

Committee for Socio-economic Analysis (SEAC)

Opinion

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

Draft

11 March 2011

**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

Chemicals concerned: *Lead and its compounds*
Chemical name: *Lead*
EC No.: *231-100-4*
CAS No.: *7439-92-1*

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

PROCESS FOR ADOPTION OF THE OPINION

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 on *21/06/2010*. Interested parties were invited to submit comments and contributions by *21/12/2010*.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on *11 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 on 29/03/2011. Interested parties were invited to submit comments on the draft opinion by 28/05/2011.

OPINION

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and 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 in jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of any part of the jewellery article.
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/EEC¹
 - ii) precious and semiprecious stones (CN code² 7103) unless they have been treated with lead or its compounds or mixtures containing these substances.
3. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market before [12-18] months after the entry into force] and jewellery articles more than 50 years old on [the date specified in the restriction on cadmium].

The definition of jewellery articles will be codified on the basis of the restriction concerning cadmium in jewellery. The definition from the cadmium restriction relates to jewellery and imitation jewellery articles and hair accessories, including bracelets, necklaces and rings, piercing jewellery, wrist-watches and wrist wear, brooches and cufflinks.³

¹ Council Directive of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (69/493/EEC).

² 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.

³ At the time of agreeing the draft opinion (11 March 2011) the European Parliament is scrutinising the restriction on cadmium in jewellery.

JUSTIFICATION FOR THE OPINION OF SEAC

Justification that action is required on a Community-wide basis

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

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 is being adopted for cadmium in jewellery⁴. 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/cm²/hr if measured by surface (0.05 µg/g/hr if measured by weight) for both the metallic and the non-metallic parts. However, the 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 children as well as for adults. 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.

⁴ At the time of agreeing the draft opinion (11 March 2011) the European Parliament is scrutinising the restriction on cadmium in jewellery.

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 sale⁵. 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 order to allow import of old jewellery it is recommended that jewellery produced before [50 years before- the specific date mentioned in the cadmium restriction] is exempted from the restriction. The [date] is proposed in order the ease the implementation by importers and enforcements authorities.

If the restriction as proposed is only based on the content of lead (% of weight) (see below) SEAC recommends exempting crystals 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 applies 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 testing⁶; and that the necessary testing method is not 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 [EN-71-3 is developed for the risk associated with swallowing items]). The need to adjust the test method will 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

⁵ REACH, Art. 3.12, defines placing on the market as supplying or making available, whether in return for money or free of charge.

⁶ It is easier to measure the migration from a whole piece of jewellery that is not too big.

understand and measure, and for imported items of jewellery it is important that restrictions for non-metal jewellery is also based on content so that producers in e.g. Asia will only have to meet similar types of requirements as those required in the US.

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 as well as precious and semiprecious stones from the restriction even though they (in particular crystals) 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 $\mu\text{g lead/cm}^2/\text{hr}$ and 0.216 $\mu\text{g lead/cm}^2/\text{hr}$. SEAC has no information whether or not these may be typical migration rates, and no information on what the costs would be to reduce the migration to a level below 0.05 $\mu\text{g lead/cm}^2/\text{hr}$.

The RAC has based its risk assessment for lead in jewellery on the assumption that a child is mouthing 10 cm^2 of the metallic parts over 1 hr per day. As compared to the metal parts of jewellery the health impact of lead exposure from crystals is considered to be relatively small, because there are indications (from the Public Consultation) of much lower migration rates. Furthermore, it is not technically feasible to replace lead from crystals. Therefore SEAC considers that the societal costs of restricting the use of crystals would be disproportionate as compared to the relatively low health impacts. Thus, SEAC considers that a derogation for crystals in jewellery is justified.

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 derogation for crystals. However, precious or semiprecious stones are sometimes treated with lead containing materials. As SEAC considers that other treatment methods are technically and economically feasible, this derogation should not apply if these stones are treated with lead or its compounds, as well as mixtures containing these substances.

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 annum⁷ 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 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 earnings was estimated to be about 30 seconds per year per child. This represents around 30% of estimated 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.

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 Background Document (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 restriction⁸ where separate efforts in order to ensure compliance of jewellery with regard to lead is required.

⁷ 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).

⁸ 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.

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, including enforceability

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, a ‘wet test’ can be performed.

If the restriction was 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.

Enforceability

SEAC agrees that the enforcement of the new regulation can be carried out by existing authorities. According to the Background Document 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 enter into force) may be somewhat above one year. Industry and trade organisations have proposed a maximum implementation period of 24 months. However this request is 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, SEAC considers 12-18 months to be an appropriate phase-in period.

Monitorability

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 will be rather limited.

BASIS FOR THE OPINION OF SEAC

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

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 as content is easier to measure in practice. Derogations for lead crystals, which contain high levels of lead, and precious and semiprecious stones, which may contain high levels of lead, are proposed as they show limited migration and a restriction was not found to be proportionate. Also jewellery more than 50 years old is proposed to be derogated.