceived weight of the pen, are considered by consumers as the key item of a higher quality pen, distinguishing it from cheap ones. Medium and high price pens are mostly manufactured in Europe. Low cost pens originate mainly from Asia, China particularly. European pen manufacturers already face tough challenges with competition from Asian manufacturers: an increase of manufacturing costs impacting more specifically the European manufacturers would enlarge the cost-gap. The risk is really to drive that industry in Europe

		to the end by adding unfair conditions to an already uneven playing field, when a level playing field allows European manufacturers to be competitive. Considering that: • the proportion of pens with a metallic nosecone being small compared with those having a plastic nose cone, the probability of mouthing a metallic nosecone is small • most of the nosecones are coated • the generated increase of manufacturing costs would penalize more the established European manufacturers than main competitors coming from Asia • the generated increase of manufacturing costs will be disproportioned to the actual improvement of safety in relation to mouthing, the European writing instruments industry can rightly claim that it is essential that nosecones as another part of writing instruments should be exempted. Reminder: functionality of lead in copper alloys Lead is added as a functional alloy constituent because lead, embedded as tiny globules (e.g. in brass alloys), acts as a lubricant and, most importantly, as a chip breaker, allowing the high performance machining of semi-products, without continuously damaging the product itself or the production tools. This results in extended tool lifetime, higher productivity and less usage of resources, together with a high quality surface of the machined material. In addition, lead exhibits corrosion-inhibiting characteristics which minimizes the corrosion/metal release of the other alloy constituents. The combination of delivered properties presents a significant challenge in the search for a suitable substitute for lead. Over the last 10-15 years, the industry has reduced, to a minimum, the amount of lead needed for a series of copper alloys while still fulfilling downstream customer requirements. Beyond nosecones Fountain pens nibs and luxury pens should also be exempted based on their very low exposure to mouthing a. Fountain pens nibs The observations made in the RAC report regarding the low exposure to mouthing of the tip of ball point pens is all the more true in respect of the nib of fountain pens : - The nib of the fountain pen is a small part, with a surface area much smaller than the 10 cm^2 assumed in the generic risk assessment; - More than ball point pens, fountain pens are not meant, and are extremely unlikely, to be left for use

		by very young children. And when used by older children, the nib of a fountain pen is extremely unlikely to be placed by them in their mouth, due to the ink visible on the pen and the more voluminous ink flow. b. Luxury pens Luxury pens, due to their value, are not intended for use by children and are even less likely to be left accessible to children in homes. Indeed consumers pay more attention to higher value pens intended to be used for a long time period. In the case of luxury fountain pens, this behavioral barrier preventing children's exposure adds to the points raised under a. above, making exposure to mouthing even lower. Luxury pens can be defined by relying on the criteria already relied upon in EU legislation and case-law for other luxury product categories (cosmetics, lighters …). They are characterized by a sophisticated design using expensive material, a luxury image and a low degree of substitutability with other fountain pens, and a distribution in outlets in accordance with the prestige and luxury image of the brand. They are designed, manufactured and placed on the market such as to ensure a continual expected use over a long period of time, are covered by a written guarantee and benefit from an after-sales service for replacement or repair of their parts over their life time.
		SEAC Rapporteurs response Thank you for your comment and the information regarding pens, their manufacture and the concept of setting a migration limit for measuring lead migration from the –most often- coated nosecones. The issue of the requested exemption for nosecones (along with any relevant information of technical/socio-economic aspect submitted via the Public Consultation) were carefully considered by SEAC and be reflected in the SEAC opinion.
96	**Date / Time:** 2014/02/12 12:27 **Organisation:** Industry or trade association	**Comment:** Comment 1: The draft SEAC opinion recommends the use of EN 71-1 (section 8.10) to define the term accessibility. Two accessibility probes are defined in EN 71-1. They have different dimensions and they overall length with their extension reach about 61 cm. First it's unclear which one is recommended to be used

	Type: BehalfOfAnOrganisation **Country:** Belgium **Name confidential:** **True**	and secondly, these probes have never been defined to evaluate what is accessible to mouth but what may be accessible to children's hand. They are used to make assessment of accessible parts of toys which are consumer products specifically designed for children and have never been defined for another purpose. Therefore recommending to use these probes to determine what can be placed in the mouth by children is inappropriate. The proposed restriction also requests to consider that 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. This approach is based on a guidance document which has been established for the purpose of providing guidance of a restriction covering toys and childcare articles which are consumer products designed to be used by children. That means that exposure to children is obvious for these products which is not the case for all categories of consumer products covered by the proposed lead restriction. Considering that approach, a hook intended to be placed in a wall at a height of 1 meter would be accessible according to the probe evaluation and since it would be smaller than 5 cm in one dimension, it would fall under the scope of the proposed restriction. The above is a non-sense from an exposure based scenario. It is therefore totally disproportionate that the sole criteria retained in the proposed restriction for assessing whether a consumer product could be placed in the mouth by children is based on a dimensional approach and an hand accessibility assessment (probes) and is not based on the likelihood of a children to place it in his mouth and to keep it. Comment 2: The SEAC draft opinion contains an interpretation on the categories that could be considered to be affected by the proposed restriction (appearing in Annex 1 of the document). It is crucial that this Annex 1 become a part of the restriction so that the scope is accurately defined, otherwise this would leave an open door to totally different interpretations of the scope. Comment 3: The proposed restriction contains a list of exemptions and in particular the following one: (vii) articles covered by European Union legislation specifically regulating lead content or migration. There is a significant list of harmonised standards under the General Products Safety Directive

		(2001/95/EC) which, for some of them, already contain lead restrictions. This list should be also taken into consideration to exclude from the proposed lead restriction the consumers' products which are already regulated for lead content or migration. Therefore item (vii) of the list of exemptions to the proposed lead restriction should be amended to indicate: « (vii) articles covered by European Union legislation including harmonised standards under the General Products Safety Directive (2001/95/EC) specifically regulating lead content or migration.
		Answer1: A migration limit is an appropriate way to cover the risks since it is based on an actual exposure scenario, which is not the case for a total content which is only hazard based. Therefore a migration limit should be retained. It's unclear how the link is made between 0.05 µg/cm2 per hr and 0.05 µg/g per hr (meaning the conversion from cm2 to g). CEN and ISO should be contacted to determine whether they have already developed or are developing standards which could help for the purpose of defining a migration method in saliva.
		SEAC Rapporteurs response Thank you for your comment on the migration limit, which will be carefully considered by Rapporteurs and SEAC. Concerning the scope, it should be noted that EN 71-1, is applicable not only for toys but also for childcare articles (as discussed in the EC guideline for phthalates[1]). Childcare articles are covered by the proposed restriction and represent a typical category of consumer articles that can be mouthed by children. Furthermore, please note that the hand-mouth activity, though contributing to exposure, is not the focus of this analysis. As explained in section B.9 of the Background Document the analysis is based on quantification of oral exposure as a consequence of mouthing behaviour. RAC has concluded (adopted opinion of December 2013) that the concept of 'not accessible by children

[1] 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)

		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) as appropriate to define the articles covered by this restriction, if combined with the relevant derogations. SEAC had agreed to this approach and overall considers that EN71-1 is appropriate to define accessibility and facilitate the judgement of whether articles fall within or out of the scope of the proposed restriction.
97	**Date / Time:** 2014/02/12 15:49 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation **Country:** United Kingdom **Name confidential:** False	**Comment:** BEAMA supports SEAC's draft opinion on possible restriction for lead and its compounds in articles that are likely to be placed in the mouth by children. The examples of articles cited in the proposal lead us to believe that this restriction is not intended to apply to Rigid PVC articles used in certain construction products. Construction products are the least likely to be placed in the mouth by children. Such articles are historically manufactured from PVC waste (recovered/recycled PVC) which may contain lead. In order not to prevent the use of recovered PVC in construction products derogation was granted in respect of cadmium by COMMISSION REGULATION (EU) No 494/2011 (Recitals 11, 12 and 14 refers). The use of recycled materials is consummate with a whole raft of EU Sustainability Goals and would be a key contributor to its resource efficiency, recycling and waste prevention targets. Recovered PVC may also contain lead; the grounds for a similar, specific exemption for use of recovered PVC in construction products under this proposal are identical. The use of lead compounds as stabilisers in new PVC will be phased out in the EU-27 by 2015 under the industry voluntary commitment. To ensure that the proposed restriction is not applied unintentionally to construction products, BEAMA requests that derogation be added to paragraph 4 as follows: VIII. mixtures and articles containing recovered PVC in rigid PVC applications
		SEAC Rapporteurs response Thank you for your comment and the information on the recycled PVC lead containing products. Please note that that the proposed restriction covers articles that can be placed in the mouth by children (whether accessible to them during normal or reasonably foreseeable conditions of use). The construction products (due to their non-consumer nature and non-typical accessibility to children) are

		therefore excluded from the scope of the proposed restriction. Therefore no exemption would be considered necessary.
98	**Date / Time:** 2014/02/13 14:11 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation **Country:** Belgium **Name confidential:** False	**Comment:** We acknowledge and recognize the importance of this regulation and in general agree with the risk approach taken. We also acknowledge the integration of the research data on lead migration from brass in saliva, leading to a derogation for 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). We further fully support the proposed exemptions. We have two remaining comments: 1.Mouthing time: In the ECI comments, submitted during the public consultation (August 2013), we assessed the information on mouthing time and developed two realistic reasonable worst case mouthing scenarios. From this assessment, we proposed a reasonable worst case daily mouthing time for lead containing materials of 20 minutes (instead of 60 min, proposed by RAC – see extract from the ECI comments August 2013). Application of this reasonable worst case mouthing time for lead containing materials (20 minutes instead of 60 minutes), into the risk based approach of the RAC document, leads to a generic proposed limit value of lead in consumer articles that can be mouthed by children of 0.15 % Pb (instead of 0.05% Pb). For brass alloys, this would lead to a proposed derogation for articles comprising brass alloys if the concentration of lead in the brass alloy does not exceed 1.5% by weight of lead (expressed as metal) (instead of 0.5%). Extract from ECI comments August 2013 a) information on mouthing time from the dossier Further evaluating the applicable mouthing time, we also consulted the RIVM report (2008) and extract the following: - The mean daily mouthing time of young children of “non-soft plastic toys, teethers, rattles” was respectively 18 minutes (3-11 month old); 6 minutes (12-23 month) and 2 minutes (24-36 month). - The 95th percentile worst case daily mouthing time of young children of “non-soft plastic toys,

		teethers, rattle" was 65 minutes (3-11 months), 18 minutes (12-23 month) and 9 minutes (24-36 month). Therefore, a mean daily mouthing time of 20 minutes and a reasonable worst case daily mouthing time of 60 minutes can be considered, across age groups. These mouthing times assume however that all non-soft objects contain lead. The Annex XV report does mention that the market share of lead-containing articles amounts to 13% (see section B.9.3.1). When assessing risks relevant to this lead restriction, it is therefore proposed to consider further refinement of the "relevant objects mouthed" by considering that only some mouthed consumer articles contain lead. Using this approach, we estimate: • a mean daily mouthing time of young children of "lead-containing consumer articles": 3 min (20 min *0.13) • a 95th percentile daily mouthing time of young children of "lead-containing consumer articles": 8 min (65 min *0.13) The daily mouthing time of "lead-containing consumer articles" is therefore estimated to range between 3 and 8 minutes. This scenario assumes however that mouthing times of "lead-containing" and "lead free" articles are equal. Although this is uncertain, it seems reasonable to consider that the daily mouthing times of "hard metallic materials" will be less then medium-hard materials (such as hard plastics and wood). We therefore developed the following realistic reasonable worst case mouthing scenarios for metallic materials: - combining the highest age-specific mean mouthing time (20 minutes/day) with the assumption that all articles contain lead, results in a realistic reasonable worst case mouthing time of 20 minutes/day - combining the 95th percentile mouthing time (60 minutes/day) with an average fraction of lead-containing articles (13% of all articles that can be mouthed), results in a realistic reasonable worst case mouthing time of 8 minutes/day Considering both approaches a realistic reasonable worst case mouthing time of 20 minutes/day for lead-containing consumer articles is proposed. This corresponds to the 95th percentile mouthing time (60 minutes/day), while considering that 30% of mouthed consumer articles contain lead (3 times the value reported in annex XV). This also corresponds to the mean daily mouthing time, assuming all mouthed consumer articles contain lead. b) New information on mouthing time (not included in the report)

		Steenbekkers, 2001 assessed various methods to describe mouthing behaviours of 42 children of ages relevant to the Proposed Restriction: ages 3-6 months (N=5), 6-12 months (N=14), and 12-18 months (N=12) for various categories of objects (fingers, toys for mouthing, other toys, non-toys). The study concludes that children between 6 and 12 months are at highest risks when mouthing of objects that are not meant to be mouthed, is involved. The mean mouthing time for non-toys during awake time was less than 10 minutes per day for all age groups. The Steenbekker, 2001 paper therefore supports, the current weight-of-evidence that indicates 20 minutes as a reasonable worst case mouthing time relevant to this restriction. 2. The introduction of a migration limit would be most useful. Such integration can be done in a tiered approach. A restriction based on content but, if migration data are available, these can used.
		Answer1: We propose a tiered approach : Tier 1: Migration data is not available for the specific lead containing alloy in the article: Restriction of lead content in articles (% lead) and parts of articles that are sold to the general public and that can be mouthed by children (e.g. at 0.05% (current proposal at 60 min mouthing time) or 0.15% (20 min mouthing time – see above). Tier 2: Migration data are available Restriction of lead migration in articles and parts of articles that are sold to the general public and that can be mouthed by children. A generic migration rate of 1 µg/cm2.h % was determined and used in the annex XV report. This value corresponds to 0.05 µg Pb/cm2.h (current proposal at 60 min mouthing time) or 0.15 µg Pb/cm2.h (20 min mouthing time – see above). For brasses, the measured migration rate of 0.1 µg/cm2.h % allowed for a proposed derogation in the annex XV dossier of 0.5% Pb in brass alloys. From a socio-economic perspective, it seems important that other industry sectors may also be enabled to develop/use such information where possible Additional data lead migration data: As a follow-up on the RAC and SEAC discussions, migration rates of lead, following the protocol used to derive a derogation for brasses, was used by a second laboratory. The metal migration data for Cu/Zn/Pb and Cu/Zn/Ni/Mn/Pb alloys further support the

		usefulness of the tests for broader families of alloys, allowing for a reduction in testing costs: - The observed intra-laboratory (coefficient of variation typically below 25%) and inter-laboratory variability (coefficient of variation below 32%) demonstrate that the test method generates reproducible data. - Consistent migration rates for Cu, Zn, Ni, and Pb, are observed for the alloys belonging to the brass alloy family - The lead migration rates for the Cu/Zn (simple brass) and Cu/Zn/Ni/Mn (member of the brass family, called nickel silver alloys) was described as: 0.1 µg Pb released /cm2.hour.%Pb. At 1 hour mouthing time, the data therefore confirm the derogation of lead, for the broad brass alloy family, at 0.5% and at 1.5% lead, if 20 minutes is accepted as reasonable worst case mouthing time. Costs of the saliva test The test lab provided a quotation for one test at 3,300 €/test. If samples are tested simultaneously, a reduction is available.
		Answer2: Functionality of lead in copper alloys (more information in ECI comments, submitted in May 2013) Lead is added as a functional alloy constituent because lead, embedded as tiny globules (e.g. in brass alloys), acts as a lubricant and, most importantly, as a chip breaker, allowing the high performance machining of semi-products, without continuously damaging the product itself or the production tools. This results in extended tool lifetime, higher productivity and less usage of resources, together with a high quality surface of the machined material. In addition, lead exhibits corrosion-inhibiting characteristics which minimises the corrosion/metal release of the other alloy constituents. Potential for reduction of lead contents in copper alloys : The combination of delivered properties presents a significant challenge in the search for a suitable substitute for lead. Over the last 10-15 years, the industry has reduced, to a minimum, the amount of lead needed for a series of copper alloys while still fulfilling downstream customer requirements. During the last years, the copper industry performed intensive research work to replace lead in free cutting brasses. This research work, however, was aimed at the production processes and material properties required in products for drinking water applications. It is not known, if the results of this research work could also fulfil the

		requirements for other production processes and applications. In addition, no research work was performed, up to now, with respect to lead containing, free cutting nickel silver alloys. Today, two substitutes for lead in free cutting brass are discussed in the context of drinking water applications: Silicon- and bismuth-containing brasses. Both have specific disadvantages. It is further important to mention that, according to their standardised compositions, both alternatives may contain up to 0.25% lead. The industry estimates large additional cost to substitute leaded brass with silicon brass (best alternative). For the total tonnage, to be substituted (49,000 T/year copper brass alloys with lead >0.5%) and used for consumer products which can be mouthed, this results in additional costs of ca. 119 million €/year. If the exemptions, outlined in the annex XV proposal (keys, locks, padlocks, musical instruments and tips) are granted, the total cost of substitution is estimated at 6.3 million €/year. For writing instruments, such as ballpoint pens, lead containing nickel silver alloys (LNS) with up to 2.5% Pb and lead containing free cutting brass up to 3.5% Pb (LB) are used. LNS is used to manufacture the ballpoint pen tips, while LB is typically used to manufacture clips and the conical "nose" of a writing instrument. According to information obtained from downstream users, the materials used for ballpoint pen tips and noses have been specifically developed and adjusted to ensure: • good machinability - high speed drilling and turning • high resistance to cracks • excellent cold deformation and concentricity in the miniaturized drilling • shining in their appearance As for keys, locks and music instruments, the production process of ballpoint pen tips and noses requires a high level of machinability performance in combination with a high precision geometry and a high surface quality of the final component. Figures can illustrate the various production steps and high material requirements on machinability (see ECI comments, submitted in May 2013). According to downstream users, a pen must guarantee the writing performance expected by the consumers, i.e. a high, intensive and smooth writing, that makes a pen attractive. For that reason, the raw materials used in the ballpoint tips must demonstrate good wear-out resistance, guaranteeing the long lasting performance required to use the entire amount of available ink. "Half-used" pens are wasteful on both raw materials and municipal landfill (recycling is not economic). LNS and LB materials allow billions of tips to be produced with the expected quality and at a competitive price. No "lead free"

		nickel silver alloys are available which provide the same level of machinability and end-use performance. The risks arising from writing instruments is lower than assessed in the generic risk assessment. Firstly, ballpoint pen tips are, more or less, inaccessible since, in order to prevent the ink from drying out, tips are either covered by a cap or manually relocated inside the pen body after use. Secondly, the surface areas of a ballpoint tip, a clip, or a metallic “nose” are much smaller than the 10 cm^2 assumed. According to downstream user information, the clip and the nose typically have surface areas of 3 cm^2 (in a few exceptional cases, up to 5 cm^2). Due to design, it is extremely difficult for the nose and the clip to be mouthed simultaneously. Finally, these components of a writing instrument are often coated. According to downstream users, the proposed restrictions on lead content, in the metallic materials used for writing instruments, would have devastating effects on their manufacturing processes. An EU ban on writing instruments cannot be the intention, or consequence, of a restriction proposal. Therefore, we propose to keep an exemption for writing instruments (tips and noses).
		Answer3: Keys, locks and music instruments use metallic components which require a high precision geometry, together with a high surface quality. Only lead-containing nickel silver alloys and brasses are presently able to fulfil these requirements in combination with a high level of machinability. More information on the functionality of lead, reductions in lead content and substitutions are outlined in the answer to question 2. Keys Keys for automotive applications and high security cylinders are mainly manufactured from nickel silver alloys with lead contents up to 1.5%. It is obvious that a proper functioning of these keys is not possible without adherence to strict tolerances for drilled holes and/or geometric profiles. An additional benefit of leaded nickel silver is the preferential wear of the alloy relative to the lock material. In a lock-and-key application, the key will generally fail first, minimising the cost of maintenance and repair. The lead content also increases the brittleness of the LPS material providing an important

		safety feature for automotive applications - manufacturers want keys which break upon impact. Keys also pose a lower health risk than assessed in the generic risk assessment of the Annex XV Dossier, where the mouthable surface area of articles was assumed to be 10 cm^2. A typical automotive key has a surface area closer to 5 cm2, leading to lower lead migration levels than those proposed by KEMI. This difference in surface area applies to all key types which are likely to be mouthed by children. It should also be noted that, in many modern automotive applications, the actual key is encased in a plastic housing. This removes the potential for lead exposure during mouthing by children. Musical instruments Lead containing nickel silver, with up to 2.5% lead, and lead-containing free cutting brasses, with up to 3.5 % lead, are used for components of music instruments, e.g. the complex rod and joint mechanism of clarinets. As for keys, no lead free nickel silver or brass alloys are available which provide the same level of machinability in combination with the required surface properties. Metallic components of music instruments are often coated with e.g. a silver layer and/or with an organic lacquer. In order to achieve the surface appearance desired by the customer, the pre-lacquered surface qualities require machining from lead containing copper alloys. The risks arising from musical instruments are lower than assessed in the generic risk assessment. Firstly, music instruments relevant to this restriction proposal are not intended for use by small children, are normally not accessible to them and cannot be handled by them. Musical instruments intended for children are already covered by other regulations, e.g. the Toys Directive. Secondly, any lead release from the materials is significantly reduced due to coating. Locks As with keys, locks require a high precision geometry together with a high surface quality. No lead copper alloys are available which provide the same level of machinability in combination with the required surface properties.
		SEAC Rapporteurs response Thank you for your support and the information on the proposed exemptions for keys, locks and

		musical instruments. In addition, your helpful input concerning migration testing and writing instruments will be carefully considered by the Rapporteurs and be further discussed with SEAC on the way to the finalisation of the opinion. Please also note that the reduced compliance cost (due to the proposed restrictions) has already been taken into account by SEAC in their draft opinion.
99	**Date / Time:** 2014/02/13 17:57 **Organisation:** Company-Manufacturer **Type:** BehalfOfAnOrganisation **Country:** Germany **Name confidential:** False	**Comment:** We acknowledge and recognize the importance of this regulation and in general agree with the risk approach taken. We also acknowledge the integration of the research data on lead migration from brass in saliva, leading to a derogation for 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). We further fully support the proposed exemptions. Nevertheless, in our opinion the restriction proposal is still very conservative due to several worst case assumptions used in the deduction of the limit value: - a daily mouthing time of 60 min. According to the information on mouthing time submitted by the European Copper Institute ECI in August 2013, a mouthing time of 20 min. is a reasonable worst case scenario. For further justification, we refer to the comments of the ECI within this public consultation. - a default surface of 10 cm2. Many consumer products which can be mouthed have a lower relevant surface area, e.g. writing instruments, keys etc. - the market survey described in chapter B.9.3. of the draft background document concludes “a market share of 11,3% for articles with a lead content above 500 ppm in any part”. This factor was not considered in the deduction of the limit value.
		Answer1: A migration limit as an additional manner to comply with the restriction would be very helpful to industry. Particularly, if the migration limit is introduced in a two-tiered approach as it is proposed: first check on the Pb content and, if the Pb content exceeds the limit, industry has the possibility to check against the migration limit. For brass the European Copper Institute had already shown, that the Pb migration from alloys is low with respect to the Pb content in the alloy. This was acknowledged by SEAC and RAC with a derogation

		for the Pb content in brass to a higher Pb limit value. Brass is the most important, but not the only alloy family which is relevant for consumer products. Another important alloy family are e.g. nickel silver alloys. Like brass, these alloys may have lead impurities due to the usage of secondary raw materials above 0,05 %. The industry needs a migration limit to be able to demonstrate that these materials are also compliant with the restriction and to be able to still use recycled materials. Additionally, many materials and metals used in articles are in a state that disables migration of lead from their surfaces, e.g. due to a coating. Industry needs a migration limit to test articles in that state, in which they are put on the market, if appropriate. A restriction solely based on a limit for the content would be a blanket exclusion from the market for all these articles. A test method for the migration of lead from metallic materials in saliva has already been developed and tested by different laboratories for Pb migration from brass alloys (for further information see the comments of the European Copper Institute). The test method can be applied to other alloys and even articles, with well-defined exposed surface area. Regulations that require migration tests on articles already exist (e.g. toys directive) without leading to unreasonable cost impacts for industry. As long as the migration limit is an optional criterion, and not a mandatory one, the costs of such a test are no issue for industry. For metallic materials, for example, the costs are reasonable (ca. 3.300 €/material) and the test has only to be performed once to demonstrate compliance. Since the chemical composition of alloys is well defined in European and international standards and can be analysed easily, the compliance could then be demonstrated via the lead content within the normal quality management of the fabricators.
		Answer2: In copper alloys, lead is added as a functional alloy constituent because lead, embedded as tiny globules (e.g. in brass alloys), acts as a lubricant and, most importantly, as a chip breaker, allowing the high performance machining of semi-finished products, without continuously damaging the product itself or the production tools. This results in extended tool lifetime, higher productivity and less usage of resources, together with a high quality surface of the machined material. In addition, lead exhibits corrosion-inhibiting characteristics which minimises the corrosion/metal release of the other alloy

		constituents. For further information we refer to the comment of the European Copper Institute, submitted in May 2013. These material characteristics are needed by our customers to manufacture the nose of writing instruments in an efficient way and to reasonable and competitive costs. Though, in principal, lead-free brass exists, the machinability of this material is inferior to free cutting brasses with functional lead content. According to our customers, a pen must guarantee the writing performance expected by the consumers, i.e. a high, intensive and smooth writing, that makes a pen attractive. For that reason, the raw materials must demonstrate good wear-out resistance, guaranteeing the long lasting performance required to use the entire amount of available ink. “Half-used” pens are wasteful on both raw materials and municipal landfill (recycling is not economic). This requirements can only be fulfilled with copper alloys which contain lead for functional reasons. Therefore, an exemption for the whole writing instruments is necessary. The risks arising from writing instruments are much lower than assessed in the generic risk assessment. The surface areas of a clip, or a metallic “nose” are much smaller than the 10 cm^2 assumed. According to information from our customers, the clip and the nose typically have surface areas of 3 cm2 (in a few exceptional cases, up to 5 cm2). Due to the design, it is extremely difficult for the nose and the clip to be mouthed simultaneously. Finally, these components of a writing instrument are often coated.
		Answer3: For the manufacturing of keys, locks and music instruments mainly lead-containing brasses and lead-containing nickel silver alloys are used. In principal, silicon-containing brasses are an alternative for lead-containing brasses. For lead-containing nickel silver alloys, no lead-free alternative exists. More information on the functionality of lead, on industry efforts to reduce the lead content in copper alloys and on substitutions are outlined in the comment from the European Copper Institute submitted in May 2013. Si-containing brasses are much more energy intensive during production than lead-containing brasses, resulting in inferior energy efficiency of the production process and in enhanced costs. In addition Si-containing brasses require separate scrap cycles.

		Industry has estimated that substituting lead-containing copper alloys with lead contents above 0,5 % used in consumer products, which can be mouthed, by Si-containing brasses would result in additional costs of ca. 119 million €/year. Details of this calculation are confidential but can be provided on request. The additional costs consist of increased material and processing costs for the fabricators of semi-finished products and additional costs for the owners of Si-containing brass scrap due to a different recycling path of Si-containing brass compared to lead-containing brass (Si-containing brass can't be used directly at the fabricators side for the production of new semis but has to be recycled at a smelter). Despite potential costs, substitution of lead containing copper alloys will result in a significant deterioration of the product quality: Keys, locks and music instruments use metallic components which require a high precision geometry, together with a high surface quality. Only lead-containing nickel silver alloys and brasses are presently able to fulfil these requirements in combination with a high level of machinability. Keys Keys for automotive applications and high security cylinders are mainly manufactured from nickel silver alloys with lead contents up to 1.5%. It is obvious that a proper functioning of these keys is not possible without adherence to strict tolerances for drilled holes and/or geometric profiles. An additional benefit of leaded nickel silver is the preferential wear of the alloy relative to the lock material. In a lock-and-key application, the key will generally fail first, minimising the cost of maintenance and repair. The lead content also increases the brittleness of the nickel silver alloys providing an important safety feature for automotive applications - manufacturers want keys which break upon impact. Keys also pose a lower health risk than assessed in the generic risk assessment in the draft background document, where the mouthable surface area of articles was assumed to be 10 cm^2. A typical automotive key has a surface area closer to 5 cm2, leading to lower lead migration levels than those proposed by the default schema. This difference in surface area applies to all key types which are likely to be mouthed by children. Musical instruments Lead-containing nickel silver, with up to 2.5% lead, and lead-containing free cutting brasses, with up to 3.5 % lead, are used for components of music instruments, e.g. the complex rod and joint mechanism of clarinets. As for keys, no lead-free nickel silver or brass alloys are available which

		provide the same level of machinability in combination with the required surface properties. Metallic components of music instruments are often coated with e.g. a silver layer and/or with an organic lacquer. In order to achieve the surface appearance desired by the customer, the pre-lacquered surface qualities require machining from lead-containing copper alloys. The risks arising from musical instruments are lower than assessed in the generic risk assessment. Firstly, music instruments relevant to this restriction proposal are not intended for use by small children, are normally not accessible to them and cannot be handled by them. Musical instruments intended for children are already covered by other regulations, e.g. the Toys Directive. Secondly, any lead release from the materials is significantly reduced due to coating. Locks As with keys, locks require a high precision geometry together with a high surface quality. No lead copper alloys are available which provide the same level of machinability in combination with the required surface properties.
		SEAC Rapporteurs response Thank you for your support and the information on the proposed exemptions (keys, locks and musical instruments). The provided input on the migration testing as well as concerning writing instruments will be carefully considered by the Rapporteurs and SEAC. The compliance cost has already been taken into account by SEAC in their draft opinion. The rapporteurs would like to emphasize that the proposed exemptions reduce the additional costs to 6.3 million €/year.
100	**Date / Time:** 2014/02/13 18:23 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation	**Comment:** About the ILA The International Lead Association is a membership body that supports companies involved in the mining, smelting, refining and recycling of lead. The ILA represents the producers of about 3 million tons of lead and almost two thirds of lead production in the western world. As secretariat to the Lead (Pb) REACH Consortium, ILA Europe (a regional branch of the International Lead Association) is acting on behalf of the Lead Registrants for several lead substances. We would like to thank SEAC for considering comments we have made previously and specifically those

	Country: United Kingdom **Name confidential:** False	concerning the approach taken to estimating perceived health benefits that may result from the restriction proposal. We remain concerned about the very high degree of uncertainty in many of the assumptions used to evaluate health benefits such as mouthing times, number of relevant articles, proportion of articles containing lead, lead content of articles etc. that make any robust estimate of risk benefit difficult. However we acknowledge that the limitations of this data are now reflected in the latest SEAC opinion through a detailed description of the four critical assumptions that have been made (pages 10-11 of the draft Opinion). We are encouraged that SEAC decided to adopt a break-even analysis to assess the proportionality of the restriction rather than attempting to use a burden of disease-approach as done previously in the 31 October 2013 Opinion. This model relied on extrapolating a predicted very small fraction of an IQ point deficit in individual children to a population level in an attempt to monetise health benefits from the proposed restriction. As we highlighted in our previous comments and as discussed at SEAC 21, small fractions of IQ points are below the limit of discrimination of IQ tests, which is approximately 3-5 IQ points depending upon the IQ test used (and confidence interval around the estimate). Thus, any predicted IQ deficit below about 3-5 IQ points cannot be considered to be a measurable adverse effect for an individual and should not be used to estimate expected health benefits across a large population. Whist the break even approach is preferable to the population burden approach to estimating health benefits; it too has some significant limitations that bring into question the proportionality of the restriction proposal. The break even calculation requires that each and every child in the target age group would need to suck on a lead containing item for 5.8 seconds per day to ensure predicted health benefits outweigh costs. This therefore suffers from the same limitation as a population burden evaluation in that very small and non-clinically relevant individual impact need to be extrapolated to having a large societal cost. Can 5.8 seconds exposure per day lead to a clinically meaningful impact on childhood IQ? The RAC concluded that a clinically meaningful impact at the individual level is 0.1 IQ points or above. This means that the child has to suck on an article for 5 minutes a day, every day and not the 5.8 seconds described in the break even analysis and therefore the actual population size that would receive a benefit from the restriction is relatively small (only 200,000 compared to the total number of children in the target age group- 5 375 152). This is comparable to the numbers estimated from the WHO disease burden approach illustrated in our previously submitted comments. We therefore believe that

		the anticipated health benefits of this restriction are still being significantly overstated and the restriction is unlikely to result in any significant or measurable positive health consequences for children across EU Member States.
		Answer1: Yes, the health risks following lead exposure from sucking articles is related to the migration of lead from the article and not a crude estimate of lead content. It is for that reason that analogous EU regulations targeted at protecting young children, such as the Toy Safety Directive, are regulated on lead migration limits rather than content. Industry has developed a test method for estimating lead migration in saliva that mimics exposure conditions that may occur when a child sucks a lead containing article. This was used in the RAC opinion to establish a higher content limit for lead in brasses. The test is robust and does not incur excessive cost with testing one article and analysis of 5 metal elements being in region of €8000. If only lead were analysed then costs are substantively lower at around €4000 per article. We believe that costs in this order would not be a deterrent to Small or Medium sized businesses or enforcement authorities. Consultation with our Members supports this conclusion.
		Answer2: No comment on this question as we do not have any additional information and rely on input from the affected downstream sector.
		Answer3: No comment on this question as we do not have any additional information and rely on input from the affected downstream sector.
		SEAC Rapporteurs response Thank you for your comment and the support on the presented break even analysis as well as concerning our efforts to indicate and clarify the various assumptions and uncertainties in the SEAC

		draft opinion. The issue of IQ impact will be further discussed in SEAC and clarifications will be provided by the Rapporteurs on the current approach. Your input on the migration testing (including the cost aspects for industry) will also be carefully considered.
101	**Date / Time:** 2014/02/14 09:33 **Type:** Individual **Name confidential:** False	**Comment:** We acknowledge and recognize the importance of this regulation and in general agree with the risk approach taken. We also acknowledge the integration of the research data on lead migration from brass in saliva, leading to a derogation for 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). We further fully support the proposed exemptions. Nevertheless, in our opinion the restriction proposal is still very conservative due to several worst case assumptions used in the deduction of the limit value: - a daily mouthing time of 60 min. According to the information on mouthing time submitted by the European Copper Institute (ECI in August 2013, a mouthing time of 20 min. is a reasonable worst case scenario. For further justification, we refer to the comments of the ECI within this public consultation. - a default surface of 10 cm2. Many consumer products which can be mouthed have a lower relevant surface area, e.g. writing instruments, keys etc. - the market survey described in chapter B.9.3. of the draft background document concludes “a market share of 11,3% for articles with a lead content above 500 ppm in any part”. This factor was not considered in the deduction of the limit value.
		Answer1: A migration limit as an additional manner to comply with the restriction would be very helpful to industry. Particularly, if the migration limit is introduced in a two-tiered approach as it is proposed: first check on the Pb content and, if the Pb content exceeds the limit, industry has the possibility to check against the migration limit. For brass the European Copper Institute had already shown, that the Pb migration from alloys is low with respect to the Pb content in the alloy. This was acknowledged by SEAC and RAC with a derogation for the Pb content in brass to a higher Pb limit value. Brass is the most important, but not the only alloy family which is relevant for consumer products.

		Another important alloy family are e.g. nickel silver alloys. Like brass, these alloys may have lead impurities due to the usage of secondary raw materials above 0,05 %. The industry needs a migration limit to be able to demonstrate that these materials are also compliant with the restriction and to be able to still use recycled materials. Additionally, many materials and metals used in articles are in a state that disables migration of lead from their surfaces, e.g. due to a coating. Industry needs a migration limit to test articles in that state, in which they are put on the market, if appropriate. A restriction solely based on a limit for the content would be a blanket exclusion from the market for all these articles . A test method for the migration of lead from metallic materials in saliva has already been developed and tested by different laboratories for Pb migration from brass alloys (for further information see the comments of the European Copper Institute). The test method can be applied to other alloys and even articles, with well defined exposed surface area. Regulations that require migration tests on articles already exist (e.g. toys directive) without leading to unreasonable cost impacts for industry. As long as the migration limit is an optional criterion, and not a mandatory one, the costs of such a test are no issue for industry. For metallic materials, for example, the costs are reasonable (ca. 3.300 €/material) and the test has only to be performed once to demonstrate compliance. Since the chemical composition of alloys is well defined in European and international standards and can be analysed easily, the compliance could then be demonstrated via the lead content within the normal quality management of the fabricators.
		Answer2: In copper alloys, lead is added as a functional alloy constituent because lead, embedded as tiny globules (e.g. in brass alloys), acts as a lubricant and, most importantly, as a chip breaker, allowing the high performance machining of semi-finished products, without continuously damaging the product itself or the production tools. This results in extended tool lifetime, higher productivity and less usage of resources, together with a high quality surface of the machined material. In addition, lead exhibits corrosion-inhibiting characteristics which minimises the corrosion/metal release of the other alloy constituents. For further information we refer to the comment of the European Copper Institute, submitted in May 2013.

		These material characteristics are needed by our customers to manufacture the nose of writing instruments in an efficient way and to reasonable and competitive costs. Though, in principal, lead-free brass exists, the machinability of this material is significant inferior to free cutting brasses with functional lead content. According to our customers, a pen must guarantee the writing performance expected by the consumers, i.e. a high, intensive and smooth writing, that makes a pen attractive. For that reason, the raw materials must demonstrate good wear-out resistance, guaranteeing the long lasting performance required to use the entire amount of available ink. “Half-used” pens are wasteful on both raw materials and municipal landfill (recycling is not economic). This requirements can only be fulfilled with copper alloys which contain lead for functional reasons. Therefore, an exemption for the whole writing instruments is necessary. The risks arising from writing instruments are much lower than assessed in the generic risk assessment. The surface areas of a clip, or a metallic “nose” are much smaller than the 10 cm^2 assumed. According to information from our customers, the clip and the nose typically have surface areas of 3 cm^2 (in a few exceptional cases, up to 5 cm^2). Due to the design, it is extremely difficult for the nose and the clip to be mouthed simultaneously. Finally, these components of a writing instrument are often coated.
		Answer3: For the manufacturing of keys, locks and music instruments mainly lead-containing brasses and lead-containing nickel silver alloys are used. In principal, silicon-containing brasses are an alternative for lead-containing brasses. For lead-containing nickel silver alloys, no lead-free alternative exists. More information on the functionality of lead, on industry efforts to reduce the lead content in copper alloys and on substitutions are outlined in the comment from the European Copper Institute submitted in May 2013. Si-containing brasses are much more energy intensive during production than lead-containing brasses, resulting in inferior energy efficiency of the production process and in enhanced costs. In addition Si-containing brasses require separate scrap cycles. Industry has estimated that substituting lead-containing copper alloys with lead contents above 0,5 % used in consumer products by Si-containing brasses would result in additional costs of ca. 119 million

		€/year. Details of this calculation are confidential but can be provided on request. The additional costs consist of increased material and processing costs for the fabricators of semi-finished products and additional costs for the owners of Si-containing brass scrap due to a different recycling path of Si-containing brass compared to lead-containing brass (Si-containing brass can't be used directly at the fabricators side for the production of new semis but has to be recycled at a smelter). Despite potential costs, substitution of lead containing copper alloys will result in a significant deterioration of the product quality: Keys, locks and music instruments use metallic components which require a high precision geometry, together with a high surface quality. Only lead-containing nickel silver alloys and brasses are presently able to fulfil these requirements in combination with a high level of machinability. Keys Keys for automotive applications and high security cylinders are mainly manufactured from nickel silver alloys with lead contents up to 1.5%. It is obvious that a proper functioning of these keys is not possible without adherence to strict tolerances for drilled holes and/or geometric profiles. An additional benefit of leaded nickel silver is the preferential wear of the alloy relative to the lock material. In a lock-and-key application, the key will generally fail first, minimising the cost of maintenance and repair. The lead content also increases the brittleness of the nickel silver alloys providing an important safety feature for automotive applications - manufacturers want keys which break upon impact. Keys also pose a lower health risk than assessed in the generic risk assessment in the draft background document, where the mouthable surface area of articles was assumed to be 10 cm^2. A typical automotive key has a surface area closer to 5 cm2, leading to lower lead migration levels than those proposed by the default schema. This difference in surface area applies to all key types which are likely to be mouthed by children. Musical instruments Lead-containing nickel silver, with up to 2.5% lead, and lead-containing free cutting brasses, with up to 3.5 % lead, are used for components of music instruments, e.g. the complex rod and joint mechanism of clarinets. As for keys, no lead-free nickel silver or brass alloys are available which provide the same level of machinability in combination with the required surface properties. Metallic components of music instruments are often coated with e.g. a silver layer and/or with an organic lacquer. In order to achieve the surface appearance desired by the customer, the pre-

		lacquered surface qualities require machining from lead-containing copper alloys. The risks arising from musical instruments are lower than assessed in the generic risk assessment. Firstly, music instruments relevant to this restriction proposal are not intended for use by small children, are normally not accessible to them and cannot be handled by them. Musical instruments intended for children are already covered by other regulations, e.g. the Toys Directive. Secondly, any lead release from the materials is significantly reduced due to coating. Locks As with keys, locks require a high precision geometry together with a high surface quality. No lead copper alloys are available which provide the same level of machinability in combination with the required surface properties
		SEAC Rapporteurs response Thank you for your support and the information on the proposed exemptions (keys, locks and musical instruments). The provided input on the migration testing as well as concerning writing instruments will be carefully considered by the Rapporteurs and SEAC. The compliance cost has already been taken into account by SEAC in their draft opinion. The rapporteurs would like to emphasize that the proposed exemptions reduce the additional cost to 6.3 million €/year. This has been taken into account by SEAC in their draft opinion.
102	**Date / Time:** 2014/02/14 09:49 **Organisation:** Company-Manufacturer **Type:** BehalfOfAnOrganisation	**Comment:** Aurubis is the leading integrated copper group and the world's largest copper recycler. Aurubis has about 6,500 employees, 16 production sites in eleven European countries and the USA. The core business is the production of copper cathode from copper concentrates, copper scrap and variety of other recycling raw material. These are processed within the Group into continuous cast wire rod, shapes, rolled products and speciality wire made of copper and copper alloys. Precious metals and other products like sulphuric acid and iron silicate slags are also produced. Overall, the alloy portfolio of Aurubis includes over 60 alloys made of the special copper materials;

	Country: Germany **Name confidential:** False	brass alloys, including BlueBrass® CuZn42, the phosphor bronzes; and special alloys We acknowledge and recognize the importance of this regulation and in general agree with the risk approach taken. We also acknowledge the integration of the research data on lead migration from brass in saliva, leading to a derogation for 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). We further fully support the proposed exemptions. Nevertheless we remain concerned about the very high degree of uncertainty in many of the assumptions used to evaluate health benefits such as mouthing times, default surface area, number of relevant articles, proportion of articles containing lead, lead content of articles etc. that make any robust estimate of risk benefit difficult Mouthing time: We support the proposal of ECI for a reasonable worst case daily mouthing time for lead containing materials of 20 minutes (instead of 60 min, proposed by RAC. For further justification see ECI comments submitted during the public consultation August 2013. . Application of this reasonable worst case mouthing time for lead containing materials of 20 minutes instead of 60 minutes, into the risk based approach of the RAC document, leads to a generic proposed limit value of lead in consumer articles that can be mouthed by children of 0.15 % Pb (instead of 0.05% Pb). For brass alloys, this would lead to a proposed derogation for articles comprising brass alloys if the concentration of lead in the brass alloy does not exceed 1.5% by weight of lead (expressed as metal) (instead of 0.5%). Default surface area : A default surface of 10 cm2 is assumed. Many consumer products which can be mouthed have a lower relevant surface area, e.g. writing instruments, keys etc.
		Answer1: A migration limit as an additional manner to comply with the restriction would be very helpful to industry. The health risks following lead exposure from sucking articles is related to themigration of lead from the article and not a crude estimate of lead content. It is for that reason that analogous EU regulations targeted at protecting young children, such as the Toy SafetyDirective, are regulated on lead migration

		limits rather than content. We support the tiered approach proposed by ECI. Tier 1: Migration data is not available for the specific lead containing alloy in the article: Restriction of lead content in articles (% lead) and parts of articles that are sold to the general public and that can be mouthed by children (e.g. at 0.05% (current proposal at 60 min mouthing time) or 0.15% (20 min mouthing time – see above). Tier 2: Migration data are available Restriction of lead migration in articles and parts of articles that are sold to the general public and that can be mouthed by children. A generic migration rate of 1 µg/cm2.h % was determined and used in the annex XV report. This value corresponds to 0.05 µg Pb/cm2.h (current proposal at 60 min mouthing time) or 0.15 µg Pb/cm2.h (20 min mouthing time – see above). Industry has developed a test method for estimating lead migration in saliva that mimics exposure conditions that may occur when a child sucks a lead containing article. This was used in the RAC opinion to establish a higher content limit for lead in brasses. Brass is the most important, but not the only alloy family which is relevant for consumer products. Another important alloy family are e.g. nickel silver alloys. Like brass, these alloys may have lead impurities due to the usage of secondary raw materials above 0,05 %. The industry needs a migration limit to be able to demonstrate that these materials are also compliant with the restriction and to be able to still use recycled materials. The migration test is robust and does not incur excessive cost.. As long as the migration limit is an optional criterion, and not a mandatory one, the costs of such a test are no issue for industry. For metallic materials, for example, the costs are reasonable (ca. 3.300 €/material) and the test has only to be performed once to demonstrate compliance. Since the chemical composition of alloys is well defined in European and international standards and can be analysed easily, the compliance could then be demonstrated via the lead content within the normal quality management of the fabricators

		Answer2: In copper alloys, lead is added as a functional alloy constituent because lead, embedded as tiny globules (e.g. in brass alloys), acts as a lubricant and, most importantly, as a chip breaker, allowing the high performance machining of semi-finished products, without continuously damaging the product itself or the production tools. This results in extended tool lifetime, higher productivity and less usage of resources, together with a high quality surface of the machined material. In addition, lead exhibits corrosion-inhibiting characteristics which minimises the corrosion/metal release of the other alloy constituents. For further information we refer to the comment of the European Copper Institute, submitted in May 2013. These material characteristics are needed by downstream users to manufacture the nose of writing instruments in an efficient way and to reasonable and competitive costs. Though, in principal, lead-free brass exists, the machinability of this material is significant inferior to free cutting brasses with functional lead content. As for keys, locks and music instruments, the production process of ballpoint pen tips and noses requires a high level of machinability performance in combination with a high precision geometry and a high surface quality of the final component. Figures can illustrate the various production steps and high material requirements on machinability (see ECI comments, submitted in May 2013). According to downstream users, a pen must guarantee the writing performance expected by the consumers, i.e. a high, intensive and smooth writing, that makes a pen attractive. For that reason, the raw materials must demonstrate good wear-out resistance, guaranteeing the long lasting performance required to use the entire amount of available ink. “Half-used” pens are wasteful on both raw materials and municipal landfill (recycling is not economic). This requirements can only be fulfilled with copper alloys which contain lead for functional reasons. The risks arising from writing instruments is lower than assessed in the generic risk assessment. Firstly, ballpoint pen tips are, more or less, inaccessible since, in order to prevent the ink from drying out, tips are either covered by a cap or manually relocated inside the pen body after use. Secondly, the surface areas of a ballpoint tip, a clip, or a metallic “nose” are much smaller than the 10 cm^2 assumed. According to downstream user information, the clip and the nose typically have surface areas of 3 cm^2 (in a few exceptional cases, up to 5 cm^2). Due to design, it is extremely difficult for the nose and the clip to be mouthed simultaneously. Finally, these components of a writing instrument are

		often coated. Therefore, we propose to keep an exemption for writing instruments (tips and noses).
		Answer3: Keys, locks and music instruments use metallic components which require a high precision geometry, together with a high surface quality. Only lead-containing nickel silver alloys and brasses are presently able to fulfil these requirements in combination with a high level of machinability. More information on the functionality of lead, reductions in lead content and substitutions are outlined in the answer to question 2. The combination of delivered properties presents a significant challenge in the search for a suitable substitute for lead. Over the last 10-15 years, the industry has reduced, to a minimum, the amount of lead needed for a series of copper alloys while still fulfilling downstream customer requirements. During the last years, the copper industry performed intensive research work to replace lead in free cutting brasses. This research work, however, was aimed at the production processes and material properties required in products for drinking water applications. It is not known, if the results of this research work could also fulfil the requirements for other production processes and applications. Potential alternatives (e.g Silicon-containing brasses.) have specific disadvantages. It is further important to mention that, according to their standardised compositions alternatives may contain up to 0.25% lead. Si-containing brasses are much more energy intensive during production than lead-containing brasses, resulting in inferior energy efficiency of the production process and in enhanced costs. In addition Si-containing brasses require separate scrap cycles.Industry has estimated that substituting lead-containing copper alloys with lead contents above 0,5 % used in consumer products by Si-containing brasses would result in additional costs of ca. 119 million €/year. Keys Keys for automotive applications and high security cylinders are mainly manufactured from nickel silver alloys with lead contents up to 1.5%. It is obvious that a proper functioning of these keys is not possible without adherence to strict tolerances for drilled holes and/or geometric profiles. An additional benefit of leaded nickel silver is the preferential wear of the alloy relative to the lock material. In a

		lock-and-key application, the key will generally fail first, minimising the cost of maintenance and repair. The lead content also increases the brittleness of the LPS material providing an important safety feature for automotive applications - manufacturers want keys which break upon impact. Keys also pose a lower health risk than assessed in the generic risk assessment of the Annex XV Dossier, where the mouthable surface area of articles was assumed to be 10 cm^2. A typical automotive key has a surface area closer to 5 cm2, leading to lower lead migration levels than those proposed by KEMI. This difference in surface area applies to all key types which are likely to be mouthed by children. It should also be noted that, in many modern automotive applications, the actual key is encased in a plastic housing. This removes the potential for lead exposure during mouthing by children. Musical instruments Lead containing nickel silver, with up to 2.5% lead, and lead-containing free cutting brasses, with up to 3.5 % lead, are used for components of music instruments, e.g. the complex rod and joint mechanism of clarinets. As for keys, no lead free nickel silver or brass alloys are available which provide the same level of machinability in combination with the required surface properties. Metallic components of music instruments are often coated with e.g. a silver layer and/or with an organic lacquer. In order to achieve the surface appearance desired by the customer, the pre-lacquered surface qualities require machining from lead containing copper alloys. The risks arising from musical instruments are lower than assessed in the generic risk assessment. Firstly, music instruments relevant to this restriction proposal are not intended for use by small children, are normally not accessible to them and cannot be handled by them. Musical instruments intended for children are already covered by other regulations, e.g. the Toys Directive. Secondly, any lead release from the materials is significantly reduced due to coating. Locks As with keys, locks require a high precision geometry together with a high surface quality. No lead copper alloys are available which provide the same level of machinability in combination with the required surface properties.

		SEAC Rapporteurs response Thank you for your support and the information on the proposed exemptions (keys, locks and musical instruments). The provided input on the migration testing as well as concerning writing instruments will be carefully considered by the Rapporteurs and SEAC. The compliance cost has already been taken into account by SEAC in their draft opinion. The rapporteurs would like to emphasize that the proposed exemptions reduce the additional cost to 6.3 million €/year.
103	**Date / Time:** 2014/02/14 13:52 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation **Country:** Belgium **Name confidential:** False	**Comment:** The European Portable Battery Association – EPBA – supports the derogation for articles which are already regulated under existing community legislation from the proposed annex XV report to restrict Lead and its compounds in articles intended for consumer use. This proposed derogation is included in the background document of 8 November 2013 and is reiterated in the opinions by the Committee for Risk Assessment and the Committee for Socio-economic Analysis. Portable batteries fall under Directive 2006/66/EC which regulates the placing on the market of batteries and the collection & recycling of waste batteries. In particular, the Directive regulates the Lead content of batteries through specific marking requirements.
		Answer1: Since it is proposed to derogate batteries from the proposed Lead restrictions, this question is not relevant.
		SEAC Rapporteurs response Thank you for your comment and the support on the proposed derogation

104	**Date / Time:** 2014/02/14 14:37 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation **Country:** Germany **Name confidential:** False	**Comment:** Hello, I would like to know, if lead bands in curtains will be forbidden in the future. Best regards Gudrun Höck BTE
		SEAC Rapporteurs response In their adopted opinion (December 2013), RAC has examined the risk aspects of lead containing curtain weights. It is noted that free hanging curtain weights are considered to be accessible, mouthable and within the range of a child so foreseeable misuse may occur. Curtain weights that are covered with a coating that prevents lead migration are considered out of scope of 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.
105	**Date / Time:** 2014/02/14 16:32 **Organisation:** Company-Manufacturer **Type:** BehalfOfAnOrganisation **Country:** Greece **Name confidential:** False	**Comment:** We acknowledge and recognize the importance of this regulation and in general agree with the risk approach taken. We also acknowledge the integration of the research data on lead migration from brass in saliva, leading to derogation for 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). We further fully support the proposed exemptions. In addition to that proposal we would like to raise some issues that probably have not considered critical and lead to the strict concentration limits of Pb, as follows: 1. Mouthing time: In the risk based approach of RAC, the proposed mouthing time for lead containing materials was 60 min, that resulted to the general concentration limit of 0,05 % Pb and 0,5% Pb for Brass alloys. However there is scientific evidence (ECI comments August 2013) that the reasonable worst case daily mouthing time for lead containing materials is 20 min. This would change the concentration limits to 0,15% Pb (generic) and 1,5% Pb (brass alloys) respectively without adding any risks to the population. The same conclusion arises from the Steenbekkers, 2001 paper that

		assessed various methods to describe mouthing behaviors of 42 children of ages relevant to the proposed restriction and that indicates 20 min as a reasonable worst case mouthing time relevant to this restriction. 2. The default surface area of 10 cm2 that assumed for the estimation of the restriction limits is not valid for many consumer products that can be mouthed by children and have a smaller surface area, such as ballpoint tips, clips, metallic noses, keys, etc. 3. The socioeconomic effect of a limit of 0,05% Pb and 0,5%Pb on brass alloys that will affect the 11,3% of the articles (market survey described in chapter B.9.3 of the draft background document) will be severe enough for the industry and the society especially in cases where the substitutes (Si, Bi) do not provide the required functionality and anticorrosion characteristics. Moreover the restricted use of scrap will influence energy efficiency (through primary metals used) and will negatively impact the environment through the reduced recycling loops. 4. The introduction of a migration limit would be more useful. Such integration can be done in a tiered approach. A restriction based on content but, if migration data are available, these can used.
		Answer1: The introduction of a migration limit to ensure an alternative manner of compliance to the restriction will be helpful for the industry. The two-tiered approach as was proposed by ECI is the best solution. According to this the first tier will be the restriction of lead content in articles (% lead) and parts of articles that are sold to the general public and that can be mouthed by children and will be implemented in cases where migration data is not available for the specific lead containing alloy in the article. The second tier will give the option to the industry to use migration data in case they are available for the specific alloy or to perform additional saliva tests for the alloys that have not been tested for migration rates. There are external certified laboratories that run these tests at a reasonable fee of 3300/test and these tests can be performed only once to demonstrate compliance. Following that test, the compliance could then be demonstrated via the lead content within the normal quality management of the fabricators, since the chemical composition of alloys is well defined in European and international standards. Regarding tier 2 and according to ECI a generic migration rate of 1 μg/cm2.h % was determined and

		used in the annex XV report. This value corresponds to 0.05 µg Pb/cm2.h (current proposal at 60 min mouthing time) or 0.15 µg Pb/cm2.h (20 min mouthing time – see above). For brasses, the measured migration rate of 0.1 µg/cm2.h % allowed for a proposed derogation in the annex XV dossier of 0.5% Pb in brass alloys. From a socio-economic perspective, it seems important that other industry sectors may also be enabled to develop/use such information where possible. For example the nickel silver alloys may have lead impurities above 0,05% due to the usage of secondary raw materials. Industry needs a migration limit to be able to demonstrate that these materials are also compliant with the restriction and to be able to still use recycled materials. The use of migration limit is a better approach to assess the impact of articles to the general public. There are articles containing metals and metal alloys that are covered by materials that disable migration (i.e coating), thus the need for migration limits is important in order to test these articles and to assess their real impact to the public. A restriction based on the concentration of lead in the alloys would exclude all these articles from the market with various socio – economic results.
		Answer2: Functionality of lead in copper alloys (more information in ECI comments, submitted in May 2013) Lead is added as a functional alloy constituent because lead, embedded as tiny globules (e.g. in brass alloys), acts as a lubricant and, most importantly, as a chip breaker, allowing the high performance machining of semi-products, without continuously damaging the product itself or the production tools. This results in extended tool lifetime, higher productivity and less usage of resources, together with a high quality surface of the machined material. In addition, lead exhibits corrosion-inhibiting characteristics which minimises the corrosion/metal release of the other alloy constituents. Potential for reduction of lead contents in copper alloys The combination of delivered properties presents a significant challenge in the search for a suitable substitute for lead. Over the last 10-15 years, the industry has reduced, to a minimum, the amount of lead needed for a series of copper alloys while still fulfilling downstream customer requirements. During the last years, the copper industry performed intensive research work to replace lead in free cutting brasses. This research work, however, was aimed at the production processes and material properties required in products for drinking water applications. It is not known, if the results of this

		research work could also fulfil the requirements for other production processes and applications. In addition, no research work was performed, up to now, with respect to lead containing, free cutting nickel silver alloys. Today, two substitutes for lead in free cutting brass are discussed in the context of drinking water applications: Silicon- and bismuth-containing brasses. Both have specific disadvantages. Silicon-containing brasses are much more energy intensive and therefore costly to produce and they require separate scrap cycles. On the other hand bismuth exhibits a series of technically and environmentally relevant disadvantages and amongst other adverse outcomes it seriously impacts the copper alloy recycling loop. It is further important to mention that, according to their standardised compositions, both alternatives may contain up to 0.25% lead. The industry estimates large additional cost to substitute leaded brass with silicon brass (best alternative). For the total tonnage, to be substituted (49,000 T/year copper brass alloys with lead >0.5%) and used for consumer products which can be mouthed, this results in additional costs of ca. 119 million €/year. If the exemptions, outlined in the annex XV proposal (keys, locks, padlocks, musical instruments and tips) are granted, the total cost of substitution is estimated at 6.3 million €/year. For writing instruments, such as ballpoint pens, lead containing nickel silver alloys (LNS) with up to 2.5% Pb and lead containing free cutting brass up to 3.5% Pb (LB) are used. LNS is used to manufacture the ballpoint pen tips, while LB is typically used to manufacture clips and the conical “nose” of a writing instrument. According to information obtained from downstream users, the materials used for ballpoint pen tips have been specifically developed and adjusted to ensure: • good machinability - high speed drilling and turning • high resistance to cracks • excellent cold deformation and concentricity in the miniaturized drilling • shining in their appearance As for keys, locks and music instruments, the production process of ballpoint pen tips and noses requires a high level of machinability performance in combination with a high precision geometry and a high surface quality of the final component. Figures can illustrate the various production steps and high material requirements on machinability (see ECI comments, submitted in May 2013). According to downstream users, a pen must guarantee the writing performance expected by the consumers, i.e. a high, intensive and smooth writing, that makes a pen attractive. For that reason, the

		raw materials used in the ballpoint tips must demonstrate good wear-out resistance, guaranteeing the long lasting performance required to use the entire amount of available ink. “Half-used” pens are wasteful on both raw materials and municipal landfill (recycling is not economic). LNS and LB materials allow billions of tips to be produced with the expected quality and at a competitive price. No “lead free” nickel silver alloys are available which provide the same level of machinability and end-use performance. The risks arising from writing instruments is lower than assessed in the generic risk assessment. Firstly, ballpoint pen tips are, more or less, inaccessible since, in order to prevent the ink from drying out, tips are either covered by a cap or manually relocated inside the pen body after use. Secondly, the surface areas of a ballpoint tip, a clip, or a metallic “nose” are much smaller than the 10 cm^2 assumed. According to downstream user information, the clip and the nose typically have surface areas of 3 cm^2 (in a few exceptional cases, up to 5 cm^2). Due to design, it is extremely difficult for the nose and the clip to be mouthed simultaneously. Finally, these components of a writing instrument are often coated. According to downstream users, the proposed restrictions on lead content, in the metallic materials used for writing instruments, would have devastating effects on their manufacturing processes. An EU ban on writing instruments cannot be the intention, or consequence, of a restriction proposal. Therefore, we propose to keep an exemption for writing instruments (tips and noses).
		Answer3: Answer: More information in ECI comments, submitted in May 2013 Keys, locks and music instruments use metallic components which require a high precision geometry, together with a high surface quality. Only lead-containing nickel silver alloys and brasses are presently able to fulfil these requirements in combination with a high level of machinability. More information on the functionality of lead, reductions in lead content and substitutions are outlined in the answer to question 2. Keys Keys for automotive applications and high security cylinders are mainly manufactured from nickel

		silver alloys with lead contents up to 1.5%. It is obvious that a proper functioning of these keys is not possible without adherence to strict tolerances for drilled holes and/or geometric profiles. An additional benefit of leaded nickel silver is the preferential wear of the alloy relative to the lock material. In a lock-and-key application, the key will generally fail first, minimising the cost of maintenance and repair. The lead content also increases the brittleness of the LPS material providing an important safety feature for automotive applications - manufacturers want keys which break upon impact. Keys also pose a lower health risk than assessed in the generic risk assessment of the Annex XV Dossier, where the mouthable surface area of articles was assumed to be 10 cm^2. A typical automotive key has a surface area closer to 5 cm2, leading to lower lead migration levels than those proposed by KEMI. This difference in surface area applies to all key types which are likely to be mouthed by children. It should also be noted that, in many modern automotive applications, the actual key is encased in a plastic housing. This removes the potential for lead exposure during mouthing by children. Musical instruments Lead containing nickel silver, with up to 2.5% lead, and lead-containing free cutting brasses, with up to 3.5 % lead, are used for components of music instruments, e.g. the complex rod and joint mechanism of clarinets. As for keys, no lead free nickel silver or brass alloys are available which provide the same level of machinability in combination with the required surface properties. Metallic components of music instruments are often coated with e.g. a silver layer and/or with an organic lacquer. In order to achieve the surface appearance desired by the customer, the pre-lacquered surface qualities require machining from lead containing copper alloys. The risks arising from musical instruments are lower than assessed in the generic risk assessment. Firstly, music instruments relevant to this restriction proposal are not intended for use by small children, are normally not accessible to them and cannot be handled by them. Musical instruments intended for children are already covered by other regulations, e.g. the Toys Directive. Secondly, any lead release from the materials is significantly reduced due to coating. Locks As with keys, locks require a high precision geometry together with a high surface quality. No lead copper alloys are available which provide the same level of machinability in combination with the required surface properties.

		SEAC Rapporteurs response Thank you for your support and the information on the proposed exemptions (keys, locks and musical instruments). The provided input on the migration testing as well as concerning writing instruments will be carefully considered by the Rapporteurs and SEAC. The compliance cost has already been taken into account by SEAC in their draft opinion. The rapporteurs would like to emphasize that the proposed exemptions reduce the additional cost to 6.3 million €/year.
106	**Date / Time:** 2014/02/14 17:53 **Organisation:** Industry or trade association **Type:** BehalfOfAnOrganisation **Country:** United States **Name confidential:** False	**Comment:** The Fashion Jewelry and Accessories Trade Association (FJATA) respectfully submits that the draft opinion of the Committee of Socio-economic Analysis (SEAC) opinion on the proposed restriction on lead and its compounds in articles placed in the European market, or in accessible parts of those articles, is not consistent with the best scientific evidence available. The proposal is not the most appropriate EU-wide measure to address the risks of lead content proportionally to its benefits because the restriction applies to adult and children's products without distinguishing between how adults and children handle such products. The proposed restriction essentially ignores the differing potential risks that are the necessary result of different usage patterns. Relatedly, it is not apparent that the proposed restriction is based on a consideration of the actual risks associated with migration in the event of accidental mouthing or ingestion. A more appropriate standard would take such factors into account. We respectfully submit that the SEAC revise its opinion as to jewelry with particular attention to ASTM F2923-11 and ASTM F2999-13, ASTM International's voluntary consensus standards for children's and adult jewelry, respectively. These standards tailor the requirements for each product category to the potential risk and exposure created by those categories. For example, ASTM F2999 (the adult standard) uses higher thresholds for lead content depending on the material than does ASTM F2923 (the children's standard) due to differing pathways for exposure. Using such limits as guides would produce a better, more

		scientifically-sound result for EU consumers while supporting harmonized safe standards recognized worldwide.
		Answer1: Migration studies are generally preferable to total content limits because they are designed to assess amounts of potentially bioavailable material that could be ingested or absorbed into the body as a result of exposure to a product, taking into account the likely routes of exposure. Total content limits may be appropriate where science supports the adoption of the limit based on migration data. Alternatively, total content screening limits may be utilized, with migration testing required in instances where the product exceeds the screening limit. This latter approach was adopted to address potential exposure risks to the target users (children or adults) due to the presence cadmium in ASTM 2923-11 and ASTM 2999-13. In each case, the screening limits and migration requirements were based tests and recommendations of the U.S. Consumer Product Safety Commission (CPSC). See CPSC Staff Report on Cadmium in Jewelry (Oct. 2010), http://www.cpsc.gov//PageFiles/115615/cadmiumjewelry.pdf. This indeed is a far better approach to managing potential exposures to any heavy metals, including lead. As an alternative to content limits, a migration standard may be useful. However, the limit should relate to the potential route of exposure. A limit such as 0.05 µg/cm2 per hr (0.05 µg/g per hr) may not be the most suitable way to measure all relevant potential exposure routes. Tests and limits to address potential exposures from accidental ingestion of substrate material, like an item of jewelry, may well differ from tests designed to measure potential exposures from licking or swallowing chips of paint or surface coatings.
		SEAC Rapporteurs response Thank you for your comment. The provided input on the migration testing and studies will be carefully considered by the SEAC Rapporteurs.
107	**Date / Time:** 2014/02/14 19:47	**Comment:** We followed the demand and present with this document the obtained migration analysis results for

	Organisation: Company-Downstream user **Type:** BehalfOfAnOrganisation **Country:** Germany **Name confidential:** **True**	curtain weights. We discussed with SGS Fresenius Institut about the necessary requirements, which an analysis should sufficiently take into account. To find an appropriate analyzing method we regarded following aspects: Expert Report on Consumer Risk when Dealing with Lead Weight Tapes in Curtains; Envirotex GmbH Private Institute for Product Safety and Environmental Protection “4.2 Exposure through oral intake It is not easily possible for a child to simply swallow a lead weight tape or parts of one. For this to happen, [….] for the purpose of sucking is conceivable. Lead itself does not dissolve in saliva. However, if 1 ‰ of the lead in the form of oxides were to be dissolved by the saliva and 50 – 90% of the 2 µg Pb that was ingested were to be immediately excreted again, a maximum of 1 mg lead would result as bioavailable;[…] this amount does not represent a hazard. To play it safe with respect to saliva extraction behavior, we recommend an analysis for lead pursuant to EN 71 Part 3 (toy standard).” Second aspect taken into account was the definition found on the Homepage of the American Environmental Assessment Homepage on 21st of January 2014 http://www.leadinspection.com/law/law.htm concerning the term mouthable, which was used by the ECHA regarding the risk presented to children. “Accessible Mouthable Surfaces are interior or exterior architectural surfaces or fixtures five feet or less from the floor or ground that form a protruding corner or similar edge, or protrude 1/2 inch or more from a flat wall surface, or are free-standing so that a child may place his/her mouth on the surface or suck the surface....” Both cited documents refer to an analysis in a saliva media. In regard of the definition for a coating and the migration limit given by the RAC a coating should guarantee, we took the following passage of the RAC report as given. “Coated articles: …In this respect RAC refers to the proposed migration limit of 0.05 µg/cm2 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....(c)). “ SGS INSTITUT FRESENIUS GmbH Consumer Testing Services – developed an analysis method to determine the migration in an artificial saliva media, which leads to a result of the demanded criteria of

		µg/g per hour. The testing results are summarized in the following table and detailed analysis reports are offered. Additionally samples of random alternative materials, which were recommended in the RAC assessment, were tested containing four stainless steel materials, of which two failed the migration limit value. Migration Limit Pb 0,05µg/g und h Sample nr. B+M Textil # SGS Fresenius Institut Sample Name Material Migration value Result 1 No. 2034465 Lead bar weights 13g/piece coated Lacquer, Blei 99,96 n.d. Pass 2 No. 2034467 stainless steel bars coated with PP fleece PP Fleece, Niro n.d. Pass 3 No. 2034469 zinc weigthing tape 22g/m PES, Zink 99,97 n.d. Pass 4 No 2034473 Lead weighting tape 14g/m standard PES, Blei 99,97 0.036 µg/gh Pass 5 No. 2034457 Lead weighting tape 14g/m lacquered lead bodies PES,Blei 99,97 + n.d. Pass 6 No. 2034470 Lead weighting tape 22g/m minimal textile coating PES, Blei 99,97 0,90 µg/gh Fail 7 No. 2034460 Stainless steel ball tape PES, Niro 0,157µg/g h Fail 8 No. 2034476 Stainless steel ball tape Grade 2000 PES, Niro 0.118µg/gh Fail 9 No. 2034468 Polymer weighting tape PES, PP + BaSO4 n.d. Pass 10 No. 2034454 Sample Mr. Schmidt: Lead weighting tape sewed to curtain. Double textile coating PES, Blei 99,97 n.d. Pass The samples 1 – 4 are B+M Textil standard products, which are to find in our brochure. Sample 5 was to find out how an additional lacquer coating lowers the migration. Sample 6 was planned as negative test to see how a thinner textile coating preserves lead transport through the coating. This product is not available and is not a product to sale. Sample 7 and 8 with a stainless steel alloy were tested by chance, failed and prove the difficulty with alternative alloys. Sample 9 is a developing project. Sample 10 is a standard product sewed into a curtain. Children get under normal circumstances only in

		contact with lead weights sewed into a curtain. Therefore, this sample represents normal conditions. If a migration of lead occurred in this sample it is below the detection limit. Finally it can be said that the presented results demonstrate that lead in curtain weights coated by B+M Textil GmbH & Co. KG are not a hazard to children or the surrounding. The only article containing lead, which failed the migration limit was covered with a minimum textile coating. This sample should show the impact of a good coating and present that production quality matters. The products of B+M Textil GmbH & Co. KG are standardized and so we can guarantee a sufficient migration protection and safety for children. Nevertheless, B+M Textil will continue to analyze the products to further improve safety. The results show that children, who might suck on a curtain containing a lead weight band will not suffer any health risks coming arising from lead weights. Therefore, a restriction for lead in curtain weights is unnecessary and the consumer is free to choose a weighting material. Please don't hesitate to contact B+M Textil for your further requests. Best regards B+M Textil **[...]**
		Answer1: A migration limit would be helpful to guarantee a safety standard for customers for lead curtain weights. Nevertheless, it is almost impossible to implement a sustitute material to lead for curtain weights and other applications, which don´t consist of any kind of alloy that need a certain amount of lead for processability reasons. Additional coating processes to prevent lead from migration leads to increasing energy efforts and critical substances like solvents, lacquer, etc..

		Answer3: A socio economic balance should therefore include the whole perspective regarding production of additional coating substances, labour, energy, environmental and recycling risk resulting from a substitution or additional coating. Lead is one of the most efficiently recycled materials which satisfies high environmental and economical considerations. A substitution of lead towards zinc, stainless steel or other alloys is not able to compensate the manufacturing efficiency lead offers today. We can say today that our lead products are regional products due to the regional recycling institutions and cannot see a substitute, which fulfils these current criteria.
		SEAC Rapporteurs response Thank you for your comment which is more relevant to the issue of coating (in link to curtain weights) as reflected in the RAC adopted opinion. This Public Consultation is restricted to the draft SEAC opinion, however your helpful information on lead migration testing and the concept of migration limit for the proposed restriction are noted and will be considered by the Rapporteurs.