

**Committee for Risk Assessment (RAC)**  
**Committee for Socio-economic Analysis (SEAC)**

**Opinion**  
on an Annex XV dossier proposing restrictions on  
**lead and lead compounds in jewellery**

**ECHA/RAC/RES-O-0000001304-85-03/F**  
**ECHA/SEAC/RES-O-0000001304-85-04/F**

**Compiled version prepared by the ECHA Secretariat of RAC's  
opinion (adopted 10 March 2011) and SEAC's opinion (adopted  
15 September 2011)**

*10 March 2011*  
*RES-O-0000001304-85-03/F*

*15 September 2011*  
*RES-O-0000001304-85-04/F*

**Opinion of the Committee for Risk Assessment  
And  
Opinion of the Committee for Socio-economic Analysis  
on an Annex XV dossier proposing restrictions of the manufacture, placing on the  
market or use of a substance within the Community**

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

<b>Chemicals concerned:</b>	<i>Lead and its compounds</i>
<b>Chemical name:</b>	<i>Lead</i>
<b>EC No.:</b>	<i>231-100-4</i>
<b>CAS No.:</b>	<i>7439-92-1</i>

This document presents the opinions adopted by RAC and SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

**PROCESS FOR ADOPTION OF THE OPINIONS**

*France* has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at [http://echa.europa.eu/consultations/restrictions/ongoing\\_consultations\\_en.asp](http://echa.europa.eu/consultations/restrictions/ongoing_consultations_en.asp) on *21 June 2010*. Interested parties were invited to submit comments and contributions by *21 December 2010*.

**ADOPTION OF THE OPINION**

**ADOPTION OF THE OPINION OF RAC:**

**Rapporteur, appointed by RAC:** *Helmut GREIM*  
**Co-rapporteur, appointed by RAC:** *Poul Bo LARSEN*

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health has been reached in accordance with Article 70 of the REACH Regulation on **10 March 2011**.

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

The RAC opinion was adopted *by consensus*.

#### ADOPTION OF THE OPINION OF SEAC

**Rapporteur, appointed by the SEAC:** *Lars FOCK*

**Co-rapporteur, appointed by the SEAC:** *Stavros GEORGIU*

#### The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on **11 March 2011**.

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

The draft opinion was published at [http://echa.europa.eu/reach/restriction/restrictions\\_under\\_consideration\\_en.asp](http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp) on **29 March 2011**. Interested parties were invited to submit comments on the draft opinion by **28 May 2011**.

#### The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **15 September 2011**. The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by 90 days by the ECHA decision on 11 March 2011<sup>1</sup>.

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

The opinion of SEAC was adopted *by a simple majority* of all members having the right to vote. The minority position, including its grounds, is made available in a separate document which has been published at the same time as the opinion.

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<sup>1</sup> Postponing the deadline to prepare final opinion of SEAC on Annex XV restriction dossier (Decision by the Director of Regulatory Affairs, 11th March 2011).

## OPINION

### THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and information submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on ***Lead and its compounds*** in jewellery is the most appropriate Community wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

RAC proposes that the conditions of the restriction should consider the following elements:

**Lead (CAS No 7439-92-1, EC No 231-100-4) and its compounds** shall not be used or placed on the market in

- i) Metallic and non-metallic parts of jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of the part;
- ii) The paragraph above does not apply when it can be demonstrated that the rate of lead release from the jewellery article or any part thereof does not exceed 0.05 µg/cm<sup>2</sup>/hr (0.05 µg/g per hr).

### THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and comments submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on ***Lead and its compounds in jewellery*** is an appropriate Community wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope and conditions are modified.

The conditions of the restriction proposed by SEAC are:

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

1. Shall not be used or placed on the market if the concentration of lead is equal to or greater than 0.05% by weight of any individual part<sup>2</sup> of the jewellery articles and hair accessories, including:
  - bracelets, necklaces and rings,
  - piercing jewellery,
  - wrist watches and wrist-wear
  - brooches and cufflinks.
2. By way of derogation, paragraph 1 shall not apply to
  - i) “Full Lead Crystal” and “Lead Crystal” as defined in Annex 1 in Council Directive 69/493/EEC<sup>3</sup>;

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<sup>2</sup> “Any part” includes the materials from which jewellery is made, as well as the individual components. The provisions in paragraph 1 also apply to individual parts when used or placed on the market for jewellery making.

- ii) internal components of watch timepieces inaccessible to consumers;
- iii) non synthetic or reconstructed precious and semiprecious stones (CN code<sup>4</sup> 7103) unless they have been treated with lead or its compounds or mixtures containing these substances.
- iv) enamels defined as vitrifiable products resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500° C.

3. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market before 12 months after the entry into force and jewellery articles produced before 10 December 1961<sup>5</sup>.

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<sup>3</sup> Council Directive of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (69/493/EEC).

<sup>4</sup> Commission Regulation (EU) No 861/2010 of 5 October 2010 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff.

<sup>5</sup> The date 10 December 1961 is proposed in order to ease the implementation by using the same date as in the Commission Regulation 494/2011.

## **JUSTIFICATION FOR THE OPINION OF RAC AND SEAC**

### **Identified hazard and risk**

#### Justification for the opinion of RAC

The restriction proposal is targeted towards lead exposure from lead-containing jewellery. RAC finds that the targeting to jewellery items is justified by the data on lead content in jewellery and lead migration from jewellery presented in the dossier.

#### *Lead content:*

In a Danish survey (Danish EPA, 2008), 58% of 170 examined jewellery pieces contained lead in the concentration range from 0.01% to 70 % lead, and 42% of the pieces contained less than 0.01% lead. In a Swedish survey (KEMI, 2008) 23 of 50 examined jewellery pieces were found to contain lead with 4 pieces above 10% lead, 9 pieces in the range of 2-10% lead, and 10 pieces below 2% lead. A second Swedish survey (KEMI, 2008) was reported in which 36 of 50 pieces of jewellery contained lead with rather similar lead contents. In a German survey (BfR, 2008) on jewellery, 78 samples out of 87 contained lead with an average lead content of 6.3% and a maximum value of 90%. In a UK survey (the Sunday Times, 2008), 24 children's jewels were examined and 8 tested positive for a high content of lead. Six of the items exceeded a lead concentration of 80%. Based on these European surveys the lead content in jewellery articles is between very low and 90 %. Also Canadian and US surveys confirm this wide variation of lead content. Moreover, according to one independent testing laboratory (Anon, 2010), it is estimated that about 10 % of jewellery sold in EU contains an average of 6% of lead and that there is some indication that the trend of lead content in jewellery is increasing. The amount of tested items was above 12,000 articles.

### **Characterisation of risks**

RAC agrees with the assessment from France that neurotoxicity, specifically neurobehavioral and neuro-developmental effects from repeated lead exposure, is the key effect that this restriction is aimed at protecting against. Children will be particularly sensitive to this hazard, given that their central nervous system is still under development. No threshold for the adverse effect has been identified in humans; therefore RAC considers that any exposure by released lead from jewellery will present a risk. In consideration of the mouthing behaviour of small children, and the possibility for lead migration, RAC concluded that lead exposure of children from jewellery may occur.

RAC considers such chronic exposure as most relevant to justify a restriction. The very few reports on acute exposures due to swallowing parts of jewellery resulted in increased blood lead levels without reporting of acute symptoms in some of the cases. In other cases the reported symptoms may also have been the result of obstruction of the gastro-intestinal passage by the swallowed piece of jewellery. A focus of the restriction to chronic exposure due to children's mouthing behaviour would also cover acute risks from lead after swallowing.

RAC supports the risk assessment of EFSA (2010), in which a lower benchmark dose level (BMD(01)) of 0.5 µg Pb/kg bw/d was derived as a dose descriptor for the potential adverse effects of lead on children. This corresponded to a change in blood level of 12 µg Pb/L and an IQ loss of 1 point. EFSA observed that children in the age group of 1- 7 years have mean background lead exposures between 0.8 and 5.5 µg/kg bw per day (e.g. from the diet and background environmental exposure). Clearly, this already exceeds the BMDL(01) level of

0.5 µg Pb/kg bw/d, and therefore any additional lead exposure would on average be expected to further increase a typical child's exposure above the dose descriptor level.

In the original proposal submitted by France, a migration limit value of 0.09 µg /cm<sup>2</sup>/hr was proposed. This was associated with a DMEL which was based on analytical measurement error. In order to use a risk-based approach, RAC judged it more appropriate to consider the EFSA BMDL (01) value (0.5 µg Pb/kg bw/d) and to apply a MoE of 10, which according to EFSA (2010) is sufficiently low to ensure no appreciable risk. This exposure of 0.05 µg Pb/kg bw/d correlates with an IQ reduction in children of 0.1 points.

Considering an exposure scenario in which a child of 10 kg bw mouths a jewel for 1 hour with a surface of 10 cm<sup>2</sup> and a weight of 10 g a tolerable migration rate from the jewellery of 0.05 µg Pb/cm<sup>2</sup>/hr or 0.05 µg Pb/g/hr is estimated. The migration rate expressed in per surface unit is in principle applicable for all kind of surfaces (metallic as well as non metallic parts). With a general assumption that the ratio between surface (in cm<sup>2</sup>) and the weight (in g) of the jewel is 1 the migration rate would most practically be set to 0.05 µg Pb/g/hr.

For metallic parts of jewellery, the association between migration rates and content of 0.05% is based on the reassessment of the Danish EPA (2008) report. RAC recognises the uncertainty in this association as presented in the BD supporting this opinion; however, RAC considers that this association is further supported by the direct consideration of the raw measurements reported in the Danish study, as migration was not detected in the three jewellery items containing less than 0.05% lead, while it was detected in two (out of three) items with lead content between 0.1 and 1%.

In the absence of specific data for the non-metallic parts of jewellery, RAC has considered the characteristics of the exposure scenario in order to assess if the value of 0.05% proposed for the metallic parts may be sufficient for protecting children from the exposure from non-metallic parts and coating materials.

Since migration due to mouthing is expected to occur only from the surface area, a depth of 0.1 mm is considered as a conservative maximum for relevant migration within one hour mouthing. For a surface area of 10 cm<sup>2</sup> and a depth of 0.1mm (0.01 cm) a maximum mouthing total volume of 0.1 cm<sup>3</sup> is estimated. Assuming a material density between 10 g/cm<sup>3</sup> for heavy metals and crystals to 1 g/cm<sup>3</sup> for plastics and woods the maximum amounts of lead in the relevant part of jewellery for the proposed limit of 0.05% would be 500 µg lead for the metallic parts of jewellery and crystals and 50 µg lead for plastics and woods. RAC considers that it is unlikely that these levels could exceed the tolerable daily exposure of 0.05 µg/kg bw/d, as the child would need on a daily basis to extract, by mouthing, more than 0.1% of the lead in crystals or more than 1% in the case of jewellery items made of plastics and woods. Thus, in absence of specific information, RAC considers that the 0.05% limit is also protective for the non-metallic parts of jewellery.

The concentration limit of 0.05% and the migration limit (0.05 µg Pb/g/hr) are based on a daily mouthing time of 1 hr. RAC notes that this is a worst-case estimate. For comparison, a daily mouthing time of 15 min would result in an exposure which is fourfold below the level to ensure no appreciable risk, a weekly mouthing time for 1 hr per week is about 7 times below this level. A detailed description of the impact of different lead exposures due to mouthing at different frequencies is given in Tables 35 and 36 of the BD.

## **Justification that action is required on a Community-wide basis**

### Justification for the opinion of RAC

Placing on the market of lead-containing jewellery occurs across the EU. Generally, there are no risk management measures to avoid lead exposure from jewellery, and so adequate measures to minimise such exposures should be implemented on a community-wide basis. In particular, this should protect children from lead exposure and the possibility of adverse effects on the central nervous system. As no threshold has been found for the harmful effect of lead on the central nervous system, and with a view to background exposure from diet and other environmental sources, any relevant lead exposure should in principle be avoided.

### Justification for the opinion of SEAC

SEAC considers a Community-wide restriction to be appropriate. Items of jewellery are placed on the market all over Europe and they are manufactured and sold in a diversified industry structure, ranging from isolated craftsmen to medium sized firms. Since the risks related to lead in jewellery extend over all EU boundaries, a harmonised risk management measure within the EU is appropriate in order to avoid trade distortions between and within actors of the jewellery supply chain that might inhibit the functioning of the internal market for jewellery.

## **Justification that the suggested restriction is the most appropriate Community-wide measure**

### *Effectiveness in reducing the identified risks, proportionality to the risks*

#### Justification for the opinion of RAC

##### *Risk Reduction Capacity*

Several restriction options are discussed in BD. RAC concluded that the most appropriate option would be to set a limit for the migration of lead under the conditions found when children might place lead-containing jewellery in their mouths. A targeted restriction option linked directly to lead migration from a given surface area or a given weight of jewellery would cover the potential for exposure.

However, RAC recognised practical as well as methodological problems with this restriction option, including that it would be more costly to monitor enforcement and compliance than an alternative option based on the content of lead in jewellery. For the metallic part of the jewellery alone, given that RAC found an association (although rather uncertain) between migration rate and overall lead content, a limit value of 0.05% is proposed. In the absence of migration rate information on non-metallic parts, RAC has assessed the applicability of the same limit value proposed for the metallic parts as explained in the section of characterisation of risks, and concluded that the limit of 0.05 % is also protective for non-metallic parts of jewellery.

#### Justification for the opinion of SEAC

Seven restriction options have been considered. They reflect different proposals covering different categories of jewellery (Precious, Fashion, etc.), and whether the restriction should be based on migration of lead or on the content of lead in jewellery articles.

SEAC notes that the Toys Directive will not cover jewellery unless it is ‘intended for children’s play’ and a restriction under the Product Safety Directive (PDS) would need to be renewed every year. Furthermore SEAC notes that under REACH a similar restriction has been adopted for cadmium in jewellery<sup>6</sup>. Therefore REACH is considered an appropriate legal instrument.

SEAC takes note of the RAC opinion to recommend a maximum content of lead in metallic and non-metallic parts of jewellery to 0.05% unless it is demonstrated that the migration rate of lead release from jewellery articles does not exceed 0.05 µg/cm<sup>2</sup>/hr if measured by surface (0.05 µg/g/hr if measured by weight) for both the metallic and the non-metallic parts. However, a standard test method mimicking mouthing conditions is not yet available.

#### *Scope*

SEAC has considered whether the restriction should be limited to children’s jewellery. In Canada and the US (BD: Section G.2.2.) lead in jewellery is restricted only for jewellery intended for children under 15 years of age and under 13 years of age respectively. However, SEAC considers it appropriate to restrict jewellery containing lead, which is intended for adults as well as for children. SEAC takes note of the RAC opinion that there is no basis to differentiate between adult and children jewellery. Furthermore, it would be difficult to enforce a restriction on children’s jewellery only.

SEAC has also considered whether jewellery containing only precious metals should be exempted from the restriction, on the grounds that such jewellery in general does not contain added lead. Since such jewellery will not contravene the restriction, no compliance costs will be incurred, other than some possible costs associated with ensuring ‘due diligence’ in the supply chain that items do not contain lead. Such ‘Quality Control’ is already largely a feature of the precious jewellery sector. Furthermore, as such jewellery will be restricted with regard to cadmium as soon as the Annex XVII entry enter into force (in 2012), no further additional ‘due diligence’ costs will be imposed.

Keeping the restriction as straightforward as possible in terms of scope and possible exemptions will ensure that ease of implementation is not compromised.

For owners of old jewellery which does not comply with the limits in the restriction, the proposal would have significant consequences and pose insurmountable challenges in terms of enforcement (though no formal assessment of this was undertaken in the dossier). Such old items would lose their marketable value (unless exported), as they would not be allowed for legal sale<sup>7</sup>. This may result in a “black market” for such items and associated problems of enforcement and compliance for “private sales” of old jewellery. SEAC proposes to address this problem in the same way as it is done in the restriction on cadmium in jewellery, by exempting jewellery placed on the market before the entry into force of the restriction. In

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<sup>6</sup> Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium).

<sup>7</sup> REACH, Art. 3.12, defines placing on the market as supplying or making available, whether in return for money or free of charge.

order to allow import of antique jewellery it is recommended to exempt jewellery produced before 10 December 1961 from the restriction.

If the restriction is only based on the content of lead (% of weight) (see below), SEAC recommends exempting crystals, vitreous enamels, internal components of watch timepieces, as well as precious and semiprecious stones from the restriction.

### *Restriction*

SEAC agrees that for metallic parts a restriction based on the content of lead is the most appropriate Community-wide measure to address the risks from jewellery containing lead. For non-metallic materials SEAC has not been able to evaluate the consequences of introducing a restriction. However, it should be noted that the cadmium restriction also applies to plasticised materials and paints used in jewellery, and that some US states have regulations on jewellery containing lead that apply to the non-metallic parts. In both cases the regulation is based on content of lead.

During the Public Consultation a number of practical problems were raised related to the proposal to base the restriction on migration per unit. These include the fact that there are difficulties in calculating the surface area; that it is difficult to identify and isolate the parts of jewellery containing lead in order to carry out the testing<sup>8</sup>; and that a necessary standard testing method has not been developed yet (adaptations to EN 71-3 have to be made in order to address the relevant type of exposure in saliva and jewellery which is too large to be swallowed). The need to adjust the test method could influence the date of entry into force of the restriction. Furthermore, in order to ensure a high level of compliance, it is regarded as important that the restriction is easy to understand and measure, and for imported items of jewellery it is important that restriction of non-metal jewellery is also based on content so that producers outside the EU will only have to meet similar types of requirements as those already in place in the US and Canada.

Therefore SEAC recommends that the restriction of lead in metal parts as well as in non-metal parts of jewellery should be based on content (w/w), and SEAC recognises that the value recommended by RAC of 0.05 % is practical and a less costly method to implement than a migration test. However, it is proposed to exempt crystals, vitreous enamels, internal components of watch timepieces, as well as precious and semiprecious stones from the restriction even though they (in particular crystals and enamels) may have a high level of lead content.

In the Public Consultation, information on 2 specific items of crystal was submitted showing a migration of lead in a magnitude of 0.082 µg lead/cm<sup>2</sup>/hr and 0.216 µg lead/cm<sup>2</sup>/hr. SEAC has no information on whether or not these may be typical migration rates.

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. With respect to crystal glass identified as cat. 3 and 4, no comments were received from the Public

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<sup>8</sup> It is easier to measure the migration from a whole piece of jewellery that is not too big.

Consultation on the SEAC draft opinion in which the derogation was proposed only on lead crystal cat. 1 and 2.

Lead is used in enamels in order to obtain certain properties in terms of colour, brightness and stability. Industry has submitted information that indicates that the handcraft sector will be severely damaged if lead enamels are restricted, especially vitreous enamels produced using a 'reactive frit' manufacturing process. Based on the information received during the public consultation of the SEAC draft opinion, the use of vitreous enamel in the manufacture of precious jewellery articles has a relative small market share of the jewellery sector. This kind of enamel jewellery is characterised by small scale artisan and handcrafted production of high value and unique pieces of jewellery. However, lead enamels might also be used in fashion jewellery, but SEAC has no information on how much this is done.

Substantive evidence regarding lead migration from enamels has not been presented to SEAC although information from a single test that lead might migrate in levels above the migration limit recommended by RAC was received<sup>9</sup>. Information on this issue came in too late for RAC to consider in its opinion. Nevertheless, such enamels should not be mouthed by children. It is proposed that an exemption should be limited only to uses for which no acceptable alternatives are available, namely vitreous enamels that require heat, approximately 500 °C in the production process. The proposed definition follows the definition as stated in French decree law no 82-223 of 25 February 1982<sup>10</sup>.

As compared to metallic jewellery, evidence of a significant health impact of lead exposure from mouthing or ingestion of crystals and vitreous enamels has not been presented. Given the uncertainties over migration rates from lead crystal and vitreous enamels as well as the developments taking place in these sectors, SEAC recommends 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. Furthermore, SEAC recognises that implementation of Classification, Labelling and Packaging (CLP) Regulation<sup>11</sup> 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.

As both enamels and crystal glass may migrate lead in levels above the limit proposed by RAC, SEAC has considered whether a label on the presence of lead and the necessity of keeping such items out of children's reach should be recommended. Apart from the protective aim of such a requirement it would also be an incentive to search for and use lead free alternatives wherever possible. However, for the same reasons that labelling was discounted as a possible risk management option for lead containing jewellery more generally, it is not considered to be justified in this case. Member States and industry may consider other ways of informing parents not to let children have access to enamels and lead crystal that might contain lead.

There are indications that lead may be present as a naturally occurring constituent in precious or semiprecious stones. SEAC considers that it would be disproportionate not to allow such stones to be used in jewellery, based on analogous argumentation used to justify the

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<sup>9</sup> The test indicates lead migration to be 4.05 µg/cm<sup>2</sup>/hr. which could be compared with to 0.05 µg/g/hr as proposed by RAC.

<sup>10</sup> Décret no 82-223 du 25 février 1982 portant application de la loi du 1er août 1905 sur les fraudes et falsifications en matière de produits ou de services en ce qui concerne l'émail et les produits émaillés ou vitrifiés.

<sup>11</sup> 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.

derogation for crystals. However, precious or semiprecious stones are sometimes treated with lead containing materials that may still be present in the stone after the treatment. As SEAC has no information that other treatment methods technically and economically feasible should not be available, this derogation should not apply if these stones are treated with lead or its compounds, as well as mixtures containing these substances.

During the Public Consultation, industry has recommended exempting the use of lead in internal parts of watches, since such parts are not accessible to children to mouth. As SEAC also considers that such an exemption will not give rise to uncertainties in relation to enforcement, SEAC recommends such an exemption which also would apply to electronic parts of electronic watches covered by RoHS Directive<sup>12</sup>. As the RoHS Directive covers the whole article containing electronic parts the limitation of the proposed exemption would mean that e.g. a metal watchband would have to meet tighter requirements than it would have solely according to RoHS. Although there may be some minor additional administrative familiarisation necessary due to these dual legislative requirements on the same articles, SEAC considers this justified given the different objectives of the legislation.

#### *Implementability*

SEAC considers that the proposed restriction is implementable for industry. For alloys used in jewellery manufacture, the proposed restriction will in practice mean a ban on their use for this purpose if they contain lead above the restriction limit. Alloys without lead appear to be widely available on the market and already used in the fashion jewellery sector. This may however still imply some adaptation of the production process for actors who presently only work with lead-based alloys. SEAC has not been able to establish whether this would pose a challenge for industry, though no comments were received in the Public Consultation that indicated otherwise.

#### *Impacts*

SEAC notes that it was not considered possible to establish a full quantitative assessment of the impacts of the restriction proposed, in particular with regards to the health consequences. Nevertheless, a partial CBA related to metal jewellery indicates that the costs of the restriction do not appear to be disproportionate. There is no indication that the placing on the market of jewellery containing lead is diminishing, but some anecdotal evidence that it may be increasing.

Taking into account the fact that jewellery will be restricted with regard to cadmium, the cost of ensuring compliance throughout the supply chain, as well as for authorities, is estimated to be €180,000 per annum, as a result of the need for additional conformity testing of jewellery identified to have a lead content within the relevant margin of precision for screening tests around the restriction limit of 0.05%.

A partial CBA shows that, in the EU, the cost of avoiding lead in jewellery including conformity testing costs is estimated to be €4.6 million per annum<sup>13</sup> based on an estimated share of 10% of all jewellery articles containing an average concentration of 6% of lead. The impacts in terms of future lost earnings associated with aggregate IQ decrement and corresponding intake of lead from mouthing jewellery that would be required for benefits to

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<sup>12</sup> Directive 2002/95/EC of the European Parliament and of the Council of the 27 January 2003 on the Restriction of the use of Certain hazardous Substances in electrical and electronic equipment.

<sup>13</sup> Prices of new jewellery are estimated to increase as a result of rising production costs (estimated to be in the order of €0.03 per piece).

equal these costs were also estimated. The average mouthing duration of jewellery (containing lead) amongst all children aged 6 months to 3 years that would result in the corresponding lost future earnings was estimated to be about 30 seconds per year per child. Although actual mouthing durations are uncertain, there is some evidence that this may represent around 30% of actual mouthing durations for jewellery containing lead.

The assessment of benefits of the partial CBA does not include other potential benefits of reducing lead exposure. These include non-cognitive functioning and other health and non-health related endpoints.

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

SEAC considers that the proposed restriction is unlikely to have any consequences for innovation and research. There is no information that indicates adverse consequences for specific regions, other social impacts, wider economic impacts or distributional impacts.

The BD (Sections E.2.3.1.1 and F1.1) gives further details.

Administrative burdens are mostly related to identifying whether raw materials, especially intermediates, and imported jewellery are in accordance with the requirements of the restriction. Additional quality controls would normally be required along the supply line in jewellery where lead can be expected to be found. If necessary, industry and retailers will have to carry out or demand the necessary testing. However, jewellery is also covered by restrictions on nickel and cadmium and is thus already subject to requirements from importers and retailers to ensure compliance. The cadmium restriction is also based on content of the substance and therefore a restriction on lead also based on content will not imply incremental practical problems and costs in relation to compliance. However, the restriction in relation to cadmium does only cover lead in metal, plasticised materials and painted coatings of the jewellery, and there might be some minor types of jewellery outside the scope of the cadmium restriction<sup>14</sup> where separate efforts in order to ensure compliance of jewellery with regard to lead is required.

For producer countries outside the EU, SEAC agrees that small producers might have difficulties to comply with different requirements in different countries to which they export. Since the US and Canadian requirements for jewellery are also based on the content of lead, the proposed restriction, which is based on content, is consistent with these regulatory requirements, such that it will ease the implementation for such countries and thereby enhance compliance with the restriction.

### ***Practicality, incl. enforceability***

#### Justification for the opinion of RAC

For metallic parts, the analysis of lead content can usually be made in a non-destructive way using X-ray fluorescence (XRF) devices; only occasionally would a destructive standard wet chemical analysis need to be performed. Many items can be tested in a short time; only the jewellery containing lead above the limit value would require migration testing.

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<sup>14</sup> Examples of jewellery covered by the lead proposal but not of the cadmium restriction would be jewellery produced of e.g. stone, bone, textiles, wood, etc. Lead levels in such materials would normally be expected to be very low.

As low migration rates may occur at higher lead contents in jewellery, RAC considers that the restriction may allow industry to market jewellery items exceeding the limit of 0.05% lead provided that the actual migration does not exceed the proposed migration rate.

However, RAC recognises that further work has to be done in order to specify how the testing for content as well as for migration should be performed. RAC emphasises that reliable methods to determine migration rates from jewellery especially at lead concentrations below 1% need to be established.

Based on the received comments, RAC considers that a migration limit based on weight instead of surface is preferable in terms of practicality and implementability, and therefore suggests the use of 0.05 µg Pb/g/hr as the best measure for migration, provided that adequate analytical methods are available.

During the public consultation conducted by ECHA, it was proposed to differentiate between fashion and precious jewellery and also jewellery intended for use by children. However, RAC did not find any basis for such differentiation.

#### Justification for the opinion of SEAC

SEAC regards the restriction to be practical and enforceable.

##### *Testing*

Testing of the content of lead in jewellery can be measured by an XRF test method. In order to verify a non-compliant content value, an ICP spectrometer 'wet test' can be performed.

If the restriction should be based on migration of lead in relation to surface area, it would be necessary to adapt the migration test EN7 1-3 in order to cover large jewellery and to establish a method for calculating the surface. However, SEAC recognises the proposal from RAC to relate the migration to the weight.

##### *Enforceability*

SEAC agrees that the enforcement of the new regulation can be carried out by existing authorities. According to the BD, the testing costs amount to between €15 and €40 per test, depending on the method and laboratory used. The XRF test method is both cheaper and easier to implement for industry actors. However, technically, it seems to be limited as it only allows an analysis of the surface layer of the jewellery articles, as well as having limited resolution. The more expensive tests would therefore be required in certain circumstances, especially where legal confirmation of screening tests is required.

SEAC considers that the proposed time for implementation (proposed to enter into force 6 months after the Regulation enters into force) may be too short, on the grounds that the restriction applies to placing on the market at all stages of the supply chain (including from retailers), and taking into account the fact that the period for stock rotation (from the initial entry into force) may be somewhat above one year. Industry and trade organisations have proposed a maximum implementation period of 24 months. However, storage through the supply chain is not relevant as jewellery sold by the importer or the producer before the end of the implementation period is covered by the derogation on jewellery placed on the market before that day. Furthermore the request of 24 months was also linked to the time needed to

make adjustments to the migration test standard, which was proposed in the original proposal from France. As the modified proposal is based on content and well established test methods are available, and the transitional period is only justified for adjusting the production process and the storage of intermediates and final jewellery by the importer or producer SEAC considers 12 months to be an appropriate phase-in period. Retailers ordering jewellery 9-12 months in advance may face problems if they do not take the necessary precautions. The transitional period used in the cadmium restriction is 6 months.

### ***Monitorability***

#### Justification for the opinion of RAC

*Included in the text directly under heading “Practicality, incl. enforceability – Justification for the opinion of RAC“ above.*

#### Justification for the opinion of SEAC

It is in practice impossible to monitor the number of children mouthing and ingesting jewellery, as well as the related health consequences.

It is possible to follow up on the amounts of jewellery which do or do not comply with the regulation and thereby have a proxy for the potential exposure to children. The outcome of the enforcement activities could be monitored, on national level as well as on Community level.

The costs of the monitoring in the form of compiling information from enforcement activities are expected to be rather limited.

### **Conclusion to the RAC opinion**

Based on a thorough evaluation of the available information, RAC proposes to limit the lead content in jewellery. Specifically the proposal is to restrict the lead content in jewellery articles and any parts thereof to 0.05%, unless it is demonstrated that the migration rate of lead release from jewellery articles does not exceed  $0.05 \mu\text{g}/\text{cm}^2/\text{hr}$  ( $0.05 \mu\text{g}/\text{g}$  per hr) for both the metallic and the non-metallic parts.

The reasoning behind the proposed restriction by RAC is the following:

The restriction conditions should ensure that the migration of lead from jewellery articles or any parts thereof placed on the market does not exceed  $0.05 \mu\text{g}/\text{cm}^2/\text{hr}$  if measured by surface or  $0.05 \mu\text{g}/\text{g}$  per/hr if measured by weight.

Due to lack of validated methods for measuring migration which mimics mouthing, RAC considers that a restriction based on content is more practicable for implementation and enforcement. From the assessment of the data available on metallic parts, RAC considers that a content of 0.05% lead in metallic parts of jewellery is appropriate for ensuring the protection level presented above.

Although there is no information on migration versus content for non-metallic parts, RAC considers that the concentration value of 0.05% is also protective for the non-metallic parts.

## **BASIS FOR THE OPINION**

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

### Basis for the opinion of RAC

The opinion in principle supports the dossier submitter's proposal for having such a restriction; however, the conditions of the opinion of RAC diverge significantly from the originally proposed restriction.

### Basis for the opinion of SEAC

The main change compared to the original restriction proposal by France is that the restriction is based on the content of lead in jewellery articles instead of release. Derogations are proposed for lead crystals, precious and semiprecious stones, vitreous enamels and the internal components of watch timepieces.

Also jewellery more than 50 years old is proposed to be derogated.