

## **ANNEX XV INVESTIGATION REPORT**

**Investigation into the state of the art of scientific information in terms of available analytical methodologies to determine migration of lead from the different materials used in jewellery as well as the availability of alternatives to these materials and to those exempted by paragraph 4 of entry 63 of Annex XVII of REACH to enable the Commission to conduct the required review of the restriction.**

**SUBSTANCE NAME: Lead and its compounds**

**IUPAC NAME: -**

**EC NUMBER: -**

**CAS NUMBER: -**

**CONTACT DETAILS OF THE REPORT AUTHOR: EUROPEAN CHEMICALS AGENCY**

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## Summary

The Commission has requested ECHA to prepare an evaluation report to assist the Commission with the conduct of the required review of entry 63 of Annex XVII to REACH. Based on ECHA's report, the Commission will consider whether to request the Agency to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend the current restriction.

To enable the Commission to conduct the required review of the restriction, the Agency has investigated the analytical methodologies available to determine migration of lead from the different materials used in jewellery and the availability of alternatives to the materials exempted by paragraph 4.

In relation to the alternatives to the exempted materials, no significant new information about availability and feasibility of alternatives has been identified compared to the situation described in the Background Document to the opinions on the lead in jewellery restriction proposal.

Therefore no changes are currently recommended for the following derogations:

- i. Crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC;*
- ii. Internal components of watch timepieces inaccessible to consumers;*
- iii. Non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances;*
- iv. Enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.*

However, the need for the derogations *i)* and *iv)* could be revisited in the future, in light of the evolving market situation and possible R&D<sup>1</sup> innovation.

In relation to a possible introduction of a migration limit, based on the information gathered and discussed in the report (including implementation issues), no change is recommended at the current time.

However, it is recommended to reassess the need and the suitability of adding a migration limit in the future when further experience and evidence will be available.

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<sup>1</sup> Research and development.

## Report

### 1. The problem identified

#### 1.1. Introduction

The Commission has requested ECHA to prepare an evaluation report to enable the Commission to conduct the required review of entry 63 of Annex XVII to REACH: [https://echa.europa.eu/documents/10162/13641/echa\\_lead\\_pah\\_commission\\_request\\_en.pdf/248461e1-cab2-9d23-9d54-42df72d26505](https://echa.europa.eu/documents/10162/13641/echa_lead_pah_commission_request_en.pdf/248461e1-cab2-9d23-9d54-42df72d26505). Paragraph 6 of entry 63 of Annex XVII to REACH, requires the Commission to review the current restriction for lead in jewellery articles by 9 October 2017. Based on this report the Commission will consider whether to request ECHA to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend the current restriction.

Based on the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) on a restriction proposal made by France, Commission Regulation (EU) No 836/2012 of 18 September 2012 was adopted (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:252:0004:0006:EN:PDF>).

To enable the Commission to conduct the required review of the restriction, the Agency has investigated the analytical methodologies available to determine migration of lead from the different materials used in jewellery and the availability of alternatives to the materials exempted by paragraph 4.

Lead and its compounds were commonly used in jewellery for its specific properties and for economic reasons. Children may be exposed to lead when they suck or unintentionally ingest jewellery. In general, the adverse health effects of lead are severe and children are more vulnerable than adults to the effects it can have on the central nervous system. To protect children from exposure to lead, France proposed that the use of lead and its compounds in the production of jewellery and the placing of such articles on the EU market should be restricted.

ECHA has gathered information through a call for evidence<sup>2</sup> and from other sources<sup>3</sup> to assess whether a lead migration limit should be established<sup>4</sup> and whether there are suitable and available alternatives for the following four derogations:

- Crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC;
- Internal components of watch timepieces inaccessible to consumers;

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<sup>2</sup> <https://echa.europa.eu/documents/10162/588104b3-65cc-ac42-ed79-05f7fd09d0bf>

<sup>3</sup> From a support contract with COWI and with the help of the Forum (using a targeted consultation of the Forum members).

<sup>4</sup> Modifying paragraph 1 (entry 63) to include maximum lead migration limit.

- Non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances;
- Enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.

## 1.2. Hazard, exposure/emissions and risk

In the “Background Document to the opinions on the Annex XV dossier proposing restrictions on Lead and its compounds in jewellery”<sup>5</sup> the severe and irreversible effects on children’s health associated with an exposure to lead are described. Children are likely to be poisoned by lead and/or its compounds as a result from an unintentional exposure (ingestion and mouthing) to small articles, such as jewellery. Exposure to lead and its compounds in children was recognised to occur mostly by the oral route, since children are likely to swallow or mouth these articles or parts of them.

RAC established that lead exposure of children up to three years from mouthing should not exceed 0.05 µg/kg bw per day. This exposure is equivalent to a migration of 0.05 µg/cm<sup>2</sup>/hr (0.05 µg/g/hr) considering one hour of mouthing per day (which potentially increases the blood lead level by 1.2 µg/L, and is equivalent to an IQ reduction of 0.1 point). RAC and SEAC noted that it was unrealistic to assume that in average a child is mouthing jewellery for 1 hr every day. However, a more conservative mouthing duration of 1 hr/d which occasionally may occur, was considered to be appropriate to ensure no appreciable risk.

To identify a tolerable lead concentration in the metallic parts of jewellery, RAC used a re-evaluation of a Danish survey<sup>6</sup> indicating an association between the lead content and the migration (with an average slope of 0.7 µg/cm<sup>2</sup>/hr per % of lead content), and from this a limit value of 0.05% was proposed. RAC noted that there is insufficient information on migration rates at lower lead concentrations and for non-metallic parts. However, RAC assessed the applicability of the same limit value proposed for the metallic parts (as explained in the section of characterisation of risks of the Background Document) and concluded that the limit of 0.05% was also protective for non-metallic parts of jewellery.

## 1.3. Justification for an EU wide restriction measure

The aim of the restriction is to minimise children’s lead exposure from jewellery 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.

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<sup>5</sup> <https://echa.europa.eu/documents/10162/c9388bba-2660-4c0e-946b-c3bbe5539940> (Background Document)

<sup>6</sup> (Danish EPA, 2008),

Marketing of jewellery which may contain lead is a general phenomenon in the EU and cannot be isolated to any specific countries. Placing on the market of lead-containing jewellery occurs across the EU.

Since the risks related to lead in jewellery extend over all EU boundaries, a harmonised risk management measure within the EU is also 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. The justifications provided in the Annex XV restriction report of France and the opinions of RAC and SEAC are considered to be still appropriate.

## 1.4. Baseline

Not relevant for this report.

## 2. Impact assessment

### 2.1. Introduction

Lead may be present in jewellery as part of the metal alloy, in solders and certain lead compounds may be used as pigments in coating of jewellery items; lead compounds are thus not necessarily present in the metallic part of the jewellery.

Alloys without lead appear to be widely available on the market and already used in the fashion jewellery sector, as noted in the Background Document to the opinions on the Annex XV dossier proposing restrictions on lead and its compounds in jewellery<sup>7</sup>.

The Background Document also states, it does not seem possible to substitute lead (by itself or in various alloys such as brass and tin containing alloys) by only one metal for its use in jewellery: it may be however envisaged to substitute it by an alloy made of several metals. Searches revealed that lead-free alloys are already available on the market for application in fashion jewellery. They usually contain the following metals in replacement of lead: tin, bismuth, copper and silver.

As reported in the Background Document, lead and its compounds are used in higher quantities in fashion jewellery compared to precious jewellery. All EU countries were mentioned as producing and importing/exporting fashion jewellery, but some countries were leaders in that market.

Fashion jewellery is the main source of lead. It can be plated with base metals and made of a variety of materials such as: brass, copper, stainless steel, titanium, soft metals (tin and lead), aluminium, ceramics, glass, plastic, resin, wood, rubber, leather, nylon, terracotta, horn, raffia, coconut, amber, imitation pearls, crystal, natural/semi-precious stones, recycled material (bones, egg shells) and all sorts of beads (made of glass, metal, resin, terracotta).

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<sup>7</sup> <https://echa.europa.eu/documents/10162/c9388bba-2660-4c0e-946b-c3bbe5539940>

The CBI (2008) reported that, in 2007, in the EU:

- 5 350 companies were producing fashion jewellery
- 22 500 companies were producing precious jewellery

indicating that about 90% of the EU produced jewellery is precious jewellery.

The CBI (2008) also indicated that the EU was among the principal importers of jewellery in the world.

According to CBI (2009) the amount of jewellery imported into the EU was around 80,000 tonnes in 2008. Of this, precious metal jewellery accounted for around 10,000 tonnes and other jewellery around 70 000 tonnes.

SEAC concluded that about 10% of all fashion jewellery placed on the market in the EU contained lead and that the average concentration of lead in these jewellery was about 6%.

In the Background Document it was also indicated an overall magnitude of 150 million pieces of jewellery placed on the market in the EU containing about 6% lead, and that this amount seemed to be growing.

Some recent trade statistics from CBI (2015)<sup>8</sup> indicated that:

- The production of jewellery in Europe showed rapid growth during 2009-2011, followed by a decrease in 2012, influenced by the economic slowdown in Europe<sup>9</sup>, and then a slow recovery in 2013 and 2014.
- The European import of jewellery displayed solid growth in 2010-2014. Intra-European imports accounted for 55% of the total European imports in 2014. Leading Developing Country suppliers are China, Thailand, India and Turkey.
- The European export of jewellery demonstrated steady growth during 2010-2014, driven by the solid demand for "Made in Europe" jewellery, especially in the fine jewellery segment. In value terms, gold jewellery is the largest exported jewellery category within Europe, accounting for more than 80% of EU's export value. Intra-European exports play an important role in European jewellery export.

## 2.2. Economic impacts

### 2.2.1. Background information

#### 2.2.1.1. Crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC

The following arguments for derogation of crystal glass were given in the Background Document to the opinions on the lead in jewellery restriction proposal: *"A number of organisations have claimed that lead free crystal glass with the required properties is not*

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<sup>8</sup> CBI (2015): [https://www.cbi.eu/sites/default/files/market\\_information/researches/trade-statistics-europe-jewellery-2015.pdf](https://www.cbi.eu/sites/default/files/market_information/researches/trade-statistics-europe-jewellery-2015.pdf)

<sup>9</sup> Production relocation to low-cost markets for branded jewellery also had an impact on the slowdown in Europe during that period (CBI, 2015).



*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."*

Further justifications are available in Appendix E of the Background Document, which concludes on issues raised during the public consultation of the draft SEAC opinion.

#### 2.2.1.2. Internal components of watch timepieces inaccessible to consumers

The following arguments for derogation were given in the Background Document to the opinions on the lead in jewellery restriction proposal: *"During the Public Consultation industry has recommended exempting the use of lead in internal components of watches, since such components 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"*

This argumentation is repeated in Appendix E of the Background Document.

#### 2.2.1.3. Non-synthetic or reconstructed precious and semiprecious stones<sup>10</sup>

The following arguments for derogation were given in the Background Document to the opinions on the lead in jewellery restriction proposal: *"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 that may still be present in the stone after the treatment. SEAC has no information which suggests that the use of lead is the only technically and economically feasible treatment method available. Therefore, this derogation should not apply if these stones are treated with lead or its compounds, as well as mixtures containing these substances."*

#### 2.2.1.4. Enamels<sup>11</sup>

The following arguments for derogation were given in the Background Document to the opinions on the lead in jewellery restriction proposal: *"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'*

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<sup>10</sup> (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances.

<sup>11</sup> Defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.

*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."*

Further justifications are available in Appendix E of the Background Document, which concludes on issues raised during the public consultation of the original draft SEAC opinion:

- Lead-free enamels are 'softer' and thus prone to 'marking' and less resistant to chemicals at atmospheric deterioration.
- The processability of lead-free enamels is more difficult than for lead containing alternatives.

### **2.2.2. Information received in the Call for evidence and through other sources**

The information gathered through the call for evidence run by ECHA from 19/04/2017 to 22/08/2017 and from a support contract with COWI<sup>12</sup> has provided a comprehensive feedback from many stakeholders interested in supporting or removing the current derogations. Some information has been submitted in the call for evidence as confidential<sup>13</sup> and it is not part of the public report.

In addition, ECHA has reported the issues related to the legal interface with Directive 69/493/EEC<sup>14</sup>, when evaluating the derogation of crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC. This is briefly discussed at the beginning of section 2.2.2.1.

#### **2.2.2.1. Crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC**

While gathering information on the availability of alternatives, ECHA discussed the legal interface of REACH entry 63 with the Directive 69/493/EEC with the Commission services.

Paragraph 4(a) of entry 63 exempts from the restriction on lead in jewellery in paragraph 1 of the entry, "crystal glass" as defined in Annex I to Directive 69/493/EEC. By virtue of the exemption, such crystal glass may continue to be placed on the market and used in

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<sup>12</sup> Information gathering done in 2017.

<sup>13</sup> See confidential Annex.

<sup>14</sup> <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31969L0493>

jewellery even though the concentration of lead (expressed as metal) exceeds 0.05% by weight.

It is the opinion of the Commission Services<sup>15</sup> that if entry 63 of Annex XVII of REACH had been adopted without paragraph 4(a), there would have been a conflict between entry 63 and Directive 69/493/EEC. REACH would have banned the sale and use of lead in crystal, which satisfied the requirements of Directive 69/493/EEC, thus triggering discussions about which legal instrument prevailed.

The current legal framework presents no changes compared to the initial context under which entry 63 entered into force and it is not under the remit of ECHA to evaluate the need for a review of Directive 69/493/EEC<sup>16</sup>.

In this report to avoid any potential conflict with the legal terminology adopted by the Council Directive 69/493/EEC, alternative products (alternatives), regarded as products not containing lead<sup>17</sup>, will be defined as "lead-free glass products".

During the information gathering process, the following issues have been considered as being critical:

- The existence of alternatives and their availability to various actors in the sector, considering possible patent issues which might be a limiting factor.
- The quality of alternatives, in particular evidence of optical and visual characteristics.

For convenience, the information gathered has been structured into two categories:

- Arguments in favour of the existence of alternatives, indicating that "lead-free glass products" have the same characteristics as crystal glass containing lead oxide as legally defined by Directive 69/493/EEC.
- Arguments not supporting the existence of alternatives and/or not in favour of removing the current derogation.

### **Arguments in favour of the existence of alternatives**

One Member State in the call for evidence noted that several stakeholders seem to be capable of producing alternatives using modern manufacturing methods. For example they noted that Swarovski in their 2017 sustainability report<sup>18</sup> state that today 100% of their

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<sup>15</sup> ECHA has requested an expert opinion to Commission Services in July 2017 on the interface of REACH entry 63 with Directive 69/493/EEC.

<sup>16</sup> One Member State highlighted in the call for evidence that the definition of crystal glass laid down in the Directive 69/493/EEC seems to be outdated, when taking into account that in modern manufacturing methods the substitution of lead in crystal is scientifically and technically possible by using a different substance than lead oxide.

<sup>17</sup> As an added constituent.

<sup>18</sup> [http://www.swarovskigroup.com/S/aboutus/Sustainability\\_report\\_2017\\_final.pdf](http://www.swarovskigroup.com/S/aboutus/Sustainability_report_2017_final.pdf)

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“crystal” is produced with a “lead-free” *Advanced Crystal formula*, containing 0.009% lead or less. Based on the information available to the Member State, the alternatives developed by Swarovski with no intentionally added lead, meet all optical and visual characteristics of crystal (as defined in Annex I of 69/493/EEC). In addition they stated that a number of different glass formulas for lead free glass exist. Therefore, the substitution of lead in crystal is scientifically and technically possible, by simply using a different substance than lead oxide. The Member State further concluded that although the definition of crystal glass laid down in the Directive 69/493/EEC requires a certain amount of lead in the material, if the key characteristics (density, refractive index and surface hardness) can be achieved without the addition of lead, the requirement for a specific lead concentration to fulfil the definitions in Directive 69/493/EEC, should be removed.

Furthermore, enforcement projects run by the same Member State showed that it was relatively common that imported low-price jewellery glass stones contained lead over the concentration limit given in the restriction. They also noted that it was difficult for companies (placing the products in the market) to obtain information on the physical characteristics of the stones, required to demonstrate if they fell under the definitions of Directive 69/493/EEC. Thus they concluded that it was difficult for companies to comply with the restriction on lead in jewellery due to the rather complicated exemption on crystal glass.

Based on publicly available information, Swarovski’s lead-free Advanced Crystal formula results to be patented in the US and 16 European countries. One example of a patent is EP 1725502 B1<sup>19</sup>, which is owned by D. Swarovski & Co. According to the public information from the patent, it is possible to achieve a substantial increase in the refractive index when decreasing the content of SiO<sub>2</sub> and increasing the content of ZnO. It is also stated that the use of LiO<sub>2</sub> (to an extent of at least 0.5%), reduces the melting and processing temperature of the glass.

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<sup>19</sup> <https://www.google.com/patents/EP1725502B1>

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**Table 1** - Lead-free glass composition, adapted from information in patent no. EP1725502B1

Example of composition of lead and barium-free crystal glass			
Oxide	Content % by weight		
	Example 1	Example 2	Example 3
SiO <sub>2</sub>	59.68	58.94	50.94
B <sub>2</sub> O <sub>3</sub>	2.99	2.99	2.99
K <sub>2</sub> O	2.00	1.99	1.00
Na <sub>2</sub> O	13.47	13.45	13.45
U <sub>2</sub> O			2.00
Li <sub>2</sub> O	1.00	2.00	
CaO	6.50	6.00	10.00
MgO	0.72	0.72	0.72
ZnO	9.00	9.00	15.00
Al <sub>2</sub> O <sub>3</sub>	0.42	0.42	2.42
Y <sub>2</sub> O <sub>3</sub>	2.00		
TiO <sub>2</sub>	2.00	1.99	0.99
ZrO <sub>2</sub>		2.00	
Sb <sub>2</sub> O <sub>3</sub>	0.22	0.50	0.50
Refractive index	1.553	1.560	1.571
Density	2.71	2.72	2.82

Lead crystal has a refractive index of at least 1.545. The examples in Table 1 all have refractive index above this level.

Other trademarks or stakeholders which, based on publicly available data, are associated with the production of alternatives without intentionally added lead, are: Stellux<sup>TM</sup><sup>20</sup> and Preciosa.

Preciosa also have 2 lead-free product lines: the MC Chaton MAXIMA<sup>®</sup><sup>21</sup>, which was created in 2013, and the MC Chaton Rose VIVA 12<sup>®</sup><sup>22</sup>. Products in both lines contain less than 0.009% lead. According to Preciosa, the refractive index of the MAXIMA products is 1.585. It is also stated that all sizes of the MC Chaton Rose VIVA 12<sup>®</sup> products are available in Preciosa's full range of colours and coatings.

<sup>20</sup> <http://www.stellux.at/Content.Node/colors-sizes/color-charts.en.html>

<sup>21</sup> <http://preciosacomponents.com/en/products/maxima-by-preciosa/>

<sup>22</sup> <http://preciosacomponents.com/en/products/mc-chaton-rose-viva/>

Searching for patents owned by Preciosa results in patent EP 2625149 B1<sup>23</sup>. According to the publicly available patent-information, the invention relates to a crystal glass with a refractive index higher than 1.53 and high mechanical strength that does not contain any compounds of lead, barium and arsenic. It is intended for the production of artificial jewellery and chandelier semi-finished products and final products made from them. The glass is also intended for the manufacture of household items.

One company (name confidential)<sup>24</sup>, submitted evidence that the manufacture of high quality crystal glass in compliance with entry 63 without exercising the derogation in section 4(a) is technically and economically feasible. However, the Association of the Glass and Ceramic Industry of the Czech Republic and Preciosa Ornella, a.s, provided confidential information not supporting this view<sup>25</sup>.

### **Arguments not supporting the existence of alternatives and/or not in favour of removing the current derogation**

Among stakeholders supporting the retaining of the current derogation there are: European Domestic Glass (EDG)<sup>26</sup>, the Federation of Handmade and Mixed Crystal and Glass-making Industries (FCVMM), a group of French Associations<sup>27</sup>, the Association of the Glass and Ceramic Industry of the Czech Republic.

The main common arguments provided in favour of retaining the derogation are:

- The addition of lead oxide lowers the melting temperature and optimises the viscosity properties increasing the duration of the work and handling time, giving artists more time to create complex objects.
- The lower melting temperature saves energy in the melting process whilst the objects are being shaped, as compared to alternatives needing higher and more frequent heating.

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<sup>23</sup>

<https://www.google.ch/patents/EP2625149B1?cl=en&dq=preciosa&hl=de&sa=X&ved=0ahUKewje7v7zOL3VAhXBblAKHcoPC40Q6AEIODACEP%201725502%20B1>

<sup>24</sup> See confidential Annex.

<sup>25</sup> See confidential Annex.

<sup>26</sup> Which is one out of five sub-sectors of Glass Alliance Europe.

<sup>27</sup> A common comment was submitted in the call for evidence from: la Chambre Syndicale Nationale de la Bijouterie, de l'Orfèvrerie, des Cadeaux et des Industries appliquées aux Métiers d'Art (BOCI), la Fédération des Cristalleries et Verreries à la Main et Mixtes (FCVMM), la Chambre Française de l'Horlogerie et des Microtechniques (CFHM), le Syndicat Professionnel des Émailleurs Français (SPEF), l'Union Française de la Bijouterie, de la Joaillerie, de l'Orfèvrerie, des Pierres et des perles (UFBJOP) avec l'appui de l'Institut du Verre et du Comité Francéclat (Comité Professionnel de Développement de l'Horlogerie, de la Bijouterie, de la Joaillerie, de l'Orfèvrerie et des Arts de la Table).

## ANNEX XV RESTRICTION REPORT – LEAD IN JEWELLERY

- The lead content provides unique optical properties in terms of refractive index, dispersion index and transmission index<sup>28</sup>.
- The presence of lead provides unique mechanical properties (e.g. lower hardness), which means easier cutting of items, as well as finer and more precise engraving, easier chemical and mechanical polishing. Furthermore, for artisan glass cutters, the fact that crystal items are easier to cut than glass reduces the onset of muscular-skeletal problems.
- A recent report assessing the exemption of lead crystal glass in electronics within the scope of the RoHS directive<sup>29</sup> concludes that a one-to-one substitute is not currently available that possess the combined thermal-mechanical-optical properties of lead compounds. The combination of these properties is especially relevant for the quality of some high-end handcrafted products.

The Federation of Handmade and Mixed Crystal and Glass-making Industries (FCVMM) in common with the other French Associations highlighted that in a crystal factory, the furnaces are never turned off and are used for crystal melting whatever the type of item manufactured. The same furnaces are used to create crystal for lights and lamps, table glasses, decorative objects or pieces of jewellery. It would not be worth dedicating a separate furnace to manufacture jewellery. The volume of jewellery produced would not justify the investment, maintenance and permanent running of a furnace solely dedicated to the production of glass for jewellery.<sup>30</sup>

The group of French Associations also highlighted that maintaining the proposed exemption is essential considering the definition of crystal under Directive 69/493/EEC.

EDG, based on follow-up correspondence<sup>31</sup> also pointed out that:

- The conclusions reached in the RoHS exemption study are also relevant for the application of lead crystal glass in jewellery. The properties needed for chandelier glass within the scope of the RoHS exemption are similar to the properties needed for glass in jewellery. Therefore the conclusions of the RoHS exemption study are also applicable for crystal glass in jewellery.
- A range of types of lead-free glasses exists and the majority of mechanically manufactured glass has moved from lead crystal glass to alternatives, but the remaining part is the highly specialized manufacture, for specific applications, and using a significant part of manual work. For this fraction of the high-end market, alternatives cannot provide the optical effects and do not allow the shapes (based on mechanical properties) that lead crystal glass does. This fraction of the high-end

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<sup>28</sup> However, there are apparently conflicting views on this issue. See also confidential annex.

<sup>29</sup> Gensch et al. (2016).

<sup>30</sup> However, different views were provided on this issue by another stakeholder. See confidential annex.

<sup>31</sup> Interviews were made by COWI.

market requires the specific combined thermal-mechanical-optical properties of lead crystal glass.

Regarding the societal aspects, French associations noted that: in France, three major crystal manufacturers (Baccarat, Lalique and Daum) produce jewellery items which represent until 10% of their turnover. The loss of this income would represent a critical damage for these companies.

#### 2.2.2.2. Internal components of watch pieces inaccessible to consumers

Several stakeholders shared comments in the public consultation: the Federation of Swiss Watch Industry, the French Association of Watchmaking and Microtechnology, *Zentralverband des Deutschen Handwerks*, Citizen Watch Co., Ltd, Seiko Instrument Inc. Outside of the call for evidence, another organisation, the Permanent European Horological Committee (CPHE) shared their comments.

The main common arguments provided by industry for a continuation of the derogation are:

- The reasons for the exemption, as identified by the ECHA's Socio-economic Analysis Committee (SEAC) in the Background Document to the opinions on the lead in jewellery restriction proposal are still justified and its removal would not improve the effectiveness of the restriction.
- There is no risk whatsoever to children and other consumers in the event of contact between the mouth and a watch, or in the unlikely event of swallowing a watch, as the alloys which contain lead are hermetically sealed within the watch casing. At no time will the consumer be exposed to lead in such an eventuality.
- Available lead-free alternatives to leaded copper alloys do not fulfil dimension, tolerance and surface quality requirements. Despite ongoing R&D efforts of industry to find alternative materials, no satisfactory solution has been found yet to be used for watch movements. The exclusive use of lead-free machining steel and copper alloys would have the following consequences: the surface roughness of parts is increased, i.e. the surface finish quality is lower, the components lack the necessary precision and dimension, the time needed to machine the materials increases, so does the tool wear and the machining energy consumption.
- RoHS exemptions relevant for electronic watches need to be taken into account. It would create an unbalanced situation in the market, if REACH restricts lead in mechanical watches and at the same time lead containing materials can continue to be used in electronic watches.<sup>32</sup> One stakeholder argues that at the most the same limits of up 0.35% (w/w) of lead in steel and up to 4% (w/w) of lead in copper alloys allowed for electronic watches should apply for mechanical watches.

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<sup>32</sup> However, it is noted that should any stricter rules be proposed under REACH, this would be taken into account during the future assessment of the relevant RoHS exemptions (approx. 2019/2020).



More specifically, the Federation of the Swiss watch industry (together with other stakeholders) provided detailed information on:

- Technical mode of operation of a timepiece movement.
- Technical necessity to use leaded copper alloys and leaded machining steels.
- Interface of REACH entry 63 with the RoHS Directive.

A timepiece movement is an assembly comprising the driving and regulating parts of a watch. For a mechanical movement, the driving energy is stocked in a barrel thanks to the barrel spring. This energy is then transmitted to the escapement by the gear train. The escapement transforms the energy into impulses to maintain the oscillations of the regulating organ at the appropriate frequency. The regulating organ, also named balance-spring, consists of a balance and a spring. These driving and regulating parts are mounted together with the bridges on a bottomplate, which are generally made of leaded copper alloys. This mechanism is supplemented by the winding and hand-setting mechanisms, accompanied in some cases by further complications. A mechanical or electronic watch movement is therefore a complex structure of a great number of small and extremely small parts with tolerances in the micro-range. In some cases, components with a diameter of only 0.07mm (equivalent to the diameter of a hair) and with lengths of 0.3mm that have to fulfil tolerances of +/- 2µ or even +/- 1µ are used. The movement is inserted into the watchcase which protects the movement hermetically against dust, humidity and shocks.

In relation to the technical necessity to use leaded copper alloys and leaded machining steels, the Federation of the Swiss watch industry noted that lead has the following properties:

- Low melting point (327°Celsius).
- Easy to handle during the casting process (at the foundry level).
- Insoluble in the matrix of leaded copper alloys and leaded machining steels; in leaded copper alloy, the interface between lead inclusions and the matrix is incoherent.
- Soft mechanical properties.

As lead is insoluble, it is distributed in small round particles or precipitates throughout the alloy. Due to its remarkable properties and distribution, lead plays a key role as a chip breaker and tool lubricant, therefore improving to a major extent the machinability of copper alloys and machining steels. Many tests on unleaded copper alloys and unleaded machining steels have confirmed that these are not viable alternatives to the alloys which are used at present in the watch industry: major difficulties were encountered during machining of the driving and regulating parts; e.g. the dimensions, tolerances and surface quality requirements were not fulfilled. The absence of equivalent quality for these parts had a negative impact on the primary functions of a watch, namely the precise time measuring function and the service life. Moreover potential alternative materials currently

do not meet other manufacturing criteria such as the productivity, the tool life and the energy consumption.

In relation to the interface of REACH entry 63 with the RoHS Directive, it was also pointed out that:

- Electronic watches are covered by the provisions of Directive 2011/65/EU<sup>33</sup> of the European Parliament and Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic appliances. Electronic watches fall within the scope of application of the directive. A list of the uses which are exempt from the restriction is found in Annex III and in this regard, machining steels and copper alloys are exempted according to points 6a and 6c, with lead contents of up to 0.35% and 4% by weight respectively. These are the same materials which are used not only in the electronic watch movements covered by the directive but also in mechanical watch movements.
- Section 6 of the first RoHS Directive contained only one single exceptional provision which covered lead as an element in steel, aluminium and copper alloys. The revised version of the directive adopted in 2009 splits Section 6 into letters a, b and c. These exemptions are reviewed periodically to determine their pertinence in the light of the technical feasibility of substitution. In the technical report made by *Gensch et al. (2016)*, the experts responsible for the verification of these exemptions (Eunomia, Fraunhofer IZM, Oeko- Institut e.V.) suggested that the exceptional provisions 6a and 6c, i.e. machining steels and copper alloys with added lead, should be repeated..
- It would be inconsistent to permit the use of leaded machining steels and leaded copper alloys for electronic watches which are covered by RoHS (regardless of the criterion of accessibility) while at the same time removing the exceptional provision for non-accessible components in Entry 63 to Annex XVII to the REACH Regulation. A lead content of 0.05% would accordingly apply to non-electronic watches. Considering that identical components are involved in watches of both types, a limit value which is 80 times more stringent would then apply to copper alloys in non-electronic watches.
- According to Section 6 of Entry 63 a modification is only justified if new scientific data including as to the availability of alternatives and the migration of lead from the articles concerned become available.

For the reasons mentioned above, these stakeholders requested the provision contained in Section 4 of Entry 63 of REACH Annex XVII for components which are fitted in wristwatches and pocket watches as well as timepieces but are not accessible to consumers to be maintained.

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<sup>33</sup> <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=celex:32011L0065>

Furthermore, *Zentralverband des Deutschen Handwerks* highlighted that from the information received from their members, it is clear the particular relevance for horologists/watchmakers to keep the current derogation. Among the identified needs for this sector it was mentioned that lead is needed as alloy in watch production to ease cut by chip removal.

### 2.2.2.3. Non-synthetic or reconstructed precious and semiprecious stones<sup>34</sup>

As this derogation is related to allowing the use of naturally occurring stones or not, it is difficult to identify alternatives. The considerations made in the Background Document to the opinions to the Lead on Jewellery restriction proposal appear to be still valid.

A group of French Associations<sup>35</sup> highlighted that the ECHA's Socio-economic Analysis Committee (SEAC) considered to be disproportionate to prohibit the use of precious and semi-precious stones in which lead is present as a naturally occurring constituent in jewellery and watchmaking. Furthermore, they noted that the risks of releasing the lead contained in this type of material can be considered extremely low. Therefore they requested maintaining this exemption because of the low risk of lead exposure from natural precious and semi-precious stones and the disproportionate aspect that the ban would have on their use in jewellery and watchmaking.

However, the lead content varies between different types of stones and for the purpose of this review, for completeness, a list of types of stones available on the market has been compiled with an indication of their typical lead content. Information on lead content in precious stones has been collected via site-specific searches<sup>36</sup>.

The result is shown in Table 2.

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<sup>34</sup> (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances.

<sup>35</sup> A common comment was submitted in the call for evidence from: la Chambre Syndicale Nationale de la Bijouterie, de l'Orfèvrerie, des Cadeaux et des Industries appliquées aux Métiers d'Art (BOCI), la Fédération des Cristalleries et Verreries à la Main et Mixtes (FCVMM), la Chambre Française de l'Horlogerie et des Microtechniques (CFHM), le Syndicat Professionnel des Émailleurs Français (SPEF), l'Union Française de la Bijouterie, de la Joaillerie, de l'Orfèvrerie, des Pierres et des perles (UFBJOP) avec l'appui de l'Institut du Verre et du Comité Francéclat (Comité Professionnel de Développement de l'Horlogerie, de la Bijouterie, de la Joaillerie, de l'Orfèvrerie et des Arts de la Table).

<sup>36</sup> <http://classicgems.net/>

**Table 2** - Overview of lead-containing precious stones and their lead content.<sup>37</sup>

Name	Lead content (%)
Altaite	61.89
Anglesite	68.32
Aschamalmite	63.76
Boleite	49.26
Bournonite	42.40
Cerussite	77.54
Clausthalite	72.41
Coronadite	24.41
Crocoite	64.11
Cylindrite	33.70
Diaboleite	67.18
Esperite	21.64
Francevillite	5.29
Galena	86.60
Hollandite	4.86
Jamesonite	40.15
Kobellite	35.45
Leadhillite	78.82
Mottramite	51.45
Phosgenite	75.99
Potosiite	55.78
Roebingite	29.40
Stolzite	45.53
Vanadinite	73.15
Wulfenite	56.44

#### 2.2.2.4. Enamels<sup>38</sup>

During the information gathering process, the following issues have been considered as being critical:

- The availability of alternative lead-free enamels.
- The quality of these alternatives in terms of optical properties, stability and processability.

A Danish supplier (name confidential) of a wide range of lead-free enamels was interviewed to gather information on alternatives. The main outcomes of the interview were:

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<sup>37</sup> <http://classicgems.net/>

<sup>38</sup> Defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.

## ANNEX XV RESTRICTION REPORT – LEAD IN JEWELLERY

- Lead-free alternatives cannot provide the same shine/sparkling effect as enamels containing lead and the same range of colours, in particular red and some yellow nuances cannot be obtained without lead.
- Lead-based enamels are easier to process and work with.

Many comments were received in the call for evidence from stakeholders (especially individual professional artists/enamellers) from France and the UK. Based on this array of inputs, there seems to be a significant individual artistic production of enamel-based jewellery in France.

The French Union for Professional Enamellers (SPEF) and many professional enamellers mentioned in the response to the call for evidence that:

- The properties of lead-based enamels are crucial for the enamel sector and enamelled jewellery.
- Vitreous enamels are comparable to lead crystal glass in term of production method and properties. Lead is thus needed to obtain the same types of optical, temperature and processing characteristics that are crucial for lead crystal glass in jewellery.
- Jewellery with lead based enamels are mainly used for luxury, fine jewellery and watch making. The enamel sector is a small sector with artisan, high-end production which targets informed clientele.
- Lead based vitreous enamels are more chemically durable than lead-free alternatives.
- With the currently available lead-free enamels, it is not possible to alternate layers with fine metallic leaves (gold and silver).
- R&D is on-going but so far no lead-free enamels provide sufficient quality as demanded by customers. The properties of alternatives are not the same as those of enamels in terms of the appearance and workability of the material.

More specifically, a group of French associations<sup>39</sup>, shared detailed information on technical and societal aspects related to the use of lead enamels. About the technical aspects, the following issues were highlighted:

- In the majority of productions, enamels go through two melting processes: an initial lead glass frit is created then it is introduced into a second mix of (lead-free) raw

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<sup>39</sup> La Chambre Syndicale Nationale de la Bijouterie, de l'Orfèvrerie, des Cadeaux et des Industries appliquées aux Métiers d'Art (BOCI), la Fédération des Cristalleries et Verreries à la Main et Mixtes (FCVMM), la Chambre Française de l'Horlogerie et des Microtechniques (CFHM), le Syndicat Professionnel des Émailleurs Français (SPEF), l'Union Française de la Bijouterie, de la Joaillerie, de l'Orfèvrerie, des Pierres et des perles (UFBJOP) avec l'appui de

material and goes through a second melting process. The mandatory sintering stage is to: 1) Reduce the possible migration of lead as far as possible<sup>40</sup>, 2) Lower the recasting temperatures. 3) Avoid the volatilisation of certain unstable raw materials. 4) Avoid dissolving certain raw materials which are soluble in water or alcohol.

- In lead in vitrifiable compositions, whether for jewellery enamel or for making crystal glasses, lead oxide is introduced into the compositions for the same reasons, being:
  - 1) Fusibility, 2) Shine and transparency, 3) Chemical durability, 4) Colour development and ease of use. In more detail:
    - 1) Fusibility: lead in vitrifiable compositions helps considerably lower the melting temperature of glass. Lead combines very easily at low temperatures to form chemically defined components with silica and boron (which are therefore stable). These two elements present in jewellery enamels are the two main network shapers which ensure the resistance of what we call the glass skeletal structure.
    - 2) Shine and transparency, due to a high refraction index.
    - 3) Chemical durability: lead does not alter the resistance of chemical agents in the glasses made with it.
    - 4) Colour development and ease of use: the enamels containing lead comprise a very wide range of colours. This oxide has the advantage to create colours that would be difficult to imitate without lead. Alkaline and alkaline-earth elements partly dissolve the metallic oxides and impede the development of certain colours. In addition, the enamels containing lead fire rapidly at a very wide range of temperatures; they can be re-fired several times with no devitrification (crystallisation) and above all they tolerate small handling errors (extra thickness, extended storage, too fine grain size, too hot oven, etc...).
- New systems of oxides without lead present major challenges for production and use. New system of oxides is based on the use of elements from alkaline-earth families and a few elements from the transition metals family. These products are melted at much higher temperatures and require much longer production times<sup>41</sup>. Currently there is a range of around 180 colours and shades for lead enamels and it would require significant time to develop a sufficient range of lead-free enamels<sup>42</sup>,

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l'Institut du Verre et du Comité Francéclat (Comité Professionnel de Développement de l'Horlogerie, de la Bijouterie, de la Joaillerie, de l'Orfèvrerie et des Arts de la Table).

<sup>40</sup> The melting phase, by forming silicate or borate complexes, makes the lead practically insoluble. This insolubility will be even greater when the glass is produced under specific conditions (e.g. temperature). In addition it was stated that some companies add a small percentage of alumina to further reduce the migration of lead in enamel jewellery.

<sup>41</sup> For example, a lead-free colour needs firing around a hundred times.

<sup>42</sup> The number of colours and shades available for lead free enamels is not available.

expected to be smaller because of the production costs but consistent to enable the enamellers to work.

- A great number of users are not satisfied by the quality of these new products due to the lack of elasticity and shine, difficulty to use in particular for firing, loss of shine over time, etc. and in general due to the significant differences with the historic enamel range of colours. Some colour shades are impossible to be created with alternatives because of the reduced range and widely differing melting points (one colour will be burned whilst the other will not have melted completely).

About the societal aspects, the following issues were highlighted:

- The production of enamel manufacturers is marginal in terms of volumes generated by “industrial” jewellery. The enamel sector is a small sector with artisan, high-end production.
- European expertise in enamelling has been internationally recognised and well-known for a long time. This sector faces a significant challenge which is safeguarding the unique expertise, the oldest of which dates back to the 11th century<sup>43</sup>.
- Some French manufacturers were interviewed in 2008 as part of UNESCO’s Intangible Cultural Heritage programme, because of the fragility of this expertise.

For the UK market, the Guild of Enamellers had a coordinating role in collecting input from various stakeholders. Technical arguments were largely provided by the enamel provider Milton Bridge Ceramic Colours Ltd. The submission in the call for evidence from the UK Guild of Enamellers covered many of the issues as the input from SPEF, including the similarity with crystal glass, as previously described. Especially it was highlighted that there would be a serious difficulty/impossibility of producing enamels with silver/gold layers if lead is banned. In addition, it was mentioned that:

- Lead-free enamels are not requested by the professional market due to their inferior properties. Despite ongoing R&D efforts of industry to find alternatives, no satisfactory solutions has been found yet.
- The use of lead-based enamels is critical for producing regalia, state insignia, medals, badges etc. where specific colours cannot be changed<sup>44</sup> and durability is of key importance.

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<sup>43</sup> The work in Limoges: <http://www.limousin-medieval.com/emaux>

Among the initiatives promoted by the French government and local authorities: labelling several manufacturers “Living Heritage Companies”, maintaining the Art of Enamelling on Metal NVQ professional qualification; financial and technical support.

<sup>44</sup> State insignia are the most indicative example.

About the societal aspects, the following issue was highlighted:

- Processing companies range from micro (one person) up to small enterprises (30-65 employees). These enterprises would largely cease to exist if lead would be banned, as customers do not accept the inferior quality of jewellery made with lead-free enamels<sup>45</sup>.

Moreover, another stakeholder, *Zentralverband des Deutschen Handwerks (ZDH)*, the German confederation of skilled crafts, highlighted that leaded enamel is of relevance in watchmaking. It is used for instance for the reproduction of face plates, in particular for historic pocket watches and clocks.

## 2.3. Practicability and monitorability

### 2.3.1. Background information

In their evaluation of the restriction proposal on lead in jewellery, RAC, as described in their opinion and Background Document<sup>46</sup>, initially found that it would have been appropriate to set a limit for the migration of lead under the conditions found when children might place lead-containing jewellery in their mouths. However, RAC recognised practical as well as methodological problems with this 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. SEAC recommended 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 recognised that the value recommended by RAC of 0.05 % was practical and a less costly method to implement than a migration test.

A number of practical problems were also identified in the Background Document related to the proposal to base the restriction on a migration limit. These included:

- difficulties in calculating the surface area of jewellery (if a migration limit would be based on surface).
- difficulties to identify and isolate the parts of jewellery containing lead in order to carry out the testing.
- lack of standard testing method (in order to address the relevant type of exposure in saliva for jewellery which is too large to be swallowed).

Furthermore, to ensure a high level of compliance, it was regarded as important that the restriction would be easy to understand and measure. For imported items of jewellery it was also considered to be important that the restriction of non-metal jewellery would be also

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<sup>45</sup> Millions of pieces of hand-made enamelled articles are likely to be produced every year in the EU, including for the automotive industry, civic regalia, watches, jewellery and craft articles, based on the info shared by Milton Bridge Ceramic Colours Ltd.

<sup>46</sup> The information related to the restriction is available at: <https://echa.europa.eu/da/previous-consultations-on-restriction-proposals/-/substance-rev/1902/term>



based on content so that producers outside the EU should only have to meet similar types of requirements as those already in place in the US and Canada.

However, SEAC in their opinion, didn't support the migration limit for a number of reasons: difficulties in calculating the surface area; difficulties to identify and isolate the parts of jewellery containing lead to carry out the testing; and that a necessary standard testing method has not been developed yet (adaptations to EN 71-3 may have to be made to address the relevant type of exposure in saliva and jewellery which is too large to be swallowed).

In their evaluation of the restriction proposal on lead in consumer articles, RAC continued to support the need for a migration limit. Due to information submitted in the public consultation from European Copper Institute, RAC supported a derogation from the content limit for lead in consumer articles for brass alloys if a prescribed migration limit is not breached. It should be noted that in this case, SEAC supported the migration limit due to information supplied in the Public Consultation.

In the discussion on the lead in consumer articles restriction and in the call for evidence related to the current review of the lead in Jewellery restriction, arguments for a migration limit were only provided for brass and tin alloys containing lead, although a paper on bioaccessibility testing for metals was also submitted. Substitutes for these alloys are available as discussed in section 2.1 but it is not clear if they are technically and economically feasible for all the uses of these materials. In the call for evidence, one stakeholder (name confidential), who claimed to be a supplier to the jewellery industry in Europe, stated that: *"Our lead free Tin alloys produced from only high grade purity metals such as Tin, Antimony, Bismuth and Copper contain lead as a impurity of 0.01 – 0.03 % . These impurities cannot be lowered any further in our materials due to the nature of the used high grade raw materials"*.

In addition, as the restriction has already entered into force, alloys used in jewellery containing lead should already meet the content limit. It is also assumed that any migration limit should not reduce the current level of protection provided by the concentration limit.

### **2.3.2. Information received in the call for evidence and via consultation of ECHA Forum Members**

The information gathered through the call for evidence run by ECHA from 19/04/2017 to 22/08/2017 and with the support of the Forum has provided a comprehensive feedback from Member States (via REACH National Enforcement Authorities, NEA) and other stakeholders.

#### **2.3.2.1. Overview of the feedback provided by industry**

In the responses to the call for evidence several organisations and individuals were in favour of a migration limit for lead in jewellery. However, only 5 comments out of 66 relating to a migration limit, were received from industry or other non-Member States organisations, providing feedback on the migration limit and/or analytical methodologies to determine migration of lead from the different materials used in jewellery.

Some respondents proposed a single migration limit, and some a dual content and migration limit. Outside of the call for evidence, another organisation (Eurometaux) shared

a paper<sup>47</sup> on inter-laboratory validation of bioaccessibility testing for metals to support the need for a migration limit. This published paper was then submitted by ECHA for the attention of the National Enforcement Authorities, NEA, for commenting, as indicated in section 2.3.2.2. However, Eurometaux didn't send any other information to support the need for a migration limit.

One of the comments received was from the European Copper Institute (ECI) who proposed that the 0.05% restriction on lead content should be accompanied by a restriction based on the rate of lead release under reasonably foreseeable conditions of use. This would be equivalent to the requirement in Annex XVII to Regulation (EC) No 1907/2006, column 2 of entry 63, referring to lead in articles. The ECI also propose to define the threshold limit values based on the reasonable release of ions after mouthing by young children, considered this scenario as a worst case exposure. However, in the latter comment they just resubmitted a paper suggesting a 20 minute scenario for mouthing by young children that had been previously been rejected by RAC. They also suggested that a migration limit for non-copper or tin alloys should be allowed if the relevant supplier could show the migration was below a certain limit.<sup>48</sup>

Other stakeholders stated (without additional supporting evidence) that:

- in addition to the current limit it would be appreciated a lead migration limit that would allow to use pewter alloys with bigger lead content for specific items galvanizing them after casting with transmission barriers like palladium and gold.
- A migration limit of 0.05 µg/cm<sup>2</sup> per hour could be an alternative option.

The paper submitted by Eurometaux was a general treatise on the use of bioaccessibility testing for metals and although it touched on lead alloys it did not specifically deal with lead in jewellery. The paper does support the previous information that industry are working on standardising tests for bioelution and migration from metals.

However, other industry respondents did not support the introduction of a migration limit, especially for the handicraft sector such as the enamelling sector, characterised by the production of unique pieces of jewellery<sup>49</sup>. One industry stakeholder, Milton Bridge Ceramic Colours Ltd, stated that: *"Given the fact that each enamel has different properties and that each individual finished article is treated individually with acid containing cleaning solution, the potential migration level of each finished article would differ. This would mean that every single finished enamelled article would need to be tested for any migration levels, which is clearly not feasible. Whilst batch testing may be possible from an economic point of*

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<sup>47</sup> Henderson et al, (2014). <http://www.sciencedirect.com/science/article/pii/S0273230014001354>

<sup>48</sup> Public study related to the metal exposure from mouthing copper and tin alloy objects: Urrestarazu et al (2014).

<sup>49</sup> One trade association, the Guild of Enamellers, collected the feedback of companies and artists using enamels in their products.

*view for large manufacturing orders, it would clearly not be feasible for the thousands of enamellers who produce one off pieces."*

In addition, the Gablonzer Industries numbering more than 100 small and mid-sized companies<sup>50</sup> throughout Germany, highly specialised in manufacturing a wide range of jewellery products, shared the following observations:

- The limit value for lead should continue to be defined by weight. The introduction of a limit based entirely on migration value, should be critically evaluated, as most of the quality assurance methods currently in place test by weight. Moreover, testing for migration is considerably more time-consuming than testing by weight. Such tests can only be carried out in specially-equipped laboratories. Such testing involves significant costs, which, due to the strong price competition on the market, cannot be passed on to customers. The considerable increase in terms of time and costs incurred by migration testing would lead to a situation in which the level of quality control could not be maintained.
- In recent years, Gablonzer Industries' companies have undertaken extensive measures (in particular by introducing X-ray fluorescence devices) to analyse incoming and outgoing materials and products, as well as carrying out tests throughout the production process. The acquisition and implementation of these measuring devices and the intensive employee training associated with them represents a major investment for the companies. The current testing methods are based on value by weight/mass. The introduction of a limit based on migration value alone would render all of these measures ineffective and worthless.
- Considering that the existing limit values is considered to be exceptionally severe and problematic<sup>51</sup>, a possible solution could be the introduction of a dual content and migration limit.<sup>52</sup>

Other stakeholders (PRECIOSA ORNELA, a.s., Association of the Glass and Ceramic Industry of the Czech Republic) proposed:

- Retaining the weight limit on lead content of 0.05%, including the exemption, for crystal glass which meets the requirement on category 1 to 4 of Council Directive 69/493/EEC, defined in Regulation 836/2012.

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<sup>50</sup> The Association of Gablonzer Industries represents approximately 70 member companies.

<sup>51</sup> Gablonzer Industries indicates as a preferred maximum lead content: 0.1 % by weight but this is not in the scope of ECHA's evaluation.

<sup>52</sup> No suggestion was made as regards a possible migration value, due to a lack of specific expertise.

- For types of glass which cannot be classified as category 1 to 4 according to Council Directive 69/393/EEC, adding a condition that these types of glass meet the lead migration limit specified in Toy Safety Directive 2009/48/EC, i.e. 160 mg/kg<sup>53</sup>.

### 2.3.2.2. Overview of the feedback provided by Member States (NEAs)

A number of Member States and their enforcing authorities (in response to a targeted consultation of the Forum members) raised several concerns related to the practicality and enforceability of a migration limit if it was implemented in the Lead in Jewellery restriction. The specific set of questions shared with the NEAs in relation to the migration limit, were the following:

1. Have you any direct experience with the enforcement of entry 63 of Annex XVII?
2. Which were/are the most critical aspects you had/have to deal with, when performing the tests? Which analytical methods were/are used?
3. Would a migration limit facilitate enforcement practices?
4. The study by Henderson et al, (2014)<sup>54</sup>, concludes that: *"for hazard and risk assessment applications, the use of these methods to generate relative release data for read-across purposes or to calculate effective concentration of metals in alloys and other complex materials appears to be acceptable."* Would you consider such a test (bioelution testing of metals) or other tests to be suitable to develop a protocol to be used by the EU authorities<sup>55</sup>?
5. Any other topic that you think it may be relevant to define whether a migration limit for lead from the different materials used in jewellery can be proposed (both technical and economic aspects, e.g. the need for a separate calculation for the coating and the substrate, the unit of the migration rate, difficulties of calculating the surface area of complex items, the cost induced by the tests).

In total 10 answers were received by Member States (including NEAs), both via the call for evidence and the specific consultation run by the Forum.

In relation to question n.1, many Member States answers indicated that a number of enforcement projects have been conducted in the last few years, in certain cases analysing significant numbers of jewellery samples. The most recent project was in 2017 and was conducted in Germany, involving about 500 articles<sup>56</sup>. In several cases jewellery was checked for their lead and cadmium content and also for its nickel migration.

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<sup>53</sup> On April 27, 2017, Directive (EU) 2017/738 was published in the Official Journal of the European Union. This amends Annex II of Directive 2009/48/EC, the Toy Safety Directive, as an adaptation to technical progress. The new restrictions will become effective on October 28, 2018. The migration limit for lead 160 mg/kg will be replaced by the new migration limit: 23 mg/kg.

<sup>54</sup> <http://www.sciencedirect.com/science/article/pii/S0273230014001354>

<sup>55</sup> EU enforcement authorities.

<sup>56</sup> About 500 articles were checked for their lead content, 6% of which were non-compliant. 5% of the articles contained lead and lead compounds in concentrations of more than 10%. About 1.5% even contained between 50-80%. 80% of the sellers sold their products on the internet. On the other side, the Norwegian Environment Agency

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In response to question n.2, several Member States reported that preliminary screenings were usually done using X-ray fluorescence (XRF) analysis, due to the simplicity of the test. Alternatively more detailed analysis to measure lead content were conducted using AAS, ICP-OES or ICP-MS or ICP-AES<sup>57</sup>, after an appropriate preparation of the samples with different methods<sup>58</sup> for metal and non-metal parts. When using AAS, ICP-OES or ICP-MS or ICP-AES, it was reported that tests could be difficult, due to the heterogeneous nature of the tested articles, being lead often concentrated in certain areas of an article (such as soldering spots). Another critical point was to have a sufficient amount of testing material, particularly from small pieces of jewellery.

In relation to question n.3, concerns were shared by all respondents and focused on the following aspects:

- From an enforcement point of view it would be much easier and more economically feasible to enforce a limit of content than a migration limit. Migration limits are often more complicated, time consuming and more expensive to implement than concentration limit tests.

Screening with XRF is a very practical and simple tool to estimate metal contents. In addition, the lead content of jewellery can be established via other conventional analysis using AAS or ICP. On the contrary, a migration rate for lead can only be determined via more specific analysis and the development of a standard will be likely needed. For the migration test, costs are expected to rise significantly and therefore the number of samples to be analysed in each campaign will be reduced.

- The more expensive and elaborated analysis for migration (compared to the total lead content) would likely exclude the possibility for an easy in-house analysis or a screening test performed by both enforcement authorities and the companies placing the jewellery on the market.
- Costs related to the use of a lead migration test for jewellery could be comparable to the ones occurring for testing nickel release. In general, for this latter type of test three samples were reported to be needed to achieve reliable results, by one

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stated that had tested 85 inexpensive metal jewellery from street stores in 2016 and found that no piece was over the limit values for lead content.

<sup>57</sup> ICP-AES: Inductively coupled plasma atomic emission spectroscopy; ICP-OES: inductively coupled plasma optical emission spectrometry; ICP-MS: Inductively coupled plasma mass spectrometry; AAS: Atomic absorption spectroscopy.

<sup>58</sup> One NEA reported they had to outsource the testing to an accredited laboratory using: CPSC-CH-E1001-08.3 Method (Standard Operating Procedure for determining Total Lead (Pb) in Children's Metal Products (Including Children's Metal Jewellery) followed by ICP-OES for total lead in metal products; CPSC-CH-E1002-08.3 Method (Standard Operating Procedure for Determining Total Lead (Pb) in Non-metal Children's Products) followed by ICP-OES for total lead in non-metal products; or a combined test for total lead and cadmium, with reference to EPA 3050B / EPA 3051 / EPA 3051A / EPA 3052 followed by ICP-OES. Another NEA mentioned as references used to measure the lead content in the metal parts of jewellery: EPA 3050B and EPA 6010C.

Member State. The migration test of nickel costed about three times more than the analysis of the nickel content<sup>59</sup>.

- The results of a migration test can be more difficult to interpret than a test that analyses the actual content of lead. The available migration tests were originally developed for analysis of new materials rather than of articles. Thus, the relevance of such test for the analysis of articles could be questioned. In addition, the material in articles are often not homogenous, which may affect the reproducibility of the test.
- No new method appears to be readily available for testing the migration of lead in materials and parts of articles that is relevant for this restriction, covering both the mouthing scenario and sucking scenario identified as routes of exposure for children.<sup>60</sup>
- Migration limits alone (without a concentration limit) would be difficult to enforce and would impede risk assessments for RAPEX<sup>61</sup>.

In addition, one Member State mentioned that for the purposes to answer ECHA's inquiry, one of its enforcement authorities conducted a small series of migration tests following the principles of the DIN EN 71-3 (used for migration testing in toys). After digestion for 2 hours in gastric acid, ca. 1% of the lead contained in tested articles migrated. Further tests were conducted on migration in synthetic mixtures of sweat (in accordance to DIN EN 1811, usually used for migration testing of nickel). Up to 3% of the lead content migrated from tested articles, depending on whether lead was present in the outer layers of the article. On average, ca. 0.5% of the lead content migrated. As expected, no lead migrated in cases where lead was only situated within the inner parts of an article.

In response to question n.4, several Member States shared the following observations:

- The method proposed by Henderson et al, (2014) is similar to the one for the wear corrosion applied for determination of the nickel migration limit. Such an analysis is time consuming, requires specific test fluids for the simulation to be applied by the laboratories and is cost-burdening. In contrast to the XRF analysis, the proposed bioelution study is destructive at the sample analysis stage, and this becomes more important in the case of expensive jewelleries. The study was performed on several metals and metal alloys, but in relation to lead, only the migration from the lead-brass alloy was examined. Experience from previous enforcement campaigns indicates that lead in its metal form (Pb<sup>0</sup>) is mostly used in jewelleries, thus bioelution results from such samples would be useful to conclude if the proposed tests are suitable for the development of a protocol. Furthermore, further

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<sup>59</sup> Based on the specific feedback of one Member State.

<sup>60</sup> Further considerations on bioelution tests, as described by Henderson et al, (2014), are discussed in relation to question 4.

<sup>61</sup> [http://ec.europa.eu/consumers/consumers\\_safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/consumers_safety/rapex/index_en.htm)

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refinement of the study would be useful in relation to the interstitial results from the lead-brass alloy, and the lead precipitation observed with pH changes and time.

- For risk assessment, the use of relative release data is preferred. However, taking into account the original purpose of the restriction, while release data would be more appropriate for sucking behaviour of children, this would not be adequate if the jewellery was swallowed and leading to short term higher lead exposures. This could cause acute toxicity as mentioned in the RAC opinion.
- More clarifications would be needed to use the method. For example, what are the specifications when grinding small amounts of samples and which equipment is needed to prevent contamination and be able to grind very small amounts of samples. It would also be needed commercial simulator liquids of a consistent quality. Migration is very sensitive to the conditions: pH, temperature etc. are critical parameters and would need to be clearly specified.
- The use of a bioelution test, while useful in assessing bioavailability and toxicology assessments, is likely to prove difficult to use in an enforcement setting.
- The cited study mentions variations of test results between laboratories >20%. This is outside the limits that would be acceptable for enforcement. This is because the test method would produce results of limited reproducibility and comparability. It would also be hardly possible to conduct tests based on this approach that would hold up in a court of law.
- It would be preferable to have the possibility to choose from a list of 3-4 testing methods. A good method is considered to be the X-ray fluorescence (XRF) which has the following characteristics: determination precision of 0.01%, non-destructive method, the deviation is automatically established in the case of more than one sample, determination may be performed outside the laboratory (with a portable equipment), possibility of instantly analysis bullet in release.

In relation to question n. 5, the following information was shared:

- Migration limits would make analysis significantly more difficult, time-consuming and costly. It would be necessary to identify areas of an article that release lead, as well as the migration rate. For coated products, an abrasion procedure would be required prior to analysis. It would also be necessary to take a number of samples for analysis purposes, which is not always feasible.
- Many types of jewellery contain a core of lead covered by other materials. Thus, migration limits can lead to different results than concentration limits. To avoid this obstacle for enforcement, migration limits should not be implemented without general concentration limits. Calculating the surface area of an article is difficult and time-consuming. The resulting uncertainties of measurement should not be underestimated. For example, the analysis method DIN EN 1811 on the release of Nickel estimates an uncertainty of 46%, compared to an uncertainty of only 10% regarding the concentration by weight.
- Difficulties in the analytical method such as calculating the surface area, coated surfaces of jewellery etc., can be expected. Based on the experiences gathered with migration tests for nickel, it can be stated that a migration test can only focus on

simple objects because of the problem of determining the contact surface. It is virtually impossible to measure the contact surface of complex shapes and the result may be influenced by the part(s) that will come into contact with the simulant for migration. Some laboratories considered that the difficulties of calculating the surface area of complex items or small size items, like rings etc. were significant and time consuming. From an enforcement point of view, a migration test is not recommended.

- The lead content of jewellery can be established via conventional laboratory methods like AAS, XRF or ICP. On the contrary, a migration rate for lead can only be determined via more specific analysis and probably the development of a standard will be needed. For the migration test, costs are expected to rise significantly and therefore the number of samples to be analysed in each campaign will be reduced.
- A software for calculating the area of the jewellery would be important if the migration limit was established.

#### 2.3.2.3. Preliminary results from REF-4 (REACH-EN-FORCE project)

REF-4 is the fourth REACH-EN-FORCE project run by REACH Forum. Some of the aims of the project were to identify non-compliance related to restrictions in the EU-market, to follow-up with enforcement actions and to achieve greater degree of compliance and thus greater degree of health and environmental protection.

The REF-4 project indicated that in checked jewellery products, there was an average 6.7 % non-compliance rate with lead, meaning that 6.7 % of jewellery products tested contained lead above the restricted concentration limit under REACH entry 63.

#### **2.3.3. Discussion on the implementation of a migration limit for the lead in Jewellery restriction**

It is of course possible that a migration limit for lead in jewellery can be introduced. This was already done for the lead in consumer articles restriction and in this case both RAC and SEAC supported its inclusion.

The option of introducing a migration test for lead jewellery needs to be assessed against the specific exposure scenarios that are being targeted: mouthing and ingestion of jewellery by children<sup>62</sup>, as identified in the Background Document<sup>63</sup>. Based on the feedback from Member States (NEAs), it seems that currently there is no protocol/test method ready to use to implement a migration limit covering all the relevant exposure scenarios and that is suitable for lead in jewellery.

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<sup>62</sup> According to one Member State: *“for sucking behaviour of children release data would be more appropriate, but if the jewellery was swallowed the whole lead content will be released.”*

<sup>63</sup> <https://echa.europa.eu/documents/10162/c9388bba-2660-4c0e-946b-c3bbe5539940>



There are several suggestions in the call for evidence on how such a migration limit might be implemented in practice: the concentration limit being replaced by a migration limit or the introduction of a migration limit alongside the content limit. The latter proposal would be in line with the lead in consumer articles restriction and therefore it would be the most preferable option.

The main issues are at present:

- There is no significant evidence of a wide desire for a migration limit at the EU level for the jewellery sector, based on the comments gathered from the jewellery industry (see section 2.3.2.1);
- There is no evidence about the current availability of a harmonised/mature method for assessing the migration of lead from jewellery, being adequate to guarantee a sufficient level of protection to children, for example as the one set by the new limit of the Toy Safety Directive, entering into force on October 28, 2018: 23 mg/kg.

The opinions of RAC and SEAC on the lead in jewellery restriction mention EN 71-3 as a possible basis for such a method (and this was used by one Member State in providing information for this report). However, this uses artificial stomach acid as a release solution and is not appropriate for a mouthing exposure scenario (although it may give some information related to ingestion of the whole jewellery).

Work is still ongoing looking at migration of lead from other media (e.g. ceramics<sup>64</sup> and textiles<sup>65</sup>) and this could inform the work in the future. However, it would need to be demonstrated that the methodology was relevant and reliable (in terms of false positives and reproducibility) for jewellery. The latter method could probably be adapted to migration from Jewellery but would need to be tested to make sure it produced relevant and consistent results.

The evidence of the adequacy of the methodology, to guarantee a suitable protection of children, appears to be especially relevant in light of the high variability of the amount of lead in jewellery articles recorded by several enforcement projects. German National Enforcement Authorities (NEAs), in 2017 conducted an enforcement project focused on lead in jewellery. About 500 articles were checked for their lead content, 6% of which were non-compliant. 5% of the articles contained lead and lead compounds in concentrations of more than 10%. About 1.5% even contained between 50-80%. 80% of the sellers sold their products on the internet. In another project, the Norwegian Environment Agency stated that had tested 85 inexpensive metal jewellery from street stores in 2016 and found that no

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<sup>64</sup> Additional information is available in the report: "Testing approaches for the release of metals from ceramic articles – In support of the revision of the Ceramic Directive 84/500/EEC".

<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/testing-approaches-release-metals-ceramic-articles-support-revision-ceramic-directive>

<sup>65</sup> CEN/TC 248/WG 28: Textiles - Test methods for analysis of EC restricted substances, specifically EN 16711-3 Title Textiles - Determination of metal content - Determination of lead release by artificial saliva solution.

piece was over the limit values for lead content. This indicating a potentially high variability in the lead content of jewellery that may be placed in the market in the EU, also taking into account that many jewellery articles may be imported from non-EU countries<sup>66</sup>. In addition, migration test may not be practically implemented (due to their complexity and costs) as an in-house method by both enforcement authorities and the majority of companies (especially SMEs), thus possibly triggering less controls on the products placed in the market. Indeed, it does not appear to be desirable to have a substantial reduction in the number of controls.

As part of the analysis, also the consequences for professionals, as enamellers, who are highly specialised artists producing unique pieces of jewellery, would need to be taken into account. As highlighted by Milton Bridge Ceramic Colours Ltd, given the fact that each enamel has different properties and that each individual finished article is treated individually with acid containing cleaning solution, the potential migration level of each finished article would differ. This would mean that every single finished enamelled article would need to be tested for any migration levels, should a migration limit replace the concentration limit. Whilst batch testing may be possible from an economic point of view for large manufacturing orders, it would not be feasible for the thousands of enamellers who produce one off pieces<sup>67</sup>.

To summarise, as exposure routes for children include both mouthing and ingestion of jewellery, it seems critical to identify a mature methodology covering both scenarios adequately and being easily<sup>68</sup> implementable, before proposing a migration limit. This also implies that the evidence of the need of a migration limit should be available. Should these conditions (evidence of need and availability of a suitable methodology<sup>69</sup>) be fully met, it is considered relevant to follow the development of the amended "Toy Safety Directive"<sup>70</sup>, which will become effective on October 28, 2018, in relation to the limit to apply<sup>71</sup>.

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<sup>66</sup> The consequences arising from the introduction of a migration limit on the European RAPEX system are not fully clear at the EU level in relation to the lead in jewellery sector.

<sup>67</sup> In the call for evidence run in 2011, the same company mentioned that they had a quotation from a local testing facility to test the lead migration rates of their enamels to specification EN 71-3. The cost was £118.50 per test.

<sup>68</sup> From both a technical and economic point of view.

<sup>69</sup> A suitable methodology should allow to obtain reproducible results, to guarantee an adequate level of protection to children.

<sup>70</sup> On April 27, 2017, Directive (EU) 2017/738 was published in the Official Journal of the European Union. This amends Annex II of Directive 2009/48/EC, the so-called Toy Safety Directive, as an adaptation to technical progress. The new restrictions will become effective on October 28, 2018. The migration limit for lead 160 mg/kg will be replaced by the new migration limit: 23 mg/kg.

<sup>71</sup> See SCHER's Opinion (2016):  
[https://ec.europa.eu/health/sites/health/files/scientific\\_committees/environmental\\_risks/docs/scher\\_o\\_170.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/environmental_risks/docs/scher_o_170.pdf)

## 2.4. Assumptions, uncertainties and sensitivities

The assumptions made and uncertainties identified in the analysis are summarised in this section. Sensitivity analysis is not relevant for this report.

### 2.4.1. Assumptions

- According to the feedback received from German National Enforcement Authorities (NEAs), the amount of lead in jewellery articles can be highly variable. In 2017, they conducted an enforcement project focused on lead in jewellery. About 500 articles were checked for their lead content, 6% of which were non-compliant. 5% of the articles contained lead and lead compounds in concentrations of more than 10%. About 1.5% contained lead between 50-80%. In addition, it was reported in the project that 80% of the sellers sold their products on the internet. In another project, the Norwegian Environment Agency stated that they had tested 85 inexpensive metal jewellery from street stores in 2016 and found that no piece was over the limit values for lead content. Lastly, the results of the REF-4, the fourth REACH-EN-FORCE project indicated that in checked jewellery products, there was an average 6.7% non-compliance rate with lead, meaning that 6.7% of jewellery products tested contained lead above the restricted concentration limit under entry 63. Thus, it is reasonable to assume that a high variability in the lead content of jewellery may occur in articles placed in the market in the EU, also taking into account that many jewellery articles may be imported from non-EU countries.
- According to some Member States, migration limits alone (without a concentration limit) would be difficult to enforce and would impede risk assessments (for RAPEX<sup>72</sup>). Impediments for RAPEX are assumed to be an element of similar concern in all the EU Member States.
- In the Background Document to the opinions on the lead in jewellery restriction proposal, it was stated that to ensure a high level of compliance, it was regarded as important that the restriction would be easy to understand and measure. For imported items of jewellery it was also considered to be important that the restriction of non-metal jewellery would be also based on content so that producers outside the EU should only have to meet similar types of requirements as those already in place in the US and Canada. These conclusions are considered to be still appropriate.
- Calculating the surface area of an article is difficult and time-consuming, as already established in the Background Document to the opinions on the lead in jewellery restriction proposal. The resulting uncertainties of measurement can be significant. One Member State provided some information on the method DIN EN 1811 used for establishing the release of nickel on articles (as a possible proxy for lead). This method for nickel was reported to have an uncertainty of 46%, compared to an

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<sup>72</sup> [http://ec.europa.eu/consumers/consumers\\_safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/consumers_safety/rapex/index_en.htm)

The Rapid Alert System enables quick exchange of information between 31 European countries and the European Commission about dangerous non-food products posing a risk to health and safety of consumers.

uncertainty of only 10% regarding the measure of concentration by weight. A similar uncertainty could be expected to occur when implementing a migration limit referring to a surface unit, for lead in jewellery.

#### **2.4.2. Uncertainties**

- It is unclear if there is a significant need for introducing a migration limit, based on the limited evidence gathered from the jewellery industry at the EU level.
- It is unclear when a suitable methodology applicable to lead in jewellery and adequate to guarantee a sufficient level of protection.
- The consequences arising from the introduction of a migration limit on the European RAPEX system are not fully clear at the EU level and would need further analysis.
- The study made by Henderson et al, (2014), mentions variations of test results between laboratories of >20%. According to some National Enforcement Authorities this test method would produce results of limited reproducibility and comparability. It is unknown to which extent it would be possible to reduce this uncertainty.
- Unique pieces of jewellery such as hand-made enamelled jewellery cannot be tested with destructive analysis methods. In addition, the high costs of complex migration tests seem to be disproportionate for individual artists who place their products on the market directly. The need for a derogation (in relation to the use of a migration test) for this type of products might be likely.
- If a migration test cannot be practically implemented as an in-house method by both enforcement authorities and the majority of companies (especially SME), due to the additional costs involved, this may result in less controls on the products placed in the market. Taking into account the potentially high variability in the lead content of jewellery placed in the EU market, it is unclear which may be the consequences of a substantial reduction in the number of controls for the safety of children.

It is also noted that one Member State highlighted that environmental risks of lead that occur during or after disposal of the articles would not be addressed by the use of a migration limit. Specific information on this aspect is not currently available.

## 3. Conclusions

### 3.1. Availability of alternatives

In relation to the alternatives to the exempted materials, no significant new information about availability and feasibility of alternatives has been identified compared to the situation described in the Background Document to the opinions on the lead in jewellery restriction proposal.

#### **Crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC**

The substitution of lead in crystal is scientifically and technically possible, using a different substance than lead oxide, as several manufacturers already do this and have patented their process or products, as described in section 2.2.2.1. For example, one stakeholder<sup>73</sup>, based on the public information available on its website, claims to produce “lead-free crystals” with a refractive index of 1.585 so that products look and feel the same, if not superior to full-lead crystal components.

Stakeholders in favour of retaining the derogation acknowledge that alternatives, in this report defined as “lead-free glass products”<sup>74</sup>, are available and confirmed that substitution has taken place for most mechanically manufactured glass.

Furthermore, based on the evidence and information described in the confidential Annex, it appears that alternatives can be manufactured with the same optical and visual characteristics as “full lead crystal” and that several patents have expired, providing the industry with additional formulae.

However, the situation for certain high-end handcrafted products, highly specialised manufacture and for specific applications is not so straight forward. For these type of products it was stated by some stakeholders that alternatives cannot deliver the combined thermal-mechanical-optical properties required for the production of these type of products. Reference was also made to a recent review of the lead crystal glass exemption in the RoHS Directive, concluding that one-to-one alternatives are not available for certain high-end applications.

This information corresponds to that partially covered in the Background Document to the opinions on the lead in jewellery restriction proposal. Therefore no changes are currently recommended. However, it is recommended that the need for the derogation could be

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<sup>73</sup> As described in section 2.2.2.1.

<sup>74</sup> In this report to avoid any potential conflict with the legal terminology adopted by the Council Directive 69/493/EEC, alternative products (alternatives), regarded as products not containing lead, are defined as “lead-free glass products”.

revisited in the future, in light of the evolving market situation<sup>75</sup> and possible R&D innovation.

It is the opinion of the Commission Services that if entry 63 of Annex XVII of REACH had been adopted without paragraph 4(a), there would have been a conflict between entry 63 and Directive 69/493/EEC. REACH would have banned the sale and use of lead in jewellery, which satisfied the requirements of the Directive, thus triggering discussions about which legal instrument prevailed. However, if the key characteristics of crystal and crystal glass can be achieved without the addition of lead, the requirement for a specific lead concentration to fulfil the definitions in Directive 69/493/EEC, could be removed.

### **Internal components of watch timepieces inaccessible to consumers**

According to the gathered information, available lead-free alternatives to leaded copper alloys do not fulfil dimension, tolerance and surface quality requirements. Despite R&D efforts of industry to find alternative materials, no satisfactory solution has been found yet. In addition, stakeholders supporting the derogation highlighted that there is no risk whatever to children and other consumers in the event of contact between the mouth and a watch, or in the unlikely event of swallowing a watch, as the alloys which contain lead are hermetically sealed within the watch casing. At no time will the consumer be exposed to lead in such an eventuality.

Due to the fact that no significant change has occurred in the recent years compared to the situation described in the Background Document to the opinions on the lead in jewellery restriction proposal, no change in the proposed derogation under entry 63 is suggested.

### **Non-synthetic or reconstructed precious and semiprecious stones<sup>76</sup>**

As this derogation is related to the use of naturally occurring stones or not, it is difficult to identify alternatives. The considerations made in the Background Document to the opinions on the lead in jewellery restriction proposal appear to be still valid.

Due to the fact that no significant change has occurred in the recent years compared to the situation described in the Background Document, no change in the proposed derogation under entry 63 is suggested.

### **Enamels<sup>77</sup>**

It is clear from the information received that lead-based enamels have a superior shine/sparkling effect and a range of colours which cannot be obtained without lead. Some

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<sup>75</sup> E.g.: new stakeholders entering the market of the alternatives with high quality lead-free product lines for jewellery, expired patents, etc.

<sup>76</sup> (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances.

<sup>77</sup> Enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.

colour shades are impossible to be created with the current alternatives because of the reduced range and widely differing melting points.

In addition, lead-based enamels are easier to process and work with. A great number of professional users are not satisfied by the quality of alternatives due to the difficulty to use in particular for firing, loss of shine over time, and lack of other properties.

Due to the fact that no significant change has occurred in the recent years compared to the situation described in the Background Document to the opinions on the lead in jewellery restriction proposal, no changes in the proposed derogation under entry 63 are recommended. However, the need for the derogation could be revisited in the future, in light of possible R&D innovation.

### **3.2. Migration limit**

Based on the analysis provided in section 2.3.3, it is recommended to reassess the need and the suitability of adding a migration limit in the future, when further experience and evidence will be available.

As exposure routes for children include both mouthing and ingestion of jewellery it seems critical to identify a mature methodology covering both scenarios adequately and being easily implementable, before proposing a migration limit. This also implies that the evidence of the need of a migration limit should be available. Should these conditions (evidence of need and availability of a suitable methodology) be fully met, it is considered relevant to follow the development of the amended "Toy Safety Directive", which will become effective on October 28, 2018, in relation to the limit to apply.

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<sup>78</sup> (Crystal glass is addressed under analysis of Exemption 29 on page 679 of the report).

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