

Committee for Socio-economic Analysis (SEAC)

Response to comments on the SEAC draft opinion on the Annex XV dossier proposing restrictions on Lead and Lead compounds in jewellery

ECHA/SEAC/RES-O-0000001304-85-04/S2

Chemicals concerned: Lead and its compounds

Chemical name: Lead

EC number: 231-100-4

CAS number: 7439-92-1

15 September 2011

Substance: **Lead (and its compounds)**
 CAS number: **7439-92-1**
 EC number: **231-100-4**

Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Lead and its compounds**.
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56	2011/05/27 United Kingdom / Industry or trade association	<p>The SEAC does not appear to have considered the use of Enamel by traditional craft Enamellers as part of this consultation. Many small scale jewellers use enamel and would be unable to determine for themselves the percentage of lead content in each colour. This may lead to a decline in an important and traditional craft skill as small scale businesses would be faced with difficulties in establishing whether or not their work complied with such a regulation.</p>	<p>It is proposed to introduce an exemption for vitreous enamels.</p>
		<p><u>Secretarial note:</u> The ECHA Secretariat contacted the submitter of the comment to obtain further data on the enamel jewellery market segment, content and role of lead in enamel, migration of lead from enamel jewellery, alternatives to the enamel in the enamel jewellery, applications of leaded and lead-free enamels, proposal for an appropriate definition of enamels and for appropriate derogation. The submitter of the comment reported that the practitioners of enamelling state in relation to available unleaded enamels that</p> <ul style="list-style-type: none"> a) Unleaded jewellery enamels do not blend or flow, b) Unleaded jewellery enamels cannot withstand multiple firings necessary and c) Unleaded jewellery cannot withstand the polishing process. <p>The respondent's submission was that the restriction</p>	

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		of the use of lead-bearing vitreous jewellery enamels would devastate the practice of some of the most highly skilled and experienced enamellers and that there is no suitable alternative available. Enamel manufacturers claimed to be able to continue to make the lead bearing enamels for industry but they would not be able to develop a wider range of lead free enamels for the relatively small market that is part of the enamelling heritage.	
		The submitter suggested that if the restriction is approved as the lead content of each enamel is different, it would not be sufficient to test only one colour but jewellery samples.	

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		<p>Because of the long life of un-used enamel it is common practice to keep or acquire enamels no longer in production, maybe only using them occasionally on a specific piece of work. Vitreous Jewellery Enamel has a long economic life and therefore compliance costs, both to the manufacturer and to the downstream user of Vitreous Jewellery Enamel (the Jeweller) would be disproportionately high. The delay of six months after legal implementation is much too short. The “speed of turnover” in enamels could realistically be anywhere between 1 and 60 years. This means that the jewellery stock made using vitreous jewellery enamel is not sold within the proposed period of 18-24 months.</p> <p>Answers to the follow-up questions by individual companies were also included in the response. These answers provide further details of the production volumes, lead content in enamel, production process, compatibility of enamel with different metals, qualitative assessment of leaching of lead from enamelled jewellery, assessment of lead-free alternatives, discussion of similarities of enamel to crystal, etc. Contributions by individual companies were claimed confidential.</p>	

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55	2011/05/27 United Kingdom / Industry or trade association	Identical with comment Ref.56.	Identical with response Ref.56.
54	2011/05/27 France / International NGO	We would like to stress the importance of the current proposed lead restriction in jewelry. First, because lead is a long known neurotoxicant, considered a non-threshold toxicant, which is already subject to several restrictions, according to the REACH regulation and sectorial regulations such as the Toys Safety Directive (TSD) 2009/48/EC or the Cosmetics directive.	Thank you for comment, though the issues highlighted are largely addressing concerns outside of SEAC remit.. The comment does not provide any supporting evidence that the proposed limit by SEAC is not appropriate, even given the fact that the Danish authorities have a stricter limit value.

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		<p>Secondly because jewelry is so far excluded from the scope of both REACH regulation and Toys Safety Directive, and can therefore be considered an important potential source of lead, especially when considering the potential exposure of children to such compounds.</p> <p>A recent study just underlined that “childhood lead exposure may have a persistent and irreversible effect on IQ during the adult years. A 30 year follow-up study in Boston found that even low level exposure to lead during childhood – that is, at or below the U.S. level of concern of 10 µg/dL – may impair adult cognitive function enough to lower IQ scores” (source: Mazumdar, M, DC Bellinger, M Gregas, K Abanilla, J Bacic and HL Needleman. 2011. Low-level environmental lead exposure in childhood and adult intellectual function: a follow-up study).</p>	
		<p>Children’s behavior (mouthing activities and hand-to-mouth behavior) implies risks of children’s exposure to lead (mostly ingestion) whether present in toys or in jewelry. Therefore a restriction of lead in jewelry is deemed urgent. Moreover, the proposed restriction should go beyond the limits set by the new Toys Safety Directive , to ensure the best effective protection of children’s health from lead exposure, and push for a revision of the new Toys Safety Directive: as stressed by the German Federal Institute for Risk Evaluation (Dr. Bärbel Vieth, BfR, Friedrich-Ebert-Stiftung 5.11.2010, Schadstoffe in Spielzeug - Auswirkungen</p>	

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		<p>auf die kindliche Gesundheit – Regelungsbedarf), the new Toys Safety Directive sets lead contents of toys at 160mg/kg of scrapped-off toy material, whereas the former TSD Directive had set a limit of 90 mg/kg, this means the new Directive results in an increased lead content of toys. This is not acceptable and the new restriction on lead shall not be aligned with the limit set by the new Toys Safety Directive.</p>	
		<p>In a 2010 report, the European Scientific Committee on Health and Environmental Risks recommended to eliminate the presence of lead and its compounds from toys, stating that “Chemical elements classified as CMR categories 1A and 1B, according to the EU Classification, Labeling and Packaging regulation, should not be present in toys as intentionally added components” (evaluation of the Migration Limits for Chemical Elements in Toys, SCHER, 1 July 2010). SEAC’s proposed restriction limit of 0, 05% by weight of any part of the jewellery article is not appropriate and should be lowered, considering that for health concerns, Danish authorities have banned the import of articles containing more than 0,01% of metallic lead/weight.</p>	

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		<p>As said before, considering the similarity of exposure to lead via jewelry as well as toys, we would therefore recommend to adopt one of the two following options of RAC/SEAC Background document to the opinions on the Annex XV dossier proposing restrictions on Lead and its compounds in jewellery “Option 4: Ban on lead and its compounds in fashion jewellery which is used and placed on the market” or in a second choice, recommend “Option 3: Option 3: Restriction on the use and placing on the market of fashion jewellery based on the lead migration rate AND the lead content”.</p> <p>Indeed, when it comes to protecting children’s health, prevention measures should be taken – we do not have to deal here with the precautionary principle, since lead’s adverse health effects have been long known and documented.</p>	
		<p>By choosing the most protective standard, the EU would pave the way for other countries’ choices, dealing with the same health concerns as in Europe, and create provide a good example to them in a regulation of lead and its compounds in jewelry that is based on children’s health protection (see: Some priority heavy metals in children toy’s imported to Nigeria, Sindiku O. K.1, Osibanjo O.1, Department of Chemistry, University of Ibadan, Nigeria. Accepted 19 January 2011).</p>	

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Ref	Date Country/Org./MSCA	Comment	Response
53	2011/05/27 Sweden / MemberState	Comments on the restriction proposal Regarding: Public consultation on SEAC draft opinion Substance: Lead and its compounds in jewellery From: Swedish Chemicals Agency Date: 27 May 2011 The Swedish Chemicals Agency wish to put forward the following comments on the restriction proposal for lead and its compounds in jewellery	
		General The Swedish Chemicals Agency considers that a restriction of lead and lead compounds in jewellery is needed to protect children. Exposure to lead and lead compounds present a risk of serious adverse effects on human health, especially for children. A ban on lead in jewellery is justified because it can not be excluded that children will be exposed to lead by placing jewellery or parts of jewellery in the mouth and even swallowing it. It is not possible to set a threshold for the lowest levels of lead in blood that can cause adverse health effects in terms of impact on the central nervous system. Specific comments on SEAC draft opinion	

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		<p>Limit value The Swedish Chemicals Agency considers it important that the restriction of lead and lead compounds in jewellery has a clear scope and that the rules are clear cut, making it easy for companies to comply and for Member States to carry out market surveillance. Administrative costs should be kept as low as possible for companies and regulators. In the current situation, there is no standardized test for the release of lead in contact with saliva. For these reasons the Swedish Chemicals Agency is of the opinion that a limit value on the maximum allowable content of lead in jewellery is preferable to a threshold for release.</p>	
		<p>Whether lead and lead compounds in jewellery is limited by imposing a limit value on the maximum allowable content and / or a maximum threshold for release of lead it is important that the limit value will be applied in such a way that the restriction achieves the intended effect. The Swedish Chemicals Agency are of the opinion that the limit value should be related to the materials in jewellery in order to ensure that lead and lead compounds in e.g. both the surface coatings and in the core materials of jewellery is covered by the restriction.</p>	<p>SEAC also thinks that the limit value should be related to the materials in jewellery in order to ensure that lead and lead compounds in e.g. both the surface coatings and in the core materials of jewellery is covered by the restriction proposal as the restriction proposal text says: "Shall not be used or placed on the market in jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of any part of the jewellery article".</p>

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		<p>Derogations In the draft opinion of SEAC a number of derogations are listed. The Swedish Chemicals Agency considers that the need for derogations from the restriction on lead in jewellery should be well informed so that they will not threaten to weaken the protection of children's health.</p>	<p>For the same reasons that labelling was discounted as a possible risk management option for lead containing jewellery more generally (section E.1.3 of the Background Document), SEAC did not consider it to be justified in the cases of derogated jewellery articles either.</p>
		<p>Transitional period SEAC favors a transitional period in the draft opinion. In order to reduce the negative financial impact on operators in the jewellery industry from the restriction of lead and lead compounds in jewellery the Swedish Chemicals Agency also considers that the restriction should be preceded by a transitional period. The transition period should however be limited to distribution and sale of jewellery that are already placed on the market at entry into force of the restriction. Placing on the market for the first time through the manufacture or importation should not be subject to a transitional period.</p>	<p>The transitional period is proposed for all jewellery produced after the date where the restriction enters into force. Jewellery placed on the market for the first time before the end of the transitional period will continue to be allowed. The transitional period is only to give sufficient time to the change of production and to cover the storage by the producer or importer of final jewellery and intermediates. If the product is sold to a retailer before that date the retailer will be able to place the jewellery on the market anyway. In the revised version it is proposed to limit the transitional period to 12 months.</p>
		<p>Result from market surveillance During the year 2008 the Swedish Chemicals Agency analyzed the content of lead in 150 pieces of jewellery with XRF. 25% of the tested products contained lead at levels between 0.1 and 38%. The jewelry is purchased in stores in Stockholm. Lead in other consumer products Given the serious health risks identified from</p>	<p>The comment is not related to the scope of the restriction proposal put forward by the SEAC draft opinion. The commentator is at liberty to prepare a restriction dossier proposing the restrictions outlined in the comment.</p>

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		<p>exposure to lead and lead compounds in jewellery The Swedish Chemicals Agency are of the opinion that there are reasons to also consider restrictions of lead and lead compounds in other consumer products where there is a significant and serious risk of adverse health effects.</p> <p>The Swedish Chemicals Agency consider that there is a need to target the use of lead and lead compounds in e.g. the following consumer products in future restriction dossiers/proposals;</p> <ul style="list-style-type: none"> • Crayons containing lead • Candle wicks containing lead • Alloys containing lead and provided to consumers for the casting of e.g. tin soldiers. 	
52	2011/05/27 Czech Republic / Industry or trade association	<p>Summary Comment of the Association of Glass and Jewellery Manufacturers of the Czech Republic / selected parts from the complete document dated 23rd May 2011/ Point 5 - Summary Comment on the French Government proposal: -- we suggest to judge protecting consumers from an attack of lead contained in jewellery according to the present European standard EN 71-3 in operation relevant to the safety of toys</p>	
		-- we support analogous opinions of associations of jewellery manufacturers of France, Italy, Spain, Great Britain and Germany	

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		-- we appreciate efforts to codify reasonable, measurable and controllable limits of lead contained in jewels and costume jewellery. In case of its putting into practice, we require the EU market to be protected more severely from imports from third countries that do not keep these limits.	
		This opinion was discussed with national competent authorities , i.e. Ministry of Environment of the Czech Republic, Ministry of Industry and Trade of the Czech Republic and Ministry of Health of the Czech Republic. Point 5.1. Comment on the opinion of SEAC dated 11th March 2011 - Draft Association of Glass and Jewellery Manufacturers of the Czech Republic read up this opinion. Its remarks are as follows :	
		-- the proposal, determining restrictions on the basis of an absolute concentration of Pb/ 500ppm/ in particular parts, is simpler and realizable more easily than the French original one. Also it is consistent methodically with the legislation in the USA	
		-- we support an exception relating to lead crystal and high lead crystal, precious stones and old jewels	
		-- we do not agree with the opinion that it is impossible to apply this test to toys and costume jewellery -- we do not recommend the XRF method. Its results can be concealed easily using decorating surface	In the opinion it is not said that it is not possible to apply this test to toys and costume jewellery – but that lead might also be present in jewellery intended for adults as well as in non costume jewellery. The XRF test is proposed as a screening test. In the cost calculations we

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		layers . It is advisable to use a method of the complete decomposition of the material tested / ICP/	have included costs related to the verification of the XRF test results by ICP. Thanks for the information – There is no information that the impacts of the restriction would influence the picture.
		Point 3 - Social- economic aspects The proposed measure /remark : meaning French proposal / impinges on the branch of industry having many years tradition as well as unique glass-making and jewellery-making know how. In particular, centers of this branch are situated in Liberec, Jablonec nad Nisou and Turnov regions.	
		Basic information : -- about 10000 employees work in the industry -- this branch has a great interest in the level of employment in Liberec, Jablonec nad Nisou and Turnov regions / en estimate of 10% working population / -- three specialized secondary schools are in existence to support the industry -- the jewellery industry has ties to next jobs in the tertiary sector / about 1000 ones / -- 110 companies are engaged in the manufacture and business, the biggest of them is Preciosa a.s., others are medium and small ones	

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		<p>The volume of production reached 6.1 billion Czech Crowns in 2009, vast majority was exported worldwide.</p> <p>The complete document was emailed to the email box of SEAT 26th May 2011.</p> <p>Signed : Member of Board of Directors Association of Glass and Jewellery Manufacturers Jablonec nad Nisou Czech Republic</p>	
51	2011/05/27 Austria / Industry or trade association	<p>1.From our point of view, any electrical watches and any jewellery with integrated electronic or electronical equipment should be excluded from any restrictions related to “lead in jewellery”, because they have a separate regulation in the ROHS-directive (2002/95/EG). Moreover there is an exception for crystal glass (see Commisions decision from 12th October 2006 regarding Nr. 29 in Annex 1 in 2002/95/EG). This is just to avoid any legal overlapping within EU-rules.</p>	<p>We suggest as far as possible to use the same definition as in the restriction on cadmium. No need for a general exemption of wrist watches has been identified – only for internal parts. Like for other jewellery it is the mouthing activities by children that give rise to concern.</p> <p>Overlapping is not by itself a problem. The requirements of both pieces of legislation have to be respected. It would only be a problem if the overlapping is conflicting, meaning that it would not be possible to meet both requirements at the same time.</p>

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		<p>2. In the Glass- and Jewellery Industry there are companies who need high qualitative tin alloys, which include at least 6 % lead for their production. This share of lead is necessary for the flow rate in the centrifugal casting production system. Although these companies and their suppliers are currently researching for tin alloys with a reduced share of lead, it is unknown, if they will succeed. For the moment, it is not possible to say how much lead is needed to work without any loss in quality. So a wider transition period is absolutely needed.</p>	<p>The information that high quality tin alloys without lead are not available on the market is not in line with information from other sources and the comment does not refer to validated data. Costs were not found to be disproportionate.</p>
		<p>Alloys with a reduced share of lead and the production process will definitely become more expensive. In any case, this has consequences for the price and for end consumer who has to pay for it. This means, that the European producers of jewellery will get under further pressure compared to the non-EU-producers (from Asia etc.), who can produce at much lower costs in general.</p>	<p>As calculated in the Background Document section the extra costs are marginal. The restriction will also apply to imported jewellery, so no cost advantage to non producers.</p>
50	2011/05/27 Austria / Industry or trade association	<p>1. From our point of view, any electrical watches and any jewellery with integrated electronic or electronical equipment should be excluded from any restrictions related to “lead in jewellery”, because they have a separate regulation in the ROHS-directive (2002/95/EG). Moreover there is an exception for crystal glass (see Commissions decision from 12th</p>	<p>See response under Ref.51.</p>

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		<p>October 2006 regarding Nr. 29 in Annex 1 in 2002/95/EG) => This is just to avoid any legal overlapping within EU-rules.</p> <p>2. In the Glass- and Jewellery Industry there are companies who need high qualitative tin alloys, which include at least 6 % lead. This share of lead is necessary for the flow rate in the centrifugal casting production system. Although these companies and their suppliers are currently researching for tin alloys with a reduced share of lead, it is unknown, if they will succeed. For the moment, it is not possible to say how much lead is needed to work without any loss in quality. So a wider transition period is absolutely needed. Alloys with a reduced share of lead will definitely become more expensive. In any case, this has consequences for the price and the end consumer who has to pay for it. This means, that the European producers of jewellery will get under further pressure compared to the non-EU-producers (from Asia etc.), who can produce at much lower costs in general.</p>	
49	2011/05/27 Czech Republic / MemberState	<p>The REACH competent authority of Czech Republic generally support the conditions of the restriction proposed by SEAC. We welcome that the proposed restrictions are not based on migration of lead per unit; we fully agree with justification given for this approach. We have no</p>	

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		<p>objection against the limit value of lead recommended by RAC of 0.05 % by weight. We note the proposed limit for migration rate of lead release from jewellery articles of 0.05 µg/g/hr taking into account that suitable test method for determining the migration rate is not yet available. .</p> <p>We recommend to specify the method for the determination of lead content in jewellery articles directly in frame of restrictions. We would propose to use ICP-MS for verification of lead concentration. We consider the derogation for Full Lead Crystal, Lead Crystal and precious and semiprecious stones as defined in the draft opinion as fully justified.</p>	<p>XRF is cheaper than ICP. The XRF test is proposed as a screening test. As a screening test, XRF was always intended to be used alongside more accurate ICP ‘wet’ testing in cases close to the bounds of precision around the limit value (where false positives and negatives may be important). In the cost calculations we have included costs related verification of the XRF test results by ICP.</p>
48	<p>2011/05/26</p> <p>United Kingdom / Individual</p>	<p>As an enameller/jeweller, I have been using lead bearing enamels in my work for 25 years. To my knowledge, there is no conclusive evidence of any danger to either the enameller, or the wearer of enamelled jewellery. Once fired, the enamel is stable and inert.</p> <p>Enamel jewellery has been sold and worn for centuries.</p> <p>If we have to stop using lead bearing enamels, it will make a significant difference in the traditional high quality of enamel work, and for a small business, the cost of replacing good, lead bearing stock, with less reliable lead free enamels would be extremely costly (both in terms of time and expense.)</p>	<p>It is proposed to introduce an exemption for vitreous enamels.</p>

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47	2011/05/26 Switzerland / Company- Manufacturer/	Comments on the frame of the public consultation on the draft opinion of ECHA's Committee for Socio-economic Analysis (SEAC) concerning a proposal to restrict lead and its compounds in jewellery in Annex XVII of Regulation (CE) 1907/2006 REACH. The Company understands the problem of lead exposure to people and especially to children that implies some dangerous effects, but only if it is ingested or sucked. We understand the need for a restriction that can be imposed, but for us this restriction is too strict for the watchmaking industry and could have dramatic impact for our brand as well as for the whole European watch industry.	It is proposed to exempt internal parts of watches.

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		<p>The manufacture is specialized in manufacturing mechanical watches, a large part of them being grand complications, studied as technical timepieces and not simply as jewellery.</p> <p>This watchmaking art is expressed in the movement, in which difficult mechanical functions are created. Regarding the complexity of the mechanical parts and the level of miniaturization, we are forced to use some technical materials that contain lead.</p> <p>Indeed, the lead used in these components facilitates turning and allows the manufacture of such pins measuring 4 tenths of a millimetre in diameter and 6 tenths of a millimetre in height. Some pieces of the movement as wheels and plates of brass or nickel silver contain lead and cannot be replaced today by another alloy.</p>	
		<p>Finally, the cases are sealed and prevent the metal leaching out. We estimate no risk of ingestion or sucking of a part which contains lead since these parts are enclosed in the case. People are just in contact with the exterior part (case) of the watch, which is made of different alloys (golden, platinum, steel).</p> <p>Electronic watches represent a small amount of our production and are already under restraint of ROHS and WEEE. As for mechanical watches, people are never in direct contact with the movement.</p> <p>That is why, we propose in accordance with the Swatch Group proposal to modify the legislation</p>	

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		project as follows: Not to include wristwatches in the definition of jewellery. Or at least, to keep inaccessible components out of the scope of the restriction. Watch straps, tighteners and wristwatch cases could however be included within the scope of the restriction.	
46	2011/05/26 Netherlands / National Authority	As a start, we would like to point out that we agree with a restriction on lead in jewellery. As lead is a known toxicant, and the use in jewellery is not necessary, it is sensible to avoid lead exposure from jewellery. Although we are in favor of the restriction and we appreciate the justifications given in the opinion and background document, we would like to comment on one specific aspect.	The comment is addressing issues outside of SEAC remit. RAC reached a conclusion on the issue highlighted and SEAC applied this conclusion to its own work. Although the commentator disagrees with the RAC conclusion, to suggest there is no basis for the subsequent SEAC work is mistaken, since it is based on the RAC's conclusions. Furthermore we believe that the sensitivity analysis undertaken in the SEA takes into account any uncertainties associated with the relationship.

Substance: **Lead (and its compounds)**
CAS number: **7439-92-1**
EC number: **231-100-4**

Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing
restriction on **Lead and its compounds**.
Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>We noticed that the Dossier Submitter, the authors of the Danish survey as well as the SCHER concluded that no direct relation could be shown between content and migration. Surprisingly, it is concluded in the background document that there is an association, based on a re-evaluation of the data. When looking at the data ourselves, we can only support the original conclusion, namely that there is no association. This because of:</p> <ul style="list-style-type: none"> - the low number of samples tested (n=25), whereof only 14 had a measurable migration; - the uncertainty and variability in the measured values (for instance, duplicates of 6 out of 14 deviated significantly, factor 1.4-26.7); - the choice of exclusion of outliers is not clear (why higher value is the outlier?, and exclusion differed between µg/g analysis and the µg/cm² analysis). - the scarcity of data points especially at the lower lead concentrations, i.e. the area of particular interest for the restriction. - correlation coefficients of only 0.8 or lower. <p>And as we are of the opinion that there is no association, we also find that there is no basis for the subsequent calculations as basis for the SEA.</p>	
45	2011/05/26 Switzerland / Industry or trade association	<p>Comments of the Federation of the Swiss Watch Industry FH</p> <p>1. The Federation of the Swiss Watch Industry FH The FH, based in Biel/Bienne, Switzerland, is the</p>	

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 Annex XV report submitted by France 15 April 2010.
 Public consultation on SEAC draft opinion started on 29 March 2011.

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		<p>leading trade association of the Swiss watch industry, with over 500 members representing more than 90 per cent of all Swiss watch manufacturers (including finished products, watch movements and components).</p> <p>With around 50,000 persons employed, the Swiss watch industry comprises the bulk of the European watch industry. Moreover it is possibly the largest client of the European watch component supply industry.</p> <p>The EU is a traditionally important market for Swiss watch exports. In 2010, the Swiss watch industry exported over 9.9 million watches with a total value CHF 4.6 billion to the Member States of the European Union. Tens of thousands of jobs in the retail trade in the EU are indirectly bound up with the Swiss watch industry and the sale of its products.</p>	
		<p>2. Comments of the FH</p> <p>a. General impression</p> <p>The FH takes the view that consistent protection of children's and adult's health is absolutely imperative and therefore supports the general thrust of the French proposal. However, we are of the opinion that the proposals submitted by RAC and SEAC in part overshoot the intended aim and would have certain undesirable effects. Obstacles are being created for the watch industry's activities which cannot in any way be justified by improved health protection.</p>	

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Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>b. Watches = Jewellery? Neither the initial French proposal nor the commentary by the RAC contains a definition of the goods covered by the concept of "jewellery". A specific list of the goods concerned, including wrist watches, is set out for the first time in the SEAC report.</p> <p>Looking at the definition of "Jewellery" provided by SEAC, we find that wrist watches are treated as purely aesthetic and ornamental objects. From a technical angle, this is incorrect because wrist watches are time measuring instruments. This means that they are subject to technical constraints in order to fulfill their function. Thus the inclusion of wrist watches in the category of purely ornamental jewellery pieces is not justified.</p> <p>This fact has been taken into consideration in the Canadian 2005 Children's jewellery regulation, in which items having a primary functional purpose like watches, eyeglasses, and belt buckles, are not classified as jewellery.</p> <p>The RAC and SEAC Background Document states that, "for practical reasons"; SEAC proposes to take over the definition used in the cadmium restriction.</p> <p>The FH considers that it is not appropriate in this case to work entirely on the basis of practical reasons.</p> <p>The EU legislator has recognized the difference between watches and jewellery and therefore included electronic watches under the heading of electronic</p>	<p>We suggest as far as possible to use the same definition as in the restriction on cadmium.</p> <p>Furthermore it is obvious that wrist-watches might be mouthed by children.</p>

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Annex XV report submitted by France 15 April 2010.
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Ref	Date Country/Org./MSCA	Comment	Response
		<p>devices (Directive 2002/95/EC RoHS). This already establishes a limit of 0.1% (w/w) in homogeneous materials for the use of lead in children and adult watches (including exceptional provisions for technical purposes).</p>	
		<p>c. More stringent limits for watches than for other electronic products/other product categories? Under the terms of the RoHS Directive, the EU legislator placed electronic watches in the category of electrical and electronic devices. It is therefore hard to understand why a limit value for lead should be applied to watches other than that imposed by the RoHS Directive to comparable technical devices such as mobile telephones or IT equipment. In our view, the risk of swallowing in the case of watches can be ruled out. The risk of mouthing activity in the case of children is also no greater for watches than for comparable electronic equipment or other products. With this respect and according to DTI (2002), one key reference cited by the SEAC background document, the number of watches mouthed by children in the frame of this study was only 6 out of 3153 objects (toys and non-toys), namely 0.2% of the total number of objects mouthed. For other product categories and which are not addressed by the restriction proposal, the figures are the following (DTI, 2002): pens, felt-tip pens and pen tops (56 items; 1.8% of total), remote controls (32 ; 1%), furniture (27 ; 0.8%) or pencils (26 ; 0.8%). By</p>	<p>It is proposed to exempt internal parts of watches.</p>

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Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Lead and its compounds**.
Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>comparison, the products most frequently mouthed by children are toys (47.2%). The restriction proposal of France concerns jewellery, which represents only 0.6% of the total number of items mouthed according to DTI. Still we understand this proposal, considering the high level of lead present in some cheap jewellery. This risk however does not occur for watches because the content of lead is already restricted to 0.1% w/w.</p>	
		<p>d. Accessibility of components containing lead At the very least, the regulatory provisions should be clarified to state that non-accessible parts and components of watches are to be excluded from the scope of application. Such components do not endanger the health of children because, firstly, the risk of mouth contact must be regarded as non-existent and, secondly a watch cannot be swallowed.</p>	<p>It is proposed to exempt internal parts of watches.</p>
		<p>3. Summary In brief, the FH submits the following request: - That watches be excluded from the scope of application of the proposed regulatory provisions. The RoHS Directive already establishes a limit for the use of lead in electronic watches and takes into consideration that watches are subject to technical constraints in order to guarantee the needed technical reliability.</p>	

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Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>- Should that request not be accepted, at the very least the non-accessible part of a watch must be excluded from the regulatory provisions. Unlike the exceptional provision defined by SEAC and the RAC for crystals, lead exposure can in fact be excluded and not only be limited in the case of the inaccessible parts of watches.</p> <p>- Furthermore and in order to keep the original properties of older watches, parts destined for the repair or maintenance of used watches should also be excluded from the regulatory provisions.</p>	<p>This is not considered to be of major relevance if internal parts of wrist-watches are exempted.</p>
39	2011/05/25 France / Industry or trade association	<p>Submission to the Socio-Economic Analysis and Risk Assessment Committee (SEAC) of the European Chemicals Agency (ECHA) produced by The National Jewellery-making, Gold Jewellery-making and Silversmiths, Gift Makers and Decorative Arts Industries Trade Association (BOCI) The Federation of Handmade and Mixed Crystal and Glass-making Industries (FCVMM) French Watchmaking Federation (FH) The French Association of Watchmaking and Microtechnology (CFHM) The French Union of Professional Enamellers (SPEF) &amp; The Saint-Eloi Association with the support of Cetehor, Technical Department of the Franc�clat Committee Within the scope of the report presented by France to</p>	

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EC number: **231-100-4**

Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing
restriction on **Lead and its compounds**.
Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>the European Chemical Agency (ECHA) regarding a proposal to restrict the use of lead and its compounds in jewellery-making, two submissions were made on this restriction project by the National Jewellery-making, Gold Jewellery-making and Silversmiths, Gift Makers and Decorative Arts Industries Trade Association (BOCI) and the Federation of Handmade and Mixed Crystal and Glass-making (FCVMM) with the support of Cetehor, Technical Department of the Franc�clat Committee (Professional Committee of Development of Watchmaking, Jewellery-making, Fine jewellery, Gold and Silversmiths and Fine Tableware). The same representatives from the French jewellery-making and crystal glass-making network, together with the French Watchmaking Federation (FH), the French Association of Watchmaking and Microtechnology (CFHM), The French Union of Professional Enamellers (SPEF) and the Saint-Eloi Association, a professional organisation of jewellery distribution networks in France, present here a new submission, this time within the scope of the SEAC's preliminary consultation of opinion in order to offer additional proposals and to supply new data on the approaches under consideration.</p> <p>Within four separate contributions, we will cover in turn the specific aspects relating to the various trades:</p> <ul style="list-style-type: none"> - I. The watchmaking sector - II. Metal alloys - III. Crystal glass 	

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 EC number: **231-100-4**

Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Lead and its compounds**.
 Annex XV report submitted by France 15 April 2010.
 Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		- IV. Enamel	
		<p><u>I. The watchmaking sector</u> 1) Observations on procedure The watchmaking sector professionals would like to draw attention to the fact that the initial restriction study was focussed on jewellery and fine jewellery-making. It relied on the assumption that young children were likely to be in contact with these items containing lead and therefore risked ingesting or placing them into the mouth.</p>	<p>The reason to include wrist-watches was to use the definition of jewellery as laid down in the restriction on cadmium. Furthermore such items might be mouthed by children, so exposure exists.</p>
		<p>For the same reasons as jewellery and fine jewellery items, wristwatches are now targeted by the SEAC's preliminary report and are included in this restriction proposal. It is particularly unfortunate that a complete business sector in no way comparable with the jewellery sector as originally designated, namely watchmaking, should be involved once the consultation phase has finished. Professional representatives from the watchmaking sector had not been able to comment during the public consultation phase, whilst the problems of the jewellery-making industry do not apply to watchmaking.</p>	<p>The consultation procedure for this change is the present consultation.</p>

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 EC number: **231-100-4**

Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing
 restriction on **Lead and its compounds**.
 Annex XV report submitted by France 15 April 2010.
 Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>2) Observations on the use of lead in watchmaking Watch movements use metal components made from brass which currently contain lead because of performance requirements during machining (use of machining brass containing less than 4% lead). Lead is used for technical reasons, mainly in terms of machining, for uses such as fixing plates, and only the use of lead allows for both production tools and the functional quality of the watch to be preserved. At the current time substitute materials cannot completely replace the technical properties of lead.</p>	<p>As a result of the comment it is now proposed to exclude internal parts of watches, as no exposure to children is likely and it seems that no practical reasons is against exclusion.</p>
		<p>Quartz watches are already subject to regulation which limits the amount of lead in the copper alloys (including brass) to 4%. Imposing this restriction would be incompatible with the RoHS regulation (n°2002/95/CE) and would present a real legal uncertainty for businesses which have made sufficient efforts to bring their industrial procedures into compliance with this ruling. Additionally, the items concerned are found, in almost all cases, inside a water-tight casing, and so there is no contact with the environment. Only professionals have access to these pieces during machining or after-sales service. The risks of ingestion or contact with the mouth are therefore nonexistent.</p>	

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 Annex XV report submitted by France 15 April 2010.
 Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>Watchmaking professionals do not therefore wish to be included in this report. On one the hand the risks of ingestion of or sucking on a watch component containing lead are very low. On the other hand, widening the scope of the restriction project to include watchmaking only occurred at the time of the SEAC's preliminary report, and therefore professional representatives of watchmaking were not able to take part in the procedure's initial consultations, and consequently were not able to put forward their case as fairly as the other sectors involved. Moreover, another European regulation already limits the content of lead in quartz watches.</p>	
41		<p><u>Metal alloys</u> 1) Using the rate of lead transference as a reference if the lead content does not conform Machining brass alloys are alloys used in the scope of manufacturing using jewellery and watch component machining techniques. This machining brass contains lead at a level of less than 4%. The lead is used as lubricant during machining, making the process easier. Studies have been carried out to try to substitute lead in these alloys, but without success. This approach was initiated by the watchmaking sector when the European directive RoHS (n°2002/95/CE) was implemented which aims to limit the use of six harmful substances including lead in electrical and</p>	<p>In the Background Document, section C.7 substitute alloys are identified. Also on the internet it is possible to find machining brass without lead. The comment on machining brass is not documented as well as the use of brass in jewellery (taken into account that the use of brass in internal parts of watches is proposed to be exempted anyway).</p>

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Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>electronic equipment. Quartz watches fall within the remit of this directive. As no substitute product is available, copper alloys (including machining brass) containing less than 4% lead have been exempted from the scope of this directive.</p>	
		<p>The same problem exists within the project to restrict lead in jewellery. In fact, at the current time, there is still no substitute product for machining brass. As regards the potential risk, the brass parts are often covered with a metal coating. This coating is made up of multiple layers of different materials such as copper and bronze. A final layer of a precious metal (gold or silver) or even palladium or rhodium completes the surface treatment. The successive layers which are added in this way guarantee an adequate protection to prevent lead transference.</p>	<p>Considerations on exposure (RAC issue) is covered in the Background Document.</p>
		<p>2) Application of a maximum transference level consistent with current regulations with similar aims The proposed maximum authorised transference level in the preliminary notice is set at 0.05 µg/g/hr, and appears to be an extremely low level according to professionals' opinion. On the one hand, this is due to the detection limits possible with measuring equipment. As was illustrated in the second report submitted by us in December 2010 to the European Chemicals Agency during the consultation process, several accredited laboratories encountered problems reaching the degrees of precision which would allow them to determine</p>	<p>Relevant test methods including screening methods are available.</p>

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Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing
 restriction on **Lead and its compounds**.
 Annex XV report submitted by France 15 April 2010.
 Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>whether an item of jewellery met the level required or not, as it was proposed, at a such low level.</p>	
		<p>On the other hand, the level selected is clearly more restrictive than that which is imposed for lead transference in other current consumer products, equally or perhaps even more likely to be accessible to children, and in particular very young children. Thus, toys or components of toys which are accessible during use in the conditions outlined in article 3 of the law of 22 February 2010, within the scope of Standard NF EN 71-3, must not exceed certain transference levels for different chemical elements. As it happens, concerning raw materials in toys which are judged to be dry, crumbly, powdery or soft - something to which we can compare the materials used in jewellery-making – the limit for lead transference is set at 13.5 µg/g that is a value 135 times higher than that of the proposed level for jewellery-making.</p>	<p>RAC issue not to be dealt with by SEAC. SEAC proposes content based approach (which is not covered by EN 71-3).</p>
		<p>3) Socio-economic impact In 2010, the fashion jewellery sector – which is the part of the jewellery industry that is the most concerned with the restriction project – counted about 2,000 employees within 745 companies and a turnover excluding VAT superior to 170 million €. Most of the companies are small and medium size ones and 66% of them have less than 20 employees.</p>	

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Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>The major part of these manufacturers – about 70% of them – uses metal alloys included in the restriction project. Consequently, given that there are no replacement materials, that it would imply substantial additional costs and that targeted companies are small ones, accepting as is the proposed regulation would threaten the entire fashion jewellery field, which seems out of proportion with its assumed health impact.</p>	<p>Alloys with lead content below 0.05% are available on the market.</p>
		<p>The possibility of relying on the rate of transference if the requirement relating to content is not met would allow the industry to continue to use certain important alloys, such as the machining brass which at the current time is impossible to substitute. In addition, measuring the rate of transference would respect the stated aim of the restriction project that is to protect children from exposure to lead through sucking an item of jewellery containing lead. Industry professionals would therefore prefer that the possibility of being able to refer to a transference rate expressed in µg/g/hr be maintained, one of the two units of measurement being proposed, still allowing completely safe use by the consumer. However, the proposed maximum level of transferred lead seems to be extremely low. It is difficult to detect by current laboratory measuring equipment and seems to be a great deal more restrictive than the levels set for lead transference in other widely used products, as is reflected in toys where it is as high as 13.5 µg/g</p>	<p>A restriction based on content is easy to implement and in the Background Document the relationship between migration and content is described.</p>

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Annex XV report submitted by France 15 April 2010.
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Ref	Date Country/Org./MSCA	Comment	Response
		compared with 0.05 µg/g/hr for the level proposed for jewellery. Industry professionals would therefore like to see the proposed level revised upwards, out of a concern for both the technical feasibility of measuring it and to remain consistent with other products.	
40		<p><u>Crystal glass: Dispensation for crystal parts in adults' and children's jewellery</u></p> <p>1) Technical limit</p> <p>It is not technically possible to replace lead in lead crystal: Standard NF 30004 Crystal recognises the only crystal containing 24% lead. It is only this lead content which allows the piece to obtain a refraction index of 1.545. Also, at the current time, we do not have the technical knowledge to replace the lead, which only leads us to one viable solution.</p> <p>The FCVMM considers the exemption of Crystal as the only alternative to the restriction on the amount of lead contained in jewellery. In fact, being by definition 24% lead, an exemption seems to be the alternative to pure and simple banning of the production of Crystal jewellery. According to the same option, an exemption would be considered for jewellery with a low rate of transference. Now it has already been shown that lead transference from Crystal is very low, and the repeated sucking of an item of jewellery made from Crystal would not therefore have any impact on a child's health.</p>	Information from a company shows that lead free crystal glass complies with the quality standards laid down in Council Directive 69/493/EEC and ISO IWA08 (see comment 33).

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Ref	Date Country/Org./MSCA	Comment	Response
		<p>2) Financial Impact From a financial point of view, if a ban on jewellery manufacturing was considered, the impact would not be insignificant, given that the three largest French manufacturers make or plan to make jewellery, up to a level of 30% of their turnover. Such a restriction without an exemption clause for crystal would certainly lead in practice to the end of jewellery-making by these manufacturers. Consequently, the cost that the crystal-manufacturing network would have to bear seems disproportionate compared with almost nonexistent health impact of crystal in jewellery.</p>	
		<p>3) Social Impact From a social point of view, because of the remoteness of the manufacturers, mainly in the eastern region of France, where the employment level is already experiencing some real difficulties, the end of production linked to jewellery-making would have undeniable consequences for jobs in the region and on the renewed energy that has been apparent recently: by way of an example, the town of Baccarat has created the "Pôle Bijou" (Jewellery Centre) and regularly organises exhibitions and events concerned with jewellery. Baccarat's manufacturing and crystal play a central role in this.</p>	

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Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>4) Crystal jewellery: a structured market The crystal jewellery market is a more structured and fragmented market, with smaller expansion than that of fashion jewellery. Crystal jewellery is much more traceable, given that there are very few factories still producing it today. They cannot be produced in an isolated manner, and sales are carried out with monitored networks. The characteristics of the crystal market therefore make identification and monitoring of products relatively easy.</p>	
		<p>General Conclusion Professionals from the different industry sectors involved have put forward several arguments which they feel are essential in this submission and which lead to different proposals, namely:</p>	
		<ul style="list-style-type: none"> - The non-inclusion of the watchmaking sector in the scope of this restriction project, taking into account: <ul style="list-style-type: none"> o the late inclusion of this profession in the list of noted trades o of the existence of the RoHS Standard whose coexistence with a new regulation would cause judicial insecurity o the very limited risks of ingestion or sucking presented by "wristwatch" components which may contain lead 	

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Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p><u>Concerning metal alloys:</u></p> <ul style="list-style-type: none"> o Maintaining, in addition to the first criterion of lead content, the second subsidiary criterion giving the possibility of having recourse to a transference rate expressed in µg/g/hr to judge whether a product conforms or not with the new legislation o The reconsideration of the extremely low level proposed of 0.05 µg/g/hr here, whereas the regulation for toys determines a maximum transference level of lead of 13.5 µg/g 	
		<ul style="list-style-type: none"> - For crystal: <ul style="list-style-type: none"> o Maintaining the proposed exemption, which is indispensable taking into account the very definition of this product o The possibility of referring to transference rates in µg/g/hr if the regulation relating to the content is not met. 	
		<ul style="list-style-type: none"> - In the case of enamel: <ul style="list-style-type: none"> o The possibility of an exemption similar to that of crystal, given that enamel is a straight line derivative of crystal, which would allow industry professionals to have a longer time period in order to undertake research on a lead-free enamel. o The potential setting up of a compulsory information label for customers on the presence of lead and the necessity of keeping the item out of 	<p>An exemption for vitreous enamels is proposed. Regulation¹ related to mixtures (such as enamels) will lead to renewed hazard reviews by 1 June 2015 which will allow the health impacts to be evaluated. This may result in re-evaluation of the derogation for enamels.</p> <p>For the same reasons that labelling was discounted as a possible risk management option for lead containing jewellery more generally (section E.1.3 of the Background Document), SEAC did not consider it</p>

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 Annex XV report submitted by France 15 April 2010.
 Public consultation on SEAC draft opinion started on 29 March 2011.

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		<p>children's reach</p> <ul style="list-style-type: none"> o Account being taken of the artisanal and historical character of this knowledge, which would be irretrievably destroyed if a drastic limitation on the use of lead in its composition was to be imposed. 	to be justified in the cases of derogated jewellery articles either.
42		<p><u>Enamel part 1</u></p> <p>1) Enamel Materials: crystal materials Enamel is a type of glass whose chemical composition and method of production are very close to those of crystal. This very old material does not benefit from any current standard as its chemical composition is down to use and history.</p> <p>a. Composition The glass obtained after mixing the constituent parts of enamel is called sintered glass and is not usable as it is. It must be mixed with other constituents, and then be melted again in order to give its final colouring. This coloured product has to be ground, then milled and calibrated in order to obtain the final enamel. The sintered glass remains fundamentally a crystal material.</p> <p>b. Enamel and public health The profession has never been the subject of complaints relating to lead poisoning. The city of Limoges, in France, where enamellers have worked their craft on metal since the 11th Century has never</p>	

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 restriction on **Lead and its compounds**.
 Annex XV report submitted by France 15 April 2010.
 Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
		<p>been made aware of a case of lead poisoning due to an enamelled product. There is never such a thing as a zero risk, but this example highlights the low risk that enamel represents in lead poisoning compared with other products. [See also the French INVS (Institute of Health Monitoring) report on lead poisoning].</p>	
		<p>2) Enamel, a historic material The art of enamelling was brought to a high degree of perfection by the Egyptians and various Asian cultures. According to archaeological discoveries, it appears that the oldest enamels date from around 1500 years BC. The ancient Greeks used coloured pastes melted into partitions. Enamelling saw a huge expansion in Europe during the last two centuries BC. During the Middle Ages and in the Renaissance there was more growth, notably in work with translucent enamels, in Italy, France, Germany and the Netherlands. In the 19th Century the Art of Enamelling had a renaissance. In Paris, enamel was favoured in Parisian Decorative Arts. Certain artists (Picasso or George Braque, for example) continued to use enamel into the 20th Century in unique works of art.</p>	<p>SEAC acknowledge that enamels have a history and are not a negligible sector.</p>

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Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing
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 Annex XV report submitted by France 15 April 2010.
 Public consultation on SEAC draft opinion started on 29 March 2011.

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		<p>3) Enamelling and Jewellery today</p> <p>a. Costly raw materials in a buoyant market</p> <p>A piece of enamelled jewellery, whether it is “fashion”, “fine jewellery” or “luxury jewellery” will always be a top of the range piece, in each of the sectors noted, because of the cost of the raw materials.</p> <p>The enamel powders and metal bases (red copper, silver and gold) represent a high proportion of the final price of the item.</p> <p>Artisan enamellers working with metal get the majority of their income from the sale of jewellery.</p> <p>95% of Studios operate thanks to sales of jewellery, of which:</p> <ul style="list-style-type: none"> -85% of enamellers work on fine jewellery pieces -5% of enamellers work on luxury jewellery items -10% of enamellers work on top of the range fashion jewellery. 	

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		<p>b. An artisanal activity with high added value The European enamelling industry remains an artisanal activity, worked by hand, with high added value and small production volumes. In Europe, a handful of studios are the last to be holders of a unique knowledge, that is to say, that mastery of these techniques is known only to them. In certain countries these studios have the benefit of State quality labels or marks and State assistance to safeguard this knowledge. Some of these studios have even been interviewed by UNESCO's Intangible Cultural Heritage department.</p> <p>c. Export: a showcase for European knowledge abroad These enamelling studios hold special knowledge which is renowned and appreciated in Europe and abroad. The main export destinations, namely in the scope of jewellery and luxury goods are Asiatic countries, themselves known for enamel-work (e.g. Chinese and Japanese cloisonné work). This art is known there and they favour our products. European enamelling work techniques are recognised there and appreciated as luxury items.</p>	

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		4) Enamelling in Europe This panorama which looks at enamel work in Europe, whilst not exhaustive, allows us to highlight the European and also very local, almost neighbourhood dimension of artisan businesses living on enamel production and use.	
		a. France - There are between 150 and 200 professional enamellers in France - 5 Enamel studios have the EPV label (Living Heritage Business, a State awarded label) - 1 Crystal works (EPV label) making enamel powders, which employs 10 people. - 2 Enamel Offices (in Limoges and Moretz) which employ staff. - 1 State training course “Enamelwork on metal” - 1 Professional association - 1 Legal Statute protecting the “enamel” product (decree N°82-223) - Numerous galleries and sales outlets which make most of their income from jewellery sales. - Numerous associations and events connected with enamelling.	

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		<p>b. United Kingdom</p> <ul style="list-style-type: none"> - There are around 80 professional enamel-workers - 1 Crystal works (the largest in Europe) with staff. - Numerous galleries and sales outlets <p>c. Spain</p> <ul style="list-style-type: none"> - There are around 100 professional enamel-workers mainly in the Fine Jewellery field. - 1 School of Enamelling in Barcelona. - Numerous galleries and sales outlets <p>d. Germany</p> <ul style="list-style-type: none"> - In Germany the enamel furnaces and all the furnace equipment are manufactured. - There are enamel studios, notably the ancient house of Fabergé, which all continue to create enamelled pieces. - Numerous galleries and sales outlets 	
44		<p><u>Enamel part 2</u></p> <p>5) What are the solutions?</p> <p>a. The risks associated with this decision Enamel-work made in European crystal factories is mainly produced for an increasingly demanding luxury industry. Transferring too quickly from one group of products to another which would no longer give the same satisfaction would have immediate, irreversible and harmful repercussions in relation to</p>	The terminology enamels is also used for some resin materials.

¹ Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH), Article 62.

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		<p>enamel manufacturers and all of the associated sub-contracting chain [jewellery maker, raw material suppliers, equipment (e.g. furnace) manufacturer, etc.]</p>	
		<p>b. Enamel without lead Research on enamel without lead has been ongoing for several years. However, the range developed is very limited in terms of colour palette, and above all these lead-free enamels do not have the required quality to be able to work correctly. In fact, test pieces carried out with lead-free enamel have, in several studios, been rejected by clients, as the finished result is dull with a plastic appearance. Moreover, with the melting point for the colours being so different, it is impossible to work with several colours at the same time because of the risk of "burning" some of them.</p>	
		<p>Conclusion on enamel The enamel-making profession is very conscious of the need to move towards solutions leading to the desired outcome of a removal of lead, but to achieve this it will take both time and public funds to support a continued research initiative. In addition, the crystal glass sector, a material very closely linked with enamel, currently has an exemption for applying the restriction with regard to lead. According to the different technical elements shown, it would appear judicious to look at the case of enamel in the same light as that of crystal. The European crystal</p>	

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		<p>manufacturers have moreover already started researches a few years ago to remove heavy metals from their enamel powders. However, this is very costly for a very restricted sector, and currently industry professionals do not have an alternative solution which would allow them to work at the same high quality or even approaching it.</p>	
		<p>The studies associated with the removal of heavy metals are expensive in both human and financial terms and are difficult for small and medium-sized businesses such as the crystal glass works to undertake. For this reason progress towards enamel free from heavy metals can only be attained within a timeframe of approximately ten years. While waiting for acceptable solutions to be found the industry would like:</p>	
		<p>a. That European enamellers can continue to live from their trade without the risk of seeing their jobs and techniques disappear. The whole of the "enamel" network is above all a network of artisans and independent workers with unique and handed-down knowledge. Because of this it is difficult to be able to estimate exactly what the socio-economic consequences would be, brought about by the restriction of lead in jewellery manufacturing...but we can estimate that thousands of artisans and employees would be greatly affected in Europe.</p>	

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		<p>b. To study the possibility of information labels for the customer concerning the presence of lead in the jewellery piece, and prohibiting it for children of less than 3 years, this being the main aim of this restriction project.</p>	
		<p>c. To benefit from a straight line exemption from crystal of which enamel is a close derivative, in order to have the benefit of the long timeframe necessary for the development of a solution without heavy metals. A research group bringing together manufacturers, sub-contractors, engineers/researchers and professionals from the sectors such as crystal glass-making would therefore be created. This group would have as its mission research into applicable solutions so as to limit the transference of lead from enamel.</p>	<p>This is appreciated. SEAC recommends in its opinion further evaluation of health impacts and if relevant to consider the socio-economic consequences of changing the derogations for lead crystal and/or vitreous enamel.</p>
		<p>Secretarial note: The ECHA Secretariat contacted the submitter of the comment to obtain further data on the enamel jewellery market segment, content and role of lead in enamel, migration of lead from enamel jewellery, alternatives to the enamel in the enamel jewellery, applications of leaded and lead-free enamels, proposal for an appropriate definition of enamels and for appropriate derogation. Two responses were received (each from Industry or trade association). The submitter of the comment in his first response confirmed that the question is of a niche sector, the</p>	

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		<p>content of lead in enamels was claimed to be between 24 and 26% and informed that the French laboratory for the jewelry sector had tested the lead migration from some enamel products with the results of between 63 and 454 µg/cm²/hr. However, the tests were not made available to ECHA as the values were being rechecked due to a suspicion that a mistake happened during the test of enamel jewelry. The submitter however provided results of another test that was carried out according to the Standards ISO 6486/1 & 2 and ISO 7086/1.</p> <p>The test is performed on a copper plate (6cm * 6cm) enameled both sides = the pieces. After 24 h in a 4% solution, we detected 9.72 mg/dm² equivalent to 0.0972 mg/cm² or sent back to the standard of 4.05 µg/cm²/hour.</p> <p>The submitter of the comment claimed there were no technical lead-free alternatives to traditional leaded enamel for some colours and for other colours the aesthetic qualities were very different.</p> <p>In another response, the submitter provided information on the production process and enamel properties that imply inertness and durability of enamel. The submitter informed of an ongoing R&D programme to sell enamels without heavy metals and that consider the marketing of this whole new range is considered for 2016-2017. According to information gathered from enamellers, about 20% of the</p>	

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		<p>production remains in stock every year. About 70% of jewelry in this production is sold in the EU and 30% is sold in export markets. Sales were claimed to remain generally local. Imports were said to be difficult to assess, however foreign enameled jewelry is very rarely seen. The material "enamel", crystalline material which is only worked on pure metals (red copper, sterling silver and first quality gold), was said to have a cost of production which remains unattractive for wholesale jewelry manufacturers/producers. Three drawbacks were listed in connection with the use of lead-free enamels, namely poor colour palette, different fusibility from one colour to another and a dull colour. The definition of enamel used in the French Decree Law (Décret n°82-223 du 25 février 1982) was suggested to be used in the opinion and solutions for the potential derogations were proposed.</p> <p>The ECHA Secretariat contacted the submitter of the comment also to clarify the availability of lead-free crystals on the market. The submitter of the comment in his response claimed that even if the formulations of so-called lead-free crystal respect the criteria which qualify the product "crystal glass" (with the density and refractive index), other representative parameters differ and bring difficulties which couldn't be resolved until now. These are:</p> <p>1/ A difference regarding the optical properties The use of lead raises the dispersion characterized by</p>	

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		<p>the number of Abbe. For a given refractive index, the presence of lead decreases a lot the number of Abbe and so increase the dispersion. This chromatic aberration comes from the decomposition of light in several color stripes which make the visual perception of lead crystal.</p> <p>2/ Difficulties with Coloured Crystal Some colours got with lead crystal couldn't be exactly duplicated, including the famous ruby colour got by the incorporation of gold. This ruby colour got with this precious element (gold) is different from other red colours and is particularly linked to the premium product made of lead crystal.</p> <p>At last, the redox state of lead crystal enable to get some specific colours by adding multivalent elements.</p> <p>3/ Fabrication of lead crystal in respect of the official Standard for the European Community.</p> <p>The Standard for the European Community 69/493/EEC defines precisely the categories of "crystal glass" and the French factories produce under the name "Crystal" only products from categories 1 and 2, which means with lead. Lead in Crystal (Category 1&2, i. e. "full lead crystal" and "lead crystal") has 1 major benefits for jewellery: it facilitates cutting and polishing cold, which is major</p>	

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		for rings for instance.	
43	2011/05/25 France / Industry or trade association	Identical with comment Ref.39.	Identical with response Ref.39.
38	2011/05/25 10:53 Germany / Industry or trade association	<p>The Association of Gablonz Industries fully supports a restriction of the use of lead and lead compounds in jewellery in order to protect consumers. We further agree that EU-wide limits are the appropriate protective measure, as they support competition on a clearly defined and harmonised basis.</p> <p>Therefore we welcome the draft opinions of SEAC and RAC as an improvement on the original French proposal. The industry's main concerns have been acknowledged and, at least in part, influenced the committees' opinion.</p>	
		<p>We particularly welcome that:</p> <ul style="list-style-type: none"> • the commission acknowledges the difficulty of isolating parts of jewellery for migration testing and the need to adjust and simplify testing methods. • the measurement unit is based on weight rather than surface. • the maximum lead content in jewellery is to be adjusted. • the implementation period is to be extended. 	

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		<p>Generally, the adjustments make the restriction of lead in jewellery at least technically, and thus theoretically, feasible. However, we are concerned that it will have far-reaching implications for the competitiveness of the market, down to jeopardising the existence of many companies. Therefore we request that the following suggestions be considered and certain elements be adjusted or more clearly specified:</p>	
		<p>1. The changeover from the materials currently used in the industry to those that are lead-free as defined by the regulation will involve a considerable increase in costs. So-called lead-free tin alloys, to mention just one product, are significantly more expensive than the alloys currently used.</p>	<p>Evidence given in the Dossier suggests that increase in price related to the use of lead free alloys is not disproportionate. In any case price of lead alloys has also increased by similar magnitude. There has been a general rise in prices of all raw materials, and this is not restricted to lead-free alternatives.</p>
		<p>To illustrate the implications for the industry, the following list shows the development of the price of pure tin at the London Metal Exchange (LME): EUR/to (month/year): 8.925,61 (04/09), 10.448,96 (08/09), 10.662,32 (12/09), 13.967,42 (04/10) Other key components of alloys are silver and antimony. Since 2008, the price of antimony, present in tin alloys in a proportion of between 1 % and 10 %, has more than trebled. Silver, which constitutes up to 2 %, will make alloys even more expensive.</p>	

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Ref	Date Country/Org./MSCA	Comment	Response
		<p>Lead-free casting metals have different working properties. The use of these metals will result in a further rise in costs. Casting moulds will deteriorate much faster or have to be replaced from the start by moulds made of other, more expensive, materials. Also, production steps will have to be re-organised and carefully separated. The slightest contamination, such as might be caused by the use of the same tools or equipment for lead-free materials and those containing lead (as defined by the regulation), would lead to non-compliance.</p>	<p>Increase in costs arising from such changes in working practice were taken into account within the sensitivity analysis developed in the SEA analysis of the dossier. This indicated that costs were not disproportionate.</p>
		<p>Moreover, the alternative materials do not meet all of the quality demands placed on them by the consumer. Adjustments to the composition of alloys, for example, will affect the quality of the surface. Also, the accustomed filigree quality will not always be able to be achieved, and there will be considerable changes to the malleability and stability of the pieces. In our experience, such issues meet with adverse reactions on the part of customers. For this reason we are – to put it mildly – unconvinced as to whether the markets will accept this change in the products, particularly since they will be accompanied by a rise in prices. Considering these issues, we would like to suggest the following: In introducing a restriction of the lead content in jewellery, it will be necessary to give both markets and manufacturers a chance to assess all the implications and accept the consequences of the new</p>	<p>There would appear to be at least some evidence that lead-free jewellery is widely available and accepted by consumers. Evidence to the contrary has not been offered during the public consultation.</p>

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		regulation. We suggest an initial maximum lead content content of 0.1 % after an implementation period of three years.	
		<p>2. The ECHA committees recommend delaying implementation by 12 to 18 months. Jewellery produced 50 years or more before the date mentioned in the restriction is to be exempted.</p> <p>This recommendation is a considerable improvement on the original proposal, however we consider the implementation period to be far too short. The rate of stock turnover of finished jewellery pieces is well in excess of one year. Furthermore, stocks of raw materials and semi-finished products would have to be considered, most of which do not comply with the new regulation. These supplies were purchased or produced with a view to the long-term. A short implementation period would mean that existing stock would neither be able to be used nor to be sold, rendering it virtually worthless.</p>	
		<p>For these and other organisational reasons relating to the complex interwoven structure of the German fashion jewellery industry, the companies will require a considerably longer implementation period to adjust to the new legislation. We consider a period of three years to be feasible. The sale of non-compliant jewellery products and components manufactured before the commencement of the restriction should be permitted. Existing stock sold after this period might be labelled accordingly.</p>	

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 Annex XV report submitted by France 15 April 2010.
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		<p>3. We also request that certain elements in the draft opinion be more clearly defined, in order to allow for a successful and workable implementation by the industry, coherence with other EU legislation and a high level of protection for consumers. We therefore recommend that the final version of the legislation should ensure that testing is carried out on the entire piece, including the plating. Additionally, the term “wet test” should be defined in more detail.</p>	
		<p>4. Finally, the question remains: how rigorously will imported goods be controlled with regard to compliance with the new legislation? Experience tells us that gaps resulting from a failure to enforce stringent controls will be exploited, putting European manufacturers of fashion jewellery at a distinct disadvantage. We would appreciate it if you would include our concerns and suggestions in the decision-making process for the EU-wide legislation on lead in jewellery. We are convinced that they will not be to the detriment of the consumer.</p>	
36	2011/05/24 United Kingdom / Individual	<p>While I understand the worry over children consuming lead in any manner, it is absurd to restrict fine enamel jewellery in this sweeping proposal. You are trying to remove a small problem by removing everything in a single gesture. The work of Fabrice, Lalique and Cartier would not be permitted under your crazy rules. As a fine enamel jewellery maker (working in Gold and Silver) I object most strongly to</p>	<p>It is proposed to introduce an unlimited exemption for vitreous enamels.</p>

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Ref	Date Country/Org./MSCA	Comment	Response
		this proposal and wonder if it can even be implimented to exclude the small problem for children - without also removing fine works of art in it's wake.	
35	2011/05/24 Germany / MemberState	Comments on behalf of the German CA: 1. We do not support the derogation for "Full Lead Crystal" and "Lead Crystal", because migration rates above the determined critical level of 0.05 µg/cm ² /hr cannot be ruled out. According to the draft SEAC opinion information of lead in crystal was submitted in the public consultation. Migration of lead from crystal was reported in a magnitude of 0.082 µg lead/cm ² /hr and 0.216 µg lead/cm ² /hr. It is stated SEAC has no information whether or not these may be typical migration rates. Therefore, we recommend to base the restriction on total content of lead as well as on migration rate as proposed by RAC.	An exemption on lead crystals is proposed also in the final opinion of SEAC as evidence of a significant health impact of lead exposure from mouthing or ingestion of crystals has not been presented. SEAC has no information on whether or not the migration rates quoted from the tests on two specific items may be typical migration rates.

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		<p>2. We already commented in the RAC process that the wording of the restriction has to be changed in order to clarify unambiguously that the lead content has to be measured in coating material as well as in the subjacent material. This problem persists with the text proposed by SEAC. We doubt that it occurs to the enforcement authorities – who face the restriction text, but not the background document – to scratch off the coating and analyze the subjacent material, especially, since everyone is happy to have a non-destructive method of analysis (XRF). Anyone, who is not intimately familiar with the issue of lead in jewellery, will probably assume that the problem is associated with the uptake of lead via the skin or abrasion and maybe subsequent ingestion. It needs a certain degree of imagination to think of a child chewing off the coating of a piece of jewel and sucking on the material underneath.</p> <p>Therefore, we herewith like to repeat our proposal to change the restriction text. RAC declared that it is not responsible for sampling and sample preparation. Who is responsible? And who ensures that this person is informed accordingly? Does SEAC recommend to analyze the material underneath the coating? Or are there cost-benefit reasons that prevent SEAC from recommending this kind of analysis?</p>	<p>Further Guidance is not relevant for the SEAC opinion. Whether it is relevant to analyse the material underneath the coating or not depends on the specific jewellery and the control systems established through the supply chain.</p>

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		<p>3. The derogation for jewellery articles more than 50 years old is not enforceable, neither for cadmium nor for lead. Usually, the jewellery articles are not labelled with the date of manufacture and it will hardly be possible for the enforcement authorities to prove that an article is younger than 50 years.</p> <p>4. We appreciate that SEAC proposes a definition of the term jewellery. However, we would like to extend this definition on the grounds of case reports cited in the background document. It should be ensured that the definition does not only comprise necklaces, bracelets, chains, anklets, finger rings, earrings and other body piercing jewels, but also, e.g.,</p> <ul style="list-style-type: none"> • pendants, e.g., for cell phones, zippers, keys, shoes, bags, pencils etc. (used, e.g., for promotion purposes), • any ornaments, buttons, rivet buttons, tighteners, fasteners etc., when these are used in garments and might be subject to mouthing. <p>Up to now, we do not see that the definition includes these applications. There is a high risk that these kinds of articles are made of cheap material and, therefore, there is a high risk of a high lead content. In addition respective cases have been described in literature. Therefore, we propose to extend the definition, although, it differs from the wording in the cadmium restriction.</p>	<p>Actually this exemption clause is only relevant for imported jewellery as jewellery placed on the market before the end of the transitional period is exempted anyway. In real life this is up to the enforcement authorities to enforce. This will be done in relation to the circumstances of which the jewellery is sold.</p> <p>It is not possible for SEAC to propose extensions of the scope.</p> <p>The list of objects mentioned in the opinion is a non exhaustive list. Cufflinks is given as an example of jewellery. SEAC Considers that some tighteners, fasteners can be regarded as jewellery and thereby covered by the restriction.</p>

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Annex XV report submitted by France 15 April 2010.
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		5. According to the restriction proposed by SEAC, wrist-watches will be considered jewellery articles. It should be clarified whether the maximum lead concentration will apply only to accessible parts (such as the outer casing and wristband) or also to internal mechanical or electronic parts of wrist-watches. If internal parts will be required to conform to the lead restriction, it should be assessed what impacts this will have on risk reduction and compliance costs as no such assessment appears to have been made so far for watch internals.	It is proposed to exempt internal parts of watches.
34	2011/05/20 United Kingdom / Individual	I am a self employed trained enamellist working with glass fused to precious metals. This is a highly skilled art form and has taken many years of learning to reach the distinct level I practice in. This type of enamelling is very expensive and is only practiced by a small number of specialists to make beautiful jewellery and art objects for the high end of the retail market.If we cannot sell our work because of the lead content a whole history will be destroyed and many self employed artists will be unemployed with all the consequences that will bring. This directive is too wide ranging and should not apply to this specialised area.	An exemption for vitreous enamels is proposed.

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Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Lead and its compounds**.
Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

Ref	Date Country/Org./MSCA	Comment	Response
33	2011/05/20 Austria / Company- Manufacturer	<p>We fully support a standard for lead and its compounds in jewellery in order to better protect consumers from lead exposure. We further agree that EU wide limits are the appropriate measure as they support competition on a clearly defined and harmonized basis.</p> <p>In this regard, we welcome the draft opinion by the Socio-Economic Analysis Committee (SEAC) as an improvement of the original French Government proposal. It seems that the industry's main concerns have been acknowledged by the committee and influenced the final opinion accordingly.</p> <p>In particular, we welcome that:</p> <ul style="list-style-type: none"> (a) the SEAC acknowledges the difficulty of isolating parts of jewellery for migration testing and the need to adjust and simplify testing methods; (b) the measurement unit is based on weight rather than surface; (c) the proposed restriction limit is set at a level, which is feasible for industry to measure. <p>Although, these changes have greatly improved the original proposal by the French Government, we believe that certain elements in the draft opinion should be clarified in order to allow for a successful and workable implementation by the industry, coherence with other EU legislation and a high level of protection for consumers:</p>	

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CAS number: **7439-92-1**
EC number: **231-100-4**

Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Lead and its compounds**.
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Ref	Date Country/Org./MSCA	Comment	Response
		(a) Watches should not be included in the scope of the restriction. The level of lead in watches is already regulated under the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2002/95/EC - RoHS). An overlapping regulation for watches would lead to incoherence and confusion within EU law.	Internal parts of watches are proposed to be exempted.
		(b) A derogation for full lead crystal and lead crystal is in our view not necessary as alternatives exist, which are already used by the industry. In this regard, we have developed a type of “crystal glass” (cat. 3 or 4 as defined in Annex I of 69/493/EEC Crystal Directive) with no intentionally added lead (with a lead content well below 500 ppm), that meets all optical and visual characteristics of “full lead crystal” (cat. 1 as defined in Annex I of 69/493/EEC), which was certified by the Fraunhofer Institute ISC. This crystal glass is in compliance with the proposed restriction, contributing to a higher level of consumer safety.	Thank you for the information. A number of organisations have claimed that lead free crystal glass with the required properties is not available. Even if “Crystal glass” (cat. 3 or 4 as defined in Annex I of 69/493/EEC Crystal Directive) with less than 0.01% lead, that meets all optical and visual characteristics of “full lead crystal” (cat. 1 as defined in Annex I of 69/493/EEC) as well as ISO IWA08 is available for the same price, these organisations maintain that lead increases the dispersion of light in crystal glass which influences the visual perception of lead crystal. Furthermore, it is claimed that some colours cannot be exactly duplicated. Therefore SEAC maintains the unlimited derogation for “Full Lead Crystal” and “Lead Crystal” in its opinion..
		(c) Concerning testing, we ask SEAC to clarify the following: (i) the final legislation should ensure that testing is carried out on the entire piece including the plating.	SEAC has not altered the view of RAC to base the restriction on jewellery and any parts thereof.
		(ii) XRF machines need to be carefully calibrated in order to produce reliable results. Hand-held XRF machines are difficult to calibrate and therefore often lead to uncertain results. Additionally, the term ‘wet	It is not up to SEAC to consider practical guidance on testing.

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Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing
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 Public consultation on SEAC draft opinion started on 29 March 2011.

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		test' should be defined more in detail.	
		<p><u>Secretarial note:</u> The ECHA Secretariat contacted the submitter of the comment to obtain further data on the crystals use in jewellery, to obtain information on the market of lead-free crystals (EU and imports), price difference between leaded and lead-free jewellery, and accessibility of European glass manufacturers to the lead-free crystal glass. Part of the response was claimed confidential. As regards the availability of the lead-free crystal to other companies on the market the submitter of the comment clarified that some of different glass formula for lead free glass are registered as a patent. There are at least four patents for manufacturing lead free glass with a high refractive index of >1,545. One of these patents has expired and can be considered as state of the art. Two other patents have currently expired in various EU member states and one of them will expire completely by February 2012. Thus, small companies should be able to produce lead free crystal glass with a high refractive index of >1.545 without violating patents.</p>	

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Ref	Date Country/Org./MSCA	Comment	Response
32	2011/05/20 Spain / Industry or trade association	DRAFT OPINION 1) We agree with the restriction criteria established by the SEAC to limit Pb content to quantities not exceeding 0.05 % by mass in any part of a jewellery article	
		2) We takes that the criterion of “any part” ought to be much more concise, establishing the biunique correspondence that exists between “jewellery article part” and “homogeneous material”	In a footnote to the proposed restriction it is specified that “Any part” includes the materials from which jewellery is made, as well as the individual components.
		3) We believe that the criterion is defined very accurately in our document (http://observatorio.aimme.es/proyectos/ficha.asp?id=10199), Annex I, page 45	Our understanding is that any parts include homogenous material as defined in the cited document: Uniformly composed material in all parts. Therefore it cannot be separated from other different materials by mechanical means.
		4) When semiprecious stones (code CN 7103) are excluded, the fact that natural stones and not artificial ones are being referred to must be specified. The artificial stones are included in CN 7104	This is done by specifying that the exemption does only apply to non synthetic or reconstructed precious and semiprecious stones.
		5) It must be made clear that the restrictions also affect artificial pearls	Unnecessary as pearls are not mentioned in the jewellery exempted in the proposed restriction.

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		<p>JUSTIFICATION FOR THE OPINION OF SEAC</p> <p>A) INTRODUCTION</p> <p>The Pb-release criterion given by the RAC (0.05 µg/g/hr) is confusing. The key question is: Per gram of what?</p> <p>If, like the SEAC, it has indicated that it is ‘per gram of any part’, our view is that it is very important that the established criterion are fully clarified:</p> <p>a) ‘Per gram of metal’ is an unacceptable proposal</p> <p>b) ‘Per gram of alloy’ would be an acceptable proposal, but if applied to Definition 3.41 of the REACH regulation</p> <p>c) ‘Per gram of homogeneous material’ is the most acceptable proposal because it distinguishes between the various parts that can make up a jewel</p> <ul style="list-style-type: none"> - Base alloy - Solder - Coatings - Decorative parts <p>Other EU legislations aimed at restricting certain hazardous substances, such as the RoHS Directive, set out the same considerations: ‘FAQs on RoHS and WEEE Directives’</p> <p>In the case of coatings, Pb can be found:</p> <ul style="list-style-type: none"> - As part of an intermediate coating within a sequence of coatings: white bronze alloy (Sn-Cu-Zn-Pb) used as an alternative to Ni - As an external solderable coating: Sn-Pb or Sn-Pb-Cu alloys 	<p>It is considered to be per gram of homogenous material, either as alloy or any other part.</p>

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		<p>- Forming part of the enamels or the varnishes and paints (pigments and drying agents) As for the non-existence of a testing method to simulate the migration conditions for Pb in contact with the saliva, this statement is not accurate, because there is an EN standard that does replicate it: EN-ISO 10271 “Dental metallic materials. Corrosion test methods (Static immersion method)”</p>	
		<p>We consider that this test’s conditions are much more representative than those established by EN 71-3 for toys</p>	<p>Not up to SEAC to consider.</p>
		<p>B) SCOPE We agree with the SEAC analysis on the Canadian legislation. However, we believe that this analysis suffers from a notable absence that has an impact on its conclusions: - Total Pb, as the % by mass of Pb contained in the entirety of the affected homogeneous material. The permitted threshold value is 0.06 % - Migratable Pb, as the % of Pb that is released from the homogeneous material on contact with a solvent. The permitted threshold value is 0.009 % In our opinion, the SEAC should take both criteria (Total and Migratable Pb) into equal consideration The value of 0.05 % proposed by the SEAC, established for the migratable Pb and without restrictions for crystals, stones or pearls, could be very much in keeping with the General Product Safety Directive (GPSD) and its Article 1.2 provisions, in</p>	<p>SEAC did not perform an analysis of the Canadian legislation.</p>

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 Annex XV report submitted by France 15 April 2010.
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		<p>accordance with the 'Precautionary Principle' that it is based on</p> <p>C) RESTRICTIONS We not fully agree with the SEAC analysis. As indicated, we take the view that the evaluation to conduct must be double: - Total Pb - Migratable Pb</p> <p>In this case, a much more accurate and rigorous approach would be to evaluate migration in terms of $\mu\text{g}/\text{cm}^2/\text{week}$, as established by EN ISO 10271 (Static immersion test)</p> <p>The application of preliminary corrosion and wear tests (EN 12472) is also significant, especially if the problem to be evaluated is masked by other Pb-free coatings</p> <p>We pay special attention to the evaluation by surface area (cm^2) in the projects that have been undertaken in recent years.</p>	
		<p>D) IMPLEMENTABILITY When the draft is published, its text must clearly define the differences that exist between the various homogeneous materials: a) Base alloys b) Solders c) Coatings (white bronzes and tin-lead)</p> <p>When the jewellery has a multilayer sequence of coatings, and if the thicknesses are appreciable, they</p>	<p>Jewellery may have so many different forms etc that it does not seem possible to include such differences in the legal text.</p>

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		<p>can have a masking effect on the base alloy or the soldered parts that hides the presence of the Pb they contain.</p>	
		<p>G) TESTING The SEAC's opinion needs to be refined. The XRF, used as a non-destructive method, is only reliable for jewellery items in their raw state (without coatings) Given that it is a superficial analysis technique, with a penetrative capability of just a few µm, the presence of coatings massively distorts the results obtained. For 'macro' situations (when the presence of Pb far exceeds a content of 0.2 % by mass) the EDXRF is a very accurate technique For contents lower than 0.2 %, and particularly at around 0.05 %, support from other techniques such as ICP-OES it's necessary To evaluate the level of Pb migration in relation to its surface, we take the view that the EN 7-3 test is not suitable and the static immersion method (EN-ISO 10271) is more representative As for the method for calculating the surface area, we are developing more reliable alternatives than the purely metrological ones described by EN 1811</p>	<p>Information from enforcement authorities indicates that XRF can be used as a screening method.</p>
		<p>H) ENFORCEABILITY We fully agree with the analysis conducted by SEAC in relation to the limitations apparent in the use of the XRF</p>	

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		In any event, we are of the opinion that a period of 6 months from the publication of the proposal would be appropriate	
		D) FINAL NOTE Many of the comments made have referred to document "Toxic metals in jewellery" which is the 2010 report on the multi-annual project We believe that all the reports resulting from these initiatives will undoubtedly be of interest to the SEAC. We remain at your disposal to provide you with these reports and we are open to any future collaboration	
31	2011/05/19 United Kingdom / Company- Manufacturer	Vitreous enamel is a component of a large percentage of product manufactured by Toye Kenning & Spencer. We have specialised in the production of product in this niche market for many years. We have monitored the health, along with the content of lead in the blood of the employees involved in the production of this product over decades and have not detected any levels higher than those normally encountered. Thus, we feel that a restriction in the use of the finished product is unnecessary A restriction in the use of lead compounds would be catastrophic to our business if it was applied. We would suggest that vitreous enamel could be exempt from this restriction.	It is proposed to introduce an exemption for vitreous enamels.

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30	2011/05/19 United Kingdom / Individual	I would like to urge that enamel on jewellery be made an exception. It would be impossible to determine the actual weight of lead in a piece of jewellery because enamel is usually applied thinly, and enamels differ in the amount of lead they contain. Although unleaded enamels are available they do not provide the same range of colours and effects that are able to be achieved with traditional enamels. I would therefore propose a total exemption of enamelled jewellery from this ban, based on the two points that enamelled jewellery is an historic art form, not a source of mass market jewellery and that production of enamelled jewellery is very small and aimed at a niche market.	It is proposed to introduce an exemption for vitreous enamels.
28	2011/05/16 United Kingdom / Industry or trade association	I am writing on behalf of the British Society of Enamellers about a proposed EU directive banning the production and sale of jewellery that has been enamelled with lead bearing enamels. We are asking that enamelled jewellery be exempted from this directive. We argue that only a small amount of enamel is used on a piece of enamelled jewellery and that the production of enamelled jewellery is very small, compared to mass market jewellery that does not contain enamel. Therefore the likelihood of a child dying from eating enamelled jewellery is extremely remote. A limited number of lead-free enamels that reach the quality of lead-bearing enamels are already available and more are being developed. It will therefore be	It is proposed to introduce an exemption for vitreous enamels.

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		<p>very difficult to tell which pieces of jewellery contain lead-bearing enamels and which ones are lead-free, making the directive very hard to enforce. Enamelled jewellery is an historic craft and has played a part in the development of European art for centuries. It is unthinkable that the high quality items produced in this area should cease.</p>	
		<p><u>Secretarial note:</u> The ECHA Secretariat contacted the submitter of the comment to obtain further data on the enamel jewellery market segment, content and role of lead in enamel, migration of lead from enamel jewellery, alternatives to the enamel in the enamel jewellery, applications of leaded and lead-free enamels, proposal for an appropriate definition of enamels and for appropriate derogation. The response to the follow-up questions explained</p> <ul style="list-style-type: none"> - the structural importance of lead in jewellery enamelling, - that leaded enamels are slightly more expensive than lead free enamels, that lead bearing enamels are essential to the practice of making precious enamelled jewellery, - that precious enamelled jewellery comprises a very small part of the overall jewellery market, that precious enamelled jewellery can be distinguished from mass market enamelled 	

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		<p>jewellery by its price and venue of sale,</p> <ul style="list-style-type: none"> - that mass produced and mass marketed precious enamelled jewellery could possibly be made just as easily using lead free enamels because these pieces incorporate only one or two colours at a time (also lead free enamels burn out after a few firings and therefore cannot be used in unique pieces based on complex designs which require many firings), and - that the historic and contemporary role of precious enamelled jewellery makes a strong case for its exemption, since lead bearing enamels are, at this time, essential for continuance of this important art/jewellery practice. 	
26	2011/05/16 United Kingdom / Individual	I think that this idea has been instigated by the United States. Lead has been taken out of US enamels - replacing it with other heavy metals - since these are of poorer quality from more traditional enamels, they are at a disadvantage commercially. Leaded enamels have been used for centuries and as far as I know the only risk to people is in their application by makers if sensible precautions are not taken. If this restriction is put in practice, what about lead crystal glassware that people actually put in their mouths? This restriction is another nonsense.	It is proposed to introduce an exemption for vitreous enamels.
25	2011/05/16 United Kingdom /	I would like to see lead banned in all types of jewellery	

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	Individual		
24	2011/05/16 United Kingdom / Individual	This piece of legislation will lead to confusion around the use of enamel in Jewellery. The proportion of lead used in enamelling is small but does vary from colour to colour. It would be very difficult for the individual crafts person using enamel to be able to specify the exact proportion. I would like to see a derogation applied to the use of enamel in Jewellery in the me way as applied to lead crystal.	It is proposed to introduce an exemption for vitreous enamels.
23	2011/05/15 United Kingdom / Individual	I fail to see how the enamel in jewellery can cause harm to anyone. Enamelled jewellery has been made for 1,000's of years, look at the stunning enamelled artifacts found at Sutton Hoo, they are one of the greatest treasures in the British Museum, and visit the museum's in Limoges, France. This is an exacting skill which needs to be supported, not 'banned'. It is an historic art form, production is very small, each piece is unique and is aimed at a niche market, not a source of mass marketing.	It is proposed to introduce an exemption for vitreous enamels.
22	2011/05/15 United Kingdom / Individual	As a professional jewellery designer maker and enameller, I am extremely concerned about this proposed ban. Banning lead from enamel would destroy our profession and an ancient craft that dates back to pre-Roman times. Lead is essential in enamel to give true clarity and beauty to enamel (vitreous glass fused to metal). Unleaded enamels are not nearly	It is proposed to introduce an exemption for vitreous enamels.

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		<p>as beautiful or have such lovely colours as leaded ones. Drinking from leaded glass has no health risks, so why the proposed ban on lead in jewellery? There is no scientific reason for this. It would be criminal to ban the manufacture of leaded enamels and the selling of jewellery containing such enamel. It is legislation gone mad. Please do not implement this proposal.</p>	
21	<p>2011/05/13 22:12 United Kingdom / Individual</p>	<p>I note that the wording of the proposed legislation makes no mention of vitreous enamel jewellery but does mention leaded crystal by way of derogation. I believe that clarification/derogation for vitreous enamel work needs to be added to avoid any confusion. Most enamels are now unleaded but there are some colours which are not possible without the addition of small quantities of lead.</p> <p>I have calculated that the percentage weight of the enamel on typical pieces is of the order of 0.02% to 0.15% of the final piece. Given that not all of the enamels used are leaded and the percentage of lead in the leaded ones is quite small, then all enamel items would be well within the limits proposed in the legislation.</p> <p>My concern is that enamel jewellery will be arbitrarily banned from sale based on ignorance, misunderstanding and the inability of most makers to prove their products to be compliant.</p>	<p>It is proposed to introduce an exemption for vitreous enamels.</p>

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20	2011/05/13 United Kingdom / Individual	I would like to comment on the use of leaded enamels on pieces of jewellery, which I assume would be included in this restriction. Please exclude leaded enamels from this restriction, it is a leaded glass, similar to leaded crystal and there is no clear indications that enamel jewellery poses any health threat. Enamelled jewellery is a specialist area of work and those of us who work as enamellers would be badly affected by this restriction. Enamellers are not unaware of the potential threat of lead to their health (as we regularly handle leaded enamels and adopt safe working practises such as using enamels either under water, or wet, until fired in the kiln; or using extraction and masks if using dry enamel)Some enamellers concerned about lead have had blood tests which have indicated no unusual raised lead levels in their blood. It would also be very difficult to calculate whether a piece of enamelled jewellery was over or under the restricted limit proposed and suggest that exempting it would be best way forward. Please, please, do not ban the use of leaded vitrious enamel in jewellery.	It is proposed to introduce an exemption for vitreous enamels.
19	2011/05/06 Switzerland / Company- Manufacturer	France proposed one year ago a restriction on lead and its compounds in both precious and fashion jewellery intended to adults and children. The Company fully agrees with this issue especially concerning children exposure. As only jewellery were concerned (no mention of watches in the proposition of France), the Company did not contribute to the	Internal parts of watches are proposed to be exempted.

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		<p>public consultation. We were surprised to note that wristwatches were added later on by SEAC in the list of articles concerned by the restriction. As the wristwatches are also in contact with the skin, this addition is an evidence but a distinction should be made between the wristwatch case and strap which are in contact with the skin and the internal components of the said case. These ones are indeed inaccessible.</p>	
		<p>Concerning the wristwatch cases and straps, the Company already fulfils the 500 ppm limit. Our specifications were set a long time ago according to international legal requirements and voluntarily based on a stricter level. It is indeed of our priorities to protect the consumer from such exposure.</p>	
		<p>For both mechanical and quartz watches and concerning the internal components, we admit that part of them contains lead at a level exceeding 500 ppm. But these components are inaccessible :</p>	
		<ul style="list-style-type: none"> • The case-back is tightened in our factory using a specific tool. • The water-resistance of the complete watch is tested to a pressure corresponding to at least 50 meters. • Our watches are designed to be shock-resistant. • Even the smallest watch of our catalogue would be very difficult to ingest knowing that the minimum diameter is appr. 36 mm without the strap. 	

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		<p>Thus, the exposure to lead with internal components is only possible if the case is opened with a specific tool before ingestion. This can only result from an abnormal use. Finally, contrary to jewellery articles which have only a decorative function, watches have decorative and technical functions (at least indication of time). To implement the latter, specific materials are needed and some of them should contain lead for technical reasons. For some of them, no immediate substitute exists. Further developments should still be carried out to find a solution.</p>	
		<p>Concerning quartz watches only (mainly 95% of the international market), the SEAC issue does not take into account that they are already covered by the European Directives 2002/95/EC RoHS and 2002/96/EC WEEE.</p>	
		<p>They restrict lead to 0.1% w/w of homogeneous material except for steel, brass and aluminium. Considering quartz watches relevant from the new legislation would signify that they should meet requirements more stringent than other electronic equipment, for instance mobile phones, which can similarly be accessible to children.</p>	
		<p>The Company proposes to amend the restriction by excluding the wristwatches from the list of categories or at least making a distinction between the exterior and the interior of the watch which is, in a normal use, inaccessible. The exterior, e.g. case, strap and tighteners, could be considered in the restriction. The</p>	

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 EC number: **231-100-4**

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		interior should not.	
		In the case of a restriction of lead for watch components, the consequences for the Company would be huge for our production by generating very high costs and investments but also for our subcontractors located in Europe. Indeed, they all developed specific equipments and/or processes for manufacturing the needed components. Restricting lead would signify the partial loss of an important industry. These consequences are tremendous compared to the expected benefits, namely the reduction of non-existent risks of ingestion or mouthing of internal watch components.	
18	2011/04/28 Switzerland/ Company- Manufacturer	Swatch Group comments in the frame of the public consultation on the draft opinion of ECHA's Committee for Socio-economic Analysis (SEAC) concerning a proposal to restrict lead and its compounds in jewellery in Annex XVII of Regulation (CE) 1907/2006 REACH.	
		1. Reminder about the initial restriction proposal : According to the initial proposal of France, the aim of the proposal is to manage the risks of lead poisoning of children resulting from the ingestion and the mouthing of leaded jewels. 2. Swatch Group comments: The Swatch Group, world leader in watchmaking, acknowledges the issue	

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 EC number: **231-100-4**

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 restriction on **Lead and its compounds**.
 Annex XV report submitted by France 15 April 2010.
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		<p>of children exposure to lead and the need to regulate the exposure of children to this substance. The Swatch Group did not contribute to the public consultation on the Annex XV restriction report submitted by France, because this report was not considering wrist-watches as jewellery articles. Such a link was suggested later by the SEAC. The Swatch Group takes due note of the arguments put forward by SEAC, RAC and France and leading to a very stringent restriction proposal, also for articles which are not intended for children and which cannot be ingested (risk of mouthing activity of articles, including adult articles). The Swatch Group already has a very stringent policy with regard to lead. Regarding accessible components of wrist-watches, the 500 ppm limit proposed by SEAC for lead in jewellery articles is already fulfilled by Swatch Group. Internal specifications based on international legal requirements applicable to watches or based on requirements set on a voluntary basis at the corporate level are equivalent or stricter than this limit. However some internal, not accessible watch components, such as the movement or the dial, may in some cases be composed of materials not fulfilling the 500 ppm limit, in particular brass. The present wording as set in the restriction proposal by SEAC is implying a restriction of lead in internal components of a watch. Such a restriction is not justified for the following reasons :</p>	

Substance: **Lead (and its compounds)**
CAS number: **7439-92-1**
EC number: **231-100-4**

Comments and response to comments on SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Lead and its compounds**.
Annex XV report submitted by France 15 April 2010.
Public consultation on SEAC draft opinion started on 29 March 2011.

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		<p>2.1. SEAC definition of watches as jewellery : By taking watches as jewellery, SEAC is not taking into account the fact that adults and children quartz watches are already covered by the European Directives 2002/95/EC RoHS and 2002/96/EC WEEE restricting lead to 0.1% by weight of homogeneous material, except for steels (0.35% Pb), brass (4%), and aluminium (0.4%). Following our estimate, quartz wrist-watches make up 95% of all watches placed on the market in Europe, the rest being mechanical watches. In our view, defining watches as jewellery is disregarding the fact that, contrary to jewellery articles which have a decorative function, watches are using many mechanical or electronic functions that require the use of some specific materials for technical reasons. In this frame quartz watches must be compared with electronic equipments such as mp3 players or pagers, but in no way with jewellery. With this respect, SEAC definition of watches as jewellery would lead to a twofold legislation pertaining to lead in quartz watches, which is not justified. Furthermore this new legislation would not include a legal mechanism enabling exemption requests, contrary to the procedure as set by Directive 2002/95/EC RoHS. Such a legislation would impose more stringent requirements for quartz watches than for other categories of electronic equipments, although these are similarly accessible to children.</p>	<p>We suggest as far as possible to use the same definition as in the restriction on cadmium. No need for a general exemption of wrist watches has been identified – only for internal parts. Like for other jewellery it is the mouthing activities by children that give rise to concern.</p> <p>Overlapping is not by itself a problem. The requirements of both legislations have to be respected. It would only be a problem if the overlapping is conflicting, meaning that it would not be possible to meet both requirements at the same time.</p>

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		<p>2.2. No risk associated with internal components : The presence of lead in some internal components of the watch does not represent any threat for consumers health and its restriction is not necessary to reach the goals formulated in the initial proposal by France. Indeed a risk of ingestion or mouthing of an inaccessible component of a wrist-watch by a child is non-existent. Our products must fulfill water and shock resistance criteria. These criteria guarantee that children cannot access to the internal components of a watch.</p>	Agreed
		<p>3. Proposals to amend the restriction : For the above mentioned reasons, we ask to ECHA's SEAC to modify the legislation project so as to : - not include wrist-watches in the definition of jewellery. Watch straps, tighteners and wrist-watch cases could however be included in the scope of the restriction, as it is the case regarding the nickel release in Annex XVII of REACH, because Swatch Group specifications for the materials of accessible components are fulfilling the 500 ppm limit proposed by SEAC. or at least - keep inaccessible components out of the scope of the restriction.</p>	Internal parts of watches are proposed to be exempted.
		<p>4. Consequences of not taking into account Swatch Group proposals : A restriction of lead in the components of the watch movement would force watch manufacturers to change their production processes substantially, which would generate very high costs and investments for manufacturers of watch</p>	

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		movements and consequently for the whole European watch industry. These costs would incomparably exceed the expected benefits, namely the mitigation of non-existent risks of ingestion or mouthing of internal watch components.	
17	2011/04/18 United Kingdom /Regional or local authority	The proposed regulatory action will improve the well being of individuals in society, so the Birmingham Assay Office supports the proposed legislation to limit the total lead content of jewellery and other proposed consumer products. We are pleased to see that the proposal is a measure of content rather than release, which will mean greater accuracy and repeatability for testing.	
16	2011/04/08 Germany / Individual	While the general aim and content of the restriction sound reasonable, the justification of the exceptions (lead crystal, precious stones and articles placed on the market before [12-18] months) is not convincing. If lead in jewellery is considered a hazard, then these excepted articles pose a hazard as well. Allowing known and unnecessary hazardous articles to be put on the market is in contradiction to the REACH philosophy. Consequently, the exceptions should be deleted. The exception for antiques (50 years or older) is reasonable, since antiques are normally not frequently used by their owners so that the risk potential is low.	No explanation of why SEAC's justification for these exemptions is unconvincing.

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14	2011/03/31 Belgium / International NGO	It is rather worrisome that it is taking so long to phase out lead from jewellery. ClientEarth fully supports the elimination of all possible sources of lead into the environment and all possible sources of exposure to lead. In this context we call for the restriction of lead in ammunitions as large quantities of lead are released into the environment in Europe each year (40,000,000 kg per year in EU-27; Hansen et al., 2004) from shooting and fishing without recovery and this unnecessary source of lead exposure must be stopped immediately. We welcome this restriction which, unfortunately is being taken too late and we hope that REACH is used to phase out other sources of lead as soon as possible.	Relevant competent authorities or COM may wish to consider further whether other sources of lead should be restricted under REACH.
13	2011/03/31 United Kingdom / Individual	1 Test methods should be defined.	Not SEAC remit.
		2 How can exempt untreated precious and semiprecious stones be distinguished from non-compliant treated stones? This will be a critical point for supplier compliance and enforcement.	This is a matter for enforcement authorities.
		3 How is the 50 years age defined? By date of manufacture?	It is defined by placing on the market. Matter for enforcement authorities.
		4 I am concerned that non-compliant jewellery may placed on the market by faking its age to falsely appear to be more than 50 years old. Guidance on how this age may be determined from an article (not merely	Matter for enforcement authorities.

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		documentation that could be faked) should be made available. Once again its a critical point for compliance that needs to be robustly defined to withstand inevitable challenges	