Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Response to comments document (RCOM)

to the opinions on the Annex XV dossier proposing restrictions on

lead and lead compounds in jewellery

ECHA/RAC/ RES-O-0000001304-85-03/S2

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Lead

EC number: 231-100-4

CAS number: 7439-92-1

04 April 2011

General comments

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
92	N	2010/12/21 18:45	/ / Individual	(A)	I would like to raise the issue of the inclusion of Precious metals in this proposal, as a member of the jewellery trade for the past 30 years and the trade representative on the British Hallmarking Council, I do not believ it necesary to include Silver Gold Platinum and Palladium in this testing process. Lead is not a desirable element in fine jewellery and as most EU countries subject precious jewellery to some form of assay testing i feel this is an unnecessary additional process in the manufacture of jewellery. I firmly support the testing of costume and alloy base metal jewellery as this industry is fraught with lead contamination of the alloys in use and has no testing system in place. please consider this when legislating this law.	DS121: Thanks. This comment has been noted. See also additional information in comment Ref 67 and 60 above.	There is no clear definition for distinguishing between fashion jewellery and precious jewellery.	Mandatory testing is not a requirement of the restriction – only compliance with limit values set. Precious jewellery sector testing should be limited. Compliance with Cadmium restriction also to be required therefore no major additional testing for lead necessary.
91	N	2010/12/21 18:09	/ / Individual	(A) (D) (E),	The changes would require that all jewellery is tested before it reaches the retail market, even precious jewellery that has been hallmarked and so already proved that it does not have a dangerous	DS122: Concerning hallmarked jewellery, see response DS48. The fact that testing costs could	No further comments.	See comment to 92. If Hallmarking is

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				(F)	level of lead. This unnecessary testing process could slow the transition of jewellery to market, adding an unnecessary hoop for jewellery businesses to jump through. The testing means would also mean extra added costs for jewellery manufacturers and suppliers.	slow the delays of market placing will be added in the BD.		ensuring that the jewellery conforms to the requirement no additional testing necessary
90	N	2010/12/21 17:48	United Kingdom /	(A)	While I applaud the attempt to remove lead from children's fashion jewellery, the inclusion in this restriction of required testing for precious metals and UK hallmarked gold, silver and platinum jewellery is absurd, adding an unnecessary step and potentially increasing costs for production and retail of items that, by their very nature, do not contain lead anyway. It's taking a sledgehammer to crack a nut, at the jewellery trade's expense	DS123: This comment has been noted. See also additional information in comment Ref 67 and 60 above.	There is no clear definition for distinguishing between fashion jewellery and precious jewellery.	See comment 91 and 92
89	N	2010/12/21 16:17	Austria /	(A) (B), (C), (F), (G)	The aim of the toys directive 8(2009/48/EC) is to protect children. It is obvious, that children suck on toys and it is even possible the they swallow toys. For that reason the toys directive foresees very strong limit values and test methods. Therefore we are in favour to orientate on the toys directive and to overtake the limit values, measurement and test-methods from the toys directive! Furthermore we are afraid, that most of the regarded companies, importers and producers aren´t informed about this public consultation (see also answer 2) or not able to answer this consultation because of language problems!	DS124: The values calculated and the exposures are specific to jewellery that is why the limit of migration is not the same than the one indicated in the Toy Directive. Furthermore the value for jewels is a migration rate in saliva while the value for toys is a migration in gastric acid. So it is very difficult to compare the different limits as they are based	The limit values proposed for jewellery are based on the latest international evaluations on lead and the method for obtaining a limit value is not exactly the	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Dossier now includes proposal for concentration

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						on different exposure assumptions see DS14. Concerning the "risk of exposure", we agree that children have more often access to toys than jewels but a child that will wear a jewel or who has freely access to a jewel will have an exposure close to his exposure to toys. Also see response DS23.	same as for the Toy Directive. Furthermore the limit value in the Toy Directive is at present re-evaluated.	limit test
88	N	2010/12/21 15:44	United Kingdom / Assay Office / The Birmingham Assay Office	(A) (C)	We agree that lead in jewellery is especially harmful if swallowed or sucked by children		Comments noted.	

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87	Y	2010/12/21 15:06 Att. ref 87	Austria / chamber /	(H)	The fashion jewellery industry welcomes further steps to protect consumers from threats of hazardous substances resulting from an unintended use of jewellery such as mouthing or swallowing. The industry has taken various steps towards reducing potentially harmful chemicals in their products and in the production chain and will continue to do so. In this regard, we welcome a regulation of lead in jewellery with a restriction based on the lead's migration rate, as this takes sufficient account of the actual risk incurring through mouthing and ingestion. However, after a thorough review of the proposal we have identified certain elements, which would make a successful implementation highly difficult, if not impossible. An implementation of this proposal as it is currently phrased could heavily affect the European jewellery industry – both manufacturers and retailers, many of whom to be classified as small and medium-sized companies. Thus, in our view, a number of specific principles should be taken into account in order to ensure an effective implementation leading to a high standard of consumer safety: □ The proposed legislation should be inspired by the standard for lead in other EU legislation, i.e. Directive 2009/48/EC (hereinafter referred to as the "toys directive"), which already constitutes a feasible and effective instrument on European level for the protection of consumers' health against the risks resulting from an exposure to lead, in particular in relation to ingestion and mouthing.	DS125: Concerning the toys Directive, see response DS23 and 124. Further, the proposed restriction recommends the use of the standard EN 71-3, used in the toys Directive (with some	See response to ref 89. In the final RAC opinion it is proposed to base the restriction on the content (0.05%) as an association between content and migration is anticipated. To derogate from this all parts of the piece of jewellery has to comply with a migration limit of 0.05 µg/g/h. RAC has taken note of the difficulties	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Dossier now includes proposal for concentration limit test

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					Should testing methods differ substantially from norm practices (e.g. those applied in the toys directive), implementation would be very difficult and a longer period than the proposed 6 months would be necessary due to a highly fragmented and complex supply chain of the jewellery industry.	adaptations). As regards the attached file : 1. for the surface measurement question and the unit of the limit, see responses DS14, DS15 and DS94 2. for the question of coating and substrate: a definition of "coating" is now integrated in the BD. Difference between "plating" and "coating" to be considered (see DS26) as well. 3. the base metal and the coating of a jewellery piece have both to be in compliance with the limit proposed (and thus added) because, in a worst case, a child might be poisoned by the ingestion of the lead contained into the coating (chronic mouthing) and then the ingestion of the lead contained in the uncoated (degraded) jewel (acute exposure). Further, if the child swallowed the leaded coated piece as a whole, he could also	concerning a migration rate per cm^2 and now proposes a migration limit per g jewellery instead.	

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						be acutely poisoned by the leaded coating and the base metal under the coating. 4. As far as the testing of the coating on the basis of the nickel Directive, it is an option to be considered. See DS28. 5. For the costs of testing, see DS32. 6. Extended time frame to be considered.		
83	Y	2010/12/21 11:51	Italy / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G (H)	SEE ATTACHED FILE Following the first contribution made by EUROFASHION BIJOUX we are presenting here a second contribution as part of the public consultation, in order to forward additional proposals based on tests purchased by accredited laboratories. These proposals, which are intended to be practical and implementable by the industry, are focused on different aspects previously discussed, ie : - Proposal of an alternative unit of lead's migration rate - Proposal of a regulatory limit value - Proposal of a test protocol for coating and substrate - Proposal of an implementation schedule of the restriction I. Proposal of an alternative unit of lead's migration rate a) The difficulty of calculating the measure in $\mu g/cm^2/hr$		Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also answers to ref 87 and ref 89.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Regarding delay period, SEAC agrees that in order to minimise

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					b) Tests results expressed in µg/cm^2/hr and in mg/kg Uncertainty of the surface calculation Uncertainty of measuring devices Differential costs of tests in the adopted unit measure To conclude, it seems that the proposed unit in µg/cm2/hr faces some important difficulties because of the uncertainty of the surface calculation and the limits of detection of the equipments in laboratory and also because of the prohibitive cost to make tests for each component. Regarding these arguments, it seems clearly preferable to maintain as a unit, the one from the standard NF EN 71-3 related to the toy's regulation, i.e. mg/kg. II. Proposal of a regulatory limit value Equal treatment for jewels and toys A standard NF EN 71-3 on toys easier to apply If we consider the preceding elements, applying to jewelry the standard NF EN 71-3, the limit value of which is 90 mg/kg, seems to be the best option. III. Test protocol proposal for the coating and the substrate a) Interpretation proposal : a definition for Coating b) Methodological proposal : product wear test IV. Proposal of an implementation schedule of the restriction a) Reminder of the times of inventory turnover in force in the sector b) Implementation schedule proposal For all this, we estimate that an implementation delay of 24 months would be in conformity with the economic reality of the sector and would therefore make it easier to apply by our companies.	DS127: See DS125 above and DS14, 15 and 94. The surface was included in the unit to not overestimate migration from big jewel that cannot be entirely put in the mouth by a child. An alternative is proposed in DS response 14.		scrappage costs, a delay of 12-18 months appropriate

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					Synthesis In conclusion, our sector wants to promote a positive approach aiming at limiting the use of lead in jewelry to levels which guarantee children's health and at determining a procedure really enforceable by companies which are mainly very small. For these reasons, French manufacturers are advocating the following proposals for the future regulation: - A calculation in which the unit is expressed in mg/kg and not in µg/cm2/hr - The application to jewelry of the limit value of 90 mg/kg already used in standard NF EN 71-3 related to toys - The recourse to wear tests made by abrasion as a way to evaluate lead release rate on coated items A 24 months implementation delay of the restriction	DS128: Extended time frame to be considered. As regards the attached file: see responses to comment Ref 31.		
82	N	2010/12/21 11:51	Germany / Industry or trade association /		The fashion jewellery industry welcomes all further steps to protect consumers from the influence of hazardous substances resulting from the unintentional misuse of jewellery. The industry has already taken various steps towards reducing potentially harmful chemicals in its products and the production chain, and will continue to do so in the future. In this regard, we welcome a regulation of the lead content in jewellery. However, after a thorough review of the proposal put forward by the French government, we have identified certain elements which would make a successful implementation extremely difficult, if not impossible.		Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. In the RAC	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Dossier now includes proposal for

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					- The proposed testing methods differ greatly from conventional standard testing practices. In order to achieve a standardisation of testing procedures and a comparability of test results, we consider it essential to implement the standard practices currently in use. - The highly fragmented and complex supply chain of the fashion jewellery industry, would make the implementation of the new proposal virtually impossible within the proposed 6-month period. - In our opinion, it is incomprehensible that the limit for lead in jewellery should be lower than that for food. - High-quality fashion jewellery is electro-plated with precious metals such as gold, rhodium or palladium. This reduces the migration of hazardous substances (e.g. lead) from the jewellery.	DS130: Agree. New considerations to that respect have been integrated in the BD. DS131: Extended time frame to be considered. DS132: The kind of exposure is different. Moreover, the limit for food cannot be considered as higher because the values for food are based on a real intake (meaning hundred grams of food/d) but children will not ingest jewellery every day. Furthermore, the limits for food are based on the old TDI and they will evolve according to the EFSA report from 2010. The TDI from EFSA and the one of our dossier are very close. DS133: Acknowledged. See also additional information in responses to comments Ref 67	opinion the regulation is primarily directed towards a limit value for lead content in jewellery of 0.05% (500 mg/kg). This is orders of magnitude higher as compared to the limit values in food.	concentration limit test Regarding delay period, SEAC agrees that in order to minimise scrappage costs, a delay of 12-18 months appropriate

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						and 60		
81	Y	2010/12/21 11:07 Att. ref 81	Spain / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G) (H)	The fashion jewelry industry welcomes the objective to protect children from hazardous substances. Nonetheless, regarding the importance of this question for Jewelry and Crystal Industry, additional information and knowledge from these professional organizations seems essential from a technical as well as from an economical point of view. Thus, several aspects of the suggested operating procedure may be problematic in their implementation, such as: -the unit of migration rate and its limit -the separate calculation for the coating and the substrate From an economical point of view, two further aspects of the proposal exposed in the report deserve to be reconsidered because of lack of conformity with the industry's reality and practice: - The cost evaluation induced by the tests set by the standard NF EN 71-3 - The enforcement period of the restriction These elements are developed hereunder. 1. Limit and unit of the proposed lead's migration rate Reminder: the proposed test to evaluate the lead's migration rate of jewelry's items is the one which is used for the toy's regulation in the standard NF EN 71-3 (Part 3: Migration of some compounds) simulating the ingestion of a toy by a child. The limit set up by the toy's regulation is 90 mg/kg. a. The difficulty of calculating the surface The possible risks of lead's exposure coming from jewelry's items can be considered as comparable to those coming from toys, which	DS134: See responses to comment Ref 69 below. As regards the attached file: see responses to comment Ref 31.	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 87 and 89.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Regarding delay period, SEAC agrees that in order to minimise scrappage costs, a delay of 12-18 months appropriate

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					mean a possible ingestion or mouthing of the item by children. The restriction proposal in jewelry is based on the standard NF EN 71-3, which only simulate a stay in gastric acid (therefore an ingestion), as no method is available for the measurement of lead migration rate in saliva. Now the enforced limit in the restriction proposal is 0.09 µg/cm2/hr. Unlike the limit set up by the toy's regulation (data in mg/kg), it would from now on be necessary to determine the item's surface in order to obtain the lead's migration rate in µg/cm2/hr. The problematic will also arise for the measure of the lead's release rate if it has to be given according to the surface, the latter's calculation often being very hard to achieve.			
80	Y	2010/12/21 10:54	France / Industry or trade association /	(A) (F)	The fashion jewelry industry welcomes further steps to protect consumers from threats of hazardous substances resulting from an unintended use of jewelry such as mouthing or swallowing. The industry has taken various steps towards reducing potentially harmful chemicals in their products and in the production chain and will continue to do so. In this regard, we welcome a regulation of lead in jewelry with a restriction based on the lead's migration rate, as this takes sufficient account of the actual risk incurring through mouthing and ingestion. However, we have identified certain elements, which would make a successful implementation highly difficult, if not impossible. An implementation of this proposal as it is	DS135: See responses to comment Ref 87 above	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 89.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Regarding delay period, SEAC agrees that in order to minimise

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					currently phrased could heavily affect the European jewelry industry – both manufacturers and retailers, many of whom to be classified as small and medium-sized companies. to ensure an effective implementation leading to a high standard of consumer safety, several arguments have to be taken into account : The proposed legislation should be inspired by the standard for lead in other EU legislation, i.e. Directive 2009/48/EC (hereinafter referred to as the "toys directive"), which already constitutes a feasible and effective instrument on European level for the protection of consumers' health against the risks resulting from an exposure to lead, in particular in relation to ingestion and mouthing. Should testing methods differ substantially from norm practices (e.g. those applied in the toys directive), implementation would be very difficult both for small and medium-sized companies and for the laboratories, -A longer period than the proposed 6 months would be necessary due to a highly fragmented and complex supply chain of the jewelry industry.	As regards the attached file: thank you for having provided some migration tests and information about the feasibility of the testing. For units see DS 14. For the comparison between toys regulation and the proposed restriction see DS 21 and DS 124 Concerning the wear tests and coating, see DS 26 - 27 Concerning the implemetation delay, an extended timeframe is now proposed.		scrappage costs, a delay of 12-18 months appropriate
79	N	2010/12/21 09:22	Austria / Industry or		I agree to the importance to protect our children. Regarding lead in fashion jewellery the point is to find realistic prescriptive limits which are possible to reach in a realistic periode of time.		Comments noted.	The restriction based on concentration should be easier

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			trade association /		And as well to controll the prescriptive limits of goods which are imported into Europe or goods which are produced here. Because there are lots of small manufacturers of fashion jewellery in Austria and Europe who will be heavily effected by such a strong restriction!			for SME to meet
78	N	2010/12/20 20:07	Spain / International organisation /		Following the first contribution made by EUROFASHION BIJOUX we are presenting here a second contribution as part of the public consultation, in order to forward additional proposals based on tests purchased by accredited laboratories. These proposals, which are intended to be practical and implementable by the industry, are focused on different aspects previously discussed, ie : - Proposal of an alternative unit of lead's migration rate - Proposal of a regulatory limit value - Proposal of a test protocol for coating and substrate - Proposal of an implementation schedule of the restriction I. Proposal of an alternative unit of lead's migration rate a) The difficulty of calculating the measure in µg/cm2/hr b) Tests results expressed in µg/cm2/hr and in mg/kg Uncertainty of the surface calculation Uncertainty of measuring devices Differential costs of tests in the adopted unit measure To conclude, it seems that the proposed unit in µg/cm2/hr faces some important difficulties because of the uncertainty of the surface calculation and the limits of detection of the equipments in laboratory and also because of the prohibitive cost to make tests for	DS138: See responses to comment Ref 83 above	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 87 and 89.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Regarding delay period, SEAC agrees that in order to minimise scrappage costs, a delay of 12-18 months appropriate

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77	N	2010/12/20 20:07	Spain / International organisation /		Following the first contribution made by EUROFASHION BIJOUX we are presenting here a second contribution as part of the public consultation, in order to forward additional proposals based on tests purchased by accredited laboratories. These proposals, which are intended to be practical and implementable by the industry, are focused on different aspects previously discussed, ie : - Proposal of an alternative unit of lead's migration rate - Proposal of a regulatory limit value - Proposal of a test protocol for coating and substrate - Proposal of an implementation schedule of the restriction I. Proposal of an alternative unit of lead's migration rate a) The difficulty of calculating the measure in µg/cm2/hr b) Tests results expressed in µg/cm2/hr and in mg/kg Uncertainty of the surface calculation Uncertainty of measuring devices Differential costs of tests in the adopted unit measure To conclude, it seems that the proposed unit in µg/cm2/hr faces some important difficulties because of the uncertainty of the surface	DS138: See responses to comment Ref 83 above	Your comments are noted and have contributed to the RAC-process for elaboration of the restriction proposal. See also response to ref 87 and ref 89.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Regarding delay period, SEAC agrees that in order to minimise scrappage costs, a delay of 12-18 months appropriate

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					calculation and the limits of detection of the equipments in laboratory and also because of the prohibitive cost to make tests for each component. Regarding these arguments, it seems clearly preferable to maintain as a unit, the one from the standard NF EN 71-3 related to the toy's regulation, i.e. mg/kg. II. Proposal of a regulatory limit value Equal treatment for jewels and toys A standard NF EN 71-3 on toys easier to apply If we consider the preceding elements, applying to jewelry the standard NF EN 71-3, the limit value of which is 90 mg/kg, seems to be the best option. III. Test protocol proposal for the coating and the substrate a) Interpretation proposal : a definition for Coating b) Methodological proposal : product wear test IV. Proposal of an implementation schedule of the restriction a) Reminder of the times of inventory turnover in force in the sector b) Implementation schedule proposal For all this, we estimate that an implementation delay of 24 months would be in conformity with the economic reality of the sector and would therefore make it easier to apply by our companies. Synthesis In conclusion, our sector wants to promote a positive approach aiming at limiting the use of lead in jewelry to levels which guarantee children's health and at determining a procedure really enforceable by companies which are mainly very small. For these reasons, French manufacturers are advocating the following			

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76	N	2010/12/20 20:06	United Kingdom / Industry or trade association /	(A (B), (C), (D)	Commentary: 15 April Annex XV Restriction Report, Proposal for a Restriction. Lead and its compounds. Summary The International Lead Zinc Research Organization (ILZRO), a not-for-profit research management organization based in the United States, has examined the 15 April, 2010 version of the "Annex XV Restriction Report, Proposal for a Restriction: Lead and its compounds" on behalf of the International Lead Association (London). Although ILZRO and ILA are supportive of efforts to reduce child exposures to lead, our review has produced a series of general and specific comments that are the source of reservations as to the practical implementation and benefits of the current restriction proposal to limit the use of lead in all forms of jewellery. • Justification for extending the restriction proposal to jewellery products intended for use by adults is lacking – indeed the range of products to which the proposal would apply is imprecisely defined.	DS139: The proposal is based on the case of accidents that have been reported (jewels intended for children and not) and on the	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. Regarding the health risk evaluation we think that we are coherent with the recent JEFCA and EFSA	Children may also mouth jewellery intended for adults. 5 minutes per week is appreciable in relation to IQ loss. Furthermore distinction between adult and children jewellery is difficult to enforce.

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					• The underlying toxicological justification for the proposal further contains a number of unsupported assumptions and technical inaccuracies. The toxicokinetic model selected to predict acute exposure is inappropriate. • Implementation of the proposal is further linked to analytical sensitivity benchmarks as opposed to actual estimates of risk of adverse health outcomes. • Exposure estimates are based upon mouthing times and leachate test procedures that are inappropriately conservative and exceed what can be termed reasonable worst case exposure scenarios. Suggestions are offered as to modifications that could be made to the existing proposal that would facilitate the identification and implementation of measures that may be needed to prevent undesirable paediatric lead exposures resulting from jewellery. General Comments Our general comments address the following issues: • Imprecise definition of 'jewels' • Items intended for use by children, fashion jewellery and	fact that children are more vulnerable than adults since lead has no-threshold effects on the CNS of children. DS140: Comment acknowledged. See also response to comment ref 76. DS141: The aim of this proposal is to protect as much as possible children from an accidental poisoning that is why worst case is used. Some refinements of the duration of mouthing are proposed and will be discussed see response DS80.	evaluations also in relation to the interpretation of the current lack of an identified threshold for adverse effects. See also response to ref 90. With regard to mouthing times RAC discusses this in BD and evaluates scenarios with various mouthing times.	Amendments already made to dossier in background document take on board already a number of the issues and concerns expressed The opinion uses the word jewellery.

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					fine jewellery • Threshold or no-threshold for Pb neurotoxicity • Establishment of exposure limits • Migration rate approach Imprecise definition of Jewels: Although both ILA and ILZRO are supportive of measures to reduce lead exposure resulting from any product intended for use by children, the current proposal proposes restrictions upon any jewellery product to which children might conceivably gain access. The proposal consistently uses the term "jewels" throughout to refer to a wide array of products that differ significantly with respect to their basic composition and function. The term "jewels" appears to be used to refer to products that include precious and semi-precious gemstones, synthetic gemstones and crystals, coloured natural or synthetic pearls, metallic ornamental articles, ceramic ornamental articles, and metal or plastic articles coated with enamels or paints. This lack of specificity in terminology complicates evaluation of the proposal in that the reader is often uncertain as to the nature of the product(s) that have been demonstrated to pose exposure risk and those that have not. Imprecision in terminology also lends uncertainty as to the precise scope of the restriction proposal. Recommendation: More precise terminology should be used to describe the full range of products that would be covered by the dossier. The proposal should also more precisely specify the types of products that have been documented to pose risk of excess lead	DS142: See DS31 for the definition of fashion jewellery proposed in the dossier. Further, "jewels" to be replaced by		The opinion is made on the basis of risk

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					exposure. This would facilitate understanding of the different products of concern, the different relative exposure risks they may pose, and the need for restrictions on the use or forms of lead in some or all of the products being evaluated. Items intended for use by children, fashion jewellery and fine jewellery: The proposal has as its impetus a small number of case studies published since 1998 describing lead intoxication in children in the United States, Canada and Japan after the ingestion of lead-containing "jewels". The case studies, in most instances, appear to entail ingestion of lead metal jewellery objects produced and marketed for use by children. Such products are clearly hazardous to children's health if ingested. However, no data are presented that demonstrate whether such incidents have occurred within the EU and/or the nature of EU products that can realistically be assumed to pose excess exposure risk. The presence of lead in "fashion jewellery" and "fine jewellery" produced for use by adults is noted, and the assumption made that children might have access to such products. Precise description of fine and fashion jewellery containing lead is generally lacking and little quantitative evidence is presented indicating that paediatric lead	"jewellery" in the dossier. Concerning the types of products concerned, it is impossible to provide a list of specific products which might cause the risk given that the few reported cases concern very diversified products. Those cannot thus be relevantly considered as representative of the risk. DS143: For the risk within the EU, see response DS7 and for the justification of the inclusion of adults jewellery within the scope, see DS30 and section A.2.1.		related to mouthing not ingestion A partial CBA has been carried out to assess the impacts of

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					exposures have resulted from such articles. While there may be some risk of lead exposure from the unintended use of adult products by children, the benefits that would accrue from extending the restriction proposal to adult products are difficult to quantify or place in proper perspective. Excessive lead exposures have been related to a variety of natural and anthropogenic lead sources within the EU but it is far from clear if adult jewellery products have significantly impacted past or current lead exposure levels. Recommendation: The relative merits of a restriction proposal upon jewellery could best be judged if placed within the context of other non occupational lead exposure sources and a quantitative assessment made of the relative contribution of different jewellery types to the overall lead exposure risks. No threshold for lead neurotoxicity: The restriction measures proposed are predicated on the assumption that there is no threshold for lead neurotoxicity and the assumption that all exposures to lead are harmful and should be avoided. This is inconsistent with recent deliberations by international bodies such as the Joint Expert Committee on Food Additives (JECFA), the deliberative body which makes international recommendations for limits on dietary lead exposure. JECFA (2010) has recently withdrawn the PTWI for lead based upon concerns that health effects might be exerted at levels lower than previously believed and issued the statement that "as the	DS144: For the reasons already set forth, the relative contribution of different jewellery types is impossible to assess. However, the other lead exposure sources have been put into perspective in the BD DS145: DS disagrees with your conclusion that '*there are levels of lead exposure at which health effects are deemed to be inconsequential*'. Lots of recent		the proposed restriction

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					dose-response analyses do not provide any indication of a threshold for the key adverse effects of lead, the Committee concluded that it was not possible to establish a new PTWI that would be health protective." However, JECFA also concluded that "the health impact at the lower range of human dietary exposure "is considered negligible by the Committee". In so saying JECFA essentially endorses the concept of an epistemic threshold for lead health effects as described in the Voluntary Risk Assessment for Lead. Although a threshold may not have been defined for lead exposure, there are levels of lead exposure at which health effects are deemed to be inconsequential. Establishment of exposure limits: The restriction proposal presents a procedure for determining the amount of lead that can be contained in jewellery items that might be contacted by young children. The proposal appropriately concludes that several potential lead exposure pathways are either likely to be negligible contributors to overall exposures and risks associated with jewellery (i.e., dermal contacts and inhalation) or are adequately screened for by consideration of the scenarios that are emphasized in the proposed restriction procedure (i.e., intake via hand-to-mouth transfer of lead from jewellery items). As a result, the proposal appropriately focuses on two potential lead exposure pathways: acute exposures that might occur following accidental ingestion of a lead-containing "jewel" and chronic exposures that might occur following mouthing of a lead-containing	publications demonstrated a non threshold effect of the lead on the nervous system and the development of infants (this fact has been largely accepted among the MS) which cannot be considered as inconsequential to our point of view.		

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					"jewel". The proposed procedure for addressing those two potential pathways considers the following key elements: • Leaching of lead from jewellery following mouthing and accidental ingestion; • Estimation of lead intake resulting from the assumed exposure scenarios; • Modelling of blood lead concentrations associated with estimated lead intake levels; and • Identification of lead exposure levels (i.e., target blood lead concentrations) of health concern. For each of these key elements, the proposal has included assumptions or approaches that appear to be highly conservative and/or do not best reflect currently available scientific information. The resulting exposure estimates likely overestimate the potential impact of jewellery upon the lead exposure of children. A migration approach based on a leaching test is proposed and would be desirable since it can provide a risk based assessment of the materials used for jewellery. Given that there is no known relationship between lead concentration in jewellery materials or coatings and the lead release rate which dictates the presence or absence of risk, appropriately designed leach tests should provide scientifically sound input for the risk calculations. Moreover, experience with the Nickel leaching standard (for materials in prolonged contact with skin) has proven that such a risk based approach can be effective. A migration based approach allows the sector and authorities to recognise the differences in migration	DS146: As there is no data on mouthing of jewels by children, conservatives approaches have been taken into account. As explain in the dossier the main point of uncertainty is the daily mouthing time of jewels. See also response DS 80.		

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					behaviours of natural lead contained in gems, tightly bound lead in crystal, lead in alloys and lead metal used as such. CONCLUSIONS The proposal to restrict the use of lead and lead compounds in jewellery has the laudable goal of reducing the exposure of young children to lead. ILA and ILZRO concur that the use of lead in any product intended for use by children should be restricted. Moreover a migration based approach is reflective of potential risk and is supported since it overrules the problem that no relationship between lead concentration in the jewel and release rate can be demonstrated. However the current proposal extends beyond products intended for use by children to include all jewellery products (inclusive of fine and costume jewellery intended for use by adults) in the absence of any observations that the latter products constitute a significant exposure risk for children. The extension is made through a variety of assumptions that combine to yield exposure scenarios that exceed the bounds of what can be termed "reasonable worst case" exposure estimates. Amongst the problematic aspects of the proposal are: • Absence of data demonstrating that adult jewellery poses exposure risk for children • Indexing of exposure limits to analytical proficiency as opposed to any estimate of effect • Assumption of analytical proficiency that exceeds real world proficiency by a factor of at least four. • Inadequate definition of the toxicological impacts of lead exposure upon children and the assumption of no threshold dose			

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					response functions. Recent studies have suggested thresholds and agencies such as JECFA have indicated that there are lead exposure levels below which effects are not significant. • Use of unvalidated pharmacokinetic models (in lieu of established models) to obtain grossly exaggerated estimated of acute exposure duration and intensity. • Inflated estimates of the likely rate of jewellery ingestion by children. • Assumption of jewellery mouthing behaviours and times that significantly over-estimate plausible real world worst-case scenarios • Proposed use of acidic leach tests that mimic the conditions of the stomach in lieu of tests that mimic contact with neutral pH saliva to predict exposure from mouthing behaviour Restrictions that limit the use of lead, particularly lead metal or coatings, to jewellery products intended for use by children would be protective of child health and feasible to implement. Extension of restriction to fashion jewellery, if properly risk-based, would require the development and validation of new testing regimens and analytical strategies for a complex array of materials – all to address a theoretical exposure risk that has not been demonstrated to have a significant impact upon child lead exposure. Inclusion of fine jewellery, made from precious metals and gemstones, in the restriction proposal would be in the absence of any observed or theoretical risk and is even harder to justify.			
75	N	2010/12/20 19:32	Austria /		We, as a jewellery manufacturer, welcome further steps to prevent our customers from dangerous material such as the various taken	DS147: Acknowledged. It would have been interesting to have	Comments noted.	The draft opinion

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			Company /		steps (eg. nickel) in past. Therefore the regulation of lead in jewellery will harm the whole european jewellery branch intensively. With the proposed value of 0.09 µg/cm²/hr there wouldn´t be any chance for most jewellery producers to stay alive. In our case, as we are producing jewellery out of a tin alloy, there wouldn´t be an alternative raw material which can fall below this value. As a consequence, we and surely a lot of our competitors all over Europe will not be able to persist.	some data on the additional (unbearable?) costs your particular activity might suffer from. As far as possible alternatives are concerned, see comment Ref 73 below.		recommends concentration limit of 0.05%w/w. So tin can be used
74	N	2010/12/20 18:56	United Kingdom / Industry or trade association /		The British Jewellers Association is in agreement with the comments provided by the Birmingham Assay Office: "Precious metal jewellery alloys, including children's jewellery, are unlikely to contain any lead as it would cause the items to fracture during manufacturing. Enamels etc. used for decoration are also lead-free as they would pose serious health issues during firing. The Birmingham Assay Office is of the opinion that precious metal products should be exempted from testing (as they are in the USA), however, non-metallic decorative coatings should be tested". We strongly advise that the British Jewellers' Association and Birmingham Assay Office be invited to contribute further comments at the next discussion/decision making process. At present, the French proposals have failed to include the impacts upon the UK jewellery sector.	DS148: Acknowledged. See also response DS24 and additional information in responses to comments Ref 67 and 60.	Comments noted.	No reason to exempt hallmarking jewellery (used in half of EU states). If hall marking ensures jewellery does not contain lead then no further cost are envisaged.
73	N	2010/12/20 18:48	Germany / Company /	(A) (C)	We are one of the leading manufacturers and distributors for tin based alloys for the jewellery industry in Germany and Austria. In general, we welcome a regulation of lead contents in jewellery in regard to the hazardous effects caused by the substance lead.		Comments noted.	

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					However, from a metallurgical point of view, we have identified certain elements, which would make a successful implementation highly difficult, if not impossible. As stated in the proposal, tin based alloys are a common and very suitable material for manufacturing jewellery and have been used over thousands of years. Lead has always been a substantial part of tin alloys used for jewellery, mainly due to technical reasons in regard to the casting process. Because of health risks and existing regulations in other branches (RoHS, Oekotex 100, etc), we developed several 'lead free' tin based alloys still suitable for casting. These alloys show a lead content of about 400mg/kg as an impurity. A lead content of about 200mg/kg in these alloys might be technically achievable, but only in conjunction with a dramatic rise in cost and a very restricted availability of high grade tin (99.99%) on the world market. Using tin alloys for casting, a proposed limit of only 0.09 µg/cm2/hr constitutes an unfeasible standard, technically as well as economically. Setting this standard as currently phrased could heavily affect the European jewellery industry – both manufacturers and retailers, many of whom to be classified as small and medium-sized companies.	DS149: Thank you for this information concerning tin alloys. As far as costs are concerned, Table 50 of the dossier shows that the average estimated cost of lead-free tin alloys (about 10.07€/kg) is not substantially higher than the average estimated cost of lead-based tin alloys (about 10.50€/kg) (for alloys with at least 90% of tin), about 4%.		In the draft opinion SEAC recommends a restriction based on concentration (0.05%)

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72	N	2010/12/20 18:19	Austria / Company /.		I agree to the importance to protect our children. Regarding lead in fashion jewellery the point is to find realistic prescriptive limits which are possible to reach in a realistic periode of time. And as well to controll the prescriptive limits of goods which are imported into Europe or goods which are produced here. Because there are lots of small manufacturers of fashion jewellery in Austria and Europe who will be heavily effected by such a strong restriction!	DS150: See response to comment Ref 79	Comments noted.	See previous comments ref 79
71	Y	2010/12/20 18:18	Austria / Company /		Behind our brand lies an Austrian company with branches in 12 countries, around 1.000 employees, some 6000 self-employed jewellery consultants, and production of 5 million items of custom jewellery per annum. As the proposal could heavily affect us and other European manufacturers we fully support the statements given on behalf of the European fashion jewellery industry. We also welcome a regulation of lead in jewellery with a restriction based on the lead's migration rate, as this takes sufficient account of the actual risk incurring through mouthing and ingestion. Nevertheless it has to be noted that especially the Limit and Measurement Method, Separate Testing of Coating and Substrate and last not least the Timing and Cost for Implementation are our main concerns. 1) A standard for lead in jewellery should be inspired by the standard for lead in the toys directive, which is based on the lead's migration rate and set in mg/kg.	DS151: Concerning the question of the unit, see DS 14 and 15.	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 89.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)

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					2) The proposed standard should be in accordance with other European legislation on lead. When compared to such existing regulation it becomes clear that the proposed standard for jewellery results in a significantly lower limit than those set for lead in toys or food, although the risk of exposure is lower in case of jewellery 3) In high quality fashion jewellery the base metal is plated with precious metals such as gold, rhodium and palladium through electroplating. This can substantially decrease the possibility of exposure to lead through mouthing and ingestion. Thus we propose to use the same approach as the one used for the nickel standard and to permit testing of the metal part of the jewellery including a plating of sufficient quality, namely precious metals applied to the substrate by means of electroplating.	DS152: The limit proposed for jewellery is not lower than the limit of the Toys Directive. The intake limit used in French proposal is 1.2µg/day compared the one used in the Toys Directive which is 0.7µg/day. See also DS 21 and 124 DS153: Acknowledged. See also DS135 and additional information in responses to comments Ref 67 and 60.		
70	N	2010/12/20 17:34	United Kingdom / Industry or trade associ	(A) (B), (C), (D) (E), (F), (G) (H)	Commentary on 'Background Document to the Opinion on the Annex XV Dossier proposing Restrictions on Lead and its Compounds in Jewellery' dated April 2010 Prepared for International Lead Association RPA		Comments noted. The restriction proposal is primarily driven by the aim for protecting against chronic	

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			ation /		16 December 2010 Commentary on 'Background Document to the Opinion on the Annex XV Dossier proposing Restrictions on Lead and its Compounds in Jewellery' dated April 2010 December 2010 prepared for The International Lead Association by Risk & Policy Analysts Limited Farthing Green House, 1 Beccles Road, Loddon, Norfolk, NR14 6LT Tel: 01508 528465 Fax: 01508 520758 Email: post@rpaltd.co.uk RPA REPORT - ASSURED QUALITY RPA Project: Ref J710 Approach: In accordance with discussions with Client Report Status: Final Report Report Prepared by: Meg Postle, Director Philip Holmes, Technical Director Panos Zarogiannis, Principal Consultant Thomas Persich, Researcher Report approved for issue by: Meg Postle, Director Date: 16 December 2010		toxicity and not acute toxicity which is less critical for derivation of a limit value for lead in jewellery.	

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					1. INTRODUCTION At the request of the International Lead Association, Risk & Policy Analysts Ltd. (RPA) have reviewed a version of the French draft Annex XV Restriction Dossier on a proposal for restriction of Lead (Pb) and its compounds in jewellery, dated April 2010. Our findings and suggestions as to approaches that may be helpful in the future development of this dossier are presented below. 2. SUBSTANTIVE COMMENTS 2.1 Issues Relating to Human Health Impact 2.1.1 Risk of adverse health consequences Section B of the Annex XV Restriction Report on lead and its compounds by the French Competent Authorities correctly reports that the toxic effects of lead in terms of both its possible acute and chronic changes have been generally established in terms of the dose-response characteristics applying to various endpoints, including the important issue of the its influence on human neurodevelopment. The particular susceptibility of young children has also been previously reported, with this relating not only to their apparently higher oral absorption rates and immature state of neurological development but also to behavioural issues such as their high level of mouthing activity compared with adults and older children. However, there is a strong basis for questioning the estimate in the draft Annex XV Restriction Report of the extent to which jewellery items are prone to being swallowed by young children and the implicit assumption that this then leads to poisoning of the child as a			

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					result of lead assumed to be present within the item. The Restriction Report correctly reports the death of a child after ingestion of a metallic charm in Minnesota in 2006 (CDC, 2006) and a number of other cases, including a case of non-fatal lead poisoning from ingestion of a toy necklace in Oregon in 2003 (CDC, 2004). It also draws on a stated 52 cases of ingestion of jewels for children under 5 years-old by 10 French emergency services between 2004 and 2007. As a dataset, however, this is a somewhat limited and incomplete basis for extrapolating to an estimate of 5000 children possibly ingesting jewellery every year in Europe and from which to also assume that this number are necessarily at risk of lead poisoning. There is considerable evidence suggesting that jewellery items as well as many other small objects – including toys – do indeed represent a real and significant risk to infants and young children with attempts to swallow objects by this age group apparently a relatively frequent occurrence. However, the major risk associated with the accidental swallowing of non-food items appears to relate to choking hazard not poisoning. Rimell et al (1995) and Steen & Zimmerman (1990) have reported that approximately two-thirds of all choke deaths among children occur in those under 3 years of age and Altmann & Ozanne-Smith (1997) showed that the level of non-food related non-fatal asphyxiation and foreign body ingestion was relatively constant over the first 3 years of life and then declined by 6 years of age. A study by Banerjee et al (1988) also found that children under 3 years were the most vulnerable to inhalation of foreign bodies. It thus appears that the risk of choking is greatest in those under 3 years of	DS154: Acknowledged. Thank you for these data. DS is aware that one of the major risk is the chocking risk. However, the risk of ingestion also exists and is (with mouthing) the risk targeted in the dossier. As regards the population potentially exposed to ingestion estimated at 5,000 children, it is an upper bound which has to be associated with a probability to swallow a piece of jewellery. This step is integrated in the BD in the new Annex F.		The opinion is based on the risk by mouthing. Possible risk related to ingestion strengthen the proportionality of the restriction.

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					age but remains appreciable until 6 years of age (Altmann & Ozanne-Smith, 1997, Reilly et al 1996, Rider & Wilson 1996 and Rimell et al 1995). Estimates drawing on data from the 1980s and 1990s suggested that in the UK there were 2600 non-fatal and 24 fatal cases of children under 4 years of age choking on objects each year, and estimated that there were over 50,000 non-fatal choking incidents and 400 deaths in children under 10 years of age (mostly under 5) each year in the EU. Incidences ranged from 0.4 (Sweden) to 3.4 (Greece) deaths per 100,000 children. Of these, 51% were attributable to food, 6% to toys and 32% to non-toy items (mainly coins) (DTI, 1996 and 1999). Other data suggest that suffocation rates in infants alone (e.g. from choking) may be 4.4 deaths per 100,000 (Public Health Service of Canada, 2009) while, in the State of Victoria Australia, hospital admission rates (1987-1995) for asphyxiation are 15.1 per 100,000 children; foreign objects accounted for about 80% of the Australian cases but most related to swallowing coins (Altmann & Ozanne-Smith, 1997). Set against this high incidence of choking, the risk of lead poisoning as a result of swallowing jewellery items seems very small. For example, considering the US population, poisoning of children by lead from any source appears to be a rare event, with some 5,800 cases per year identified in the US population of children below 6 years of age. Importantly, of these only 1.8% arose from causes other than domestic exposure to old (lead-containing) paint and this 1.8% included - in addition to jewellery - candles, spices and minim blinds (Goldman 2007). The US CDC also estimated the rate of	DS155: Thank you for this information and data.		

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					death due to all causes of unintentional poisoning (not just lead-related) for 0-9 year olds in 2006 to be 0.15 per 100,000 (CDC, year not specified) while in Canada, jewellery was not identified as a significant contributor to causes of unintentional poisoning in the young (0-19 years of age), for which all causes combined accounted for 20 per 100,000 hospitalisations per year and 0.3 deaths per 100,000. Most of these occurred in the 15-19 year age group and, hence, are highly unlikely to be related to the swallowing of jewellery. Importantly, focusing on the European situation, a database established by RoSPA (2010) reports that, for the UK population of children (0-4 years), the yearly incidence of suspected poisoning from all sources that were considered of sufficient concern to require hospital attendance was only 25,950 during 2000-2002, of which an average of 20 cases (0.077% of total) were attributable to suspected poisoning by jewellery items. Furthermore, this database showed that poisoning accounted for only 4.1% of the 481 incidents involving jewellery in this age group. Regrettably, the underling poisonous agent(s) in the jewellery was not reported and, while it may be assumed that a proportion of these cases may be attributable to the presence of lead, it is know that several other toxic metals including cadmium are present in some jewellery items so not all these cases might, in fact, be attributable to lead poisoning. Adopting the UK annual estimate of 20 children per year of hospitalisation (not death) attributable to poisoning by jewellery, and extrapolating from the estimated total size of the UK population of 59,217,592 to that of the EU-27 (484,636,747) for the year 2002			

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					(Eurostat, 2010) indicates that there might be of the order of 164 cases of jewellery-related poisoning of children of up to 4 years of age across Europe each year of sufficient severity to require hospitalisation. A more refined approach would be to base this extrapolation on the size of the child population. Eurostat provides data on national populations under 5 years of age. For the UK, the relevant population in 2002 was 3,448,236 while for EU-27 it was 25,200,752 children. Using these population values, suggests there would be only 146 cases of jewellery-related poisonings of children. Of these, an unknown proportion may reflect lead toxicity but, given that several other toxic metals have been found in some jewellery, it is considered unlikely that all these cases would be attributable to this particular substance. This casts significant doubt on the robustness of the Restriction Report's estimate of the number of children affected as about 5,000 per year. We would also note that no detail is provided on the locations of the 10 French emergency services that have documented cases on children swallowing jewellery items. Thus it is not possible to judge whether these are representative of all French emergency services (e.g. in terms of the size of the population covered by each of them) or indeed of any other emergency service across the EU. Finally, it is also worth noting that the information on the French emergency services summarised in Section G.5 does not indicate what the composition of the offending items in those 52 cases were. Therefore, it should have been made clearer in the text in Section			

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					F.1.2 that not all 5,150 children potentially swallowing a jewellery item each year would necessarily be exposed to lead (as the metal is unlikely to be contained in all items swallowed by children). The Restriction Report correctly identifies that, based on the Danish Study, it is not possible to address the safety concerns with regard to the presence of lead in jewellery items in terms of the percentage lead content (this aspect is discussed further below). Rather, the key property on which any risk assessment would have to be based is the extent to which lead migrates out of a piece of jewellery under specified conditions. The report is also helpful in establishing the limitations of current methodologies to allow the accurate determination of this property. 2.1.2 Health Consequences of Exposure Episodes Section B of the dossier includes discussion on the nature of the hazard that might be faced by young children through mouthing or swallowing lead-containing jewellery items. Issues related to estimating the degree of exposure that may arise from such activities are discussed in relation to exposure issues below. We would draw attention, however, to the degree of uncertainty that surrounds the consequences of acute or episodic exposure to lead, as opposed to continuous exposures such as would be associated with contamination from dietary sources, for example with regard to the consequences for cognitive development and the extent to which recovery might occur following an acute exposure, or even following a reduction in the level of episodic or even continuous exposure.	DS157: Unavailable information DS158: As lead is considered to induce non-threshold effects on the neuro-development of children, it would be difficult to consider a total recovery after an acute exposure even if the PbB level decreases. Concerning the chronic exposure, since, again, lead induces effects on the cognitive		In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Dossier now includes proposal for concentration limit test. For the practicality issue it should be taken into account that the jewellery is also covered by new regulation on cadmium Acute risks from ingestion not considered

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					Thus, any estimate of impact based on acute/subacute exposure situations (such as from swallowing or intermittent mouthing) needs to be treated quite differently from situations when one is attempting to estimate the consequences of chronic exposure. In particular, the clinical consequences of these different exposure patterns are known to be quite distinct and it would be questionable were attempts to infer the outcome of acute or subacute exposures to be inferred from epidemiological or experimental data relating to chronic exposures. This is particularly important in the case of this Restriction since it is firmly established that, for example, mouthing activity falls rapidly form the age of 1-2 years and can be regarded as minimal by 5 years of age. The dossier would certainly benefit from a detailed exploration of these aspects, for example, based on a quantitative analysis of the risk of adverse effects and, within a SEA, the consequences in terms of health impacts. In particular, this should draw on recent literature and make an attempt to account for uncertainty within variables via some form of sensitivity analysis. This may allow for a better estimate of the scale of impact on IQ that is likely to occur as a result of intermittent exposures due to mouthing. This could be done, for example, in a 'reverse SEA' that would seek to determine the level of benefit required in order for particular restriction options to be justified. 2.2 Issues Relating to Exposure to Lead The statements that jewellery is a significant potential source of lead and, therefore, an appreciable risk to the population, are not adequately placed in context against the size of the population	development with no threshold, even an exposure during 2 years would be sufficient to induce effects. Moreover, the length of exposure is not the most important factor; the specific time-frame of exposure would also matter.		in CBA. SEA analysis amended in this respect

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					segment that may be at risk from such exposures (for which there are limited direct data) and the predominant sources of exposure of the entire population. 2.2.1 Background of Falling Population Exposure to Lead While the report mentions the raft of measures which have resulted in dramatic falls in exposure to lead over recent decades, of which the most significant legislation has been the reduction of lead in petrol through Council Directives 85/220/EEC, 98/70/EC and 2003/17/EC, it would perhaps have been useful to include data illustrating the extent to which people's, particularly children's, blood lead concentrations have fallen in most countries over the recent decades. This would place the focus of the dossier in better context against the falling overall risk to the human population now posed by lead and its compounds. For example, as of 1990, emissions from the road transport sector were responsible for over 70% of total environmental emission of Pb. Following the withdrawal of Pb from use in this sector, emissions from this source decreased by >95% (EEA, 2010). When current sources of Pb exposure in the general population are considered (see Table 1), it can be clearly seen that the principal remaining source of exposure is in relation to intake via the diet (about 60% of TDI) with, in children, intake from soil and dust being the next most significant source. Thus, the Restriction dossier is likely to significantly over-estimate the number of cases of poisoning/deaths that are attributable to Pb in jewellery. Table 1: Child's Average Daily Intake from Environmental Lead Exposure	DS159: An attempt to quantify the impact of lead poisoning on IQ is integrated in Section E.2.3.1.1 of the BD. DS160: This is briefly mentioned at the beginning of the dossier in section A.1.2.1. DS161: These data have been		

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					Average Daily intake of Pb for children aged 1-3 years (µg/kg bw/day) % of the TDI (3.6 µg/kg bw/day) Dietary 2.1 58.3 Soil and dust 0.18 5 Outdoor air 0.001 0.03 Environmental tobacco smoke 0.012 0.34 Total 2.293 63.7 Source: Adapted from EFSA(2010) These changes in exposure levels have been reflected in dramatic changes in the systemic lead levels across the population. For example, in the early 1970s, childhood blood lead concentrations of 400 µg/L were not uncommon. However, the geometric mean blood lead level of 1 to 5 year olds in the US had fallen to 150 µg/L by the late 1970s and to 20 µg/L by 1999. In Sweden, levels had stabilised at only 20 µg/L in 7-11 year olds in the period 1995 to 2001 and a geometric mean level of 34.4 µg/L has been reported in 2.5 year olds in the UK (Koller et al, 2004). This reduction in blood lead is expected to be maintained or indeed further improved upon in the forthcoming period due to implementation of additional agreed measures, such as a reduction in the drinking water standard from 25 to 10 µg/L (HPA, 2009) and continued restriction of the use of lead-containing fuels. Indeed, Stromberg et al (2008) report that the average blood Pb reduction has been approximately 5% per year since the start of reduction/banning of Pb in petrol. This reduction has been hailed as "a particular success story" by the European Environment Agency	added to the BD in section B.4.11.2.		

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					and a report by the World Health Organisation (WHO, 2010) on children's health concluded that "Eliminating Pb exposure from gasoline has been one of the most significant environmental health improvements in recent times". 2.2.2 Likelihood of Lead Being Present in Jewellery Focusing now specifically on the risk of exposure from jewellery, we note that the Restriction dossier indicates that, based on the cited Danish Study, it is not possible to address safety concerns on the presence of lead in jewellery items, in terms of percentage lead content. Rather, it is correctly noted that the key property on which any risk assessment should be based is the extent to which lead migrates out of a given piece of jewellery under conditions relevant to mouthing or swallowing of the item. The dossier is also helpful in establishing the limitations of current methodologies to allow the accurate determination of this property. Against this background, the precise scope that should be placed on any restriction of Pb in jewellery is an important aspect that warrants further consideration within the dossier. In particular, there is a question over whether there is adequate justification to include all forms of jewellery given the evidence as to the amount of lead that is likely to be present in precious items and gemstones. For example, the survey of chemicals present in jewellery carried out for the Danish Ministry of the Environment (2008) analysed 318 jewellery parts from 170 pieces. It demonstrated that there was a much greater chance of a high lead content occurring in cheaper metal jewellery articles than more expensive ones; the results are summarised in Table 2.			In the draft opinion SEAC

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					Table 2: Content of Pb in Relation to Euro/Gram* Cost of jewellery item (Euro/gram) % of items with Pb content of Number of jewellery items < 0.01 0.01-1 1-5 5-10 >10 1.34 70 22 2 0 6 37 Total 170 *exchange rate calculated from http://www.xe.com (1 Denmark Krone = 0.134 Euro (09/11/2010)) Source: Danish Ministry of the Environment (2008) As might be anticipated, precious jewellery (i.e. those with high gold or silver content) is the most expensive and, as cost increases, the lead content of items falls significantly. Thus, over 70% of items valued at more than 1.34 euro per gram had a lead content of	DS162: These data refer to Table 3-8 section 3.4.4. of Danish EPA 2008 report. Indeed, DS perfectly agrees that fashion jewellery is likely to contain much lead than precious jewellery.		recommends a restriction based on concentration (0.05%)
69	N	2010/12/20 15:43	Spain / Industry or trade association /	(A) (B), (C), (D (E), (F), (G) (H)	The fashion jewelry industry welcomes the objective to protect children from hazardous substances. Nonetheless, regarding the importance of this question for Jewelry and Crystal Industry, additional information and knowledge from these professional organizations seems essential from a technical as well as from an economical point of view. Thus, several aspects of the suggested operating procedure may be problematic in their implementation, such as: -the unit of migration rate and its limit -the separate calculation for the coating and the substrate From an economical point of view, two further aspects of the proposal exposed in the report deserve to be reconsidered because of lack of conformity with the industry's reality and practice:	DS163: See responses to comment Ref 81 above	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 87 & 89.	See response to ref 81

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					- The cost evaluation induced by the tests set by the standard NF EN 71-3 - The enforcement period of the restriction These elements are developed hereunder. 1. Limit and unit of the proposed lead's migration rate Reminder: the proposed test to evaluate the lead's migration rate of jewelry's items is the one which is used for the toy's regulation in the standard NF EN 71-3 (Part 3: Migration of some compounds) simulating the ingestion of a toy by a child. The limit set up by the toy's regulation is 90 mg/kg. a. The difficulty of calculating the surface The possible risks of lead's exposure coming from jewelry's items can be considered as comparable to those coming from toys, which mean a possible ingestion or mouthing of the item by children. The restriction proposal in jewelry is based on the standard NF EN 71-3, which only simulate a stay in gastric acid (therefore an ingestion), as no method is available for the measurement of lead migration rate in saliva. Now the enforced limit in the restriction proposal is 0.09 µg/cm2/hr. Unlike the limit set up by the toy's regulation (data in mg/kg), it would from now on be necessary to determine the item's surface in order to obtain the lead's migration rate in µg/cm2/hr. The problematic will also arise for the measure of the lead's release rate if it has to be given according to the surface, the latter's calculation often being very hard to achieve. Additional comment on the calculation of the external surface for Crystal:			

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					It is usual that jewelry is made by opacifying the surface of Crystal by frosting. In this case, the specific surface, which means the reactive one after the lixiviation test, is clearly bigger than the "stretched" surface in purpose. The division factor of the analytical result is then largely minus and the ratio mass of lead/unit area greatly overestimated. This enhances the doubts that we can have on the relevance of measuring the surface of the targeted items. b. Inadequacy between suggested method of calculation and nature of identified risks. As previously mentioned, the suggested unit in the report for lead restriction in jewelry is the same as the one used for nickel restriction in jewelry. The risk related to the exposure to jewelry releasing nickel is an allergy risk due to skin contact. Now, this has nothing to do with lead in terms of exposure risk as with lead, mouthing and ingestion are the dangers brought forth. Therefore the suggested unit in the toy's regulation (mg/kg) is more appropriate than the one suggested in the restriction project which corresponds to a combination of the toy and nickel in jewelry regulations. There is no reason to treat jewelry different from toys. Moreover is it easier to implement. c. The necessity of an analytical coefficient and the difficulty to determine a limit value Another fact related to the standard NF EN 71-3 has to be considered. Indeed, according to the standard, the analytical results have to be corrected by an analytical coefficient in order to take into account the measure's uncertainty. It is these results that have to be			

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					below the imposed limit. It is obvious that an analytical coefficient should also be applied to the results under jewelry restriction, yet this point isn't addressed in this limitation proposal. Moreover, the limit determined within the report seems extremely restrictive, as it refers to the surface's calculation (unit : µg/cm2/hr) rather than the unit used for toys (mg/kg). Lab tests have been performed on samples in accordance to the test protocol defined in the standard NF EN 71-3. Results were calculated under the standard in mg/kg and under the suggested restriction in µg/cm2/hr. Sample 1 : A free-cutting brass with 3% lead - Lead's migration rate obtained under the toy's regulation: 8.54 mg/kg - Lead's migration rate obtained under the suggested regulation for jewelry: 19 µg/cm2/hr (this result hasn't been amended with a coefficient) Sample 2 : First sort of crystal : Lead Crystal A - Lead migration rate obtained under the toy's regulation : 0.15 mg/kg - Lead migration rate obtained under the suggested regulation for jewelry: 0.082 µg/cm2/hr (this result hasn't been amended with a coefficient) Sample 3 : 2nd sort of crystal : Lead Crystal B - Lead migration rate obtained under the toy's regulation : 0.37 mg/kg - Lead migration rate obtained under the suggested regulation for jewelry: 0.216 µg/cm2/hr (this result hasn't been amended with a			

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					coefficient) The observed results considerably vary regarding the suggested unit and the performed tests show that the limit set for jewelry's items is much more severe than the one set for toys while the risks and possible exposures are the same. We also note that regarding all the existing legal requirements on lead, whether European or international, detailed in the report pages 46, 47, 48 and 49, the limit value is always expressed in ppm or in mg/kg. It therefore appears that with the same risks and exposures, the restriction limit value for the use of lead in jewelry is much more severe than the one set under the toy regulation, and this without being justified. We fully agree to the application of a migration rate, but to be set in mg/kg. 7 d. Detection limits of analytical equipments The report doesn't precise the analytical method to use in order to measure the lead's migration rate. It simply says that the inductively coupled plasma spectroscopy (ICP) and the flame atomic absorption spectrometry are suitable techniques. Whatever the technique is, the suggested lead's migration rate of 0.09µg/cm2/hr is very low and, regarding the size of the sample, can be close or even below to the detection limits of the measuring equipments. Now the closer we are to the limit of the measuring equipments the most the precision and the reliability of the measure decrease. 2. Separate calculation for Coating and substrate Reminder : the restriction proposal advocates that the adaptation to			

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					the standard NF EN 71-3 (which should be used to implement the lead's migration test) should be done. One of them is for coated jewelry. The Coating will have to be separated from its substrate. Both materials should be tested separately and the addition of both lead's migration rate so determined shouldn't overtake the limit value to meet the regulation. Initially, the matter is to precisely determine what "coating" means. A clear and precise definition of coating would be necessary. Furthermore, there are coatings which are nearly impossible to remove. Example of difficulty to locate the boundary between component and coating in the case of crystal : It is often applied an ornamental coating by the superposition of several layers made of different types (SiO2, TiO2, Au, …). The thickness of this kind of coating is usually of 2 to 3 µm, and its entire mass on the item is below 10 mg which make it impossible to analyze under the standard EN71-3, §7. However this standard imposes to separate it by mechanical action while, by nature, the 2 elements are strongly linked to the substrate crystal which is a heavy technical problem. 3. The evaluation of costs induced by tests under the standard NF EN 71-3 Regarding the tests which should be implemented by both companies and authorities during the controls, it is indicated in the pages 95 and 96 of the report that the cost of a test for a compound such as lead under the standard NF EN 71-3 is 22 euros. We are surprised by this figure, which appears to us to be very much			Costs of testing independently

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					below the reality especially if techniques such as ICP or atomic absorption spectrophotometry are used. If the company wants to be sure of the conformity of its items with the standard, they purchase themselves a testing through independent laboratory. The cost for this will be very much higher than the one indicated in the report. After consulting a private and independent lab (CRITT in Schiltigheim) that could purchase the test, the unit cost per tested compound is 191 euro. 4. The delay of implementation of the restriction The delay suggested in the report is 6 months after the legal implementation of the annex XVII of REACH law. The assumption that jewelry stocks aren't consistent and that a renewal of collections is made every 6 months is highlighted. However this approach ignores the economical reality of the jewelry industry. In the exemption agreement for deadline payment between suppliers and specialized distributors in watchmaking, Jewelry, Silvermaking, agreement extended in 2009 the 2nd of April by decree, it is established that stocks rotation is very often above one (1) year as it is revealed by the study of Society 5 : Jeweler, watchmaker (2008) Sells / stocks * under observation Sells / stocks Months needed to sell Common Jeweler and watchmaker 0,87 14 months Diffusion Jeweler and watchmaker ** 1,28 9 months Jeweler*** 0,9 13 months * stock valued at selling price, in selling point taking part to the survey			verified and updated in BD In the draft opinion an extension of transitional period to 12-18 months

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					City or commercial center * Out fabrication and special orders The 6 months delay suggested to apply this restriction is extremely short regarding the economical figures of the industry and therefore could be only satisfied with considerable harm to the fashion jewelry industry and resellers.			
67	Y	2010/12/20 14:39 Att. ref 67	United Kingdom / Industry or trade association /			DS164: As regards the attached file: 1.As regards the Paints Directive 1999/45/EC, it only contains an obligation of labelling, which DS thinks to be insufficient (see also section E.1.3.). 2. As regards the lead content of precious jewellery, thank you for this information about the fact that hallmarking is not a guarantee of zero lead (although lead is not/little used in practice). 3. Thank you also for the information about alternatives. 4. The toxicity of zinc is already mentioned in the dossier (C.4.2.) 5. Concerning testing: it seems not to be clear whether this	Comments noted.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%). Screening testing is possible by use of XRF.

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
						comment is referring to EN 71-3 or not. 6. Concerning the need for stock to be exempted, an extension of the timeframe is under consideration, which should allow for their sale.		
64	N	2010/12/20 12:08	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F), (G)	The Irish Competent Authority (IECA) would like to thank the French CA for the work it has undertaken to prepare this Annex XV dossier to propose a restriction on lead (and its compounds) in jewellery. In general, we support the principle that a permanent EU restriction on Lead (and its compounds) in jewellery should be introduced to address the risk to human health. We would also like to contribute the following comments and observations in relation to the Annex XV restriction dossier under the specified headings: A - Suggested restriction A.1 Limit value: during the review of Annex XVII in 2008-2009, some of the limit values were changed to % (w/w) for consistency. In light of this, we would like to suggest that consideration is given, to how the new limit value unit (µg/cm2/hr) correlates with this approach. A.2 Asterisk statement: Due to the format of Annex XVII it will not be possible for an asterisk to reside on the 'conditions of restrictions' column title. We believe this information should be incorporated into the entry text.	DS165: See DS 14 and 15.	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also answer to ref 87.	A revised

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					A.3 Wording: If the limit is to apply to the entire article and/or each individual part of the article, we would suggest using the following amendments to paragraph 1 and 2: 1. Shall not be used in jewellery articles, or any parts thereof, if the lead migration rate from such articles is greater than 0.09 µg/cm²/hr. 2. Articles, or any parts thereof, which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph. A.4 Antiques and jewellery already on market: We believe it may be necessary to consider a possible exemption for antique jewellery or jewellery that is already available on the EU market. A.5 Definition of jewellery: The proposed restriction will apply to both precious and fashion jewellery. For clarity, we would suggest it may be necessary to include a definition for jewellery. We believe the proposal in Section E.2.1.2.3 Manageability i.e. to base the definition on the one used in the TARIC code with an addition to cover jewellery which is clad with precious metal may be a good option. A.6 IE entry in Table 22 (pg. 49) and table 56 (pg. 124). Table 22 contain a list of national regulations in EU Member States concerning the use of lead and its compounds in fashion jewellery. This includes an entry which suggests that Ireland has put in place national legislation to regulate 'electronic jewellery'. This is on the	DS166: The French CA maintains its proposal and its position on the definition of "article". DS168: See DS143 and DS31 DS169: This information is extracted from consultation. Further, the Table quotes a national law as a transposition of a EU directive. As a		wording is included in the draft opinion A.4 In draft opinion it is proposed to follow the cadmium restriction (i.e. that the restriction does not apply to jewellery on the market 6 month after EIF of the cadmium restriction). A6 The row in table 22 (now 24) deleted as proposed and Directive

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					basis of information provided by Ireland's Department of Environment, Heritage and Local Government (DoEHLG) in Question 3 of the French questionnaire in June 2009 (see pg. 142). A similar entry is included in Table 56. We would like to request that the 'Ireland' entry should be deleted from Tables 22. Instead we suggest that a new row is included at the beginning of Table 22 as follows: Country: EU Regulation/Action: Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Jewellery article: Watches Requirement: The maximum concentration value of lead tolerated by weight in homogenous material = 0.1% The reason for requesting this amendment is as follows: S.I. 341 of 2005 simply transposed the RoHS Directive in Ireland and does not go beyond the requirements of the RoHS Directive. It should not be considered a national regulation in the context of Section B.9.1.1 part C and Table 22. B – Information on hazard and risk B.1 Migration rate: Table 14 indicates the identified studies on the presence of lead in fashion jewels, the majority of information is on lead content, not lead migration rate. It is difficult to interpret this data in the context of the proposed migration rate limit (µg/cm2/hr) and where migration rates are proposed as they are presented with different units (e.g. mg/kg).	consequence, DS has no reason so far to modify this entry. DS170: This table aims at providing data on the presence of lead in jewellery		20002/95 included in table 24 as well

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					C – Information on alternatives C.1 Identification of potential alternative substances and techniques: It is reported that it does not seem possible to substitute lead by only one metal for its use in jewellery, but instead for an alloy of several metals. Lead-free alloys are already available on the market for fashion jewellery, including silver, tin, zinc, copper and bismuth. Although risks to human health relating to tin, bismuth, copper and silver are discussed in Section C.2-C.6, in our opinion it is not clear from the information presented as to whether the alternatives are considered acceptable from a human health perspective. D – Justification for action at EU level D.1 Incidence of lead poisoning: There is an information gap with respect to incidents of lead poisoning in the EU from jewellery. We acknowledge that it may be difficult to gather information on such incidents of lead poisoning however we would expect this to be reflected in the Annex XV dossier. E – Why a restriction is the most appropriate EU-wide measure E.1 Enforcement of restriction: If documentary evidence (e.g. safety data sheets/supply chain lists/certificates of compliance from suppliers etc.) does not clarify whether or not lead or its compound with a migration limit greater than 0.09µg/cm2/hr are 1) being used in articles being produced in the EU or 2) contained in articles imported from outside the EU, then an enforcement inspector would need to sample the articles and test them.. We suggest that specific information about sample preparation and testing could be contained in the FAQs on the Restriction pages of the ECHA website.	DS171: The conclusions of the section on alternatives have been clarified in the BD. DS172: See DS7 DS173: This is an ECHA matter.		

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					E.2 EN 71-3 Standard: Paragraph 3 of the proposed restriction entry specifies that the migration rate should be performed according to the EN 71-3 standard. This standard may be updated in the future or a more relevant standard may become available. Therefore, rather than specifying a particular standard, we suggest replacing the text in paragraph 3 with the following: "The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2". We suggest that any necessary adaptations to EN 71-3 should be contained in any guidance note that may accompany the restriction, stored for example in the FAQs on the Restriction pages of the ECHA website. F – Socio-economic assessment of the proposed restriction F.1 Enforcement costs: There are technical and economic issues related to enforcement and monitoring which may be more significant than expected in the dossier. The MSCA feedback indicates higher costs associated with the testing and enforcement of a lead migration rate compared to lead content limit. From a technical point of view there are unresolved issues related to calculating the surface area and the volume of solution to be used etc. In our opinion, a lead content limit may be more practical for enforcement. However, it is not clear from the information presented in the dossier whether it is possible to set a lead content rate that would ensure the same level of risk reduction as the proposed lead migration rate.	DS174: This is a Forum issue. DS175: See new Annex C.		In the draft opinion SEAC recommends a restriction based on concentration (0.05%)

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					F.2 Socio-economic analysis: While the dossier concludes that the restriction proposal seems to be economically feasible, there is no systematic presentation or analysis of the socio-economic data in either section E or F to support this conclusion. Some of the information required to present an analysis similar to the Canadian example is available in the dossier, but the stage of analysing this data to reach a conclusion about economic feasibility is not presented. For example, information on economic impacts such as purchasing alternative raw materials (e.g. that the replacement of lead with an alternative is estimated to cost between 15,000 and 150,000) could be balanced against the estimates of the number of children swallowing jewels each year and the estimated costs of such cases (extrapolated from the Canadian data if no other data is available). F.3 Location of SEA content in dossier: We believe it would have been beneficial if the socio-economic data and analysis had been presented in a single section of the dossier. G – Consultation Precious jewellery sector: It is stated on pg. 22 of the Annex XV dossier that 'consultation has been focused on the fashion jewellery sector as only fashion jewels were targeted in the restriction proposal at the time of the consultation'. We would be concerned at the lack of consultation/communication involving the precious jewellery sector, seeing that it is being proposed that restriction covers precious jewellery as well as fashion jewellery.	DS176: see new Annex D DS177: Public consultation has brought many comments and expression now from precious jewellery sector.		Amended CBA undertaken DS followed Annex XV layout.
61	N	2010/12/17 14:20	Netherlands		Vereniging Gebra is an organisation (non –profit) for retailers in the Mixed Branche (housewares, ceramics) and toys. As a part of the		Your comments are noted and	

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			/ retailassociation /		assortment lots our members sell fashionable jewellery. Gebra has 800 members together exploiting more than 2.500 shops in the Netherlands. Our general comments on Annex XV proposing restrictions for lead: 1. For all parties in the chain (manufacture retail) it will be much more workable to use one standard for measuring migration of lead. Exposure to lead is lower in jewellery than in toys or food. 2. Examining migration by measuring the surface of jewellery is complex because of the shape of most jewellery. In that case there is a high risk of inaccurate measurements. This will have the effect that there is a risk that the aim of protection against migration will not be reached. It will also increase the cost of testing. We would therefore prefer measuring migration by weight (in mg/kg) like applied in the toy directive or other jewelry regulations in the USA, Canada or Denmark. 3. The risk of mouthing toys is in our point of view higher than the risk of mouthing jewellery. Jewellery isn't used for playing by children whereas toys are explicitly produced to be played with by children. The chance of mouthing by children is rare compared with the chance of mouthing toys. The same can be said when compared with the EU standards for food whereas food is explicitly produced for mouthing. 4. The low level limits of lead in jewellery will result in problems with the implementation of substitutes for lead. All substitute alloys will have in one way or the other some pollution or impurity. Because of the low levels even substitute alloys cannot be	DS178: See DS21, DS124 and DS132 DS179: See DS15 and 94 DS180: DS agrees. DS181: Acknowledged	have contributed to the RAC process for elaboration of the restriction proposal. See also answer to ref 87.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%). Re. 3 the CBA is based on mouthing of non- toys. Re 4. The level is above the level for impurities in e. tin.

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					used. 5. The delay of six months after legal implementation is much too short. What we call in the Netherlands the "speed of turnover" will be somewhere between 0,5 – 1 year. This means that the jewellery stock is sold in a period of 12 to 24 months and not within a period of 6 months. Vereniging Gebra Zoetermeer, December 17 th 2010	DS182: Extended timeframe to be considered		Re 5 In the opinion an implementation period of 12-18 months is recommended
60	Y	2010/12/17 13:33 Att. ref 60	Austria / Company /	(A (B), (C), (F), (G)	The fashion jewellery industry welcomes further steps to protect consumers from threats of hazardous substances resulting from an unintended use of jewellery such as mouthing or swallowing. The industry has taken various steps towards reducing potentially harmful chemicals in their products and in the production chain and will continue to do so. In this regard, we welcome a regulation of lead in jewellery with a restriction based on the lead's migration rate, as this takes sufficient account of the actual risk incurring through mouthing and ingestion. However, after a thorough review of the proposal we have identified certain elements, which would make a successful implementation highly difficult, if not impossible. An implementation of this proposal as it is currently phrased could heavily affect the European jewellery industry – both manufacturers and retailers, many of whom to be classified as small and medium-sized companies. Thus, in our view, a number of specific principles should be taken into account in order to ensure an effective implementation leading to a high standard of consumer safety: - The proposed legislation should be inspired by the standard	As regards the attached file: 1. For the surface measurement question and the unit of the limit, see responses DS14, DS15 and DS94 2. For the question of coating and substrate: a definition of "coating" is now integrated in the BD. Difference between "plating" and "coating" to be considered (see DS26) as well. 3. The base metal and the coating of a jewellery piece have both to be in compliance with the limit proposed (and thus added) because, in a worst case, a child might be poisoned by the ingestion of the lead contained into the coating (chronic	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 82, 87 and 89.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					for lead in other EU legislation, i.e. Directive 2009/48/EC (hereinafter referred to as the "toys directive"), which already constitutes a feasible and effective instrument on European level for the protection of consumers' health against the risks resulting from an exposure to lead, in particular in relation to ingestion and mouthing. - Should testing methods differ substantially from norm practices (e.g. those applied in the toys directive), implementation would be very difficult and a longer period than the proposed 6 months would be necessary due to a highly fragmented and complex supply chain of the jewellery industry. Keeping this in mind, we would like to make some specific comments on the comparability of the risk resulting from lead in jewellery to that from lead in toys, the need for a standard which takes into account other EU standards for lead, as well as the important role of plating in the prevention of exposure to lead. 1. A standard for lead in jewellery should be inspired by the standard for lead in the toys directive, which is based on the lead's migration rate and set in mg/kg. Such a standard would cover better the protection of consumers' health. The toys directive constitutes an instrument, which is proven to be effective in ensuring consumer	mouthing) and then the ingestion of the lead contained in the uncoated (degraded) jewel (acute exposure). Further, if the child swallowed the leaded coated piece as a whole, he could also be acutely poisoned by the leaded coating and the base metal under the coating. 4. As far as the testing of the coating on the basis of the nickel Directive, it is an option to be considered. See DS28. 5. For the costs of testing, see DS32. 6. Extended time frame to be considered. 7. Thank you also for the information about lead content as impurities in high quality jewels and the currently research on new lead-free casting technologies. DS183: Extended timeframe to be considered		Extended time frame recommended. In the draft opinion SEAC recommends a restriction based on

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					safety regarding an exposure to lead incurring through mouthing and ingestion. As the risk resulting from lead in jewellery is comparable, the toys directive provides a sufficient basis for a standard aiming at protecting consumers from such a risk (cf. pages 3-6 of the attached document). 2. The proposed standard should be in accordance with other European legislation on lead. When compared to such existing regulation it becomes clear that the proposed standard for jewellery results in a significantly lower limit than those set for lead in toys or food, although the risk of exposure is lower in case of jewellery (cf. in this regard the studies mentioned on pages 5-6 of the attached document). Adults and children naturally ingest food and several toys are actually intended for mouthing and biting, while a hazard from jewellery occurs only accidentally through unintended use. It can therefore be concluded that with a less likely risk of exposure the proposed limit value for lead in jewellery would be much stricter than that set for lead in food or toys. 3. In high quality fashion jewellery the base metal is plated with precious metals such as gold, rhodium and palladium through electroplating. This can substantially decrease the possibility of exposure to lead through mouthing and ingestion. Thus we propose to use the same approach as the one used for the nickel standard and to permit testing of the metal part of the jewellery including a plating of sufficient quality, namely precious metals applied to the substrate by means of electroplating. In this regard it has to be added that due to the strength of the bond between plating layers in jewellery, the	DS184: For the unit, see DS14 and 15. DS disagrees that the risk are comparable however, see DS23. DS185: It is very difficult to compare the different limits as they are based on different exposure assumption see DS14. Concerning the "risk of exposure", we agree that children have more often access to toys than jewels but a child that will wear a jewel or who has freely access to a jewel will have an exposure close to his exposure to toys. DS186: acknowledged. See also additional information in responses to comment Ref 67.		concentration (0.05%)

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					plating remains at the substrate even after unusually strong force is applied (cf. tests on pages 8-10 in the attached document). Furthermore, as electro-plated deposits represent metallic layers, they show a high degree of tenacity and hardness and have accordingly good abrasion resistance properties. Additionally, precious metals in particular are inert to a wide range of chemicals (including strong acids). Contact with saliva during chewing or sucking will not cause any interaction with precious metals such as rhodium or gold. Thus, platings used in jewellery can decrease the possibility of exposure to lead through mouthing and ingestion, which should be taken into account in the current proposal (cf. pages 8-10 of the attached document).			
59	N	2010/12/17 11:45	Spain / Industry or trade association /	(A) (B), (C), (D (E), (F), (G (H)	The fashion jewelry industry welcomes the objective to protect children from hazardous substances. Nonetheless, regarding the importance of this question for Jewelry and Crystal Industry, additional information and knowledge from these professional organizations seems essential from a technical as well as from an economical point of view. Thus, several aspects of the suggested operating procedure may be problematic in their implementation, such as: -the unit of migration rate and its limit -the separate calculation for the coating and the substrate From an economical point of view, two further aspects of the proposal exposed in the report deserve to be reconsidered because of lack of conformity with the industry's reality and practice: - The cost evaluation induced by the tests set by the standard NF EN 71-3	DS188: Please refer to responses to comment Ref 31 above.	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 87 & 89.	In the draft opinion SEAC recommends lead crystals and precious stones to be exempted, and all other types of jewellery to be restricted if lead content is above 0.05 %.

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					- The enforcement period of the restriction These elements are developed hereunder. 1. Limit and unit of the proposed lead's migration rate Reminder: the proposed test to evaluate the lead's migration rate of jewelry's items is the one which is used for the toy's regulation in the standard NF EN 71-3 (Part 3: Migration of some compounds) simulating the ingestion of a toy by a child. The limit set up by the toy's regulation is 90 mg/kg. a. The difficulty of calculating the surface The possible risks of lead's exposure coming from jewelry's items can be considered as comparable to those coming from toys, which mean a possible ingestion or mouthing of the item by children. The restriction proposal in jewelry is based on the standard NF EN 71-3, which only simulate a stay in gastric acid (therefore an ingestion), as no method is available for the measurement of lead migration rate in saliva. Now the enforced limit in the restriction proposal is 0.09 µg/cm2/hr. Unlike the limit set up by the toy's regulation (data in mg/kg), it would from now on be necessary to determine the item's surface in order to obtain the lead's migration rate in µg/cm2/hr. The problematic will also arise for the measure of the lead's release rate if it has to be given according to the surface, the latter's calculation often being very hard to achieve. Additional comment on the calculation of the external surface for Crystal: It is usual that jewelry is made by opacifying the surface of Crystal by frosting. In this case, the specific surface, which means the			

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					reactive one after the lixiviation test, is clearly bigger than the "stretched" surface in purpose. The division factor of the analytical result is then largely minus and the ratio mass of lead/unit area greatly overestimated. This enhances the doubts that we can have on the relevance of measuring the surface of the targeted items. b. Inadequacy between suggested method of calculation and nature of identified risks. As previously mentioned, the suggested unit in the report for lead restriction in jewelry is the same as the one used for nickel restriction in jewelry. The risk related to the exposure to jewelry releasing nickel is an allergy risk due to skin contact. Now, this has nothing to do with lead in terms of exposure risk as with lead, mouthing and ingestion are the dangers brought forth. Therefore the suggested unit in the toy's regulation (mg/kg) is more appropriate than the one suggested in the restriction project which corresponds to a combination of the toy and nickel in jewelry regulations. There is no reason to treat jewelry different from toys. Moreover is it easier to implement. c. The necessity of an analytical coefficient and the difficulty to determine a limit value Another fact related to the standard NF EN 71-3 has to be considered. Indeed, according to the standard, the analytical results have to be corrected by an analytical coefficient in order to take into account the measure's uncertainty. It is these results that have to be below the imposed limit. It is obvious that an analytical coefficient should also be applied to the results under jewelry restriction, yet			

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					this point isn't addressed in this limitation proposal. Moreover, the limit determined within the report seems extremely restrictive, as it refers to the surface's calculation (unit : µg/cm2/hr) rather than the unit used for toys (mg/kg). Lab tests have been performed on samples in accordance to the test protocol defined in the standard NF EN 71-3. Results were calculated under the standard in mg/kg and under the suggested restriction in µg/cm2/hr. Sample 1 : A free-cutting brass with 3% lead - Lead's migration rate obtained under the toy's regulation: 8.54 mg/kg - Lead's migration rate obtained under the suggested regulation for jewelry: 19 µg/cm2/hr (this result hasn't been amended with a coefficient) Sample 2 : First sort of crystal : Lead Crystal A - Lead migration rate obtained under the toy's regulation : 0.15 mg/kg - Lead migration rate obtained under the suggested regulation for jewelry: 0.082 µg/cm2/hr (this result hasn't been amended with a coefficient) Sample 3 : 2nd sort of crystal : Lead Crystal B - Lead migration rate obtained under the toy's regulation : 0.37 mg/kg - Lead migration rate obtained under the suggested regulation for jewelry: 0.216 µg/cm2/hr (this result hasn't been amended with a coefficient) The observed results considerably vary regarding the suggested unit			

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					and the performed tests show that the limit set for jewelry's items is much more severe than the one set for toys while the risks and possible exposures are the same. We also note that regarding all the existing legal requirements on lead, whether European or international, detailed in the report pages 46, 47, 48 and 49, the limit value is always expressed in ppm or in mg/kg. It therefore appears that with the same risks and exposures, the restriction limit value for the use of lead in jewelry is much more severe than the one set under the toy regulation, and this without being justified. We fully agree to the application of a migration rate, but to be set in mg/kg. 7 d. Detection limits of analytical equipments The report doesn't precise the analytical method to use in order to measure the lead's migration rate. It simply says that the inductively coupled plasma spectroscopy (ICP) and the flame atomic absorption spectrometry are suitable techniques. Whatever the technique is, the suggested lead's migration rate of 0.09µg/cm2/hr is very low and, regarding the size of the sample, can be close or even below to the detection limits of the measuring equipments. Now the closer we are to the limit of the measuring equipments the most the precision and the reliability of the measure decrease. 2. Separate calculation for Coating and substrate Reminder : the restriction proposal advocates that the adaptation to the standard NF EN 71-3 (which should be used to implement the lead's migration test) should be done. One of them is for coated			

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					jewelry. The Coating will have to be separated from its substrate. Both materials should be tested separately and the addition of both lead's migration rate so determined shouldn't overtake the limit value to meet the regulation. Initially, the matter is to precisely determine what "coating" means. A clear and precise definition of coating would be necessary. Furthermore, there are coatings which are nearly impossible to remove. Example of difficulty to locate the boundary between component and coating in the case of crystal : It is often applied an ornamental coating by the superposition of several layers made of different types (SiO2, TiO2, Au, …). The thickness of this kind of coating is usually of 2 to 3 µm, and its entire mass on the item is below 10 mg which make it impossible to analyze under the standard EN71-3, §7. However this standard imposes to separate it by mechanical action while, by nature, the 2 elements are strongly linked to the substrate crystal which is a heavy technical problem. 3. The evaluation of costs induced by tests under the standard NF EN 71-3 Regarding the tests which should be implemented by both companies and authorities during the controls, it is indicated in the pages 95 and 96 of the report that the cost of a test for a compound such as lead under the standard NF EN 71-3 is 22 euros. We are surprised by this figure, which appears to us to be very much below the reality especially if techniques such as ICP or atomic absorption spectrophotometry are used.			

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					If the company wants to be sure of the conformity of its items with the standard, they purchase themselves a testing through independent laboratory. The cost for this will be very much higher than the one indicated in the report. After consulting a private and independent lab (CRITT in Schiltigheim) that could purchase the test, the unit cost per tested compound is 191 euro. 4. The delay of implementation of the restriction The delay suggested in the report is 6 months after the legal implementation of the annex XVII of REACH law. The assumption that jewelry stocks aren't consistent and that a renewal of collections is made every 6 months is highlighted. However this approach ignores the economical reality of the jewelry industry. In the exemption agreement for deadline payment between suppliers and specialized distributors in watchmaking, Jewelry, Silvermaking, agreement extended in 2009 the 2nd of April by decree, it is established that stocks rotation is very often above one (1) year as it is revealed by the study of Society 5 : Jeweler, watchmaker (2008) Sells / stocks * under observation Sells / stocks Months needed to sell Common Jeweler and watchmaker 0,87 14 months Diffusion Jeweler and watchmaker ** 1,28 9 months Jeweler*** 0,9 13 months * stock valued at selling price, in selling point taking part to the survey **City or commercial center *** Out fabrication and special orders			

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					The 6 months delay suggested to apply this restriction is extremely short regarding the economical figures of the industry and therefore could be only satisfied with considerable harm to the fashion jewelry industry and resellers.			
58	N	2010/12/17 11:41	Spain / International organisation /	(A) (B), (C), (D (E), (F), (G (H)	The fashion jewelry industry welcomes the objective to protect children from hazardous substances. Nonetheless, regarding the importance of this question for Jewelry and Crystal Industry, additional information and knowledge from these professional organizations seems essential from a technical as well as from an economical point of view. Thus, several aspects of the suggested operating procedure may be problematic in their implementation, such as: -the unit of migration rate and its limit -the separate calculation for the coating and the substrate From an economical point of view, two further aspects of the proposal exposed in the report deserve to be reconsidered because of lack of conformity with the industry's reality and practice: - The cost evaluation induced by the tests set by the standard NF EN 71-3 - The enforcement period of the restriction These elements are developed hereunder. 1. Limit and unit of the proposed lead's migration rate Reminder: the proposed test to evaluate the lead's migration rate of jewelry's items is the one which is used for the toy's regulation in the standard NF EN 71-3 (Part 3: Migration of some compounds) simulating the ingestion of a toy by a child. The limit set up by the	DS189: Please refer to responses to comment Ref 31 above.	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 87 & 89.	See comment ref 31

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					toy's regulation is 90 mg/kg. a. The difficulty of calculating the surface The possible risks of lead's exposure coming from jewelry's items can be considered as comparable to those coming from toys, which mean a possible ingestion or mouthing of the item by children. The restriction proposal in jewelry is based on the standard NF EN 71-3, which only simulate a stay in gastric acid (therefore an ingestion), as no method is available for the measurement of lead migration rate in saliva. Now the enforced limit in the restriction proposal is 0.09 µg/cm^2/hr. Unlike the limit set up by the toy's regulation (data in mg/kg), it would from now on be necessary to determine the item's surface in order to obtain the lead's migration rate in µg/cm^2/hr. The problematic will also arise for the measure of the lead's release rate if it has to be given according to the surface, the latter's calculation often being very hard to achieve. Additional comment on the calculation of the external surface for Crystal: It is usual that jewelry is made by opacifying the surface of Crystal by frosting. In this case, the specific surface, which means the reactive one after the lixiviation test, is clearly bigger than the "stretched" surface in purpose. The division factor of the analytical result is then largely minus and the ratio mass of lead/unit area greatly overestimated. This enhances the doubts that we can have on the relevance of measuring the surface of the targeted items. b. Inadequacy between suggested method of calculation and nature			

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					It therefore appears that with the same risks and exposures, the restriction limit value for the use of lead in jewelry is much more severe than the one set under the toy regulation, and this without being justified. We fully agree to the application of a migration rate, but to be set in mg/kg. 7 d. Detection limits of analytical equipments The report doesn't precise the analytical method to use in order to measure the lead's migration rate. It simply says that the inductively coupled plasma spectroscopy (ICP) and the flame atomic absorption spectrometry are suitable techniques. Whatever the technique is, the suggested lead's migration rate of 0.09µg/cm2/hr is very low and, regarding the size of the sample, can be close or even below to the detection limits of the measuring equipments. Now the closer we are to the limit of the measuring equipments the most the precision and the reliability of the measure decrease. 2. Separate calculation for Coating and substrate Reminder : the restriction proposal advocates that the adaptation to the standard NF EN 71-3 (which should be used to implement the lead's migration test) should be done. One of them is for coated jewelry. The Coating will have to be separated from its substrate. Both materials should be tested separately and the addition of both lead's migration rate so determined shouldn't overtake the limit value to meet the regulation. Initially, the matter is to precisely determine what "coating" means. A clear and precise definition of coating would be necessary. Furthermore, there are coatings which are nearly impossible to			

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					remove. Example of difficulty to locate the boundary between component and coating in the case of crystal : It is often applied an ornamental coating by the superposition of several layers made of different types (SiO2, TiO2, Au, …). The thickness of this kind of coating is usually of 2 to 3 µm, and its entire mass on the item is below 10 mg which make it impossible to analyze under the standard EN71-3, §7. However this standard imposes to separate it by mechanical action while, by nature, the 2 elements are strongly linked to the substrate crystal which is a heavy technical problem. 3. The evaluation of costs induced by tests under the standard NF EN 71-3 Regarding the tests which should be implemented by both companies and authorities during the controls, it is indicated in the pages 95 and 96 of the report that the cost of a test for a compound such as lead under the standard NF EN 71-3 is 22 euros. We are surprised by this figure, which appears to us to be very much below the reality especially if techniques such as ICP or atomic absorption spectrophotometry are used. If the company wants to be sure of the conformity of its items with the standard, they purchase themselves a testing through independent laboratory. The cost for this will be very much higher than the one indicated in the report. After consulting a private and independent lab (CRITT in Schiltigheim) that could purchase the test, the unit cost per tested compound is 191 euro. 4. The delay of implementation of the restriction			

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					The delay suggested in the report is 6 months after the legal implementation of the annex XVII of REACH law. The assumption that jewelry stocks aren't consistent and that a renewal of collections is made every 6 months is highlighted. However this approach ignores the economical reality of the jewelry industry. In the exemption agreement for deadline payment between suppliers and specialized distributors in watchmaking, Jewelry, Silvermaking, agreement extended in 2009 the 2nd of April by decree, it is established that stocks rotation is very often above one (1) year as it is revealed by the study of Society 5 : Jeweler, watchmaker (2008) Sells / stocks * under observation Sells / stocks Months needed to sell Common Jeweler and watchmaker 0,87 14 months Diffusion Jeweler and watchmaker ** 1,28 9 months Jeweler*** 0,9 13 months * stock valued at selling price, in selling point taking part to the survey **City or commercial center *** Out fabrication and special orders The 6 months delay suggested to apply this restriction is extremely short regarding the economical figures of the industry and therefore could be only satisfied with considerable harm to the fashion jewelry industry and resellers.			
57	N	2010/12/16 17:17	/ / Liech		The Liechtensteiner "Amt für Umweltschutz" (Office of Environmental Protection) welcomes further steps to protect		Your comments are noted and	

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			tenstein MSCA		consumers from threats of hazardous substances resulting from an unintended use of jewellery such as mouthing or swallowing. We understand that the restriction is based on the lead's migration rate, which adequately simulates the risk incurred through mouthing and ingestion. However, we are concerned that the proposed method of testing required to implement the regulation might lead to substantial difficulties resulting from the fact that measurement is to be based on surface rather than weight of the jewellery. From industry participants we have learned that such measurement method leads to high tolerances and deviations and might make a safe and fast implementation of the regulation very difficult. We suggest that known and proven testing methods such as in EN 71-3 (toy regulation) or in other countries (USA, Canada, Denmark…) are to be applied.	DS190: For the question of the surface measurement, see DS15 and 90. DS191: Under consideration. See DS14	have contributed to the RAC process for elaboration of the restriction proposal. See also response to ref 87 & 89.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)
55	Y	2010/12/16 10:25 Att. ref 55	Spain / International organisatio	(A) (B), (C), (D (E), (F), (G	SEE ATTACHED FILES	DS192: See responses to comment Ref 81 above.	Your comments are noted and have contributed to the RAC process for elaboration of	See comment ref 81

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			n /	(H)			the restriction proposal. See answer to ref 87	
54	Y	2010/12/15 17:07 Att. ref 54	/ / Norway MSCA	(A)	France propose to restrict lead and its compounds in jewellery. They propose to restrict all jewellery, both precious and fashion, intended for adults as well as for children, which has a lead migration rate greater than 0,09 µg/cm^2/hr. In general Norway welcomes the proposed regulation on lead and its compounds in jewellery. The Norwegian Government has established national targets for eliminating or substantially reducing releases of priority hazardous substances by 2010 with a view of eliminating them by 2020. The substances included in the target are given in the Governments list of priority hazardous substances (the Priority List). Lead is one of the substances in this list. We support that the restriction shall apply to both precious and fashion jewellery intended for adults as well for children, and that each individual part of the jewellery shall be considered. Recommendations should be given to ensure that the relevant homogenous part of the jewel/article is examined. However we do not support a restriction based on lead migration rate, and the use of migration test as proposed. The migration tests are resource demanding and expensive and require good competence to evaluate/verify documentation from the suppliers. We suggest a regulation based on a threshold limit related to content of lead and its compounds, as % weight per weight. To optimize use	DS193: As regards a restriction based on a % limit, see DS14 and new Annex C (option 7).	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See answer to ref 87	In the draft opinion SEAC recommends a restriction based on

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					of resources for enforcement/increase the capacity of controls it will be a prefer to carry out screening tests with use of XRF and follow up these with analytical methods on determination of substance content as % weight per weight. This will also correspond with the new restriction proposal of cadmium content in jewellery. This corresponds also with some current national restrictions given, e.g. DK and to the regulation on certain hazardous substances, included lead and its compounds in consumer products included jewellery that will be proposed from Norway. The term "jewellery" has to be defined and ensured that it applies to jewellery in broad sense including items such as key rings, phone charms, brooches and hair accessories. These are items that easily can be mouthed by children.	DS194: As regards the definition of "jewellery", see DS31.		concentration (0.05%) SEAC recommends to use the definition of jewellery used in Cadmium restriction in the draft opinion.
53	Y	2010/12/15 11:15	Spain / International organisation /	(A) (B) (C) (D) (E), (F), (G) (H)		As regards the attached file, see responses to comment Ref 31.	No comments.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
44	Y	2010/10/18 17:53 Att. ref 44	/ / Denmark MSCA	(A) (B)	In general Denmark supports restrictions of the use of lead in jewelleries articles. Lead has very serious effects and the use of lead should therefore be restricted in products where it is possible. Therefore, Denmark has a regulation on lead in jewelleries where the content is restricted and has to be below 100 ppm. The Chemical Inspection Service of the Danish EPA has made enforcements of lead in jewelleries and the results of the enforcement are reported in the comments in section IV. Although Denmark recognise that migration pr unit scientifically is the most appropriate way to measure the exposure, loss of acceptable methods, practicalities and cost for the producers as well as for the importer, implies that Denmark prefers to base a restriction on the content of lead instead of the migration.	DS195: As regards the attached file: 1. Adaptations/new costs of the new standard 71-3 after 2013, to be considered? 2. For the question of the surface measurement, see DS15 and DS90. 3. Thank you for the information on the control of lead in jewellery during 2008-2010.	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal.	Comments used in CBA
37	Y	2010/09/20 21:36	/ / Individual	(E)	**Comments Summary** **E. Justification why a restriction is the most appropriate Community-wide measure** **E.1.2. Options for restriction** The use of x-ray fluorescence spectrometry as a screening test before EN 71-3 should be considered by the market surveillance authorities. E.2.1.2.2. Enforceability B – Concerning the coating EN 12472 does meet the requirements of section 8.1.1 of EN 71-3 The significance of errors in the surfaces area measurement needs to	DS1: A two-steps approach based on content and (then) migration is now integrated in the BD. XRF method is considered to that respect DS4: The question of the surface	No further comments	No further comments

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					taken in the context of the metal release value. The use of the analytical correction factors in EN 71-3 should be replaced by a measurement uncertainty approach.	measurement and its difficulties (also relative to the coating) has been dealt with in the BD.		
36	N	2010/09/20 17:46	/ / Sweden MSCA	(A) (B) (C)	We welcome this restriction proposal that will help to reduce the exposure of children to a well-known toxic substance. Enforcement projects in Sweden have shown that some jewels contain such concentrations of lead that there is a need for regulating the use of lead in jewellery. The fact that several cases of severe lead poisoning resulting from misuse of jewels by children who have swallowed or repeatedly mouthed them strengthen the need to restrict lead in jewels.	DS6: Thank you for your comment.	No comments	No comments
35	N	2010/09/20 16:36	/ / United Kingdom MSCA	(A) (B) (C) (E) (F)	We appreciate the large amount of work that has gone in to compiling this Annex XV dossier but feel that the dossier needs to present a stronger case for this restriction. a) We agree that given the well known hazards of exposure to lead, particularly for children, there is a need to regulate lead use in jewellery. However, the few cases of acute poisoning/harm cited in the dossier are from outside the EU and there is not a clear enough picture of the scope of the problem within the EU. We believe that the case has not been sufficiently made that the restriction proposal is proportionate to the actual risk.	DS7: re a) There is no explicit reported case in the EU but, as said in the dossier, data on cases are rare because jewellery is an unusual source of lead poisoning and it is difficult to identify it when it is actually the cause of poisoning. Moreover, it is difficult to know the share of lead-containing jewels among all jewels placed on the EU market (and thus the exact exposure) but what one knows that about (estimated) 5,000 children	a) Mouthing is considered the primary reason for the restriction.	Re a) The main reason for the proposed restriction is mouthing and not swallowing.

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
						swallow jewels every year (see section F.1.2)		
					b) More detailed information on the scale of the problem within the EU and further analysis of all available RMO are needed.	DS8: For the scale, see response DS7. For the available RMOs, see section E.1.3 and B.5.1.1.	b) The exact scale is not known, however data from different surveys in EU countries on the frequency and the lead content in jewellery indicates that lead in jewellery may occur in a significant part of the jewellery.	Re b) SEAC draft opinion considers issues in relation to precious jewellery, jewellery especially intended for children, jewellery already on the market
					c) In different sections of the document, the neurotoxic effects are described as being non threshold or that it has not been possible to identify a threshold. We think this is potentially misleading. In our opinion, neurotoxicity is regarded as threshold effect, but it has not yet been possible identify what the threshold is. We suggest that discussion of neurotoxicity is changed to reflect this uncertainty, as the risk management of threshold and non threshold effects may be	DS9: In recent reports (2010) from EFSA or JECFA it is considered that effects on the neurodevelopment of children resulting from an exposure to lead (reduction in IQ points for instance) have no threshold.	c) No threshold for this adverse effect has been identified. However, as a substantial part of children in	

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					significantly different.		EU is already exposed above the identified BMDL01 level, any additional exposure from e.g. jewellery would add on to this effect level, so in that sense lead may be handled as a non-threshold chemical. Also it is not known whether a lower threshold below the current background exposure level exists.	

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31	Y	2010/09/17 18:00	France / Industry or trade association / Chambre Syndicale de la Bijouterie (BOCI) & Fédération des Cristalleries et Verreries à la Main	(E) (F)	Following the report presented by France to ECHA regarding a restriction proposal lead use and its compounds in jewelry, the National Federation of Jewelry, Plate, Gifts and Crafts Industry of France (BOCI), and the Federation of Crystal and Glassware (FCVMM) with the support of CETEHOR, the technical department of Comité Francéclat (the French professional committee for Watches, Jewelry and Tableware) wish to participate in the public consultation initiated by ECHA on this topic. The fashion jewelry industry welcomes the objective to protect children from hazardous substances. Nonetheless, regarding the importance of this question for Jewelry and Crystal Industry, additional information and knowledge from these professional organizations seems essential from a technical as well as from an economical point of view. **Use of lead and its compounds in jewelry** Thus, several aspects of the suggested operating procedure may be problematic in their implementation, such as: -the unit of migration rate and its limit -the separate calculation for the coating and the substrate From an economical point of view, two further aspects of the proposal exposed in the report deserve to be reconsidered because of lack of conformity with the industry's reality and practice: - The cost evaluation induced by the tests set by the standard NF EN 71-3 - The enforcement period of the restriction These elements are developed hereunder.	DS10: Crystal industry is several times mentioned in the dossier (section E.1.2, E.4, etc.). During the preliminary consultation, it seemed that lead contained in crystal was supposed to not migrate. Based on this information, crystal industry should not be impacted (see 2nd bullet in section E.4). DS11: Testing costs considerations for the impacted industry actors are further developed in the BD.	Comment noted. According to RAC opinion the proposal is to restrict the lead content in jewellery, unless it is demonstrated that the migration rate of lead release does not exceed a migration limit (expressed on a weight basis) of 0.05 µg Pb per g jewellery/h. Thus RAC has taken note of the difficulties by expressing a migration limit on surface	In SEAC draft opinion crystals and precious stones are exempted, see Background Document.

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			et Mixtes (FCVMM)		**1. <u>Limit and unit of the proposed lead's migration rate</u>** Reminder: the proposed test to evaluate the lead's migration rate of jewelry's items is the one which is used for the toy's regulation in the standard NF EN 71-3 (Part 3: Migration of some compounds) simulating the ingestion of a toy by a child. The limit set up by the toy's regulation is 90 mg/kg. **a. The difficulty of calculating the surface** The possible risks of lead's exposure coming from jewelry's items can be considered as comparable to those coming from toys, which mean a possible ingestion or mouthing of the item by children. The restriction proposal in jewelry is based on the standard NF EN 71-3, which only simulate a stay in gastric acid (therefore an ingestion), as no method is available for the measurement of lead migration rate in saliva. Now the enforced limit in the restriction proposal is 0.09 µg/cm^2/hr. Unlike the limit set up by the toy's regulation (data in mg/kg), it would from now on be necessary to determine the item's surface in		basis. Further RAC notes that a reliable migration test method that mimics mouthing is not at hand but has to be developed. No further comments Comments noted	Re 1a) SEAC proposes to base the restriction on the content of lead

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					order to obtain the lead's migration rate in µg/cm2/hr. The proposed unit for the lead's restriction in jewelry is the same as the one used for nickel restriction in jewelry items intended to be in skin contact. Although in order to measure the surfaces, the report suggests following the standard NF EN 1811+A1 used to perform the measure of nickel release. Now, as mentioned by the French laboratory of General Directorate for Competition Policy, Consumer Affairs and Fraud Control and the General Directorate of Customs and Indirect Duties in the report suggesting the restriction, the standard NF EN 1811+A1 is very disputed concerning the surface's measure. Therefore, the difficulty to measure the item's surface having several shapes and often complex shapes creates various results for one identical item by different laboratories. This variation has a strong impact on the defined nickel release values. **The problematic will also arise for the measure of the lead's release rate if it has to be given according to the surface, the latter's calculation often being very hard to achieve.** <u>Additional comment on the calculation of the external surface for Crystal:</u> It is usual that jewelry is made by opacifying the surface of Crystal by frosting. In this case, the specific surface, which means the reactive one after the lixiviation test, is clearly bigger than the "stretched" surface in purpose. The division factor of the analytical result is then largely minus and the ratio mass of lead/unit area greatly overestimated. This enhances the doubts that we can have on the relevance of	DS12: Additional information obtained from public consultation allows moderating a little this debate about the measurement of the surface with the standard EN 1811. This information is integrated in the dossier in section E.2.1.2.2. However, to make the debate more balanced, the arguments given here by BOCI, FCVMM and CETEHOR are also integrated in section E.2.1.2.2. DS13: Acknowledged		SEAC agrees that there are uncertainties also for calculating area. There is less uncertainty if the limit is related to the weight of the jewellery. Re DS20 The BD explains that compared to the metal parts of jewellery the health impact of lead exposure from crystals is considered to be

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					measuring the surface of the targeted items. **b. Inadequacy between suggested method of calculation and nature of identified risks.** As previously mentioned, the suggested unit in the report for lead restriction in jewelry is the same as the one used for nickel restriction in jewelry. The risk related to the exposure to jewelry releasing nickel is an allergy risk due to skin contact. **Now, this has nothing to do with lead in terms of exposure risk as with lead, mouthing and ingestion are the dangers brought forth.** Therefore the suggested unit in the toy's regulation (mg/kg) is more appropriate than the one suggested in the restriction project which corresponds to a combination of the toy and nickel in jewelry regulations. There is no reason to treat jewelry different from toys. Moreover is it easier to implement.	DS14: It was written in the dossier that it does not seem to be possible to transfer µg/cm²/hr in mg/kg. See section E.2.1.2.1. *"given the variability in terms of materials and of forms which are used in the articles of the jewellery sector, it does not seem possible to go from a unit in "µg/cm²/hr" to another one in "µg/kg/hr" even though it is acknowledged that it would make the proposal more enforceable*." After some discussions, this approach could be considered. The migration rate unit could be converted from µg/cm²/h to µg/kg/h assuming a sphere of 10 cm² area and the weight of this sphere using the relevant metal with the highest density. Probably the most relevant metal would be the lead with a density of 11.35 g/cm^3 but as precious	Note that migration limit based on migration per g jewellery has also been assessed in BD and taken into account in the opinion.	relatively small, because there are indications of much lower migration rates.

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					c. The necessity of an analytical coefficient and the difficulty to determine a limit value Another fact related to the standard NF EN 71-3 has to be considered. Indeed, according to the standard, the analytical results have to be corrected by an analytical coefficient in order to take into account the measure's uncertainty. It is these results that have to be below the imposed limit. It is obvious that an analytical coefficient should also be applied to the results under jewelry restriction, yet this point isn't addressed in this limitation proposal. Moreover, the limit determined within the report seems extremely restrictive, as it refers to the surface's calculation (unit : µg/cm^2/hr)	jewels are also in the scope of the restriction, the platinum could be considered with a density of 21.5 g/cm^3. This value would be 26.67 µg/kg/h considering lead and 14.08 µg/kg/h considering platinum. But the µg/kg approach will lead to a higher conservative value for thin jewels which possess a large surface for a low weight. However, the debate about the unit is relevant and the issue has been taking into account in the BD. DS15: Agree that this uncertainty coefficient should be integrated in the analytical results. But concerning the µg/cm²/h approach may be this coefficient should be revised concerning the uncertainties of the surface measurement.		

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					rather than the unit used for toys (mg/kg). Lab tests have been performed on samples in accordance to the test protocol defined in the standard NF EN 71-3. Results were calculated under the standard in mg/kg and under the suggested restriction in µg/cm^2/hr. <u>Sample 1 : A free-cutting brass with 3% lead</u> - Lead's migration rate obtained under the toy's regulation: 8.54 mg/kg The limit value of the migration rate set by the toy's regulation is 90 mg/kg. The lead migration rate of the tested sample is therefore far below the limit value and is so consistent with the toy's regulation. - Lead's migration rate obtained under the suggested regulation for jewelry: 19 µg/cm^2/hr (this result hasn't been amended with a coefficient) The limit value of the migration rate under the suggested restriction is 0.09 µg/cm^2/hr. The lead migration rate of the tested sample is far above the limit value and isn't consistent with the regulation suggested for jewelry. <u>Sample 2 : First sort of crystal : Lead Crystal A</u> - Lead migration rate obtained under the toy's regulation : 0.15 mg/kg The limit value of the migration rate set by the toy's regulation is 90 mg/kg. The lead migration rate of the tested sample is therefore far below the limit value and is so consistent with the toy's regulation. - Lead migration rate obtained under the suggested regulation for	DS16: Thank you for this information. DS17: As said in the dossier, the risk from the misuses of jewels is not the same (ingestion + mouthing), thus the risk assessment and the limit are not the same either. DS18: Thank you for this information.	Comments noted	SEAC proposes to exempt lead crystals from the restriction. Not clear whether the crystals

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					jewelry: 0.082 µg/cm^2/hr (this result hasn't been amended with a coefficient) The limit value of the migration rate under the suggested restriction is 0.09 µg/cm^2/hr. The lead migration rate of the tested sample is slightly below the limit value and so is consistent with the regulation suggested for jewelry. However, the complexity of producing this kind of material can't guarantee that the results will always be below the limit value. <u>Sample 3 : 2nd sort of crystal : Lead Crystal B</u> - Lead migration rate obtained under the toy's regulation : 0.37 mg/kg The limit value of the migration rate set by the toy's regulation is 90 mg/kg. The lead migration rate of the tested sample is therefore far below the limit value and is so consistent with the toy's regulation. - Lead migration rate obtained under the suggested regulation for jewelry: 0.216 µg/cm^2/hr (this result hasn't been amended with a coefficient) The limit value of the migration rate under the suggested restriction is 0.09 µg/cm^2/hr. The lead migration rate of the tested sample is far above the limit value and isn't consistent with the regulation suggested for jewelry. **The observed results considerably vary regarding the suggested unit and the performed tests show that the limit set for jewelry's items is much more severe than the one set for toys while the risks and possible exposures are the same.**	DS19: Thank you for this information. DS20: The second and third tests carried out on crystals show (even very low) lead migration. It seems thus that lead might migrate from crystal. This is important information to have for the dossier independently on the debate about the unit of the limit. DS21: The variation is not linked to the units of limits but to toxicological and exposure considerations which are different. The toys regulation	As can be seen from DS21 the tolerable exposure of a child in	mentioned in the comment are covered by the derogation.

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					We also note that regarding all the existing legal requirements on lead, whether European or international, detailed in the report pages 46, 47, 48 and 49, the limit value is always expressed in ppm or in mg/kg. **It therefore appears that with the same risks and exposures, the restriction limit value for the use of lead in jewelry is much more severe than the one set under the toy regulation, and this without being justified. We fully agree to the application of a migration rate, but to be set in mg/kg.**	lead migration rate of 90 mg/kg was calculated considering that a child daily ingests 8 mg of toy and that the quantity of bioavailable lead resulting from the use of toys should not exceed 0.7 µg/day ($0.7x10^{-3}/8x10^{-6} \approx 90$ mg/kg). DS22: Agree except for Directive 84/500/EC where the surface is taken into account. For information, an additional restriction option is now considered in the dossier consisting in a two steps approach based on 1st/lead content and then/lead migration. DS23: See response DS14 for the debate about the unit. Besides, the fact that the limit for toys is less severe than the proposal does not appear to be a relevant argument to change the proposal. The calculation of the limit of 0.09µg/hr/cm2 is	connection with the present limit value from the Toy Directive is 0.7 µg Pb/day. For jewellery RAC uses a tolerable level of 0.5 µg Pb/day for a child weighing 10 kg, i.e. a rather comparable exposure and risk level. RAC assessed in BD that the limit value in µg Pb/cm2/h could be transferred to µg Pb/g/h. See BD and RAC opinion.	

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					d. Detection limits of analytical equipments The report doesn't precise the analytical method to use in order to measure the lead's migration rate. It simply says that the inductively coupled plasma spectroscopy (ICP) and the flame atomic absorption spectrometry are suitable techniques. Whatever the technique is, the suggested lead's migration rate of 0.09µg/cm^2/hr is very low and, regarding the size of the sample, can be close or even below to the detection limits of the measuring equipments. Now the closer we are to the limit of the measuring equipments the most the precision and the reliability of the measure decrease.	scientifically-based and results from rationales presented in the dossier. Further, as explained at the beginning of E.1.3., the limit stipulated for toys "*is not supposed to protect the child if the whole toy is accidently ingested whereas in the approach that is chosen in this restriction dossier, it is considered that the whole jewel may be ingested"*. DS agrees nevertheless that enforcement and applicability constraints are important and have to be highlighted.	d) Up to the Commission to specify details concerning the analytical methods and procedures in connection with the restriction.	
					2. <u>Separate calculation for Coating and substrate</u> Reminder : the restriction proposal advocates that the adaptation to the standard NF EN 71-3 (which should be used to implement the lead's migration test) should be done. One of them is for coated jewelry. The Coating will have to be separated from its substrate. Both materials should be tested separately and the addition of both lead's migration rate so determined shouldn't overtake the limit value to meet the regulation. Initially, the matter is to precisely determine what "coating" means. A clear and precise definition of coating would be necessary.	DS24: It is indicated in the report in the section E.2.1.2.2. DS25: Agree but ICP spectroscopy, for example, can measure very low concentrations (few ppb) DS26: Coating is defined as following according to the	It is noted that wear test may be a possible option to introduce in order to mimic release from intact and damaged coating.	Re 2 – SEAC proposes to base a restriction on the content of lead – it is more easy to measure

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					Furthermore, there are coatings which are nearly impossible to remove. Moreover, the great diversity and complexity of types and shapes of jewelry articles, as well as production techniques, make it extremely hard, nearly impossible, to implement this recommendation. The systematic separation of all coatings seems unrealistic especially as it will be very challenging for companies to test each component of a jewel, which can sometimes be made of several pieces and coatings. <u>Example of difficulty to locate the boundary between component and coating in the case of crystal :</u> It is often applied an ornamental coating by the superposition of several layers made of different types (SiO2, TiO2, Au, …). The thickness of this kind of coating is usually of 2 to 3 µm, and its entire mass on the item is below 10 mg which make it impossible to analyze under the standard EN71-3, §7. However this standard imposes to separate it by mechanical action while, by nature, the 2 elements are strongly linked to the substrate crystal which is a heavy technical problem. It is suggested in the report to take inspiration from the standard NF EN 12472 used for the nickel's rule. This standard follows the methodology which consists to simulate the use and corrosion in	standard NF EN 71.3: "*all layers of materials formed or deposited on the base material or toy, including paints, varnishes, lacquers, inks, polymers or other substances of a similar nature, whether they contain metallic particles or not, no matter how they have been applied to the toy and which can be removed by scraping with a sharp blade*." This definition has been added in the BD. DS27: Thank you for this information DS28: This argument has been added to the dossier in section E.2.1.2.2. However, as said in the dossier in the same section, "*As (mouthing) may be performed by the child whatever the size of the jewel is, it is necessary that all jewels are being tested according to this standard: indeed, a toy (and,*		

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					order to determine the amount of nickel released by coated items. However, concerning this standard, it is not planned to separate the coating from the substrate as suggested in the restriction proposal. A wear test is made on the coated item followed by the test of nickel's release according to the standard NF EN 1811+A1. **3. <u>The evaluation of costs induced by tests under the standard NF EN 71-3</u>** Regarding the tests which should be implemented by both companies and authorities during the controls, it is indicated in the pages 95 and 96 of the report that the cost of a test for a compound such as lead under the standard NF EN 71-3 is 22 euros. We are surprised by this figure, which appears to us to be very much below the reality especially if techniques such as ICP or atomic absorption spectrophotometry are used. If the company wants to be sure of the conformity of its items with the standard, they purchase themselves a testing through independent laboratory. The cost for this will be very much higher than the one indicated in the report. After consulting a private and independent lab (CRITT in Schiltigheim) that could purchase the test, the unit cost per tested compound is 191 euro.	*possibly a jewel) which is too large to be swallowed may clearly be mouthed/sucked and may result in chronic lead poisoning (InVS (2008))".* DS29: The difficulties of applicability related to some specific coatings have been highlighted in the BD DS32: Thank you for this information. The cost of 22€ for one component is extracted from RPA report (2009) which has consulted the fees of the Sheffield Assay Office (from this link: http://www.assayoffice.co.uk/Analytical-Services/Jewellery_Testing_Fees.asp). It would have been useful to have the source of information of this figure.		Re DS 32: Information from DS regarding costs of testing is verified and correct.

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<tr><td></td><td></td><td></td><td></td><td></td><td>4. <u>The delay of implementation of the restriction</u>
The delay suggested in the report is 6 months after the legal implementation of the annex XVII of REACH law. The assumption that jewelry stocks aren’t consistent and that a renewal of collections is made every 6 months is highlighted.
However this approach ignores the economical reality of the jewelry industry. In the exemption agreement for deadline payment between suppliers and specialized distributors in watchmaking, Jewelry, Silvermaking, agreement extended in 2009 the 2nd of April by decree, it is established that stocks rotation is very often above one (1) year as it is revealed by the study of Society 5 :Jeweler, watchmaker (2008)
Sells / stocks * under observation
<table>
<tr><th></th><th>Sells / stocks</th><th>Months needed to sell</th></tr>
<tr><td>Common Jeweler and watchmaker</td><td>0,87</td><td>14 months</td></tr>
<tr><td>Diffusion Jeweler and watchmaker **</td><td>1,28</td><td>9 months</td></tr>
<tr><td>Jeweler***</td><td>0,9</td><td>13 months</td></tr>
</table></td><td>DS33: Thank you for this information. The delay proposed is now longer.</td><td>No comments</td><td></td></tr>
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					*** stock valued at selling price, in selling point taking part to the survey** **City or commercial center *** Out fabrication and special orders The 6 months delay suggested to apply this restriction is extremely short regarding the economical figures of the industry and therefore could be only satisfied with considerable harm to the fashion jewelry industry and resellers.			
27	N	2010/09/14 15:34	/ / Germany MSCA	(A) (B) (C) (E)	Comment of the German CA We support the proposal for a restriction of lead and lead compounds in jewellery, and emphasizes that the proposed option for Risk Management Measures is adequate. The efforts undertaken by the French Competent Authority are highly appreciated. The degree of risk reduction achieved with the proposed restriction will depend on information of the different actors in the supply chain and other enforcement activities. The Advice of the Forum on the enforceability of the proposed restriction (from July 16th, 2010) should be taken into account: - The term "jewels" has to be defined. "Jewels" can be precious or fashion jewels and may be intended for adult or childrens use.	DS34: As said in the dossier, "*because of a lack of a clear definition, because children can come into contact with adult jewels, and also because it is expected that the use of lead and its compounds is marginal in the sector of precious jewels, decision was made to include*		The SEAC draft opinion proposes to use the same definition of jewellery as is used in the cadmium restriction (the

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					It should be ensured that it does not only comprise necklaces, bracelets, chains, anklets, finger rings, earrings and other body piercing jewels, but also, e.g., □ pendants, e.g., for cell phones, zippers, keys, shoes, bags, pencils etc. (used, e.g., for promotion purposes), □ hair accessories, □ wrist-watch cases, watch straps and tighteners, □ (any ornaments, buttons, rivet buttons, tighteners etc., when these are used in garments and might be subject to mouthing.)?	*both types of jewels"* (section A.1.2.2. and see also E.1.2.). No additional information so far allowing a further distinction. DS35: The restriction focuses on jewellery. No harmonised definition exists concerning such other items and furthermore, it would be very difficult to be exhaustive in listing all possible items (very diversified and hardly identifiable) which would be covered by "jewellery", in particular "fashion jewellery" (and even more difficult if the scope was widened to other articles). As said in the dossier "*the definition proposed for a fashion jewel could be the one used in the TARIC code (…), but an addition should be made in this case concerning jewels which are clad with precious metal".* See section E.2.1.2.3 for more details. DS36: The restriction is not targeted only on production but	No further comments to the DS reply.	wrist-watches, hair accessories, brooches and cufflinks are mentioned). These are exempted from the TARIC definition, but seem to be defined as a group (note 9(a)). – See E.2.1.2.3. Pendants to e.g. cell phones are not covered by the TARIC definition nor the Cadmium proposal

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						on 'use' in general. The wording of the entry is thus in line with the definitions given in REACH regulation.		
					- Clarification of the wording and simplification of the possibility to update the analytical method: 1. The production of jewellery articles with a lead migration rate greater than 0.09 µg/cm²/hr of the article or any parts thereof is prohibited. 2. Jewellery articles with a lead migration rate greater than 0.09 µg/cm²/hr of the article or any parts thereof shall not be placed on the market. 3. For demonstrating the conformity of articles with paragraphs 1 and 2 the CEN standard recommended by the ECHA shall be used.	As far as "parts" are concerned, the French CA maintains its proposal based on its position on the definition of "article".	No further comments	
					- It has to be decided if the second hand market should be excluded or not.	DS37: As "placing on the market" is included in the entry, the second hand market is implicitly included.	No further comments	
					- A guide for sampling and sample-preparations is needed. It should be clear that coating should be tested separately. There are cases of children poisonings cited in the Dossier where children chewed off the decorative coating of a piece of jewel and sucked on the exposed cores of the jewel, which were made of lead. Therefore not only the coating should be tested separately, but also the subjacent material. - The Forum emphasises that regulation of contents of lead in articles is more enforceable than regulations with limit values on the migration rate and that the proposed limit value should correspond to the Toy safety directive in order to have comparable results. A limit		Details concerning sampling and sample preparations are related to enforcement and not discussed by RAC.	Concerning the guide for sampling and sample preparations. For Commission consideration after opinion if appropriate

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					value expressed in % w/w would also correspond to the proposed limit value for cadmium in jewellery. However, this option has been discussed in the Dossier. As there is no correlation between lead content of a jewel and the quantity of lead which can migrate from the article, this option is not considered to be effective. Limiting the amount of lead contained in fashion jewels might not necessarily reduce the exposure and consequently the health risks and it might even induce distortions and biases in the articles targeted and the actors impacted. This option could wrongly set aside highly leaded jewels but with an expected low lead migration rate (such as jewels made of crystal or glaze) and inversely, might let lower leaded jewels but with higher migration rate. The Forum proposal to use a migration rate expressed as µg/kg/h is not a solution as well, because there is not necessarily a correlation between weight and surface of a jewel. We would therefore prefer to base the restriction on the migration rate although it is difficult to measure or estimate the surface of a jewel. - A standardized analytical method should be recommended and be available before the restriction enters into force. - The Forum would prefer to use the XRF/XFA method for scanning of lead in articles because it is cheaper and easier than using analytical methods for analyzing the migration. However, as only the lead content can be measured with XRF/XFA, the use of this method would render the restriction ineffective.	DS38: Agree. As said in the dossier, in addition to the coating, *"the jewel should also be tested after removal of any coating"* (section E.2.1.2.2.). DS39: For information, to complete the options examined in the dossier, an 'option 7' has been investigated based on a two-steps approach (see new Annex C). DS40: The standard recommended is EN 71-3 with some adaptations (and EN 12472 for the coating) DS41: This method does not indeed apply to migration tests but it is now mentioned in option 2 (and in the new option 7 in Annex C).	How testing should be performed for mimicking coated and uncoated conditions has to be developed. RAC in the final opinion proposes a restriction based on a lead content in jewellery of 0.05%. To derogate from it should be documented that migration (on a weight basis) is less than 0.05 µg Pb per g jewellery / h.	

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					- In the assessment of the alternative substances the zinc risk assessment report finalised under the existing substances regulation should be taken into account: http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/zincmetalreport072.pdf . So far results from the voluntary risk assessment reports prepared by industry for lead and copper are cited in the Dossier. The presentation of the environmental issues is very condensed and undifferentiated and probably does not contribute much to the decision-making process. - As the restriction proposal recommendation is based on a risk based limit value, aggregated exposure should be considered. Such a consideration is in line with the REACH Guidance for the preparation of an Annex XV dossier for restrictions. The EFSA (European Food Safety Agency) Panel on Contaminants in the Food Chain (CONTAM) has published a scientific opinion on lead in Food in April this year (EFSA Journal 2010; 8(4):1570). This opinion is an important summary of the current knowledge of the toxicology on lead and the exposure via food and drinking water. It is highly recommended that the restriction proposal on lead in	DS42: Thank you for this suggestion but there seems to be no new information in this report compare to the information already provided in the dossier.	RAC in the opinion notes that no reliable method for a migration test mimicking mouthing is at hand and that a method has to be developed. Whether standards with regard to analytical methods should apply is up to Commission to decide. No further comments. Assessment of environmental effect is not part of the	

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					jewellery should consider the assessment of the EFSA. The CONTAM Panel of the EFSA identified developmental neurotoxicity in young children as critical adverse effect of lead on which to base the risk assessment. The panel concluded that the provisional tolerable weekly intake (PTWI) of 25 µg/kg b.w. set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is no longer appropriate due to the fact that there was no evidence for a threshold for developmental neurotoxicity as critical endpoint. The panel determined the 95th percentile lower confidence limit of the benchmark dose (BMD) of 1 % extra risk (BMDL01) of 0.5 µg/kg b.w. per day as a reference point for the risk characterisation of neurodevelopmental effects in children. The estimated dietary intake (food and drinking water) of children aged 1- 7 years ranges from 0.8 to 5.5 µg/kg b.w. per day and exceeds the BMDL01 intake level of 0.50 µg/kg b.w. per day by a factor of up to 10. Consequently the lead exposure of children by other products has to be minimized. For deriving a risk based migration limit for lead from jewellery the aggregated exposure by sources other than the dietary lead intake of children, ingestion of soil or toy material has to be included. Because of the high background exposure of children, it is highly recommended to define a proportion of the DMEL which is being contributed by a certain product group. Therefore, this proportion of the DMEL should be kept lower than 5%, when deriving a risk based migration limit for jewellery. Furthermore the DMEL derived in the restriction report should be discussed in comparison to BMDL01 value of the EFSA. Uncertainties underlying the exposure	DS43: EFSA report was published after the submission of the restriction proposal. Of course, DS has taken now into account this report regarding 1st/the other sources of lead exposure and 2nd/the relevant critical values and the parameters used to estimate the lead migration values (based on BMDL). DS44: Conclusions of both reports have been included in the restriction dossier. DS45: The background has been taken into account in the calculation of the DMELc as it corresponds to an exposure that will not change significantly the actual blood lead level of the child. This has been translated as the lowest detectable variation of blood lead level.	justification for the restriction. Data from EFSA and the JECFA opinion has been important for the opinion making. RAC has (as EFSA) used a MoE of 10 in relation to the BMDL(01) for obtaining a non-appreciable exposure level.	

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					estimations should be discussed in more detail. Furthermore, a more thorough discussion on lead speciation would be helpful, as a more thorough consideration of lead speciation might lead organo-lead compounds to become exempted from the substances concerned in this restriction dossier. Throughout the document a special case of acute poisoning is mentioned and described several times. In order to avoid unnecessary repetition it is suggested to describe this case in detail when first mentioning it reference to this section in subsequent parts of the document. General comment on Chapter C, Discussion of Alternatives It should be stated that the release of metal ions from alloys might be different compared to pure metals. This influences the availability for absorption if swallowed or mouthed. The document should demonstrate that the authors are aware of the fact that alloys might have considerably different properties in comparison to the elemental metals present in the respective alloy.	DS46 This discussion has been added in the BD. DS47: This restriction focuses on the release of Pb from jewels and not on the speciation of Pb in the jewels. With this approach all lead compounds are covered. If a jewel producer uses for example organo-lead compounds, it is his responsibility to prove that there are no or acceptable migration from the jewel. DS48: Agree. This has been taken into account in section C of the BD.	No further comments No further comments	
25	Y	2010/08/19 15:04	/ / Cyprus MSC	(A)	Comments on the Annex XV restriction report on Lead and its compounds in jewelry The Department of Labour Inspection (DLI) is in favor of the			

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			A		proposed restriction for Lead and its compounds in jewelry articles. <u>Market Surveillance data of 2010</u> As is already mentioned in the report, DLI has performed in 2008 a market surveillance campaign where the presence of lead in a substantial percentage of jewels was revealed. The target of that campaign was to examine the presence and migration rate of nickel from non-precious jewels and other articles that come in direct and prolonged contact with body parts. Before the analysis for nickel migration is performed the samples are first scanned with X-ray Fluorescence (XRF) for qualitative analysis of the content. In a similar campaign performed this year the results showed that 24 out of the 60 tested samples where either totally or partly made of lead. In these items lead is usually in the core of the jewel. In some cases the buttoning of jewels is made of lead. In relation to the 2008 market surveillance results an increasing trend for the use of lead in jeweled items is observed. Additionally, no relation can be established between the probability of containing lead and the country of origin of the jewel. <u>Analytical considerations</u> In the restriction report it is proposed to use for the migration rate of lead analysis the standard EN 71-3 (amended accordingly). However, the restriction should also cover the accidental release from broken or damaged items. We would therefore prefer to have a restriction providing for separately testing the uncoated part of the	DS49: XRF Method mentioned in the new option 7 (see response D22 above). DS50: If allowed, results to be quoted to complete data of section B.2.2. DS51: DS is not sure whether it is possible to add this in the entry. This is a Forum issue.	RAC in the opinion notes that no reliable method for a migration test	In BD it is mentioned that there are indications of greater content of lead in jewellery. For Commission consideration after opinion if appropriate.

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					jewelry in the text of the restriction. By adding this reference only in the text of the standard these cases are not sufficiently covered. If, also, the reference to the standard is removed from the text of the restriction by the end of the adoption of the proposal, this provision will not be legally binding at all. Finally we are also in favor of including the precious jewelers in the restriction since the presence of lead in them is not covered by the Hallmarking convention and the respective national legislations.	DS52: Agree.	mimicking mouthing is at hand and that a method has to be developed. No further comments.	
23	Y	2010/08/12 17:36	See ref 22		See attached file, which should be read together with my other comments, already submitted.			
22	N	2010/08/12 17:32	Belgium / International NGO / European Environmental Bureau		1. On behalf of the EEB I would like to congratulate and thank the French Competent Authority for providing the first dossiers for consideration by SEAC. Being first is always challenging, and I think a good job has been done. Please note that the comments here relate to SEA elements of the dossier and that EEB may wish to also submit comments on other areas (e,g, the risk assessment). 2. The issue of lead in jewellery should be considered worthy of regulation given the information on the health effects of lead and the data on lead content of jewellery given in Section B2.2 (summarised in Table 14 on p. 29) and information in B9.3.1 about cases of lead poisoning linked to jewellery. 3. The words 'jewellery' and 'jewel' are used interchangeably in the dossier. However the word 'jewellery' is preferable (jewel more usually meaning precious or semi-precious gemstones,	DS53: Thank you. DS54: The BD uses now the word 'jewellery'.	No further	

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					jewellery referring to items for personal adornment more generally). 4. The restriction should be applied to jewellery in its broadest sense, including items such as key rings and phone charms. Both are attractive to children, and key rings in particular are often given to small children to keep them entertained (quiet!) in cafes and such places. Such items have become more elaborate in recent years and fit within a description of jewellery as 'items of adornment'. The cited CDC [2006] reference highlights the death of a child following ingestion of a lead pendant from a bracelet – such pendants can clearly be attached to many things outside of a traditional view of 'jewellery'(such as key rings). Illustration is given in the attached file. 5. Specification of the restriction against the lead migration rate rather than lead content is a pragmatic response to an otherwise difficult problem. I understand that the logic for this is based on the use of lead in some items (lead crystal or lead glass) for which the migration rate is significantly less than metallic lead to warrant separate treatment. The requirement that migration rate be assessed for items with coatings removed and that the limit should apply to the total for the coating alone and the uncoated item, seems to overcome a number of possible problems. However, it would be useful to have a listing of the sort of things that would pass and would not pass the migration rate specified. 6. The inclusion of precious as well as fashion jewellery is appropriate. 7. The quote about cost estimates in Canada lacks context – possible $60,000 cost to manufacturers but this needs to be assessed	DS55: For enforcement purposes, the scope of the restriction proposal focuses on (fashion and precious) jewellery. See response DS35 above on the difficulty to widen the scope to other (very diversified and hardly identifiable) articles. DS56: Size, shapes and types of the jewellery articles concerned are so variable that such a listing would be impossible to make and could not be exhaustive. DS57: This CBA is given as an example. No much more	comments to DS reply. No further comments No further comments	Re 5 and DS 56 Agree with DS56, but US approach http://www.cpsc.gov/library/foia/foia09/brief/leadfinalrule.pdf might be used as a guidance on materials. Re 7 and 8 New information on

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					against company turnover to show whether or not it may be considered significant. However, the Canadian results, combined with the French lead exposure data, suggest that the benefits would outweigh the costs (the Canadians estimate that the Regulation would be efficient if between 60 and 100 cases of lead poisoning were avoided over the lifetime of the measure, the French data indicate that in a country the size of Canada about 350 children would ingest a jewel that possibly contains lead each year). 8. The calculations of additional costs due to use of lead-free alloys in jewellery (p.114) demonstrate that it is possible to come up with cost estimates for which uncertainty is not too great. However, the analysis does not account for the lower density of tin (6.99g/cm3) than lead (11.34g/cm3). Accounting for this would reduce the estimates shown by 38% to a range of €9,400 to €94,000. I would find it interesting to normalise this against the number of fashion jewellery items sold across Europe – this must be a figure in the millions, which implies a cost of the restriction per item of a few €cents at most. This becomes important in Section F2.8 (Consumers and households) where it is stated that a price increase would most affect poorer consumers – I think the impact would be so small that it would not be noticed. Also, consumers benefit from safer products. 9. Despite some issues about the way that the analysis has been performed and presented that are discussed in the attached file, the information provided is sufficient to demonstrate that costs of the restriction will be low, alternatives to the use of lead exist, and a significant number of children stand to benefit from greater	information is available about it. DS58: A cost-benefit analysis is now added to the BD1, integrating this type of reasoning. DS59: The data basing these calculations were erroneous (mistakes in the unit). They have been corrected in section B.2 and the (rough) estimation of Box 1 has been removed. For the new estimation of additional costs, see section C.7 and the partial CBA added to the BD DS60: See Section E.2.3.1. DS61: Indeed, it is said in section F.2.8. DS62: Thank you.		costs is included in section E of the BD. From the practical point of view the definition of jewellery article proposed in the SEAC draft opinion is the same as is in the cadmium restriction.

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					protection. On this basis there is sufficient evidence to accept the proposal for a restriction. **Consultation Response on Socio-Economic Assessment and the Dossier on 'Lead in Jewellery'** **On behalf of the EEB, European Environmental Bureau** The comments that follow are from the perspective of socio-economic assessment. EEB may wish to provide additional comment from other perspectives (e.g. risk assessment). Main comments about the merits of the proposed restriction have been supplied via the webform. This file contains some supporting information on the definition of jewellery and on methodological issues. ***Comments on the proposed restriction*** 1. By way of illustration about my concerns on the definition of jewellery, the figure below shows a 'Dog key ring and mobile phone charm set'. Whilst there is no evidence that the example shown contains lead or anything else that is harmful, it does demonstrate that the definition of jewellery needs to extend beyond bracelets, earrings, necklaces, rings and piercings to include key rings, etc. Perhaps the right phrase is something along the lines of 'jewellery and jewellery-like items'.	DS63: See responses DS35 and DS55 above about the difficulty to widen the scope.	No further comments	Re 6: See Section E.2.3.1.1. of the BD

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					 ***Comments on the methods used and presentation of results*** 2. A number of reasonable alternatives have been considered. Some more information about differences in ecological risks between the alternatives would have been useful, though I think unlikely to change the conclusions reached in the dossier. This raises important questions about the extent to which it is necessary to characterise the impacts of alternatives. 3. Some of the market data are old – for example, on p.63 we are told that 26% of world silver production is used in photography, based on data for 2000. In the intervening 10 years this use has probably fallen significantly through the use of digital cameras. However, I believe that medical use of silver has increased significantly over this period. 4. The test of economic feasibility in Section C seems misplaced, given the presence of SEA in Section F. I wonder what would happen if the use of alternatives was considered	DS64: This is outside the scope (although interesting). DS65: Agree but no more recent data available to those respects. DS66: In principle, SEAC does give their opinion on economic feasibility.	Re DS66: RAC does not make economical	

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					economically infeasible by RAC but economically desirable by SEAC. This could be the case, for example, if silver was the only alternative to the use of lead. Whilst the cost difference per tonne of metal is large between silver and lead, the amounts used in any jewellery item are so small (I estimate a few €cents at most) as to make very little difference to the price to consumers. 5. Some elements have been omitted from the SEA (e.g. effects on workers), though they are qualitatively reviewed. I would caution against the assumption that this is appropriate to other cases. Whilst attention should focus on the main objective of the restriction a proper understanding of secondary costs and benefits is important and may avoid counter-productive actions. I was concerned by use of the words 'not relevant to this proposal' – I think a distinction can be drawn between what is relevant for the risk assessment and what is relevant for the SEA. 6. The summary of the SEA in Section F8 could be improved. In particular, the statements about economic impacts should have been given more context. For example, it would be useful to know how big anticipated changes in cost are likely to be relative to the turnover of the sector (as a first indication of significance to the companies that would be affected) or per item purchased. The Table does not provide quantitative estimates of cost although some are given in the text. I don't think that the main text supports the statement that 'Economic costs are expected to be high for small actors'. Even if this is true, how are we to interpret	DS67: The lead amount contained in jewellery items is very various. Some items contain 10%, other (fewer) contain 80%. DS68: The effects on workers haven't been omitted. Workers exposure to lead is not examined in this dossier (outside the scope). It was thus considered to be not proportional to further elaborate on that impact. DS69: 'Not relevant' refers to the scope initially defined. DS70: See Section E.2.3.1.1 and Annex D.	evaluations.	*Re 5* Worker exposure per se is not outside the scope of a BD. In the SEA all elements in principle are relevant, even if it not the specific problem the proposal attempts to address. Re 6. New partial CBA is included in the BD.

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					the words 'high' and 'small actors'? 7. The SEA is too defensive about uncertainties, and could be more adventurous in seeking to quantify health impacts. This may require a more scenario-based approach. By stopping short of quantification in a number of areas for a chemical about which an enormous health literature exists, it might be concluded that it is not possible to perform a detailed quantitative SEA for any chemical. Whilst I appreciate the good work done by the French Competent Authority, I suggest SEAC have a session to discuss what could be improved on for future work on other proposals.	DS71: See Section E.2.3.1.1		

Specific comments

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
88	N	2010/12/21 15:44	United Kingdom / Assay Office /	(A (C)	For consistency the restriction selected should be the same as that imposed by existing EU regulations ie EN71-3 of toy regulations. This sets the migration limit at 90mg/kg. This is a better and more measurable limit than the proposal of measuring migration as a factor of surface area.	DS196: For the question of the limit unit and the surface measurement, see DS14, DS15 and DS90.	The limit values proposed for jewellery are based on the latest international evaluations on lead and the method for obtaining a limit value is not exactly the same as for the toy directive. Furthermore the limit value in the Toy Directive is at present re-evaluated. Se also the answer to ref 87.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)
87	Y	2010/12/21 15:06	Austria / chamber /	(H)	Keeping this in mind, we would like to make some specific comments on the comparability of the risk resulting from lead in jewellery to that from lead in toys, the need for a standard which takes into account other EU standards for lead, as well as the important role of plating in the prevention of exposure to lead. 1. A standard for lead in jewellery should be inspired by	DS197: See responses to comment Ref 87.	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal. See also	See comment ref 87

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					the standard for lead in the toys directive, which is based on the lead's migration rate and set in mg/kg. Such a standard would cover better the protection of consumers' health. The toys directive constitutes an instrument, which is proven to be effective in ensuring consumer safety regarding an exposure to lead incurring through mouthing and ingestion. As the risk resulting from lead in jewellery is comparable, the toys directive provides a sufficient basis for a standard aiming at protecting consumers from such a risk (cf. pages 3-6 of the attached submission). 2. The proposed standard should be in accordance with other European legislation on lead. When compared to such existing regulation it becomes clear that the proposed standard for jewellery results in a significantly lower limit than those set for lead in toys or food, although the risk of exposure is lower in case of jewellery (cf. in this regard the studies mentioned on pages 5-6 of the attached submission). Adults and children naturally ingest food and several toys are actually intended for mouthing and biting, while a hazard from jewellery occurs only accidentally through unintended use. It can therefore be concluded that with a less likely risk of exposure the proposed limit value for lead in jewellery would be much stricter than that set for lead in food or toys. 3. In high quality fashion jewellery the base metal is plated with precious metals such as gold, rhodium and palladium through electroplating. This can substantially decrease the possibility of exposure to lead through	DS198: See DS153.	response to ref 82 & 89.	

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					mouthing and ingestion. Thus we propose to use the same approach as the one used for the nickel standard and to permit testing of the metal part of the jewellery including a plating of sufficient quality, namely precious metals applied to the substrate by means of electroplating. In this regard it has to be added that due to the strength of the bond between plating layers in jewellery, the plating remains at the substrate even after unusually strong force is applied (cf. tests on pages 8-10 in the attached submission). Furthermore, as electro-plated deposits represent metallic layers, they show a high degree of tenacity and hardness and have accordingly good abrasion resistance properties. Additionally, precious metals in particular are inert to a wide range of chemicals (including strong acids). Contact with saliva during chewing or sucking will not cause any interaction with precious metals such as rhodium or gold. Thus, platings used in jewellery can decrease the possibility of exposure to lead through mouthing and ingestion, which should be taken into account in the current proposal (cf. pages 8-10 of the attached submission).			
76	N	2010/12/20 20:06	United Kingdom / Industry or trade association /	(A (B), (C), (D)	Specific Comments Page 16, para. 5: An estimate is provided that up to 5,000 children in the EU may ingest a "jewel" each year. Although the document later indicates it cannot predict what fraction of these jewels may contain hazardous amounts of lead, the value must be less than 100%. A range could be provided, based upon the country specific survey data presented in the proposal (e.g. Table 14) of	DS199: In the BD, an average value of 10% of lead-containing jewels is used as an estimate	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal e.g. in respect to describe relevant	See updated CBA

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					the number of children potentially at risk for acute exposure. Recommendation: ingestion statistics should be adjusted for the best estimates of the prevalence of lead in jewellery. Based upon estimates from Germany and Cypress (page 22) this is likely to be between 1% and 23% of jewellery items for potentially affected populations that range from 50 to 1150 children. Pages 38 – 43, Toxicokinetics: The summary provided of lead toxicokinetics is overly simplified and at times inaccurate. For example: • The incorrect impression is given that lead accumulates within bone and that bone lead concentration increases with age. While it is true that the total mass of lead in the bone increases because skeletal mass increases as a child grows, overall concentration of lead in bone is relatively constant if external exposure is constant. Today's adults have higher bone lead levels than children because of higher historical exposures to lead, not bioaccumulation of lead in bone. • Lead transfers to the developing foetus because it can easily cross the placental barrier – not because it is released from bone. Recommendation: this section requires significant revision so as to be both factually correct. We recommend to the Rapporteur country that the Voluntary Risk Assessment for Lead and other reviews cited as the source for much of this information be reviewed and corrections made.	(section E.1.1.). DS200: Agreed, the BD will be corrected accordingly DS201: It has never been written that lead transfers to the foetus because it is release from bones. The exact quotation is 'Since lead can easily cross the placental barrier, the exposure of children starts *in utero* and lasts during the lactation period'.	exposure mouthing scenarios and for choosing a relevant migration test method. Regarding the health risk evaluation with regard to the association between blood lead levels and IQ loss we think that we are coherent with the recent JECFA and the EFSA evaluations.	

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					Page 43, Thresholds: While the specific target blood lead concentration used to assess allowable lead exposures in the restriction proposal is based on consideration of the analytical feasibility of detecting certain blood lead concentrations (5 µg/L), the underlying health risk foundation for applying the selected approach is the assumption that no threshold for adverse lead impacts on health can be identified based on the currently available scientific literature. Because the proposed approach thus emphasizes potential health effects that may be associated with extremely low-level lead exposures (i.e., including exposure levels that may approach 0 mcg/L), in applying such an approach it is especially important to ensure that there is a sound understanding of the nature of the effects that may be associated with lead exposures in this range, the quantitative dose-response relationships and biological mechanisms of action that underlie any such effects, and the clinical significance and potential persistence of any observed effects. As is acknowledged in the restriction proposal, uncertainty is associated with efforts to quantify potential health effects associated with low-level lead exposures. However, the proposal proceeds to adopt (page 111) dose response assumptions from a single publication by Lanphear et al., 2005) with only passing review of more recent scientific studies of low level lead exposure. For low lead exposure levels, the contributions of potential lead impacts to adverse health effects (such as			

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					impacts on IQ) become relatively smaller and smaller when compared to impacts associated with other contributing social and environmental factors (e.g., social and parenting factors; Koller et al., 2004; Binns et al., 2007). As discussed in the Voluntary Risk Assessment for Lead, and acknowledged by the EU's Scientific Committee on Health and Environmental Risks (SCHER) in its VRAL review (SCHER, 2008), "any effects present [at blood lead concentrations that are less than a defined 'practical' no-observable-adverse-effects-level (NOAEL) of 50 mcg/L] are considered secondary in magnitude to other factors influencing child development." In addition, the documentation of the approach should clearly distinguish between aspects of lead toxicity that have actually been observed in studies of populations that have experienced consistently low-level exposures and those aspects of lead toxicity that have only been observed in populations with higher-level exposures. The restriction proposal references three specific studies as support for the no-threshold hypothesis (Canfield et al., 2003; Lanphear et al., 2005; Schnaas et al., 2006). These papers all present a dose-response function between blood lead concentrations and neurocognitive effects (e.g., IQ) that is non-linear, and the authors state that they observed a larger effect per unit increase in blood lead concentration at lower blood lead levels (i.e., that they observed a supra-linear dose-response curve). More recent studies have focused on populations with very low blood lead concentrations and have made clear			

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					that there is considerable uncertainty in the no-threshold and supra-linear dose response hypotheses. A review of this more recent literature demonstrates the inconsistent characterization of the dose response function for lead health effects at low blood lead levels. The study of Lanphear et al (2005) is prominently cited as evidence of lack of a threshold because it is a pooled analysis including data for a large number of children. However, only 244 of the 1,333 included children had peak blood lead concentrations below 100 µg/l; only 103 had peak blood lead concentrations less than 75 µg/L; and most (69) of these 103 children came exclusively from the Rochester study (Canfield et al., 2003). In essence, present statements regarding lack of a threshold and dose response functions are based upon the study of a relatively small number of children and are not being confirmed by the more recent literature evaluating larger cohorts of children with lower blood lead levels. For example, two recent studies provide evidence that there is a blood lead threshold for health effects. In one study of 488 British children, blood lead measurements collected when the children were 30 months old were analyzed relative to several measures of academic performance and behaviour at 7 to 8 years old (Chandramouli et al., 2009). Based on these analyses, these authors concluded that "Threshold effects were apparent, with no effects on outcomes at blood lead levels of 2-5 mcg/dl," (20 – 50 mcg/L) and with no "marked deterioration" in behavioral effects until blood lead concentrations were greater than 100			

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					mcg/L. Similarly, Surkan et al. (2007) evaluated data from 380 children from Boston, Massachusetts, and rural Maine, from whom concurrent blood lead and cognitive function measurements were collected between the ages of 6 and 10 years old. Scores for children with blood lead concentrations between 30 and 40 mcg/L did not differ significantly from scores for children with blood lead concentrations between 10 and 20 mcg/dL, although scores for children with blood lead concentrations between 50 and 100 mcg/dL differed significantly from the lowest blood lead category. Although the authors do not discuss these results in terms of a threshold for effects, these analyses are consistent with a threshold at 40 to 50 mcg/L – a blood lead level 10-fold higher than the reference value applied for the assessment of risk in the restriction proposal. Other recently published studies (e.g. Chiodo et al., 2007) and Kim et al., 2009) have failed to observe a threshold – but neither have they confirmed supra-linear dose responses suggested by Lanphear et al (2005). A comprehensive review of all recently published studies is inappropriate for these comments. However, it is essential for the restriction proposal to communicate the scientific uncertainty inherent in any estimates of low-level lead exposure effects upon child development. It is difficult to study very low blood lead concentrations when the measurement error is large compared to the range of blood lead concentrations in the population. The difficulty of determining the shape of the dose-response relationship increases with proximity to	DS202: DS disagrees. It has been demonstrated (please refer to recent EFSA and JECFA reports (2010)) that the effects of		

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					analytical detection limits. Recommendation: while it is entirely appropriate to state that no threshold has been detected for lead health effects (in most but not all studies), it is equally valid to assert that the presence of a threshold cannot be readily resolved with existing psychometric testing tools and blood lead measurement techniques at blood lead levels lower than 50 mcg/L. Page 43, measurement error: The target blood lead concentration used to assess allowable lead exposures from chronic jewellery contacts (5 mcg/L) was selected to represent the "smallest measurable PbB level variation." This concentration was set based on the standard deviation observed in a French inter-laboratory proficiency testing program evaluating a small number of laboratories involved in blood lead concentration analyses (AFSSAPS, 2009). This level was identified as being applicable for a target blood lead concentration of 20 mcg/L. In indexing limits to analytical benchmarks, the selected approach avoids the significant limitations that exist in the information available for characterizing the potential health effects associated with low-level exposures to lead. Indeed, selection of a health based benchmark would, to a large extent, be arbitrary and subject to substantial uncertainty regarding its biological, public health, and practical significance. Under such circumstances, indexing to analytical benchmarks might at first seem to be a sensible alternative. However, under	lead on the neurodevelopment of children are no-threshold effects.		

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					closer examination it produces yet another set of complex problems that results in the promulgation of exposure limits that are both variable and unrelated to adverse health impacts. The reference value selected in the proposal is grounded in a single small study of analytical proficiency – and avoids decisions regarding the nature or magnitude of lead intake associated with specific types or degrees of adverse health impacts. The value selected is thus as arbitrary as any value that would have emerged from analysis of the health data. Other choices could have been made based on consideration of the other available information defining the accuracy of blood lead analysis. In particular, the "smallest measurable PbB level variation" is highly dependent on the blood lead concentration range being measured, the analytical method that is used, and the capabilities of the laboratory conducting the analyses. For example, although the French study indicates fairly small standards of deviation for samples analyzed by both Atomic Absorption Spectroscopy (AAS) and Inductively Coupled Plasma-Mass Spectroscopy (ICP-MS), it was noted in the study that the coefficients of variation were highest in the lower concentration samples (i.e., ~20 µg/L), ranging from 24.6 to 37.4% (AFSSAPS, 2009). In addition, recently generated Wisconsin blood lead proficiency testing data for 2010 in the United States reported mean standard deviations up to 17 µg/L across all analytical methods (AAS, ICP-MS, and Anodic Stripping Voltammetry) and concentrations (WSLH, 2010a,b,c).	DS203: We choose to use the smallest measurable variation for a PbB level of 20µg/L since it is the mean estimated PbB level for children. Moreover the range of		

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					For proficiency samples analyzed by AAS (the most commonly used method), standard deviations ranged from 8 to 21 µg/L (WSLH, 2010a,b,c). Recommendation: comprehensive studies of analytical lab performance have produced recommendations from the US Centers for Disease Control that, for investigative actions, laboratories set their internal quality control limits to +/- 20 µg/L or ±10 %, whichever is greater (Parsons and Chisolm, 1997). For blood lead screening programs in the general population, quality control limits are increased to +/- 40 µg/L. Although ILZRO does not concur that analytical sensitivity is the proper basis on which to establish risk based limits, a value of +/- 40 µg/L is more indicative of the measurement error routinely encountered in real world monitoring programs. If a more accepted proficiency value had been selected for the target blood lead concentration, then the resulting lead intake estimate derived using the US EPA's IEUBK model would be correspondingly changed. For example, if a target blood lead concentration that is four times the current value had been selected (i.e., a value of 20 mcg/L rather than 5 mcg/L), the corresponding lead intake estimate – and the estimated allowable lead leaching estimate – would have increased by a similar amount (i.e., by approximately four-fold). For example, for a 13-month old child, the lead intake required to generate a blood lead increment of 50 mcg/L in the IEUBK model (relative to a baseline blood lead concentration of 0 mcg/L) is 2.57 mcg/day, while the intake associated with	variation depends on the PbB level measured. Finally, we acknowledged the fact that smallest levels can be measured but we choose to use the variation representative for the tests which are the most routinely used in laboratories.		

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					an increment of 20 mcg/L is 12.1 mcg/day (a factor of 4.7 greater). The preceding also illustrates a problematic inaccuracy inherent in a reference value indexed to analytical sensitivity – that of nonlinear toxicokinetics. Using the IEUBK model, the amount of incremental lead intake required to increase the estimated blood lead concentration by a given amount increases as the baseline blood lead concentration increases. For example, the lead intake required to increase a young (13-month old) child's blood lead concentration from 0 to 5.0 mcg/L is 2.57 mcg/day, the intake required to increase a young child's blood lead concentration from 20 to 25 mcg/L is 2.9 mcg/day, and that required to increase a young child's blood lead concentration from 100 to 105 mcg/L is 5 mcg/day, or approximately twice as much intake as required for a baseline blood lead concentration of 0 mcg/L to yield the same incremental blood lead concentration increase. This result occurs because lead absorption is nonlinear with increased intake (i.e., that the degree of absorption decreases as the amount of lead intake increases). Thus, the approach applied in the proposal reflects an unrealistic low-end estimate of analytical proficiency and couples it with incorrect toxicokinetic assumptions that no other lead exposure occurs from any other sources. Pages 43 – 44: DNEL/DMEL calculations and inappropriate pharmacokinetic modelling: Only limited information is provided regarding the modelling			

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					approaches used to estimate the amount of lead intake that would be associated with the blood lead concentrations chosen as target levels for the two exposure scenarios of concern. However, based on the provided information, it appears that the Sharma model – which was used to estimate exposures associated with the accidental ingestion scenario – is not a technically sound approach for use in this scenario and does not yield an accurate perspective on likely actual exposure conditions. In particular, this model yields estimates of lead body burden that differ from other widely accepted modelling approaches. A modified version of the lead exposure model presented in Sharma et al. (2005) was used to estimate the amount of lead intake that would generate the target blood lead concentration of 40 mcg/dL (400 mcg/L) either 2 days or 5 days following ingestion of a lead-containing piece of jewellery. Annex D briefly summarizes the equations and parameters used in this calculation and notes that the model used is "an extension of that proposed by Sharma et al. (2005) completed by an equation proposed by O'Flaherty (1991) to take into account children's growth." The Sharma et al. (2005) analysis in fact evaluated chronic lead exposures from air and diet for children in India, not acute exposures and was not designed to address exposure situations of the short duration assumed for the accidental ingestion scenario (i.e., 2 or 5 days). Sharma et al. (2005) state that their exposure model is based on a 1993 version of the O'Flaherty model	DS204: We are aware of the differences between the model used in the dossier and the others ones like the O'flaherty model. The Sharma model was principally used because it is more conservative. The principal difference is not due to the absorption of the gastro intestinal tract parameter but due to the modelisation of the bone compartment and the exchanges between bone and blood. And there is not a great difference between applying an absorption factor of 0.5 (RMS approach) or having the absorption from 0.58 to 0.4		

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					(O'Flaherty, 1993), which was "simplified by neglecting the detailed performances of lead in bone, which is used to relate the respiratory and dietary lead exposures with PbB [blood lead]; the half life of lead in bones is several years." While Sharma et al. note that they validated their simplified exposure model using data from two studies (Azar et al., 1975; Rabinowitz et al., 1976), neither of these validation sets involved acute short term exposures such as that being modelled in Annex D. Instead, the validation data derived from the Rabinowitz et al. (1976) study were based on two subjects who were exposed to a lead tracer under controlled conditions for 104 days (for one subject) and 124 days (for the other) in a study that was designed to evaluate the kinetics of lead metabolism for a lead intake level approximating the subjects' typical pre-study chronic intake level. Similarly, Azar et al. (1975) examined the relationship between blood lead concentrations and chronic exposures to lead in air. In addition, both of the data sets Sharma et al. used for model validation involved adults; however, fractional bone turnover is much higher in children than in adults (O'Flaherty, 1997). Thus, by excluding model components that account for bone metabolism, the simplified Sharma model will be particularly prone to providing inaccurate predictions for children. This concern is confirmed in a comparison of the predictions of the Sharma and the complete O'Flaherty model. The O'Flaherty model (O'Flaherty, 1998) was applied by ILZRO to assess the validity of the calculations in	according to the age of the child. Furthermore, the half-life of lead in blood estimated with the Sharma model (1.5-2.5 month) is closer to usual half-life values (36 days from VRA) than the one estimated by ILZRO with the O'flaherty model (± 2 days). It would be interesting to have the report of the modelisation made by ILZRO with the O'flaherty model to made a real comparison with the Sharma model. The VRA presents a study from Robert *et al* (2001) which shows that children with a blood leads of 250-290 µg/L requires 24 months to decline less than 100 µg/l. and that higher is the peak the long it will take to decrease below 100 µg/L. Following these results we will maintain the use of the Sharma model for this assessment. Roberts, J.R., Reigart, J.R.,		

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					Annex D, assuming that a three year old child is exposed to an elevated lead concentration for 5 days. (A two-day exposure duration is too short of a time period to model using the O'Flaherty model.) In the O'Flaherty model, the fractional absorption of lead from the gastrointestinal tract declines from 0.58 at birth to 0.08 after age 8 years. For a three year old, the fractional absorption of lead is approximately 0.4 (O'Flaherty, 1997; Figure 4-3). The O'Flaherty model assumes that absorption is non linear with increasing dose (i.e., higher doses are absorbed to a lesser degree; O'Flaherty, 1998). The Sharma model assumes a fractional lead absorption of 0.5, but it is not clear from the available documentation whether absorption is assumed to be dose-dependent. Using the O'Flaherty model, a higher lead intake (i.e., 4,120 µg/day) is required for a three year old to achieve the target blood lead concentration of 40 µg/dL in 5 days of exposure than was derived in the proposal using the simplified Sharma model (i.e., 1,600 µg/day). The magnitude of the difference in the model results is not explained solely by the absolute difference in assumed lead absorption (i.e., the lead intake estimated to yield the target blood lead concentration in the O'Flaherty model is a factor of 2.6 times greater than that estimated using the simplified Sharma model, while the assumed absorption in the Sharma model is only a factor of 1.25 times greater than that applied in the O'Flaherty model). The difference in the two model results most likely results from the nonlinear absorption component that is incorporated in the O'Flaherty model and most other	Ebeling, M., Hulsey, T.C. (2001). Time Required For Blood Lead Levels To Decline In Nonchelated Children. Clin Toxicol 39: 153-160		

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					modern exposure assessment models. The results from the two models were also reviewed to assess the amount of time that would be required for the child's elevated blood lead concentration to drop to a concentration less than 100 mcg/L following cessation of the elevated lead exposure. Assuming that the elevated lead exposure ceased after the 5 day exposure period, the O'Flaherty model predicts that it would require only 7 days for the blood lead concentration to fall below 100 µg/L. By contrast, the simplified Sharma model estimates that it would take 150 days for the blood lead concentration to drop below 100 µg/L. Thus, after the 5-day elevated exposure period ceases, the assumed rate of blood lead decline in the simplified Sharma et al. model is much slower than that reflected in the O'Flaherty model, which incorporates a more detailed evaluation of the kinetics of lead in bone. Elements to address bone metabolism are a central component of the O'Flaherty model, and the model was developed to reflect the observations that lead from blood plasma is incorporated into forming bone, and that lead in bone is returned to plasma as bone is resorbed (O'Flaherty, 1998). Bone thus serves to modulate and stablize lead in blood concentrations and it is physiologically implausible that an elevated lead exposure lasting only 5 days could yield sufficient lead uptake to cause a child's blood lead concentration to remain greater than 10 mcg/L for 5 months as predicted by the simplified Sharma model. In addition to providing a more detailed evaluation of the role of bone in lead kinetics, the O'Flaherty model also			

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					offers the advantages that it is a validated model that has been available for many years and has been applied in a number of contexts. For example, it is described by US Environmental Protection Agency (US EPA) in the 2006 Air Quality Criteria document for lead (US EPA, 2006) and is identified in the Voluntary Risk Assessment for Lead as one of two primary models used to evaluate children's lead exposures (with the other model being the US EPA's Integrated Exposure Uptake Biokinetic [IEUBK] model). By contrast, the Sharma et al. model does not appear to be a widely used or internationally recognized model. For example, a literature review has found no subsequent articles that have used this model for blood lead prediction. Recommendation: the blood lead modelling in Annex D should be conducted using the O'Flaherty model rather than the simplified Sharma model, based on the observations that the O'Flaherty model provides a more detailed, validated and technically sound foundation for assessing lead exposures and has greater use and acceptance. It is also noted that a comparison of the table of physiological and toxicokinetic parameters listed in Annex D, with those listed in Sharma et al. (2005) yielded discrepancies between the two listings: • The "exponent" symbols were omitted from the expressions used in the "Values" column of the Annex D table presenting physiological and toxicokinetic parameters, which would lead to confusion regarding the correct	DS205: The presentation of equations and parameters will be checked to make it more understandable.		

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					expressions. • The units should be listed for each set of parameters in the Annex D table, as are presented in the Sharma et al. (2005) listing. • The parameter descriptor "rapidly perfused tissues" in the Sharma et al. documentation was changed to "well perfused tissues" in the Annex D documentation (e.g., the variable for the volume of rapidly perfused tissue – VRA – was changed to VWP), and the parameter descriptor "slowly perfused tissues" was changed to "poor perfused tissues" (e.g., VSL was changed to VPP). However, the expression for VPP included in the Annex D table presenting physiological and toxicokinetic parameters still refers to VRA rather than to VWP. • In Sharma et al. (2005), the value for VRA (VWP in the Annex D documentation) uses an exponent of 0.85 for body weight, not 0.86 (i.e., for consistency with the Sharma documentation, the value listed in the Annex D table presenting physiological and toxicokinetic parameters should be 0.01*BW0.85 - VLI - VKI, not 0.01*BW0.86 - VLI – VKI). • Similarly, in Sharma et al. (2005), the value for VSL (VPP) does not use an exponent of 0.86 on body weight. The value is listed in the Sharma et al. documentation as BW - VLI - VKI - VRA - VBO; however, the Annex D table presenting physiological and toxicokinetic parameters lists the value as (BW)0.86 - VLI - VKI - VRA - VBO.	DS206: This is a typographical error and will be corrected.		

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					Most of these discrepancies appear to reflect typographical or editorial type errors that would not necessarily result in incorrect calculations using the information presented in the Annex D documentation; however, the accuracy of the calculations should be verified. The use of the US EPA's IEUBK model to assess the lead intake-blood lead concentration relationship in the mouthing scenario appears to have been undertaken accurately. The three intake values shown in Annex C of the proposal and modelled using the IEUBK model appear to have been correctly entered into the model and do yield an incremental increase in blood lead concentration of 5 µg/L. These estimates are only accurate, however, assuming that the lead intake from mouthing jewellery occurs on a regular basis (e.g., approximately daily) over an extended period of time. Pages 54-55, overly conservative assumptions regarding mouthing behaviour: Another excessively conservative element of the modelling approach used to estimate lead intake is the default mouthing time used in the assessment. Specifically, the proposed approach applies a mouthing time estimate derived based on observations of children between the ages of 7 to 12 months as the value used in deriving the lead migration rate for the mouthing scenario. The assumed mouthing time of 86 min/day represents a 75th percentile value for the total for two categories of objects that a child might mouth – i.e., "other toys" and "non-toys." In the study that forms the basis for this mouthing time			

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					estimate (Steenbekkers, 2001), the remainder of the observed mouthing time was attributed to two categories of objects that are specifically intended for mouthing (e.g., pacifiers and teething toys). The conservative nature of the mouthing time estimate selected for use in the proposal is made evident by the fact that the proposed 86 min/day duration (for two categories of objects that are not specifically intended for mouthing) is greater than the average mouthing duration for all categories of objects included in the original study, including objects such as pacifiers and teething toys (i.e., 71.3 minutes; Steenbekkers, 2001). Several additional aspects of this assumption are highly conservative. First, by combining mouthing times for "other toys" and "non-toys," the approach inherently assumes that all of the child's mouthing time with objects that are not specifically intended for mouthing will be spent mouthing a piece of lead-containing jewellery. The blood lead concentration modelling approach for the mouthing scenario also assumes that this mouthing behaviour (i.e., approximately 1.5 hr/day of mouthing a lead-containing piece of jewellery) will persist over an extended period of time. Second, the selected mouthing time assumption is based on data for 7 to 12 month old children, the age group with the highest estimates of mouthing time of the age groups examined in the study. However, this age group may not be the group most likely to mouth a piece of lead-containing jewellery for an extended period of			

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					time. Indeed, it is more likely that infants in this age group would choke on an object of the assumed size (i.e., 10 cm2, or somewhat larger than a 1 euro coin) before experiencing chronic lead exposures and effects. By contrast, the mouthing time estimates for the next highest age group – 13-18 month old children – are far lower than those for the 7-12 month age range, with the combined total for "other toys" and "non-toys" being approximately 40% of that for the younger age range (i.e., 35 min/day vs. 86 min/day). This age range provides a more plausible target population for the assumed exposure scenario, and the mouthing time estimates for this age range provide a more realistic worst case exposure scenario for this component of the analysis. Third, the mouthing duration estimates drawn from the Steenbekkers (2001) study are based on daytime durations of mouthing behaviour, which were then multiplied by a factor of 1.5 to account for night time mouthing. Again, this element of the mouthing assumption is highly conservative for the types of objects (i.e., a piece of jewellery not designed for mouthing) and age range of the target population. Recommendation: Adjustment of the mouthing time estimates is indicated – age appropriate estimates should be applied and mouthing times reduced to a fraction of the mean (as opposed to the upper 75th percentile) mouthing time values to reflect the fact that jewellery will not be the sole type of item mouthed by a child and that mouthing is unlikely to occur on a daily basis. Presumptions of linearity of lead release over time:	DS207: DS agrees that the assumptions concerning the mouthing duration of children are very conservative. As accepted in response DS 80, a refinement of this parameters will be made probably considering only one category of object.		

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					Impacts of lead upon blood lead calculated to be associated with mouthing behavior assume linear and constant lead release over time. In reality, the lead migration rate associated with mouthing behavior is likely to be non-linear and far more complex than suggested here. Although there has been little need, until now, to study lead migration from materials used in jewellery, extensive studies have been conducted of materials used in food preparation and serving. Food contact materials include lead-glazed ceramics and lead crystal – materials that are also used in jewellery and of a compositional nature (lead contained within a crystalline matrix) also likely to mimic the crystalline structure of alloys containing low levels of lead. Lead release from such materials has been extensively studied and demonstrated to be non-linear in several important respects. Studies conducted of crystal ware under conditions of consumer use (Guadagnino et al. 2000) have determined that lead elution into beverages is not a linear function of contact time. For example, the lead content of wine will increase from 30 µg/L to 80 µg/L in the first 5 minutes of contact time in stemware. Lead elution then slows - after 60 minutes of contact time lead in wine concentration will increase to approximately 120 µg/L. More lead is released in the first five minutes of contact than in the subsequent 55 minutes. Any effort to establish a constant release rate applicable to such materials will be erroneous. The underlying mechanism of this observed non-	DS208: Concerning the non linearity of lead release, the literature will be checked and will be integrated in the dossier if it can be generalized to all kinds of jewels and if data are sufficient to build a model. May be it can be integrated in measurement method to made a first "wash" of the jewel. And measuring the migration rate during the first flush and after the first flush.		

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					linearity is likely applicable to many of the constituent materials of jewellery. Under conditions of consumer use, the highest lead levels in beverages are observed with the first use of the lead crystal item. Lead elution with subsequent uses becomes increasingly limited. The contamination of beverages by lead upon first use of a product results from the the initial dissolution of surface lead contaminants and the subsequent diffusion of lead from the crystal glass matrix. The initial rapid release of lead can largely be controlled by adequate washing procedures that remove trace surface lead contaminants. The slower release of lead is controlled by diffusion of lead from the silicate matrix within which it is contained. With repeated uses, diffusion of lead from the interior surfaces of stemware results in the formation of thin layers of glass matrix that have been depleted of readily diffusible lead (Bertoncello et al, 2004; Guadagnino et al, 2002). In repeated use scenarios, levels of lead released into beverages are observed to rapidly decline (by a factor of 10 or more) as the product is used. The preceding non-linearity would be expected for any lead crystal or lead-glazed ceramic component of jewellery. Although ILZRO is not aware of detailed studies that have characterized the process of lead release from metal alloys or gemstones used in jewellery, the same principles of release are expected to apply. An initial rapid release of surface lead contamination would be expected – the magnitude of which would vary as a function of the extent to which jewellery has been cleaned prior to consumer purchase			

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					and use. Rapid release surface lead release will then be followed by a slow release process governed by basic principles of diffusion kinetics. In multiple contact scenarios, as a function of the dissolution rates of the other constituent materials of jewellery, lead release would be anticipated to decline as readily diffusible lead is depleted from the article surface and a lead-depleted alloy matrix forms on the surface of the jewellery article. The ramifications of these non-linear processes are significant. Migration test data will reflect the rapid release of surface lead contaminants and over-estimate long-term lead release in multiple contact chronic mouthing scenarios. Lead release will also be non-linear as a function of time, invalidating assumptions of constant hourly release rates central to the estimates of exposure. Overestimation of exposure will be greatest in the daily mouthing exposure scenario that seems to be of greatest concern. Lead Leaching Tests: Using exposure models, the proposal identifies two lead migration rates for use in characterizing jewellery that would be subject to the proposed restriction. A migration rate of 0.09 mcg/hr/cm2 is identified as a safe migration rate for evaluating jewellery in the context of a mouthing scenario, while a migration rate of 23 mcg/hr is identified as a safe migration rate for evaluating jewellery in the context of an accidental ingestion scenario. In the first scenario, it is assumed that a child would mouth the jewellery for approximately 1.5 hr/day over an extended period of time. In the second scenario,			

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					it is assumed that the child swallows the jewellery and that the jewellery is retained in the body for 2 or 5 days before being excreted or otherwise removed. In both cases, the analytical method proposed for use in assessing lead leaching from jewellery is an extraction method intended to reflect gastric conditions. While such a method is perhaps appropriate when assessing potential leaching from jewellery that has been swallowed – and thus would experience gastric conditions, such conditions would not be representative of the leaching potential that would be encountered by a piece of jewellery that is mouthed. Thus, the proposed migration approach, as suggested in the proposal, is overly conservative and unrealistic for assessing potential exposures associated with mouthing of jewellery. The pH of saliva is much less acidic than that of the gastric compartment. Specifically, the pH of saliva is in the neutral range (approximately 7; RIVM, 2002; US CPSC, 1998), while that of the gastric compartment is highly acidic (e.g., paediatric gastric pH has been observed to be on the order of 2 under fasting conditions, with transient increases to a pH of approximately 4 following ingestion of food; Ruby et al., 1996). To the extent that the gastric extraction procedure maintains the test system pH at the lower end (or less than the lower end) of this range, the test system will not only subject the jewellery item to more aggressive extraction conditions than would be encountered during mouthing, but may also reflect more aggressive extraction			

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					conditions than would be encountered under realistic exposure conditions following accidental ingestion. Moreover, the conditions under which the jewellery would be exposed to the leaching fluid (i.e., saliva or gastric fluid) would differ substantially. For a swallowed piece of jewellery, the jewellery would be in contact with the leaching fluid on an extended basis, with the potential for ongoing contact over much or all of the jewellery surface. By contrast, contacts of saliva with a mouthed piece of jewellery are likely to be highly variable from one individual or contact event to another – with some events including extended sucking of the jewellery, and others including only intermittent or limited saliva-jewellery contacts. Again, the mouthing contacts are likely to lead to far less aggressive leaching conditions than those that might be encountered in the gastric compartment. The proposal states that the leaching method based on gastric conditions was selected for use in the proposed approach because no "standard" approach was available for assessing lead migration in saliva. However, protocols have in fact been developed to assess chemical leaching in conditions similar to saliva (e.g., a methodology developed by the US Consumer Product Safety Commission [US CPSC] to assess migration of diisononyl phthalate (DINP) from polyvinyl chloride (PVC) children's products [US CPSC, 1998]) and have been adapted to assess lead leaching from objects due to contacts with saliva. It should also be noted that methods have been developed to simulate the	DS209: Concerning the leaching test, it would be more relevant to have a standardized test protocol for leaching in saliva but waiting for such standardization would postpone the applicability of the restriction. The method used for DINP migration seems to not be a standard and the in-vitro test are an average 39.5 times lower than in-vivo test (US CPSC 1998). So to have a similar migration test		

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					leaching that would occur during passage of an object from the gastric environment to the intestines, reflecting different durations spent in the two environments (e.g., 2 hr in the gastric environment, followed by 8 hr in the intestinal environment) and the different pH in the two environments (e.g., ~1 in gastric fluid and ~7 in intestinal fluid). Recommendation: Use of an approach that better reflects the leaching conditions posed by saliva contact is justified and would be superior to the use of the gastric leaching methodology which incorporates far more aggressive leaching conditions than would be posed by saliva contact. Another aspect of the proposed leaching approach that appears overly cumbersome is the inclusion of a surface area in the leaching evaluations. Specifically, for items that are evaluated for lead leaching potential following mouthing, a specific surface area (10 cm2) is included in the calculations, and the target leaching rate is expressed in units of mcg/cm2/hr. This approach will be useful in the standardisation of results for large objects but it is not clear what benefit is added to the evaluation approach by including surface area measurements in the assessment for small items that have a surface area significantly less than 10 cm2. A final aspect of the proposed leaching approach that seems overly conservative is the element of the approach that addresses the potential for lead-containing jewellery to have a coating that may also contain lead. The proposed approach requires that the piece of jewellery be	for lead in-vivo tests have to be conducted to correct in-vitro test. If a leaching test for saliva is available, a second test would have to be conduct to assess migration in stomach to consider acute exposure when a child swallows a jewel. DS210: Concerning the surface estimation due to the uncertainties and the possible overestimation of jewels smaller than 10 cm² some solution are in discussion. See DS 14.		

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					tested both with the coating intact, and with the coating removed (to model potential lead leaching from the jewellery in a "new" condition and also leaching from the jewellery after the coating has worn off). The leaching results from both of these tests are then to be added together to determine whether the jewellery exceeds the proposed leaching limit. This approach yields an estimate of leaching potential that would not be encountered during actual exposure conditions, that is, the surface area of the jewellery could not simultaneously be both entirely coated and entirely uncoated. Instead, a child would be exposed to a piece of jewellery with the entire surface area either entirely coated or entirely uncoated, or at some intermediate stage of coating coverage (which might, for a transitory period, result in leaching from smaller portions of each of the two types of surfaces). As a result, compliance should be assessed based on the more conservative of the results from the tests of the coated or uncoated states, i.e., based on the coating status yielding the higher leaching potential. Substitutes: A number of metals (copper, silver, tin, zinc, bismuth and their alloys) are noted as substitutes for lead in jewellery. The list of candidate materials, while not all-inclusive, is reasonable and reflects patterns of material usage in the manufacturing of fine jewellery. The discussion would, however, benefit from cautionary words on the potential lead content of substitute materials. From an absolute standpoint, none of the substitutes are truly lead free although lead levels can be	DS211: 1. DS is aware of the difficulties linked to the approach proposed about the measurement of the lead in coating. The use of wear tests is now integrated (and recommended) in the BD (section E.5.). 2. DS is aware that lead-free		

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					significantly reduced during the metal refining process. ASTM (2010) specifications for many of the materials cited permit variable amounts of lead as a function of metal quality grade. For example, silver grades of 99.90, 99.95 and 99.99 purity have maximum permitted lead contents of 0.025, 0.015, and 0.001% lead. While it is generally presumed that fine jewellery will use only high purity silver, patterns of material usage in inexpensive products is unknown. Pure silver is seldom used in jewellery due to lack of durability and silver alloys (92.5% silver) constitute sterling silver. Copper is normally the alloying metal employed (0.004% lead content or higher) but other metals can be used. Solders used in the manufacture of silver jewellery can also contain lead at significantly higher concentrations. Similarly, the lead content of zinc will vary as a function of zinc grade, being as high as 0.5 – 1.4% in Prime Western zinc or as low as 0.003% lead in Special High Grade zinc. Alloys of metals such as zinc, copper and tin (brass and bronze) can also contain lead at concentrations that range from 0.05 to 10% or more. Even steel can contain lead at concentrations of 0.2 – 0.35%. The wide range of alloy specifications, with varying lead contents, should be acknowledged and care urged in the selection of materials to be used in jewellery. This is particularly true for items manufactured for use by children which will have a tendency to utilize less expensive metal alloys (brass, bronze etc.) References	alloys can contain small percentages of lead		

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					Agence Francaise de Securite Sanitaire des Produits de Sante (AFSSAPS). 2009. "Annales du Controle National de Qualite des Analyses de Biologie Medicale: Plombemie. [Annals of National Quality Control - Analyses of Medical Biology: Blood Lead.]" 12p., November. ASTM (2010). Annual Book of ASTM Standards, Section 2, Nonferrous metal products. Vol. 02.04, ASTM International, West Conshohocken, PA, USA Azar, A; Snee, RD; Habib, K. 1975. "An epidemiological approach to community air lead exposure using personal air sampler." In Lead. (Eds.: Griffin, TB; Nelson, JH), Academic Press, London, UK, p254-290. Bertoncello, R., Milanes, L., Bouquillon, A., Dran, J.-C., Mille, B. and Salomon, J. 2004. Leaching of lead silicate glasses in acid environment: compositional and structural changes. Applied Physics A: Materials Science and Processing 79:193 – 198. Binns, HJ; Campbell, C; Brown, MJ. 2007. "Interpreting and managing blood lead levels of less than 10 microg/dL in children and reducing childhood exposure to lead: Recommendations of the Centers for Disease Control and Prevention Advisory Committee on Childhood Lead Poisoning Prevention." Pediatrics 120(5):e1285-1298. Canfield, RL; Henderson, CR; Cory-Slechta, DA; Cox, C; Jusko, TA; Lanphear, BP. 2003. "Intellectual impairment in children with blood lead concentrations below 10 deciliter." N. Engl. J. Med.			

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70	N	2010/12/20 17:34	United Kingdom / Industry or trade association /	(A (B), (C), (D) (E), (F), (G) (H)	Commentary on 'Background Document to the Opinion on the Annex XV Dossier proposing Restrictions on Lead and its Compounds in Jewellery' dated April 2010 Prepared for International Lead Association RPA (16 December 2010) Commentary on 'Background Document to the Opinion on the Annex XV Dossier proposing Restrictions on Lead and its Compounds in Jewellery' dated April 2010 December 2010 prepared for The International Lead Association by Risk & Policy Analysts Limited Farthing Green House, 1 Beccles Road, Loddon, Norfolk, NR14 6LT Tel: 01508 528465 Fax: 01508 520758	DS212: See responses to general comment Ref 70 above	Comments noted. The restriction proposal is primarily driven by the aim for protecting against chronic toxicity and not acute toxicity which is less critical for derivation of a limit value for lead in jewellery.	See comment ref 70

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					Email: post@rpaltd.co.uk RPA REPORT - ASSURED QUALITY RPA Project: Ref J710 Approach: In accordance with discussions with Client Report Status: Final Report Report Prepared by: Meg Postle, Director Philip Holmes, Technical Director Panos Zarogiannis, Principal Consultant Thomas Persich, Researcher Report approved for issue by: Meg Postle, Director Date: 16 December 2010 1. INTRODUCTION At the request of the International Lead Association, Risk & Policy Analysts Ltd. (RPA) have reviewed a version of the French draft Annex XV Restriction Dossier on a proposal for restriction of Lead (Pb) and its compounds in jewellery, dated April 2010. Our findings and suggestions as to approaches that may be helpful in the future development of this dossier are presented below. 2. SUBSTANTIVE COMMENTS 2.1 Issues Relating to Human Health Impact 2.1.1 Risk of adverse health consequences Section B of the Annex XV Restriction Report on lead and its compounds by the French Competent Authorities correctly reports that the toxic effects of lead in terms of both its possible acute and chronic changes have been			

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					generally established in terms of the dose-response characteristics applying to various endpoints, including the important issue of the its influence on human neurodevelopment. The particular susceptibility of young children has also been previously reported, with this relating not only to their apparently higher oral absorption rates and immature state of neurological development but also to behavioural issues such as their high level of mouthing activity compared with adults and older children. However, there is a strong basis for questioning the estimate in the draft Annex XV Restriction Report of the extent to which jewellery items are prone to being swallowed by young children and the implicit assumption that this then leads to poisoning of the child as a result of lead assumed to be present within the item. The Restriction Report correctly reports the death of a child after ingestion of a metallic charm in Minnesota in 2006 (CDC, 2006) and a number of other cases, including a case of non-fatal lead poisoning from ingestion of a toy necklace in Oregon in 2003 (CDC, 2004). It also draws on a stated 52 cases of ingestion of jewels for children under 5 years-old by 10 French emergency services between 2004 and 2007. As a dataset, however, this is a somewhat limited and incomplete basis for extrapolating to an estimate of 5000 children possibly ingesting jewellery every year in Europe and from which to also assume that this number are necessarily at risk of lead poisoning. There is considerable evidence suggesting that jewellery			

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					items as well as many other small objects – including toys – do indeed represent a real and significant risk to infants and young children with attempts to swallow objects by this age group apparently a relatively frequent occurrence. However, the major risk associated with the accidental swallowing of non-food items appears to relate to choking hazard not poisoning. Rimell et al (1995) and Steen & Zimmerman (1990) have reported that approximately two-thirds of all choke deaths among children occur in those under 3 years of age and Altmann & Ozanne-Smith (1997) showed that the level of non-food related non-fatal asphyxiation and foreign body ingestion was relatively constant over the first 3 years of life and then declined by 6 years of age. A study by Banerjee et al (1988) also found that children under 3 years were the most vulnerable to inhalation of foreign bodies. It thus appears that the risk of choking is greatest in those under 3 years of age but remains appreciable until 6 years of age (Altmann & Ozanne-Smith, 1997, Reilly et al 1996, Rider & Wilson 1996 and Rimell et al 1995). Estimates drawing on data from the 1980s and 1990s suggested that in the UK there were 2600 non-fatal and 24 fatal cases of children under 4 years of age choking on objects each year, and estimated that there were over 50,000 non-fatal choking incidents and 400 deaths in children under 10 years of age (mostly under 5) each year in the EU. Incidences ranged from 0.4 (Sweden) to 3.4 (Greece) deaths per 100,000 children. Of these, 51% were attributable to food, 6% to toys and 32% to non-toy			

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					items (mainly coins) (DTI, 1996 and 1999). Other data suggest that suffocation rates in infants alone (e.g. from choking) may be 4.4 deaths per 100,000 (Public Health Service of Canada, 2009) while, in the State of Victoria Australia, hospital admission rates (1987-1995) for asphyxiation are 15.1 per 100,000 children; foreign objects accounted for about 80% of the Australian cases but most related to swallowing coins (Altmann & Ozanne-Smith, 1997). Set against this high incidence of choking, the risk of lead poisoning as a result of swallowing jewellery items seems very small. For example, considering the US population, poisoning of children by lead from any source appears to be a rare event, with some 5,800 cases per year identified in the US population of children below 6 years of age. Importantly, of these only 1.8% arose from causes other than domestic exposure to old (lead-containing) paint and this 1.8% included - in addition to jewellery - candles, spices and minim blinds (Goldman 2007). The US CDC also estimated the rate of death due to all causes of unintentional poisoning (not just lead-related) for 0-9 year olds in 2006 to be 0.15 per 100,000 (CDC, year not specified) while in Canada, jewellery was not identified as a significant contributor to causes of unintentional poisoning in the young (0-19 years of age), for which all causes combined accounted for 20 per 100,000 hospitalisations per year and 0.3 deaths per 100,000. Most of these occurred in the 15-19 year age group and, hence, are highly unlikely to be related to the swallowing of jewellery.			

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					Importantly, focusing on the European situation, a database established by RoSPA (2010) reports that, for the UK population of children (0-4 years), the yearly incidence of suspected poisoning from all sources that were considered of sufficient concern to require hospital attendance was only 25,950 during 2000-2002, of which an average of 20 cases (0.077% of total) were attributable to suspected poisoning by jewellery items. Furthermore, this database showed that poisoning accounted for only 4.1% of the 481 incidents involving jewellery in this age group. Regrettably, the underling poisonous agent(s) in the jewellery was not reported and, while it may be assumed that a proportion of these cases may be attributable to the presence of lead, it is know that several other toxic metals including cadmium are present in some jewellery items so not all these cases might, in fact, be attributable to lead poisoning. Adopting the UK annual estimate of 20 children per year of hospitalisation (not death) attributable to poisoning by jewellery, and extrapolating from the estimated total size of the UK population of 59,217,592 to that of the EU-27 (484,636,747) for the year 2002 (Eurostat, 2010) indicates that there might be of the order of 164 cases of jewellery-related poisoning of children of up to 4 years of age across Europe each year of sufficient severity to require hospitalisation. A more refined approach would be to base this extrapolation on the size of the child population. Eurostat provides data on national populations under 5 years of age. For the UK, the relevant population in 2002 was 3,448,236 while for EU-			

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					27 it was 25,200,752 children. Using these population values, suggests there would be only 146 cases of jewellery-related poisonings of children. Of these, an unknown proportion may reflect lead toxicity but, given that several other toxic metals have been found in some jewellery, it is considered unlikely that all these cases would be attributable to this particular substance. This casts significant doubt on the robustness of the Restriction Report's estimate of the number of children affected as about 5,000 per year. We would also note that no detail is provided on the locations of the 10 French emergency services that have documented cases on children swallowing jewellery items. Thus it is not possible to judge whether these are representative of all French emergency services (e.g. in terms of the size of the population covered by each of them) or indeed of any other emergency service across the EU. Finally, it is also worth noting that the information on the French emergency services summarised in Section G.5 does not indicate what the composition of the offending items in those 52 cases were. Therefore, it should have been made clearer in the text in Section F.1.2 that not all 5,150 children potentially swallowing a jewellery item each year would necessarily be exposed to lead (as the metal is unlikely to be contained in all items swallowed by children). The Restriction Report correctly identifies that, based on the Danish Study, it is not possible to address the safety concerns with regard to the presence of lead in jewellery			

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					items in terms of the percentage lead content (this aspect is discussed further below). Rather, the key property on which any risk assessment would have to be based is the extent to which lead migrates out of a piece of jewellery under specified conditions. The report is also helpful in establishing the limitations of current methodologies to allow the accurate determination of this property. 2.1.2 Health Consequences of Exposure Episodes Section B of the dossier includes discussion on the nature of the hazard that might be faced by young children through mouthing or swallowing lead-containing jewellery items. Issues related to estimating the degree of exposure that may arise from such activities are discussed in relation to exposure issues below. We would draw attention, however, to the degree of uncertainty that surrounds the consequences of acute or episodic exposure to lead, as opposed to continuous exposures such as would be associated with contamination from dietary sources, for example with regard to the consequences for cognitive development and the extent to which recovery might occur following an acute exposure, or even following a reduction in the level of episodic or even continuous exposure. Thus, any estimate of impact based on acute/subacute exposure situations (such as from swallowing or intermittent mouthing) needs to be treated quite differently from situations when one is attempting to estimate the consequences of chronic exposure. In particular, the clinical consequences of these different exposure patterns are known to be quite distinct and it			

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					would be questionable were attempts to infer the outcome of acute or subacute exposures to be inferred from epidemiological or experimental data relating to chronic exposures. This is particularly important in the case of this Restriction since it is firmly established that, for example, mouthing activity falls rapidly form the age of 1-2 years and can be regarded as minimal by 5 years of age. The dossier would certainly benefit from a detailed exploration of these aspects, for example, based on a quantitative analysis of the risk of adverse effects and, within a SEA, the consequences in terms of health impacts. In particular, this should draw on recent literature and make an attempt to account for uncertainty within variables via some form of sensitivity analysis. This may allow for a better estimate of the scale of impact on IQ that is likely to occur as a result of intermittent exposures due to mouthing. This could be done, for example, in a 'reverse SEA' that would seek to determine the level of benefit required in order for particular restriction options to be justified. 2.2 Issues Relating to Exposure to Lead The statements that jewellery is a significant potential source of lead and, therefore, an appreciable risk to the population, are not adequately placed in context against the size of the population segment that may be at risk from such exposures (for which there are limited direct data) and the predominant sources of exposure of the entire population. 2.2.1 Background of Falling Population Exposure to			

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					Lead While the report mentions the raft of measures which have resulted in dramatic falls in exposure to lead over recent decades, of which the most significant legislation has been the reduction of lead in petrol through Council Directives 85/220/EEC, 98/70/EC and 2003/17/EC, it would perhaps have been useful to include data illustrating the extent to which people's, particularly children's, blood lead concentrations have fallen in most countries over the recent decades. This would place the focus of the dossier in better context against the falling overall risk to the human population now posed by lead and its compounds. For example, as of 1990, emissions from the road transport sector were responsible for over 70% of total environmental emission of Pb. Following the withdrawal of Pb from use in this sector, emissions from this source decreased by >95% (EEA, 2010). When current sources of Pb exposure in the general population are considered (see Table 1), it can be clearly seen that the principal remaining source of exposure is in relation to intake via the diet (about 60% of TDI) with, in children, intake from soil and dust being the next most significant source. Thus, the Restriction dossier is likely to significantly over-estimate the number of cases of poisoning/deaths that are attributable to Pb in jewellery. Table 1: Child's Average Daily Intake from Environmental Lead Exposure Average Daily intake of Pb for children aged 1-3 years			

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					(µg/kg bw/day) % of the TDI (3.6 µg/kg bw/day) Dietary 2.1 58.3 Soil and dust 0.18 5 Outdoor air 0.001 0.03 Environmental tobacco smoke 0.012 0.34 Total 2.293 63.7 Source: Adapted from EFSA(2010) These changes in exposure levels have been reflected in dramatic changes in the systemic lead levels across the population. For example, in the early 1970s, childhood blood lead concentrations of 400 µg/L were not uncommon. However, the geometric mean blood lead level of 1 to 5 year olds in the US had fallen to 150 µg/L by the late 1970s and to 20 µg/L by 1999. In Sweden, levels had stabilised at only 20 µg/L in 7-11 year olds in the period 1995 to 2001 and a geometric mean level of 34.4 µg/L has been reported in 2.5 year olds in the UK (Koller et al, 2004). This reduction in blood lead is expected to be maintained or indeed further improved upon in the forthcoming period due to implementation of additional agreed measures, such as a reduction in the drinking water standard from 25 to 10 µg/L (HPA, 2009) and continued restriction of the use of lead-containing fuels. Indeed, Stromberg et al (2008) report that the average blood Pb reduction has been approximately 5% per year since the start of reduction/banning of Pb in petrol. This reduction has been hailed as "a particular success story" by the European Environment Agency and a report by the			

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					World Health Organisation (WHO, 2010) on children's health concluded that "Eliminating Pb exposure from gasoline has been one of the most significant environmental health improvements in recent times". 2.2.2 Likelihood of Lead Being Present in Jewellery Focusing now specifically on the risk of exposure from jewellery, we note that the Restriction dossier indicates that, based on the cited Danish Study, it is not possible to address safety concerns on the presence of lead in jewellery items, in terms of percentage lead content. Rather, it is correctly noted that the key property on which any risk assessment should be based is the extent to which lead migrates out of a given piece of jewellery under conditions relevant to mouthing or swallowing of the item. The dossier is also helpful in establishing the limitations of current methodologies to allow the accurate determination of this property. Against this background, the precise scope that should be placed on any restriction of Pb in jewellery is an important aspect that warrants further consideration within the dossier. In particular, there is a question over whether there is adequate justification to include all forms of jewellery given the evidence as to the amount of lead that is likely to be present in precious items and gemstones. For example, the survey of chemicals present in jewellery carried out for the Danish Ministry of the Environment (2008) analysed 318 jewellery parts from 170 pieces. It demonstrated that there was a much greater chance of a high lead content occurring in cheaper metal jewellery articles than more expensive			

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					ones; the results are summarised in Table 2. Table 2: Content of Pb in Relation to Euro/Gram* Cost of jewellery item (Euro/gram) % of items with Pb content of Number of jewellery items < 0.01 0.01-1 1-5 5-10 >10 1.34 70 22 2 0 6 37 Total 170 *exchange rate calculated from http://www.xe.com (1 Denmark Krone = 0.134 Euro (09/11/2010)) Source: Danish Ministry of the Environment (2008) As might be anticipated, precious jewellery (i.e. those with high gold or silver content) is the most expensive and, as cost increases, the lead content of items falls significantly. Thus, over 70% of items valued at more than 1.34 euro per gram had a lead content of			
44	Y	2010/10/18 17:53	/ / Denmark MSCA	The proposal (A), Information on hazard and risk (B)	Comments to section A (Suggested restriction) The proposal of restricting lead in jewelleries is by restricting the migration of lead. Denmark would rather see a restriction of lead by the content. There are several reasons why Denmark is convinced that the best way to regulate lead in jewelleries would be by restricting the content: □ Denmark has good experiences with enforcement of lead contents in jewellery. The control takes place by means of X-ray fluorescence (XRF) this means that only possible illegal products are selected for a standard wet chemical analysis (ICP-OES). This screening control can already at first hand indicate	DS213: See new Annex C (option 7) and also responses to general comment Ref 44 above.	Your comments are noted and have contributed to the RAC process for elaboration of the restriction proposal.	See comment ref 44

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					whether or not the jewellery contains lead above the limit value. If on the other hand, migration is to be measured, this screening method could only be used to identify whether or not the product contains lead and all lead cointanings products would then have to be analysed further with the migration test. □ Technically, an analysis for lead content is considerably easier and most likely much cheaper as for migration and the analysis can be performed by almost all laboratories. Preparations for testing are easy and by means of a standard analytical balance, the content can be calculated by simple mathematics. □ A migration analysis, on the other hand, is a simulation of what is thought to go on in the stomach. The subsequent measuring of lead is simple, but migration calculations are difficult and are based upon a number of assumptions. Moreover, there is not yet standardized method for measuring lead migration from jewellery. Development of a standard test often takes long time and this might extend the time before the regulation can enter into force as was seen with the nickel directive. □ Therefore, we recommend that a control program be based on lead content and not migration. Denmark has long and good experiences with using 100 ppm as an impurity threshold limit value. □ Regulating the content will make it easier for both manufacturers and enforcements, because both parties can use XRF to screen the jewelleries, which is a cheap and non-destructive method.	DS214: DS is aware of the environment higher protection provided by a restriction based on lead content. This aspect is not developed in the dossier since environmental impact is not in the scope of the		

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					Regulating the content will also protect the environment. It is clear that the dossier does not take the environmental risk into consideration. By regulating the content of lead of a concentration of 100 ppm, considerations to both human health and the environment is taken care of. If lead is regulated by migration, jewelleries could still contain relatively high amounts of lead, even though the migration rate is under the proposed limit. As shown in the report "Survey and health assessment of chemicals substances in jewelleries" (http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/udgiv/publications/2008/978-87-7052-853-5/html/default_eng.htm) there are as also stated in the dossier no connection between the content and the migration. As an example a relatively high content of 21.42 % lead was found in a jewellery, but the migration was below the detection limit, and in another case the content of lead was 1.2 % and the migration was relatively high with an average value of 363 ug/g. It should be noted that the migration was measured to artificial saliva and according to the standard EN 71-3 as proposed in the dossier. When regulating the migration, there will therefore be jewelleries with high contents of lead and when the jewelleries are getting disposed lead will end up in the environment and contribute to the indirect exposure of the consumers. This will be prevented by restricting the content instead of the migration. A restriction of the content of lead of 100 ppm	restriction. .		

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					in jewelleries would also be in line with the proposed regulation from the Commission (draft 1 June 2010) on cadmium in jewelleries. The proposal on cadmium is a limit of the content of 100 ppm. Having the same kind of regulation would make it much easier to comply with and enforce. Likewise for producers and importers control analyses can be conducted at the same time with one analyse. Denmark can support extending the scope of the restriction to also include jewellery-like products like for example hair accessories, brooches and cufflinks that are also included in the proposal of the restriction of cadmium. Comments to section B (Information on hazard and risk) A chronic DMEL, DMELc, is set on the basis of the smallest measurable variation of blood lead concentration (PbB). The model IEUBK is then used to calculate this measurable variation to a DMELc for children in different age groups and the lowest DMELc is used to calculate an acceptable migration rate from jewelleries. The IEUBK calculates PbB to an external DMELc, but on page 55 below table 28 it says: "As a reminder, an oral absorption rate of 50 % has been taken into account in the calculation of the DMELc." This indicates that the DMELc calculated from IEUBK is an internal DMELc. If this is the case the oral absorption of 50 % should be taken into account when calculating the migration rate. It should be clarified whether the DMELc is an external or an internal DMELc.	DS215: It is an external DMELc it will be clarified in the next BD version.		

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
36	N	2010/09/20 17:46	/ / Sweden MSCA	(A) (B) (C)	Suggested restriction (A) We agree with the proposal to restrict lead in both fashion and precious jewellery since children cannot distinguish between fashion and precious jewels; it is therefore essential that this restriction covers both. We support the recommendation in the First advice from the Forum for enforcement (adopted on 16 August 2010) that the restriction should be based on content rather than migration. Such a change will mean lower costs for enforcement as well as for importers and sellers of jewellery, while maintaining a high level of protection for human health and environment. Information on hazard and risk (B) There is considerable evidence demonstrating that the developing brain is more vulnerable to the neurotoxicity of lead than the mature brain. In children, an elevated blood lead level is inversely associated with a reduced Intelligence Quotient (IQ) score and reduced cognitive functions. The dose-effect relationship between blood lead levels and IQ indicates a nonlinear curve that reflects a greater relative impact at lower lead concentrations. The provisional tolerable weekly intake (PTWI) of 25µg/kg b.w set by JECFA is no longer appropriate since several studies shows no evidence for a threshold for developmental neurotoxicity. Since the blood lead levels in children today are quite close to the levels that can adversely affect children, any attempt to reduce lead exposure should be supported.	DS72: Thank you. DS73: These considerations have been included in the BD (see Section E.2.3.1.1). DS74: This consideration has been integrated in the BD.	RAC primarily bases the restriction on content (0.05% Pb in jewellery) and only for derogation purposes a migration limit (0.05 µg Pb per g jewellery/h) is proposed. No further comments.	Issue about migration versus content as the basis for the restriction is addressed in the SEAC draft opinion which now concludes that the restriction based on content measurement is most appropriate measure.

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					Information on alternatives (C) In section C of the proposal concerning the alternatives it seems reasonable to insert the option that no alternative is necessary, i.e. is there a need for alternatives or is it possible just to exclude lead and not replace it with something else.	DS75: If lead is one of the component of alloys sometimes used in jewellery, and if it is removed from these alloys, it must be inevitably replaced in these alloys.	Lead may not necessarily be substituted by other metals that are not already present in the alloy.	Re C. It is dependent on the alloy in question. If it is an alloy consisting of 97% lead it obviously has to be replaced by something (if you still want to have an alloy). If it is an alloy containing 5,5 % lead it might be possible just to replace it by other metals already just in that alloy. The issue is not considered further as the outcome of the analysis is that alternatives exist.
35	N	2010/09/20	/ /	(A)	A) Suggested restriction			

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
		16:36	United Kingdom MSCA	(B) (C) (E) (F)	It is noted that other RMOs are discussed in the dossier. However we would like to see a more robust analysis of these options. Consideration should be given to limiting the restriction to only jewel items intended for children on the basis that the risk to young children is the target of the restriction. Given that the targeted risk has not been clearly established as a problem within the EU, application of the restriction to all jewels appears to represent an overly cautious approach. P15 A2.1 Second paragraph We are not convinced that pregnant women form a significant at risk group, as indiscriminate mouthing of foreign objects is much less likely than for children.	DS76: A comparative analysis of the different possible RMOs is provided in the dossier. This analysis is considered as sufficiently robust. DS77: As said in the dossier, "*It is highlighted that the articles which are mouthed by children under 36 months consist of many items which are not intended for them" (section A.1.2.1.).* It seems thus relevant that the proposed restriction applies to all jewels, whether they are intended for children or not. Although the reported cases do not concern the EU, field studies show that there is a significant number of leaded jewellery items on the EU market (see section B.2.2). As a result, it can be expected that the risks are similar for the EU DS78: The risk for pregnant women is still noticed in the dossier, since a possibility still exists that a pregnant woman will have a mouthing behaviour,	No further comments to DS reply. No further comment	

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
						which could lead to effects on the foetus.		
					B) Information on hazard and risk P 22 B.2 Manufacture and Use The two countries listed, Germany and Cyprus state that lead containing fashion jewellery may constitute 1% and 23 % of the market respectively. What are the figures for the rest of the EU/what is the average figure?	DS79: These data are not available. The other Member States did not provide data on that aspect during the consultation.		
					P 43 B5.11.4 We think the use of the term DMEL is misleading for two reasons: Firstly, as we have commented above, neurotoxicity is considered to have a threshold, the issue is that it can't be identified. Secondly, the "DMELc" has been estimated from background blood-lead levels in an unexposed population, not from hazard information. Therefore we think "DMELc" is the wrong term to use here. We suggest that consideration is given to changing the DMELc, to at least a DNELc, with a clear explanation of how it has been derived.	DS80: Thank you for this suggestion. But, based on the recent JECFA and EFSA reports, effects of lead on the neurodevelopment of children are considered to have no threshold. See also response DS9 above.	As no threshold has been identified for the neurotoxic effects of lead a DMEL value approach is the most relevant approach.	
					P43 B.5.11.2 Background levels. Given there is a range of values given for background exposure it would be helpful if the values to be used could be highlighted in the text. P51 B.9.3.1 –reported cases of childhood lead poisonings	DS81: Agree. The background values used for the restriction have been highlighted in the BD.		

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					The health risks of lead are well known and well documented. The data given to support this restriction all come from the US and Canada. Although it is accepted that children in the EU could swallow and mouth this jewellery is there any evidence from across the EU that it is a problem here? P53 B9.3.2.2 consumer exposure It would be more helpful to try and quantify the exposure from both mouthing and swallowing objects by constructing some exposure scenarios using typical worst case values for the amount of lead released by the jewel. For example CONSEXPO could be used to estimate potential exposure from mouthing and ingestion. Generating quantitative exposure values would allow a more robust, quantitative risk characterisation to be performed. This will help to establish the scale of the risk. P55 – it seems overly conservative to add together the default mouthing times for other toys and non toys. It should be sufficient to use the highest value.	DS82: The first statement refers to general effects of lead exposure. As far as the reported cases are concerned, see also response DS7 above: although the reported cases do not concern the EU, field studies show that there is a significant number of leaded jewellery items on the EU market (see section B.2.2) such as reported by Cyprus and Germany. As a result, it can be expected that the risks are similar for the EU. DS83: some exposure scenarios have been added as examples. DS84: Agree this could be taken into account for refinement of the exposure scenario.	It has to be acknowledged that several European surveys have found lead in a rather significant fraction of the jewellery, thus a potential exists for lead exposure by mouthing or swallowing. Scenarios regarding exposure from mouthing have been further discussed in RAC and taken into account in BD. No further comments.	Re DS82: Information in BD demonstrates that lead is present in jewellery, and that since no threshold has been identified low dose “exposure incidents” can result in IQ losses.

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					B.10. Risk Characterisation This assessment takes into account children up to 36 months, is this a valid/representative population to use for the restriction proposal? Most, if not all, children's jewellery has a label not for children under 36mths due to small parts – choking hazards. Fashion jewellery for adults is unlikely to be left in child's possession and certainly not on a daily basis.	DS85: The children up to 36 months are representative since they have a specific mouthing and swallowing behaviour which could represent a risk for them. Moreover, accidents do arrive even if jewellery has a restriction label (in particular because 1/ jewellery articles are not most of the time packaged and 2/even packaged, the packaging is thrown away). For the justification of the inclusion of jewellery intended for children and not, see response also DS34 above.		
					P59/60 B.11 Summary of hazard and risk. A discussion on the uncertainties related to all of the calculated values would have been helpful in putting the conclusions of the risk assessment into perspective.	DS86: Thank you for this suggestion.		
					C) Information on alternatives The document states there is little information about possible alternatives. Is there relevant information in the Canadian documents or the nickel restriction in jewellery dossier?	DS87: No relevant information is included in these both documents.	Further data on these issues would have been helpful.	
					The sections entitled human health risks to substitute metals should be more properly titled hazards, as there is no information on exposure from which to make an estimate of risk. It would help greatly if more information on the human health risks of the potential	DS88: The titles of sections are imposed by the format for REACH Annex XV Dossiers. DS89: Agree but to our	No further comments	

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					substitutes could be included. It would also be very helpful to include information on the dissolution rates of the proposed substitutes (if available) E) Why a restriction is the most appropriate EU-wide measure There is little discussion of options other than restriction to address this problem. Some discussion of why action under the Toy Directive or the General Product Safety Directive was not thought to be appropriate would have helped place the proposal in context. From the information we have gathered from regulatory bodies within the UK, jewellery items that are intended for children as play items are viewed as being covered by the Toy Directive and could be regulated that way. If the company claim it is not a toy then there are alternative measures that could then be taken using the General Product Safety Directive. There is nothing that links a restriction directly to the objective of intervention i.e. No attempt to estimate number of lives that will be save or number of ill health cases avoided. It would be helpful if estimates were made of the costs to industry and to regulators of implementing the restriction, particularly in terms of monitoring jewellery for either the presence of lead or its migration rate. P100 E4 – main assumptions It would be interesting to know what the consequences are of using incorrect surface area measurements or not	knowledge, these data are not available. DS90: These two RMOs are discussed in section E.1.3. DS91: Annex I of 2009 Toys Directive states that "*Fashion accessories for children which are not for use in play"* (exemption 19). The proposal focuses on jewellery (ornamental) items. Regarding jewels as play items, they are "toys" and are thus specific. Their lead content is thus regulated through Toys Directive (in the limit currently set). DS92: Some elements to that respect are given in section F.1. Moreover, see Section E.2.3.1.1 DS93: See additions made in section E.1.2. option 2 + new annex C.	To derogate from the restriction based on Pb content in jewellery RAC in the final opinion further proposes a migration limit	

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					having the surface area measurement available to calculate the migration rate given that most jewels have an irregular shape/volume. P101 E5 – scope of the restriction. Should the average migration rate for composite articles be used to trigger the restriction, rather than migration rates for individual component parts? P101 E5 – Summary of the justification It is difficult to put the justification into context as there is no real idea of the scale of the problem relative to the different population groups in the EU, i.e. we accept that Pb poisoning can happen but how likely is it? F) Socio-economic Assessment of proposed restriction From the description of the costs and benefits, it is difficult to assess the proportionality of the proposal as there have been limited calculations of costs and benefits. We think it would be proportionate to develop the quantification and monetisation further (specific suggestions below). Exposure and health impact of lead in jewellery has been	DS94: The question of the surface measurement is discussed in section E.2.1.2.2 with new addition in the BD. DS95: The average migration rate of the jewel is an underestimation of the exposure for big jewels where children might only mouth a part of the jewel. Furthermore, using a system which differentiates small and big jewels for the calculation of the migration rate would be too complicated. DS96: For the scale of the risks in the EU despite the lack the reported case, see response DS7. DS97: A cost-benefit analysis is now provided in Section E.2.3.1.1. DS98: Agree that the proportion of mouthing time of lead jewellery will be less than 100%.	(expressed on a weight basis) of 0.05 µg per g jewellery/h. The migration limit pertains to all parts of the jewellery. No further comments.	Re DS99: In the new Annex F it is not said that all will be exposed, but it

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					based on mouthing times for children under the age of 36 months. It appears that an assumption has been made that children are exposed to lead throughout this period. Is this realistic? We think it is more likely that lead jewellery would make up a small proportion of the mouthing times. If information on this is not available, sensitivity analysis could be used with various proportions. It is misleading to suggest that all children across Europe would experience health benefits. The estimated number of children who swallow a jewel each year could be used as a proxy to determine a minimum number/proportion of children across Europe that would experience health benefits. It should also be possible to estimate a minimum benefit from the above number by (using benefit transfer from the publications on page 108) multiplying this with an average cost per incident / central estimate of the effects of poisoning. How many deaths have there been a result of lead poisoning? The "value of a fatality prevented" could be added to the minimum benefit estimate. Is it possible to put these incidents in context – how does the number of jewels swallowed compare to other the number of other accidents children have? COSTS: The operating costs only address the material substitution between lead and tin – it does not appear to account for any changes in machinery used / process / storage etc that might be needed as a result of changing	But it is difficult to assess this proportion and to state that it will be small. A sensitivity analysis will not help in this case. The mouthing time is in direct relation with the intake. If the mouthing time decreases by 50% the exposure to lead will decrease by 50%. DS99: Done in (new) Section E.2.3.1.1. For the mouthing case, all children are considered to be possibly exposed (given their behaviour); for the ingestion case, only a part of these children are considered. DS100: Death is considered as an extreme case. See Section E.2.3.1.1 DS101: The data basing the calculations provided in Box 1 were erroneous (mistakes in unit). They have been corrected in section B.2 and the (rough) estimation of Box 1 has been removed. For the new estimation	Mouthing scenario has been further discussed in RAC.	is calculated how many hours in total all children in Europe may mouth a jewel with lead in order to equalise the cost of substitution. It is based on a number of assumptions.

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					from one to the other. Box 1 on page 114 is very useful and clearly set out. It would be proportionate to do further quantitative analysis in this way: -Administrative burden: using an example of what type of burdens will be on industry and cost associated with doing this - Enforcement campaigns – for example testing equipment and visits to industry. -Inspection / enforcement costs with respect to imports Will there also be an administrative burden for formulators etc to prove to ECHA/MS that they are compliant?	of additional costs, see section C.7 and the CBA added to the BD (Section E.2.3.1.1). Other costs than substitution costs are not quantified since there is no information about those costs and it has been considered to be not proportional to go further. They are however qualitatively described in section E.2.1.1.2.1. and new Annex D. DS102: some (qualitative) elements have been added in section F.2.4 and some brief clarification as regards the importers' burden. DS103: Enforcement has been mainly analysed regarding monitoring costs and campaigns (section E.2.). DS104: Formulators are (indirectly) concerned by the restriction if they supply, for example, leaded alloys to manufacturers of jewellery items. In this case, the manufacturers have to check if the alloys they purchase are in		Re DS 103: The cost for monitoring has been described on a aggregated level in section E of BD. However for campaigns etc it is up to national activities and priorities.

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					Will there be a reduction in innovation and research with respect to lead – for example, will industry not look into maintaining the use of lead in jewellery but reducing the migration rate? Is there any information on how much of the increase cost will be passed on to consumers in the form of higher prices? P104 F1.1.1 Lead migration rates of jewels on the EU market It would be helpful to know how many of the migration test results gave a value above the LOD and what an average value of these were. If a large number were below the LOD then how valid is it to use the highest and lowest values? It is not clear even how representative these values were of the test carried out. Although it is mentioned that these test were not supposed to be representative of the EU market the results have been used in this way. A discussion on the uncertainties around this issue would have been beneficial. P104 F1.1.2 – Exposure assessment We suggest that it is more likely to be the shape/volume that defines how big an object can be wholly placed in the mouth, rather than the surface area. It has been found to be useful to also look at average values of exposure (daily quantity of Pb ingested) as well as the minimum and maximum when carrying out	conformity or not. DS105: DS thinks it is not proportional to elaborate on that aspect. However, impact on R&D is mentioned in section F.2.7. and F. 8. DS106: 14 results of the migration rate gave a value above the LOD. The average value of the results is 111.9 µg/g, which is between the highest and the lowest values used in F.1.1. DS107: A discussion on uncertainties has been added in the BD. DS108: Agree but no information available about shape/volume. Concerning the use of an average value of exposure, children will generally be exposed to the same jewel (for		

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					an exposure assessment. This also ties in with the practice of using average expected values in health impact assessments.	example a necklace worn by them) so the average migration rate of jewels is considered to be irrelevant. Furthermore, the sample of jewels used for this exposure assessment is considered to be not representative of the EU market so the average migration rate of the sample is considered to not represent the jewels market.		
27	N	2010/09/14 15:34	/ / Germany MSCA	(B) (C) (E)	Comment of the German CA A.1.1The identity of the substance, p. 11 This is confusing as the dossier covers lead and all its organic and inorganic compounds. However in the identity table only elemental (metallic) lead is presented. Most probably the lead ion is the toxic species. Thus, we suggest to state that the document intends to cover all lead compounds used in jewellery which might liberate the lead ion and that elemental lead (7439-92-1) is selected as prototype / surrogate for all other lead compounds. A.1.2.2.Conditions of restriction p.13-15 The unit of the migration limit should be mg/kg or µg/kg as in the toys directive and as used in the proposed analytical method EN 71-3, which corresponds to a measurement period of two hours. It is more enforceable and easier to control. The proposed unit µg/cm2/hr needs an estimation of the surface, which is combined with a very high uncertainty. Based on a cube with a surface of	DS109: It has been added in the section A.1.1. DS110: For the debate about the unit, see response DS14 above.	Note that migration limit based on migration per g jewellery has also been included in BD and taken into account in the	

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					10 cm2, which can be in contact with the mouth and on the density of lead, the proposed migration limit of 0.09 µg/cm2/hr would result in 36 µg/kg/hr. p. 13 Scope of the restriction The proposed restriction should also apply to body piercings and jewellery or pendants sold or distributed with other products like shoes or journals. p. 14 Measurement methods It is recommended that the available standard EN 71-3 should be used for testing the migration from jewels. The coating can have a high impact on the migration from jewellery made of plastic and of alloys. The EN 71-3 does not include decoating of alloy jewels, which represent the main market on fashion jewels. Furthermore the separate testing of the coating itself is not possible. No method exists for removing and isolating the coating reproducibly from alloys. The analytical measurement uncertainty would exceed an acceptable value by far. It is recommended, that the migration rate is quantified for the original jewel (whether it is coated or not) and for the decoated jewel. No migration rate should exceed the migration limit. A.1.2.2 Conditions of restriction, p. 14	DS111: All these articles are considered as jewellery items. Regarding other articles such as key rings or other accessories, they are not included in the scope of the proposal. To that respect, see response DS35 above. DS112: The standard EN 71-3 includes the test of coatings in its section 8.1. The proposal thus recommends this procedure (see section E.2.1.2.2.) S113: These difficulties relative to the coating have been highlighted in the BD. DS114: Such articles are not	opinion. RAC has to focus their evaluation on the scope addressed in the dossier. RAC in the opinion notes that no reliable method for a migration test mimicking mouthing is at hand and that a method has to be developed. No further	

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					It is not clear and understandable for the reader, why other lead containing articles such as key rings, coins etc. are not addressed by this dossier because they might also represent a major source of lead poisoning.	included in the dossier for enforcement purposes. Such articles (and jewellery items as well) are not considered as a "major" source of lead poisoning since these sources are unusual. For major sources see section B.4.11.2. Moreover, they are not clearly identifiable and an exhaustive list could be impossible to make (to allow compliance and monitoring). See also response DS35 above.	comments	
					A.2.1 Identified hazard and risk p. 15 The results of the EFSA scientific opinion on lead in food and the opinion of the German Human Biomonitoring Commission (Bundesgesundheitsblatt-Gesundheitsforschung- Gesundheitsschutz 2009.52:983-986) should be summarized. It should be pointed out clearly, that no evidence for a threshold for developmental neurotoxicity exists and the PTWI derived by JECFA is not longer valid. There is clear evidence that neurotoxic and endocrine effects in children have been identified in blood levels of lead below 100 µg/l.	DS115: Thank you for this suggestion. Both EFSA and JECFA conclusions have been added in the revised document. Those from the GHBC opinion will be as well if there is new and relevant information. DS116: This information has been added in the BD.		
					- Subnumbering 2, p.16: It is stated that unusual exposures to usually not suspected articles containing lead might exist. A more	DS117: These unusual exposures are examined and listed in		

Ref	Att	Date	Country/ Organisation/ MSCA	Type*	Comment	DS Response	RAC Rapporteurs	SEAC Rapporteurs comments
					convincing explanation should be given why articles different from fashion jewels have not been addressed in this dossier. B.1. and B.1.1 Identity of the substance(s) and physical and chemical properties, p 19f: See general comment on lead speciation and selection of elemental (metallic) lead as prototype. B.1.3. Use Physico-chemical properties p. 21. The table might be omitted because it regards only one substance of several lead compounds addressed in this document. B.1.4. Justification for grouping p. 25 As the liberated Pb ion is the toxic species it might be added, that substances capable of liberating the toxic species are targeted by this document. B.2.2. Use of lead and its compounds in fashion jewels p. 27-31. Table 14, line 3, entry Germany: The lead solubility has to be corrected to lead migration. B.4. Environmental Fate Properties p. 34-35 Degradation	several studies which are quoted in the dossier (such as InVs, 2006b and 2008). DS118: See response DS47 above on speciation and on selection of elemental lead as prototype. DS119: Disagree. Even if the report mentions all lead compounds, the restriction concerns lead and the elemental lead is indicated as prototype. But a clarification has been added in the report in the section A.1.1. DS120: It has been done in the revised version of the document. DS121: In BfR (2008), it is said *"Lead solubility could be quantified in 54 out of the 96 (56%) samples examined. The mean value released in the gastric acid simulation test was 73.5 mg/kg; the maximum value was 663 mg/kg" (§3.1.2.1).* DS122: See response DS64		

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					and Bioaccumulation/Biomagnification: might be an issue for organic lead compounds (as in the case of mercury). B.5.6.3. Nervous system effects p.39 - It is highly recommended that the results of the EFSA assessment should be included (see remarks to A.2.1.). The threshold of 100 µg Pb/l blood cannot be assumed as safe anymore. - Besides French data on blood lead levels there are also German data on blood levels in children aged 3-14 years published recently (Number of samples =1560, range	above. DS123: Done in the BD.		
23	Y	2010/08/12 17:36	International NGO / European Environmental Bureau					

Specific question 1:

Question to the health authorities: Do you have further information (any new statistics, surveys etc.) related to children exposure to lead (mouthing and swallowing) and how many cases of exposure relate specifically to jewellery containing lead? Please, provide a brief description of the cases.

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
83	Y	2010/12/21 11:51	Italy / Industry or trade association /	(A (B), (C), (D (E), (F), (G (H)	SEE ATTACHED FILE		Your comments and information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
82	N	2010/12/21 11:51	Germany / Industry or trade association /		As we are not a health authority, this question is not applicable. However, as an employers' association, we have no knowledge of any cases of lead poisoning resulting from the misuse of jewellery by children or adults.		Your comments and information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
81	Y	2010/12/21 11:07	Spain / Industry or trade	(A (B), (C),	SEE ATTACHED FILE		Your comments and information are noted and have	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			association /	(D (E), (F), (G (H)			contributed to the RAC process for elaboration of the restriction proposal.	
78	N	2010/12/20 20:09	Spain / Industry or trade association /		SEE GENERAL COMMENTS		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
77	N	2010/12/20 20:07	Spain / International organisation /		SEE GENERAL COMMENTS		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
73	N	2010/12/20 18:48	Germany / Company /	(A (C)	To be addressed by health authorities.		Your comments/information are noted and have contributed to the RAC process	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
							for elaboration of the restriction proposal.	
69	N	2010/12/20 15:43	Spain / Industry or trade association /	(A) (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
64	N	2010/12/20 12:08	/ / Ireland MSCA	(A (B), (C), (D) (E), (F), (G)	The Health and Safety Authority has no relevant information		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	

Specific question 2:

The two last questions are to the producers and importers of jewellery: Of the total volume of your production (or import) of jewellery, what is the percentage of lead-containing jewellery? If possible please state the total volume as kilograms or tonnes/year. Please give volumes and percentages for non-precious jewellery and precious jewellery separately.

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
89	N	2010/12/21 16:17	Austria / Please select organisation type.. /	(A) (B), (C), (F), (G)	Although we are not a producer or an importer we want to give following remark to this question: if the intension of this question is trying to find out, how big the volume of lead containing jewellery within the EU is, you have to bear in mind, that most of the affected companies aren´t informed about this public consultation, till now! There are many "one person companies" and other "small companies" who are producing costume jewellery as a handcraft and are selling this kind of jewellery as bijoutery on handcraftmarkets etc. From our point of view it is simple impossible to get concrete figures to that question. Beside that it is impossible to estimate the full consequences of the proposed regulation.	DS216: Comment acknowledged	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
83	Y	2010/12/21 11:51	Italy / Industry or trade	(A) (B),	SEE ATTACHED FILE		Your comments/information are noted and	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			association /	(C), (D) (E), (F), (G) (H)			items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
82	N	2010/12/21 11:51	Germany / Industry or trade association /		We currently have no detailed information.		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
81	Y	2010/12/21 11:07	Spain / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
78	N	2010/12/20 20:09	Spain / Industry or trade association /		SEE GENERAL COMMENTS		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
77	N	2010/12/20 20:07	Spain / International organisation /		SEE GENERAL COMMENTS		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
75	N	2010/12/20 19:32	Austria / Company /		We are producing non-precious jewellery out of Sn55Pb39Sb6 in a total volume of 4000kg/year	DS217: Thank you for this information	Your comments/information are noted and items relevant for RAC have contributed to the	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
							RAC process for elaboration of the restriction proposal.	
73	N	2010/12/20 18:48	Germany / Company /	(A) (C)	To be addressed by jewellery manufacturers.		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
71	Y	2010/12/20 18:18	Austria / Company /		We produce only non precious jewellery and 25% of that is lead containing jewellery.	DS218: Thank you for this information	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
69	N	2010/12/20 15:43	Spain / Industry	(A) (C),	SEE ATTACHED FILE		Your comments/informat	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			or trade association /	(D) (E), (F), (G) (H)			ion are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
67	Y	2010/12/20 14:39	United Kingdom / Industry or trade association /		See paper attached.		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
64	N	2010/12/20 12:08	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F), (G)	The Health and Safety Authority has no relevant information		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
							proposal.	
60	Y	2010/12/17 13:33	Austria / Company /	(A (B), (C), (F), (G)	Even high quality jewellery has a certain problem of lead content due to unintended impurities. In 70% of our products lead constitutes such an impurity. In 30% of our products lead is added (at a rate of 3 – 4%) in order to improve the castability of the materials used. At the moment our products are in full compliance with current US standards for adult jewellery and warning labels for children. Also, the jewellery industry is undertaking additional steps in order to further reduce the amount of lead in jewellery. Projects to develop new casting technologies for the remaining lead containing products are in process and will be completed according to a phase out plan.	DS219: See responses to general comment Ref 60 above	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	

Specific question 3:

Do you see any technical or cost-related problems in producing or importing only lead-free jewellery? If so, please specify.

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
89	N	2010/12/21 16:17	Austria /.. /	(A) (B), (C), (F), (G)	As far as we know there is an absolute need for tin-solder, which contains lead. No substitute exists. We have been told, that ;somewhere; a lead free tin solder could exist, but on the one hand we didn´t get any confirmation for that (who is the supplier? and on the other hand we have been told, that lead-containig tin solder is needed for quality reasons. It is supposed that there exists lead free tin solder for the electronic industry. But this can´t be used in the jewellery industry because it reacts different in the galvancic-process, which is an important part in the jewellery industry but not in the electric industry! Furthermore lead is needed for the casting-mold. It could be possible, that in a very small percentage impurities come form the mold into the jewellery. Even in that implausible case, the 0,09 µg/cm2/hrcould easily be exceeded. Another thing are the testing methods: we	DS220: Comment acknowledged	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal. See the answer to this ref above under general comments.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) . This is above the quality standard of tin.

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					don´t understand that there are other testing methods and limit values are used than in the toys-directive (2009/48/EC). The French proposal is aimed to protect children: but it is obvious, that children are rather sucking on toys or even swallowing it, than sucking on jewellerys or swallowing it! So it seems to be clear, that there should be an orientation on the Toys-Directive! So the measurement methods of the Toys directive which is mg/kg and not µg/cm2/hr should be kept! Beside that in the Toys Directive (which primarily aim is to protect children!) the limit value is 90 ppm lead. The proposed 0,09 µg/cm2/hr is much lower and in practice it is not possible to reach this value if tin solder is used!	DS221: Please note that the Toys Directive used lower limits than the one included in the French proposal. The intake limit used is 1.2µg/day compared to the one used in the Toys Directive which is 0. 7µg/day. See also DS222. Concerning the toys Directive and the limit in mg/kg, see response DS14.		
					As far as we know, sometimes the substrate can contain lead. But above the substrate of the jewellery there is a coating. It is not possible, that lead migrates through the coating!	DS223: DS disagrees. It is possible since with time, mouthed coated piece of jewellery might release lead from the substrate because of the coating degradation. The poisoning from the substrate is of course also possible if the jewel is ingested.		
					Beside that we dont´understand the propsed test methods: how should it be possible to separate the coating from the substrate	DS224: The migration testing method proposed is by essence destructive since it is based on acid. On the		

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					without destroying the jewellery. For small companies it is simple impossible to follow the proposed testing methods. Small companies are buying the components from different supplieres. Because of the long supplychain it is easily possible that there are some impurieties in the endproduct. But for the importer or the producer it is not possible to prove such low limit values. As we are sure, that the majority of the regarded companies aren´t informed about this topic till today, a transition period of only 6 month is much to short and unrealistic. Companies have to get the chance, to be informed, to get to know if and where they can buy lead free tin-solder, they have to get the chance to proof if it is possible to use lead free tin solder in the galvanic process etc. If this really all works a transition period of at least 3 years is the absolute minimum!	contrary, a test based on saliva could be not automatically destructive (the item is supposed to resist to contact with saliva), except if it also implies a "mouthing" simulation. DS225: Extended timeframe to be considered.		In the draft opinion transitional period recommended to be extended to 12-18 months
87	Y	2010/12/21 15:06	Austria / chamber /	(H)	Concerning technical problems: 1. The proposed limit of 0.09 µg/cm2/hr constitutes an unfeasible and uncertain standard leading to severe technical problems as regards surface calculation and testing. Europe should apply coherent testing methods for lead across different	DS226: Please see response to general comment Ref 60 above.	Your comments/information are noted and items relevant for RAC have contributed in the RAC process for	See comments ref 60

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					legislations (cf. pages 1-6 of the attached submission). According to the proposal, the lead's migration rate of an item has to be obtained through determining its surface. Such a surface measurement is difficult for items of jewellery because they are often produced in very different and complex shapes. In this regard, when calculating the surface of an identical item different laboratories often achieve differing results, whereas the same piece of jewellery can be declared as compliant as well as non compliant (cf. pages 1-4 of the attached submission). A measurement entailing such high uncertainties will be disadvantageous for consumers' safety, because it is not able to provide clear results on the compliance of jewellery items with the proposed standard. Additionally, as mentioned above, the proposed standard introduces extremely low limits in comparison to weight measurements. Such low levels are technically very difficult to reach and control. The tolerances of measurement equipment are higher than this, which will lead to a decrease in the precision and the reliability of the measure, introducing yet		elaboration of the restriction proposal. See the answer to this ref above under general comments.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					another element of uncertainty. In this regard, several consulted laboratories calculated a rate of 10% uncertainty (cf. pages 1, 5 of the attached submission). Thus, it can be concluded that the calculation of an item's surface as well as the available mechanisms for control entail a high amount of uncertainty due to the very low standard in µg/cm2/hr proposed in the report. Such uncertainties will not contribute to a higher level of consumer safety. 2. The proposed separate testing of the coating and the substrate will lead to severe technical problems, if this is also applied to electroplated precious metal coatings. As the proposal suggests that the plating and the substrate of electroplated jewellery should be tested separately, the plating will have to be separated from its substrate. Such an obligation would be nearly impossible to implement in the jewellery industry because of the close bond of precious metal plating and the base metal as well as the layer composition and the related thickness. The systematic separation of all platings would oblige companies to remove and test each plating layer of each component a			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					jewel. However, this would be very challenging because a jewel can sometimes consist of several pieces and plating layers. Furthermore, a separation of the layers of fashion jewellery is often very difficult, because of the characteristics of the bond. Fashion jewellery is traditionally mostly made of non-precious base materials and finally plated. Most plating is done by electro-deposition of precious metals such as gold and rhodium and represents a complex layer sequence. Due to the very low thickness values of the layers (e.g. ornamental plating is usually 2-3 µm thick), the strength of the bond between plating layers and the demand of area-related reporting [µg/cm2/h] sample preparation seems impracticable if not impossible. Please note in this regard that although the reportsuggests taking inspiration from the standard used for nickel, this standard does not prescribe a separation of the plating from the substrate (cf. pages 8-10 of the attached submission). Concerning cost-related problems: Hereunder, three elements of the proposal are a source of concern: 1. the cost of the testing, 2. the short			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					enforcement period and in connection with this 3. the nature of the industry's supply chain. 1. Regarding the tests which should be used for controls by both, companies and authorities, the report indicated an amount of 22 Euro for a test for a compound such as lead. This amount is unrealistic, especially regarding the use of techniques such as ICP or atomic absorption spectrophotometry, which are needed due to the proposed low limit values. After consulting several private and independent laboratories we received the information that the unit cost per tested compound ranges from 128 – 159 Euro. However, these costs refer only to the testing of one single component of a jewellery piece (e.g. pendant) and the same cost will possibly also apply to any other additional component (e.g. the chain). Furthermore, investment costs for laboratory equipment present a substantial expense factor. Due to existing regulations in Denmark, Canada and the US, jewellery manufacturers have already installed equipment to measure the lead content by weight (mg/kg). If the current proposal comes into force in the EU, extensive			Testing costs have been confirmed with various testing labs and BD has been updated in this respect

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					investments in new equipment and tests at external laboratories would become necessary. The costs for such internal and external testing according to the proposal would be ten times higher (3.000.000 Euro for investment + operation) than our proposed alternative (300.000 Euro). Thus, the cost for testing will constitute a considerable financial burden (cf. pages 11-12 of the attached submission). 2. The suggested delay of 6 months after the legal implementation of Annex XVII of REACH is based on the wrong assumption that jewellery stocks undergo a permanent renewal of collections in a rhythm of at least 6 months, similar to the fashion industry. The reality of the jewellery industry is different and the period needed to sell stocks can amount to 14 months (please cf. page 12 of the attached submission). Thus, the suggested 6 months delay is extremely short and could considerably impact the fashion jewellery industry and resellers. 3. The complete value chain in jewellery making entails several organizations which produce components such as chains, closures, linkages etc. This creates a			Testing costs have been incorporated into the CBA Extended transitional period for implementation of 12-18 months recommended in draft opinion

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					complex supply chain with many players. All of these players have to be informed and trained to use exclusively compliant material. Furthermore, a system of compliance checks has to be implemented. This will be extremely costly and time consuming. A realistic time frame to guarantee compliance by all players will amount to 3 years, should the proposal enter into force unchanged. However, should all suggested changes be accepted, compliance could be achieved within 2 years. A shorter period would make implementation virtually impossible and will severely damage the complete industry. Moreover, these difficulties are aggravated by the fact that sufficient compliant material will have to be made available from very restricted sources (cf. in this regard answers given to question 4, as well as page 13 of the attached submission). Detailed analysis of economic effects on the EU fashion jewellery industry: The total EU market value of fashion jewellery is estimated at 3.5 billion Euro. Using this figure as a basis we estimated the costs of removing lead containing pieces from the supply chain for the whole EU fashion jewellery industry to			Costs of compliance checks incorporated into CBA, Extended transitional period for implementation of 12-18 months recommended Therefore scrappage

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					be approx. the following: - Employee cost, process cost, scrap and recycling cost: 14 Mio. Euros - Cost of scrapped stock: 350 to 550 Mio. Euros - Loss in sales: 500 Mio. Euros - Compensation payments for contracts with independent retailers: 350 Mio. Euros o Total cost approx. 1,4 billion Euros			costs minimised; other costs are in line with upper range in sensitivity analysis from CBA
83	Y	2010/12/21 11:51	Italy / Industry or trade association /	(A) (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
82	N	2010/12/21 11:51	Germany / Industry or trade association /		Extremely low limits While we appreciate and support any measures that protect babies and young children from the effects of hazardous substances, we consider the test parameters (mouthing for 1.5 hours a day for children of 7-12 months) extremely severe. To illustrate our argument, we would like to draw the following comparison:	DS227: Please note that according to the new 2010 report of EFSA, since it has been demonstrated that lead has no-threshold effects on the CNS of children, the acceptable levels of lead in food would probably be revised for lower limits.	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					Limits for the daily lead intake from food are listed in 466/2001/EC for different foods. Under the present proposal, the maximum daily intake of lead for a child aged between 7 and 12 months is 0.0012mg/day. This corresponds to 60ml milk, 12g meat or fruits or 6g of fish or cereals per day. According to the new proposal, jewellery would have to conform to much stricter limits than food. The suggested lead migration rate is extremely low and in all probability below the detection limits of much measuring equipment. Applying the limits of the new proposal, the materials available on the market which are currently classed as lead-free, would no longer meet the stringent regulations. As a consequence, even these alternative materials would no longer be allowed to be used in the manufacturing of fashion jewellery. A reduction of the lead content of the various alternative materials is, however, not technically feasible. This means that the production of a range of fashion jewellery components would no longer be possible.	DS228: About the comparison of limit for food and for jewellery, see DS153. DS229: Comment acknowledged.	proposal. See the answer to this ref above under general comments.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					Separate calculation of coating and base material The restriction proposal advocates the separate calculation of the lead content of substrate and coating. From our viewpoint, it is not understandable why the migration rates of base metals and coatings should be added. This could lead to situations in which two low readings, each of which are in compliance with the regulation, when added together, would no longer comply with the legal limit. This is neither understandable, nor does it make any sense. The wording, as it stands, would be tantamount to a prohibition of multi-layer jewellery. Moreover, the great diversity and complexity of types and shapes of jewellery articles as well as production techniques, make it extremely hard, if not impossible, to implement this recommendation. In other community legislation serving the same purpose of protecting human health from potentially harmful metals, namely the nickel directive, coatings of sufficient quality may explicitly be used to prevent exposure. We suggest using the same approach as well as the testing conditions and requirements. High resistance to abrasion and a variety of	DS230: As regards the question about the coating and the wear test, see responses to comment Ref 31, §2, 3, 4.		

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					substances Electro-plated coatings display a high degree of hardness and abrasion resistance. They are also inert to a huge variety of chemicals. Gold and rhodium platings are resistant even to strong acids. Contact with saliva during chewing or sucking will definitely not cause any interaction with precious metals. As far as crystal stones are concerned, it is not technically possible to separate the different layers. Here, too, we recommend the implementation of the guidelines of the nickel directive.			
81	Y	2010/12/21 11:07	Spain / Industry or trade association /	(A) (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE	DSXX: See responses to comment Ref 31.	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
80	Y	2010/12/21 10:54	France / Industry or trade associat	(A) (F)	Concerning technical problems: 1. The proposed limit of 0.09 µg/cm2/hr constitutes an unfeasible and uncertain standard leading to severe technical	DS231: Please see response to general comment 60 above	Your comments/information are noted and items relevant for	See ref 60

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			ion /)		problems as regards surface calculation and testing. Europe should apply coherent testing methods for lead across different legislations. According to the proposal, the lead's migration rate of an item has to be obtained through determining its surface. Such a surface measurement is difficult for items of jewellery because they are often produced in very different and complex shapes. In this regard, when calculating the surface of an identical item different laboratories often achieve differing results, whereas the same piece of jewellery can be declared as compliant as well as non compliant. A measurement entailing such high uncertainties will be disadvantageous for consumers' safety, because it is not able to provide clear results on the compliance of jewellery items with the proposed standard. Additionally, as mentioned above, the proposed standard introduces extremely low limits in comparison to weight measurements. Such low levels are technically very difficult to reach and control. The tolerances of measurement equipment are higher than this, which will lead to a		RAC have contributed to the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					decrease in the precision and the reliability of the measure, introducing yet another element of uncertainty. In this regard, several consulted laboratories calculated a rate of 10% uncertainty. Thus, it can be concluded that the calculation of an item's surface as well as the available mechanisms for control entail a high amount of uncertainty due to the very low standard in µg/cm2/hr proposed in the report. Such uncertainties will not contribute to a higher level of consumer safety. 2. The proposed separate testing of the coating and the substrate will lead to severe technical problems, if this is also applied to electroplated precious metal coatings. As the proposal suggests that the plating and the substrate of electroplated jewellery should be tested separately, the plating will have to be separated from its substrate. Such an obligation would be nearly impossible to implement in the jewellery industry because of the close			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					bond of precious metal plating and the base metal as well as the layer composition and the related thickness. The systematic separation of all platings would oblige companies to remove and test each plating layer of each component a jewel. However, this would be very challenging because a jewel can sometimes consist of several pieces and plating layers. Furthermore, a separation of the layers of fashion jewellery is often very difficult, because of the characteristics of the bond. Fashion jewellery is traditionally mostly made of non-precious base materials and finally plated. Most plating is done by electro-deposition of precious metals such as gold and rhodium and represents a complex layer sequence. Due to the very low thickness values of the layers (e.g. ornamental plating is usually 2-3 µm thick), the strength of the bond between plating layers and the demand of			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					area-related reporting [µg/cm2/h] sample preparation seems impracticable if not impossible. Please note in this regard that although the report suggests taking inspiration from the standard used for nickel, this standard does not prescribe a separation of the plating from the substrate. Concerning cost-related problems: Hereunder, three elements of the proposal are a source of concern: 1. the cost of the testing, 2. the short enforcement period and in connection with this 3. the nature of the industry's supply chain. 1. Regarding the tests which should be used for controls by both, companies and authorities, the report indicated an amount of 22 Euro for a test for a compound such as lead. This amount is unrealistic, especially regarding the use of techniques such as ICP or atomic absorption spectrophotometry, which are needed due to the proposed low limit values. After consulting several private and independent laboratories we received the information that the unit			

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					cost per tested compound ranges from 128 – 159 Euro. However, these costs refer only to the testing of one single component of a jewellery piece (e.g. pendant) and the same cost will possibly also apply to any other additional component (e.g. the chain). Furthermore, investment costs for laboratory equipment present a substantial expense factor. Due to existing regulations in Denmark, Canada and the US, jewellery manufacturers have already installed equipment to measure the lead content by weight (mg/kg). If the current proposal comes into force in the EU, extensive investments in new equipment and tests at external laboratories would become necessary. 2. The suggested delay of 6 months after the legal implementation of Annex XVII of REACH is based on the wrong assumption that jewellery stocks undergo a permanent renewal of collections			

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					in a rhythm of at least 6 months, similar to the fashion industry. The reality of the jewellery industry is different and the period needed to sell stocks can amount to 14 months. Thus, the suggested 6 months delay is extremely short and could considerably impact the fashion jewellery industry and resellers. 3. The complete value chain in jewellery making entails several organizations which produce components such as chains, closures, linkages etc. This creates a complex supply chain with many players. All of these players have to be informed and trained to use exclusively compliant material. Furthermore, a system of compliance checks has to be implemented. This will be extremely costly and time consuming. A realistic time frame to guarantee compliance by all players will amount to 3 years, should the proposal enter into force unchanged. However, should all suggested changes be accepted, compliance could be achieved within 2			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					years. A shorter period would make implementation virtually impossible and will severely damage the complete industry.			
79	N	2010/12/21 09:22	Austria / Industry or trade association /		To produce lead-free casted fashion jewellery is extremely difficult because of the state of technology. It is extremely difficult to get alloys and solders which are not containing lead and if so they don't have the same charakteristics which lead to a more complex and time-consuming production. Also high quality tin casting contains lead so again the material needs to be changed which requires another prozess and increases the costs dramatically.	DS232: Please See response to general comment 72 above.	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	Availability of lead free alloys has been checked. See table 50 of the BD.
78	N	2010/12/20 20:09	Spain / Industry or trade association /		SEE GENERAL COMMENTS		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
77	N	2010/12/20 20:07	Spain / International organisation /		SEE GENERAL COMMENTS		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
75	N	2010/12/20 19:32	Austria / Company /		There are technical as well as cost-related problems caused by: A) In our production process there is no alternative raw material than a tin alloy - and these alloys wouldn´t reach the target specified. B) The cost-raleted problems for the commonaltity will be caused by unemployed workers!	DS233: Comment acknowledged. As regards the question of tin alloys, see comment 73 and response DS149 above	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	See ref 73
73	N	2010/12/20 18:48	Germany / Company /	(A) (C)	Achieving a limit of 0.09 µg/cm2/hr using a tin alloy is unfeasible due to the following reasons: Technical problems. 1. Pure tin (Sn99.9%) used for tin based casting alloys is exclusively available at the London Metal Exchange. The standard for	DS234: See DS149	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					pure tin traded at the LME is set equivalent to the EN 610:1996, Grade designation 99.85%, with a maximum lead content of 500mg/kg. (http://www.lme.com/downloads/metalsspecs/LMEspecification_Tin_111010.pdf) Typical analysis of 99.9% tin brands usually show a lead impurity of 300-400mg/kg. High grade tin (99.99%) with a lead content of max. 40mg/kg is very rarely available and takes high premiums on prices. 2.Casting tin is alloyed with other metals like antimony, bismuth, copper or silver to achieve a smoother surface, to harden the material. The alloying process with other metals ads to the original lead content of the tin. For e.g. a pewter alloy used for dishes and tableware consists of 95% tin, 3% antimony and 2% copper. With no lead added to the alloy, we achieve a min. possible lead content of about 300mg/kg. 3.Tin and tin alloys made according to EN611-1:1995 with no lead alloyed allow a max. lead content of 2,500mg/kg. These alloys are state of the art for products with contact to food. Cost related problems: 1.World market prices for metals have skyrocketed during the last 12months. The		elaboration of the restriction proposal.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					availability for several non-ferrous metals (tin, antimony, bismuth) used in tin alloys has degraded significantly. The use of high grade tin (low lead 99.99%) and high grade antimony (99.8%) and their high premiums will make tin alloys become economically stale. 2. The proposed separate testing of the coating and the substrate will not only lead to severe technical problems, but will be very costly. The measurement of the lead content by weight (mg/kg) as mandatory in Denmark, Canada and the US, is much more cost efficient and easier to achieve.			
72	N	2010/12/20 18:19	Austria / Company /.		To produce lead-free fashion jewellery is extremely difficult because of the state of technology. It is extremely difficult to get alloys and solders which are not containing lead and if so they don't have the same charakteristics which lead to a more complex and time-consuming production. Also high quality tin casting contains lead so again the material needs to be changed which requires another prozess and increases the costs dramatically.	DS235: Remarks noted.	Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)
71	Y	2010/12/20	Austria		Concerning technical problems:	DS236: Please refer to response to	Your	See ref 60

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
		18:18	/ Company /		1. The proposed limit of 0.09 µg/cm2/hr constitutes an unfeasible and uncertain standard leading to severe technical problems as regards surface calculation and testing. Europe should apply coherent testing methods for lead across different legislations. 2. The proposed separate testing of the coating and the substrate will lead to severe technical problems, if this is also applied to electroplated precious metal coatings. As the proposal suggests that the plating and the substrate of electroplated jewellery should be tested separately, the plating will have to be separated from its substrate. Such an obligation would be nearly impossible to implement in the jewellery industry because of the close bond of precious metal plating and the base metal as well as the layer composition and the related thickness. Concerning cost-related problems: 1. Regarding the tests which should be used for controls by both, companies and authorities, the	general comment 60.	comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					report indicated an amount of 22 Euro for a test for a compound such as lead. This amount is unrealistic, especially regarding the use of techniques such as ICP or atomic absorption spectrophotometry, which are needed due to the proposed low limit values. 2.The suggested delay of 6 months after the legal implementation of Annex XVII of REACH is based on the wrong assumption that jewellery stocks undergo a permanent renewal of collections in a rhythm of at least 6 months, similar to the fashion industry. The reality of the jewellery industry is different and the period needed to sell stocks can amount to 14 months. Thus, the suggested 6 months delay is extremely short and could considerably impact the fashion jewellery industry and resellers. 3. The complete value chain in jewellery making entails several organizations which produce components such as chains, closures, linkages etc. This creates a complex supply chain with many players. All of these players have to			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					be informed and trained to use exclusively compliant material. Furthermore, a system of compliance checks has to be implemented. This will be extremely costly and time consuming. A realistic time frame to guarantee compliance by all players will amount to 3 years, should the proposal enter into force unchanged. However, should all suggested changes be accepted, compliance could be achieved within 2 years. A shorter period would make implementation virtually impossible and will severely damage the complete industry. Moreover, these difficulties are aggravated by the fact that sufficient compliant material will have to be made available from very restricted sources.			
69	N	2010/12/20 15:43	Spain / Industry or trade association /	(A) (B), (C), (D) (E), (F),	SEE ATTACHED FILE		Your comments/information are noted and items relevant for RAC have contributed to the	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
				(G) (H)			RAC process for elaboration of the restriction proposal.	
67	Y	2010/12/20 14:39	United Kingdom / Industry or trade association /		Yes - see paper attached.		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
64	N	2010/12/20 12:08	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F), (G)	The Health and Safety Authority has no relevant information		Your comments/information are noted and items relevant for RAC have contributed to the RAC process for elaboration of the restriction proposal.	
60	Y	2010/12/17 13:33	Austria /	(A (B),	Concerning technical problems: 1. The proposed limit of 0.09	DS237: Please refer to response to	Your comments/informat	See ref 60

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			Company /	(C), (F), (G)	µg/cm²/hr constitutes an unfeasible and uncertain standard leading to severe technical problems as regards surface calculation and testing. Europe should apply coherent testing methods for lead across different legislations. According to the proposal, the lead's migration rate of an item has to be obtained through determining its surface. Such a surface measurement is difficult for items of jewellery because they are often produced in very different and complex shapes. In this regard, when calculating the surface of an identical item different laboratories often achieve differing results, whereas the same piece of jewellery can be declared as compliant as well as non compliant (cf. pages 1-4 of the attached document). A measurement entailing such high uncertainties will be disadvantageous for consumers' safety, because it is not able to provide clear results on the compliance of jewellery items with the proposed standard. In this regard, an analysis of lead migration by weight measurement constitutes a much more feasible approach, as it produces clearer results. Additionally, as mentioned above, the proposed standard introduces extremely low	general comment 60.	ion are noted and items relevant for RAC have contributed in the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					limits in comparison to weight measurements. Such low levels are technically very difficult to reach and control. The tolerances of measurement equipment are higher than this, which will lead to a decrease in the precision and the reliability of the measure, introducing yet another element of uncertainty. In this regard, several consulted laboratories calculated a rate of 10% uncertainty (cf. pages 1, 5 of the attached document). Thus, it can be concluded that the calculation of an item's surface as well as the available mechanisms for control entail a high amount of uncertainty due to the very low standard in µg/cm²/hr proposed in the report. Such uncertainties will not contribute to a higher level of consumer safety. 2. The proposed separate testing of the coating and the substrate will lead to severe technical problems, if this is also applied to electroplated precious metal coatings. (cf. pages 8-10 of the attached document). As the proposal suggests that the plating and the substrate of electroplated jewellery should be tested separately, the plating will have to be separated from its substrate.			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					Such an obligation would be nearly impossible to implement in the jewellery industry because of the close bond of precious metal plating and the base metal as well as the layer composition and the related thickness. The systematic separation of all platings would oblige companies to remove and test each plating layer of each component a jewel. However, this would be very challenging because a jewel can sometimes consist of several pieces and plating layers. Furthermore, a separation of the layers of fashion jewellery is often very difficult, because of the characteristics of the bond. Fashion jewellery is traditionally mostly made of non-precious base materials and finally plated. Most plating is done by electro-deposition of precious metals such as gold and rhodium and represents a complex layer sequence. Due to the very low thickness values of the layers (e.g. ornamental plating is usually 2-3 µm thick), the strength of the bond between plating layers and the demand of area-related reporting [µg/cm2/h] sample preparation seems impracticable if not impossible. Please note in this regard that although the report suggests taking inspiration from the			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					standard used for nickel, this standard does not prescribe a separation of the plating from the substrate (cf. pages 8-10 of the attached document). Concerning cost-related problems: Hereunder, three elements of the proposal are a source of concern: 1. the cost of the testing, 2. the short enforcement period and in connection with this 3. the nature of the industry's supply chain. 1. Regarding the tests which should be used for controls by both, companies and authorities, the report indicated an amount of 22 Euro for a test for a compound such as lead. This amount is unrealistic, especially regarding the use of techniques such as ICP or atomic absorption spectrophotometry, which are needed due to the proposed low limit values. After consulting several private and independent laboratories we received the information that the unit cost per tested compound ranges from 128 – 159 Euro. However, these costs refer only to the testing of one single component of a jewellery piece (e.g. pendant) and the same cost will possibly also apply to any other additional component. On average a piece of jewellery consists of 16 separate components resulting in testing costs of			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					approx. 1.700 Euros for one item. Furthermore, investment costs for laboratory equipment present an additional expense factor, as it will be necessary to control the lead content of every production batch due to the proposed low level. In this regard, probably the best way to ensure adherence will be to install internal laboratories at every production location and test samples at external laboratories for additional approval. However, due to existing regulations in Denmark, Canada and the US, jewellery manufacturers have already installed equipment to measure the lead content by weight (mg/kg). If the current proposal comes into force in the EU, extensive investments in new equipment and tests at external laboratories would become necessary. The costs for such internal and external testing according to the proposal would be ten times higher (3.000.000 Euro for investment + operation) than our proposed alternative (300.000 Euro). Thus, the cost for testing will constitute a considerable financial burden (cf. page 11-12 of the attached document). 2. The suggested delay of 6 months after the legal implementation of Annex			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					XVII of REACH is based on the wrong assumption that jewellery stocks undergo a permanent renewal of collections in a rhythm of at least 6 months, similar to the fashion industry. The reality of the jewellery industry is different and the period needed to sell stocks can amount to 14 months (please cf. page 12 of the attached document). Thus, the suggested 6 months delay is extremely short and could considerably impact the fashion jewellery industry and resellers. 3. The complete value chain in jewellery making entails several organizations which produce components such as chains, closures, linkages etc. This creates a complex supply chain with many players. All of these players have to be informed and trained to use exclusively compliant material. Furthermore, a system of compliance checks has to be implemented. This will be extremely costly and time consuming. A realistic time frame to guarantee compliance by all players will amount to 3 years, should the proposal enter into force unchanged. However, should all suggested changes be accepted, compliance could be achieved within 2 years. A shorter period would make implementation			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					virtually impossible and will severely damage the complete industry. Moreover, these difficulties are aggravated by the fact that sufficient compliant material will have to be made available from very restricted sources (cf. in this regard answers given to question 4, as well as page 13 of the attached document). Detailed analysis of economic effects on the EU fashion jewellery industry: Our estimate for the total EU market value of fashion jewellery amounts to 3.5 billion Euro. Using this figure as a basis we looked at the costs of removing lead containing pieces from the supply chain for the whole EU fashion jewellery industry which would amount to approx. the following: - Employee cost, process cost, scrap and recycling cost: 14 Mio. Euros - Cost of scrapped stock: 350 to 550 Mio. Euros - Loss in sales: 500 Mio. Euros - Compensation payments for contracts with independent retailers: 350 Mio. Euros Total cost approx. 1,4 billion Euros A restriction as proposed would not only amount to higher costs, but would have a serious effect - in a range still to be assessed			

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					– on the whole fashion jewellery industry not operating on the basis of precious metals such as silver.			

Specific question 4:

What alternative metals would replace lead in jewellery?

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
89	N	2010/12/21 16:17	Austria /.. /	(A (C), (F), (G)	Substitutes are not known at all!!		The comments are noted.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%). In BD table 46 specific lead free alloys are mentioned.
87	Y	2010/12/21 15:06	Austria / chamber /	(H)	Lead free alternatives with respect to alloys needed to produce jewellery pieces are readily available and to a large extent used by the industry. However, at the extremely low levels called for in the proposal even impurities can lead to non compliance of certain products and most lead free materials would contain such a level of impurity. For example also high quality tin casting contains lead so again the material needs to be changed which requires another prozess and increases the costs dramatically. Thus, at these low levels silver might be the only safe way to avoid problems and uncertainties. It should be noted, that silver	DS238: See responses to general comment Ref 71	The comments are noted.	Price and availability of lead free alloys have been checked. The price difference has been incorporated in the partial CBA in the BD. See also table 50 of the BD.

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					is over 20 times more expensive than currently used alloys. Such a restriction would not only amount to higher costs but could also lead to an effective elimination of all fashion jewellery not made from silver from the market. In this regard, the proposal would make the use of recycled materials virtually impossible due to impurities (cf. page 12 of the attached submission).	DS239 : As regards the attached file, see responses to comment Ref 60		
83	Y	2010/12/21 11:51	Italy / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		The comments are noted.	
82	N	2010/12/21 11:51	Germany / Industry or trade association /		Currently, there are a number of lead-free alternatives available on the market. However, at the extremely low levels called for in the proposal, even the smallest impurities can lead to non-compliance of certain products. Most lead-free alloys used in the manufacturing of fashion jewellery components would fall into this category, as the danger of impurities is great and technical limitations preclude a further		The comments are noted.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					reduction of the lead content. In this context, silver is regularly mentioned as an alternative. However, silver is 40 times more expensive than the currently used alloys and would make our products prohibitively expensive. In this regard, the proposal would lead to the effective elimination from the market of all fashion jewellery not made from silver. In Germany alone this would endanger several thousand jobs in the jewellery industry.	DS240: Comment acknowledged. For information, in the comment 80 below, it is indicated that silver is 20 times more expensive.		
81	Y	2010/12/21 11:07	Spain / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		The comments are noted.	
80	Y	2010/12/21 10:54	France / Industry or trade association /)	(A) (F)	Silver might be the only safe way to avoid problems and uncertainties. It should be noted, that silver is over 20 times more expensive than currently used alloys.	DS241: Thank you for this information.	The comments are noted.	Not in accordance with the general information from stakeholders
79	N	2010/12/21 09:22	Austria / Industry or trade		Also high quality tin casting contains lead so again the material needs to be changed which requires another prozess and increases the costs dramatically.	DS242: Comment acknowledged. Apparently new lead-free casting technologies are being developed. See comment 60 and DS 187.	The comments are noted.	In the draft opinion SEAC recommends a restriction based on concentration

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			association /					(0.05%)
78	N	2010/12/20 20:09	Spain / Industry or trade association /		SEE GENERAL COMMENTS		The comments are noted.	
77	N	2010/12/20 20:07	Spain / International organisation /		SEE GENERAL COMMENTS		The comments are noted.	
75	N	2010/12/20 19:32	Austria / Company /		There is no material which can be casted and is able to achieve the proposed target!	DS243: Comment acknowledged. Apparently new lead-free casting technologies are developing. See comment 60 and DS 187.	The comments are noted.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)
73	N	2010/12/20 18:48	Germany / Company /	(A) (C)	Using lead free tin based alloys with a minimum of 90% tin and a given lead content of about 300-400 mg/kg should be sufficient for the protection of consumers' health. However, at the extremely low levels stated in the proposal, even impurities can lead to non compliance of certain products and most lead free metals would contain such a	DS244: See DS149.	The comments are noted.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) = 500 mg/kg

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					level of impurity.			
72	N	2010/12/20 18:19	Austria / Company /		Also high quality tin casting contains lead so again the material needs to be changed which requires another prozess and increases the costs dramatically.	DS245: See DS242 above.	The comments are noted.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)
71	Y	2010/12/20 18:18	Austria / Company /		Lead free alternatives with respect to alloys needed to produce jewellery pieces are readily available and to a large extent used by the industry. However, at the extremely low levels called for in the proposal even impurities can lead to non compliance of certain products and most lead free materials would contain such a level of impurity. Thus, at these low levels silver might be the only safe way to avoid problems and uncertainties. It should be noted, that silver is over 20 times more expensive than currently used alloys.	DS246: Comment acknowledged.	The comments are noted.	
69	N	2010/12/20 15:43	Spain / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		The comments are noted.	
67	Y	2010/12/20	United		See paper attached.		The comments are	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
		14:39	Kingdom / Industry or trade association /				noted.	
64	N	2010/12/20 12:08	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F), (G)	The Health and Safety Authority has no relevant information		The comments are noted.	
60	Y	2010/12/17 13:33	Austria / Company /	(A (B), (C), (F), (G)	Alternative alloys which are considered "Lead free" are readily available and to a large extent used by us. However, the term "lead free" is misleading. At the extremely low levels called for in the proposal even impurities and minor contamination of lead which can be found in almost any material and alloy can lead to non compliance of certain products. Thus, at these low levels high quality metals, in particular silver, might be the only safe way to avoid problems and uncertainties, but even high-quality metals from recycling sources may not necessarily be compliant. It should also be noted, that silver is over 20 times more	DS247: See DS246	The comments are noted.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					expensive than currently used alloys. Furthermore, the proposal would make the use of recycled materials virtually impossible due to impurities of lead from various metal sources during recycling (cf. page 12 of the attached document).			

Specific question 5:

Would you see any practical problems in ensuring compliance with the possible restriction? If so, please specify.

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
91	N	2010/12/21 18:09	/ / Individual	(A) (D) (E), (F)	additional cost and legislation for jewellers who already comply with assay regulations and testing		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
89	N	2010/12/21 16:17	Austria /	(A) (B), (C), (F), (G)	see question 3!		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
88	N	2010/12/21 15:44	United Kingdom / Assay Office /	(A (C)	The proposal of measuring migration according to surface area over time is difficult to measure and will be difficult to ensure repeatability. Adopting the migration factor set by the toy regulations of 90mg/kg will ensure consistency across different regulations, and better repeatability in	DS248: Please refer to responses DS14, 15 and DS90 concerning the surface measurement and the limit in mg/kg.	Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					practice		proposal.	
87	Y	2010/12/21 15:06	Austria / chamber / Austrian federal economic chamber	(H)	1.) The proposed separate testing of the coating and the substrate and the subsequent addition would be a de-facto prohibition of multi-layer coatings or of coatings altogether. The method would lead to a situation where the base metal and the coating on their own would be in compliance with the regulation. Yet, the combination of both would be prohibited (cf. page 7 of the attached submission). 2.) A precise definition of the term "coating" excluding electroplated precious metal coatings is necessary for the implementation but missing in the draft proposal (cf. page 7 of the attached submission). 3.) The testing methods for the proposed standard cannot be applied easily in standardized laboratories – unlike testing methods for a standard in mg/kg. Furthermore, weight based measurement is already applied in various legislations in the EU as well as internationally (e.g. US and China). Thus, for the industry it would be more consistent and practical to apply similar methods and standards. Additionally, a standard expressed in mg/kg would also lead to a more harmonized	DS249: 1. for the question of coating and substrate: a definition of "coating" is now integrated in the BD. Difference between "plating" and "coating" to be considered (see DS26) as well. 2. the base metal and the coating of a jewellery piece have both to be in compliance with the limit proposed (and thus added) because, in a worst case, a child might be poisoned by the ingestion of the lead contained into the coating (chronic mouthing) and then the ingestion of the lead contained in the uncoated (degraded) jewel (acute exposure). Further, if the child swallowed the leaded coated piece as a whole, he could also be acutely poisoned by the leaded coating and the base metal under the coating. 3. As far as the testing of the coating on the basis of the nickel Directive, it is an option to be considered. See DS28. See also response DS26.	Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					approach within the European legal system, where limit values regarding lead have so far always been expressed in mg/kg or ppm (cf. pages 3, 11 of the attached submission). 4.) Due to the complex supply chain of the jewellery industry, the proposed enforcement period of 6 months is too short to successfully implement and comply with the proposed standard (for further information, please cf. comments made under Question 3). 5.)The use of leadfree tin casting as well as the performance of lead free solder is a practical problem, as well as the use of lead crystals in fashion jewellery would be a problem. To change it the whole process within companys needs to be changed dramatically which is a technical, personal and financial problem.			
83	Y	2010/12/21 11:51	Italy / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
82	N	2010/12/21 11:51	Germany / Industry or trade association /		o The proposed limits would preclude the use of virtually all feasible alternative materials and strike a devastating blow to the fashion jewellery industry. o The proposed enforcement period of 6 months is too short to successfully implement and comply with such drastic standards. o Testing methods should be consistent with the internationally recognised testing methods already in use, in order to ensure the reliability and comparability of measurements.	DS250: Noted. This comment will be taken into account. DS251: Extended timeframe to be considered. DS252: See DS125 and DS130	Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) Extended timeframe recommended
81	Y	2010/12/21 11:07	Spain / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
80	Y	2010/12/21 10:54	France / Industry or trade association /	(A) (F)	1. The proposed separate testing of the coating and the substrate and the subsequent addition would be a de-facto prohibition of multi-layer coatings or of coatings altogether. The method would lead to a situation where the base	DS253: See responses to comments 60 and 71	Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction	See ref 60

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					metal and the coating on their own would be in compliance with the regulation. Yet, the combination of both would be prohibited. 2. A precise definition of the term "coating" excluding electroplated precious metal coatings is necessary for the implementation but missing in the draft proposal; 3. The testing methods for the proposed standard cannot be applied easily in standardized laboratories – unlike testing methods for a standard in mg/kg. Furthermore, weight based measurement is already applied in various legislations in the EU as well as internationally (e.g. US and China). Thus, for the industry it would be more consistent and practical to apply similar methods and standards. Additionally, a standard expressed in mg/kg would also lead to a more harmonized approach within the European legal system, where limit values regarding lead have so far always been expressed in mg/kg or ppm.		proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					4. Due to the complex supply chain of the jewellery industry, the proposed enforcement period of 6 months is too short to successfully implement and comply with the proposed standard .			
79	N	2010/12/21 09:22	Austria / Industry or trade association /		As mentioned above what you are asking is working almost leadfree and leadfree tin casting is a practical problem as well as the performance of lead free solder in attition to that ledcrystall is used for stones which are applicated to fashion jewellery. To change it the whole process within companys needs to be changed dramatically which is a technical, personal and financial problem.	DS254: See responses to comment 72	Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%) lead crystals and precious stones are exempted
78	N	2010/12/20 20:09	Spain / Industry or trade association /		SEE GENERAL COMMENTS		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
77	N	2010/12/20 20:07	Spain / International		SEE GENERAL COMMENTS		Your comments/information are noted and	In the draft opinion SEAC recommends a restriction based on

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			organisation /				have contributed to the RAC process for elaboration of the restriction proposal.	concentration (0.05%)
73	N	2010/12/20 18:48	Germany / Company /	(A) (C)	1. The definition of a 'lead free' alloy is settled very differently in recent European and International Standards. For e.g. 'lead free' according to the RoHS guideline 2002/95/EG is defined by a lead content lower than 0,1% weight (1,000 mg/kg). The proposed limit of 0.09 µg/cm²/hr for jewellery is significantly lower limit than these limits and also those set for lead in toys or food, although the risk of exposure is lower in case of jewellery. 2. The testing methods for the proposed standard cannot be applied easily in standardized laboratories – unlike testing methods for a standard in mg/kg. 3. The proposed enforcement period of only 6 months is impractical. Jewellery manufacturers will need 2-3 years time to test and establish new materials.	DS255: Please note that the kind of exposures described in the proposal are different from an exposure via toys or food, that is why you cannot compare the different proposed limits DS256: See response to comment 60.	Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	In the draft opinion SEAC recommends a restriction based on concentration (0.05%)
72	N	2010/12/20 18:19	Austria / Compan		As mentioned above what you are asking is working almost leadfree and leadfree tin casting is a practical problem as well as the	DS257: Your comments have been noted.	Your comments/information are noted and	In the draft opinion SEAC recommends a restriction based on

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			y /.		performance of lead free solder in attition to that ledcrystall is used for stones which are applicated to fashion jewellery. To change it the whole process within companys needs to be changed dramatically which is a technical, personal and financial problem.		have contributed to the RAC process for elaboration of the restriction proposal.	concentration (0.05%)
71	Y	2010/12/20 18:18	Austria / Company /		1. The proposed separate testing of the coating and the substrate and the subsequent addition would be a de-facto prohibition of multi-layer coatings or of coatings altogether. 2. A precise definition of the term “coating” excluding electroplated precious metal coatings is necessary for the implementation but missing in the draft proposal 3. The testing methods for the proposed standard cannot be applied easily in standardized laboratories – unlike testing methods for a standard in mg/kg. Furthermore, weight based measurement is already applied in various legislations in the EU as well as internationally (e.g. US and China). Thus, for the industry it would be more consistent and practical to	DS258: See responses to comment 60	Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					apply similar methods and standards. Additionally, a standard expressed in mg/kg would also lead to a more harmonized approach within the European legal system, where limit values regarding lead have so far always been expressed in mg/kg or ppm. 4. Due to the complex supply chain of the jewellery industry, the proposed enforcement period of 6 months is too short to successfully implement and comply with the proposed standard (for further information, please cf. comments made under Question 3).			Extended timeframe recommended
69	N	2010/12/20 15:43	Spain / Industry or trade association /	(A) (B), (C), (D) (E), (F), (G) (H)	SEE ATTACHED FILE		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
67	Y	2010/12/20 14:39	United Kingdom /		Yes, major - see paper attached.		Your comments/information are noted and	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
			Industry or trade association /				have contributed to the RAC process for elaboration of the restriction proposal.	
64	N	2010/12/20 12:08	/ / Ireland MSCA	(A) (B), (C), (D) (E), (F), (G)	The Health and Safety Authority has no relevant information		Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	
60	Y	2010/12/17 13:33	Austria / Company /	(A (B), (C), (F), (G)	1. The proposed separate testing of the coating and the substrate and the subsequent addition would be a de-facto prohibition of multi-layer coatings or of coatings. The method would lead to a situation where the base metal and the coating on their own would be in compliance with the regulation. Yet, the combination of both would be prohibited (cf. page 7 of the attached document). 2. A precise definition of the term "coating" excluding electroplated precious metal coatings is necessary for the implementation but missing in the draft proposal (cf. page 7 of the attached document).	DS259: See responses to comment 60	Your comments/information are noted and have contributed to the RAC process for elaboration of the restriction proposal.	

Ref	Att	Date	Country/ Organisation/ MSCA	Type	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
					3. The testing methods for the proposed standard cannot be applied easily in standardized laboratories – unlike testing methods for a standard in mg/kg. Furthermore, weight based measurement is already applied in various legislations in the EU as well as internationally (e.g. US and China). Thus, for the industry it would be more consistent and practical to apply similar methods and standards. Additionally, a standard expressed in mg/kg would also lead to a more harmonized approach within the European legal system, where limit values regarding lead have so far always been expressed in mg/kg or ppm (cf. pages 3, 11 of the attached document). 4. Due to the complex supply chain of the jewellery industry, the proposed enforcement period of 6 months is too short to successfully implement and comply with the proposed standard (for further information, please cf. comments made under Question 3).			

Document reference:

Ref 54: http://echa.europa.eu/documents/10162/13641/ref54_attachment_lead_and_its_compounds_en.pdf

Ref 87: http://echa.europa.eu/documents/10162/13641/ref87_attachment_lead_and_its_compounds_en.pdf

Ref 81: http://echa.europa.eu/documents/10162/13641/ref81_attachment_lead_and_its_compounds_en.pdf

Ref 67: http://echa.europa.eu/documents/10162/13641/ref67_attachment_lead_and_its_compounds_en.pdf

Ref 60: http://echa.europa.eu/documents/10162/13641/ref60_attachment_lead_and_its_compounds_en.pdf

Ref 55: http://echa.europa.eu/documents/10162/13641/ref55_attachment_lead_and_its_compounds_en.pdf

Ref 44: http://echa.europa.eu/documents/10162/13641/ref44_attachment_lead_and_its_compounds_en.pdf