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

Background document
to the opinions on the Annex XV dossier
proposing restrictions on
Lead and its compounds in jewellery

ECHA/RAC/RES-O-0000001304-85-03/S1
ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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

This Background Document (BD) shall be regarded as further reference material to the opinions of the Committees for Risk Assessment and Socio-economic Analysis. It contains further details and assessment in addition/beyond the justifications provided in the opinions including, where relevant, information that has been received during the opinion making process and may be used to better understand the opinions and their justifications. The BD is a supporting document based on the Annex XV restriction report submitted by France, and updated to support the opinions of the Committees.

29/03/2011

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List of acronyms

AFSSET	French Agency for Environmental and Occupational Health safety
BAF	Bioaccumulation factor
BASF	Biota-to-sediment accumulation factor (see Bioaccumulation factor)
BCF	Bioconcentration factor
BfR	Federal Institute for Risk Assessment
BMDL	Benchmark Dose (Lower Confidence Limit)
BMF	Biomagnification factor
BOCI	Trade association of producers of fashion jewels
bw	Bodyweight
CBI	Centre for the Promotion of Imports from developing countries
CDC	Center for disease control
CETEHOR	Technical Centre for the watch and jewellery industry
CNS	Central nervous system
CPDHBJO	Professional Committee for the Development of the French Watch, Clock, Jewellery and Silverware industries
CPSC	Consumer Product Safety Commission
CPSIA	Consumer Product Safety Improvement Act
CSR	Chemical safety report
d	Day
DMEL	Derived Minimal Effect Level
DMELc	Chronic Derived Minimal Effect Level
DNEL	Derived No Effect Level
DNELa	Acute Derived No Effect Level
DOC	Dissolved organic carbon
DTx (e.g. DT50)	Disappearance time for x%
dw	Dry weight
ECHA	European Chemicals Agency
ECI	European Copper Institute
ECx	Effective concentration x%
EPA	Environmental Protection Agency
ERA	Environmental risk assessment
FAAS	Flame atomic absorption spectroscopy
GFAAS	Graphite furnace atomic absorption spectrophotometry
GI	Gastrointestinal
HC5-50	Hazardous concentration
IEUBK	Integrated Exposure Uptake Biokinetic Model for Lead in Children
ILA	International Lead Association
INERIS	National Institute for Industrial Environment and Risks
InVS	French Institute for Public Health Surveillance
IQ	Intelligence quotient
Kd, Kp	Partition coefficient
KEMI	Swedish Chemicals Agency
Koc	Soil organic carbon-water partitioning coefficient
Kow	Octanol-water partition coefficient
LCx	Lethal concentration x%
LDx	Lethal dose x%
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest observed effect concentration
LOQ	Limit of quantification
MDI	Mental Developmental Index
MS	Member State

MSCA	Member State Competent Authority
NIOSH	National Institute of Occupational Safety and Health
NOAEL	No Observed Adverse Effect Level
NOEC	No observed effect concentration
OC	Organic content
PbB	Blood lead
PBPK	Physiologically Based Pharmacokinetic
PEC	Predicted environmental concentration
PNEC	Predicted no-effect concentration
PTWI	Provisional tolerable weekly intake
RIVM	National Institute for Public Health and the Environment
RMO	Risk management option
SCF	Scientific Committee on Food
SCHER	Scientific Committee on Health and Environmental Risks
SSD	Species sensitivity distribution
STOT	Specific target organ toxicity
SVHC	Substance of very high concern
TCNES	Technical committee on new and existing substances
TDI	Tolerable daily intake
TGD	Technical guidance document
VRAR	Voluntary risk assessment report
WHO	World Health Organization
ww	Wet weight

A. Proposal

A.1. Proposed restriction

A.1.1. The identity of the substances

The substances concerned herein are all lead compounds used in jewellery which might liberate the lead ion. Instead of giving an exhaustive list of all lead compounds, only elemental lead is selected and presented as prototype for all other lead compounds.

Table 1: Identity of the substance

Substance name	IUPAC name	CAS Number	EINECS	Formula	Purity and impurities
Lead	Lead	7439-92-1	231-100-4	Pb	The restriction shall apply to lead whatever its purity is[1]

Reference number for submission to the Registry of Intention: 4982fb69-1672-4360-b24b-5f362aba1e51

A.1.2. Scope and conditions of restriction

A.1.2.1. Retrospective and context

For transparency reasons the retrospective and context as presented by the French CA as dossier submitter is presented below. RAC and SEAC have not commented this part of the proposal.

Since the 1970s, lead and its compounds have been submitted to several Regulations limiting their use in many different products such as petrol, cosmetics, electronic equipments, toys etc. (for more information on the regulations related to lead and its compounds, see Section B.5.1.1). As a result of these implemented Regulations, children's exposure to lead has progressively decreased. However, since the 1990s, children lead poisoning from **unusual sources** has been reported. Amongst these sources are fashion jewellery articles from which lead might be released. In Europe, lead and its compounds are not regulated for their use in jewellery (neither fashion, nor precious jewellery). They are not even regulated for fashion jewellery intended for children, as these articles are exempted from the new Toy Safety Directive 2009/48/EC[2].

Lead may be present in jewellery as part of the metal alloy, but also in solders and certain lead compounds may be used as pigments in the coating; they are thus not necessarily present in the metallic part of the jewellery. Consequently, both metallic and non-metallic jewellery are potential sources of exposure to lead (Yost J.L. and Weidenhamer J.D. (2008)). Concentrations of lead which have been measured in different studies are very variable: from 0.000002% to over 99% (BfR (2008); CDC (2006)). The presence of lead may be either intentional, or unintentional. In the latter case, lead may be present as an impurity resulting from recycling processes (Weidenhamer J.D. and Clement M.L. (2007a); Weidenhamer J.D. and Clement M.L. (2007b); Weidenhamer J.D. and Clement M.L. (2007c); Fairclough G. *et al.* (2007)).

[1] The restriction dossier shall apply also to organic and inorganic lead compounds whatever their purity is.
[2] See Annex 1 of Directive 2009/48/EC:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:170:0001:0037:en:PDF.

Given the fact that lead is considered as a non-threshold toxic substance for neurotoxic effects and given the specific vulnerability of children, exposure to this substance should be avoided as much as possible. Indeed, it can result in the damage of their central nervous system, thus adversely impacting their development. Considering lead toxicological profile, wearing lead containing jewellery (i.e. exposure via dermal route) does not seem to result in any health risk. On the contrary, mouthing or accidentally ingesting jewellery which contain lead can result in health risks.

Such potential health risks have been confirmed by reported cases in the international literature. Indeed, several cases of children poisoning resulting from the misuse of jewellery (mouthing and ingestion) are documented in the international literature (see section B.5.3.1), the worst case being the death of a four-year-old child who had ingested a bracelet's pendant containing 99% of lead, in the USA in 2006 (CDC (2006)). Further to this accidental death, the company which had supplied the pendant as a free gift with the purchase of a pair of shoes was recently fined one million dollars, the largest sum ever imposed by the United States' Consumer Product Safety Commission (CPSC) for violating the law on dangerous products which restricts the level of lead in toys and items intended for children in the USA. This accident shows the importance of regulating such products.

In 2006, the French Institute for Public Health Surveillance (InVS) asked, in a technical note dealing with unusual sources of children lead poisoning, for a ban on lead in all products for which a substitution is economically acceptable (InVS (2006b)). It mentions that lead is still widely used in products which are not intended for children but which may accidentally be used by them and result in lead poisoning. Consequently, in its investigation guide for lead poisoning (InVS (2006a)), InVS proposes a questionnaire in which, among others, it is asked whether the child often puts some metallic objects in his mouth such as jewellery for instance. According to Maas R.P. *et al.* (2005), lead-containing products with moderate or low exposure potential are becoming acknowledged as having public health significance. The authors conclude on the necessity of identifying and eliminating unregulated sources of lead exposure from common consumer products. For Weidenhamer J.D. and Clement M.L. (2007c), given the high neurotoxicity of lead to young children, inexpensive jewellery items pose a potential yet avoidable threat to children's health.

In this context, the European Commission Working Group "Limitations on Marketing and Use of Dangerous Substances and Preparations" decided at the end of 2007 to examine the issue of lead in jewellery. Member states were first expected to provide some additional information related to this issue. In March 2008, Germany, Denmark and Sweden informed on the presence of high levels of lead in metal jewellery, which could constitute risks for human health, in particular for children. Greece expressed concern for jewellery imported into the EU which contains lead (and cadmium). In July 2008 meeting, France, Germany, Greece and Denmark expressed again their concern about that issue and the interest of limiting the use of lead in jewellery through reports and notes (InVS (2006b); BfR (2008); InVS (2008)). These concerns were supported by several studies led in Europe, the USA, Canada and Japan in which a great number of tested fashion jewellery contained lead (Canada Cazette (2005); Danish EPA (2008); DGCCRF (2008); KEMI (2008); Maas R.P. *et al* (2005); Weidenhamer J.D. and Clement M.L. (2007b); Weidenhamer J.D. and Clement M.L. (2007c)) (for further details, see section B.2.2) and by the numerous reminders issued by the US CPSC for this type of articles for several years (KID (2004)).

It has to be noted that in 2007, the Swedish Chemicals Agency (KEMI) and the Swedish Environmental Protection Agency (EPA) proposed their government to set up a national legislation restricting the use of lead in consumer articles and in jewellery specifically (under the Chemical Products Ordinance 1998:944). The Swedish government has not yet acted on that issue. KEMI also pressed, at European level, for prohibition under the General Product Safety Directive 2001/95/EC of cast jewellery and accessories containing lead because of a marked and serious risk of harm to health (KEMI (2007)) with a proposed concentration limit of 0.1% lead by weight and a concentration limit for functional metal parts in jewellery of 0.3% lead by weight. Germany also recommended the inclusion of fashion jewellery for children in the provisions of the Toys Safety Directive 88/378/EEC (BfR (2008)).

In the USA and Canada, legislation is already implemented in order to limit exposure to lead via some consumer products with a special target on costume jewellery: in the Consumer Product Safety Improvement Act of 2008 (CPSIA) for the USA and in the Children's Jewellery Regulations of May 10^{th} 2005 "on jewellery for children under 15" for Canada (for further details, see section E.1.3). Furthermore, KEMI (2007) specifies that introduction of rules prohibiting lead in jewellery was under consideration in Japan.
Denmark also adopted a regulation concerning the concentration of lead for imported and sold products, including jewelleries.

Moreover, according to the International Lead Association Europe (ILA), the EU Voluntary Risk Assessment Report on lead and some inorganic lead compounds (LDAI (2008a; LDAI (2008b)) concluded a potential risk from the use of lead in children's costume jewellery due to the potential for accidental ingestion. On the basis of these conclusions, ILA, representing a significant proportion of EU lead manufacturers, indicated during consultation that it "does not support the use of [metallic] lead in children's fashion jewellery."

It is highlighted that the articles which are mouthed by children under 36 months consist of many items which are not intended for them (RIVM (2008)). RIVM recommends that "the exposure assessment of all toys which can be placed in the mouth or can be crawled on by children should include exposure scenarios for young children, regardless of the intended age category of the toy" (RIVM (2008)). This is clearly the case of jewellery which is not intended for children but with which children can easily come into contact.

In the USA, between 1990 and 2004, jewellery constituted the largest number of units (more than 152 million of units) recalled among children's products recalled for elemental lead (KID (2004)). Consequently, this issue is not just anecdotal. However, as these products are not regulated in most European countries, such information is not available for these countries.

As a consequence of those Working Group meetings, alerts, reports and analyses, France suggested, at the end of 2008, to consider the possibility of preparing an Annex XV Dossier under REACH Regulation and initiated the process for adopting a restriction in Annex XVII.

In 2009, BfR (Federal Institute for Risk Assessment) published an opinion which supports the WHO's demand to urge government and industry to entirely eliminate substances in toys, such as lead, that are likely to result in adverse toxic effects (WHO (2007)) and which asks to apply the ALARA principle (as low as reasonably achievable) to lead in toys and other consumer products (BfR (2009)).

A.1.2.2. Conditions and scope of restriction

Conditions of the restriction

Opinion of RAC
Metallic and non-metallic parts of jewellery articles shall not be used or placed on the market if the lead concentration is equal to or greater than 0.05% by weight of the part;

Paragraph above does not apply, when it can be demonstrated that the rate of lead release from the jewellery article or any part thereof does not exceed 0.05 $\mu g/cm^2/hr$ (0.05 µg/g per hr)

Draft opinion of SEAC
Lead and its compounds shall not be used or placed on the market in jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of any part of the jewellery article.

However, a derogation for crystal parts ('Full Lead Crystal' and 'Lead Crystal' as defined in Annex I in Council Directive 69/493/EEC)[3] of jewellery articles is proposed and a derogation for precious and semiprecious stones (CN code[4] 7103) unless they have been treated with lead or its compounds or mixtures containing these substances is proposed.

In addition, it is proposed that the restriction shall not apply to articles placed on the market before [[12-18] months after the entry into force] and jewellery articles more than 50 years old on [the date specified in the restriction of cadmium].

SEAC proposes to use the definition of jewellery articles as defined in the restriction concerning cadmium in jewellery[5]. The definition from the jewellery restriction relates to jewellery and imitation jewellery articles and hair accessories, including bracelets, necklaces and rings, piercing jewellery, wrist-watches and wrist wear, brooches and cufflinks.

Otherwise this restriction proposal uses the definitions given in the REACH regulation:

▪ A "use" is defined as *"any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing,* ***production of an article*** *or any other utilisation"* (Article 3-24).

▪ "Placing on the market" is defined as: "*supplying or making available, whether in return for payment or free of charge, to a third party.* ***Import shall be deemed to be placing on the market*** (Article 3-12).

▪ A "supplier of an article" is defined as: *"any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market"* (Article 3-33).

▪ A "producer of an article" is defined as: *"any natural or legal person who makes or assembles an article within the Community"* (Article 3-4).

▪ An "importer" is defined as: *"any natural or legal person established within the Community who is responsible for import"* (Article 3-11).

▪ An "import" is defined as "*the physical introduction into the customs territory of the Community"* (Article 3 -10).

Scope of the restriction

The proposed restriction applies to all jewellery, whether they are intended for children or not. In the framework of REACH Regulation, these items are considered as "articles" such as defined by article 3-3: "*object*(s) *which during production* (are) *given a special shape, surface or design which determines* (their) *function to a greater degree than does* (their) *chemical composition"*.

The proposed restriction shall apply to both precious and fashion jewellery. This choice is mainly based on manageability reasons. Indeed, there is no clear definition for what a fashion jewellery is even though fashion jewellery may be differentiated in practice from precious jewellery, according to RPA (2009) depending on the used material (presence of precious metal alloys in precious jewellery and use of a variety of materials in fashion jewellery), on the place where they are sold, on the pricing structure (fashion jewellery is significantly cheaper than precious jewellery) and on the presence of a

[3] Council Directive of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (69/493/EEC).
[4] Commission Regulation (EU) No 861/2919 of 5 October 2010 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Custom Tariff.
[5] At the time of agreeing the draft opinion (11 March 2011) the European Parliament is scrutinising the restriction on cadmium in jewellery.

hallmark which indicates that jewellery is precious (however, the absence of a hallmark does not necessarily mean that the article is a piece of fashion jewellery). Moreover, it is acknowledged that the majority of reported cases involve fashion jewellery and not precious ones. However, because of a lack of a clear definition, because children can come into contact with adult jewellery, and also because it is expected that the use of lead and its compounds is marginal in the sector of precious jewellery, decision was made to include both types of jewellery. Section E.2.1.2.3 presents more information on the differences between fashion and precious jewellery.

Concerning the scope of the restriction proposal, SEAC proposes to have a derogation for crystal parts of jewellery articles and for precious and semi-precious stones as described above.

As indicated by the French CA as dossier submitter it is highlighted that this restriction dossier only deals with jewellery although some other lead containing articles (such as key rings, coins etc.) may also be mouthed and accidentally swallowed by children and, as such, represent also potential health risks for this vulnerable population which are not addressed by the current restriction proposal.

The French proposal for focusing on lead in jewellery was based on their assessment that many of the reported cases deal with jewellery and this is their reason for targeting this restriction proposal on this type of articles.

SEAC proposes to use the same definition of jewellery articles as is used in the cadmium restriction for jewellery, as described above.

Measurement methods

The proposed restriction aims at preventing lead poisoning of children because of the misuse of jewellery articles which contain lead and its compounds.

Lead content is the quantity of lead that is present in the jewellery's composition whereas lead migration rate is the quantity of lead which can be released by the jewellery, during a certain time, generally under acidic conditions, simulating the use or misuse of the jewellery (e.g. mouthing or ingestion). RAC agrees that **the limitation of lead migration rate should be considered to be the most relevant indicator of potential exposure**. However, taken into account the technical difficulties for a realistic measurement of migration rates at the low level required for this restriction RAC has re-evaluated the Danish survey and identified statistically significant correlations between the lead content in metallic parts of the jewellery and the measured migration rates.

As a consequence, RAC considers that a limit value of 0.05% for the metallic parts of jewellery based on the established migration rates would protect against non tolerable exposure. No information is available on non-metallic parts; however RAC considers that this limit value of 0.05% is also protective for the non-metallic parts of jewellery based on the exposure scenario and suggests the use of the same limit until specific information may become available.

Accordingly, a migration limit of 0.05 µg Pb/ cm^2 per hr or 0.05 µg Pb/g per hr should be used for allowing jewellery containing lead concentrations above the proposed content limit to be used or placed on the market.

Several testing methods are available for the measurement of the lead migration rate from jewellery. The quantity of lead is measured without any distinction of the origin of lead (presence as metallic lead, or as part of an inorganic or organic compound) (for further details on these methods, see section E.2.1.2.2). RAC is aware that currently there are not standardised procedures for migration testing and measuring of lead in saliva, and suggests the development of reliable methods to perform and detect migration at the recommended rate.

The lead content of 0.05% for the metallic and non-metallic parts or the migration rate of 0.05 μg/cm² per hr or 0.05 μg Pb/g per hr for the metallic or non-metallic parts should be considered for each individual part of the jewellery**.** When tests are performed on several parts of an article, the analytical results of each part should be compared to the limits of 0.05% or 0.05 μg/cm²/hr (or 0.05μg Pb/g per hr). If a part has either a content or a migration rate, as appropriate, which exceeds the corresponding limit, it should be considered that the article is not allowed to be used or placed on the market.

For metallic parts, examination regarding lead content can be done in a non-destructive way using X-ray fluorescence (XRF) devices. Thus only in relevant occasions a destructive standard wet chemical analysis has to be performed.

For migration measurements, France as a dossier submitter proposed to use the available standard **EN 71-3** which is already used for testing the migration of certain elements from toys. Several adaptations have to be considered. First, as mouthing activity can result in significant exposure, jewellery should be tested even if they cannot be ingested by a child because of their size, i.e. even if they do not fit in the so-called "small parts cylinder" referred to in EN 71-3 (and defined in the standard EN 71-1-A9). Secondly, coated jewellery should be tested after removal of their coating; in this case, the sum of both migration rates (coating alone and jewellery without its coating) should not exceed the proposed limit in the restriction. Indeed, high levels of lead (23%) have been measured in the coating of inexpensive plastic jewellery items (Yost J.L. and Weidenhamer J.D. (2008)), demonstrating the importance of taking into account the potential exposure resulting from coatings. More information on EN 71-3 and on the necessary adaptations is available in Section E.2.1.2.2. RAC recognises that further work has to be done in order to specify how the testing for content as well as for migration should be performed. RAC emphasises that reliable methods to determine migration rates from jewellery especially at lead concentrations below 1% need to be established.

SEAC considers that the restriction based on content measurement using the 0.05% as proposed by RAC for the metallic parts of jewellery articles it most practical and less costly method to implement.

For non-metallic parts of jewellery SEAC has not been able to evaluate the consequences of introducing a restriction neither based on content nor migration. However, taking into account Forum advice and that in e.g. USA the regulation on jewellery containing lead is based on content which also applies to the non-metallic parts of jewellery, SEAC recommends that the restriction of lead also in non-metallic parts of jewellery should be based on content and proposes to use the same content limit than for metallic parts of jewellery articles. However, it is proposed to exempt crystals and precious and semiprecious stones from the restriction. As compared to the metal parts of jewellery the health impact of lead exposure from crystals is considered to be relatively small, because there are indications of much lower migration rates. Furthermore it is not technically feasible to replace lead from 'Full Lead Crystals' and 'Lead Crystals' as defined in no. 1 and 2 in Annex I to Council Directive of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (69/493/EEC). For crystal glass as defined in no. 3 and in the Annex I to (69/493/EEC) other metal oxides might by used and therefore lead is not required There are indications that lead may be present as a naturally occurring constituent in precious and precious stones. SEAC considers that it would be disproportionate not to allow such stones to be used in jewellery, based on analogous argumentation used to justify the derogation for crystals. However, precious or semiprecious stones are sometimes treated with lead containing materials. As SEAC considers that other treatment methods are technically and economically feasible, this derogation should not apply if these stones are treated with lead or its compounds, as well as mixtures containing these substances.

Wording of the restriction text for Annex XVII

1. Original proposal from the dossier submitter (France)

Designation of the substance, of the group of substances or of the mixture	**Conditions of restriction***
Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be used in jewellery articles if the lead migration rate from such articles is greater than 0.09 µg/cm²/hr. 2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph. 3. The measure of the migration rate specified in paragraph 1 should be performed under the acidic conditions, the temperature and the duration specified in EN 71-3 standard.

* The limit value should normally relate to individual articles, parts or materials that a complex article consists of.

2. Restriction proposal from the dossier submitter (France) in the first version of the background document

Based on the first FORUM advice France modified the restriction proposal accordingly:

Designation of the substance, of the group of substances or of the mixture	**Conditions of restriction***
Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be used in jewellery articles if the lead migration rate from such articles is greater than 0.09 µg/cm²/hr. 2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph. 3. For demonstrating the conformity of articles with paragraphs 1 and 2 the CEN standard recommended by the ECHA shall be used

* The limit value should normally relate to individual articles, parts or materials that a complex article consists of.

3. Final suggested text by RAC

Taking into account the discussions in the RAC, the re-evaluation of the Danish migration data, the second FORUM advice and the information provided during the public consultation, RAC proposes in its opinion the following restriction to be transposed in Annex XVII:

Designation of the substance, of the group of substances or of the mixture	**Conditions of restriction**
Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	Shall not be used or placed on the market in i) Metallic and non-metallic parts of jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of the part; ii) The paragraph above does not apply when

	it can be demonstrated that the rate of lead release from the jewellery article or any part thereof does not exceed 0.05 µg/cm^2/hr (0.05 µg/g per hr).

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4. Final suggested text by SEAC (draft opinion)

Based on discussions in the SEAC, on the RAC opinion, on the second Forum advice and on the information provided during the public consultation, SEAC proposes in its draft opinion the following restriction to be transposed in Annex XVII:

Designation of the substance, of the group of substances or of the mixture	**Conditions of restriction**
Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be used or placed on the market jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of any part of the jewellery article. 2. By way of derogation, paragraph 1 shall not apply to i) "Full lead Crystal" and "Lead Crystal" as defined in Annex I in Council Directive 69/493/EEC).[6] ii) Precious and semiprecious stones (CN code[7] 7103) unless they have been treated with lead or its compounds or mixtures containing these substances. 3. By way of derogation, paragraphs 1 shall not apply to jewellery articles placed on the market before [[12-18] months after the entry into force] and jewellery more than 50 years old on [the date specified in the restriction on cadmium].

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

It is important to consider that consumers may still be exposed to lead in jewellery which is already in their households. Based on this, **the importance of communicating on the human health risks resulting from these articles and, to a larger extent, from all articles which may contain lead and which may be mouthed and/or ingested by children is highlighted**. This communication could take the form of the ones proposed by Health Canada and which are available at:
http://www.hc-sc.gc.ca/cps-spc/alt_formats/hecs-sesc/pdf/pubs/cons/jewellery-bijoux-eng.pdf
http://www.cmhc-schl.gc.ca/odpub/pdf/61941.pdf

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

[7] Commission Regulation (EU) No 861/2919 of 5 October 2010 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Custom Tariff.

A.2.Summary of the justification

A.2.1. Identified hazard and risk

Description of and justification for targeting of the information on hazard and exposure

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

Lead content

In a Danish survey (Danish EPA, 2008), 58% of 170 examined jewelleries contained lead in the concentration range from 0.01% to 70 % lead. In a Swedish survey (KEMI, 2007) 23 of 50 examined jewelleries were found to contain lead with 4 pieces above 10% lead, 9 pieces in the range of 2-20% lead, and 10 pieces below 2% lead. A second Swedish survey (KEMI, 2008) was reported in which 36 of 50 pieces of jewellery contained lead. In a German survey (BfR, 2008) on jewellery 78 samples out of 87 contained lead with an average lead content of 6.3% and a maximum value of 90%. In a UK survey (the Sunday Times, 2008), 24 children´s pieces of jewellery were examined and 8 tested positive for a high content of lead. Six of the items exceeded a lead concentration of 80%. Based on these European surveys the lead content in jewellery articles is between very low and 90%. Also Canadian and US surveys confirm this wide variation of led content. Moreover, according to one independent testing laboratory (Anon, 2010), it is estimated that about 10% of jewellery sold in EU contains on the average about 6% of lead and that there is some indication that the trend of lead content in jewellery is increasing. The amount of tested items was above 12,000 articles (see Table 14).

Characterisation of risks

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

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

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

In the original proposal submitted by France, a migration limit value of 0.09 µg /cm^2/hr was proposed. This was associated with a DMEL which was based on analytical measurement error. In order to use a risk-based approach, RAC judged it more appropriate to consider the EFSA BMDL (01) value (0.5 µg

Pb/kg bw/d) and to apply a MoE of 10, which according to EFSA (2010) is sufficiently low to ensure no appreciable risk. This exposure of 0.05 µg Pb/kg bw/d correlates with an IQ reduction in children of 0.1 points.

Considering an exposure scenario in which a child of 10 kg bw mouths a piece of jewellery for 1 hour with a surface of 10 cm^2 and a weight of 10 g a tolerable migration rate from the jewellery of 0.05 µg Pb/cm^2/hr or 0.05 µg Pb/g/hr is estimated. The migration rate expressed in per surface unit is in principle applicable for all kind of surfaces (metallic as well as non-metallic parts). With a general assumption that the ratio between surface (in cm^2) and the weight (in g) of the jewellery is 1 the migration rate would most practically be set to 0.05 µg Pb/g/hr.
For metallic parts of jewellery, the association between migration rates and content of 0.05% is based on the reassessment of the Danish EPA (2008) report. RAC recognises the uncertainty in this association as presented in the background document supporting this opinion; however, RAC considers that this association is further supported by the direct consideration of the raw measurements reported in the Danish study, as migration was not detected in the three jewellery items containing less than 0.05% lead, while it was detected in two (out of three) items with lead content between 0.1 and 1%.

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

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

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

A.2.2. Justification that action is required at Community-wide basis

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

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

A.2.3. Justification that the proposed restriction is the most appropriate measure

In accordance with ECHA (2007), justification that the proposed restriction is the most appropriate measure has to be supported by an evaluation of the proposal regarding three criteria: effectiveness, practicality and monitorability. In a comparative perspective, possible alternative risk management options have also to be evaluated with these criteria (for the definitions of these criteria, see section E.2.).

Justification by RAC

Risk Reduction Capacity

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

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

Practicality (including enforceability) and monitorability

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

As low migration rates may occur at higher lead contents in jewelleries, RAC considers that the restriction may allow industry to market jewellery items exceeding the limit of 0.05% lead provided that the actual migration does not exceed the proposed migration rate.
However, RAC recognises that further work has to be done in order to specify how the testing for content as well as for migration should be performed. RAC emphasises that reliable methods to determine migration rates from jewellery especially at lead concentrations below 1% need to be established.

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

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

Conclusion

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

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

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

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

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

Justification by SEAC

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

SEAC notes that the Toys Directive will not cover jewellery unless it is 'intended for children's play' and a restriction under the Product Safety Directive (PDS) would need to be renewed every year. Furthermore SEAC notes that under REACH a similar restriction is being adopted for cadmium in jewellery[8]. Therefore REACH is considered an appropriate legal instrument.

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

Scope

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

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

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

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

For owners of old jewellery which does not comply with the limits in the restriction, the proposal would have significant consequences and pose insurmountable challenges in terms of enforcement (though no formal assessment of this was undertaken in the dossier). Such old items would lose their marketable value (unless exported), as they would not be allowed for legal sale[9]. This may result in a "black market" for such items and associated problems of enforcement and compliance for "private sales" of old jewellery. SEAC proposes to address this problem in the same way as it is done in the restriction on cadmium in jewellery, by exempting jewellery placed on the market before the entry into force of the restriction. In order to allow import of old jewellery it is recommended that jewellery produced before [50 years before- the specific date mentioned in the cadmium restriction] is exempted from the restriction. The [date] is proposed in order the ease the implementation by importers and enforcements authorities.

If the restriction as proposed is only based on the content of lead (% of weight) (see below) SEAC recommends exempting crystals as well as precious and semiprecious stones from the restriction.

<u>Restriction</u>

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

During the Public Consultation a number of practical problems were raised related to the proposal to base the restriction on migration per unit. These include the fact that there are difficulties in calculating the surface area; that it is difficult to identify and isolate the parts of jewellery containing lead in order to carry out the testing[10]; and that the necessary testing method is not developed yet (adaptations to EN 71-3 have to be made in order to address the relevant type of exposure in saliva and jewellery which is too large to be swallowed [EN-71-3 is developed for the risk associated with swallowing items]). The need to adjust the test method will influence the date of entry into force of the restriction. Furthermore, in order to ensure a high level of compliance, it is regarded as important that the restriction is easy to understand and measure, and for imported items of jewellery it is important that restrictions for non-metal jewellery is also based on content so that producers in e.g. Asia will only have to meet similar types of requirements as those required in the US.

Therefore SEAC recommends that the restriction of lead in metal parts as well as in non-metal parts of jewellery should be based on content (w/w), and SEAC recognises that the value recommended by RAC of 0.05 % is practical and a less costly method to implement than a migration test. However it is

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

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

proposed to exempt crystals as well as precious and semiprecious stones from the restriction even though they (in particular crystals) may have a high level of lead content.

In the public consultation information on 2 specific items of crystal was submitted showing a migration of lead in a magnitude of 0.082 µg lead/cm^2/hr and 0.216 µg lead/cm^2/hr. SEAC has no information whether or not these may be typical migration rates, and no information on what the costs would be to reduce the migration to a level below 0.05 µg lead/cm^2/hr.

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

There are indications that lead may be present as a naturally occurring constituent in precious or semiprecious stones. SEAC considers that it would be disproportionate not to allow such stones to be used in jewellery, based on analogous argumentation used to justify the derogation for crystals. However, precious or semiprecious stones are sometimes treated with lead containing materials. As SEAC considers that other treatment methods are technically and economically feasible, this derogation should not apply if these stones are treated with lead or its compounds, as well as mixtures containing these substances.

Implementability

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

Impacts

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

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

A partial CBA shows that, in the EU, the cost of avoiding lead in jewellery including conformity testing costs is estimated to be €4.6 million per annum[11] based on an estimated share of 10% of all jewellery articles containing an average concentration of 6% of lead. The impacts in terms of future lost earnings associated with aggregate IQ decrement and corresponding intake of lead from mouthing jewellery that would be required for benefits to equal these costs were also estimated. The average

[11] Prices of new jewellery are estimated to increase as a result of rising production costs (estimated to be in the order of €0.03 per piece).

mouthing duration of jewellery (containing lead) amongst all children aged 6 months to 3 years that would result in the corresponding lost earnings was estimated to be about 30 seconds per year per child. This represents around 30% of estimated actual mouthing durations for jewellery containing lead.

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

Having considered uncertainties through sensitivity analysis SEAC concludes that the restriction is justified.

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

Sections E.2.3.1.1 and F.1.1 give further details.

Administrative burdens are mostly related to identifying whether raw materials, especially intermediates, and imported jewellery are in accordance with the requirements of the restriction. Additional quality controls would normally be required along the supply line in jewellery where lead can be expected to be found. If necessary, industry and retailers will have to carry out or demand the necessary testing. However, jewellery is also covered by restrictions on nickel and cadmium and is thus already subject to requirements from importers and retailers to ensure compliance. The cadmium restriction is also based on content of the substance and therefore a restriction on lead also based on content will not imply incremental practical problems and costs in relation to compliance. However, the restriction in relation to cadmium does only cover lead in metal, plasticised materials and painted coatings of the jewellery, and there might be some minor types of jewellery outside the scope of the cadmium restriction[12] where separate efforts in order to ensure compliance of jewellery with regard to lead is required.
For producer countries outside the EU, SEAC agrees that small producers might have difficulties to comply with different requirements in different countries to which they export. Since the US and Canadian requirements for jewellery are also based on the content of lead, the proposed restriction, which is based on content, is consistent with these regulatory requirements, such that it will ease the implementation for such countries and thereby enhance compliance with the restriction.

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

Practicality, including enforceability

SEAC regards the restriction to be practical and enforceable.

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

If the restriction was based on migration of lead in relation to surface area, it would be necessary to adapt the migration test EN7 1-3 in order to cover large jewellery and to establish a method for calculating the surface.

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

SEAC considers that the proposed time for implementation (proposed to enter into force 6 month after the Regulation enters into force may be too short, on the grounds that the restriction applies to placing on the market at all stages of the supply chain (including from retailers). and taking into account the fact that the period for stock rotation (from the initial enter into force) may be somewhat above one year. Industry and trade organisations have proposed a maximum implementation period of 24 months. However this request is also linked to the time needed to make adjustments to the migration test standard, which was proposed in the original proposal from France. As the modified proposal is based on content and well established test methods are available, SEAC considers 12-18 months to be an appropriate phase-in period.

Monitorability

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

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

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

B. Information on hazard and risk

Sections B1 to B3 are considered additional information and have not been commented by RAC. However, SEAC has analysed the data and has provided further information. Compared to the original Annex XV report as provided by France, this background document does not include sections related to the environment. RAC considered them not relevant for this restriction proposal.

B.1. Identity of the substances and physical and chemical properties

As mentioned previously, this restriction proposal globally concerns lead and all its compounds. Indeed this restriction is targeted to the health effects of lead in children, effects which may be induced not only by lead but also indirectly by its compounds as they may release lead while the use or misuse of jewellery articles containing them.

Moreover, no information was identified concerning the lead compounds which are specifically present in jewelery. As a result, because of this lack of data, proposing a limited list of lead compounds used in jewellery is difficult and it would possibly result in the non identification of relevant lead compounds leading to a non efficient risk management. Consequently, the choice was made to be protective in this restriction proposal and thus to target lead and all its compounds, in reference to Annex XVII Nickel entry.

As it was considered not relevant to present the requested information of the following sections for all lead compounds, only data related to metallic lead is expressed.

B.1.1. Name and other identifiers of the substance

The following table reports the name and other identifiers of elemental lead.

Table 2: Lead identification

EC number	231-100-4
EC name	Lead
CAS number	7439-92-1
CAS name	Lead
IUPAC name	Lead
Annex I index number	Not applicable
Molecular formula	Pb
Molecular weight range	207.2 g/mol

Structural formula:

Pb

B.1.2. Composition of the substances

Jewellery can contain lead and some of its compounds. It is very difficult to determine which lead compounds and in which quantities these are present in the jewellery given the great variety of this type of products and the lack of information about their composition. The same observation applies to impurities: no information about purity/impurities of lead and its compounds when used in jewellery is available. It is also highlighted that lead itself may be considered as an impurity in the alloys used for the production of the jewellery as its presence may be, sometimes, unintentional.

No standard for lead, lead alloys or lead compounds used in jewellery was identified.
However, according to LDAI (2008a), CEN standard EN 12659 sets out official European specifications for the purity of four key grades of metallic lead as exposed in the following table.

Table 3: Purity of metallic lead according to CEN standard EN 12659 (reproduced from LDAI (2008a))

Impurity	**Material Number and indicative lead content (%)**			
	PB990R – 99.99 %	**PB985R – 99.985 %**	**PB970R – 99.97 %**	**PB940R – 99.94 %**
Ag max	0.0015	0.0025	0.0050	0.0080
As max	0.0005	0.0005	0.0010	0.0010
Bi max	0.0100	0.0150	0.030	0.060
Cd max	0.0002	0.0002	0.0010	0.0020
Cu max	0.0005	0.0010	0.0030	0.0050
Ni max	0.0002	0.0005	0.0010	0.0020
Sb max	0.0005	0.0005	0.0010	0.0010
Sn max	0.0005	0.0005	0.0010	0.0010
Zn max	0.0002	0.0002	0.0005	0.0005
Total	0.010	0.015	0.030	0.060

Some requirements apply also to lead compounds in crystal, as indicated in the following table.

Table 4: Requirements of lead tetraoxides for crystal and ceramic applications according to CEN standard EN 13086:2000 (extracted from LDAI (2008a))

Requirement	Unit	Red lead (glass)	Red lead (ceramics)
PbO content (mass fraction)	%	22.6 max	22.6 max
PbO_2 content (mass fraction)	%	27.0 min	27.0 min
Pb_3O_4 content (mass fraction)	%	77.4 min	77.4 min
Apparent Density (Schott)	g/cm^3	-	-
Tamped Density	g/cm^3	-	-

For all the reasons previously exposed, it is considered that the restriction dossier shall apply to lead and its compounds whatever their purity.

B.1.3. Physico-chemical properties

Table 5: Overview of physicochemical properties of elemental lead (LDAI (2008a))

Property	Value
Physical state at 20°C and 101.3 kPa	Silver-bluish metal, solid
Melting/freezing point	327.43°C
Boiling point	1740°C
Relative density	11.34 g/cm^3
Vapour pressure	133 Pa at 973°C
Surface tension	Not applicable
Water solubility	185 mg/L
Partition coefficient n-octanol/water (log value)	Not applicable
Flash point	Not applicable
Flammability	Non highly flammable
Explosive properties	Not explosive
Self-ignition temperature	Not applicable
Oxidising properties	No oxidising properties
Granulometry	Not applicable
Stability in organic solvents and identity of relevant degradation products	Not applicable
Dissociation constant	Not applicable
Viscosity	Not applicable
Auto flammability	Not applicable
Reactivity towards container material	Not applicable
Thermal stability	Not available

B.1.4. Justification for grouping

This restriction proposal is targeted to the health effects of lead in children, effects which may result from an exposure to lead which can migrate from jewellery articles. For that purpose, the restriction proposal globally concerns lead and all its compounds which might liberate the lead ion. This grouping is justified by the following reasons: 1/ The lead ion is the toxic species. So it is considered that all compounds which might liberate it in acid conditions. It concerns organic, inorganic, ions…lead compounds.and 2/ The exact lead compounds contained in jewellery are unknown. As a consequence, the restriction covers all lead compounds to be more protective.

B.2. Manufacture and uses

This section should contain the available information on production, import and export of the substances concerned by this proposal, on their own, in preparations or in articles. In particular, the data from CSRs should be reported here. However, no CSR was available at the time of elaboration of this restriction proposal by France. Data on manufacture and uses documented below has thus been collected from other sources:

1/ MSCAs consultation (for more details, see section G.1)
2/ Industry actors consultation (for more details, see section G.3.1)
3/ Other sources: CBI (2001); CBI (2002); CBI (2008); CBI (2009). The economic and statistic portal Ecostats of FRANCECLAT (from the CPDHBJO, Professional Committee for the Development of the French Watch, Clock, Jewellery and Silverware industries) and data from KEMI (2007)
4/ Public consultation organised by ECHA

Consultation has been focused on the fashion jewellery sector as only fashion jewellery was targeted in the restriction proposal at the time of the consultation. This section is thus more focused on fashion jewellery than on precious jewellery. However, it has to be highlighted that jewellery which was identified in the reported cases of lead poisoning were mostly fashion jewellery articles. Consequently, it is appropriate to propose a section more focused on fashion jewellery

Data on production, import and export of **lead-containing jewellery** is very difficult to collect. No EU wide data exists on annual aggregate volumes (by weight) of costume jewellery sold in the EU. Indeed, first, industry actors often simply do not have the information about the composition of the fashion jewellery they place on the market or the precise raw materials composing the parts of the jewellery they shape. Secondly, many fashion (and fashion lead-containing) jewellery articles are imported from countries outside the EU and are not clearly labelled with their composition for importers and for final consumers. Thirdly, the EU market of fashion jewellery is atomistic (both on supply and on demand sides), fragmented and it spreads all over Europe. Fashion lead-containing and lead-free jewellery are dispersed, sold in various shops, of any size and not only in specialized jeweller's shops. Moreover, they are produced in much diversified structures, going from the isolated craftsman to the medium-size firm. Besides, this market is instable and the number of firms' openings and shut-downs strongly fluctuates. As a consequence, this singular market structure makes difficult the identification of data about industry actors and articles and their quantification.

These difficulties are reflected in feedbacks from consultations carried out during the preparation of this restriction proposal:

MSCAs have been sent a questionnaire (provided in the original Annex XV report) to obtain data on the market and uses of lead-containing jewellery in their Member State. Answers to this questionnaire were received from 15 Member States (for more details see section G.1). As far as manufacture, import and export of fashion jewellery articles are concerned, most of the Member States answered that no information was available within their country about that issue. The indicated reasons are that there is no national statistics made on this specific sector or that fashion jewellery is not explicitly categorized in their national accounting systems. Some of them confirmed that the fashion jewellery sector is very wide (going from craft industry to non-specialised hobby sector). As a result, this consultation did not provide any data on tonnage. The only quantitative data collected is the following:

- **German ChemG estimates that approximately a maximum of 1% of jewellery sold in Germany may contain lead.**
- **Cyprus department of labour inspection traces at least 13 importers of lead-containing jewellery and, based on data from market surveillance, estimates that 23% of sold jewellery would contain lead.**

It can be noticed that the estimated part of lead-containing jewellery which is sold in both countries is very different.

Industry actors have also been consulted through a survey carried out by INERIS (for further details see section G.3.1; for the complete study, please refer to INERIS (2009)). They were consulted via a web-based questionnaire (the structure of the questionnaire and the type of questions which were included are provided in the original Annex XV report). More than 3000 firms have been surveyed in the EU. These included: manufacturers/importers/exporters of lead, producers/importers/exporters of fashion jewellery and European federations of these sectors. Results have not been successful as only about 50 questionnaires have been returned. As reported in INERIS (2009), although these answers are not numerically significant, they still provide some information:
Lead use in the fashion jewellery sector was reported in several EU countries.
Worries about the impacts of a possible modification of the regulation concerning the use of lead and its compounds in fashion jewellery on the quality and the appearance of the products and on the production costs.
A relatively small mobilisation of the consulted actors in the fashion jewellery sector (which may result from the fact that this sector consists of many small and very small companies).

The relatively unsuccessful outcome of this survey may be explained by the reasons mentioned in the introduction of this section: the lack of knowledge of many industry actors regarding their jewellery's composition, especially if jewellery is imported and the difficulty to identify and exhaustively cover all the actors. Another explanation could be added: the reluctance of industry actors to give information or quantitative data about their activities for competition and confidentiality reasons. Besides, these difficulties have been confirmed by several interviews led with industry actors during the survey period.

Nevertheless, data on production, import and export of jewellery has been collected from other sources such as the ones from the Centre for the Promotion of Imports from developing countries (CBI (2001); CBI (2002); CBI (2008), CBI (2009)), Ecostats and KEMI (2007). From these different sources, it can be inferred that EU is a leading world market for fashion jewellery, ranking second after the USA (CBI (2001); CBI (2002)). All EU countries seem to produce and import/export fashion jewellery, but some countries are leaders on that market: Italy, France, the UK, Germany, Spain, the Netherlands and Austria.

The following sections are deliberately more focused on fashion jewellery since higher quantities of lead and its compounds are expected to be used in this type of articles compared to precious jewellery.

B.2.1. Manufacture, import and export of jewellery articles

B.2.1.1. Production of jewellery articles

Fashion jewellery

CBI (2009) indicates that fashion jewellery production is mainly concentrated in Austria, Spain, Italy, France and increasingly Poland (amber) and Czech Republic (crystals). Between 2003 and 2007, the EU production value rose from €1,093 to €1,135 million (see Table 6). This increase may be explained by a higher demand for medium-high quality pieces of base metal (titanium), combined with crystals, glass, beads or stones. This growth occurred in all countries, except for the UK, Germany, Italy, Belgium, Austria (rather constant) and Hungary (CBI (2008)).

Table 6: EU production of fashion (costume) jewellery from 2003 to 2007 in million € (extracted from CBI (2008))

	2003	2005	2007	Average annual % change in value
Total EU	1,093	1,086	1,135	1

CBI (2008) reports that, in 2007, in the EU:
- 5,350 companies were producing fashion jewellery, employing about 20,000 people.
- 22,500 companies were producing precious jewellery, employing about 94,000 people.

Precious jewellery

According to CBI (2008), about 90% of the EU produced jewellery is precious jewellery. In 2007, EU accounted for more than 25% of the global jewellery production. Between 2003 and 2007, the value of European precious jewellery production decreased from €10,995 to €10,201 million with an annual average of -1.9%.

B.2.1.2. Import of jewellery articles[13]

CBI (2008) indicates that EU is among the principal importers of jewellery in the world.

Fashion jewellery

Concerning fashion jewellery imports, from 2003 to 2007, values rose from €1,445 million to €2,301 million, and volumes rose from 56,951 to 97,277 tonnes CBI (2008). For this period, the volume of Chinese jewellery supplies (mostly consisting of fashion jewellery, silver jewellery and hair accessories) to the EU more than doubled: from 29,812 to 61,357 tonnes, making China the main volume supplier to the EU. About 34% of the EU imports were supplied by EU countries in 2007 (Austria being the main supplier, followed by Germany and France).

Table 7: EU imports of fashion (costume) jewellery from 2003 to 2007 in value (in million €) and volume (in tonnes) (extracted from CBI (2008))

	2003		2005		2007		Average annual % change in value
	Value	Vol.	Value	Vol.	Value	Vol.	
Total EU,	1,445	56,951	1,953	71,905	2,301	97,277	12.3
of which from developing countries	558	30,673	1,008	56,206	1,224	67,770	21.7

CBI (2008) reports that fashion jewellery of base metal represented €666 million and, in volume, 22,526 tonnes. It includes all jewellery made of metal, soft metal (tin and lead), stainless steel, titanium, brass, copper or alpaca (alloy of copper, brass and zinc). Imports of fashion jewellery of base metal whether or not clad represented, in 2007, €230 million and, in volume, 6,564 tonnes.

[13] CBI (2009) specifies that used data are '*primarily taken from Eurostat. Eurostat bases its statistics on information supplied voluntarily by EU Customs Authorities and EU companies. However, not all transactions are registered, particularly trade between the smaller EU countries and their transactions with non-EU sources. Consequently, intra-EU trade tends to be understated. This point is particularly important for this market sector, as it contains many small items. On the other hand, figures for trade between the larger EU states and the rest of the world (extra-EU) are more accurately registered. Nevertheless, they must be treated with extreme caution and are only intended to give an indication of trade flows in the international jewellery market*.'

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 costume jewellery around 70,000 tonnes.

Precious jewellery

Concerning precious jewellery articles, Italy, France and Germany were the largest EU importers. The following table presents the imports of precious jewellery articles.

Table 8: EU imports of precious jewellery articles from 2003 to 2007 in value (in million €) and volume (in tonnes) (extracted from CBI (2008))

	2003		2005		2007		Average annual % change in value
	Value	Vol.	Value	Vol.	Value	Vol.	
Total EU,	9,657	9,080	11,451	14,236	13,474	11,746	8.6
of which from developing countries	3,356	5,156	4,202	5,251	4,849	5,970	9.6

B.2.1.3. Export of jewellery articles[14]

Concerning export, no information specific to fashion jewellery was available. The data provided in the following table concern both precious and fashion jewellery. CBI (2008) mainly explains the increase of exports by an increase of trade between EU Member States because of the EU enlargement.

Table 9: EU exports of jewellery 2003-2007 in value (in million €) and volume (in tonnes) (reproduced from CBI (2008))

	2003		2005		2007		Average annual % change in value
	Value	volume	value	volume	value	Volume	
Total EU, of which:	12,902	21,977	14,581	28,122	16,861	31,324	6.9
Intra-EU							
Extra-EU	3,403	15,147	3,760	19,681	5,039	23,501	10.3
Dev. countries	9,499	6,830	10,635	8,441	11,822	7,823	5.6
	1,261	2,059	1,549	2,907	2,296	3,156	16.2

B.2.1.4. Placing on the market (except import) / consumption of jewellery articles

Fashion jewellery

Fashion jewellery has a very wide distribution network. According to CBI (2008), it varies from department stores, accessory chain stores, bijouterie shops, clothing stores, gift shops, hypermarkets, perfumeries, mail order, telesales, online sellers and street markets CBI (2008) mentions that the competition is more intense among online sellers, department stores, fashion accessory stores, clothing

[14] Please refer to footnote related to the import of jewellery, as it also applies to the exports.

stores and hypermarkets as they offer accessible costume jewellery and are expanding in Eastern EU states.

In 2007, EU consumption was €23,955 million for jewellery (precious and fashion jewellery) with a consumption for fashion jewellery of €4,647 million (CBI (2008)). Since 2003, fashion jewellery has enjoyed a substantial growth with much cheap jewellery being imported from China and India. Since 2007, consumers have turned away from precious jewellery towards silver and fashion jewellery due to global recession and to the huge price rise of precious metals. Many consumers are more interested in good design and affordable price than in the intrinsic value of jewellery. In 2007, EU costume jewellery sales represents 24% of the value of all the jewellery sold in the EU. However, in terms of volume their share is dominant.

Differences in consumption are observed between EU Member States: consumption per capita is much higher in countries which have a low population and a high expenditure on precious jewellery. CBI (2008) reports an increase of sales of costume jewellery especially in UK, Ireland, Greece, Spain, the Netherlands, Scandinavia and in many Eastern EU Member States. Costume and silver jewellery seem to be preferred by consumers who are more conscious on price and less on material composition. CBI (2008) analyses that the principal drivers of the fashion jewellery market are: a large variety of material, a diversity of decorations, a variety in design and personalised items. Such a diversity in styles associated with an accessible price is appreciated by all consumers (women of different ages, teens and men).

Table 10: Value of EU consumption of fashion (costume) jewellery manufactured in the EU from 2003 to 2007 in million € (extracted from CBI (2008))

	2003	2005	2007	Average annual % change in value
Total EU	€4,902	€4,496	€4,647	-1.3

Distribution data by price class was only identified for France for 2003 and 2004. It is summarised in the following table.

Table 11: French distributional data by price for fashion jewellery

Price class (sale prices including VAT)	**Placing on the market (domestic distribution and exports on the EU market)**			
	Volume in million of articles		**Value in million euros**[15]	
	2003	**2004**		
< €30	20.6 (average price of €5)	22.2 (average price of €7)	€111	€149
From €30 to €100	4.1 (average price of €49)	3.9 (average price of €50)	€203	€195
> €100	0.6 (average price of €185)	0.7 (average price of €188)	€110	€137
Total	25.3	26.8	€424	€481

Source: Ecostats (http://www.ecostat-cpdhbjo.com/ accessed in February 2010)

Data from this table shows that the most distributed jewellery (in volume) on the market are the cheapest ones with more than 80% of total sales volume. Yet, different existing market studies show that most of the cheapest fashion jewellery are imported from Asian countries (and from China more specifically). Besides, trends analyses plan an increase of sales of this kind of articles within the EU with the development of Chinese imports and of EU imports from developing Asian countries in general (such as Thailand and India) (CBI (2002)).

[15] Differences which may be observed by comparing the figures of the different tables possibly result from the fact the several sources have been used for this information (Ecostats and CBI reports). For instance, hair ornaments are taken into account in CBI reports, whereas they are not included in Ecostats data.

Precious jewellery

From CBI (2008), the specialist distribution dominates in most EU countries. The main channels for precious jewellery are jewellers, gold and silver smiths, boutiques and galleries supplied through wholesalers. Most of them are independent with a growing number belonging to a chain store, franchise or buying/voluntary group. In this report, it is specified that precious jewellery represented 81% of all jewellery which were sold in the EU in 2007 and that the value of precious jewellery sales increased by an annual average of 1.4% between 2003 and 2007 (from €18,220 million to €19,308 million).

B.2.1.5. Overall volume of the fashion jewellery market in the EU

According to CBI (2009), an estimated 200 million articles of jewellery were sold in the EU, with most pieces sold in France (65 million) and the UK (61 million). The greater part of volume sales in these two Member States, as well as in Spain, Germany and the Netherlands were costume and silver jewellery pieces, particularly earrings and neckwear. According to RPA (2010) it seems that around 50% (i.e. 100 million) of all jewellery articles made in and placed on the market in EU are costume jewellery. Although not specified by CBI (2009), the estimate of 200 million articles of jewellery is considered to be an estimate for the number of EU- produced jewellery articles that are sold in the EU (since it would certainly be an underestimate of total EU and imported jewellery, based on the fact that a figure of 200 million articles would imply an unrealistic weight per article according to aggregate tonnage figures for imports alone (see below)).

For the purpose of this background document it is important to have an estimate of the amount of fashion jewellery imported into the EU, too. Since it is known that the aggregate volume (by weight) of costume jewellery imported into the EU was about 70,000 tonnes from non-EU countries, and assuming an average weight of one article of costume jewellery imported into the EU is 50 g per article, then the number of articles of costume jewellery imported into the EU is estimated at around (70,000 tonnes ÷ 0.05kg) = 1.4 billion pieces per annum[16]. It is acknowledged that the number of jewellery articles is not in fact known and there is a high degree of uncertainty with this estimate. Nevertheless, anecdotal support for such an order of magnitude figure for the number of articles is provided for example by evidence on the number of jewellery articles which have been recalled by the USCPSC for containing lead above the regulatory limits (see http://www.cpsc.gov/cpscpub/prerel/prhtml04/04174.html). UCCPSC recalled 150 million articles (of which about half actually contained lead), which were placed on the market in 2004 by just 4 importers. Given that around 10% of fashion jewellery is thought to contain lead (see B2.2), then the figure of 1.4 billion for the total number of fashion jewellery articles seems plausible (assuming the size of the EU market is roughly similar to the US).

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The volume of imports of jewellery has been growing by about 20% per annum in the past years. If the lead content of imported jewellery has not changed, the amount of lead containing jewellery would thus also be growing with the same order of magnitude.

The above estimate would entail, assuming that most jewellery would be worn by women that on the average between 5 and 10 pieces of jewellery would be bought every year by all women in the EU. Based on the expert opinion of a major Finnish jewellery importer (pers comm. 2011.) this seems to be an overestimate. Rather, based on their market surveys, it was estimated that the average consumption would be between 3 and 5 pieces of jewellery per woman (and less than 1 per man). In other words,

[16] It is recognised that an average weight per jewellery article of 50g is uncertain. Nevertheless, evidence on the average weight of hallmarked jewellery (see http://www.gfms.co.uk/Press%20Releases/Real%20World%20Analysis%20of%20the%20UK%20Gold%20Market.pdf) suggests that the average weight for hallmarked jewellery is below 10 grammes for each category of hallmark shown. It is therefore assumed that a weight of 50 grammes is a plausible average weight for costume jewellery items.

the order of magnitude of pieces of jewellery placed on the market in the EU seems to be somewhat under 1 billion per annum (some of these being precious metal jewellery).

Mindful of the uncertainty in the import volumes, **it is estimated for the purposes of this background document that the annual consumption of fashion jewellery in the EU is 1.5 billion. Of this 1.4 billion would be imported and 0.1 billion produced in the EU.** However, it is recognised that this estimate is likely to be an overestimate. At the same time it is clear that if the consumption of fashion jewellery continue growing as in the past (about 20% per annum from developing countries) it would take only 5 years to double the market. In other words, the use of 1.5 billion as the estimate of annual consumption of fashion jewellery seems to give a reasonable order of magnitude in particular in the next years to come.

B.2.1.6. Structure of the EU fashion jewellery market

As regards the structure of the EU fashion jewellery market, the few data collected are reported below:

Table 12: Information on structure of the EU fashion jewellery market

Country	Actors	Number	Employment (number of employees)
France	Producers	861 (2006) 796 (2007) 791 (2008)	2275 (2006) 2082 (2007) 2154 (2008)
	Distributors (retailers)	10 079 (2004)[17]	-
	importers	13 (2002)	
Spain	producers	120 (2000)	-
	importers	12 (2002)	
Italy	producers	120 (2000)	-
	importers	14 (2002)	
Germany	producers	130 (2000)	-
	importers	11 (2002)	
The Netherlands	importers	20 (2002)	-
	Distributors: (Retailers) (Mail order)	4 (2002) (3) (1)	-
UK	importers	11 (2002)	-

Source: Ecostats; CBI (2002)

In most countries, jewellery is handmade and labour intensive. The data reported above includes the identifiable largest industry actors since many small workshops and stores which make and/or distribute fashion jewellery is not identifiable. Therefore, this data only provides a sample of the real number of producers and distributors in EU Member States which is thus expected to be (probably substantially) higher as indicated in section B.2.1 for instance for jewellery producers. This confirms the fragmentation of the fashion jewellery EU market. Of course, market structure is not identical from one country to another and fragmentation and decentralisation are more or less important. Nevertheless, in general, distribution channels are very heterogeneous: manufacturers of fashion

[17] This figure includes downtown jewellery shops, jewellery shops in shopping centres, fashion jewellery stores and jewellery sold in supermarkets. Fashion jewellery sold in clothes shops, by mail order selling and big stores are considered as not quantifiable and are thus not included.

jewellery, designers, cheap stores, clothing stores, specialised chains, perfume shops, hair-dresser shops, home direct sales, etc. (see Figure in section F.2). Fashion jewellery shops seem to be the most favoured distribution channel. Moreover, in the EU, small operations (less than 20 employees) represent the highest share of producers of fashion jewellery (and jewellery in general) (in terms of number): 76% in Germany in 2001, 98% in France in 2006 and more generally 89% in Europe (Ecostats; CBI (2002)).

It is important to underline again that the reported information in this section refers to production, imports and exports of fashion and precious jewellery articles without any distinction between lead-containing jewellery and other jewellery. Data which would enable to make this distinction is not available since macroeconomic aggregates and national account systems do not display lead-containing jewellery as a specific category. As a consequence, the few data likely to help in the quantification of the amount of leaded fashion jewellery placed on the EU market can only be extracted from the different field studies led in Europe on that issue and from publications which are summarised in the following section.

B.2.2. Use of lead and its compounds in fashion jewellery

No use for lead and its compounds has been identified under REACH Regulation since no CSR was available at the time of this restriction proposal. However, past regulatory experiences and existing risk assessments and investigations on those substances indicate that lead and its compounds are used in many fields. Giving an exhaustive list of all uses of lead and its compounds would be long and useless regarding the focus of this proposal. Nevertheless, information on total lead content and on migratable lead from fashion jewellery which has been identified in international literature is provided in this section.

Different studies which took place in Europe (and in the world) show that fashion jewellery items contain lead and/or its compounds (and often above the concentration limits set up in national regulations when they exist) despite several recalls during the last past few years (KEMI (2007); KID (2004); University of North Carolina (2009); French customs[18]).

Danish EPA (2008) reports that generally, **no relation between the type of jewellery (necklace, bracelet etc.) and the lead content could be made**. In addition, **no relation could be established between the probability of containing heavy metal and the country of origin of the jewellery**, even though it was specified that 30% of the 37 jewellery imported from China contained more than 0.01% lead. Also no relation was found between shop type and purchase of jewellery with a high content of heavy metals; however, concerning lead, it is reported that **there seems to be a greater chance of a large content of lead in the cheaper metal jewellery**. Finally, there was no relation between the lead content and the three product categories: gold (which includes jewellery coated with gold and golden-like jewellery – does not necessarily mean that the jewellery contains precious metal), silver-like and non-precious metal. In addition to test for lead content, some jewellery was also tested for lead migration. The **results of these tests did not show a direct relation between migration rate and lead content**[19] and did not allow to conclude about the potential influence of a coating (migration tests were performed in artificial sweat).

From the information provided by KEMI (2007)**, a very large proportion of cast and soldered jewellery may contain 20-40% of lead and sometimes even 50%**. They also report that some jewellery with high levels of lead present on the Swedish market carry a recycling mark, which may make the consumer think that these products do not contain any hazardous substance.

[18] http://www.douane.gouv.fr/page.asp?id=3258
[19] After reassessing the Danish survey data (Danish EPA, 2008) RAC found an association (although rather uncertain) between migration rate and overall lead content.

Maas R.P. *et al.* (2005) estimated **the probability of purchasing jewellery which contains more than 10% of lead at over 54%** in a large California retail store sample. Weidenhamer J.D. and Clement M.L. (2007c) determined that a significant share of inexpensive children's and fashion jewellery imported to the USA was highly leaded: **an average lead content of 44% (by weight) was measured by the authors**, which is higher than the average lead content of 30.6% measured by Maas R.P. *et al.* (2005).

Yost J.L. and Weidenhamer J.D. (2008) studied, among others, the lead content of coatings of beads. Their results show that **such coatings may contain up to 23% of lead**. The authors conclude that such high levels of lead imply that lead-based paints have been used to obtain the glossy finishes on these jewellery items. Consequently, they alert on the fact that, even though the lead contamination rate of plastic jewellery is not as high as the one measured for inexpensive metal jewellery articles, **the apparent use of lead-based paints to coat these plastic jewellery items merits regulatory concern along with metal jewellery articles.**

From the gathered information, it seems that lead may be used intentionally in the jewellery but also, on the contrary, its presence may be unintentional and may result from contamination due to recycling activities of leaded electronic waste. Weidenhamer J.D. and Clement M.L. (2007b) hypothesize that recycled circuit board solders are used to produce some heavily leaded imported jewellery sold in the USA. They base their hypothesis on the fact that the combined lead-tin-copper content of 6 jewellery ranged from 93.5 to 100%, which would be suggestive of a solder-based source material. Weidenhamer J.D. and Clement M.L. (2007a) measured that the average antimony content of 39 jewellery items was 3% and they compared it to the range of antimony content of battery lead standard reference material which is 2.95% antimony by weight. According to the authors, the similarity in composition of these jewellery samples to battery lead supports the hypothesis that some battery lead is recycled into highly leaded jewellery (the tested jewellery contained more than 90% lead by weight). This is confirmed by the owner of a Chinese alloys' factory who explained that some of the leaded alloy that is sold to the jewellery producers in the Yiwu area (China) originates from electronic wastes which comes by boat from "western" countries (Fairclough G. *et al.* (2007)). Weidenhamer J.D. and Clement M.L. (2007c) report that individual charms on one pin contained 0.04% and 100.6% lead (by weight) respectively. According to them, this variability may reflect the opportunistic use of source materials for these jewelleries.

Fairclough G. *et al.* (2007) reports that the owner of a Chinese producer of fashion jewellery for teenagers declared that his favourite material for this type of products was a metallic alloy made of at least 70 to 80% lead.

The following table summarises the information which has been gathered on the presence of lead in fashion jewellery.

Table 13: Identified studies on the presence of lead in fashion jewellery

Country	Study	Results
Denmark	Danish EPA (2008) Purchase of 170 pieces of metal jewelleries Note that a scientific opinion from the SCHER on the Danish EPA report has been published in 2010: SCHER (2010)	Test on lead content (170 pieces of jewellery divided in 318 parts) ▪ > 0.01%: 58% of all examined pieces of jewellery ▪ 69.6%: maximum measured (Testing method: XRF screening) Test on lead migration rate (25 jewellery parts) ▪ 14 samples had a lead migration rate above the detection limit. ▪ lead migration rates comprised between 2 and 540 µg/g (or 2 and 280 µg/cm²) (Testing method: "Migration to artificial sweat" according to DS/EN 1811:2000)
Sweden	KEMI (2008) May 2008	50 pieces of jewellery tested: 23 out of 50 contained lead: ▪ < 2%: 10 ▪ from 2 to 10%: 9 ▪ above 10%: 4 (No information available on the testing method)
	KEMI (2008) September 2007	50 pieces of jewellery tested: 36 out of 50 contained lead: ▪ < 2%: 23 ▪ from 2 to 10%: 7 ▪ above 10%: 6 (No information available on the testing method)
Germany	BfR (2008) Surveys in the German Länder	Test on lead content (87 samples): ▪ lead quantified in 78 samples: from 0.000002% to 90% (average of 6.3%) (No information available on the testing method) Test on lead migration rate (96 samples): ▪ lead migration rate quantified in 54 samples ▪ mean value: 73.5 mg/kg ▪ maximum value: 663 mg/kg ▪ Lead solubility (54 out of 96 samples tested) was about 0.0073% in average, the maximum value being 0.066% (Testing method: EN 71-3) Test on lead migration rate of fashion jewellery intended for children (28 samples): ▪ lead migration rate quantified in 11 samples ▪ mean value: 100 mg/kg ▪ maximum value: 580 mg/kg (Testing method: EN 71-3)
UK	Article from The Sunday Times[20] 24 items of children's jewellery bought in London and Birmingham	Test on 24 children's pieces of jewellery: ▪ 8 tested positive for 'high' levels of lead. ▪ 6 items had one or more components with more than 80% lead. (No information available on the testing method)
France	French customs[21]	17,600 fashion jewellery items from one targeted container

[20] Deadly poison found in children's jewellery, published in The Sunday Times (August 19, 2007) http://women.timesonline.co.uk/tol/life_and_style/women/families/article2284276.ece (accessed in March 2010).
[21] http://www.douane.gouv.fr/page.asp?id=3258

		from China were analysed by the French customs and results indicated that the articles did not comply with French regulation which prohibits use of certain lead compounds in paints and in coated imitation pearls (see section B.9.1.1 about regulations)
Canada	Canada Gazette (2005) National survey 95 children's pieces of jewellery examined	Test on 95 pieces of jewellery: ▪ > 0.0065% lead: 94% of the analysed pieces of jewellery ▪ 50% to 100% lead : 69% of the analysed pieces of jewellery ▪ < 10% lead: 31% of the analysed pieces of jewellery (No information available on the testing method)
USA	Yost J.L. and Weidenhamer J.D. (2008) 124 beads were analysed from 102 jewellery articles obtained from discount stores in north central Ohio	Test for lead content: ▪ > 30 µg lead: 9 beads (Testing method: digestion for 24 h in 10 mL of 1 M nitric acid and analysis by FAAS) Test for accessible lead: ▪ < 175 µg lead: all beads (when the number of beads on the jewellery was taken into account, 6 pieces of jewellery would exceed 175 µg accessible lead) ▪ maximum accessible lead: 49 µg for one bead (Testing method: US CPSC (2005a) and analysis by FAAS) Scraping of beads to analyze the coating: ▪ Up to 23% of lead in the coating (Testing method: scraping of beads with a razor blade, followed by digestion in 5 mL of 50% nitric acid for 24 hours and analysis by FAAS)
	Weidenhamer J.D. and Clement M.L. (2007c) 139 samples of jewellery purchased in 10 different retail chains in the USA (<10$ each) Many of these items were clearly designed for children.	Lead content: ▪ average lead content: 44% ▪ < 0.06% lead: 41% of the samples ▪ > 50% lead: more than 50% of the samples ▪ > 80% lead: 43% of the samples ▪ > 90% lead: 24% of the samples Acid leachable lead content (10 items tested): ▪ > 175 µg over 6 hours: 6 items ▪ > 1000 µg over 6 hours: 3 items (Same testing method as Maas et al (2005) + a subset of samples tested according to US CPSC 2005a)
	Weidenhamer J.D. and Clement M.L. (2007b) Study of 16 samples out of the 139 used in Weidenhamer and Clement (2007a) containing 20-80% lead	In 6 samples, lead, tin and copper accounted for 92.2 – 100% of the mass of the samples (21 to 30% of tin, 65 to 76% of lead, up to 4% for copper). (Testing method: digestion in HNO_3 for lead and copper and digestion in $HCl:HNO_3$ (3:1 v/v) for tin and analysis by FAAS[a])
	Maas R.P. *et al.* (2005) 285 pieces of metallic jewellery items purchased in 20 stores in California	Test for lead content on 285 samples: ▪ 0 to 3% of lead: 45.7% of the samples ▪ 3 to 10% of lead: 6.8% of the samples ▪ 10 to 50% of lead: 8% of the samples **▪ > 50% of lead: 39.5% of the samples** ▪ > 75% of lead: 11.5% of the samples (Testing method: dissolution in HNO_3 and analysis using FAAS[a]) Surface wipe experiment on 97 samples:

		▪ < 1 µg of lead transferred to the wipe: 31% of samples ▪ 1 to 10 µg of lead transferred to the wipe: 47% of samples ▪ 10 to 50 µg of lead transferred to the wipe: 17% of samples ▪ > 50 µg of lead transferred to the wipe: 5% of samples (Each sample wiped during 10 seconds, and another 10 seconds with the other side of the wipe – digestion of the wipe with HNO_3/H_2O_2 and analysis using GFAAS[b])
	University of North Carolina (2009)	A survey of inexpensive jewellery (less than $20) revealed that 70% of the jewellery contained lead. (No available information on the testing method)
	KID (2004)	Over 152 million pieces of vending machine jewellery were recalled between 1990 and 2004. Some had a concentration of lead up to 30%. These were toy necklaces, children's rings and metal toy jewellery. (No available information on the testing method)
Japan	KEMI (2007)	According to KEMI (2007), there have been cases of poisoning in Japanese children who have ingested large quantities of lead from jewellery. One of the items of tested jewellery released 56 times the quantity of lead which is allowed in the USA[22] (No available information on the testing method)

[a] Flame atomic absorption spectroscopy
[b] Graphite furnace atomic absorption spectrophotometry

Some evidence (see Table 14) on plausible estimates for use in this background documents was collected from a large sample of data (>12,000 articles) provided by an independent testing laboratory (Anon, 2010). These data indicated that **around 10% of costume jewellery articles placed on the market in the EU contained more than >0.03% in weight of lead** (US limit value in August 2009 = 0.03% in weight; and 0.009% in surface coating)[23]. **The data also indicated that average lead concentration in those articles containing lead above the limit value was around 6%**[24].

Table 14: **Average lead content in jewellery in 2009 and 2010, based on the tests made in one independent laboratory in the EU**

[22] At the time of the KEMI report (2007), US Regulation required that the products should have less than 175 µg of migratable lead.

[23] The representativeness of this sample is possibly biased in a number of way – firstly, it will include articles which do not end up on the market (since they contain lead and are withdrawn by those requested the testing), but also will not include articles that are not sent for testing but do end up on the market. The direction of bias is unclear. It should be noted that evidence from a Danish EPA study (Danish EPA, 2008) suggest that 58% of articles taken from a sample of jewellery available on the retail market contained lead at >0.01%. However it should be noted that the sample was weighted to include jewellery that had a proportionally equal distribution of price per gram; a proportionally equal distribution between the product types (rings, necklaces etc.); a proportionally equal distribution between product categories (gold, silver etc.); a representative distribution in relation to country of origin; a reasonable distribution of purchases in the different types of retail outlets. As such it was aiming at taking a sample from across the whole distribution of articles available, rather than a representative sample.

[24] The US limit value of 0.03% in weight is taken as indicating the presence of lead in jewellery which would pose a risk to health and hence would fall within the scope of regulatory action.

	Below 0.005%	*Between 0.005% and 0.03%*	***Share above limit value***	*Average lead content (above 0.005%)*	***Average lead content above limit value****	*Maximum lead content in the samples*	*Number of components*	*Number of jewellery articles*	*Components per article*
2009	75.0 %	14.7 %	**10.3 %**	1,1 %	**2.6 %**	67%	17,447	7,204	2,4
2010 (Jan-Oct)	75.0 %	15.9 %	**9.1 %**	3,7 %	**10.1 %**	40%	13,752	5,577	2,5
Pooled	75.0 %	15.3 %	**9.7 %**	2,4 %	**6.4 %**	54%	31,199	12,781	2,4

Source: Anon (2010)
US limit value in August 2009 0.03% in weight (and 0.009% in surface coating)
*this is the average concentration in the 9.7% above the limit value of 0.03%

B.2.3. Uses advised against by the registrants

As no CSR was available to the French CA at the time of the restriction proposal, this section cannot be documented.

B.2.4. Description of targeting

As already mentioned above, the targeted population is children as a sub-group of consumers of jewellery articles (intended for them or not) since they are particular sensitive to lead. This targeting is ground on toxicity data presented in section B.4, and on several alerts and cases documented from different countries (see section B.5.3.1).

B.3. Classification and labelling

B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Several lead compounds are classified in the CLP Regulation (based on information from Regulation 1272/2008/EC[25] of the European Parliament and of the Council and on Commission Regulation 790/2009/EC[26]). One can notice that elemental lead is not classified.

The lines of the following table are highlighted in blue for substances which are identified as Substances of Very High Concern (SVHC) and which are included in the Candidate List[27].

[25] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF
[26] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:en:PDF
[27] http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp (Accessed on March 22nd 2010).

Table 15: Classification of the lead compounds according to CLP Regulation

International Chemical Identification	EC	CAS	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
lead hexafluorosilicate	247-278-1	25808-74-6	Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H360-Df H332 H302 H373** H400 H410
lead compounds with the exception of those specified elsewhere in this Annex	-	-	Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H360-Df H332 H302 H373** H400 H410
lead alkyls	-	-	Repr. 1A Acute Tox. 2 * Acute Tox. 1 Acute Tox. 2 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H360-Df H330 H310 H300 H373** H400 H410
lead diazide lead azide	236-542-1	13424-46-9	Unst. Expl. Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H200 H360-Df H332 H302 H373** H400 H410
lead diazide; lead azide [≥ 20 % phlegmatiser]	236-542-1	13424-46-9	Expl. 1.1 Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H201 H360-Df H332 H302 H373** H400 H410
lead chromate	231-846-0	7758-97-6	Carc. 1B Repr. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H350 H360-Df H373** H400 H410
lead di(acetate)	206-104-4	301-04-2	Repr. 1A STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H360-Df H373** H400 H410
trilead bis(orthophosphate)	231-205-5	7446-27-7	Repr. 1A STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H360-Df H373** H400 H410
lead acetate, basic	215-630-3	1335-32-6	Carc. 2 Repr. 1A	H351 H360-Df

			Classification	
			STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H373** H400 H410
lead(II) methanesulphonate	401-750-5	17570-76-2	Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Skin Irrit. 2 Eye Dam. 1	H360-Df H332 H302 H373** H315 H318
Lead sulfochromate yellow; C.I. Pigment Yellow 34; [This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77603.]	215-693-7	1344-37-2	Carc. 1B Repr. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H350 H360-Df H373** H400 H410
Lead chromate molybdate sulfate red; C.I. Pigment Red 104; [This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77605.]	235-759-9	12656-85-8	Carc. 1B Repr. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H350 H360-Df H373** H400 H410
lead hydrogen arsenate	232-064-2	7784-40-9	Carc. 1A Repr. 1A Acute Tox. 3 * Acute Tox. 3 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H350 H360-Df H331 H301 H373** H400 H410
lead 2,4,6-trinitro-*m*-phenylene dioxide; lead 2,4,6-trinitroresorcinoxide; lead styphnate	239-290-0	15245-44-0	Unst. Expl Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H200 H360-Df H332 H302 H373** H400 H410
lead 2,4,6-trinitro-*m*-phenylene dioxide; lead 2,4,6-trinitroresorcinoxide; lead styphnate (≥ 20 % phlegmatiser)	239-290-0	15245-44-0	Expl. 1.1 Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H201 H360-Df H332 H302 H373** H400 H410

- "*" indicates that the classification corresponds to the minimum classification for a category.
- For certain hazard classes, e.g. STOT, the route of exposure should be indicated in the hazard statement only if it is conclusively proven that no other route of exposure can cause the hazard in accordance to the criteria in Annex I. Under Directive 67/548/EEC the route of exposure is indicated for classifications with R48 when there was data justifying the classification for this route of exposure. The classification under 67/548/EEC indicating the route of exposure has been translated into the corresponding class and category according to this Regulation, but with a general hazard statement not specifying the route of exposure as the necessary information is not available. These hazard statements are indicated by the reference "**".

B.3.2. Classification and labelling in classification and labelling inventory/ Industry's self classification(s) and labelling

In LDAI (2008a), which has been submitted by industry, a classification was proposed according to the studies provided in this report. According to LDAI (2008a), the following health classifications appear as appropriate for inorganic lead compounds:

- Repr. 1A - H360D / Repr. Cat. 1; R61: May cause harm to the unborn child.

LDAI (2008a) stipulates that based upon solubility data, and the probable presence (based upon production process) of lead oxide, extension of this classification to lead metal powder can be considered.

- Repr. 1A – H360F / Repr. Cat. 1; R60: May impair fertility

Carc. 2 – H351 / Carc. Cat. 3: R40: Limited evidence of a carcinogenic effect – for all inorganic lead compounds but not for lead metal

STOT Rep. 2 H373 / Xn; R48/20/22: Harmful: Danger of serious health effects by prolonged exposure trough inhalation and if swallowed

R11: Highly flammable for dibasic lead phosphate

B.4. Human health hazard assessment

Since the targeted population of this report is the infants and the children, reported effects of the lead on human health mostly focus on this sub-population.

The lead in blood (or PbB) level is considered as the best biomarker for an exposure to lead. Lead in blood does not necessarily correlate with the total body burden of lead, but this value has the advantage that a wealth of information can be linked to the PbB especially the effects of low exposure on the central nervous system functions in children (EFSA (2010)). PbB level increases when exposure rises and stabilizes after a while. According to recent publications, a variation of PbB of less than 3 µg/L is considered as not representative of a variation in the exposure (Labat L. *et al.* (2006); Olichon D. *et al.* (2007)). However, RAC considered more appropriate to base the assessment in the recent EFSA opinion (EFSA, 2010)

B.4.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

B.4.1.1. Absorption

The oral and the inhalation routes are the most significant routes of exposure to lead, whereas dermal absorption is considered as minimal.

Oral absorption rate

Lead gastro-intestinal (GI) absorption can result from intake from food, drinking water, lead deposited in the upper respiratory tract that can eventually be swallowed, and non-food materials that may be ingested, mostly by children via normal mouthing activity, or via extreme behaviour, like pica.
GI uptake of lead occurs in the duodenum. In this mechanism, both active transport and diffusion through intestinal epithelial cells are involved.

Concerning adults, orally ingested lead is absorbed differently depending on the time duration between the exposure and the last meal: adults who have just eaten a meal orally absorb 3-15% of the ingested amount of lead, whereas adults who have not eaten for a period of 24h absorb about 20-70% of the ingested amount of lead. The calcemia can also impact this oral absorption rate: the higher the calcemia is, the lower GI absorption is. The oral absorption can also be affected by low levels of iron and zinc (Bismuth C. *et al.* (2000)) or by the intake of Vitamin D (Fullmer C.S. (1990)), for instance a low iron intake and a deficient iron status was associated with increased PbB (EFSA, (2010)).

Concerning children, even though data are more limited, an oral absorption rate of 40-50% for lead and its compounds can be determined for children from 2 weeks to 8 years (ATSDR (2007); LDAI (2008a)). However, studies conducted by Manton W.I. *et al.* (2000) have shown that this high dietary lead intake estimate may be incorrect for very young children, since the lead intake may increase as the ratio of lead to calcium decreases. However, this suggestion has not been confirmed yet.

Conclusion: For oral uptake, an absorption rate of 50% will be used, based on data for the youngest children.

Inhalation rate

Deposition and absorption of inhaled lead containing particles are influenced by their size (LDAI (2008a)).
For the small particles (0.1 to 0.5 µm), a dissolution occurs in the lungs and the substance will be then available for a systemic absorption. The inhalation absorption rate is considered to be 100%. This latter value has been confirmed in animal studies.
For larger particles, 5 to 10% will be absorbed via the GI tract.

Dermal absorption

The dermal absorption of lead trough unabraded (no irritation) skin has been established as less than 0.1% (ranging from 0.01% to 0.18% in studies) and is then considered to be of less significance than absorption trough the respiratory or gastro-intestinal routes (LDAI (2008a)).

B.4.1.2. Metabolism

Inorganic lead ion in the body is not known to be metabolised or biotransformed. It does form complexes with a variety of proteins and non-protein ligands. It is primarily absorbed, distributed, and then excreted, often in a complexed form.
Inorganic lead is not converted in the body. Unabsorbed lead, which is ingested via the food, is released through the faeces, while absorbed lead, which is not retained, is released via the kidneys (WHO (2003)).

B.4.1.3. Distribution

Once it is absorbed, inorganic lead appears to be distributed to both soft tissues (blood, liver, kidney, etc.) and mineralising systems (bones, teeth) in a similar manner regardless of the route of absorption.
The distribution of lead seems to be similar in children and adults, but in adults a larger fraction of lead is stocked in bones. Indeed, more than 90% of the total amount of accumulated lead ends up in bone and tooth in adults, while in children, 75% is accumulated in bones (LDAI (2008a)), but its concentration increases with age.
The distribution of lead in the body is initially dependent on the rate of delivery by the bloodstream to the various organs and tissues. A subsequent redistribution may then occur, based on the relative affinity of particular tissues for the element and its toxicodynamics there. For example, lead has a different half-life in the three distinct tissue pools. Blood lead is considered as the most labile compartment with a half-life of about 30 days, and bone lead as the most stabile with a half-life of up

to several decades but with significant variation with the type of bone in question. Lead in soft tissue has a half–life of approximately 40 days (ATSDR (2007)).
Since concentration of lead is related to the calcemia, lead can be released from the bones in situations where the person suffers from calcium deficiency or osteoporosis (LDAI (2008a)).

It should be noted that lead is easily transferred to foetuses during pregnancy, since during this event the mobilisation of bone lead increases, apparently as the bone is catabolised to produce the foetal skeleton. This bone resorption during pregnancy can be reduced by ingestion of calcium supplements (EFSA (2010)).

B.4.1.4. Elimination

In children, lead is progressively accumulated in the body and it mostly resides in bone. It is then very slowly eliminated (as indicated previously, half-life can be 10 to 20 years). Lead can then induce an internal exposure a long time after the end of the exposure (LDAI (2008a)).
The elimination is mostly via urine (> 75%) and digestion (15-20% via bile and faeces) (TNO (2005)).

B.4.2. Acute toxicity

B.4.2.1. Animals

In studies performed in animals, effects were observed at doses ranging from 300 to 4000 mg/kg bw (LDAI (2008a)).
By oral route: lead oxide, lead tetroxide, lead phthalate dibasic and lead sulphate tribasic have a LD_{50} > 2000 mg/kg bw.
By dermal route: lead oxide, dibasic lead phthalate, tribasic lead sulphate and dibasic lead phosphate have a LD_{50} > 2000 mg/kg bw.
By inhalation route: lead oxide has a LC_{50} > 5 mg/mL.

B.4.2.2. Humans

Very few data exist on acute poisoning. The US National Institute of Occupational Safety and Health (NIOSH) determined that acute lethal dose for an adult is 21 g (equivalent to 450 mg/kg bw) by oral route, and 21,000 mg/m^3 for 30 minutes by inhalation route. However, the latter kind of poisoning is very rare.

Serious lead poisoning can cause death, especially in children, like a 4-year-old boy, who swallowed a leaded charm by accident, which was composed of 99.1% of lead (CDC (2006)). At the time of death, the boy had a PbB level of 1800 µg/L (see cases reported in section B.5.3.1).

It should be noted that, when an acute poisoning occurs (e.g. ingestion of an object composed of lead), the PbB reaches a peak, but it does not reflect the total amount present in the body.

Obvious signs of acute lead poisoning involve dullness, restlessness, irritation, poor power of concentration, headache, vibrations in muscles, stomach cramps, kidney injuries, hallucinations and loss of memory. These effects can occur at PbB levels of 800-1000 µg/L in children (TNO (2005)). US EPA has furthermore identified a LOAEL value of 600-1000 µg/L related to colic in children as a result of lead poisoning. Then a LOAEL of 800 µg/L (ATSDR (2007)) and a NOAEL of 400 µg/L (TNO (2005)) could be identified for acute effects in children.

But due to the long elimination half-life of lead in the body, chronic toxicity is a much greater risk.

B.4.3. Irritation

In general, lead does not induce any irritation, except for lead oxide which is a moderate skin irritant at doses of 100 mg for 24hr. However, this effect does not lead to any classification (Danish EPA (2008)).

B.4.4. Corrosivity

According to LDAI (2008a), no study documenting corrosivity to the eye, skin or lung in humans or in animals following exposure to lead or its compounds is available.

B.4.5. Sensitisation

Studies performed in animals indicate an absence of skin sensitising potential for the tested compounds (lead oxide, dibasic lead phthalate, dibasic lead phosphite, lead acetate) (LDAI (2008a)).

B.4.6. Repeated dose toxicity

As exposed in section B.3.1, some lead compounds are classified as STOT RE 2 (H373 - May cause damage to organs through prolonged or repeated exposure).

Lead is a poison by chronic accumulation. Signs of chronic lead poisoning include among others: sleepiness, irritation, headache, pains in the joints and problems related to the stomach- and intestinal system.
Chronic exposure to lead can also induce neurological effects such as: uneasiness, forgetfulness, irritation, dullness, headache, tiredness, impotence, decreased libido, dizziness and weakness.

B.4.6.1. Hematological effects

Effects of lead on blood can be detected at low levels of exposure but are not deemed to be adverse. As exposure intensity increases, the constellation of observed effects becomes increasingly diverse until impacts upon haeme synthesis are observed and which would be considered as adverse.
At quite low levels of lead (< 100 µg/L) an inhibition of enzymes such as ALAD implicated in the haeme synthesis is observed. These enzymatic effects are not considered as adverse but are sometimes used as biomarkers of lead exposure.

At higher levels of lead exposure, the cumulative impacts of lead upon multiple enzymes in the haeme biosynthetic pathway begin to impact the rate of haeme and haemoglobin production. Decreased haemoglobin production can be observed at blood lead levels above 400 µg/L in children. Impacts on haemoglobin production sufficient to cause anaemia are associated with blood lead levels of 700 µg/L or more (LDAI (2008a)).

B.4.6.2. Renal effects

Kidneys are the target organ of lead: some effects can be observed from a PbB level of 100 µg/L. It seems to be the biological function which is affected at the lowest dose (LDAI (2008a)). Colic is a recognized symptom of a lead poisoning, which could occurred at PbB from 1000 µg/L (SCOEL, 2002).

Effects which are generated by lead on kidneys are the same in animals and in humans, the cells brush border in proximal tubules are affected. These effects could lead to a nephropathy with a tubular atrophy.

In children, a study has demonstrated the effects of lead poisoning on proximal tubules via an environmental exposure from 30-350 µg/L (LDAI (2008a)).

B.4.6.3. Effects on the central nervous system (CNS)

In young children, brain is the primary target organ. When PbB level is above 800 µg/L, an encephalopathy can be observed (LDAI, 2008a) (characterised by ataxia, coma or convulsions). Lead has an effect on the development and the maturation process of the cognitive functions of children.

If prenatal lead exposure occurs, in most studies no effect is reported if the maternal exposure is below 250 µg/L. Nevertheless it was demonstrated that a PbB level of 100 µg/L could induce effects on endpoints of uncertain significance (e.g. neurological soft signs) (Boucher *et al*. (2009)).

Table 16: Summary of the effects of lead on the CNS in children depending on the PbB

PbB in children (µg/L)	Effects
700-1000	Classical lead poisoning encephalopathy which could be lethal without any treatment
450-700	Minor form of the classical lead poisoning encephalopathy (could get worse)
< 450	Neurotoxic effects
100 and even < 100	Severe and lasting cognitive effects (IQ). (No Threshold determined so

	far)
No threshold	Reduction of the audition

WHO (2003) describes a number of studies, which indicate a possible correlation between reduced IQ (Intelligence Quotient) and a PbB level < 100 µg/L (PbB level of 56 µg/L). This correlation has been confirmed recently. In a recent report of JECFA (2010) it is indicated that so far no threshold for the key adverse effects of lead, the neurodevelopment of children has been identified. The JECFA considers that an exposure of 1.9 µg of lead/kg body weight per day is associated with a population decrease of 3 IQ points, which is considered as "of concern".

In its recent report, published in April 2010, EFSA evaluates the environmental exposure of children to lead. EFSA has calculated a $BMDL_{01}$ (Benchmark Dose Limit) of 12 µg/L, which corresponds to the PbB level at which a 1% change on human intellectual function (loss of one IQ point) will occur, due to an exposure to lead. By using the IEUBK model, this PbB level of 12 µg/L has been associated to a lead intake of 0.5 µg/kg bw/day.

In France, the threshold of 100 µg/L is used to define a case of lead poisoning (saturnism). This level is also the one retained by many other health and consumer institutes such as the US CDC. However in fact, laboratories are now able to measure much lower doses. The LOQ (Limit of quantification) is now around 1-10 µg/L (Olichon D. *et al.* (2007)).

Table 17: Recommendations of the French Institute for Public Health Surveillance (Reproduced and translated from InVS (2006a)) for lead poisoning in children

Blood lead level	Health-based management recommendations for caring
< 100 µg/L	No poisoning Follow-up of PbB every 6 months up to 1 year or 6 years if the child belongs to a susceptible group
100-249 µg/L	Control of the PbB every 3 to 6 months Compulsory declaration Elimination of the poisoning sources
250-449 µg/L	Control of the PbB every 3 to 6 months Child is sent to facilities which are able to evaluate the PbB and to consider a chelation therapy. Compulsory declaration Elimination of the poisoning sources
≥ 450 µg/L	Very urgent to send the child to facilities able to measure the impact of the poisoning and to treat it. Compulsory declaration Elimination of the poisoning sources

According to the analysis performed in LDAI (2008a), available data do not permit the identification of a threshold for lead's effects on CNS in children.

According to the most recent studies, the effects of lead on the nervous system following a chronic exposure seem to have no threshold (JECFA, (2010); EFSA, (2010)). These effects on the neurodevelopment at low concentrations have become apparent only recently because new studies now include children born in the post-leaded-petrol era.

For information, the median of measured blood lead levels for French children is now 15-20 µg/L, the 90^{th} percentile is around 30-40 µg/L and the measurement accuracy 3 µg/L (Labat L. *et al.* (2006);

Olichon D. *et al.* (2007)). Even though this study was performed only in France, it is among the most recent ones and is expected to provide an order of magnitude for the European children of this age category.

B.4.7. Mutagenicity

Occupational exposure to lead is associated with increased mitotic activity in peripheral lymphocytes, increased rate of abnormal mitosis and increased incidence of chromosomal aberrations and sister chromatid exchange, at PbB level ranging from 220 to 890 µg/L (TNO (2005)). However, these results on chromosomal aberrations are contradictory since other studies performed with similar PbB ranges did not demonstrate such effects.

Moreover, it has been demonstrated recently that an exposure to lead is able to lower the DNA's repair ability and is therefore responsible for an increase of DNA's damages (Karakaya A.E. *et al.* (2005); Mendez-Gomez J. *et al.* (2008)).

B.4.8. Carcinogenicity

According to IARC (2006), most of inorganic lead compounds are classified as "potentially cancer-causing in humans" (Group 2A), based on epidemiologic studies in which cancers of the stomach and of the lungs were noted. Organic lead compounds are not classified as to their cancer-causing ability in humans.

In Europe, lead acetate is classified as Carc. 2 (H351), since a carcinogenic effect has been observed in animals only. LDAI (2008a) proposes to extend this classification to all inorganic lead compounds, since they have a greater bioavailability compared to other lead compounds.

B.4.9. Toxicity for reproduction

In humans, there are clear indications that high levels of lead cause adverse effects on both male and female reproductive functions. Less is known concerning reproductive effects following a chronic exposure to low levels. However, if the PbB level is above 200 µg/L, an abortion or still-born baby risk exists and several studies reported that the length of gestation is affected at PbB level of 150 µg/L and above (ATSDR (2007)). It was reported in 1999 that the risk of spontaneous abortion nearly doubles for every 5 µg/dL increase in blood lead levels (Borja-Aburto V. *et al*. (1999)).

Effects on sperm may start to appear at blood lead levels of 400 µg/L. Moreover, a Finnish study has observed a significant increase of the risk of spontaneous abortion among the wives of men whose PbB level was 300 µg/L or higher during spermatogenesis (TNO (2005); LDAI (2008a)).

Since lead is able to cross the blood-placental barrier, it can induce a developmental neurotoxicity. It has been demonstrated that both maternal plasma and whole blood lead during the first trimester (but not in the second or third trimester) were significant predictors ($p<0.05$) of poorer Mental Developmental Index (MDI) scores (ATSDR (2007)). As a possible explanation, Hu H. *et al.* (2006) speculated that lead might be affecting the process of neuronal differentiation, which is primarily a first-trimester event.

Another recent study of Schnaas L. *et al.* (2006) reported an association between prenatal lead exposure and intellectual function. According to the authors, IQ of 6 to 10-year-old children decreased significantly only with increasing natural-log third trimester PbB, but not with PbB at other times during pregnancy or postnatal PbB measurements. However, because their observations began after the 12th week of pregnancy, the effects of the first trimester PbB could not be examined. As with other studies, the dose-response PbB-IQ function was log-linear, with a steeper slope at PbB <100 µg/L (RIVM (1995)).

B.4.10. Other effects - Specific effects

Lead poisoning in pregnant women

Since lead can easily cross the placental barrier, the exposure of children starts *in utero* and lasts during the lactation period. PbB level is correlated to the serum calcium: the demineralization of the skeleton observed during pregnancy and lactation induces a migration of the lead accumulated in the mother's bone to the fetus and the infant. This transferred amount of lead is directly linked to lead accumulated by the mother (resulting from a cumulated exposure) rather than to the maternal exposure during pregnancy.

The maternal and the fetal PbB levels are quite identical. The teratogenic effects observed in animals were not noted for humans, but it seems that the risk of spontaneous abortions, growth retardation and premature delivery appear when PbB level is above 250 µg/L (LDAI (2008a)).

Table 18: Summary of the effects of an exposure to lead in children

	PbB (µg/L)					
	No threshold	56	100	400	700	800
Hematological effects			Inhibition of ALAD (i.e. haeme synthesis) : used as biomarker of lead exposure (LDAI 2008a)	↓ hemoglobin production in children (LDAI 2008a)	Anaemia (LDAI 2008a)	
Effects on kidney			Affection of the biological function Animals/humans : nephropathy (tubular atrophy) (LDAI 2008 a)			
Developmental neurotoxicity	Possible reduced IQ (WHO, 2003 ; JECFA, 2010 ; EFSA, 2010)					Encephalopathy Effect on the cognitive functions (development, maturation) (LDAI, 2008a)

Overall conclusion: According to all the effects observed in children and particularly effects on the neurodevelopment which seem to occur with no threshold, it should be considered that a threshold for the effects of lead on children could not be identified. The effects of lead on the neurodevelopment of children would be then considered as the most relevant effect in order to perform the risk assessment.

B.4.11. Derivation of DNEL(s)/DMEL(s) or other quantitative or qualitative measure for dose response

B.4.11.1. Tolerable Daily Intake (TDI)

WHO first established in 1995 a TDI value of **3.6 µg/kg bw/day** for both adults and children. This value is based on the fact that it has been demonstrated that an intake of 3-4 µg Pb/kg bw does not affect the PbB of children or any increase in the body burden of lead, whereas an intake of 5 µg Pb/kg bw leads to an increase of the PbB and consequently results in lead retention. At this time, the threshold for lead poisoning in children was 100 µg/L. Then, from the TDI, a PTWI (Provisional Tolerable Weekly Intake, i.e. the maximum amount of a contaminant to which a person can be exposed per week over a lifetime without an unacceptable risk of health effects) of 25 µg/kg bw/week was derived.

However, WHO (2003) reports a possible correlation between reduced IQ and a PbB level below 100 µg/L (56 µg/L). Such measures have been possible thanks to an increase of the performance of the analytical methods. Consequently, Danish EPA (2008) suggested that the TDI of 3.6 µg/kg bw/d should be divided by a factor of 2 in order to take account of this effect. As a result, a new TDI value of **1.8 µg/kg bw/day** was proposed by Danish EPA. More recently, in the 2010 JECFA report already mentioned, the committee (composed of FAO and WHO experts) estimated that a PTWI of 25 µg/kg bw is associated with a decrease of at least 3 IQ points in children and indicated that if such effect may be insignificant at the individual level, this change should be considered as important when viewed as a shift in the distribution of IQ. The committee then concluded that this PTWI could no longer be considered as health protective and then withdrew it. They also concluded that it was not possible to establish a new PTWI since the effect of lead on the IQ points seemed to have no threshold.

B.4.11.2. Background levels

According to WHO, more than 80% of the daily intake of lead originates from food, soil and dust (Danish EPA (2008)).

Danish EPA (2008) also estimated the background levels of lead present in food and drinking water (19 µg/d) and in the air (9.1 ng/m^3). These background levels have been used to calculate a margin to the TDI value for children and adults, which represents the "extra amount" of lead, which humans can ingest on a daily basis without experiencing any health related effects. These values are presented in Table 19.

For children in the age of 4-6 years-old, the average intake reported was 9.7 µg/day.

Table 19: Background exposure of lead in Denmark and margin to TDI value (µg/kg bw/d) (Danish EPA (2008))

Background exposure (µg/kg bw/day)	Children (4-6 years)		Adults	
	Average	95-percentile	Average	95-percentile
Food and beverages	0.485	0.77	0.317	0.517
Air	0.005	0.005	0.003	0.003
Total Background exposure	0.49	0.78	0.32	0.52

Margin to TDI value (= 1.8 – Total Background exposure)	1.31	1.02	1.48	1.28

The values proposed by Danish EPA for background levels are much lower than the European mean (DG SANCO (2004)) for the background levels of lead in food and drinking water: 42 µg/day for adults. The values for adults reported by DG SANCO (2004) range from 1.1 (Ireland) to 133 µg/d (Portugal). These differences could be influenced by different consumption patterns for instance, or because in some areas there were a former use of lead materials in water installations. In this report, only two values of the background exposure to lead are available for children: 40 µg/day in France and 26 µg/day in Germany. This information is summarised in the following table.

Table 20: Mean background exposure (µg/day) to lead in various countries in Europe - values measured before 2001 (DG SANCO (2004))

Background exposure in food and beverages	Children	Adults
Belgium	Not available	38
Denmark	Not available	18
Finland	Not available	6
France	40 (age 3-14 years)	57
Germany	26 (age 4-6 years)	47
Greece	Not available	25
Italy	Not available	30
Norway	Not available	21
Portugal	Not available	133
Sweden	Not available	5
United-Kingdom	Not Available	27
European Mean	**-**	**42**

RIVM (2008) reports that the Health Council of The Netherlands estimated in 1997 the background exposure of lead resulting from intake of food, water and air for children aged 1-4 years to be 2.0 µg/kg bw/day. This value represents a daily intake of 12 µg/day for a child of 1 year (6 kg bw) and 20 µg/day for a child of 4 years (10 kg bw).

Glorennec P. *et al.* (2007) recently reported the background exposure (including air, food, water, soil and dust) to lead for children from 6 months to 3 years-old. They established a median weekly exposure dose of 7.5 µg/kg bw/week (equivalent to 1.07 µg/kg bw/day) and a 95th percentile of 13.5 µg/kg bw/week (1.93 µg/kg bw/day).

The EFSA (2010), in its recent report, makes an overview of the estimated dietary and non-dietary exposure to lead, which is summarized in the table below.

Table 21: Daily intake of lead by children under the age of 36 months

	Daily intake of lead by children µg/kg bw/day	
	Min	**max**
Food	1.1	5.51
Soil and dust	0.18	0.8
Outdoor air	0.001	0.003
Environmental tobacco smoke	0.012	0.052
Total	**1.293**	**6.365**

JECFA report (2010) described the mean dietary exposure estimates for children of 1 to 4 years old which range from 0.03 to 9 µg/kg bw/day. The report associates these dietary estimates to a health impact:

- The lower end (0.03 µg/kg bw/day) is considered as negligible by the JECFA Committee, (a level of 0.3 µg/kg bw/day was considered to be associated with a decrease in 0.5 IQ point)

The higher end of the exposure range (9 µg/kg bw/day) is higher than the level of 1.9 µg/kg bw per day calculated to be associated with a population decrease of 3 IQ points, which is deemed by the JECFA Committee to be "of concern".
It should furthermore be stressed that these estimates do not include the sources of exposure other than the dietary one.

Consequently, several figures are available for the background exposure to lead, depending on the country, on the study and on the child's age.

B.4.11.3. Acute DNEL (DNELa)

An acute LOAEL has been chosen based on effects, such as irritation, poor power of concentration, vomiting or convulsions, observed after an acute exposure with associated PbB levels ranging from 800 to 1000 µg/L. The LOAEL of 800 µg/L is selected as this figure is representative of acute effects following a single (massive) exposure, and not of effects which could be assimilated to acute ones but which can be observed after chronic exposure (TNO (2005); LDAI (2008a)).
Since colic have been reported in children at 600 µg/L (ATSDR (2007)), and a NOAEL of 400 µg/L is proposed by ATSDR, a NOAEL of 400 µg/L was selected in this report.

As this NOAEL has been determined for humans and more specifically for children, neighter security factor is needed for the inter-species variability, nor for intra-species since children already constitute a vulnerable population.

Consequently, a DNEL for acute exposure (DNELa) of 400 µg/L will be used for the risk assessment.

RAC has not further discussed the appropriateness of this acute DNEL value as acute toxicity with a NOAEL of 400 µg/L is not considered to be the critical end-point in relation to mouthing of jewellery.

B.4.11.4. Chronic DMEL (DMELc)

According to the most recent studies and particularly to the JECFA report (2010), it has been demonstrated that effects on the neurodevelopment (and effect on IQ points) that occur in children, no threshold has been identified. Then, concerning chronic exposure, it was decided to establish a 'safe' daily intake based on the smallest measurable variation of the PbB level and to then derive a DMEL (Derived Minimum Effect Level) instead of a DNEL.

Moreover, since the JECFA (2010) concluded that, based on the fact that no threshold for the key adverse of lead has been identified, it is not suitable to derive a PTWI anymore.
Consequently, in the Annex XV report the daily intake which would not generate a variation higher than this smallest measurable variation has been calculated based on the smallest measurable variation of the PbB level which could be considered as the smallest measurable level of exposure (as explained below).

The smallest measurable variation of the PbB level

To select the smallest measurable concentration, a target blood lead level of 20 µg/L was used as it corresponds to the geometric mean of blood lead level of children of 0 to 6 years-old (Glorennec P. *et al.* (2007)). Although this study was performed only in France, it is among the most recent ones and is expected to be representative for the European children of this age category.

According to AFSSAPS (2009) the smallest measurable variation of a PbB level of 20 µg/L is **5 µg/L**; it is based on the standard deviation determined in a French inter-laboratories analysis for a target blood lead level).

Use of a PBPK model

US EPA has developed a toxicokinetic model: IEUBK (Integrated Exposure Uptake Biokinetic Model for Lead in Children). From an ingested amount of lead, IEUBK can model the amount of lead, which is absorbed (internal dose) and it can predict the associated PbB level. This model has been selected as it is one of the most commonly used for PbB level assessment and it is the best validated one (Mushak P. (1998)).

Consequently, IEUBK model is used to estimate the daily intake, which will not generate a variation of the PbB level greater than 5 µg/L. The following DMELs have been obtained (for more details on the model calculations, see Annex A):

Table 22: Modelled chronic DMELs

Age of the children (months)	DMELc value (µg/kg bw/day)
3-6	0.16
7-12	0.16
13-24	0.21
25-36	0.22

No background level has been used for the calculation of the chronic DMELs since the final result was not significantly affected when background levels were integrated in the calculations of the model.

For comparison the approach used in the Toy Directive consists of not exceeding 5% of the tolerable daily intake (TDI). In this case, 5% of the TDI corresponds to 0.18 µg/kg bw/da.
*In its recent report already mentioned, EFSA (2010) evaluates the environmental exposure of children to lead.*Table 23 *presents the different values obtained from using the different approaches concerning the daily intake.*

- *The first column presents the values obtained using the present approach: a value of 5 µg/L as the smallest measurable variation of the PbB level and the IEUBK model with the parameters presented in this restriction dossier.*
- *The second column presents the values obtained using the $BMDL_{01}$ value of 12µg/L reported by EFSA and the IEUBK model with the parameters presented in this restriction dossier*
- *The third column presents the values calculated in the EFSA report (dose of ingested lead associated with a PbB of 12 µg/L and the IEUBK model with EFSA parameters).*

Table 23: Comparison of the Annex XV and the EFSA approaches

	5 µg/L IEUBK	12 µg/L IEUBK	0.5 µg/kg bw/day EFSA
Age class (month)	Daily intake µg/day		
0-12	1.66	4.30	5.04

13-24	2.57	6.67	6.17
25-36	3.11	8.10	7.21
Age class (month)	**DMELc**	**$BMDL_{01}$ µg/kg bw/day**	**$BMDL_{01}$**
0-12	0.16	0.43	0.5
13-24	0.21	0.54	0.5
25-36	0.22	0.56	0.5

*It should be noted that EFSA obtains only one $BMDL_{01}$ because they only used one body weight value (20 kg corresponding to a child of 5 years old), in the parameters of the IEUBK model. Since these calculations use rather uncertain assumptions RAC bases its risk evaluation for lead exposure of children from mouthing jewellery on an average body weight of 10 kg, and 10% of the EFSA **$BMDL_{01}$** value of 0.5 µg/kg bwt per day (i.e. 0.05 µg/kg bw d).*

In section B.5.3.1., the 'safe' migration rate inferred from the EFSA approach and the 'safe' migration rate proposed for the present restriction are compared.

RAC conclusion

RAC notes that the proposed DMELc value of 0.16 – 0.22 µg/kg bw/d (depending on the age of a child) are based on the smallest measurable variation of a blood lead level of 5 µg/L that can be analytically verified.

According to the recent EFSA (2010) opinion on lead a lower benchmark dose level of 0.5 µg Pb/kg bw/d corresponds to a change in blood level of 12 µg Pb/L and an IQ loss of 1 point. RAC supports this risk assessment. RAC also agrees with EFSA that MoE of 10 or greater in relation to the BMDL (01) level should be considered sufficient to ensure no appreciable risk. The resulting exposure of 0.05 µg/kg bw/d, which EFSA considers 'sufficient low to ensure no appreciable risk', is taken by RAC as point of departure for the risk assessment.

B.5. Exposure assessment

B.5.1. General discussion on releases and exposure

B.5.1.1. Summary of the existing legal requirements

Managing the health risks for children caused by lead and its compounds in jewellery is at the crossroads of three types of regulations: regulations on lead and its compounds, regulations on children's products and regulations on jewellery. As shown below, at present, there is no European legislation covering this particular issue as a whole: EU legislation related to lead and its compounds is scattered and it deals with very wide groups of products. Legislation on products intended to be used by children does not include jewellery items, legislation on fashion jewellery is partial and mainly national, when it exists, and finally legislation on precious jewellery is national and usually does not deal with other metals than the precious ones.

Regulations related to the use of lead and its compounds in preparations, articles or consumer products

Preparations, articles or consumer products are regulated through several EU directives as regards their health (and environmental) risks. A non exhaustive list is presented in Table 24.

Table 24: List of regulations related to the use of lead and its compounds in preparations, articles or consumer products (non exhaustive list)

EU regulations	Legal requirements
Directive 76/768/EC on cosmetics	▪List of substances that cosmetic products must not contain (including lead and its compounds)
Directive 98/70/EC on petrol	▪prohibition of leaded gasoline (except aircraft) ▪lead content < 0.005 g/l
Annex XVII of REACH: restriction of the use of certain hazardous substances	▪Direct restriction of PbCo, 2PbCO3, and PbSo in preparations intended to be used as paints ▪substances classified as CMR may not be sold to the public (lead compounds are Repr. Cat 1 and lead hydrogen arsenate in Carc. Cat 1)
Directive 91/157/EEC on batteries and accumulators containing certain dangerous substances	▪no prohibition ▪collection and recovery targets for batteries and accumulators containing more than 0.4% of lead by weight
Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (including 2006 ATP) and Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)	▪substances restricted in a waste management perspective ▪articles concerned: electric light bulbs, luminaires, households appliances, IT, telecommunications and office equipment, home equipment: tv, audio-visual equipment, lighting equipment, electrical and electronic tools (such as watches), toys, leisure and sports equipment and automatic dispensers ▪substances < 0.1% by weight in homogeneous material ▪ electronic modules and used in quartz and watches (2006 ATP): maximum of 37% of lead in solder alloys ▪ promotion of the collection and recycling of such equipments
Directive 2000/53/EC on end-of-life Vehicles	▪products concerned: cars and goods transport vehicles < 3.5 tons ▪substances as lead and its compounds < 0.1% by weight in homogeneous material ▪lead can be found in alloys and in components such as batteries and vibration dampers
Directive 2009/48/EC on toys	▪total prohibition of certain substances or preparations in toys except those which are essential to their functioning. In this case, they are submitted to a maximum concentration defined for each substance individually ▪Bioavailability resulting from the use of toys < 0.7µg/day (EN 71-3) ▪lead migration limit from toys = 90 mg/kg (EN 71-3) ▪lead migration limit = 13.5 mg/kg dry, brittle, powder-like or pliable toy material ▪lead migration limit = 3.4 mg/kg liquid or sticky toy material ▪lead migration limit = 160 mg/kg scraped-off toy material
Directive 84/500/EEC on ceramics articles intended to come into contacts with foodstuffs	▪.maximum permitted quantity of lead is 0.8mg/dm² for articles which cannot be filled or which can be filled but not deep (25mm), 1.5mg/l for cooking ware and storage vessels which can be filled by more than 3 litres and 4.0 mg/l for other articles (+50% of these thresholds tolerated)
Directive 2001/95/EC on General Product Safety	▪only safe products for consumers are placed on the market (conception and/or information) ▪information system (RAPEX)
Directive 94/62/EC on packaging	▪requirements on the design of packaging and packaging waste ▪special article 11 on SVHC (including lead): concentration level in packaging and packaging components < 100 ppm (mg/kg)

Directive 86/278/EC on Sewage sludge in agriculture	▪prohibition of the use of sludge for levels of lead > 1000-1750 mg/kg dry matter in sludge intended to be used in agriculture
Commission Regulation 466/2001 on contaminants in foodstuffs	▪ lead level in milk, meat, fish, shellfish, cereals, vegetables, fruits, berries, oils, fats, fruit juice and wine must be between 0.02 mg/kg by wet weight (cow's milk) and 1.5 mg/kg w.w. (mussels)
Directive 98/83/EC on quality of water intended for human consumption	lead content < 10 µg/l in water for human consumption
Directive 88/344/EEC on extraction solvents in foodstuffs	▪residues of solvents used in food industry ▪lead content in extraction solvents < 1 mg/kg
Directive 88/388/EEC on flavourings for use in foodstuffs and to source materials for their production	▪ lead content in flavourings < 10 mg/kg
Directive 69/493/EEG on crystal glass	▪prescription of the use of lead in crystal glass ▪>30% of content of lead in "full crystal glass" cat. 1 ▪[24%, 30%[of content of lead in "full crystal glass" cat. 2

None of the previously identified regulations specifically covers lead and its compounds in fashion or precious jewellery.

Regulations related to products intended to be used by children

The only identified EU regulation for this type of products is Directive 2009/48/EC on toys, mentioned in the previous table. However, this regulation explicitly excludes fashion jewellery (for children) from its scope (annex I of the Directive[28]).
Other directives do mention children's protection but are not specific: Directive 76/768/EC on cosmetics, Directive 2001/95/EC on general Product Safety and Commission Regulation 466/2001 on contaminants in foodstuffs. Directive 2002/95/EC covers some electrical and electronic toys (Electric trains or car racing sets, video games, computers, etc.) but mainly in an environmental protection perspective.

Regulations related to fashion jewellery articles

There is no specific EU regulation managing the potential health and/or environmental risks from fashion jewellery, except for RoHS Directive 2002/95/EC which regulates lead in electronic watches (2006 ATP) and an entry of the REACH Annex XVII which limits nickel content in some jewellery articles (earrings, necklaces, bracelets and chains, anklets, finger rings, wrist-watch cases, watch straps and tighteners) mentioned above.
Fashion jewellery (intended for children or not) might contain lead and its compounds and this category of products is not regulated at EU level. At national level however, several EU Member States have implemented regulations regarding lead in jewellery. These regulations (and those of non-EU countries given for informative purposes) are documented in Table 25.

Table 25: National regulations in EU Member States concerning the use of lead and its compounds in fashion jewellery (non exhaustive list)

Country	Regulation/Action	Jewellery article(s)	Requirements
EU countries			
EU	Directive	Paints and	Labels of packages of paints and varnishes

[28] "fashion accessories for children which are not for use in play" is mentioned as an exemption (exemption 19).

	EC/1999/45[29] concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations	varnishes (potentially concern jewellery)	containing lead in quantities exceeding 0.15% (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars: "Contains lead. Should not be used on surfaces liable to be chewed or sucked by children." In the case of packages the contents of which are less than 125 millilitres, the particulars may be as follows: « Warning! Contains lead »
EU	Regulation/Action: Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment.	Watches	The maximum concentration value of lead tolerated by weight in homogenous material = 0.1%
France	Arrêté of February 1st 1993	Imitation pearls	Restriction on import and placing on the market of imitation pearls which have a coating containing the following lead salts: lead carbonates CAS n°598-63-0 and CAS n°1319-46-6 and lead sulphates CAS n°7446-14-2 and CAS n°15739-80-7 - when the pearls are sold in bulk or used in jewellery and fashion jewellery items
Denmark	▪Statutory order n°856 of 05.09.2009 (replacing Statutory order of 2007 and 2000)	Products containing lead, including jewelleries	Ban on the import or sale of certain products, including jewelleries, containing more than 0.01% of lead in the homogeneous single parts of the product
Non EU countries			

[29] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:200:0001:0068:EN:PDF.

USA	New Children's Products Safety Laws of February 10th 2009	Children's products including children's jewellery	Children's products/jewellery cannot be sold if they contain more than 300 ppm (0.03%) total lead. (This limit was initially set up at 600 ppm and products exceeding this limit were required to have a maximum migratable lead of 175 µg[30]). It is expected to be revised to 100 ppm by August 14th 2011, unless the Commission determines that it is not technologically feasible.
Canada	Children's Jewellery Regulations of may 10th 2005 " on jewellery for children under 15 "	Jewellery intended for children (except merit badges, medals for achievement or other similar objects normally worn only occasionally)	Sale, import and advertise are authorised if the children's jewellery contains not more than 600 mg/kg (0.06% by weight)[31] of total lead and not more than 90 mg/kg (0.009% by weight) of migratable lead[32].

Regulations related to precious jewellery articles

There is no specific regulation managing the potential health and/or environmental risks from precious jewellery at EU level, except, as mentioned for fashion jewellery for an entry of the REACH Annex XVII limiting nickel content in some jewellery articles.
The other existing EU legal requirements on precious jewellery mainly concern trade and conception (duties, system of hallmarking, etc.)[33].
Precious jewellery is however regulated at national levels in EU Member States. Consultation with CETEHOR (Technical Centre for the watch and jewellery industry) revealed that such regulations usually impose some requirements on the minimal content of precious metals (such as gold, silver, platinum), but no specification on maximal levels for other metals/substances.

Other (non-regulatory) actions implemented within the EU

Some voluntary actions have also been implemented in the EU. During consultation, MSCAs gave some information about such actions. For example, in 2007, voluntary actions have been undertaken by sellers of fashion jewellery articles to phase-out lead in Sweden (KEMI (2007)). Their actions included measures such as asking their suppliers to only receive jewellery with limited concentrations of lead. According to KEMI, these actions had a very limited impact, since the quantity of lead-containing jewellery articles which are placed on the market is still significant (see data in section B.2.6). The Netherlands reported as well one (isolated) example where, on a voluntary basis, a store chain recalled jewellery containing lead. Outside the EU, voluntary actions undertaken in Canada in 1999 and 2000 gave the same unsatisfactory results (Canada Gazette (2005)). According to Health Canada, factors in the ineffectiveness of voluntary measures to remove lead-containing children's

[30] This value is based upon a *"review of the scientific literature and calculation of the effect of ingested lead on the blood lead level, taking into account a child's physiology (e.g., body weight, blood volume), the bioavailability of lead, body compartmentalization of the lead, and normal elimination of an ingested item from the gastrointestinal tract"* (US CPSC, 2005b) and on the assumption that an ingestion of 175 µg of accessible lead in a short period would avoid exceeding the 100 µg/L level of concern from acute exposure.
[31] Consistent with the Canadian regulation on the maximum lead limits for surface coating materials under the Canadian Hazardous Products Act.
[32] Consistent with the EU migratable lead limit standards for toys (EN 71-3) intended for children under six years of age.
[33] Such as, e.g. Commission Regulation (EEC) No 2539/90, Commission Regulation (EEC) No 2536/89 of 21 August 1989, Commission Regulation (EEC) No 1761/80 of 4 July 1980, Commission Regulation (EEC) No 2845/78.

jewellery from the Canadian marketplace are the following: the range of costume jewellery items sold in Canada is very large and is constantly changing; and the number of companies that import and sell costume jewellery in Canada is also very large. Such arguments are expected to also apply to countries other than Canada.

B.5.1.2. Summary of the effectiveness of the implemented risk management measures

The summary expressed by France is presented below:

As documented in Section B.5.3.1, several cases of lead poisoning due to the misuse by children of lead-containing jewellery are reported; implying that the implemented risk management measures are not sufficient. Moreover, as explained in Section A.2.1 of the original Annex XV report, the reported cases are expected to be an underestimation of the actual number of children who are poisoned by lead and its compounds in these articles. Indeed, lead exposure from mouthing articles may result in blood lead levels which are below the ones which would be observed with an ingestion of lead-containing jewellery and such chronic poisoning may be difficult to detect by doctors even though it can result in serious health effects. Also, monitoring and health surveillance systems are not adapted to the detection of lead poisoning resulting from sources which are considered as 'unusual' (such as jewellery).

B.5.2. Manufacturing

B.5.2.1. Occupational exposure

Not relevant for this proposal, even though it may be expected that workers can be exposed to lead and its compounds while producing jewellery which contain these substances.

B.5.2.2. Environmental release

The environment may be contaminated by lead and its compounds which can be released during the production of lead containing jewellery. However, this restriction dossier is targeted on the risks for consumers which may result from the use of such jewellery. Consequently, this section is not relevant for this proposal.

B.5.3. Misuse of jewellery articles

B.5.3.1. General information

Reported cases of children lead poisonings due to the misuse of jewellery articles

Since 1998, cases of lead poisoning have been clearly identified as resulting from the misuse of jewellery by children who have swallowed or repeatedly mouthed them (or parts of them). The observed symptoms of these cases go from headaches and diarrhoeas to death. The different cases are reported in Table 26.

Table 26: Cases of children poisonings due to ingestion/mouthing of jewellery

Country	Year	Age of the child	Cause of poisoning	Origin of the jewellery	Effects/data	Actions	Sources

USA	2006	4	Ingestion of a bracelet charm (99.1% lead) sold with Reebok shoes (Minnesota)	China	PbB = 1800 µg/L Vomiting, pain in the stomach, poor oral intake, 'sore tummy', symptoms of indolence, child's death	article recalled	CDC (2006); InVS (2008)
	2003	4	Ingestion of a necklace's pendant (38.8% lead) bought from a vending machine (Oregon)	India	PbB = 1230 µg/L Abdominal cramping, vomiting, diarrhea without fever, inability to eat or sleep because of abdominal pain	Nationwide recall in Sept. 2003	KID (2004); InVS (2008); CDC (2004); Levin R. *et al.* (2008)
	<1999	2	Mouthing of necklace's metal beads (2% lead) while wearing of the jewellery during 3 days	China	PbB = 430 µg/L (Detected thanks to a routine screening)	-	InVS (2008); Jones T.F. *et al.* (1999)
	<1998	9	Mouthing of necklace's metal bead	China	PbB = 180 µg/L	-	InVS (2008); Jones T.F. *et al.* (1999)
Canada	1998	5	Chewing off the decorative coating and sucking on the pendant made of pure lead covered with a decorative coating	-	Pendant contained 1022 ppm of lixiviable lead Elevated blood lead level	-	InVS (2008); Canada Gazette (2005)
	1998	-	Chewing off the decorative coating and sucking on the exposed cores of a child's necklace	-	Test on the jewellery: almost 75% lead	-	Canada Gazette (2005)
Japan	-	-	There have been cases of poisoning in Japanese children who have ingested	-	One piece of the tested jewellery released 56 times the quantity of lead allowed in the USA[34]	-	KEMI (2007)

[34] At the time of the KEMI report (2007), US Regulation required that the products should have less than 175 µg of migratable lead.

			large quantities of lead from jewellery.				

France as dossier submitted has considered that these cases are an underestimation of the actual children lead poisonings from this type of articles.

Because most of the time, in case of acute poisoning, a gastroenteritis is diagnosed, since the symptoms are often vomiting and abdominal pain, the diagnosis of lead poisoning resulting from ingestion of leaded foreign body by children may be delayed or even not considered.

Lead content in jewellery

In a Danish survey (Danish EPA, 2008) 58% of 170 examined jewelleries contained lead in the concentration range from 0.01% to 70 % lead. The average lead concentration of the 314 samples tested is 3.7%. The lead content was determined by a XRF device (X-ray measurement) and lead content in jewellery down to 0.01-0.02% could be measured.

In a Swedish survey (KEMI, 2008) 23 of 50 examined jewelleries were found to contain lead with 4 pieces above 10% lead, 9 pieces in the range of 2-10% lead, and 10 pieces below 2% lead. A second Swedish survey (KEMI, 2008) was reported in which 36 of 50 pieces of jewellery contained lead. No data on the average concentration is made available.

In a German survey (BfR, 2008) on jewellery 78 samples out of 87 contained lead with an average lead content of 6.3% and a maximum value of 90%.

In a UK survey (the Sunday Times, 2008) 24 children´s jewellery were examined and 8 tested positive for a high content of lead. Six of the items exceeded a lead concentration of 80%.

Informal information on the lead content of jewellery from one independent testing laboratory (Anon, 2010) has been received (see Table 14). The 17,447 samples tested in 2009 had a mean lead concentration of 1.1% (minimum 0.01%, maximum 67%). The mean lead concentration of the 13,752 samples tested between January and October 2010 is 3.7% (minimum 0.01%, maximum 40%). The calculation of the mean value is based on any results of >0.005%. Approximately 75% of the samples tested in 2009 and 2010 contained lead below 0.005%.

Based in the information presently available RAC concludes that the reasonable average range of lead concentration in jewellery is 3-6%.

Target population

Exposure to lead from jewellery may occur for each category of the general population (children and adults).

However, among the general population, children are the most at-risk individuals, especially children below 36 months (RIVM (2008)). Indeed, the frequency of their mouthing activities and hand-to-mouth behaviours is higher than the ones of older children and adults.

As a result, protecting children under the age of 36 months should also protect the rest of the general population.

B.5.3.2. Exposure Assessment

Workers' exposure is not relevant for this restriction proposal

Based on the fact that children under 36 months may accidentally ingest small objects because of their oral exploration behaviour and that they mouth a broad range of items including not only toys, but also other objects which are not intended to be mouthed (RIVM (2008)), **the 3 following uses are considered for the exposure assessment of children (below 36 months) to lead from jewellery:**

Use 1: Mouthing of jewellery containing lead (chronic exposure),

Use 2: Hand-to-mouth activity after hand contacts with a leaded jewellery (chronic exposure),

Use 3: Accidental ingestion of a leaded jewellery (acute exposure).

Uses 1 and 2 are only assessed on a chronic basis. This is based on a protective approach: as chronic DMELs are lower than the acute DNEL and as exposure during one event is the same whether it is considered as an acute or as a chronic event, a chronic risk assessment is considered as a worst case compared to an acute risk assessment. The cases of accidental exposure (Use 3) reported between 1998 and 2006 comprise one lethal case, one case with symptoms of acute lead intoxication, and three cases with increased blood lead levels without reported symptoms. In 2 other case reports the lead content of the jewellery has been given only. Although RAC is aware that there is underreporting of such events and their health consequences the committee concludes that acute lead intoxication from swallowing pieces of jewellery alone is not a major cause for a restriction of lead in jewellery. The major concern is the chronic lead exposure from repeated mouthing lead containing jewellery.

Dermal exposure is considered negligible compared to exposure via oral route as dermal absorption of lead is very low (0.1%).

Given lead physico-chemical properties, exposure via inhalation is not relevant when considering the misuse of jewellery articles.

Use 1: Mouthing of jewellery containing lead

Although exposure assessment should be based on the quantity of lead that is released by the jewellery into the matrix (sweat, saliva or gastric acid), the available information on the migration rates at different lead concentrations in the jewellery are inaccurate, especially at lead concentration below 1%. However, as described below a statistical re-analysis of the migration data presented in the Danish EPA survey (2008) allow the conclusion that a linear correlation between lead content and migration can be assumed even at lead concentrations below 1%. The resulting lead exposures (µg/kg bw per day) from mouthing jewellery containing lead concentrations between 0.05 and 50% have been calculated as given in Table 28.

<u>Analysis of the Danish migration data</u>

Migration of lead from the jewellery heavily depends on the jewellery itself. The presence of a coating, the type of coating, the state of the jewellery (whether it is in good condition or not), the other constituents of the jewellery – all of these are parameters which may influence lead migration from the jewellery. Moreover, the Danish survey (Danish EPA (2008) did in their analyses not find a correlation between the lead content in the jewellery and the migration rate. As this is the most relevant available study regarding the relationship between the lead content and the expected migration, and a trend was apparent at high lead content levels, RAC has re-evaluated the raw data provided in this study, excluding 2 datapoints considered as outliers and also taking into account the data below the detection level.

The RAC analysis has been based on individual measurements and confirms that, as indicated in the study report, no statistically significant correlation is observed in the study when all data are considered together, either for the migration estimated as µg/cm^2/hr (Correlation Coefficient = 0.14, p=0.51) or as µg/g (Correlation Coefficient = 0.21, p=0.29). However, a further assessment, calculating the percentage of lead migrated in to the solution, suggests that data are not randomly distributed, but in fact there seems to be a tendency relating the lead content with the migration, which is not observed in the raw data due to the dispersion of the data at low lead content levels, dispersion confirmed for some measurements with up to 26 times difference between duplicated measurements. As observed in the Figure below, the data are basically within an order of magnitude for lead levels above 10% while cover up to four orders of magnitude at low lead contents.

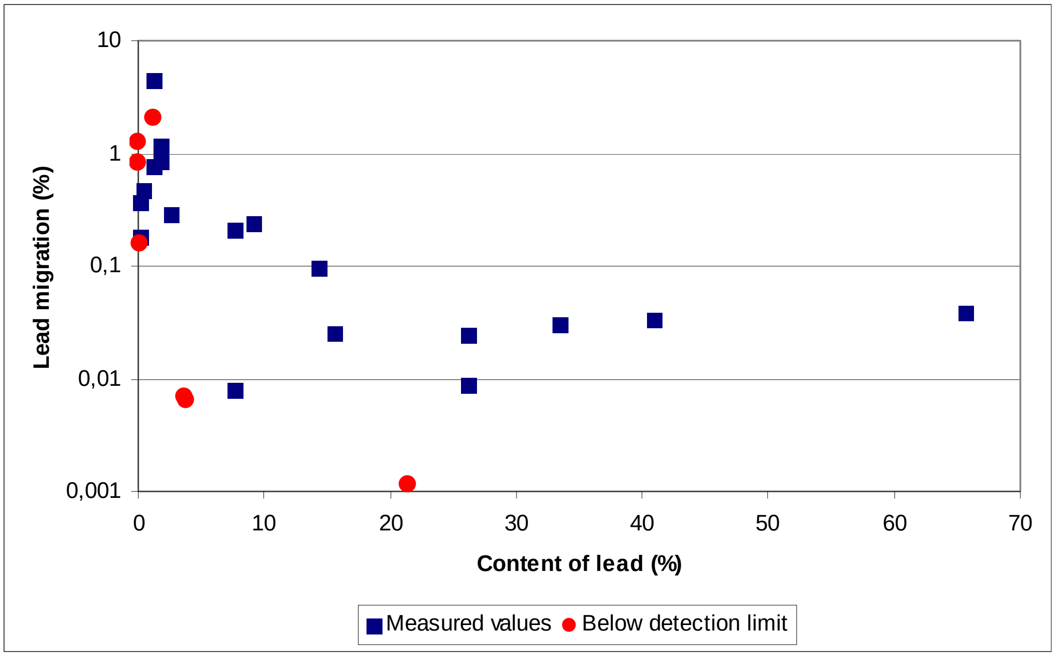


Figure 1. Comparison of the lead content and the percentage of lead migrated in to the solution calculated from the raw data of the Danish survey.

The Stem-and-Leaf analysis confirms that the two highest values (above 1% migration) should be considered as outliers.

When these outliers are excluded, a statistically significant linear correlation is observed for the migration expressed as µg/g (Correlation Coefficient = 0.57, p=0.004).

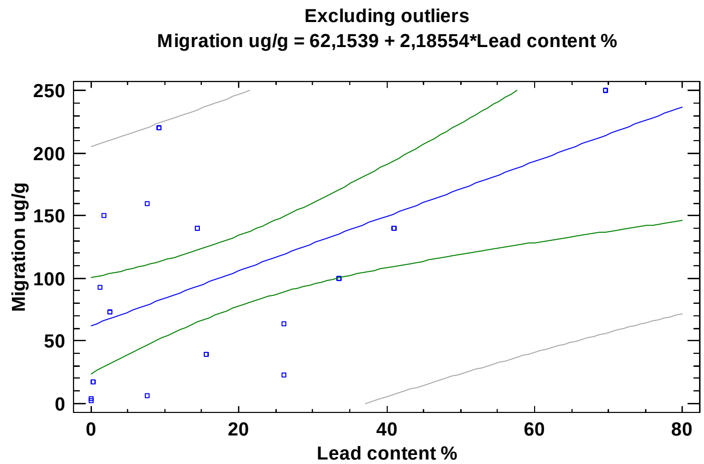
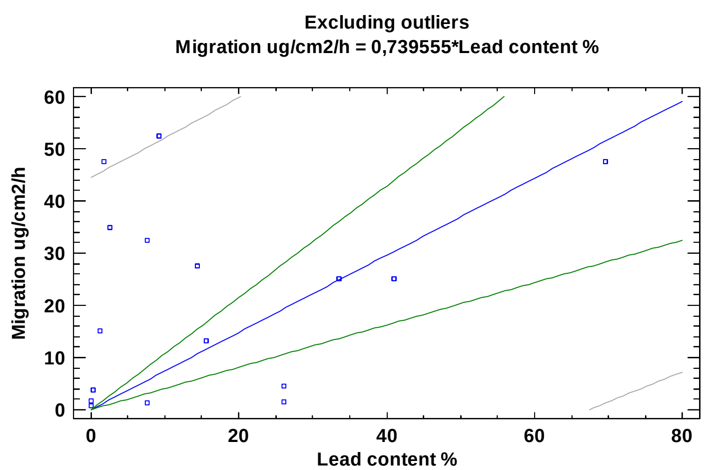


Figure 2. Correlation between the lead content and the migration per surface unit calculated from the raw data of the Danish survey.

The slope is likely biased due to high percentage of values below the level of detection at low lead contents. This bias may explain the high level of migration estimated for a 0% lead content, which is obviously incoherent.

When the correlation is forced to estimate 0 migration at 0% lead content, highly significant correlations are observed for migration expressed as µg/cm^2/hr (Correlation Coefficient = 0.69, p<0.0001) and as µg/g (Correlation Coefficient = 0.79, p<0.0001), although there is a high variability at low lead content levels.



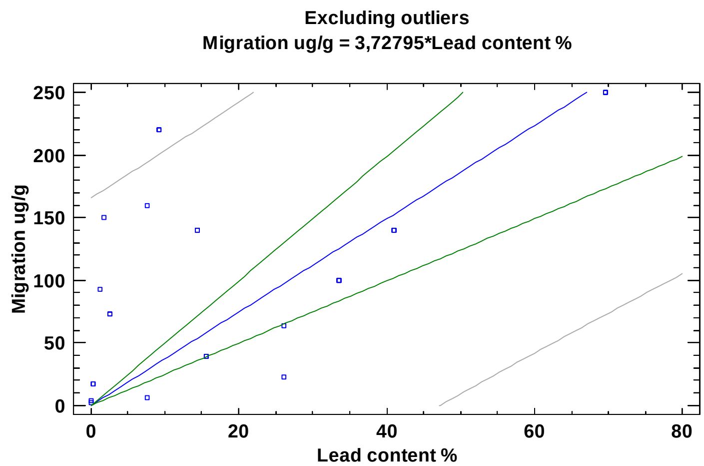


Figure 3. Forced (0,0) correlations between the lead content and the migration calculated from the raw data of the Danish survey.

It should be also noted that linear correlations are observed for the migration values measured for jewellery items with lead concentrations above 15%, both for migration expressed as µg/cm²/hr (Correlation Coefficient = 0.90, p<0.0003) and as µg/g (Correlation Coefficient = 0.98, p<0.0001). When forced to the origin, the correlation coefficients become 0.97 and 0.984 respectively.

As presented in the table below, the slopes observed for the different adjustments are very similar:

Table 27: Slopes of linear correlation between lead content and lead migration (per cm² or per g jewellery) calculated from the raw data of the Danish survey

Adjustment	Slope µg/cm².hr.%	P	Slope µg/g.hr.%	p
All data except outliers Forced to (0,0)	0.7 ± 0.2	<0.0001	0.9 ± 0.15	<0.0001
Lead content >15% Forced to (0,0)	0.6 ± 0.1	<0.0001	0.8 ± 0.05	<0.0001
Lead content >15% No forced	0.7 ± 0.1	<0.0001	1.0 ± 0.08	<0.0001

Although the uncertainty of the adjustments is high due to the variability observed at low lead levels, the re-evaluation of the raw data suggests a linear correlation between the lead content and the migration rate. Despite the uncertainties, the slope values of 0.7 µg/cm².hr % or a slope factor of 0.9 µg/g.hr % seem to be proper figures based on the available data and will be used in the following estimations.

Additional relevant information from the Danish study is that migration at levels of concern was detected in two out of three jewellery items with a lead contain between 0.1 and 1%. Migration was due to the rather high analytical detection limit not detected in the items with measured lead content below 0.1% (the only exception is a measurement in article 88.1 a "Silver-like ring without stone" with over 93% of Cu, for which some migration was observed although the XRF screening did not detect lead in the composition). However, it should be noted that these data are not conclusive as the detection level was high and, therefore, insufficient for demonstrating more precise migration at these low levels.

A statistically significant correlation (Correlation Coefficient = 0.91, $p<0.0001$) is observed between the two methods employed in the Danish study for reporting migration (expressed as µg/cm^2/hr or as µg/g/hr).

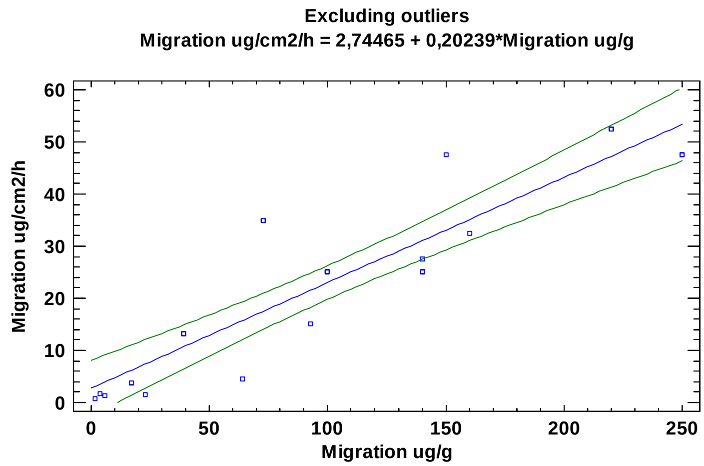


Figure 4. Correlation between migration measurements based on surface and content from the Danish survey

<u>Conclusions from the reassessment of the Danish EPA (2008) report</u>

The Danish EPA report is the only information available to RAC for setting correlations between lead content and lead migration. The study only covers metallic parts of jewellery. A clearly lineal trend correlating lead content and lead migration is observed at the highest lead content. The extrapolation of this correlation to low lead contents is associated to high uncertainty. The statistical significance of the correlation depends on the selected assumptions. However, as demonstrated above a slope of about 0.7 µg/cm^2.hr.% is consistently observed. The data also indicates a good correlation between migration based on surface and migration based on weight.

A more pragmatic approach is the use of the raw data from Danish EPA (2008) report, without assuming correlations at the low lead content levels. The most relevant data are the six measurements in jewellery parts containing less than 1% lead. Migration was not detected in the three jewellery items containing between 0.02 and 0.03% lead; migration was however detected in two (out of three) items with lead content between 0.11 and 0.36% lead.

<u>Exposure from mouthing jewelleries containing lead at various levels</u>

As no data concerning the specific activity of mouthing jewellery is available the information about mouthing of toys and other articles provided in the “children’s toys fact sheet” of ConsExpo (reference model of REACH guidance chapter R15 on consumer exposure) has been used.

According to the migration rate of 0.7 µg/cm^2/hr per % of lead content a lead concentration of 1% results in a migration of 7 µg per 10cm^2 per hr. If this amount is ingested by a 10 kg child the exposure is 0.7 µg/kg bw per day. Assuming that a linear correlation between lead content and migration rate exists at all lead concentrations the migration rates and the daily exposure at lower concentrations have been calculated as given in Table 28.

Using the migration rate of 0.9 µg/g/hr per % lead content lead exposure of 9 µg/kg bw per day can be calculated in relation to a 10 kg child mouthing a jewellery item of 10 g with a lead content of 1%.

Table 28: Lead exposure from 1 hr mouthing jewellery containing lead concentrations between 0.05 and 50%.

Lead content in jewellery	Lead exposure Migration rate 0.7 µg/cm²/hr	Lead exposure Migration rate 0.9 µg/g/hr
(%)	(µg/kg bw per day)	(µg/kg bw per day)
0.05	0.035	0.045
0.1	0.07	0.09
1	0.7	0.9
3	2.1	2.7
6	4.2	5.4
10	7	9
25	17.5	22.5
50	35	45

Based on the original data of the Danish survey (2008) migration rates at lead concentrations in the material between 0.05 and 50 % have been calculated. For a scenario in which a child (10 kg) is mouthing a piece of jewellery of 10 g (or 10 cm^2) for 1 hr, and using the lowest and highest migration rates from the Danish EPA study (respectively 2 $\mu g/cm^2/4hrs$ and 280 $\mu g/cm^2/4hrs$), the resulting exposure estimates range from 0.5 to 135 µg/kg bw/day.

Daily mouthing time

As described by RIVM (2000) mouthing of jewellery may cover mouthing of articles that are not designed for this activity. In this way, “pacifiers” and “toys for mouthing” are not considered. Jewellery worn by a child could be assimilated to the “other toys” category as it is always available to him. In addition, jewellery which is not worn but that can be reached by a child may be considered as a “non toy”.

As jewellery may be included in “other toys” and ”non toys”, both categories are selected for the assessment, as a worst case approach. The following table summarizes the mouthing times that are used in the assessment for the different age categories:

Table 29: Default mouthing times for jewellery used in the assessment

Age (months)	Default mouthing times (min/day)	Default mouthing time (hr/day)
3-6	35	0.58
7-12	86	1.43
13-18	35	0.58
19-36	9	0.15

For its exposure assessment RAC uses a daily mouthing time of 1 hour.

Surface of jewellery in contact with the mouth (S)

This parameter represents the surface of the jewellery that can be in contact with the mouth at a same time. The value of 10 cm² proposed in RIVM (2002) and in RIVM (2008) is used.

Uncertainties of exposure assessment

This exposure assessment is based on many assumptions, among which:

- migration results from the Danish report are obtained for only 25 parts of jewellery; as a result they are not representative of the EU jewellery market.
- only fashion jewellery has been tested.
- migration rate in the saliva is extrapolated from a migration rate in the sweat.
- the method that is used to measure the migration rate presents some biases (SCHER (2010)).
- the migration rates used for the calculations are based on 4 h migration values and thus the proportional migration for e.g. 5 minutes of mouthing may be an underestimation if actually most migration occur in the start during migration testing.
- exposure parameters such as the duration of mouthing activity are protective since they have been derived for risk assessment purposes and thus, they tend to overestimate exposure.

Contribution of mouthing to the background exposure

The EFSA scientific opinion on lead in food (EFSA, 2010) has estimated the daily lead intake of children up to three years from food, soil, dust, outdoor air and environmental tobacco smoke (background exposure). Their results have been presented in Table 21 with a total daily intake between the minimum of 1.3 and the maximum of 6.4 (1.293 and 6.365) µg/kg bw/day. The increases of the minimum and maximum background exposures from mouthing jewelleries for one hr per day containing different amounts of lead are given in Table 30.

Table 30: Total exposure (minimal and maximal background exposure) plus exposure from mouthing jewellery containing lead between 0.1 and 50%. Minimal and maximal background exposures of 1.3 and 6.4 µg/kg per day.

Lead Content	exposure µg/kg bw	Min	total (µg/kg bw)	Max	total (µg/kg bw)
0.1%	0.07	1.3	1.37	6.4	6.47
1%	0.7	1.3	2	6.4	7.1
10%	7	1.3	8.3	6.4	13.1
50%	35	1.3	36.3	6.4	41.4

The Table shows that additional exposures from a daily mouthing of jewellery for 1 hr that contains 0.1% lead increases the minimal background exposure of 1.3 µg/kg bw by about 10% (9.1%). It is about 1% at the maximal background exposure of 6.3 µg/kg bw. Considering that a daily exposure of 0.16 µg/kg bw will lead to no measurable increase in the blood lead level of 20 µg/L the change of blood lead concentration from mouthing jewellery that contains 0.1% lead will not be detectable.

Conclusion

Even if the data on migration rates of lead from jewellery are not fully representative of the market of jewellery, it can be considered that the contribution of the exposure by mouthing a metallic part of jewellery containing lead exceeding 0.1% to the total daily lead intake becomes significant (and exceeds the tolerable exposure).

Exposure assessment from non-metallic parts

In the original dossier proposed by France, the restriction is based on migration and no information is provided on the correlation between lead content and lead migration for non-metallic materials such as crystals, gems, plastic, painted woods, etc. Additional information on migration from non-metallic parts of jewellery was provided by industry during the Public Consultation; migration values well exceeding 0.05 µg lead/g measured with the EN 71-3 standard were reported. No information on the lead content of those articles was submitted, and therefore, no correlations between content and migration can be established. There is also no information on the relationship between the migration as measured under the EN 71-3 standard and the expected migration to saliva by mouthing.

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

Considering an exposure scenario in which a child of 10 kg bw mouth a jewellery article for 1 hour with a surface of 10 cm^2 and a weight of 10 g this would imply a tolerable migration rate from the jewellery of 0.05 µg $Pb/cm^2/hr$ or 0.05 µg Pb/g/hr. The migration rate expressed in cm^2 is in principle applicable for all kind of surfaces (metallic as well as non-metallic parts). With a general assumption that the ratio between surface (in cm^2) and the weight (in g) of the jewellery is 1 the migration rate would most practically be set to 0.05 µg Pb/g/hr. This assumption is in lime with the exposure scenario, which is based on a 10 g piece of jewellery with a surface area of 10 cm^2 independently of the material.

Migration to saliva due to mouthing is expected to occur only from the surface area of the mouthed part of the jewellery (including coating when relevant). A depth of 0.1 mm can be considered a conservative maximum for relevant migration within one hour mouthing.

The total volume exposed to mouthing can be estimated from the surface and depth values indicated above. For a mouthing surface area of 10 cm^2 with a mouthing relevant depth of 0.1 mm (0.01 cm) a maximum mouthing total volume of 0.1 cm^3 is estimated. This volume can be transformed in weight using the material density, a density value ranging from 10 g/cm^3 for heavy metals and crystals to 1 g/cm^3 for plastics and woods has been considered in this assessment. Therefore, the total weight of the jewellery surface considered relevant for migration by mouthing ranges from 1 g for heavy metals and crystals to 0.1 g for plastics and woods.

From the calculation presented above, a limit of 0.05% for the metallic parts of jewellery is proposed. If this suggested limit of 0.05% lead in the material is implemented, the maximum total amount of lead in the parts of jewellery relevant for the mounting scenario would range from 500 µg lead in the case of heavy metals and crystals to 50 µg lead for plastics and woods.

RAC considers that it is unlikely that this levels could exceed the tolerable daily exposure of 0.05 µg/kg bw/d, as the child would need on a daily basis to extract, by mouthing, more than 0.1% of the lead in crystals or more than 1% in the case of jewellery items made of plastics and woods.

As the risk is based on repeated chronic exposure, these levels of extraction of the jewellery material on a daily basis are unlikely to be exceeded. In addition, if repeatedly exceeded, it is expected that the extraction could lead to a deterioration of the jewellery item, particularly for coated articles, avoiding further exposures.

Conclusion

In the absence of data on lead migration rates from non-metallic parts of jewellery, it can be considered, from the assessment presented above, that the contribution of the exposure by mouthing non-metallic parts of jewellery containing lead at levels not exceeding 0.05% is not expected to result in a significant contribution to the total daily lead intake.

Use 2: Hand-to-mouth activity after hand contacts with a leaded jewellery (chronic exposure)

Exposure resulting from the hand-to-mouth activity depends on the amount of lead which is available on the hands. Typically, a possible situation resulting in this kind of exposure is when a child plays with jewellery: lead migrates from the jewellery to the sweat of the hands and, because lead is available on the hands of the child, it can be ingested via hand-to-mouth contacts.
As information on the frequency and the duration of children contacts with jewellery is very scarce, a worst case approach could consist of considering that the child wears jewellery and that he sucks the part of his body which is in contact with the jewellery.

The model used to calculate the exposure resulting from this use is based on the available fraction of lead which can be transferred from hand to mouth. However, information is lacking to characterize this parameter and trying to estimate it would result in a high level of uncertainty.
Moreover, the “safe” lead migration rate calculated for the mouthing activity (use 1) should protect the child in case of use 2. Indeed, the amount of lead which is released on the skin and then ingested by hand-to-mouth transfer will be lower than the amount of lead directly ingested via object-to-mouth contact, considering that the frequency of hand-to-mouth activity is the same as the one of object-to-mouth activity.

As a consequence, use 2 is not considered relevant for the determination of a “safe” lead migration rate.

Use 3: Accidental ingestion of a leaded jewellery (acute exposure)

The French proposal is presented below.

Children may also be exposed to lead because of accidental ingestion of small jewellery (as mentioned in previous sections, one case reported in the USA in 2006 resulted in the death of a child). In this case, the child is exposed to the amount of lead that is released by the jewellery in the stomach’s gastric fluid. It is however difficult to determine the time the jewellery will remain in the stomach: in certain cases, the jewellery stays in the stomach and is not eliminated by the body, in other cases, the jewellery is eliminated in the faeces. The longer the ingested article is blocked in the stomach, the higher the quantity of lead will be released by the article (considering a constant migration rate).
Some cases could be extreme, as reported by Mowad E. *et al.* (1998): a 8-year-old child was suffering from pica and several sinkers (20 to 25) were found in his stomach. The sinkers were not eliminated by faeces even after 30 days of gastric lavages. Also, small articles or parts of articles can be blocked in the appendicitis and an appendectomy would be necessary or the jewellery has to be extracted using an endoscopy or a gastrotomy (InVS (2008)).
As no information on the possible time of residence of jewellery in the stomach was available, two calculations for two different times of residence are considered: 2 days of residence is considered as a realistic case (considering that, in spite of a great variation between children, it may correspond to an average value for normal elimination via faeces for a young child) and 5 days a worst-case (corresponding to the duration between the first signs of poisoning and the death of the child reported by CDC (2006)).

<u>Mathematical model</u>
The ingested amount of lead if jewellery is swallowed at once is given by the following equation:

$$Q_{stomach} = F_{jewel\text{-}stomach} \times 24 \quad \text{(Eq. 1)}$$

$Q_{stomach}$	Quantity of ingested lead	µg/day
$F_{jewel\text{-}stomach}$	Lead migration rate from the jewellery to the stomach	µg/hr

From Equation (1), the following equation is derived to express $\mathbf{F_{jewel\text{-}stomach}}$:

$$\mathbf{F_{jewel\text{-}stomach} = Q_{stomach} / 24} \quad \textbf{(Eq. 2)}$$

$Q_{stomach}$	Quantity of ingested lead	µg/day
$F_{jewel\text{-}stomach}$	Lead migration rate from the jewellery to the saliva	µg/hr

Exposure parameters

Quantity of ingested lead ($Q_{stomach}$)

The quantity of ingested lead ($Q_{stomach}$) necessary to reach the DNELa of 400 µg/L (considered as a "safe" level for acute effects) is estimated. In order to do this, a model developed by INERIS, based on equations proposed by Sharma M. *et al.* (2005) and O'Flaherty E.J. (1991) has been used. For more information on the model, please refer to INERIS (2010) and to Annex B.
This model has been used to estimate the daily ingested quantity of lead that will result in a PbB level of maximum 400 µg/L (DNELa) for the two selected times of residence of the jewellery in the stomach: 2 days and 5 days. For more details on the calculations performed with this model, see Annex B. The lowest (i.e. the most protective) quantity of ingested lead for each age class is presented in the following table.
As for chronic exposure, an oral absorption rate of 50% has been used.

Table 31: **Modelled $Q_{stomach}$ in order to remain below a PbB of 400 µg/L (PbB protective for acute effects)**

Age (months)	$Q_{stomach}$ for 2 days of residence (µg lead/d)	$Q_{stomach}$ for 5 days of residence (µg lead/d)
3-6	1350	560
6-12	1720	710
12-18	2350	960
18-36	2820	1170

Information from the previous table can be interpreted in the following way: if jewellery releases 1350 µg lead/day during 2 days in the stomach of a child of 3-6 months, his blood lead level would not exceed 400 µg/L and this child would not experience acute health effects due to lead exposure.

Results

The calculation of the "safe" lead migration rates is performed for each age category, according to Eq. 2.

Table 32: Safe" maximum lead migration from jewellery to stomach considering acute effects

Age (months)	"Safe" maximum lead migration rate from jewellery to stomach for 2 days of residence (µg/hr)	"Safe" maximum lead migration rate from jewellery to stomach for 5 days of residence (µg/hr)
3-6	56.25	23.33
7-12	71.67	29.58
13-18	97.92	40.00
19-36	117.50	48.75

Conclusion

The most protective values of the "safe" migration rates calculated for each use (1 and 3) are presented in the following table. The most "at risk" age category is 3-6 months for use 3 (acute exposure) and 7-12 months for use 1 (chronic exposure).

Table 33: Summary of "safe" migration rates

Use 1 - Mouthing of a jewellery Lead migration limit for saliva (µg/hr/cm²)	Use 3 – Accidental ingestion of a jewellery Lead migration limit for stomach (µg/hr)
0.09	23.33

B.6. Risk characterisation

B.6.1. Exposure to leaded jewellery

B.6.1.1. Human health

B.6.1.1.1. Workers

Not relevant for this proposal.

B.6.1.1.2. Consumers

Three different uses have been identified (see section B.5.3.2.for details). Two of them address chronic exposure: use 1 corresponding to a repeated poisoning from mouthing leaded jewellery and use 2 corresponding to a repeated poisoning from hand-to-mouth activity after repeated or long-duration contacts with leaded jewellery. The third one (use 3) addresses acute poisoning: accidental ingestion of leaded jewellery or a leaded part of jewellery.

Use 2 has been waived for the exposure assessment due to high uncertainty on its parameters and due to the fact that protecting against use 1 should also protect against use 2.

As already expressed, "safe" values for a lead migration rate have been determined in the gastric compartment for the acute exposure (use 3) and in saliva for the chronic exposure (use 1). The following Table 34 summarises these limits.

Table 34: Summary of "safe" lead migration rates for use 1 and use 3

Use 1 - Mouthing of jewellery Lead migration limit for saliva (µg/hr/cm²)	Use 3 - Ingestion of jewellery Lead migration limit for stomach (µg/hr)
0.05	23.33

According to the recent EFSA (2010) opinion on lead a lower benchmark dose level of 0.5 µg Pb/kg bw/d corresponds to a change in blood level of 12 µg Pb/L and an IQ loss of 1 point. RAC supports this risk assessment. RAC also agrees with EFSA that MoE of 10 or greater in relation to the BMDL (01) level should be considered sufficient to ensure no appreciable risk. The resulting exposure of 0.05 µg/kg bw/d, which EFSA considers 'sufficient low to ensure no appreciable risk', is taken by RAC as point of departure for the risk characterisation.

EFSA observed that children in the age group of 1-7 years have mean background lead exposures between 0.8 and 5.5 µg/kg bw per day (e.g. from the diet and background environmental exposure). Clearly, this already exceeds the BMDL(01) level of 0.5 µg Pb/kg bw per day, and therefore any additional lead exposure would on average expected to further increase a typical child's exposure above the dose descriptor level.

Calculation of tolerable lead content in jewellery

From the migration rates in Table 28 the tolerable lead content in jewellery can be calculated. With a tolerable exposure of 0.05 µg/ kg bw d and a migration rate of 0.7 µg/cm^2/hr per % of lead in jewellery a tolerable lead content of **0.07%** lead can be calculated.
(0.05 µg/ kg bw x 10 kg/ (0.7 µg/cm^2 hr % x 10 cm^2 x 1hr) = 0.07%).

Using the migration rate expressed in relation to g of jewellery at tolerable lead content of **0.056% lead** can be calculated.
(0.05 µg/ kg bw x 10 kg/ (0.9 µg/g hr % x 10 g x 1hr) = 0.056%).

Taking into account the above calculations a tolerable lead content in jewellery of 0.05% is proposed. RAC recognises the uncertainties in the extrapolation of the migration-content correlations to these low lead levels, but notes that this value is further supported by the direct consideration of the raw measurements reported in the Danish study, as migration was not detected in the three jewellery items containing less than 0.05% lead, while it was detected in two (out of three) items with lead content between 0.1 and 1%.

The impact of lead exposure on the IQ from mouthing jewellery

As a preliminary approach RAC has estimated the impact of mouthing lead containing jewellery on the IQ. This calculation assumes a linear correlation between lead content and lead migration at all lead concentrations in jewellery. The estimated impact of the IQ is based on the EFSA (2010) and Jusko et al (2005) evaluations on the dose response that assume a loss of about 6 IQ points when the blood lead content increases from 10 to 100 µg/L. The results are given in Table 35. They are based on a daily mouthing time of 1 hour and a mouthed surface of 10 cm^2

Table 35: The impact of lead exposure on the IQ from mouthing jewellery of different lead concentrations for 1 hr per day.

Lead content in jewellery	Lead exposure	Increase of blood lead level	IQ reduction
(%)	(µg/kg bw per day)	(µg/l)	(points)
0.05	0.035	0.84	0.07
0.1	0.07	1.68	0.14
1	0.7	16.8	1.4
3	2.1	46	3.8
6	4.2	83	6.9
10	7	125	8.7

25	17.5	234	10.3
50	35	354	12

The Table shows that a continuous daily 1 hr mouthing of jewellery that contains 0.05% lead leads to an IQ reduction below 0.1 IQ point reduction that is 10% of the exposure EFSA (2000) considers “sufficiently low to ensure no appreciable risk”.

Mouthing times less than one hour per day or frequencies less than every day have a correspondently lower impact on the IQ. For example, mouthing a metallic piece of jewellery containing 0.1% lead once a week for 1 hr results in an IQ impact of 0.02, which is about five-fold below the level of no appreciable risk.

Using the migration rate of 0.9 µg/g/hr (in stead of the surface based migration rate of 0.7 µg/ cm^2 /hr) the exposure from a 10 g jewellery would be 29% higher which then would lead to a corresponding higher impact in IQ loss.

Estimation of the IQ impact from mouthing jewellery containing 3 and 6 % lead

Since the available information so far indicates that the average lead content in jewellery is between 3 and 6% the IQ impacts of mouthing jewellery that contains 6 and 3% lead for daily, weekly and monthly mouthing times of 5 and 15 min is calculated. For comparison the IQ impact from mouthing jewellery containing 1 and 0.1% lead has been calculated. IQ impacts that exceed 0.1 point are in bolt. Impacts below 0.1 point (marked with *) are considered sufficient low to ensure no appreciable risk.

The results presented in Table 30 indicate that at 1% lead content the IQ impact always exceeds 0.1 point. At 0.1% lead the IQ impact of 0.1 points is exceeded only in case of daily 15 min mouthing both jewellery containing 3 and 6%. Thus a lead content in jewellery of 0.1% seems to be the limit for tolerable average exposure.

Table 36: Estimated IQ impacts from mouthing jewellery of 3 and 6% lead content for 5 and 15 min as compared to mouthing jewellery of 1 and 0.1% lead content.

	Mouthing time 5 min.				Mouthing time 15 min.		
% lead	Daily	Weekly	Monthly		Daily	Weekly	Monthly
6	**0.7**	**0.11**	0.03*		**2.1**	**0.323**	0.091*
3	**0.35**	0.054*	0.016*		**1.05**	**0.162**	0.048*
1	**0.12**	0.02*	0.005*		**0.35**	0.054*	0.016*
0.1	0.012*	0.002*	0.0005*		0.035*	0.00054*	0.0016*

B.6.1.1.3. Indirect exposure of humans via the environment

Not relevant for this proposal.

B.6.1.1.4. Combined exposure

The French proposal is presented below.

At the time of this restriction proposal, there is no available standard for the measurement of lead migration in saliva, whereas several methods can be employed to measure lead migration rate in gastric compartment. Considering the pH of saliva, migration of lead in saliva should be lower than migration of lead in the gastric compartment since the stomach's pH is more acid. As a result, a standard for the measurement of lead migration rate in gastric compartment can be used for the migration in saliva as a worst-case measure and as no specific method is available.

Consequently, both migration rates (for use 1 and use 3) are expected to be measured with the same test simulating gastric conditions.

On this basis, **the lead migration rate derived for chronic exposure (use 1) is more conservative, since it appears that the jewellery would need to have a surface higher than 466.6 cm² (=23.33/0.05) to reach the lead migration limit for acute exposure (use 3). It seems reasonable to think that most of the jewellery which can be ingested have a surface below 466.6 cm².**

Furthermore, the migration rate for acute exposure (use 3) is protective for acute effects but not chronic effects. Indeed, this "acute" migration limit prevents from reaching a PbB level of 400 µg/L after jewellery residence time in stomach of 5 days. However, as modelled in the study from INERIS (2010) (see Annex B), the half life of lead for a newborn is about 1.5 month and 2.5 months for a 3 year-old child and it will take about 90 days after exposure for a newborn to recover a PbB below 100 µg/L and about 150 days for a 3 years old child in case the jewellery remains 5 days in the stomach. Consequently, such migration rate may not protect from neurotoxic effects as they may be induced at concentrations below 100 µg/L.

For these reasons, the chronic use 1 is considered to be protective compared to the acute use 3 and it is selected in order to propose only one lead migration limit for the restriction.

According to RIVM (2008), for many toys, both mouthing and direct ingestion may occur and, depending on the properties of the toy and on physico-chemical properties of the chemical under consideration, one of these uses is likely to be more relevant for systemic exposure than the other. Still according to RIVM (2008), only the most relevant use needs to be considered. It may be envisaged that such recommendation should also apply to articles other than toys and, for instance, jewellery. In this assessment, the selection of the chronic use as being protective for the acute use is grounded on the same approach.

B.7. Summary on hazard and risk

Exposure to lead and its compounds occurs mostly by the oral route less via inhalation, since the dermal route is considered as negligible. However, in the present risk assessment, only the oral route has been considered since this restriction deals with the misuse of jewelllery by children (who are likely to swallow or mouth these articles or parts of them) resulting in an oral exposure leading to a possible lead poisoning.

Three different uses have been identified (see section B.5.3.1 for details), two of them concerning a chronic exposure: use 1 corresponding to a repeated poisoning from mouthing leaded jewellery and use 2 corresponding to a repeated poisoning from hand-to-mouth activity after repeated or long-duration contacts with leaded jewellery. The third one (use 3) concerns acute poisoning: accidental ingestion of leaded jewellery or a leaded part of jewellery.

Use 2 has been waived for the exposure assessment due to high uncertainty on its parameters and due to the fact that protecting against use 1 should also protect against use 2.

Few data exist concerning acute exposure to lead. A well documented severe case is a 4-year-old boy, who accidentally swallowed a leaded charm composed of 99% of lead. This poisoning caused the death of this boy; his PbB level was 1800 µg/L. However, it has been determined that acute effects in children could happen at doses around 800 µg/L. Consequently, a threshold for acute health effects of 400 µg/L has been chosen.

Using a PBPK model developed by INERIS based on Sharma M. *et al.* (2005) and O'Flaherty E.J. (1991) equations, the daily intakes which do not result in an exceeding of 400 µg/L have been determined for two exposure durations (duration of residence of the jewellery in the stomach: 2 days and 5 days). The duration of 5 days of residence has been selected as a worst case approach. These modelled daily intakes represent intakes which will not generate a PbB level higher than the chosen NOAEL for acute effects (400 µg/L).

Table 37: Modelled $Q_{stomach}$ in order to remain below a PbB of 400 µg/L (PbB protective for acute effects)

Age (months)	$Q_{stomach}$ for 2 days of residence (µg lead/day)	$Q_{stomach}$ for 5 days of residence (µg lead/day)
3-6	1350	560
6-12	1720	710
12-18	2350	960
18-36	2820	1170

Concerning chronic exposure to lead, the most relevant effect is on the central nervous system (CNS). Observational data suggests that so far no threshold could be identified for such effects in children. Consequently, the DS decided to use the IEUBK model developed by the US EPA for lead exposure of children. Using this model, it was possible to calculate a daily intake which does not generate a variation of PbB level greater than 5 µg/L (corresponding to the smallest measurable variation in blood lead levels).

However, RAC decided to use a risk based approach and agreed on the exposure of 0.05 µg/kg bw per day, which EFSA considers “sufficiently low to ensure no appreciable risk”. This exposure is equivalent to a migration of 0.05 µg/cm²/hr, potentially increases the blood lead level by 1.2 µg/L, and is equivalent to an IQ reduction of 0.1 point.

For uses 1 and 3, two lead migration limits, one in saliva for the chronic exposure (use 1) and one in the gastric compartment for the acute exposure (use 3) have been determined (see Table 34).

For these reasons, the chronic use 1 is considered to be protective compared to the acute use 3 and it is selected in order to propose only one lead migration limit for the restriction: 0.05 µg/cm²/hr.

Summary and Conclusion

The aim of the proposed restriction is to minimise children’s lead exposure from mouthing jewellery. This requires limitation of the lead content in jewellery. From its evaluation and amendment of the restriction proposal it is concluded as follows:

1. 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/cm²/hr (0.05 µg/g/hr) considering one mouthing hour per day, potentially increases the blood lead level by 1.2 µg/L, and is equivalent to an IQ reduction of 0.1 point. The RAC agrees with the conclusion of EFSA (2010) that this exposure is considered sufficient to ensure no appreciable risk.

2. Identification of a tolerable lead concentration in jewellery. This requires information on the concentration, which during mouthing for 1 hr does not exceed a daily lead exposure of 0.05 µg/kg bw. For metallic parts the re-evaluation of the Danish survey indicated an association (although rather uncertain) between the lead content and the migration (with an average slope of

0.7 µg/cm^2/hr per % of lead content), and thus a limit value of 0.05% is proposed. RAC notes that there is insufficient information on migration rates at lower lead concentrations and for non-metallic parts. However, RAC has assessed the applicability of the same limit value proposed for the metallic parts as explained in the section of characterisation of risks, and concluded that the limit of 0.05% is also protective for non-metallic parts of jewellery. Moreover, since lead migration below 1% lead in jewellery is difficult to measure a restriction on the basis of a specific lead migration rates requires sufficiently sensitive methodology.

3. Exposure at different mouthing scenarios. RAC and SEAC note that it is unrealistic to assume that in average a child is mouthing jewellery for 1 hr every day. To estimate exposures at more realistic scenarios for the health impact assessment RAC in cooperation with SEAC and ECHA Secretariat has calculated the exposures at scenarios different from mouthing a jewellery article 1 hr per day. These calculations are based on the data given in Table 35 of this Background Document. Moreover, the definition of a realistic exposure scenario needs reliable data on the average lead concentration of jewellery, which can be mouthed by children. So far, in accordance with SEAC RAC has evaluated mouthing scenarios of 5 and 15 min per day, per week and per month of jewellery that contains lead between 0.1 and 6%. From Table 36 RAC concludes that even a lead limit of 0.1% is seen acceptable, considering that it is unlikely that an average child mouths a piece of jewellery every day for 15 min during the first three years of life. For a more conservative mouthing duration of 1 hr/d which occasionally may occur a limit value of 0.05% would protect against exposure above the tolerable daily intake of 0.05 µg Pb/ kg bw per day.

4. Lead content in jewellery: The studies so far available report average concentrations between 1.1 and 6.3%. SEAC carried out further information gathering and has concluded that about 10 % of all fashion jewellery placed on the market in the EU contains lead and that the average concentration of lead in these jewellery is about 6 %. This information can be applied to estimate the impact of the proposed restriction.

C. Available information on alternatives

Information is presented in the original dossier regarding the availability of alternative substances. RAC notes that although the toxicological potentials of the alternatives have been properly described no risk assessment for their use as alternatives in jewellery has been presented in the Annex XV report.

Taking into account that a threshold has not been identified regarding the exposure of children to lead RAC considers that a more detailed assessment of the alternatives is not needed in this particular case. For setting this opinion RAC has also considered that as the alternatives are covered by the REACH Regulation industry has the legal obligation to identify a safe use for all the alternative substances described in the dossier.

For transparency reasons the assessment provided by the French CA as dossier submitter is copied below without being commented by RAC.

The possible decrease in the use of lead and its compounds in jewellery (and therefore in exposure) is partly dependent on the availability, on the technical feasibility of alternative options and on their costs.

Information about possible alternatives to lead and its compounds in jewellery is difficult to obtain. During consultation of industry actors, via the INERIS survey (see more details in Section G.3.1), no information was obtained on possible substitution of lead in the jewellery sector. The information reported in this section has mainly been collected from the consultation of MSCAs, certain industry actors and other international data sources.

This section is deliberately more focused on fashion jewellery since no information was identified on the use of lead and its compounds in precious jewellery and since it was reported by an Italian Federation of precious jewellery manufacturers that "lead is absolutely not present in traditional goldsmith and jewellery which are constituted by precious metals" and that, "with regard to jewellery with gemstones, enamels and pearls, or other precious metals added to the precious metal manufactured products, […], in most cases, the presence of lead is to be excluded, or, anyway, its percentage is absolutely negligible and marginal."

C.1. Identification of possible alternative substances and techniques

As already mentioned, fashion jewellery can be plated with base metals and made of a variety of other 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).

In jewellery articles, lead is generally not used by chance. It is used on purpose for its specific properties and for economical reasons.
First, by its specific properties, lead provides some interest to producers of fashion jewellery. Indeed, it gives a certain quality and appearance to jewellery which is searched by producers. The use of metal lead makes fashion jewellery items heavier and they thus appear to be more "precious" than they really are to consumers. Moreover, the use of some lead compounds in coatings confers the jewellery some type of metallic aspect to the surface and provides shades of colour. As regards functionality, lead metal also shows interesting properties: it is dense and easy to shape and to work with (high malleability with low fusion point) and it allows then performing welding and soldering. As far as alloys are concerned, consultation of industry actors indicated that lead is mainly used in copper/lead alloy and in tin/lead alloy (also called "white metal") with a content of lead of 6% in average[35]. These alloys can be treated in surface with rhodium, palladium, gold and silver.

Secondly, on an economic point of view, the use of lead (in alloys in particular) makes lead-containing jewellery cheaper.

Consulted industry actors indicated that a possible alternative to lead would be the use of silver. From the available information, substitution by silver seems to be technically feasible, but not economically feasible. This alternative has already been experienced by several firms in the French fashion jewellery industry (see Section G.3.2). Health Canada also mentions tin, zinc, nickel and low-lead pewter as other alternative metals to lead (Canada Gazette (2005)). Pewter is a metal alloy, which may be composed of various amounts of tin, antimony, bismuth, copper, and/or lead. Over the years, these combinations have varied greatly but today's pewter alloy is comprised mainly of tin.

In a general manner, it does not seem possible to substitute lead 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[36].

[35] This information has been provided by BOCI (French trade association of manufacturers of fashion jewels) during consultation. More information is available in section G.3.2.
[36] http://www.contenti.com/products/metals/176-888.html (accessed in March 2010).
http://www.purityalloys.com/Pewter_Alloys.html (accessed in March 2010).

Consequently, this section on alternatives focuses on silver, tin, zinc, copper and bismuth. Availability, human health risks and environmental risks are presented separately for each metal. However, the technical and economical feasibility is discussed in a general part at the end of this section as all previous metals are not aimed at being used separately but as part of alloys.
Nickel will not be assessed because of its hazardous properties (classified as Carc. 2, Stot RE 1, Skin Sens. 1) and as it is already restricted in the REACH Annex XVII.

C.2. Assessment of silver

The following tables present general information about silver's identity and several physicochemical characteristics.

Table 38: Silver identity

EC number	231-131-3
EC name	Silver
CAS number	7440-22-4
CAS name	silver
IUPAC name	Silver
Annex I index number	Not applicable
Molecular formula	Ag
Molecular weight range	107.86 g/mol

Table 39: Overview of silver physicochemical properties (CRC (2005))

Property	Value
Physical state at 20°C and 101.3 kPa	Solid
Melting/freezing point	961.78°C
Boiling point	2162°C
Relative density	10.5 g/cm^3
Flammability	Not highly flammable
Explosive properties	Not explosive
Oxidising properties	No oxidising properties

Available data on this alternative which is reported in the following sections is mainly French. The industry actors who have experienced the substitution of lead by silver in France report interesting feedbacks for the assessment.

C.2.1. Availability of silver

The use of silver in jewellery can be considered as an available alternative to lead. Indeed, silver is a wide-spread metal and is already largely used in the jewellery sector.
For example, in 2007 and 2008, respectively 16,390 and 16,585 million of pieces of jewellery made of silver were placed on the market in France. These volumes represented a value of sales of respectively 542 and 569 million euros with an average price of 33 euros for 2007 and 34 euros for 2008 (Ecostats, 2007; 2008). Trends show that sales of silver-containing jewellery have increased since the last past years (+ 5% between 2007 and 2008 for example) and are expected to keep on

increasing in the future (CBI (2008)). Silver jewellery represents a rather significant share of the market in terms of value: 11% of the total sector sales in 2008 in France.

Concerning EU market, CBI (2008) reports that Asian countries (such as China) export much silver jewellery to the EU and that, in terms of volume, consumption of silver jewellery has increased in almost all EU countries since 2006.

Silver jewellery is considered as precious jewellery if the jewellery is made of massive silver. If silver is used for plating or only in one part of jewellery (chain, pendant, etc.), the jewellery then falls into the category of fashion jewellery. Jewellery made of silver (even partly) is attractive to consumers (in particular for necklaces, rings and bracelets) because it is cheaper than jewellery made of other (precious) raw materials (such as jewellery plated with gold for example).

In terms of reserves, silver is abundant. **In 2000, the world mineral production of silver amounted to 18,022 tons, with a demand of 29,000 tons, shared between industry (42%), jewellery (32%) and photography (26%)[37].**

As a consequence, silver can be considered as an available material to substitution of lead in jewellery. However, data is not sufficient to conclude about the timeframe needed to switch to that alternative.

C.2.2. Human health risks related to silver

Based on an animal study conducted in four different species, an oral absorption for humans of 4.4% was derived as a conservative estimate (RIVM (2008)).

The critical effect of silver in humans is argyria, a medically benign but permanent bluish-grey discoloration of the skin. Argyria results from the deposition of silver in the dermis and also from silver-induced production of melanin. Although the deposition of silver is permanent, it is not associated with any adverse health effects. No pathologic changes or inflammatory reactions have been shown to result from silver deposition. However, **silver can induce dermatitis and eye irritation** (ATSDR (1990)).

From a case review concerning intravenous use of silver arsphenamine in syphilis patients, US EPA (2005) concluded to a LOAEL for mild argyria of 0.014 mg/kg bw/day for this sensitive sub-population. Since this LOAEL has been estimated for a sensitive sub-population, RIVM (1995) has calculated a **TDI of 0.005 mg/kg bw/day for more general population**.

Drinking water and food seem to be the major sources of exposure to silver. Even if specific data for children is lacking, a daily intake for adults has been estimated to be comprised between 0.06 and 1.3 µg/kg bw (RIVM (2008)).

C.2.3. Environment risks related to silver

As mentioned previously, this dossier is targeted at health effects and not at environmental effects, but it was considered relevant to present some environmental data such as PNECs for the proposed alternatives.

No relevant data related to environment risks due to the use of silver in jewellery was identified.

A high amount of environmental data on silver is available through literature and reports, but data differs from ranges of value and may be conflicting. In addition, there is currently no PNEC derived by consensus and no validated risk assessment at the European or International level for this metal. Consequently, it is not considered appropriate to present this data for the present proposal.

[37] To satisfy this demand, about 5,900 t of silver were recycled (21 %) and about 4,700 t were destocked (16 %). Source: http://www.mineralinfo.org (accessed on Nov. 23rd 2009).

Sources of information which were consulted:
http://ecb.jrc.ec.europa.eu/
http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp
http://www.sciencedirect.com/
http://www.inchem.org/pages/sids.html
http://www.epa.gov/
http://www.who.int/en/
http://www.ineris.fr/
http://www.rivm.nl/en/
http://www.atsdr.cdc.gov/
(Key words: silver, PNEC, ecotoxicology, effect assessment, risk assessment)

C.2.4. Other information on silver alternative

Not relevant for this proposal.

C.3. Assessment of tin

The following tables present general information about tin's identity and several physicochemical characteristics.

Table 40: Tin identity

EC number	231-141-8
EC name	Tin
CAS number	7440-31-5
CAS name	Tin
IUPAC name	Tin
Annex I index number	Not applicable
Molecular formula	Sn
Molecular weight range	118.71 g/mol

Table 41: Overview of tin physicochemical properties (CRC (2005))

Property	Value
Physical state at 20°C and 101.3 kPa	White or grey metal, solid
Melting/freezing point	231.93 °C
Boiling point	2602 °C
Relative density	7.3 g/cm^3
Flammability	Not highly flammable
Explosive properties	Not explosive
Oxidising properties	No oxidising properties

Data and feedbacks on possible substitution of lead by tin come from consultation of industry actors in France and from different international data sources.

C.3.1. Availability of tin

Tin is already used in fashion jewellery, in particular in tin/lead alloys. This alloy is appreciated for its good conductivity and its relatively low fusion point (specific to the association of tin and lead). It is thus mainly used in jewellery soldering.
World reserves of tin are mainly located in Asia (Indonesia, Malaysia, China) and South America (Bolivia and Brazil). In Europe, few countries produce tin (Portugal is the largest -and still modest- supplier). Therefore the EU needs in tin are mainly satisfied by imports. World production of tin amounted to 217,000 tons[38] in 1999.

Tin is an abundant metal. It can thus be considered as available from this standpoint. However, as far as timing is concerned, data is not sufficient to conclude.

C.3.2. Human health risks related to tin

It has been demonstrated that the absorption of inorganic compounds of tin from the gastrointestinal tract in humans is very low with as much as 98% being excreted directly in the faeces (EFSA (2005)).

Tin is not essential for humans and there is no data on deficiency effects resulting from an inadequate intake of inorganic tin. Due to its low absorption in the gastrointestinal (GI) tract, inorganic tin has a low systemic toxic potential. **The only effect observed in humans is an acute irritation of the mucosa of the GI tract** (no known chronic effects) which was reported for consumers drinking fruit juices containing high concentrations of tin (≥ about 200 mg/kg product).

Based on the level of 200 mg/kg in food as the approximate threshold for adverse GI effects in humans, JECFA (1982) has proposed a **TDI of 2 mg/kg bw/day**, a value which has been maintained in its later evaluations. This value of TDI has been adopted by RIVM in 1991 (RIVM (2008)).

C.3.3. Environment risks related to tin

No relevant data related to environment risks due to the use of tin in jewellery was identified.
As for silver, a high amount of environmental data on tin is available through literature and reports, but some data differs from ranges of value and may be conflicting. In addition, there is currently no PNEC derived by consensus and no validated risk assessment at the European or International level for this metal. Consequently, it is not considered appropriate to present these data for the present proposal.

Sources of information which were consulted:
http://ecb.jrc.ec.europa.eu/
http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp
http://www.sciencedirect.com/
http://www.inchem.org/pages/sids.html
http://www.epa.gov/
http://www.who.int/en/
http://www.ineris.fr/
http://www.rivm.nl/en/
http://www.atsdr.cdc.gov/
(Key words: tin, PNEC, ecotoxicology, effect assessment, risk assessment)

C.3.4. Other information on tin alternative

Not relevant for this proposal.

[38] Source: http://sigminesfrance.brgm.fr/telechargement/substances/Sn.pdf (accessed in March 2010).

C.4. Assessment of zinc

The following tables present general information about zinc's identity and several physicochemical characteristics.

Table 42: Zinc identity

EC number	231-175-3
EC name	Zinc
CAS number	7440-66-6
CAS name	Zinc
IUPAC name	Zinc
Annex I index number	Not applicable
Molecular formula	Zn
Molecular weight range	65.39 g/mol

Table 43: Overview of zinc physicochemical properties (CRC (2005))

Property	Value
Physical state at 20°C and 101.3 kPa	Bluish-white metal, solid
Melting/freezing point	419.53°C
Boiling point	907°C
Relative density	7.1 g/cm^3
Flammability	Not highly flammable
Explosive properties	Not explosive
Oxidising properties	No oxidising properties

Feedbacks on possible substitution of lead by zinc come from consultation of Health Canada and data is extracted from different international sources.

C.4.1. Availability of zinc

Zinc is already currently used in fashion jewellery, specifically in alloys. Many alloys contain zinc such as brass (zinc/copper alloy) and various binary combinations with aluminium, antimony, bismuth, gold, iron, lead (as aforementioned), silver, tin, etc. Among these alloys, the consulted stakeholders reported that zinc/lead alloy is the most commonly used in fashion jewellery.

Worldwide mining production of zinc has increased from 6.9 to 8.1 million of tonnes from 1993 to 1999. Zing consumption has also increased. Since 2001, a decrease of the price of zinc has been observed. In 1999, the four biggest producers of zinc were China (1.476 million of tonnes), Australia (1.163 million of tonnes), Canada (1 million of tonnes) and Peru (0.9 million of tonnes)[39].

Zinc may also be considered as an abundant metal. It is thus available from this standpoint. However, as far as timing is concerned, data is not sufficient to conclude.

[39] http://sigminesfrance.brgm.fr/telechargement/substances/Zn.pdf (accessed in March 2010)

C.4.2. Human health risks related to zinc

Absorption of dietary zinc ranges from 15 to 60%. When zinc intake increases, the fractional absorption decreases and intestinal excretion increases while urinary losses remain fairly constant. Under fasted conditions, absorption was measured to be as high as 81%. When humans are under-supplied in zinc, absorption may be higher still. Zinc appears to be absorbed by both a passive diffusion and a saturable carrier-mediated process. The carrier mediated mechanism appears to be more important at low zinc levels (SCF (2003b); US EPA (2005)).

Zinc is an essential element for humans, as co-factor in enzymes playing a role in general growth and development, in testicular maturation, neurological function, wound healing and immunocompetence. Well-known zinc containing enzymes include superoxide dismutase, alkaline phosphatase and alcohol dehydrogenase.

Recommended dietary allowance as proposed by the SCF in 1993 is 9.5 mg/day for adult males and 7.0 mg/day for females. US guidelines recommend daily intakes of 11 mg/day and 8 mg/day for men and women respectively (SCF (2003b)). On a body weight basis, US guidelines are somewhat higher in young children (0.23 mg/kg bw/day versus 0.13-0.15 mg/kg bw/day in adults) (US EPA (2005)).

Zinc can be toxic when exposure exceeds physiological needs. The effects of zinc supplementation have been studied in several human studies of longer duration. As is concluded by SCF (2003b), **chronic zinc toxicity is associated with symptoms of copper deficiency**.

Overt adverse effects (e.g. anaemia, neutropaenia, impaired immune responses) are evident only after feeding zinc in the form of dietary supplements in excess of 150 mg/day for long periods. At lower intake levels (100-150 mg/day), the picture is less clear.

SCF points out that short-term balance studies would indicate adverse effects on copper retention at intakes as low as 18.2 mg/day. However, more recent longer-term balance studies indicate that positive copper balance can be maintained at 53 mg/day zinc in post-menopausal women for 90 days provided copper intakes are adequately high (3 mg/day). **Overall SCF concludes that the data indicate a NOAEL of 50 mg/day for adults.**

Infants, more than adults, appear to be particularly sensitive to zinc deficiency, possibly as the result of their higher zinc requirements on a per body weight basis. Concerning toxic effects, data are limited to a few animals studies indicating that young animals are more susceptible to excess intake of zinc (no usable human data) (ATSDR (2005)).

At high concentrations, inorganic zinc compounds are irritating to the skin. Zinc oxide however is used to promote the healing of burns and wounds and is a well-known anti-inflammatory agent used in creams for dermal care of babies and infants.

SCF (2003b) concluded to a NOAEL of 50 mg/day based on the absence of any adverse effect on a wide range of relevant indicators of copper status (as the critical endpoint) in human studies. This value leads to **a TUIL (Tolerable Upper Intake level) of** about 7 mg/day leading to **0.5 mg/kg bw/day (body weight 15 kg) for children 1-3 years old**. This value has been adopted by RIVM as well (RIVM (2008)).

C.4.3. Environment risks related to zinc

No relevant data related to environment risks due to the use of zinc in jewellery was identified.

As for the previous alternatives, a huge amount of environmental data on zinc is available through literature and reports, but some data differs from ranges of value and may be conflicting. In addition, there is currently no PNEC derived by consensus and no validated risk assessment at the European or international level for this metal. Consequently, it is not considered appropriate to present these data for the present proposal.

Sources of information which were consulted:
http://ecb.jrc.ec.europa.eu/

http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp
http://www.sciencedirect.com/
http://www.inchem.org/pages/sids.html
http://www.epa.gov/
http://www.who.int/en/
http://www.ineris.fr/
http://www.rivm.nl/en/
http://www.atsdr.cdc.gov/
(Key words: zinc, PNEC, ecotoxicology, effect assessment, risk assessment)

C.4.4. Other information on zinc alternative

Not relevant for this proposal.

C.5. Assessment of copper

The following tables present general information about copper's identity and several physicochemical characteristics.

Table 44: Copper identity

EC number	231-159-6
EC name	Copper
CAS number	7440-50-8
CAS name	Copper
IUPAC name	Copper
Annex I index number	Not applicable
Molecular formula	Cu
Molecular weight range	63.546 g/mol

Table 45: Overview of copper physicochemical properties (CRC (2005))

Property	Value
Physical state at 20°C and 101.3 kPa	Red metal, solid
Melting/freezing point	1084.62 °C
Boiling point	2562 °C
Relative density	8.96 g/cm^3
Flammability	Not highly flammable
Explosive properties	Not explosive
Oxidising properties	No oxidising properties

C.5.1. Availability of copper

Copper is already used in certain fashion jewellery.

Copper major producers correspond to a relative limited number of countries: Chile, USA, Canada, Russia, Zambia, Peru, Poland, Australia, China and Indonesia. Worldwide production was estimated to be about 12.7 million of tonnes in 1999, and was largely dominated by Chile (4.4 million of tonnes) and the USA (1.6 million of tonnes)[40].

As for the previous mentioned alternatives, copper is an abundant metal. It can be thus considered as available from this standpoint. However, as far as timing is concerned, data is not sufficient to conclude.

C.5.2. Human health risks related to copper

The percentage absorption of dietary copper depends on the amount of copper ingested, with the percentage absorption decreasing with increasing intakes. A series of studies in humans demonstrated that a 10-fold increase in dietary copper resulted in only twice as much copper being absorbed. A theoretical maximum absorptive capacity of 63-67% has been estimated from aggregate results of human copper absorption studies at various copper daily intakes.
With typical diets in developed countries the average copper absorption has been estimated to be in the 30-40% range (SCF (2003a)). Limited evidence in humans and animals suggests that the process of absorption is less easily saturated in young humans than in older ones, which could lead to higher absorption rates in the former. However no quantitative estimate is available (ATSDR (2004)).

Human data indicates that the most pronounced effects of chronic copper toxicity are on liver function whilst acute effects of copper toxicity are primarily observed in the GI tract, as a local intestinal irritation effect.
Acute copper toxicity in drinking water appears to have a threshold of approximately 6 mg/L. For longer exposures, SCF (2003a) considered liver damage as the critical endpoint. After long-term copper intake of 30 mg/day or 60 mg/day for several years, acute liver failure appeared, according to O'Donohue J.W. *et al.* (1993) report for a single case. Several other human studies indicated an absence of adverse liver effects after a prolonged intake of 7 to 10 mg/day. From a 12-weeks supplementation study by Pratt W.B. *et al.* (1985) an overall NOAEL of 10 mg/day for liver effects was selected.
For other toxicity endpoints, the available data is limited. Poor quality studies of copper compounds in rats and mice suggest absence of carcinogenic activity. Genotoxicity data is inconclusive. In developmental and reproduction studies testicular degeneration and reduced neonatal body and organ weights were seen in rats at dose levels in excess of 30 mg Cu/kg bw/day over extended time periods, and fetotoxic effects and malformations were seen at high dose levels (>80 mg Cu/kg bw/day) (IPCS (1998); SCF (2003a)).

Copper is an essential element which is required for normal growth and development. Signs of copper deficiency in infants and children include anemia that is unresponsive to iron supplementation, neutropenia, bone abnormalities, and hypopigmentation of the hair. Indian childhood cirrhosis and idiopathic copper toxicosis are two syndromes associated with high intake of copper. Both are characterized by severe liver damage in infants and children (< 5 years of age). The syndromes have been linked to genetic defects, due to which copper metabolic capacity is exceeded in certain individuals, leading to excessive copper concentrations in the liver. Several reports indicate that children may be more sensitive to the gastro-intestinal effects produced by copper but the evidence on this issue is inconclusive as of yet (ATSDR (2004)).

Some medical case studies show that copper may produce dermal contact dermatitis. No dose response information for this supposed effect is available. Data on skin-irritating potential is lacking (ASTDR (2004)).

For children, the most relevant toxicological limit value seems to be a Tolerable Upper Intake level of 0.083 mg/kg bw/day derived by SCF in 2003 (RIVM (2008)).

[40] http://sigminesfrance.brgm.fr/telechargement/substances/Cu.pdf (accessed in March 2010)

C.5.3. Environment risks related to copper

No relevant data related to environment risks due to the use of copper in jewellery was identified.

A huge amount of environmental data on copper is available through literature and reports, but some data differs from ranges of value and may be conflicting.
However, for copper and its compounds there are currently PNECs derived by consensus, reviewed by experts at TCNES and partly validated at the European Union Level in the framework of the Existing Substances Regulation (EEC) 793/93 (ECI (2008)).

Consequently, it was decided to present the PNECs extracted from the environment parts of ECI (2008) for the following reasons:
- this report synthesises a large amount of relevant environmental data;
- it was conducted in the framework of the European Regulation Substances;
- it provides data and methodology which were discussed, reviewed and partly validated by consensus at the TCNES.

In addition, to our knowledge, no other complete and synthetic report on the risk assessment for copper and its compounds exists.
The different PNECs extracted from ECI (2008) are presented below.

Freshwater compartment including sediment
A freshwater PNEC of 7.8 µg Cu/L was used as reasonable worst case PNEC for Europe in a generic context in absence of site-specific information on bioavailability parameters (pH, DOC, hardness).
A sediment PNEC of 1741 mg Cu/kg OC, corresponding to 87 mg Cu/kg dry weight for a sediment with 5 % O.C.(TGD default value) was carried forward as reasonable worst case PNEC for Europe in a generic context.

Microbiological activity in sewage treatment systems
A PNEC of 0.23 mg/L was carried forward as PNEC to the risk characterisation.

Soil compartment
A terrestrial PNEC of 78.9 mg Cu/kg dw was used as reasonable worst case PNEC for Europe in absence of site-specific information on soil properties.

Concerning the comparison of the environmental toxicity of lead with the proposed alternative metals, the toxicity to environment is a much more critical issue for metals than for organic chemicals. Indeed, some essential parameters for metals such as bioavailability corrections, normalisation to compartments properties or natural background are not always taken into account in the derivation of the different available PNECs. Consequently, to our knowledge, comparison of the different available PNECs would only have limited meaning.
In the present case, this is particularly true for the freshwater PNECs (bioavailability has been taken into account in the derivation of the PNEC for copper but not for lead) and for the terrestrial PNECs (the normalisation to the properties of soils has been considered for copper but not for lead).

C.5.4. Other information on copper alternative

Not relevant for this proposal.

C.6. Assessment of bismuth

The following tables present general information about bismuth's identity and several physicochemical characteristics.

Table 46: Bismuth identity

EC number	213-177-4
EC name	Bismuth
CAS number	7440-69-9
CAS name	Bismuth
IUPAC name	Bismuth
Annex I index number	Not applicable
Molecular formula	Bi
Molecular weight range	208.98 g/mol

Table 47: Overview of bismuth physicochemical properties (CRC (2005))

Property	Value
Physical state at 20°C and 101.3 kPa	Gray white soft metal, solid
Melting/freezing point	271.4°C
Boiling point	1564°C
Relative density	9.79 g/cm^3
Flammability	Not highly flammable
Explosive properties	Not explosives
Oxidising properties	No oxidising properties

C.6.1. Availability of bismuth

Bismuth is already used in certain alloys which are sold for application in fashion jewellery.

The biggest worldwide producers of bismuth in 1999 were Peru (1000 tonnes), China (855 tonnes), Japan, Mexico and Canada. Most of the mining production comes from the treatment of copper, lead and zinc ores. Deposits where bismuth is indicated as principal metal are very rare[41].

From this information, bismuth can be considered as available. However, as far as timing is concerned, data is not sufficient to conclude.

C.6.2. Human health risks related to bismuth

The major part of the information provided in this section is extracted from:
http://www.lenntech.com/periodic/elements/bi.htm (accessed in March 2010)
and from Toxicology Desk Reference, Vol. I, Ed. Taylor and Francis, 1999 available at:
http://books.google.fr/books?id=uM49rmz1vEsC&pg=PA197&lpg=PA197&dq=ATSDR+bismuth&source=bl&ots=nskM9uXXP9&sig=Zc0wzteum6tsZsrl62KqYk379pQ&hl=fr&ei=xrKgS5upHtWy4QaIvZiMDg&sa=X&oi=book_result&ct=result&resnum=2&ved=0CBMQ6AEwAQ#v=onepage&q=ATSDR%20bismuth&f=false (accessed in March 2010)

Bismuth and its salts are able to cause damages in kidneys, although these effects are generally very weak. However, high doses can be lethal. Serious and sometimes fatal poisoning may occur from the injection of large doses into closed cavities and from extensive application to burns (in form of soluble bismuth compounds).
Compared to other heavy metals, bismuth is considered as a less toxic heavy metal, since its effects seem reversible.
Bismuth could cause effects by respiratory or oral exposure. It is eliminated from the body via the faeces and the kidney.

When inhaled in an acute exposure bismuth is toxic. It may be a nuisance dust causing respiratory irritation and it may cause foul breath, metallic taste and gingivitis.
By ingestion bismuth may cause nausea, loss of appetite and weight, malaise, albuminuria, diarrhea, skin reactions, stomatitis, headache, fever, sleeplessness, depression, rheumatic pain and a black line may form on gums in the mouth due to deposition of bismuth sulphide.
Bismuth is a skin and eyes irritant.

Concerning chronic effects, by inhalation, bismuth may affect the function of the liver and the kidneys. **By ingestion it may affect the function of the liver and the kidneys**. It may cause anemia, black line may form on gums and ulcerative stomatitis. Bismuth can also cause neurotoxicity such as encephalopathy. After a prodromal phase of 2 to 6 weeks, a clinically manifest disease appeared which would last for 24 to 48 hours. Symptoms are myoclonia, changes in awareness, abasia or astasia. Patients generally recovered in 2 to 6 weeks.

Bismuth is not considered as a human carcinogen.
Bismuth is toxic only for large and repeated doses. No TDI seems to be available for bismuth.

C.6.3. Environment risks related to bismuth

No relevant data related to environmental risks due to the use of bismuth in jewellery was identified.

[41] http://sigminesfrance.brgm.fr/telechargement/substances/Bi.pdf (accessed in March 2010).

Few environmental data on bismuth is available through literature and reports. As there is currently no PNEC derived by consensus and no validated risk assessment at the European or international level for this metal, it is not considered appropriate to present these data for the present proposal.

Sources of information which were consulted:
http://ecb.jrc.ec.europa.eu/
http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp
http://www.sciencedirect.com/
http://www.inchem.org/pages/sids.html
http://www.epa.gov/
http://www.who.int/en/
http://www.ineris.fr/
http://www.rivm.nl/en/
http://www.atsdr.cdc.gov/
(Key words: bismuth, PNEC, ecotoxicology, effect assessment, risk assessment)

C.6.4. Other information on bismuth alternative

Not relevant for this proposal.

The lack of quantitative information about the risks generated by the possible alternatives to lead in jewellery for health is important. That is the reason why the information provided in the above sections is mainly qualitative. Information on TDI or TUIL are available for most of them but it could have been useful to have some information about the migration rates of these metals from jewellery articles as well. However, this kind of information does not seem to be available.

The table below nevertheless provides some insight of the risks of each alternative examined.

Table 48: Comparison of the TDI/TUIL of the different alternatives assessed

Metal	**TDI or TUIL** (mg/kg bw/day)
Lead	Not relevant since effects of lead on children's CNS seem to occur without a threshold
Silver	0.005
Tin	2
Zinc	0.5
Copper	0.083
Bismuth	Not available

By comparing the different TDI or TUIL of the possible alternatives to lead, it appears that, on this basis, lead seems to be the most toxic since the derivation of a TDI is not appropriate. Bismuth could be the least toxic alternative according to its low toxicity and the possible reversibility of its effects.

C.7. Technical and economic feasibility of lead-free alloys alternatives

Information available on the websites from American (US and Canada) manufacturers of alloys used specifically in jewellery has been collected and is summarised in Table 49. This non-exhaustive information on the different alloys available on the market shows that there is a wide range of lead-based and lead-free alloys with different compositions. **The replacement of lead-based alloys by lead-free alloys seems already technically feasible as there are already lead-free alloys (containing tin, copper, bismuth, silver or and zinc) available on the market for an unequivocal use in jewellery.**

Furthermore, this feasibility was partly confirmed by the information collected during the consultation. For example, French industry reported that the use of lead-free alloys containing silver was tested and they reported that they obtained an equal quality of the product in terms of product hardness. It was said that silver is relatively ductile and very malleable which is very convenient for its use in jewellery. It is also resistant to air corrosion, is bright and offers many possibilities in the design.

Nevertheless, this substitution may have technical or economical impact that should be separated from discussion on feasibility. For example, tin is a soft and silver-grey metal. It is also resistant to corrosion and malleable. However, it is moderately ductile and much lighter than lead (density of grey tin is 5.8 g/cm^3 and it is 7.4 g/cm^3 for white tin, whereas density of lead is 11.3 g/cm^3). One can thus expect that it would not perform the exact same functions as lead in the jewellery. Zinc can be used in lead-free alloy for its colouring property (blue-grey metal) that is rather lighter compared to lead (with a density of 7.1 g/cm^3 comparable to that of white tin) and brittle at high temperatures but it is a metal which is resistant to corrosion like lead. Finally, copper can be added in order to increase strength and hardness. It is highly probable that jewellery producers can find technical equivalent alloys as they are apparently already available and used.

According to some consulted industry actors (see Section G.3.2), replacement of tin/lead alloy by tin/silver alloy is not economically sustainable for fashion jewellery. Indeed, they mention that the use of precious metals such as silver would increase production costs of alloys of a factor of 2 or 3 without allowing manufacturers and distributors to sell the jewellery at a higher price. Indeed, the jewellery would remain in the category of 'fashion jewellery' because of its mixed content of precious and non precious materials. The loss could be then significant especially because, when an alloy is used for the manufacture of fashion jewellery, it is used for the product scale as a whole, for homogeneity reasons. As a consequence, the substitution of tin/lead alloy to tin/silver alloy for example should be used for all the articles composing the set of jewellery (bracelet, necklace, earrings etc.). The additional cost would thus have to be reported also on the other jewellery constituting the set.

In terms of prices, quotation of silver is substantially higher than other non-ferrous metals (see 5). It is difficult to check the "increase of a factor 2 or 3" announced by the industry actors consulted since no data was found about their precise production costs and in particular concerning the contribution of the raw material (alloy) in the final production cost of the jewellery. It is true that, provided the price of silver, the replacement of lead only by silver should considerably increase the production costs. However, this assertion is questionable and the increase in production cost is probably lower. First, the highest amount of silver identified in the lead-free alloys from the data available is 0,5% (w/w) and it seems that other cheaper metals (than silver) like tin, copper and bismuth can contribute to replace the lead in lead-free alloys.

A basic calculation consisting of estimating the cost associated with constituent metals used in specific alloys available on the market is provided in Table 49. The alloy prices are of course higher than the calculated price based on cost of the constituting metals[42]. This rough calculation shows that the estimated costs of lead-free alloys containing silver (€12 on average) should be around 20% higher

[42] Actual market prices of some of the alloys are available on the internet and suggest that the price per kg is around 3-4 times the cost of the constituent metals per kg for lead free alloys,

than the lead-based alloys containing less than 10% of lead (€10 on average). As an example, if it is considered that the contribution of the raw material is around 20 to 30% of the final costs of the jewellery and the cost of metal raw materials represent only a portion of the costs of the alloys, the impact on final price of the jewellery should be moderate.

As already mentioned, according to industry (see section B.3.2), the alloys which are used in fashion jewellery contain on average 6% of lead. Using the same way of calculation as expressed in the previous paragraph (Table 49), it is estimated that the cost of the metals in the lead-based alloys containing 6% is €13.64. The price of lead-free alloy is estimated at €14.94 on average. This would imply an increase of 9.5% of the cost of the metals in alloys for most jewellery manufacturers.

It is acknowledged that metal prices have increased significantly in the year since this restriction dossier was first produced. For example, the average price level of lead is around US$ 2500 per tonne at the time of writing (March 2011) rather than the US$ 1930 per tonne given in the Table 49. Furthermore, predictions for the coming years suggest that metal prices will remain high. Nevertheless, metal prices do fluctuate and there is uncertainty regarding world market prices of metals/alloys in the future. As such, the analysis of costs associated with substitution, performed in section E, allows for uncertainty of 30% over increasing future metal prices by way of a sensitivity analysis that includes a corresponding upper bound cost estimate.

For jewellery producers using cheaper alloys containing very high amounts of lead (> 70%), the increase in alloys costs is expected to be significantly higher.

This additional cost of the alloy would likely to be passed on down the supply chain. As a result, sales price of the jewellery produced with these alternatives alloys would be slightly higher.

As a conclusion, use of alloys containing several alternative metals to lead seems to be technically feasible. The main drawback of the alternatives which have been assessed is a negative impact on the supply cost of the alternative metals and consequently on the sale price of jewellery.

In its cost-benefit analysis of the 2005 Canadian regulation on children's jewellery, Health Canada came to the conclusion that *"switching to alternate metals will increase the metal component price of the product from two to ten times. The metal component cost of jewellery is significant, while manufacturing costs, which vary with the intricacies of the jewellery and the workmanship involved, may also be significant"* (Canada Gazette (2005)).

Table 49: Quotations of several metals

Quotation (in US $ / tonne) http://www.metalprices.com/ (accessed on 09/02/2010)						
Tin	Antimony	Lead	Cadmium	Copper	Bismuth	Silver
14,925	6,500	1,930	3777.8	6328.5	17222.2	498,020

Table 50: Basic calculation of the cost of metal raw materials of an alloy based on its composition and on the price of the metal

Company name	**Type of alloy**	**Commercial name**	**Tin**	**Antimony**	**Lead**	**Cadmium**	**Copper**	**Bismuth**	**Silver**	***Estimated cost of the alloy (US$/kg)***	***Estimated cost (€/kg)[43]***
Contenti[44] (US)	Lead-based	HP88	0.88	0.015	0.09	0.015				*13.46*	*9.77*
		92A	0.925	0.02	0.055					*14.04*	*10.19*
	Lead-free	92-8 (Pewter)	0.92	0.075			0.005			*14.25*	*10.35*
		MPK	0.98				0.0025	0.015	0.0025	*16.15*	*11.72*
Alchemy Casting[45] (CAN)	Lead-based	SB03		0.03	0.97					*2.07*	*1.50*
		SB04		0.04	0.96					*2.11*	*1.53*
		SB06		0.06	0.94					*2.20*	*1.60*
		CT Metal	0.01	0.13	0.86					*2.65*	*1.93*
		#10 Linotype	0.04	0.12	0.84					*3.00*	*2.18*
		6/8 Toning Metal	0.06	0.08	0.86					*3.08*	*2.23*
		10/11 Toning Metal	0.1	0.11	0.79					*3.73*	*2.71*
		70BH	0.7	0.05	0.24		0.01			*11.30*	*8.20*
		#70	0.7	0.06	0.24					*11.30*	*8.20*
		#886	0.88	0.06	0.06					*13.64*	*9.90*
		#932	0.95	0.02	0.03					*14.37*	*10.43*
	Lead-free	#908	0.9	0.08			0.02			*14.08*	*10.22*
		BM91- Pewter alloy	0.91	0.08			0.01			*14.17*	*10.28*

[43] Using an exchange rate USD / Euro of 1 USD = 0.726 Euros (09/02/2010) The factual prices of the alloys will be higher as the calculation of the costs in this table is based on the prices as given in table 45 of the metals used for producing the alloys.
[44] http://www.contenti.com/products/metals/176-888.html
[45] http://www.alchemycastings.com/lead-products/jewelry.htm

		#927	0.92	0.07			0.01			*14.25*	*10.34*
		BM92 - Pewter alloy	0.92	0.08						*14.25*	*10.35*
		#954	0.95	0.038			0.012			*14.50*	*10.53*
		#981	0.98	0.01				0.01		*14.86*	*10.79*
		#97-SA	0.97					0.025	0.005	*17.40*	*12.63*
Purity Casting Alloys[46] (CAN)	Lead-free	Pewter Alloy	0.9175	0.069			0.01	0.0025		*14.25*	*10.34*
		Silver Pewter	0.97				0.0025	0.025	0.0025	*16.17*	*11.74*

[46] http://www.purityalloys.com/Pewter_Alloys.html

D. Justification for action on a Community-wide basis

Marketing of lead containing jewellery is a general phenomenon in EU and cannot be isolated to any specific countries within EU. As in most EU-countries there are no risk management measures to avoid lead exposure from jewellery, adequate measures to minimise lead exposure from jewellery should be implemented on a community wide basis in order to protect children from lead exposure and adverse effects on the CNS. As no lower threshold has been found for the harmful effect of lead on the CNS any additional lead exposure should in principle be avoided.

D.1. Considerations related to human health risks

Effects of lead exposure on children may be severe and irreversible and for now, no threshold can be scientifically determined for the effects on their central nervous system. Furthermore, the risk of poisoning is not limited geographically to one unique country or group of countries: it potentially affects any consumer and, consequently, any child within the EU. Children are expected to globally present the same behavioural routines whatever their origin and nationality are. They may come into contact with jewellery while being in their homes, in recreational areas and more generally in their everyday environment.

Independent and heterogeneous national measures would manage the risk in a less satisfying way than the Community since it is important that an action is coercive as well as harmonised and coherent in order to increase as much as possible children’s health protection.

D.2. Considerations related to internal market

Jewellery is distributed and sold all over Europe, in very various shops, of all size and not only (and even rarely, for fashion jewellery) in specialized jeweller’s shops. These articles are produced in much diversified structures, going from the isolated craftsman to the medium-size firm, and many of them are imported from inside and outside the EU. Section B.2 shows that trade physical flows of these articles are numerous and multidirectional within and between Member States. Therefore, the market of jewellery, especially of fashion jewellery, (from supply and demand sides) is atomistic and dispersed in the whole Europe.

As far as the use of lead and its compounds in jewellery is concerned, compared to independent national actions, **a community-level action would avoid trade distortions between industry actors of the jewellery supply chain of the different MS**. Uncoordinated national regulations might indeed be redundant, contradictory and/or unbalanced and thus hinder commercial relations on the internal market.

Indeed, **isolated national restrictions on limitations of the use of lead and its compounds in jewellery could constitute an important (even unintentional) distortive instrument towards neighbouring competitive firms**. Industry actors, who would be directly submitted to the new implemented regulation inside their country, would have to conform to new requirements whereas theirs competitors in other EU countries would have to comply with other (potentially less strict) national restrictions or no restriction at all. Firms of the EU jewellery sector would thus be unequally impacted because of additional costs for some (regulated) actors and of competitive advantages for the others. In that situation, additional costs would be due to the compliance to the new requirements, e.g. through the use of alternative, but more expensive, substances (such as those identified in section C) or the investment in R&D to investigate new techniques to produce jewellery with the same quality, but without lead. Whatever the content of national regulatory actions could be, regulated firms might be disadvantaged and lose markets shares. On the contrary, foreign EU competitors would be advantaged by the capture of a new demand (switch of the demand from the regulated - more costly - countries to the less strictly - or not - regulated countries). Besides, this situation would oppose the EC

Competition Law according to which flows of working people, goods, services and capital shall be free in a borderless Europe and firms shall be equally treated on the common market. Yet, isolated and non-harmonised national measures on the use of lead and its compounds in jewellery might constitute a clear trade barrier to entry. Finally, **it may be redundant and also costly to introduce actions to control the identified risks caused by the production, the import and the placing on the market of jewellery containing lead and its compounds, separately in each Member State**.

For all these reasons, it is considered relevant to take a measure on a Community-wide basis before the publication of other reported cases of lead poisoning from jewellery and new tests' results which may lead Member States to take isolated national measures.

E. Justification why a restriction is the most appropriate Community-wide measure

In this section, possible risk management options (RMOs) are first identified and described. Then, the proposed restriction and its alternative options are compared with other relevant community-wide RMOs.

E.1. Identification and description of risk management options

E.1.1. Risk to be addressed – the baseline

The "baseline" is the "business as usual situation", that is, the situation in the absence of the proposed restriction or any further RMO taking into account potential downward or upward trends.

From the information available it is clear that currently jewellery well exceeding the lead content considered as concern according to the evaluation of RAC and SEAC can be found in the EU market.

The risk to be addressed herein is the risk of lead poisoning resulting from a misuse (accidental ingestion/mouthing) of jewellery by children. This concern is grounded on several alerts and cases documented in the international literature (see section B.5.3.1). Although lead exposure of children, of workers and of the general population has dramatically decreased since the 1970s, this specific type of poisoning constitutes an unacceptable health risk. Indeed, children are particularly vulnerable to lead effects and no threshold has been identified for the effects on their central nervous system. Damages to their health might be severe and irreversible. Even though the risk occurs during the (mis)consumption stage, many actors along the supply chain are affected by this issue. **Each piece of lead-containing jewellery might thus be theoretically the cause of a poisoning. Industry actors who produce, import and place on the market such articles are then concerned.**

It is difficult to quantify the exact amount of jewellery (and lead-containing jewellery) placed on the EU market because this sector, and especially the fashion jewellery sector, is fluctuant and fragmented and because trade flows are very dynamic between EU Member States (and with outside). However, analysis and data presented in section B.2 provide an overview of the importance of quantities and amounts engaged into that sector.

It is estimated that of 10% of fashion jewellery placed on the market in the EU contain lead and that these pieces of jewellery have an average lead content of 6% (Table 14). Furthermore, imports of fashion jewellery have been growing rather fast. In the past decade the average growth rate of imports has been over 20% from developing countries. According to information collected from one independent testing laboratory (Anon 2010) there are no signs that the average lead content is decreasing – rather the share of lead-containing fashion jewellery seems to be increasing (see Table 14). **In sum, the overall magnitude of the risk is that some 150 million pieces of jewellery are placed on the market in the EU containing about 6% lead, and this amount seems to be growing.**

The risk of children mouthing these jewellery articles is real and likely to increase in the future with the envisaged extension of the fashion jewellery market.

It may be expected that tests for lead in jewellery will keep on being performed in several Members States revealing the presence of this substance and possibly of its compounds. This will even reinforce the concern that many Member States expressed on that issue and it may possibly result in the adoption of national regulations to manage these risks. In this case, these risks will not be controlled on a harmonised way across the EU.

E.1.2. Options for restriction

Six alternative options for a REACH restriction of the use of lead and its compounds in jewellery were initially proposed in the original dossier and a seventh option was added by the French CA following the recommendations included in the conformity check report. These options are presented in this section.

Option 1: Restriction on the use and placing on the market of <u>fashion</u> jewellery based on the <u>lead migration rate</u>

As already mentioned in this report, the lead migration rate is considered as the most relevant indicator to describe potential exposure from the use/misuse of jewellery. The approach consisting of defining a migration rate to manage risks resulting from the exposure to lead has already been used in certain regulations, such as the Toys Directive 2009/4/EC.
In the fashion jewellery sector, this option would impact producers, importers and distributors. Under this option, the actors who place fashion jewellery on the market have the responsibility to make sure that the lead migration rate from their products does not exceed a certain limit.
It is necessary to have testing methods which are available to measure a lead migration rate in order for the industrial actors to be able to comply with the restriction and for the authorities to be able to control that the restriction is respected. Such methods are available and are presented in section E.2.1.2.2.

Option 2: Restriction on the use and placing on the market of <u>fashion</u> jewellery based on the <u>lead content</u>

Like option 1, this option is expected to impact producers, importers and distributors of the fashion jewellery sector.

This option has been considered quite early in the process of elaboration of this restriction dossier. Indeed, restricting the use of lead and its compounds in fashion jewellery intuitively drives towards the limitation of their lead content. Besides, as expressed in sections B.5.1.1 and E.1.3, several countries have implemented that kind of limitation:
Denmark with a ban on import and sale of products, including jewelleries, containing more than 100 ppm (mg/kg) of lead (or mercury) in the homogeneous single parts of the product (national Law n°308 of May 17th 1995 and Statutory order n°856 of Sept. 9th 2009 replacing n°1082 of Sept. 13th 2007; replacing Statutory order n°1012 of Nov. 13th 2000).
In the USA, children's jewellery and other children's products may not contain more than 300 ppm lead in any part of the product (with some exceptions, such as inaccessible parts). This limit is expected to be revised to 100 ppm in August 2011, unless the Commission determines that it is not technologically feasible.

In Canada, a double limit is set via the Children's Jewellery Regulations of May 10th 2005 "on jewellery for children under 15" which authorise their sale, import and advertisement only if the total lead content in the product is below 600 mg/kg (0.06% by weight) (with less than 90 mg/kg (0.009% by weight) of migratable lead).

	Health Canada « Determination of total lead in surface coating material in consumer product » (2008-11-13)	**Health Canada "Determination of total lead in Metallic Consumer Product" (10/31/2008)**	**NF T30-201 (january 1981)**	**US-CPSC "Determination of content and availability of lead" (2/3/2005)**
Limit of Quantification (LOQ)	81 mg/kg pb	130 mg/kg pb	No LOQ. This method is used for paints with a lead content between 0.05 and 2%	No data
Analysis	Atomic Absorption Spectrometry with flame	Atomic Absorption Spectrometry with flame	Atomic Absorption Spectrometry with flame	Atomic Absorption Spectrometry with ICP spectrometer

As for option 1, it is necessary to have access to an available method to test the total lead content of a product. Such methods are available and presented below:

For the analysis part of the methods presented above, other analytical methods can be used. They are the following:
• **XRF method**: X-ray Fluorescence Spectrometry.
• **ICP-OES**: Optic Emission Spectrometry with plasma.
• **ICP-MS**: Mass Spectrometry with plasma

The choice of the method to be used to measure lead content would have to take into account economic and technical aspects. Regarding economic (and especially costs) aspects, a few data about costs of these methods are available in the literature: the XRF method would cost about 15€ per testing (RPA 2009) for one component tested and the methods based on ICP-OES would cost between 16.40€ and 40€ per testing with a marginal cost between 6 and 16€ (RPA 2009). The XRF method shows advantages. First, it seems to be the cheapest. One may also note that, as a restriction under REACH on Cadmium in jewellery is in the pipe-line (based on cadmium content), it might be expected that the cost of also analyzing percentage of cadmium in a first step when doing an analysis of lead with XRF would be low. Moreover, a field-portable XRF instrument is expected to be not prohibitively expensive and easy to use. However, technically, this method is limited since it would only allow for an analysis of the surface layer of the tested jewellery articles and seems to have also limited resolution.

From enforceability standpoint, this option is interesting. Indeed, as other countries have a limit on content of lead in jewellery (such as abovementioned), this option could be interesting for example as Asian suppliers are likely to follow such specifications already. Moreover, it might be expected that testing lead content is globally easier to implement for industry actors (compliance) and for authorities (monitoring) than testing migration since such methods are already commonly used and based on routines (not destructive and immediate answer). They should thus be implemented rather quickly.

The French assessment of this option was as follows:

Despite these advantages, and as explained in the previous sections, such option does not seem relevant as there is no correlation between the lead content of jewellery and the quantity of lead which can migrate from the article (Danish EPA (2008); BfR (2008)). Therefore, limiting the amount of lead contained in fashion jewelleries might not necessarily reduce the exposure and consequently the health risks and it might even induce distortions and biases in the articles targeted and the actors impacted. Indeed, option 2 could wrongly set aside highly leaded jewelleries but with an expected low lead migration rate (such as jewellery made of crystal or glaze) and inversely, might let lower leaded jewellery but with higher migration rate.
As a consequence, this option does not seem to be effective as it is not expected to adequately manage the identified risks and it will not be further assessed in this report.

The RAC re-evaluation of the Danish EPA survey has found association between lead migration and lead content for the metallic parts of jewellery, and therefore RAC suggests the use of content for these metallic parts and after assessment of applicability of the same limit value for non-metallic parts of jewellery and concluded that using same limit value for non-metallic parts ensures same level of protection. SEAC considers that the restriction based on content measurement to be practical and easy to implement and this option has been further assessed under Section E.2.3.

Option 3: Restriction on the use and placing on the market of <u>fashion</u> jewellery based on the <u>lead migration rate AND the lead content</u>

Contrary to the previously exposed options for restriction, option 3 is more restrictive. It implies to limit the lead migration rate from fashion jewellery articles and the lead content as well. This option is interesting to be considered in a context where the legislator wants to minimize as much as possible the risk, based on a precautionary approach. This option has been implemented in Canada, via the Children's Jewellery Regulations of May 10th 2005 "on jewellery for children under 15" which authorise their sale, import and advertisement only if the total lead content in the product is below 600 mg/kg (0.06% by weight) with less than 90 mg/kg (0.009% by weight) of migratable lead.

Limiting the total lead content of a jewellery article can be seen as complementary to the limitation of the lead migration rate. Indeed, the migration rate is expected to depend on the state of the jewellery: a measured migration rate on a jewellery article which is in good condition may be much lower than if it is measured on used jewellery (jewellery in bad condition), as some possibly protective coating may be damaged following the repeated uses of the jewellery. For this reason, limiting both lead content and migration rate may be relevant for a very conservative approach.

The French assessment of this option was as follows:

Compared to option 2, which completely sets aside lead migration rate, this option seems to be more appropriate. However, it is more restrictive than option 1. To consider the issue of jewellery in bad condition, it could be envisaged as part of option 1 to test the migration rate of the jewellery without their coating in order to be more conservative. Consequently, option 3 will not be further assessed in this report.

Option 4: <u>Ban</u> on lead and its compounds in <u>fashion</u> jewellery which is used and placed on the market

In this option, lead and its compounds would be prohibited from being used in fashion jewellery.
This restriction is expected to have a positive impact on children’s health protection. Indeed, lead may be considered as a non-threshold toxic substance and as such, exposure to it should be avoided as

much as possible. This would clearly go in the favour of a total ban. However, for enforcement purpose, the restriction has to contain a concentration limit; consequently, in this case, it would be necessary to base the restriction on the analytical possibilities in order to propose the lowest lead content measurable.
Moreover, for actors who use materials like crystal (which contains, by definition, a certain level of lead) or glaze in their fashion jewellery, this option could be synonym of an impossibility of producing and placing on the market their articles. In this case, based on data on the releases of such materials and on the identified risks, it would probably be necessary to propose some derogation.

The French assessment of this option was as follows:

As a result, this option appears to be quite extreme in terms of impacts on industrial actors as the resulting health benefits are expected to be comparable with the ones obtained with options 1, 3 and 6 and will not be further assessed in this report.

In its report on the socio-economic impact of a potential update of the restriction on the marketing and use of cadmium (RPA (2009)), RPA concludes that concerning the use of this substance in jewellery, the most suitable restriction option would be a complete restriction on use of cadmium in these articles. According to this report, some of the reasons for this conclusion are that cadmium is a non-threshold carcinogen and that there is no recognised standardised method for the measurement of cadmium migration rate.
Concerning lead, as already mentioned, it can also be considered as a non-threshold toxic substance for neurotoxic effects. However, a recognised standardised method is available for the measurement of lead migration rate in toys, EN 71-3 (which may also be used for jewellery). This is one of the reasons which may explain the choice of different proposed options for the management of risks related to cadmium and lead in jewellery.

Option 5: Ban on lead and its compounds in SOME fashion jewellery which are used and placed on the market

A less restrictive option than option 4 would be a ban on lead and its compounds only in some fashion jewellery articles. The advantage of such an option would be that it allows a risk differentiation by category of products. However, this option presents two important drawbacks.

The first foreseen difficulty is to define which articles have to be restricted and according to which criteria. The jewellery for which accidental ingestion is most likely to happen (due to their size, shape, etc.) could be for example chosen. However, health risks resulting from mouthing jewellery would not be controlled and it has been demonstrated that such health risks cannot be ignored. Another possibility would be to base the restriction only on jewellery intended for children. In this case, it would be necessary to define an age above which it is expected that children would not exhibit such mouthing behaviour. In all cases, such limitation of the scope of the restriction implies that children only use articles which are intended for them. This is clearly not the case as it is not unusual that **they come into contact with many articles which are not intended for them**. Consequently, the effectiveness of such an option might be limited because of the biases induced by the choice of the jewellery concerned.
Secondly, industry actors might be unequally impacted. This option seems less restrictive but it may be the source of economic and trade distortions within the fashion jewellery sector.

The French assessment of this option was as follows:

As a consequence, this option is not proportionate to the risk (it is not sufficiently targeted to the exposures) and might be distortive. Furthermore, it would not be easily practicable. For these reasons it will not be further assessed in this report.

Option 6 (the proposed restriction): Restriction on the use and placing on the market of jewellery (fashion and precious) based on the lead migration rate

In this option, the scope is extended, compared to what is proposed in the other options: in addition to fashion jewellery, this option also affects precious jewellery. **The proposition of this option results from the lack of clear definition for what fashion jewellery is** (see E.2.1.2.3). Moreover, although precious jewellery is not expected to contain non-precious metals, they might still contain lead and/or its compounds. Indeed, precious jewellery are hallmarked as a guarantee of their quality and composition. However, the hallmarks system seems not to be enough to assure an absence of lead since, as explained further in E.2.2.1.3., it only gives guarantee of the minimum quantity of precious metal in the material. As a consequence, the article may still contain lead. Inversely, and as already mentioned, the absence of a hallmark does not necessarily mean that the article is a fashion jewellery. With no clear definition of a fashion jewellery, it is thus expected that a restriction only affecting fashion jewellery will be very difficult to implement.

The French assessment of this option was as follows:

Taking into account the arguments of the discussions of the previous options, it is proposed to base option 6 on the lead migration rate which is considered to be the most relevant indicator of exposure. As this option was identified later on compared to the other ones, it could not be part of the consultation process.

Option 7 (the two steps approach initially suggested by RAC and SEAC): Two-steps option for Restriction on the use and placing on the market of jewellery (fashion and precious) based on the lead content and (under conditions) on lead migration rate

Based on the RAC, SEAC and Forum suggestions, the French CA has considered an additional option for restriction (option 7) which is examined in Annex C.

This restriction option would take place in two steps: first, the jewellery articles placed on the market would have to be tested regarding their lead content and then, the articles which would not comply with the first concentration limit set by the authorities would have to comply to a migration limit. The content limit would allow a quick and enforceable implementation of the regulation. However, if there is not always a direct relationship between lead content and lead migration (in particular in the case of non-metallic parts of jewellery), the second step is necessary in order to further distinguish between 'unsafe' and 'safe' lead-containing jewellery. The limit for migration allows lead-containing jewellery without non-tolerable migration to be placed on the market, while avoiding other jewelleries containing (migratable) lead to be legally placed on the market.

E.1.3. Other Community-wide risk management options than restriction

Managing the health risks for children caused by lead and its compounds in jewellery is at the crossroads of three types of regulations: regulations on lead, regulations on children's products and regulations on jewellery. As shown in section B.5.1.1, at present, there is no European legislation covering this particular issue as a whole.

During consultation, several contacts proposed to use the same limits which are already used either in the Canadian legislation or in the US legislation, so that it would make the restriction more practical as this type of restrictions are already implemented. These two legislations are described in more details below:

- The Canadian 2005 Regulation restricts lead in children's jewellery to a maximum of 600 mg/kg of total lead of which a maximum of 90 mg/kg of migratable lead. Both limits must be met. *"The 90* *mg/kg migratable lead standard is consistent with European Union migratable lead limit standards for toys intended for children under six years of age* (EN 71-3). *The 600 mg/kg total lead standard is consistent with maximum lead limits for surface coating materials under the Hazardous Products Act"*[47] (Canada Gazette (2005)). This double limitation is the outcome of a compromise based on the balance between benefits for health and costs for industry. In 2000, before the Canadian regulation was drafted and adopted, Health Canada had informally required industry actors to comply with a limitation of 65 mg/kg of total lead in fashion jewellery. However, this requirement was estimated to be too strict: *"After consulting with industry on the implications of these recommendations, Health Canada has determined that a maximum lead limit of 65 mg/kg for children's jewellery is too restrictive, since it would not permit the use of reasonably priced alternatives to lead and would not permit the practice o reworking lead. Insistence on this standard would have a negative economic impact on the industry, reduce consumer choice and probably result in a significant increase in the price of children's costume jewellery. The limits of 90 mg/kg leachable lead and 600 mg/kg total lead are low enough to protect children against the effects of lead exposure while minimizing the impact on industry"* (Canada Gazette (2005)).

In this legislation, the limit set up for the migration rate is thus based on the one established in EN 71-3, which is a standard related to toys. In this standard, the lead migration rate of 90 mg/kg was calculated considering that a child daily ingests 8 mg of toy and that the quantity of bioavailable lead resulting from the use of toys should not exceed 0.7 µg/day ($0.7 \times 10^{-3}/8 \times 10^{-6} \approx 90$ mg/kg). The quantity of 8 mg which is used in EN 71-3 was derived for material which can be "scraped off" from the toy i.e. it is not supposed to protect the child if the whole toy is accidently ingested whereas in the approach that is chosen in this restriction dossier, it is considered that the whole jewellery article may be ingested. As a consequence, it is not the same approach. However, it is acknowledged that jewellery may also have a coating which can be scraped off by children. In this case, it is recommended in the restriction that the coating should be removed and also tested (for more details, see section E.2.1.2.2).

Also, it is considered in this restriction proposal that the safe lead migration rates which were calculated are conservative enough to protect children from lead poisoning and that there is no need for adding a limitation concerning the total lead content of the jewellery.
For these reasons, the limits set up in the Canadian legislation are not considered relevant for this restriction proposal.

▪ The US 2009 regulation restricts lead in children's products (including jewellery) to a maximum of 300 ppm of total lead. However, as already mentioned in the restriction dossier, the lead content of a jewellery may not be considered as a reliable indicator of exposure. For this reason, the choice was made not to base the restriction proposal on the US regulation.

Concerning voluntary actions, according to feedback from KEMI (2007), their impact is very limited since the quantity of lead-containing jewellery articles which are placed on the market is still significant (see data in section B.2). Such voluntary actions are also reported to be ineffective by Health Canada because the range of costume jewellery items sold in Canada is very large and is constantly changing; and the number of companies that import and sell costume jewellery in Canada is also very large. Such arguments should also apply to countries other than Canada.

Another option could consist of labelling the jewellery/alloys for jewellery concerning their lead composition and of warning the producer/importer about the potential health risks of its products or the consumer about the health risks of mouthing such articles. Such option exists for example for lead-containing paintings. However, for the present issue, it might be not sufficient because in practice, jewellery articles are not kept in their packaging and thus the information concerning lead composition

[47] The 2005 *Hazardous Products Act* is a Canadian Act which prohibits the advertising, sale and importation of hazardous products.

and the warning will not remain with the jewellery and it can be expected that the consumer will not remember it. Moreover, it can also be expected that parents are primary worried about the risk of choking of their children coming from the ingestion of small articles. They may be even probably more worried about this than about lead migration and consequently already try to make their children not put jewellery into their mouth. Consequently, it is not expected that a label will impact their behaviour.

Therefore, none of the community-wide regulation currently in place covers the specific risk targeted herein. Indeed, some of them regulate the use of lead and/or its compounds in consumer products but do not address jewellery; some others regulate articles intended to be used by children but do not include jewellery for children (and of course not jewellery in general neither), the existing European regulations covering fashion jewellery articles are either targeted on specific types of jewellery (and thus incomplete), or do not restrict lead and its compounds; and finally, regulations on precious jewellery are focused on precious metals and not on other metals/substances.

As a result, it may be interesting to consider possible amendments to some of those regulations in order to assess whether they could be adapted to manage the specific risk targeted in this dossier.

Amendments to existing regulations

The possible amendments which could be considered are the following:

1. Amendments to the Toys Directive by removing its exemption 19. This modification could be interesting but it shows two limits: on one hand, jewellery articles (even those intended for children) cannot reasonably be considered as “toys” in the sense that they are not intended for use to play and on the other hand, even though the exemption 19 was removed, fashion jewellery which would be covered by the Directive would only be fashion jewellery for children. Given its particular scope, this directive is thus intrinsically too limited to cover all fashion jewellery items (for children and for adults) and precious jewellery. **This amendment would thus be incompletely effective and will not be further assessed.**

2. Amendments to Directive 2001/95/EC on General Product Safety.

As already mentioned in section A.1.2.1., the Swedish Chemicals Agency (KEMI) pressed, in 2007, for a limitation under Directive 2001/95/EC with a special attention to jewellery (and soldered and cast accessories, chalks, candles and lead-containing alloys) (KEMI (2007)). According to the KEMI proposal, an alternative to the introduction of a restriction under REACH regulation could be to introduce a limitation under this Directive consisting in a concentration limit of 0.1% lead by weight and 0.3% lead by weight for metal parts of jewellery (KEMI (2007)). Among the different amendments presented earlier, it seems to be the only one which could be considered as large enough to embody children safety as regards (all) fashion and precious jewellery articles containing lead and its compounds.

According to Directive 2001/95/EC, “producers shall be obliged to place only safe products on the market”. Consequently, producers (and importers) must place on the market products which comply with the general safety requirements. In addition, they must provide consumers with the necessary information in order to assess a product's inherent threat, particularly when this is not directly obvious, and take the necessary measures to avoid such threats (e.g. withdraw products from the market, inform consumers, recall products which have already been supplied to consumers, etc.). Distributors are also obliged to supply products that comply with the general safety requirement, to monitor the safety of products on the market and to provide the necessary documents ensuring that the products can be traced.

In this Directive, both acute and chronic health risks are taken into account in assessing what a safe product is. As a result, at first sight, Directive 2001/95/EC seems to be relevant to manage the health risks targeted in this dossier. Moreover, the requirement for safer jewellery articles appears to be compatible with this Directive considering the following definitions:

- a 'product' is defined as: "*any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers* ***even if not intended for them****, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.*" (article 2 a))
- a 'safe product' is defined as *"any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular: (i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance; (…) (iv) the categories of consumers at risk when using the product,* ***in particular children*** *and the elderly."* (article 2 b))

According to Article 13 of the Directive, "*If the Commission becomes aware of a serious risk from certain products to the health and safety of consumers in various Member States, it may, after consulting the Member States, and, if scientific questions arise which fall within the competence of a Community Scientific Committee, the Scientific Committee competent to deal with the risk concerned, adopt a decision in the light of the result of those consultations, in accordance with the procedure laid down in Article 15(2), requiring Member States to take measures from among those listed in Article 8(1)(b) to (f) if, at one and the same time:*
(a) it emerges from prior consultations with the Member States that they differ significantly on the approach adopted or to be adopted to deal with the risk; and
(b) the risk cannot be dealt with, in view of the nature of the safety issue posed by the product, in a manner compatible with the degree of urgency of the case, under other procedures laid down by the specific Community legislation applicable to the products concerned; and
(c) the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure a consistent and high level of protection of the health and safety of consumers and the proper functioning of the internal market."

It can be considered that the identified risk is a "serious risk from certain products to the health and safety of consumers in various Member States". Consequently, it could be argued that the Commission could adopt a decision in the frame of this Directive. However, such decision shall be valid for a period not exceeding one year, even though it may be confirmed for additional periods not exceeding one year (Article 13.2). This would result in a non permanent management of the risks as such Decision would be applicable only during a period of one year maximum. **Consequently, a restriction under REACH seems to be more adequately targeted to the identified risks and this RMO will not be further assessed.**

As a conclusion of this section, voluntary action by industry is not considered to be suitable to the management of the identified health risks and no legislation other than REACH is expected to adequately manage these risks. Consequently, only the different options for a restriction will be further assessed in the following section.

E.2. Assessment of risk management options

The RMOs evaluated by RAC are:

- Option 1: Restriction on the use and placing on the market of <u>fashion</u> jewellery based on the <u>lead migration rate</u>
- Option 2: Restriction on the use and placing on the market of <u>fashion</u> jewellery based on the <u>lead content</u>
- Option 3: Restriction on the use and placing on the market of <u>fashion</u> jewellery based on the <u>lead migration rate AND the lead content</u>
- Option 4: Ban on lead and its compounds in <u>fashion</u> jewellery which is used and placed on the market

- Option 5: Ban on lead and its compounds in SOME fashion jewellery which is used and placed on the market
- Option 6 (the restriction proposed by the French CA in the Annex XV dossier): Restriction on the use and placing on the market of jewellery (fashion and precious) based on the lead migration rate
- Option 7 (the two steps approach initially suggested by RAC): Two-steps option for Restriction on the use and placing on the market of jewellery (fashion and precious) based on the lead content and (under conditions) on lead migration rate

Options 1, 2, 4 and 5 (option 3 is a combination of option 1 and option 2 and option 6 was identified later on during the preparation of the dossier, once industry consultation had already been performed) have been proposed during the consultation process conducted by the French CA before submitting the Annex XV dossier to MSCAs, national health institutes and industrial actors. The summary outcome of this consultation is presented below (more details are available in section G.1 and in INERIS (2009)).

From the consultation carried out among Member State Competent Authorities (MSCAs) and industrial actors about risk management options, the major points can be summarised as follows:

- **MSCAs seem to be more in favour of a total ban of lead and its compounds in fashion jewellery.**
- **Industry actors seem to be more in favour of a restriction on the migration rate.**
- **The options based on the migration rate seem to be more costly to introduce in the view of the MSCAs.**
- **High costs are associated by industry actors to the options which propose a ban on lead and its compounds.**
- **Whatever the base of the restriction is (lead content or lead migration rate), MSCAs and industry actors express the need for agreed testing methods and for clear definitions.**
- **Concerning the ban only for some jewellery articles, difficulties are foreseen to determine which jewellery should be regulated.**
- **Lead migration rate is reported to be more representative of the actual exposure and thus it seems to be more appropriate to base the restriction on it than on the lead content.**
- **Some industry actors highlighted the necessity of lead presence and relative high lead content for certain uses like crystal.**
- **Several respondents proposed to use migration rates which are used in other implemented regulations.**

As summarized in section A and such as requested in ECHA (2007), each of these options must be compared regarding three criteria: effectiveness, practicality and monitorability.

▪ “**Effectiveness**” is defined such as the RMO must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk.

▪ “**Practicality**” is defined such as the RMO must be implementable, enforceable and manageable; “Implementability” implies that the actors involved are capable in practice to comply with the RMO. To achieve this, the necessary technology, techniques and alternatives should be available and economically feasible within the timeframe set in the RMO. “Enforceability” means that the authorities responsible for enforcement need to be able to check the compliance of relevant actors with the RMO. The resources needed for enforcement have to be proportional to the avoided risks. “Manageability” supposes that the RMO should take into account the characteristics of the sectors concerned (for instance, the number of SMEs) and be understandable to affected parties. The means of its implementation should be clear to the actors involved and the enforcement authorities and access to the relevant information should be easy. Furthermore, the level of administrative burden for the actors concerned and for authorities should be proportional to the risk avoided.

- "**Monitorability**" is defined such as it must be possible to monitor the results of the implementation of the RMO. Monitoring is understood widely and may cover any means to follow up the effect of the RMO in reducing the exposure. The most appropriate means of monitoring depend on the type of measure and on the related conditions. Such monitoring may include, for example, follow up of the amounts of substance manufactured and imported, follow up of the amounts of substance used for different uses, measuring of the concentration of the substance in preparations or articles, measuring of the relevant emission and/or exposure levels, etc.

Before assessing in details all the identified options, a comparison is provided in the following table based on these criteria and on the different arguments and feedbacks identified in literature and received during consultation.

Table 51: Comparison of the six identified options proposed by the French CA and the seventh option proposed by RAC

Option	Effectiveness		Practicality	Monitorability
	Risk reduction capacity	Proportionality		
Option 1 Restriction on the use and placing on the market of fashion jewellery based on the lead migration rate	+++	++	++	+
Option 2 Restriction on the use and placing on the market of fashion jewellery based on the lead content	-	++	++	++
Option 3 Restriction on the use and placing on the market of fashion jewellery based on the lead migration rate AND the lead content	+++	+	+	+
Option 4 Ban on lead and its compounds in fashion jewellery which is used and placed on the market	+++	-	-	-
Option 5 Ban on lead and its compounds in SOME fashion jewellery which is used and placed on the market	+++	-	-	-
Option 6 Restriction on the use and placing on the market of jewellery (fashion and precious) based on the lead migration rate	+++	++	++	+
Option 7 Restriction on the use and placing on the market of	+++	++	+	+++ for lead content

jewellery (fashion and precious) based on the lead content and the lead migration rate				+ for migration

From the outputs of this comparison, only options 1 and 6 were assessed in more detail in the French Annex XV report. The French proposal with some RAC comments is presented in the following sections. In addition SEAC made cost calculations for the restriction option 2, which are included in the following sections.

E.2.1. Restriction option 1: Restriction on the use and placing on the market of fashion jewellery based on the lead migration rate

E.2.1.1. Effectiveness

E.2.1.1.1. Risk reduction capacity

E.2.1.1.1.1. Changes in human health risks/impacts

Option 1 is expected to induce positive changes in human health protection. Indeed, by limiting the lead migration rate of fashion jewellery, it will reduce the risk of children poisoning both from acute exposure (accidental ingestion) and from chronic exposure (mouthing of the articles). The fashion jewellery with which children are likely to come into contact will be safer and the identified risks should be thus adequately controlled.

This option would apply 6 months after the entry into force of the amendment of REACH Annex XVII and would be expected to have positive impacts on children health immediately after its application.

E.2.1.1.1.2. Changes in the environmental risks/impacts

Not relevant for this proposal **even though it is expected that a reduction of the use of lead and its compounds will have a positive impact on environmental protection.**

E.2.1.1.1.3. Other issues

Not relevant for this proposal.

E.2.1.1.2. Proportionality

E.2.1.1.2.1. Economic feasibility

To comply with the migration limit proposed, moderate efforts needed from industry actors may be considered: they might face **additional costs due to use of more expensive raw materials, to new training of workforce and to the implementation of systematic testing practices of their articles**. These costs are further examined in section F. Moreover, it is possible that the process of production or placing on the market is lengthened because of the systematisation of migration tests that this option implies.

The economic feasibility of this option depends on the industry actors concerned.

The industry actors who would choose to substitute to alternatives would have to mainly face substitution costs and, perhaps, additional operating and adjustment costs as well, due to adaptation to alternatives' specific properties of workers, equipments and machines. These costs are examined in sections C.7 and F (Annex D). Adjustment costs are difficult to assess (and it has also been considered to not implement further investigation on those costs for proportionality reasons) but substitution costs have been estimated above: the contribution of the raw material has been estimated to be around 20 to 30% of the final price of a jewellery article (section C.7). Regarding the respective (estimated) costs of lead-free and lead-containing alloys, substitution would imply an increase of about 7% of the cost of

the alloys for jewellery manufacturers who would switch to lead-free alloys (for alloys containing up to 10% lead) (see also section C.7). It can be also expected that, some industry actors (in particular those who produce/use lead-containing alloys) might have no choice but switching to alternatives to lead as, from the limit set up for the lead migration rate, it can be expected that it might be very difficult then to keep on using lead as a constituent of the alloys.
However, the industry actors who would keep on producing lead-containing jewellery articles and/or lead-containing alloys for jewellery would have to comply with the restriction and therefore bear testing/certification costs. The compliance/testing costs for migration are reported in RPA (2009) with **a cost of about 22 euros for testing one component with method EN 71-3.** If two components are tested (for instance, authorities can test jewellery for both lead and cadmium migration rates), the cost is reported to be about 35 euros. For three components, it is of about 50 euros and for four components or more: around 65 euros (RPA (2009)). Globally, the biggest efforts might be expected to be made by micro and small firms. However, as discussed in section E.2.3.1.1., only a fraction of such compliance/testing certification costs are expected to be incremental for lead testing (due to other 'overlapping' legislative requirements related to cadmium in jewellery).

Finally, as already mentioned, this option would apply **6 months** after the amendment of REACH Annex XVII comes into force. This delay is considered to be reasonable considering the fact that, as indicated in section B.2.4, collections of fashion jewellery are changed according to seasonal fashion trends. This suggests that the stocks of actors who place fashion jewellery on the market are rapidly renewed. Moreover, a manufacturer of alloys (which can be used in fashion jewellery), when consulted for the prices of his alloys, indicated that, given the fluctuation of the costs of raw materials, costs of alloys are varying and as a result, such alloys are manufactured following customers' demand. As a consequence, it is not expected that these actors will have high stocks of leaded alloys that will remain unsold because of the implementation of this restriction proposal.

E.2.1.1.2.2. Technical feasibility

As regards the technical feasibility, the proposed restriction seems to fulfil this criterion. A method for migration tests to be carried out in order to control the migration rate of lead from the jewellery is available and scientifically recognised (for further details, see Section E.2.1.2.2). It is thus technically operational. However, these migration tests are not always known and used by industry actors, especially by small distributors and SMEs. As mentioned above, a period of training is thus to be taken into account for some actors in order to be able to use these tests even though, it may be expected that many actors will have the tests performed by external laboratories.

However, RAC is aware that no standardised procedures are available at the time of giving its opinion for migration testing which mimics mouthing or for measurement of lead in artificial saliva. There is therefore a need for the development of reliable methods to perform and detect migration mimicking mouthing conditions at the recommended rate.

As to the potential implementation of alternative substances to lead: they are also available and already used in the fashion jewellery sector since lead-free alloys are already available for this type of application. It would however still imply an adaptation of the production process for actors who presently only work with lead-based alloys.

E.2.1.1.2.3. Other issues

Not relevant for this proposal.

As a whole, restriction option 1 is considered as effective since it is targeted to the identified risk and to actors in the supply chain associated to the risk (producers, importers, distributors) and it is consistent with the legal requirements already in place. The proposed restriction will reduce the targeted risk and seems rather proportional.

E.2.1.2. Practicality

E.2.1.2.1. Implementability

Industry actors concerned by the proposed restriction should be capable to comply with its requirements in practice since migration tests (even though development of methods is needed) and alternatives are technically available and economically feasible. However, a delay may be necessary to adapt the production techniques to the alternatives and to implement an adequate control of the lead migration rate along the supply chain. As already mentioned in the previous sections, micro and small firms may encounter more difficulties for the implementation of the restriction.

E.2.1.2.2. Enforceability

For enforcement purposes, it is recommended that the restriction contains a restriction limit so that enforcement authorities can set up an efficient supervision mechanism. Supervision from the authorities should be feasible in principle through regular controls of jewellery samples.

SCHER (2010) recommends performing repeated discontinuous extractions separated by a "dry spell" of the metal in order to mimic the mouthing behaviour of children, which is a dynamic process. However, no such method is currently available and no method is available for the measurement of the lead migration rate which mimics mouthing. Nevertheless, several methods have been developed and are used for the measurement of lead migration rate in acidic conditions which simulate the gastric compartment. It is recognised that these methods are not suitable to assess migration in the saliva but they can be used in the view of a protective approach. Indeed, considering that gastric conditions are supposed to increase the migration rate of lead compared to the saliva which is less acidic, they may be used as a conservative approach. Such methods are described in the following table. They are useful for the enforcement authorities but they should also be used by the industrial actors to control their products' quality. Such methods allow the measurement of the quantity of lead which may migrate from the jewellery under certain conditions and whatever the original form of lead is (it may be present as metallic lead or as a lead compound).

Table 52: Comparison of the different methods available for the measurement of lead migration rate

	EN 71-3	Health Canada (2008)	US CPSC (2005)	EN 1388-2
Product analysed	Lead migration rate **Toys**	Lead migration rate **Jewellery**	Lead migration rate **Jewellery**	Lead migration rate Materials and articles in **contact with food stuffs** – silicate surfaces (ceramic ware and others)
Size of the sample	Has to fit into the « small parts cylinder » (EN 71-1-A9)	Has to fit into the « small parts cylinder »	N.A.	Distinction between flat and shallow dish
Extraction	0,07 mol/L HCl	0,07 mol/L HCl	0,07 mol/L HCl	0.07 mol/L CH_3COOH
Volume of extraction	Sufficient volume to just cover the	Sufficient volume just to cover the	50 times the weight of the	- <u>Dish that can be filled</u>:

solution	toy	sample	jewellery	Fill the sample until the limit of spill. - Dish that can not be filled: Sufficient volume to cover the dish
Temperature	37 +/- 2 °C	37 +/- 2 °C	37 °C	22 +/- 2°C
Extraction duration	2 hours	2 hours	1 + 2 + 3 hours ("shaker bath")	24 hours
Number of extractions	1	1	3	1
Separation	- Decantation - Filtration	Filtration	N.A.	N.A.
Analysis	Not indicated, but ICP or flame atomic absorption spectrophotometer could be used.	Flame atomic absorption spectrophotometer at 283 nm	ICP	Flame atomic absorption spectrophotometer at 283 nm

'N.A.' for 'Not Available'

The most suitable method regarding the restriction seems to be the one proposed in standard EN 71-3 for the two main following reasons:

- **It is a European standard.**
- **It is already used for regulatory purposes (in the framework of the Toys Directive 2009/48/EC).**

In this method, the lead migration rate is measured during two hours. The US CPSC proposes a method (US CPSC (2005)) in which lead migration rate is measured in the following conditions: it is extracted three times with renewal of the extraction solution. Yost J.L. and Weidenhamer J.D. (2008) made some tests using the CPSC method which showed that the majority of the lead migration occurred during the 1st extraction (one hour). Such results confirm that the duration of two hours proposed in EN 71-3 is suitable and that the measured migration rate during these 2 hours will be higher than the one which would be measured after a longer period of time. As such, measuring the lead migration rate during the 1st two hours is a conservative approach. This is confirmed by RIVM (2008) which proposes, in the framework of toys testing, to carry out only one migration test, for toys intended for repetitive use, as it is considered to be the worst-case exposure to the migrating substance.

For these reasons, EN 71-3 is recommended by France as a dossier submitter for enforceability of the proposed restriction. However, when using this method one should consider the following adaptations:

A- Concerning type of migration solution

In EN 71-3 a hydrochloric acid solution is used to mimic gastric fluid. The migration test should be modified to mimic the mouthing conditions.

B - Concerning the size of the non-metallic jewellery

Toys shall not be tested according to EN 71-3 if they are not supposed to be ingested by the children, i.e. if they do not fit entirely the so-called "small parts cylinder" (defined in the standard EN 71-1-A9) which is a device that approximates the size of the fully expanded throat of a child under three years old. However, the identified health risks considered in this restriction deal not only with the accidental ingestion of jewellery, but also with the mouthing of the jewellery. As the latter activity may be performed by the child **whatever the size of the jewellery is, it is necessary that all non-metallic**

jewellery parts are being tested according to this standard: indeed, a toy (and, possibly jewellery) which is too large to be swallowed may clearly be mouthed/sucked and may result in chronic lead poisoning (InVS (2008)).
As bigger jewellery need to be tested using EN 71-3, it may be necessary to adapt the quantities of migration solution.

C – Concerning non-metallic parts and non-metallic coating/ surface treatment
High levels of lead (up to 23%) have been measured in the coating of inexpensive plastic jewellery items (Yost J.L. and Weidenhamer J.D. (2008)). Such results demonstrate the importance of taking into account the potential exposure resulting from the non-metallic coating/ surface treatment of jewellery articles.
A European standard, EN 12472, is available for the simulation of wear and corrosion of coated items. It was originally developed for the regulation which addresses health risks related to nickel in jewellery articles. The suitability of this method to the issue of lead and its compounds in jewellery is however unknown. Analytical tests would probably be needed to assess its relevance. Further, one may be aware that the great diversity and complexity of types and shapes of jewellery articles, as well as production techniques, might make the systematic test of coating challenging for companies which would have to test each component of a jewellery article, which can sometimes be made of several coatings.

It should be highlighted that the migration rate is defined in µg/cm²/hr. This implies that the surface of the tested jewellery needs to be measured. For this measurement, it is recommended to use the method proposed in the European standard EN 1811. Consultation with the SCL, which is the laboratory of the French Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) and of the French General Directorate of Customs and Indirect Duties (DGDDI) revealed that European standard EN 1811 is contested especially for the part dealing with the measurement of surface area as it seems to lead to a great variation of the results. Consequently, the relevance of expressing the lead migration rate per surface unit is questioned by the laboratory as it is considered that it may lead to dispute. The difficulty to measure the item's surface having several shapes and often complex shapes might create various results for one identical item by different laboratories. According to the French BOCI, CETEHOR and the FCVMM[48] (2010), this variation might have a important impact on the defined release value and thus on the applicability of the regulation proposed. These arguments can nevertheless be qualified by the fact that, according to other consulted information sources, this debate is to be moderate. For lead migration values clearly above or below the migration limit proposed, acceptable errors occurring in the surface area measurement might not significantly contribute to the decision (compliance or not of the tested article). However, where the lead migration value approaches the limit proposed (likely to concern only a low percentage of tested articles), errors occurring in the surface area might become significant (Individual, 2010).

Based on RAC evaluation, it seems possible to go from a unit in "µg/cm²/hr" to another one in "µg/g/hr" and this is acknowledged that it would make the proposal more enforceable.

The great variety in terms of jewellery which is placed on the market and in terms of localisation of the selling points may make the controls difficult in practice and induce significant control costs if authorities want to implement numerous and regular control campaigns. However, **it is envisaged that such campaigns are already organised by authorities to control the applicability of entry #27 of REACH Annex XVII dealing with nickel in jewellery and that the necessary equipment for these tests is already available in the laboratories.**

[48] Federation of crystal and glassware.

E.2.1.2.3. Manageability

The means of implementation of the proposed restriction (migration tests, switching to alternative substances etc.) are clear and understandable to the actors involved but an information/training effort may be needed for some of them (possibly the smallest ones and the distributors).
The method which will have to be used to ensure compliance of the products with the restriction is already available as a standard; which is supposed to facilitate the manageability of the restriction for both authorities and industrial actors.

An issue dealing with manageability may be however related to the question as to "What is the definition of fashion jewellery?". Indeed, **there is no harmonised definition for "fashion jewellery"**. Many synonyms were identified while preparing the restriction dossier, such as "costume jewellery", "imitation jewellery", "funk jewellery". Moreover, as already mentioned, this category includes a great variety of types of jewellery with important differences in terms of their composition, their price and their selling points.

Concerning their composition, fashion jewellery may be made of base metals (plated or not with silver and/or gold) and a variety of other 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).
Concerning their type, fashion jewellery may, for instance, include: bracelets, necklaces, chains, earrings, piercings, rings, links, charms, pins, brooches, ankle chains, curb bracelets, hair ornaments (headbands and scrunchies accessories, etc) and the different parts of those articles (clasps, pendants, beads).

An indicated in RPA (2009), fashion jewellery can be composed of (a) precious metal(s) or (b) a mix of precious and non-precious metals or (c) non-metal materials. During consultation, several definitions were proposed by some actors:
"An ornamental/decorative item intended for regular wear on the body or on clothing or clothing accessories"[49] by Health Canada.
"Any jewellery (including hair ornaments) which does not contain massive precious metals" by the French jewellery professional federations Cetehor and BOCI.

Fashion jewellery may be differentiated from precious jewellery, according to RPA (2009) depending on the used material (presence of precious metal alloys in precious jewellery and use of a variety of materials in fashion jewellery), on the place where they are sold, the pricing structure (fashion jewellery is significantly cheaper than precious jewellery), the presence of a hallmark (or CCM) which indicates that jewellery is precious (however, absence of a hallmark does not necessarily mean that the article is a fashion jewellery article).

As all articles which are imported in or exported from the EU need to be classified, the General Directorate of Customs and Indirect Duties (DGDDI) was contacted in order to have information on a possible way to categorise fashion jewellery. DGDDI indicated that such classification is performed using a TARIC code and that the code for "Imitation jewellery" is "7117"[50]. Note 11 of chapter 71 indicates that "for the purposes of heading 7117, the expression 'imitation jewellery' means articles of jewellery within the meaning of paragraph (a) of note 9 (but not including buttons or other articles of heading 9606, or dress-combs, hairslides or the like, or hairpins, of heading 9615), not incorporating

[49] It is used in the Canadian 2005 Children's jewellery regulation. According to Health Canada, items like watches, eyeglasses, and belt buckles, which have a primary functional purpose, are not classified as jewellery; however, any charms, beads, or other decorative components on these items should meet the lead content limits for children's jewellery (see Section G.2)

[50] http://ec.europa.eu/taxation_customs/dds/cgi-bin/tarchap?Taric=7117000000&Download=0&Periodic=0&ProdLine=80&Lang=EN&SimDate=20100407&Country=----------&YesNo=1&Indent=0&Action=0#OK (Accessed in April 2010).

natural or cultured pearls, precious or semi-precious stones (natural, synthetic or reconstructed) nor (except as plating or as minor constituents) precious metal or metal clad with precious metal". Note 9a) states that "... the expression 'articles of jewellery' means : a) any small objects of personal adornment (gem-set or not) (for example, rings, bracelets, necklaces, brooches, earrings, watch-chains, fobs, pendants, tiepins, cuff links, ...".

This definition indicates that fashion jewellery do not incorporate precious metal. This implies that, according to this definition, fashion jewellery articles which are plated with precious metals are not considered as fashion jewellery. However, the previous mentioned definitions indicate that "fashion jewellery" can be composed of or clad with precious metals and it has been reported possible that such articles may contain and release lead and its compounds. For this reason, it is considered that they should be included in the scope of the proposed restriction.

Based on this information, in this option, the definition proposed for fashion jewellery could be the one used in the TARIC code above mentioned, but an addition should be made in this case concerning jewellery which is clad with precious metal.

E.2.1.3. Monitorability

E.2.1.3.1. Direct and indirect impacts

According to ECHA (2007), monitoring may cover any means to follow up the effect of the proposed restriction in reducing the exposure. **The evolution of the percentage of fashion jewellery which has a lead migration rate above the limit proposed in the restriction may be an indicator of the effect of the proposed restriction.** In order to provide such indicator, the measure of lead migration rate of fashion jewellery which is placed on the market has to be monitored. As presented in Section E.2.1.2.2, a method is available. **Stakeholders involved in this monitoring activity are authorities responsible for enforcement of the REACH restrictions in the different Member States and the laboratories which will be in charge of performing the lead migration rates measurements.**
Monitoring the implementation of the proposed restriction could also be carried out through the follow up of the actions undertaken by industry actors to comply with the proposed restriction (adaptation process, alternatives adoption, systematisation of migration testing, etc.).
It may be highlighted that monitoring might unequally concern industry actors since micro and SMEs (and non-specialised actors) can be more difficult to identify on the market and thus to control. As a result, since they are more easily localisable, the largest actors may experience more controls relatively. It is not seen as a problem *per se* but it may induce biases in the monitoring of the implementation of the restriction.

E.2.1.3.2. Costs of the monitoring

Costs of monitoring include testing costs also for public authorities, which would have to control jewellery placed on the market (by testing them). As mentioned above, RPA (2009) reports **a cost of about 22 euros for testing one component with method EN 71-3**. If two components are tested (for instance, authorities can test a jewellery article for both lead and cadmium migration rates), the cost is reported to be about 35 euros. For three components, it is of about 50 euros and for four components or more: around 65 euros. These costs were reported from a UK laboratory and are provided as an indication. **They may vary between laboratories and between Member States.**
Costs of the measuring campaigns may increase due to the difficult identification and localisation of many actors on the market. Consequently, authorities may choose to only control the largest firms and to not push the prospecting further; in this case, costs would be reduced but monitoring would be partial.

E.2.1.4. Overall assessment of option 1 for restriction

The overall assessment of option 1 for restriction is summarised in Table 58 Feedbacks from MSCAs and EU institutes surveyed during consultation seem to recognise its effectiveness towards the risk reduction and its proportionality although they sometimes question its enforceability.

Equally, the feeling of industry actors from the jewellery sector has been documented about that option: firms largely opted for this option. According to them, limitation of lead migration rate from jewellery is the only significant limitation which can have an impact on human health. This option is considered to be a realistic and reasonable way to manage the risks.

The main foreseen difficulties in this restriction option are related to the lack of definition for "fashion jewellery" and to the measurement of the surface area of a jewellery article.

E.2.2. Restriction option 6 (the proposed restriction by France): Restriction on the use and placing on the market of jewellery (fashion and precious) based on the lead migration rate

E.2.2.1. Effectiveness

E.2.2.1.1. Risk reduction capacity

E.2.2.1.1.1. Changes in human health risks/impacts

For the same reasons as the ones exposed in Section E.2.1.1.1.1 (the lead migration rate is the most relevant indicator of exposure, thus it is the most relevant parameter to regulate), option 6 is expected to reduce the risk of children lead poisoning from both acute exposure (ingestion of a jewellery article) and chronic exposure (mouthing of a jewellery article).

It is envisaged that option 6 will increase human health protection even more than option 1 as the scope of option 6 is greater than the scope of option 1 (it takes into account both fashion and precious jewellery).

As for option 1, option 6 would apply 6 months after the entry into force of the amendment of REACH Annex XVII and would be expected to have positive impacts on children health immediately after its application.

E.2.2.1.1.2. Changes in the environmental risks/impacts

Not relevant for this proposal even though it is envisaged that limiting the use of lead and its compounds in fashion and precious jewellery will have a positive impact on environmental protection.

E.2.2.1.1.3. Other issues

During consultation (see section G.3.2 for more details), CETEHOR reported that, depending on the MS, there is a specific legislation which addresses the production and the placing on the market of articles made of precious metals (in France, gold, silver and platinum are considered as precious metals). In France, it is in the French General Tax Code[51] which stipulates, among others, specific minimum contents for gold, silver and platinum. Depending on the content of these metals, a hallmark is present on the jewellery. If jewellery has a content of gold which is below 37.5%, it will not be possible to call it "gold jewellery" when it is placed on the market. For other metals which are non-precious, there is no regulation (except the one for nickel) which requires maximum levels. From this information, it can be considered that lead is not regulated in precious jewellery and it may be envisaged that precious jewellery such as "gold" jewellery (which contain a minimum of 37.5% gold) may also contain lead.

Consequently, including precious jewellery in this restriction proposal seems relevant in terms of effectiveness.

[51] http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006069577 (accessed in March 2010).

E.2.2.1.2. Proportionality

E.2.2.1.2.1. Economic feasibility

In option 6, both fashion jewellery and precious jewellery sectors are affected by the restriction. As already discussed in Section E.2.1.1.2.1, **this option appears to be economically feasible for the fashion jewellery sector and it is expected to be the same for the precious jewellery sector as it can be assumed that lead is much less used in precious jewellery than in fashion jewellery.** This is confirmed by information obtained during consultation of the MSCAs: according to an Italian Federation of precious jewellery manufacturers, “lead is absolutely not present in traditional goldsmith and jewellery which are constituted by precious metals.” Still according to this federation, “With regard to jewellery with gemstones, enamels and pearls, or other precious metals added to the precious metal manufactured products, […], in most cases, the presence of lead is to be excluded, or, anyway, its percentage is absolutely negligible and marginal.”

Based on this information, it can be considered that option 6 is economically feasible.

As already mentioned, this option would apply **6 months after the entry into force of the amendment of REACH Annex XVII**.

This delay is considered to be reasonable for the same reasons as the ones stated in section E.2.1.1.2.1: the stocks of the actors who place fashion jewellery on the market are rapidly renewed, alloys intended for use in fashion jewellery seem to be manufactured following customers’ demand and as such, stocks are not expected to be important. Moreover, concerning precious jewellery, a delay of 6 months is not considered to have significant impact, as the use of lead and its compounds in this sector is expected to be marginal.

E.2.2.1.2.2. Technical feasibility

Based on reasons exposed in Section E.2.1.1.2.2 (technical feasibility of option 1) and on the fact that the presence of lead in precious jewellery is supposed to be marginal, **option 6 also appears to be technically feasible.**

E.2.2.1.3. Other issue

Not relevant for this proposal.

As a conclusion, option 6 is considered to be effective since it is targeted to the identified risks and to the actors of the supply chain associated to the risk. It is expected to reduce children’s exposure to lead, resulting in the reduction of health risks and it is expected to be technically and economically feasible.

E.2.2.2. Practicality

E.2.2.2.1. Implementability

No significant difference of implementability is identified compared to option 1.

E.2.2.2.2. Enforceability

As lead migration rate measurement methods are the same for fashion and precious jewellery, no significant difference of enforceability is identified compared to option 1 for restriction. The proposed method is the same as the one proposed for option 1 (see section E.2.1.2.2) with the same proposals for adaptations. The same difficulty as mentioned for option 1 is foreseen considering the variability of the results of the measurement of a jewellery surface area (more details are presented in section E.2.1.2.2).

Possible additional costs of control for authorities may be envisaged as they will have to include precious jewellery in their control campaigns. However, it may be expected that authorities responsible for the enforcement of the restriction will concentrate their efforts more on the fashion jewellery sector than on the precious jewellery sector, as lead and its compounds are suspected to be more present in the articles of the former sector.

E.2.2.2.3. Manageability

Concerning manageability, option 6 is expected to fulfil this criterion in a better way than option 1. Indeed, in the case of option 1, an important issue was highlighted concerning the identification of the articles which are targeted in this option: in the absence of a clear definition of what fashion jewellery is, difficulties were foreseen concerning a clear definition of the scope of the restriction. **In option 6, with an enlargement of the scope to precious jewellery, the scope of the restriction is much clearer and this option is consequently expected to be more manageable than option 1.**

As a conclusion, option 6 is considered to be practical.

E.2.2.3. Monitorability

E.2.2.3.1. Direct and indirect impacts

No significant difference in monitorability is identified compared to option 1 as it is expected that authorities responsible for the enforcement of the restriction will concentrate more on the fashion jewellery sector than on the precious jewellery sector.

E.2.2.3.2. Costs of the monitoring

Costs of monitoring are expected to be comparable to the ones of option 1.

E.2.2.4. Overall assessment of restriction option 6

The overall assessment of option 6 is summarised in Table 51.

As indicated in the previous sections, option 6 was identified after the end of consultation of MSCAs and industry actors. However, as option 6 only differs from option 1 in the sense that it includes precious jewellery in addition to fashion jewellery, it is expected that MSCAs would support it in the same way as option 1. Considering the fact that the presence of lead is negligible and marginal in precious jewellery (according to an Italian Federation of precious jewellery manufacturers), it is expected that industrial actors would also support it in the same way as option 1.

One of the main foreseen difficulties for option 1 which was the lack of definition for "fashion jewellery" is thus circumvented with option 6. However option 6 presents the same issue with the difficulties related to the measurement of the surface area of a jewellery article.

E.2.3. Restriction option 2: Restriction on the use and placing on the market of fashion jewellery based on the lead content

SEAC has assessed only the Economic feasibility of this restriction option.

E.2.3.1. Proportionality

E.2.3.1.1. Economic feasibility

This analysis of costs is meant to illustrate the likely order of magnitude of the costs related to the restriction of lead in jewellery. The calculations attempt to give some perspective on the proportionality of costs and benefits on a relative basis. The analysis is partial and does not cover all elements that might be covered in a complete evaluation. In particular, not all cost impact categories have been analysed due to a lack of data, and it has been necessary to rely on assumptions and simplifications that are required to make the analysis tractable in the absence of some key data and information. Furthermore, the boundaries of analysis are limited in terms of the scope of the restriction (e.g precious metal jewellery are (realistically) assumed to contain no lead and thus incur no regulatory costs) and the accounting stance taken, which does not differentiate between cost impacts that might be incurred within the EU or outside of the EU.

In a recent analysis of impacts from a similar EU Restriction on Cadmium in Jewellery (RPA, 2010), the lack of specific data and information on many of the parameters needed to estimate costs was deemed to be sufficiently difficult that no estimation was attempted. Therefore the results of this analysis should be treated with caution and considered in context. The analysis is undertaken on a per annum (annual cost) basis for a non-specific date after entry into force of the restriction. Baseline data and information is taken from the period 2008-2010.

It is assumed that for the purposes of this analysis the price differences are small enough that firms or consumers would not reduce the overall number of pieces of jewellery sold. In other words, the income or price elasticities of jewellery are not taken into account as their impact is conjectured to be small. This is also according to the cost guidance of the restriction proposals.

It has not been possible to estimate some cost items. These are described below for completeness.

Supply and Distribution costs; Manufacturers may have to spend time and resources finding new suppliers for substitute inputs. Manufacturers may have to find alternative markets for products which exceed the proposed lead restriction limits and which continue to be produced. Finally importers, retailers and distributors may have to find suitable suppliers to replace the supply of products that exceed the proposed lead restriction limits

Reformulation/re-design costs; Manufacturers may have to re-formulate and/or re-design their products in order to ensure that they do not exceed the proposed lead restriction limits. For example, this may involve research and development costs related to determining how their products would have to be altered in order to meet the restriction.

Facilities and Equipment costs; Manufacturers may require additional equipment and/or changes to their facilities to ensure products do not exceed the proposed lead restriction limits.

Compared to the compliance cost (i.e. higher price of fashion jewellery) as a result of a restriction the above costs are considered to be small.

The basic assumptions concerning the jewellery market have been given in Section B.

Table 53: Number of items of jewellery placed on the market annually in the EU (2010) assuming that 10% of jewellery contain lead (million)

Imported jewellery	EU produced jewellery	Total	Of which, jewellery containing lead
1 400	100	1 500	150

Source: Section B.2

Average lead concentration in the jewellery was estimated at 6%. This is used for a central and upper bound estimate as it is not conjectured that the average lead content could be higher. However, a lower bound estimate of 3% is used for sensitivity analysis.

Unit cost of jewellery

It was not possible to obtain accurate data on the average production cost of costume jewellery sold in the EU (in order to base estimation on the incremental production cost of substituting lead in costume jewellery). However, data were available on the value of costume jewellery imported into the EU. This could be used as a proxy of the production cost (taking into account the various mark-ups/margins on production cost). According to CBI (2009), the import value of costume jewellery imports to the EU (including intra EU imports) is €2.352 billion (import volume, including intra EU imports = 104,590 tonnes). Assuming an equal value per tonne between all costume jewellery imports and non-intra EU imports, then the import value of non-intra EU imports is (70000 t ÷ 104590 t) x €2.352 billion = €1.574 billion per annum.

Based on the number of articles of costume jewellery imported into the EU estimated earlier at 1.4 billion articles per annum[52], the average value of an imported costume jewellery article is (1.574 ÷ 1.4) = €1.12 in 2007 price level, **being €1.19 in 2010 price level[53].** This figure is used in the subsequent analysis as an anchor for the estimation of incremental production costs (taking into account markups/margins, etc) for imported costume jewellery.

For EU produced fashion jewellery Table 11 was used as the basis for estimating the average cost of jewellery in the market segment that is likely to be relevant for the analysis. It was shown that the average price of a relatively cheap (under €30) jewellery item was €7 (including VAT). Adjusting this cost to 2010 price level and removing the VAT, a comparable cost to imported items was established. **The same €7 per jewellery** item was used in the cost analysis for domestically produced jewellery. It should be noted that there are more expensive fashion jewellery made in the EU. However, these are likely to be of such a (high) quality that they would not contain lead.

Additional costs of lead free jewellery

Higher (incremental) production costs resulting from the use of higher priced substitute inputs (lead free alloys) to meet the proposed restriction requirements will be incurred. These costs would initially be met by manufacturers. These costs are expected to be passed onto importers, retailers and ultimately to consumers as the jewellery markets are not known to have any particular distortions.
The impact on production input substitution costs will depend on a number of parameters, including:

[52] It should be noted that CBI (2009) quotes a total figure of 200 million articles of jewellery sold in the EU, and hence the use of a figure of 1.4 billion articles used here alongside the import value figure derived from CBI (2009) would seem to be inconsistent. However for reasons explained elsewhere in this document, as well as the fact that CBI (2009) does not explicitly link the number of articles with the import value, the estimate of 200 million is considered to be a significant underestimate of total jewellery and more likely to relate to EU produced jewellery sales.

[53] Evidence for a figure of €1.19 as being in the right ball park is furthermore suggested by comments made in the public consultation on the lead in jewellery restriction (JDA, 2010), which gives a cost figure of €0.43 – €1.30 per item of jewellery.

- The proportion of items currently containing lead was suggested to be around 10%, (see above).
- The lead concentration in the jewellery was assumed to be around 6% (see above).[54]
- The price difference between alloys that contain lead and those that do not was assumed to be 8%. For sensitivity analysis an upper bound of 30% higher (see section C.7) and 30% lower from that central estimate has been applied to illustrate the sensitivity of price difference of alloys to the fluctuations of world market prices of metals. This is based on the difference due to metal prices of 9.5 % as described in Table 50 and adjusted for the fact that the metal is only a part of the raw material cost in alloys and the differences in densities of the metals involved[55].
- The proportion of production costs accounted for by the casting metal component of the jewellery. Whilst no specific information is available on the average proportion typically found for costume jewellery, anecdotal evidence from CBI (2009) suggesting a figure of around 30% may be plausible[56].

The approach to estimation of production input substitution costs uses the average value of a costume jewellery article imported into the EU as an anchor for estimating the cost of production inputs. Substitution costs are then estimated as follows:

- The average import value of a costume jewellery article is estimated above (see above) at €1.19.

- As discussed above, the cost of the casting metal component in an article of costume jewellery is assumed to account for around 30% of the import value. Furthermore, the price difference for a lead free alloy over a lead containing alloy was reported to be around 8 % of the wholesale price of such alloys. The incremental production substitution cost of replacing lead containing alloys is thus estimated at around 3% of the average import value[57]. Nevertheless, the use of lead free alloys may also involve further costs in terms of other input production process changes due to the use of an alternative alloy (e.g. increased energy required to melt higher melting point lead-free alloys, etc). These are not included in the central estimate of the increase to the material costs, but rather are factored into the sensitivity analysis undertaken later[58].

The average incremental production input cost of substituting lead based alloys in costume jewellery per article is thus estimated (in 2010 price level) at: (8% x 30% x €1.19) = €0.0286. A lower bound

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[54] Documented concentrations (naturally) vary considerably above and below this average. Where lead is present as a component of a specific alloy used in the manufacture of costume jewellery, the entire alloy will need to be replaced with a lead free variant. Although lead may also feature in other uses in the manufacture of costume jewellery (e.g. solder, etc), this analysis only considers its function as a casting metal component of the jewellery.

[55] The density of lead is 11.3 g/cm3, tin 7.3 g/cm3, antimony 6.7 g/cm3 and copper 9.0 g/cm3 (weighed average - 7.3). Therefore the difference in material need for jewellery where the volume and not the weight would be the relevant substitution parameter would be 35 % lover.

[56] CBI (2009) provides an illustrative example of the margins involved in calculation of final consumer price – this suggests that material costs make up around 30% of import (CIF) value, though this will clearly depend on the type of article, etc, as well as the general price level of metals (taking note of the discussion on uncertainty in the price level of metals in section C7).

[57] It should be noted that this estimate is rather conservative compared to one estimate of the additional cost of higher material costs reported in Health Canada (2009), This reported the response of one Canadian manufacturer who estimated additional costs of between 375 and 525 dollars per year from higher material costs, based on a level of annual sales of jewellery of 5000 dollars (ie additional costs from higher materials costs of around 10% of sales value).

[58] It should also be noted that the analysis does not take into account factors such as the fact that lead and lead free alloys may have different densities and hence different volumes would be required to produce the same quantity of costume jewellery. Again the sensitivity analysis can be used to incorporate such uncertainties.

estimate of 20% was used in conjunction with the assumption that the average lead content would be only 3% in fashion jewellery placed on the market in the EU.

For EU produced jewellery it was conjectured that a similar increase in the production costs would incur due to increased price of the alloy. The share of raw material cost in jewellery was thought to be lower in the EU (due to higher labour costs and the fact that the design of the jewellery pays a more important role in the value added). The share was estimated to be 6%. Given the uncertainties with this figure an upper bound estimate of 30% higher (see section C.7) and a lower bound estimate of 30% lower was used to illustrate the effect of fluctuations in world market prices of metals. The Central estimate of the increase per fashion jewellery was thus (8% x 6% x €7=) € 0.034.

The calculations to estimate the total additional production input substitution cost of replacing lead containing alloys in all fashion jewellery articles sold in the EU are shown in Table 54 and Table 55.

Table 54. Total additional cost of substituting lead for fashion jewellery assuming that 140 million pieces of imported fashion jewellery with an average cost of €1.19 and 6% (or 3%) average lead content were replaced by lead free jewellery. Costs are for all lead free fashion jewellery placed on the market in one year.

Uncertainty	Average % of lead in jewellery (that contains lead)	Share of raw material cost in jewellery (%)	Additional cost for lead free alloys	Additional cost per jewellery item containing lead (€)	Total additional cost of substituting lead for fashion jewellery (€000)
Lower bound	3 %	20 %	5.6 %	€0.013	€1 871
Central case	**6 %**	**30 %**	**8.0 %**	**€0.029**	**€4 009**
Upper bound	6 %	30 %	10.4 %.	€0.037	€5 212

Table 55. Total additional cost of substituting lead for fashion jewellery assuming that 10 million pieces of EU produced fashion jewellery with an average cost of €7 and 6% (or 3%) average lead content were replaced by lead free jewellery. Costs are for all lead free fashion jewellery placed on the market in one year.

Uncertainty	Average % of lead in jewellery (that contains lead)	Share of raw material cost in jewellery (%)	Additional cost for lead free alloys	Additional cost per jewellery item containing lead (€)	Total additional cost of substituting lead for fashion jewellery (€000)
Lower bound	3 %	4.2 %	5.6 %	€0.016	€165
Central case	**6 %**	**6.0 %**	**8.0 %**	**€0.034**	**€336**
Upper bound	6 %	7.8 %	10.4 %	€0.057	€568

The total additional production input substitution cost of replacing lead containing alloys in all fashion jewellery imported into the EU is estimated at € 4.0 million in the central case. The total additional production input substitution cost of replacing lead containing alloys in all fashion jewellery produced in the EU is estimated at € 0.3 million in the central case.

Product testing costs

Under the proposed restriction, although products do not require to be certified as being in compliance by an accredited 3rd party, suppliers (retailers, wholesalers, importers) will nevertheless have a 'due diligence' duty to ensure that their products are in compliance with the legislation. Suppliers will also have to ensure, and where necessary prove to authorities, that they have taken all reasonable steps to avoid an offence being committed. As discussed by RPA (2009), what constitutes 'reasonable steps' will depend on the company's circumstances, such as the size of its operation and its position in the supply chain. The presence of lead will need to be traceable along the supply chain. Jewellery manufacturers may need to contact their suppliers to obtain evidence (such as a certificate) that their products meet the lead restriction requirements. Likewise, importers, distributors, and wholesalers will need to make enquiries to ensure they are in conformity. In the absence of such information or certification, the supplier will need to ascertain via alternative means whether the articles can be supplied on the market. The main mechanism for doing so will be by testing article samples. Such testing could be carried out by the supplier themselves (if they have the necessary equipment) or by an accredited laboratory.

In order to estimate the costs associated with product testing, a number of assumptions and parameters are required as follows:

- The incremental number of lead concentration tests that would follow the introduction of the restriction – All jewellery articles will already be subject to compliance requirements regarding levels of cadmium in jewellery. As such, due to these 'overlapping' multiple legislative requirements, testing for lead concentration will not incur any incremental costs, since the screening tests (mainly based on XRF testing technology – see below) for cadmium concentration in jewellery will also screen for lead concentration. Furthermore, it is known that a certain amount of screening/testing is already undertaken on a voluntary basis[59]. However, in order to confirm that articles that in the XRF test were found to contain lead above the limit is in non-compliance it may still be necessary to undertake some proportion of ICP testing (for content based restrictions) and some proportion of migrations test if a migration limit applies to non-metal parts of jewellery. Such confirmatory testing costs would be incremental. Testing is done on the basis of samples of jewellery from production batches (see below). Although 10% of jewellery articles are currently estimated to contain lead, the number of non-compliant jewellery will decrease over time as compliance increases (with increasing awareness of the restriction and enforcement activity). For the purposes of this analysis, it is assumed that this falls to a steady state of 2% of jewellery. Furthermore, it is assumed that confirmatory testing will be required (following screening tests) on 10% of jewellery articles found to be non-compliant in screening if the restriction is based on content and 20 % if the restriction is based on migration approach and that all batches are screened. Although there is no specific evidence that 10% and 20% are appropriate figures for the proportion of non-compliant batches that would require confirmatory testing, it is known that such testing would only be required for samples for which the initial screening test indicated a value around the limit value (around which XRF screening tests may provide false positive and false negative results). Batches with a lead concentration well above the limit value would not require further confirmatory testing since the accuracy of XRF testing is sufficient at such higher levels. The average of 10% and 20% (i.e. 15%) is thus used as a conservative value, and include any confirmatory testing also undertaken by regulatory authorities for enforcement purposes (see next section).

[59] It is known that at just one (anonymous) commercial testing laboratory in one member state, around 7000 costume jewellery articles per year are currently being tested for lead concentration (Anonymous, 2010). The laboratory is in an EU country with no national legislation concerning lead in jewellery. Whilst it is thought that most of this testing is thus done on a voluntary basis, either so that those sending items for testing reduce their legal liability regarding any lead poisoning, or for public relations consideration, it may be the case that some testing is undertaken by domestic manufacturers wishing to export their products to countries with legislative requirements concerning lead in jewellery.

- The cost per test – As discussed above, only confirmatory tests following screening are considered to be incremental in this analysis. The principle type of test used to confirm lead concentration is ICP-OES. Costs associated with this test method have been reported by RPA (2009). Based on this and more recent evidence obtained for the present analysis (personal communications, 3 Anonymous Testing Laboratories), the cost per test for ICP-OES testing is estimated at around €30 per jewellery part. It is assumed that the updated migration test would cost the same.

- The number of production batches of costume jewellery sold in the EU – The number of costume jewellery articles sold in the EU per year was estimated at 1.5 billion (see previous section). RPA (2009) report that a typical batch size consists of 10,000 articles (though this is not quoted as being an average size of batch). Other evidence (submitted during the public consultation for this lead restriction (JDA, 2010) suggest a typical batch size of 300-600 jewellery articles. For the purposes of this analysis, it is assumed that an average production batch size consists of 500 costume jewellery articles[60], such that the number of batches of imported jewellery is estimated at 3,000,000 batches[61].

The calculations to estimate the total annual incremental cost of costume jewellery testing sold in the EU are shown in the table below[62]. As shown in the central case, since the number of production batches on which confirmatory testing is undertaken by industry (manufacturer/importers/retailers) was assumed to be 15% of the production batches that are non-compliant (2%), **the total annual incremental cost of costume jewellery testing is estimated at = €270,000[63].**

Table 56: Total additional testing costs

	Range		
	Lower	**Central**	Upper
% of costume jewellery containing lead after implementation	1%	**2%**	3%
Share of jewellery ICP tested % (percentage in brackets relates to share if conformity testing of non-metals is done by migration test)	7%	**15%**	20%
Average cost per IPC test or migration test (€)	€30	**€30**	€30
Number of batches with lead after	30,000	**60,000**	90,000

60 The number of production batches will be greater than the number of 'style' batches.

61 Based on information from an industry expert (personal communication, 2010) there are approximately 400 importers importing around 800 batches of costume jewellery each year in the UK. This suggests around 320,000 batches are imported to the UK each year. If the UK represents around 20% of total EU imports then this would suggest around 1.6 million batches per year. The estimate of 3 million in the text is thus probably reasonable. Furthermore, evidence from http://handmadetoyalliance.blogspot.com/2010/02/allowing-xrf-testing-for-cpsia.html suggests that there are around 1 million jewellery products on the market in the US. If this is true then, even though this includes all jewellery products (not just costume jewellery), it would seem reasonable that the number of production batches of costume jewellery would be at least of a similar order of magnitude.

62 It should be noted that the present analysis does not include any incremental screening costs that might arise (for example if projected levels of cadmium testing are insufficient to ensure sufficient testing is undertaken to ensure compliance with lead in jewellery restriction, or if additional fees are charged for XRF testing of more than one metal). Furthermore, possible reactions of industry (especially SME's) are not known and have not been able to be incorporated into the analysis. For example, if XRF screening costs are in fact found to be incremental and significant, then industry may react by reducing the level of overall testing (and hence the level of compliance with the restriction), etc.

63 15% x 2% x 3,000,000 x €30=€270,000

implementation (500 per batch)			
Additional cost per jewellery item containing lead (€)	€0,004	**€0,006**	€0,012
Total additional testing cost (€000)	€63	**€270**	€540

The table below summarises the total compliance costs per annum based on Table 54, Table 55 and Table 56.

Table 57: Total compliance costs per annum (€000) – central case as well as lower and upper bound

	Lower bound	**Central case**	Upper bound
Substitution cost of imported fashion jewellery	€1 871	**€4 009**	€5 212
Substitution cost of EU produced fashion jewellery	€165	**€336**	€568
Testing cost	€63	**€270**	€540
Total	**€2 099**	**€4 615**	**€6 320**

E.3. Comparison of the risk management options

Restriction options 1 and 6 were compared as regards the three mentioned criteria and scored in the following table. Economic feasibility of the option 2 was analysed by SEAC.

Table 58: Overall assessment of restriction options 1 and 6 proposed by the French CA

	Effectiveness		Practicality			Monitorability	
	Reduction risk capacity	Prop. to the risks	Implement.	Enforc.	Manag.	Direct and indirect impacts	Costs of monit.
Restriction option 1	+++	Economic feasibility ++ Technical feasibility ++ Targeting to the risk +++	++	+(+)	++	+++	++
Restriction option 6 (the proposed restriction by the French CA)	+++	Economic feasibility ++ Technical feasibility ++ Targeting to the risk +++	++	+++	++	+++	++

+++ criterion fully met
++ criterion partly met
+ criterion barely met

Based on a qualitative ranking, restriction options 1 and 6 seem to fulfil all criteria in the same way except for enforceability. For this criterion, option 6 which has a better defined scope is more appropriate. As a conclusion, option 6 is the proposed restriction by the French CA.

To conclude this section, an amendment to REACH Annex XVII would allow a stable legal solution to manage the identified risks (lead poisoning of children resulting from the ingestion and from the mouthing of jewellery articles) and to provide a secure legal framework for firms producing and placing on the market jewellery articles.

RAC conclusions

Basically, RAC agrees in general with the French evaluation regarding the different options to restrict lead in jewellery although it points out that the restriction should apply to the metallic and the non-metallic parts of jewellery.

In addition, based on a re-evaluation of the data and taking into account the second Forum advice "*In accordance with the 1st advice given by the Forum, the Forum prefers that the limit value for lead does not refer to migration but to the content of lead since this is more practical for enforcement.*" RAC is proposing a limit for the metallic and the non-metallic parts based on lead content which can be overridden if the migration rate is not exceeded.

SEAC conclusions

SEAC agrees with RAC that for metallic parts a restriction based on the content of lead is the most appropriate community wide measure to address the risk from jewellery containing lead.

For non-metallic parts of jewellery SEAC has not been able to evaluate the consequences of introducing a restriction neither based on content nor migration. However, taking into account Forum advice (see above) and that in e.g the USA the regulation on jewellery containing lead is based on content, which also applies to the non-metallic parts of jewellery, SEAC concludes that the restriction of lead also in non-metal parts of jewellery should be based on content and SEAC recognises that the value recommended by RAC of 0.05% is practical and a less costly method to implement than a migration test. This is also supported by the comments received via the public consultation, which highlighted practical problems related to the migration measurements.

RAC has based its risk assessment for lead in jewellery on the assumption that a child is mouthing 10 cm^2 of the metallic parts over 1 hr per day. As compared to the metal parts of jewellery the health impact of lead exposure from crystals is considered to be relatively small, because there are indications of much lower migration rates. Furthermore it is not technically feasible to replace lead from 'full Lead Crystals' and 'Lead Crystals' as defined in no. 1 and 2 in Annex I to Council Directive of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (69/493/EEC). For crystal glass as defined in no. 3 and in the Annex I to (69/493/EEC) other metal oxides might by used and therefore lead is not required. There are indications that lead may be present as a naturally occurring constituent in precious and semiprecious stones. SEAC considers that it would be disproportionate not to allow such stones to be used in jewellery, based on analogous argumentation used to justify the derogation for crystals. However, precious or semiprecious stones are sometimes treated with lead containing materials. As SEAC considers that other treatment methods are technically and economically feasible, this derogation should not apply if these stones are treated with lead or its compounds, as well as mixtures containing these substances.
For practical reasons, SEAC recommends using the same definition for jewellery articles that is used for the similar restriction of cadmium in jewellery.

E.4. Main assumptions used and decisions made during analysis

For transparency the assessment conducted by the dossier submitter is copied below. It should be noted that the RAC and SEAC opinion suggests a modified option due to the reasons presented above.

The restriction proposal was developed in a way which is as transparent as possible. Stakeholders' consultation is fully reported in section G and so are the outputs of this consultation.

Main assumptions used and decisions made during the analysis are the following;

The smallest measurable variation of blood lead level has been used as a basis for the derivation of a chronic DMEL.

PBPK models have been used to link blood lead level with a quantity of ingested lead for the derivation of the acute DNEL and of the chronic DMELs.

Assumptions have been made on the parameters used in the exposure assessment, such as duration of mouthing of a jewellery article, surface of a jewellery article which is in contact with the mouth for the "use 1", time during which the ingested jewellery remains in the stomach for the "use 3", etc.

A conservative approach is used for the testing method: the migration test simulates gastric compartment whereas, while mouthed, the jewellery is supposed to release lead in the saliva in quantities which are expected to be lower than in the gastric compartment.

It has been assumed that the surface of a jewellery article can be measured in order to calculate a lead migration rate in µg/cm²/hr; which may be difficult in practice for jewellery with an uncommon shape, as reported during consultation of SCL (see section G.4.2) following experience gained with the nickel restriction in jewellery (entry #27 of the REACH Annex XVII).

It has been assumed that the proposed restriction does not impact the sector of crystal glass. By definition, crystal glass contains high levels of lead (from 6% to about 30%). However, considering the stability of such material, it is not expected that these high content levels result in a lead migration rate which would be above the restriction limit. In case the proposed restriction would impact the industrial actors who use crystal glass in jewellery articles, it is expected that these actors will comment on the restriction proposal, during the public consultation period, with information on the potential release of lead by this type of products. In this case, the necessity to add a derogation to the proposed restriction could be analysed for this specific type of glass.

It has been assumed that the proposed restriction does not impact the sector of jewellery articles made with treated stones. Treated stones are gemstones which have been treated to enhance their appearance (colour, brightness, etc.). Lead is often used to treat gemstones in order to obstruct clefts and hide colour defaults (like rubies filled with leaded glass). This proceeding makes also the treated gemstones cheaper. As lead is set into a glass matrix, it is expected that it will impede its migration and that lead migration rate would not exceed the restriction limit. However, as for crystal glass, in case the proposed restriction would impact the industrial actors who use treated stones in jewellery articles, it is expected that these actors will comment on the restriction proposal, during the public consultation period, with information on the potential release of lead by this type of products. In this case, the necessity to add a derogation to the proposed restriction could be analysed for this specific type of use.

It has been assumed that the proposed restriction does not impact the sector of jewellery articles made of glaze. As for crystal glass and treated stones, in case the proposed restriction would impact the industrial actors who use glaze in jewellery articles, it is expected that these actors will comment on the restriction proposal, during the public consultation period, with information on the potential release of lead by this type of products. In this case, the necessity to add a derogation to the proposed restriction could be analysed for this specific type of use.

The lead content of a jewellery article is not considered to be representative of the potential exposure of a child accidentally ingesting or mouthing the jewellery, contrary to the lead migration rate.

Percentage of lead in precious jewellery with gemstones, enamels and pearls, or other precious metals added to the precious metal manufactured products, is considered as negligible and marginal. This assumption is based on information provided by a federation of precious jewellery manufacturers. Considering this assumption, impact of the proposed restriction on the sector of precious jewellery is expected to be minimal.

Many other small articles possibly contain lead and its compounds (such as key rings and coins for instance). Their misuse by children (accidental ingestion and mouthing) may result in the same risks as the ones identified in this dossier. Decision was made not to include them in the scope of this restriction. However, it is highlighted that such small articles also represent a potential health risk for the vulnerable population constituted by children under the age of three.

E.5. The proposed restriction and summary of the justifications

Considering:

- The **severity and irreversible characteristic** of risks associated with an exposure to lead, especially for **children;**
- The fact that **jewellery with a high lead exposure potential** (due to high lead content and or migration rate) can be placed on the market without any control;
- The fact that **such health risks cannot be managed by policy options other than the restriction** under REACH;

The restriction is considered to be the only adequate tool to manage the risks posed by lead and its compounds in jewellery articles.

As presented in section A., the proposed restriction, its conditions, scope and justifications are the following.

Conditions and the scope of restriction (RAC opinion)

RAC proposes to limit the lead content in jewellery. Specifically the proposal is to restrict lead content in jewellery articles and any parts thereof to 0.05%, unless it is demonstrated that the migration rate of lead release from jewellery articles does not exceed 0.05 µg/cm²/hr (0.05 µg/g per hr) for both metallic and non-metallic parts.

Formally transposed in Annex XVII, the proposed restriction is the following:

Designation of the substance, of the group of substances or of the mixture	**Conditions of restriction***
Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	Shall not be used or placed on the market in i. Metallic and non-metallic parts of jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of the part; ii. The paragraph above does not apply, when it can be demonstrated that the rate of lead release from the jewellery article or any part

	thereof does not exceed 0.05 $\mu g/cm^2/hr$ (0.05 µg/g per hr)

The restriction shall apply to all jewellery (**both precious and fashion jewellery**) **whether they are intended for children or not.**

No derogation is proposed by RAC in this restriction.

According to RAC the lead content of 0.05% or the migration rate of 0.05 $\mu g/cm^2/hr$ (**0.05 µg/g per hr) should be considered for each individual part of the jewellery.** When tests are performed on several parts of an article, the analytical results of each part should be compared to the limit of 0.05% or 0.05 $\mu g/cm^2/hr$ (0.05 µg/g per hr) as appropriate. If a part has a content or migration rate which exceeds this limit, it should be considered that the article is not allowed to be used or placed on the market.

For metallic parts, examination regarding lead content can be done in a non-destructive way using X-ray fluorescence (XRF) devices. Thus only in relevant occasions a destructive standard wet chemical analysis has to be performed.

For the migration rate measurements, France as a dossier submitter proposed to use the available standard **EN 71-3** which is already used for testing the migration of certain elements from toys. Several adaptations have to be considered. First, as mouthing activity can result in significant exposure, jewellery articles should be tested even if they cannot be ingested by a child because of their size, i.e. even if they do nor fit in the so-called "small parts cylinder" referred to in EN 71-3 (and defined in the standard EN 71-1-A9). RAC recognises that further work has to be done in order to specify how the testing for content as well as for migration should be performed. RAC emphasises that reliable methods to determine migration rates from jewellery especially at lead concentrations below 1% need to be established. The migration test should be modified to mimic mouthing conditions instead of using artificial gastric fluid, and should be performed after the item has been subjected to a wear test (EN 12472).

Conditions and the scope of restriction (SEAC draft opinion)

Designation of the substance, of the group of substances or of the mixture	**Conditions of restriction**
Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be used or placed on the market in jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of any part of the jewellery article. 2. By way of derogation, paragraph 1 shall not apply to i) "Full Lead Crystal" and "Lead Crystal" as defined in Annex 1 in Council Directive 69/493/EEC[64]. 11) Precious and semiprecious stones (CN code[65] 7103) unless they have been treated with lead or its compounds or mixtures containing these articles.

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

	3. By way of derogation, paragraphs 1 shall not apply to jewellery articles placed on the market before [[12-18] months after the entry into force] and jewellery more than 50 years old on [the date specified in the restriction on cadmium].

The definition of jewellery articles will be codified on the basis of the restriction concerning cadmium in jewellery. The definition from the cadmium restriction relates to jewellery and imitation articles and hair accessories, including bracelets, necklaces and rings, piercing jewellery, wrist-watches and wrist wear, brooches and cufflinks.[66]

SEAC considers that the restriction based on content measurement using the 0.05% as proposed by RAC for the metallic parts of jewellery articles it most practical and less costly method to implement.

For non-metallic parts of jewellery SEAC has not been able to evaluate the consequences of introducing a restriction neither based on content nor migration. However, taking into account Forum advice and that in e.g. USA the regulation on jewellery containing lead is based on content which also applies to the non-metallic parts of jewellery, SEAC recommends that the restriction of lead also in non-metal parts of jewellery should be based on content and proposes to use the same content limit than for metallic parts of jewellery articles. However, it is proposed to exempt crystals and precious and semiprecious stones (see above) from the restriction.

RAC has based its risk assessment for lead in jewellery on the assumption that a child is mouthing 10 cm^2 of the metallic parts over 1 hr per day. As compared to the metal parts of jewellery the health impact of lead exposure from lead crystals is considered to be relatively small, because there are indications of much lower migration rates. Furthermore it is not technically feasible to replace lead from lead crystals.

There are indications that lead may be present as a naturally occurring constituent in precious and semiprecious stones. SEAC considers that it would be disproportionate not to allow such stones to be used in jewellery, based on analogous argumentation used to justify the derogation for crystals. However, precious or semiprecious stones are sometimes treated with lead containing materials. As SEAC considers that other treatment methods are technically and economically feasible, this derogation should not apply if these stones are treated with lead or its compounds, as well as mixtures containing these substances.

Summary of the justifications

- Severe and irreversible effects on children's health are associated with an exposure to lead.
- Since the past few years, feedbacks from studies and surveillance activities from EU and worldwide health institutes and agencies have reported several serious alerts of children poisoned by lead and/or its compounds resulting from a misuse (ingestion/mouthing) of small articles, such as jewellery (see Section B.5.3.1). Moreover, many reasons exposed in Section

[65] Commission Regulation (EU) No 861/2010 of 5 October 2010 amending Annex I to Council Regulation (EEC) No 2658 on the tariff and statistical nomenclatures and on the Common Customs Tariff.
[66] At the time of agreeing the draft opinion (11 March 2011) the European Parliament is scrutinising the restriction on cadmium in jewellery.

A.2 suggest that the few cases documented are only a small proportion of the actual number of children poisoned by this kind of articles.

- This restriction proposal does not focus only on jewellery intended for children since it is recognized that children may come into contact with adult jewellery which contains lead.
- Restriction proposal by RAC is based on the lead content of the jewellery article which is considered to be an appropriate Community-wide measure. However RAC considers that in case the content is higher than the proposed limit value, it is possible to use a limit value for migration to demonstrate the sufficient level of protection. SEAC proposes a restriction to be based only on content of lead in jewellery articles as it is easier to measure in practice. Derogation for crystals and precious and semi-precious stones are proposed, as well as for jewellery more than 50 years old.
- To manage the identified risks in an efficient way, action is required at Community-wide basis because of the severity and the extent of the risks and because of the negative effects independent national actions would have on industry actors and on the internal market.
- A restriction under REACH is considered to be the most appropriate Community-wide measure as regards effectiveness, practicality and monitorability. A detailed analysis of these criteria is available in section E.

It needs to be highlighted that several studies suggest that leaded waste materials such as lead battery waste and solder materials might be recycled in consumer products such as jewellery (Weidenhamer J.D. and Clement M.L. (2007a); Weidenhamer J.D. and Clement M.L. (2007b); Fairclough G. *et al.* (2007)). Consequently, **it is also necessary that adequate regulations manage a responsible recycling of leaded wastes.**

In the same way, because of the very high quantities of articles which are placed on the market, their great variety and the diversity of their origins, **a quality control of the whole supply chain is absolutely necessary so that the restriction measure can efficiently manage the targeted health risks.**

F. Socio-economic Assessment of Proposed Restriction

RAC has not commented this section of the Background document.

F.1.1. Partial Cost-Benefit Analysis of restricting jewellery containing lead

F.1.1.1. Introduction

The purpose of this partial CBA is to compare the benefits of restricting the manufacture and sale of jewellery containing lead with the costs of such a restriction.

It should be noted that the analysis is meant to be illustrative and not necessarily a reflection of reality. The analysis is partial and does not cover all elements that might be covered in a more realistic evaluation. In particular, the analysis that only takes into account effects on lifetime earnings related to cognitive ability (IQ) impacts as a result of children's mouthing (non-ingestion) behaviours between the ages of 0.5 to 3 years. Furthermore, a number of other benefits of reducing lead exposure are not included in this analysis, such as those related to non-cognitive functioning and other health related endpoints (Cardiovascular Morbidity and Mortality), delinquent behaviour and crime, as well as any health care costs associated with exposure (Gould, 2009, Robinson, 2007). The analysis is partial also in that it does not consider possible benefits in relation to ingestion (swallowing) of jewellery, exposures to older children, as well as, worker protection during manufacture. In comparing the benefits with the costs, it should be noted (as described in the costs analysis - see section E.2.3), that a number of costs elements have also not been able to be estimated or included in the analysis. As such, this analysis does not necessarily provide a scientifically robust assessment of all impacts, but rather is intended to give some perspective on the order of magnitude of the most important elements, such that the proportionality of costs and benefits can be considered on a relative basis.

The general approach taken to this cost-benefit exercise is firstly, to calculate, on the basis of the reduction in lifetime earnings per IQ point lost, the ‘break even’ level of cognitive ability (IQ) impacts that would equate with the total additional cost of restricting the use of lead in the production of jewellery consumed in the EU. The corresponding blood lead level and aggregate lead intake exposure in the population of children that would result in such a ‘break even’ level of IQ impacts is then estimated. Finally, a number of exposure ‘profiles’ that would give rise to such a lead intake in the population of children are derived, and a comparison made with corresponding benchmarks of actual ‘mouthing’ exposure behaviours related to jewellery containing lead.

F.1.1.2. Costs of Restricting the Manufacture and Sale of Jewellery containing lead

As described in detail in section E2.3.1.1, the total costs of restricting the manufacture and sale of the 10% of costume jewellery articles containing lead in average concentration of 6% is estimated (for the purposes of the present exercise) at €4.6 million per annum (with a lower estimate of €2.1 and a higher estimate of €6.3 million per annum) (see .

F.1.1.3. Valuation of the Reduction in Lifetime Earning Per IQ point and the ‘break even’ level of Cognitive Ability (IQ) impacts[67]

[67] In this analysis, it is assumed that the consequence of lead exposure on IQ is irreversible, though work by Soong et al (1999) and Solon (2008) suggest support for the possibility that there may in fact be some degree of reversibility of IQ impacts. Furthermore, remedial action is often possible, and the costs of such action could be included in the analysis. However as discussed earlier, this analysis attempts to consider a somewhat restricted set of benefits.

Reduction in Lifetime Earnings per IQ Point

As reported elsewhere (EPA 2006), a large number of epidemiological studies have reported associations between lead and different measures of cognitive abilities that may affect educational and work-related achievements. Although the related benefits are typically described in terms of the effect of lead on IQ and earnings, in fact a number of interrelated neurological effects are encompassed, which impact on educational attainment, the likelihood of employment, earned income, and household production.

These effects and the corresponding impact of lost earnings and household production are important both to affected individuals, but also due to their impact on net national production. Although this 'human capital' perspective reflects a relatively narrow view of social welfare losses, available economic research provides little empirical data on society's willingness to pay to avoid a decrease in a child's IQ. The human capital perspective will only represent a component of society's WTP to avoid IQ decreases. As a consequence the effect on earnings may understate the impact on societal welfare, as measured by society's WTP. Nevertheless the impact on lifetime earning is a widely accepted measure of related benefits.

The relationship between earning and cognitive ability is in simple terms governed by the fact that earning are the product of the likelihood of employment and the wages earned if employed, which are both directly affected by cognitive ability. In addition, cognitive ability also affects education, which in turn affects wages and employment. As mentioned earlier, though not considered further here, there may also be other non-cognitive neurological effects of lead that can effect education and work. It should be re-iterated that the impact on lifetime earnings serves as a conservative (lower bound) estimate of the total value individuals place on changes in IQ, since they will value such changes independently of the impact on earnings. Furthermore, such impacts on earnings will not account for the value of uncompensated labour (work at home/volunteer labour), even though the value of such labour could be affected by changes in IQ.

Although there are many studies that have included estimates of the impact of IQ changes on lifetime earnings (Muir and Zegarac, 2001; Landrigan et al, 2002; Grosse, 2002; Rice and Hammitt, 2005; Trasande et al, 2005; Rosenblatt, 2007; Griffiths et al, 2007; Spadaro and Rabl, 2008; Pizzol et al (2010), these are all essentially based on estimates derived from two earlier studies by Schwartz (1994) and Salkever (1995). The estimates of the IQ premium in those studies, which were obtained by comparing lifetime earnings of individuals with different IQ levels, holding other factors, like occupation or age, constant found that each 1 point increase in IQ would increase lifetime earnings by around 1.8 to 2.3%. However, as discussed by Zax and Rees (2002), previous evidence regarding the relationship between intellectual capacity and earnings is not entirely consistent, Furthermore, recent analyses appear to cast some doubt on the earlier findings of Schwarz and Salkever (Grosse, 2007; Gayer and Hahn, 2007). Heckman et al (2006) for example finds, using improved measures to take account of the quality of people's education, that a 1% difference in cognitive ability made only a 0.6 % difference in hourly wages – less than a third of the Schwartz and Salkever range (though the Heckman et al findings are for young men, for whom the relationship between IQ and earnings is somewhat weaker than for older men, and women). Zak and Rees (2002), estimated the wage premium at 0,8 to 1.4 percent for men. Grosse (2007) in a recent review suggests that the association between cognitive ability and earnings found by Schwartz (1994) and Salkever (1995) appears to have been overestimated. In particular, it is suggested that Salkever reported direct effects of cognitive ability on earnings of men and women that are high relative to estimates from the labour economics literature (Kiker and Condon, 1981, Cohn and Kiker, 1986; Murnane, Willett and Levy, 1995; Bound, Griliches and Hall, 1986), One implication is that the environmental health studies based on the Schwartz and Salkever estimates are likely to have overstated the economic impact of changes in cognitive ability resulting from environmental exposures to children, particularly those studies that have used the Salkever estimates.

For the purposes of the present analysis, the value of earnings to be used to quantify the impact of changes in IQ on lifetime earnings is estimated using the analysis of Grosse (Appendix I in Haddix et al., 2003). In this analysis, earnings were comprised of two broad components: wages/fringe benefits and household production. Wage estimates were based on the Current Population Survey (U.S. Census, 2001 Supplement as cited in Grosse, 2003) and included salary income, overtime pay, bonus pay, and self-employment earnings. Fringe benefits included health insurance and retirement pay. Grosse assumed that the average person worked 250 days per year. Household production included a number of activities such as cleaning, cooking, and child care, for which individuals are typically not compensated but are known to be valued; he assumed that household services need to be performed every day. Combining the data for men and women and using a 3% discount rate, Grosse (2003) estimated the present value of labour market earnings over a lifetime of an infant was $692,000 (2000$). The discounted present value of an infant's lifetime labour market and household production was estimated to total $956,000 (2000$). Converting to Euros using Purchasing Power Parity adjusted exchange rates for 2000 and then uprating to 2010 price levels, suggests discounted present value of lifetime earnings of €761,100 and a discounted present value of lifetime labour market and household production of €1,051,758

Using the 0.8 to 1.4 percent wage premium for each 1 point increase in IQ estimated by Zak and Rees (2002) suggests that the reduction in earnings per IQ point is around €6,100 - €10,650, whilst the reduction in labour market earnings and household production is around €8,400 - €14,700. The central estimate of the value of the reduction in earnings per IQ point is thus assumed to be €10,000 (€2010)[68,69].

'Break even' level of Cognitive Ability (IQ) impacts

Given the above central estimate of the value of the reduction in earnings per IQ point, the 'break even' level of cognitive ability (IQ) impacts from mouthing jewellery containing lead, that would equate with the total additional cost of restricting the use of lead in the production of jewellery consumed in the EU each year equals [€4.6m/€10,000=] 460 IQ points.

F.1.1.4. Blood Lead Level and Aggregate Lead Intake in the Population of Children resulting in 'Break Even' level of IQ impacts

In order to calculate the increase in blood lead level and corresponding aggregate lead intake from mouthing jewellery containing lead that would result in the 'break even' level of IQ impacts, it is necessary to describe the relationship between lead intake exposures and IQ. This relationship is, in accordance with the approach taken by EFSA (2010), described in terms of a two step process that firstly requires a description of the dose-response relationship between IQ and blood lead level, and secondly a description of the relationship between lead intake exposure and blood lead levels.

As considered by EFSA (2010) and in accordance with the conclusion of RAC in section B of this background document, the dose-response relationship for low-level lead exposures and IQ is derived

[68] As there is no evidence to suggest that decreased IQ alters the components of household production (although it certainly may), the estimate including household production loss is not considered to be as appropriate as the labour market earnings reduction. Nevertheless the central estimate includes part of the estimated range that includes the household production component.

[69] It should be noted that WTP estimates for lead reduction suggest a somewhat lower, albeit uncertain estimate of impact. Agee and Crocker (1996) examine parental decisions in purchasing chelation therapy for their children. Chelation therapy reduces the lead in children's bodies. Lutter (2000) links this estimate of the willingness to pay for lead reduction in children to an estimate of the relationship between lead and IQ scores. He finds that parental choices on chelation therapy suggest a willingness to pay between €1,250 and €2,150 per IQ point (€2010).

from the findings of Lanphear et al (2005)[70]. The estimated relationship is given in terms of an inverse log-linear model, which was chosen by the authors as the preferred model for analyzing the quantitative relationship between IQ score and concurrent blood lead level. This was of the form:
IQ = α - 2.7 log (concurrent B-Pb) + γ confounders,

Based on this relationship, average IQ loss per 1 µg/L is estimated at 0.0513 IQ points for blood lead exposures below 100 µg/L[71] (assuming an even distribution of IQ loss in the range below 100 µg/L)[72]. This also follows the approach of Gould (2009). This converts to an expected loss of 1 IQ point per 19.48 µg/L blood lead level.

Turning now to the relationship between blood lead level and lead intake exposure, EFSA (2010) used the Integrated Exposure Uptake Biokinetic (IEUBK) model for lead in children to convert blood lead levels into intake exposure values. The IEUBK model is the most widely validated exposure assessment model, which uses a multi-compartmental model linking to an exposure and probabilistic model of blood lead distributions in populations of children 0-7 years[73].

Using the IEUBK model, the amount of incremental lead intake required to increase the estimated blood lead concentration by a given amount increases as the baseline blood lead concentration increases. This is because lead absorption is nonlinear with increased intake (ie, the degree of absorption decreases as the amount of lead intake increases). In order to estimate the incremental lead intake that would result in an expected increase in blood lead level of 19.48 µg/L, it is first necessary to consider the baseline of lead exposures from other sources.

As discussed in section B.4.11.2 of this document and section 7.5 of EFSA (2010), the principal source of daily intake of lead by children under the age of 36 months is from dietary sources. The average daily intake from dietary sources is estimated at 3.1 µg/kg bw/day (for an average child consumer – upper values), out of a total daily intake of lead from dietary and non-dietary sources of 3.955 µg/kg bw/day.

Using the IEUBK model (win version 1.1 build 11), the incremental lead intake from mouthing jewellery that would be required to increase the blood lead concentration by 19.48 µg/L of a child of

[70] The Lanphear (2005) study is based on a pooled analysis of a large number of children. The dose-response function between blood lead concentrations and IQ effects sis such that there are larger effects per unit increase in blood lead concentration at lower blood lead levels (ie a supra linear dose-response function). However evidence from other recent studies (Chandramouli et al., 2009; Surkan et al., 2007; Chiodo et al., 2007; and Kim et al., 2009) suggests some degree of uncertainty in the shape of the dose-response function and the apparent lack of a threshold at low blood lead levels,

[71] Although this does not fully describe the extent of the dose-response relationship for all exposure values, it is appropriate to use that portion of the dose-response curve that relates to low level lead exposures (<100 µg/L), as well as corresponding to the background levels of blood lead likely to be prevalent in the EU population of children (WHO, 2009).

[72] It should be noted that the approach taken by EFSA (and also as concluded by RAC) to derive a Benchmark Dose from the Lanphear et al (2005) dose-response relationship, would estimate a value of IQ loss per 1 µg/L that is based only on that part of the dose-response curve that is relevant to deriving a benchmark dose value. For the purposes of health impact assessment/expected disease burden analysis (Fewtrell et al, 2004) that is undertaken here, a 'best-estimate' of expected IQ loss per 1 µg/L for the dose-response curve below 100 µg/L is used instead, though this is of course still estimated on the basis of the same dose-response relationship used by EFSA (2010).

[73] According to EPA (2002), while the IEUBK model provides a fairly good estimate of risk from exposure to lead, as with all models, it has limitations to its use. In particular, it is suggested that the model should not be used for exposure periods of less than three months, or in which a higher exposure occurs less than one per week or varies irregularly. Whilst such concerns would not seem to apply to exposures related to food, it is unclear to what extent the same is true of exposures from jewellery items. Nevertheless, it is assumed that the lead intake from mouthing jewellery occurs on a regular basis over an extended period of time, such that the IEUBK model is appropriate for the present exercise.

average body weight of 12 kg[74], given a background daily intake from dietary sources of 3.1 µg/kg bw/day, is estimated to be 1.23 µg/kg bw/day[75].

Based on this daily intake of lead from mouthing jewellery, the aggregate intake of lead that would result in the 'break even' level of IQ impacts of 460 points can be estimated. However, before doing so it is first necessary to consider the time window during which exposure causes damage to IQ, since the 'break even' level of IQ impacts needs to be comparable to the costs on an annualised basis. The sensitivity of the brain to lead is greatest during the first 2 years of life, although the precise time distribution of the IQ damage is not known. The study by Lanphear et al (2005) found that the effect on IQ is highly correlated to four blood lead indices, including the concurrent (i.e. closest to IQ testing) blood lead level, peak blood lead level measured at any time before the IQ test, average lifetime blood lead level measured from 6 months to concurrent blood lead test, and early childhood blood lead concentration (defined as mean blood lead from 6 to 24 months)[76].

When estimating the daily lead intake in the IEUBK model a period of 1 year is used as the exposure period. Such an assumption allows the break even analysis to be expressed in terms of relevant exposure scenarios that are framed in terms of annual exposure parameters, thereby allowing direct comparability with the annualised costs, without the need to make any adjustments for differing time frames. However, the analysis considers IQ impacts to children between 6 months and 3 years (see later) as the relevant age that children are exposed. Although this does not necessarily imply that the relevant period of exposure 'sensitivity' that would give rise to IQ impacts is from 6 months to 3 years, for the purposes of the present analysis it is assumed that this is in fact the case[77].

[74] Average body weight of children of 0.6 months to 3 years (as the relevant group for which this analysis considers impacts – see later) is 12 kg.

[75] For the assessment of lead intake that would give rise to an expected increase in blood lead level of 19.48 µg/L, it has been necessary to make a number of simplifying assumptions when using the IEUBK model. It has been assumed that a 12 kg child is exposed during the age of 13-24 months only (ie a 1 year period). It has also been assumed that all routes of exposure other than dietary and mouthing of jewellery are negligible (and hence set to zero in the model). The oral absorption fraction of lead has been set at 50% for both dietary and mouthing jewellery intakes. In order to assess the intake of lead from mouthing jewellery that would result in a blood lead level of 19.48 µg/L a 'reverse modelling' process was used, whereby the parameter input for mouthing jewellery intake was changed until the requisite increase in blood lead level was reached - given the background daily intake of food of 3.1 µg/kg bw/day results in a blood lead level of 56 µg/L, then the jewellery mouthing intake was changed until estimated blood lead level reached (56 + 19.4=) 75.4 µg/L. Finally it should be noted that this approach to estimating the intake that would result in an increase in blood lead level of any given amount is static and assumes for example, that each subsequent incremental increase of a given blood lead level (beyond that resulting from the background dietary intake), requires the same lead intake as for the initial increase.

[76] It should be noted that given the assumption about exposure period and age of the child used in the IEUBK modelling exercise, it may be more appropriate to make use of the dose-response relationship between IQ score and early childhood blood lead level from the Lanphear et al (2005) study, than the relationship based on concurrent blood lead level, to estimate the daily intake of lead from mouthing jewellery. Nevertheless, for the present exercise we are restricted to using the dose-response relationship based on the use of the concurrent blood lead level. It is thought that although this may result in an overestimate of IQ impact per µg/L, the magnitude is small since the results of the regression analyses for the two blood lead measures were similar. As noted earlier in the main text, the concurrent blood lead level exhibited the strongest relationship with IQ and hence was the authors preferred model.

[77] For the purposes of the present analysis it is assumed that the estimate of IQ impact in a population, as outlined above, is consistent with a constant exposure. Furthermore, the half life of lead in blood is relatively short (WHO 1995). Therefore, although the IEUBK model indicates that a 1 year period of exposure (of a 12 kg child from 13-24 months) would increase blood lead level by 19.48 µg/L, it is assumed that for a corresponding loss of 1 IQ point, a period of exposure from 6 to 36 months is necessary. Furthermore, it is equally correct to assume for example, that the damage incurred during a 1 year exposure by children between the age of say 0 and 1 year only, is the same as the damage during a 3 year exposure between the ages of 0 and 3 years. The reason is that if the 'sensitive period' is only 1 year, then the IQ loss from a 1 year exposure affects a cohort that is 3 times smaller but at a damage rate that is 3 times greater, as compared to the situation involving a 1 year exposure where the 'sensitive period' is 3 years instead. It is nevertheless acknowledged that the relationship between IQ changes and short term fluctuations In blood lead levels is uncertain, and that continuous 'background'

Since it was estimated that a daily intake exposure of 1.23 µg lead/kg bw per day would result in an increase in blood lead concentration of 19.48 µg/L, then assuming that the 'sensitive' exposure duration that results in corresponding IQ impacts is from 6 months to 3 years, the effect of only one year intake exposure would thus be 2/5 of the total loss of IQ, implying that an intake exposure of 3.075 µg/kg bw/day would result in a loss of 1 IQ-point for 1 year of exposure[78].

Assuming therefore a daily intake of 3.075 µg/kg bw/day would result in a loss of 1 IQ point, the aggregate intake that would result in the 'break even' level of IQ impacts of 460 points equals (3.075 x 460=) 1414.5 µg/kg bw/day

Furthermore, assuming an average weight of children of 0.6 – 3 years of 12 kg, the aggregate intake of lead per day that would result in the 'break even' level of 460 IQ points equals (1414.5 x 12=) 16974 µg/day. Over a 1 year period this would require that the aggregate intake exposure would need to be (16974 x 365=) 6.196 million µg lead in order to result in the 'break even' level of IQ impacts of 460 points[79].

F.1.1.5. Estimation of exposure 'profiles' that would result in the 'break even' level of IQ impacts

Given the aggregate 'break even' intake exposure of 6.196 million µg lead, it is necessary to describe this in terms of some relevant and meaningful exposure 'profiles' that would result in such an aggregate exposure. In order to derive some relevant and meaningful exposure 'profiles' it is first necessary to estimate the intake exposure from a 'standard exposure episode' of jewellery mouthing. A 'standard exposure episode' is used as a benchmark scenario from which relevant and meaningful exposure 'profiles' can be developed. The 'standard exposure episode' requires a number of parameters that characterise it to be specified. In particular it is necessary to specify the average lead concentration of a piece of jewellery, the area of a 'typical' piece of jewellery, the migration rate of lead from jewellery, the mean weight of a child that mouths the piece of jewellery and the length of time that the 'standard exposure episode' lasts.

For the purpose of the present analysis, and in accordance with the cost exercise, it is assumed that the average concentration of lead in jewellery is 6 %. The mean weight of a child between the ages of 6 months and 3 years is around 12 kg, the surface area of a 'typical' piece of jewellery is 10 cm^2.

With regards to the migration rate of lead in jewellery, according to the analysis undertaken in the exposure assessment for mouthing jewellery containing lead (section B.5.3), the migration rate of lead from jewellery was estimated to be 0.7 $\mu g/cm^2/h$ per % concentration of lead. Given the surface area of a typical piece of jewellery of 10cm^2, and an average weight of a child between the ages of 6

exposures will be the main source of exposure upon which cognitive impacts have been a consequence.

[78] It is acknowledged that the prediction of a 1 IQ point loss for a daily intake exposure of 3.075 µg/kg bw is derived from population based estimates, and as such a population based loss of 1 IQ points may not correspond to a measurable IQ impact on an individual child, since such a loss is smaller than the error for repeat IQ measurements on an individual child. However, the approach taken for the break-even analysis undertaken here is based on estimation of population based (expected) impacts, such that the use of a population based IQ loss is acceptable.

[79] Given that exposures from episodic events such as mouthing jewellery as likely to be irregular, the estimate of total lead intake exposure would ideally be converted to an 'equivalent chronic (regular/continuous) intake exposure' that would lead to a given IQ loss. This is however beyond the scope of the present analysis.

months and 3 years of 12 kg, the intake exposure would be (0.7 µg x 10 cm^2÷12 kg=) 0.58 µg/kg bw per hour for a piece of jewellery with 1% lead content [80].

A 'standard exposure episode', characterised by a child of 12 kg mouthing a 10 cm^2 (surface area) piece of jewellery containing 6 % lead, therefore results in an intake of 42 µg per hour.

Since the aggregate intake that would result in the break even level of IQ impacts was 6.196 million µg lead, then on the basis of an individual intake of 42 µg per 'standard exposure episode', the 'break even' number of hours of jewellery mouthing is [6.196m/42=] 147,512.

From this, it is then possible to derive a number of more relevant and meaningful break even exposure 'profiles' which can be compared to corresponding benchmarks of actual 'mouthing' exposure behaviours related to jewellery containing lead.

Break even exposure profile 1: average mouthing duration per EU child between 6 months and 3 years

The first 'break even' exposure profile estimates the average amount of time that each EU child between the ages of 6 months and 3 years would have to mouth a 'typical' (as defined previously) jewellery item containing 6 % lead.

Given the number of hours with 'standard exposure episodes' was estimated to be 147,512 and since there are approximately 16.7 million children between the ages of 6 months and 3 years in the EU[81], then the average mouthing duration per EU child (from 6 months – 3 years) that would result in the break even level of IQ impacts is [147,512*3600/16.7 million=] 32 seconds (per year of mouthing those items that would otherwise have been placed on the market in one year if the restriction was not introduced).

Break even exposure profile 2: number of children with annual/weekly/daily exposure of average 'default' mouthing duration

This break even exposure 'profile' considers how many children between the ages of 6 months and 3 years would have to mouth a 'typical' jewellery item containing 6 % lead on a regular annual/weekly/daily basis for a fixed average 'default' mouthing duration.

The average 'default' mouthing duration is based on the weighted mean time for mouthing of non-toys and toys not intended for mouthing, suggested by RIVM (2002) for exposure assessments for different age groups between 6 months and 3 years. This is estimated to be 4.5 minutes[82].

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[80] As discussed in section B5 (p45-49), a linear correlation has been assumed between migration rate and lead content. It should be noted that there are concerns over the validity of this assumption (as well as the fact that there is an implicit assumption of linearity of lead release over time). Nevertheless, even in the case where there is no quantitative relationship between migration and concentration, it is necessary to assume some level of intake exposure for an average article of jewellery containing lead, and hence in the absence of better data, the value of 3.48 µg/kg bw per day is assumed to be reasonable (albeit based on an estimate of migration under gastric (highly acidic) conditions).

[81] Estimated on the background of 20 million children between 0 and 36 month.

[82] This is based on a Dutch study (http://www.rivm.nl/bibliotheek/rapporten/612810012.pdf - table 6 on the typical mouthing behaviour of children [normal case]). It is a weighed average of mouthing behaviour in the following age groups: 7-12 month (9.4 minutes daily), 13-18 month (7.2 minutes) and 19-36 months (2 minutes). The value of 4.5 minutes also corresponds approximately to the mouthing duration that was estimated to result in an appreciable risk as defined according to the exposure scenario considered in section B of the Background Document (table 36).

For daily exposures, the annual aggregate of 'default' duration mouthing would thus be [4.5 x 365=1642.5 minutes] = 27.375 hours

For weekly exposures, the annual aggregate of 'default' duration mouthing would thus be [4.5 x 52 = 234 minutes] = 3.9 hours.

For an annual exposure, the annual aggregate of 'default' duration mouthing would be (4.5 minutes=) 0.075 hours.

Given the number of hours with 'standard exposure episodes' was estimated to be 147,512, then the number of children having a single annual exposure of 'default' duration of 4.5 minutes that would result in the break even level of IQ impacts equals [147,512/0.075=] 1,966,829 children (per year of mouthing those items that would otherwise have been placed on the market in one year if the restriction was not introduced). Alternatively, at least 1 in every 8 EU children between age 6 months and 3 years would have to have one annual exposure of 4.5 minutes.

The corresponding number of children having weekly exposures of 'default' duration of 4.5 minutes that would result in the break even level of IQ impacts equals [147,512/3.9=] 37,824 children (per year of mouthing those items that would otherwise have been placed on the market in one year if the restriction was not introduced). Alternatively, at least 1 in every 442 EU children between age 6 months and 3 years would have to have a weekly exposure of default duration. At the individual level, according to Table 36 in B.5.3, a weekly exposure of 4.5 minutes is considered to reduce IQ by 0.11.

The corresponding number of children having a daily exposure of 'default' duration of 4.5 minutes that would result in the break even level of IQ impacts equals [147,512/27.375=] 5389 children per year (mouthing those items that would otherwise have been placed on the market in one year if the restriction was not introduced). Alternatively, at least 1 in every 3099 EU children between age 6 months and 3 years would have to have a daily exposure of default duration.

A summary of all the calculations undertaken as part of the break even analysis is provided in the sensitivity analysis section F.1.1.7, in Table 59.

F.1.1.6. Comparison with benchmarks of actual mouthing exposure behaviours related to jewellery containing lead.

In order to consider whether the 'break even' level of IQ impacts is more or less than the actual level of IQ impacts from mouthing jewellery items containing lead that would have been placed on the market if the restriction was not introduced, it is necessary to have some data of actual mouthing exposure behaviour of children. The above exposure 'profiles were based on hypothetical profiles, since actual exposure behaviour of EU children related to mouthing jewellery containing lead is not well established. Nevertheless, it has been possible to make a comparison to some data on actual mouthing behaviours of children in the UK for which some information concerning the actual items mouthed is available (DTI, 2002).

DTI (2002) reports the results of an observational study that sought to estimate the total time that children within the age range of 1 month to 5 years are expected to mouth items per day. Although it is unclear how representative the estimates found in the study are of mouthing behaviours of EU children, the study can be considered to give some order of magnitude of actual behaviours since it is based on actual observations from 236 children.

The study recorded the items mouthed by children according to a number of categories, including, Dummy/soother, Fingers, Toys, Other Objects, Not Recorded. For the purposes of the present analysis, the mouthing times recorded under 'other objects' are used (since the study appears to have recorded jewellery items under this category).

The estimated mean daily mouthing time for all items mouthed under the 'other objects' category was 15.79 minutes for children between the ages of 1 month and 5 years[83]. The estimated total daily mouthing time for the 'other objects' category was 3728 minutes for all 236 children.

The study recorded the specific items of jewellery that were mouthed by the sample of children. In total, under the 'other objects' category, a total of 1665 items were mouthed. The number of items of jewellery that were mouthed can be estimated from the information contained in Appendix G of the report (which records each of the specific items mouthed).

The following items are listed which correspond to jewellery items[84]

Item	**Number of times mouthed**
Hair clip	4
Hair slide	1
Watches	6
Bangle	1
Beads	1
Bracelet	1
Ring	1
Gold necklace	1
Badge	3
Necklace	5
TOTAL	**24**

The total number of jewellery items mouthed was thus 24 out of 1665 (1.44%) items in the 'other objects' category (1.44% of items).

Assuming that the total amount of time spent mouthing an object is proportionate to the frequency that the item is mouthed, then the total amount of time spent mouthing jewellery items by the 236 children is estimated to be (1.44% of 3728 minutes) 53.7 minutes per day (or 0.228 minutes per child).

Since it is estimated that only 10% of costume jewellery articles contain lead then the total amount of time spent by the 236 children mouthing jewellery items containing lead is estimated to be (0.144% of 3728 minutes) 5.37 minutes per day (or 0.0228 minutes per child)[85].

The number of minutes of mouthing jewellery containing lead per child per year is thus estimated at [0.0228 x 365=] 8.30 minutes. It should be noted that this is the time spent mouthing the total number of such item which are already in circulation, rather than the additional items that come into circulation each year (which is the appropriate comparator to make with the 'break even' level.

[83] Although the break even analysis as conducted for children between the ages of 6 months to 3 years, the benchmark comparison undertaken here is made on the basis of mouthing behaviours for children from 1month to 5 years, since as described later, the information recording the specific items mouthed did not record which age group was mouthing the specific item.

[84] The precise description is sometime unclear and hence we list items that could be reasonably assumed to be classified as jewellery.

[85] It is acknowledged that costume jewellery only makes up some proportion of the total amount of jewellery and that the figures reported here do not take this into account. Nevertheless, the analysis assumes that most jewellery that children might come into contact with will most likely be non-precious (even though at least one of the recorded items in the sample was a gold necklace) and hence only account is taken of the proportion that might contain lead (10%).

However, it is not possible to estimate the mouthing time for the additional jewellery items that come into circulation each year, without making some assumptions about what proportion of the total jewellery items in circulation is made of up the additional jewellery items that come into circulation each year. In order to simplify the analysis, it is furthermore assumed that for any new jewellery item added to the circulation each year, an old jewellery items is removed from circulation, and that the lifetime of an item of jewellery is 5 years (ie the items in circulation will be completely renewed every 5 years).

On this basis then, the number of minutes of mouthing jewellery containing lead per child per year for additional jewellery items that come into circulation per year is estimated at [8.30/5=] 1.66 minutes (99.6 secs).

Although this analysis of actual behaviours related to mouthing jewellery containing lead is highly speculative and based on some heroic assumptions, it provides an order of magnitude comparator to the 'break even' level of mouthing time estimated under exposure 'profile' 1, reported earlier as being 32 seconds

If the estimate of mouthing times from the DTI (2002) report can be considered to be representative of EU children (in the relevant age range), then the actual mouthing durations of children related to jewellery containing lead would appear to be greater than that required to achieve a 'break even' level of mouthing duration per year (as estimated under exposure 'profile' 1, subject to the uncertainties and assumptions made in the above analysis.

F.1.1.7. Sensitivity Analysis and Summary of Break-Even Calculations

Based on the general approach outlined in the previous sub-sections, a sensitivity analysis can be performed, in which the impact of varying some of the key parameters on the break even calculations can be seen. Table 59 shows the upper and lower bounds, as well as the central estimates of the break even calculations according to the various parameters, as indicated. It can be seen that the estimated actual mouthing duration found in the previous sub-section (99.6 seconds) exceeds the break even mouthing duration shown in the table (in Bold italic) in all cases, although in the upper bound case the difference is small.

Table 59. Sensitivity Analysis and Summary of Break even calculations for lead in jewellery (starting from three different estimates of total costs)

	unit	calculation	Low cost-high IQ value-high dose response	Central estimate	High cost - low IQ value-low dose/response
Total cost of restriction per year, €	€	a	2,100,000	4,600,000	6,300,000
Reduction in Earnings per IQ point, €	€	b	15,000	10,000	5,000
Number of IQ points lost to break even	points	c=a/b	140	460	1260
Daily lead intake per IQ-point loss	µg	d	0.50	1.23	1.23
Adjustment factor for 1 year equivalent intake	factor	e=	1.0	2.5	2.5
Daily lead intake per IQ loss (1 year equivalent intake)	µg	f=e*d	0.50[1]	3.075	3.075
Lead intake per kg bw per day required to equal cost	µg	g=c*f	70	1415	3875
Lead intake (per child (12 kg) per day) required to equal cost	µg	h=g*12	840	16,974	46,494

Lead intake (per child (12 kg) per year) required to equal cost	µg	i=h*365	306,600	6,195,510	16,970,310
Migration rate for 1 % lead content	µg /cm^2	j	0.9	0.7	0.7
Migration rate for 6 % lead content,10 cm^2	µg	l=j*6*10	54.0[2]	42.0	42.0
Mouthing hours to result in required beak even lead intake	hours	m=i/l	5,678	147,512	404,055
Number of 0.5-2.5 years children in EU		n	16.7mill	16.7mill	16.7mill
Mouthing duration (Seconds per child per year) required to reach break even point (benefits=cost)	***sec***	***p=m*3600/n***	***1***	***32***	***87***
Required number 4.5 minutes events to reach break even point		**q=m*60/4,5**	**75,704**	**1,966,829**	**5,387,400**
Required number of children with weekly exposure of 4.5 minutes to reach break even point		**r=m*60/(4.5 *52)**	**1,456**	**37,824**	**103,604**
Ratio of children required to mouth 4.5 minutes weekly to reach break even point		s=r/n	0.0001	0.0023	0.0062
Inverse ratio			11,471	442	161
Required number of children with daily exposure of 4.5 minutes to reach break even point		**u=m*60/(4. 5*365**	**207**	**5,389**	**14,760**
Ratio of EU children required to mouth 4.5 minutes daily to reach break even point			0.0000	0.0003	0.0009
Inverse ratio			80,518	3,099	1,131

[1] Assumes a daily intake of 0.5 µg lead/kg b.w. per day corresponds to a loss of 1 IQ point for 1 year of exposure (based on lower (95 percentile) benchmark dose approach adopted by EFSA, 2010) - see (B.4.6.3)

[2] Assumes a standard exposure episode', characterised by a child of 12 kg mouthing a 10g piece of jewellery containing 6 % lead for one hour, based on a migration rate of 0.9 µg/g/hr per % concentration of lead (as per the alternative migration rate for lead containing jewellery found in section B5, page 45-49 of this background document).

F.1.1.8. Overall conclusion

The costs of substituting lead with other metals are estimated to be €4.6 million per annum (with a lower bound estimate of €2.1 million and upper bound estimate of €6.3 million). The associations between lead and different measures of cognitive abilities are typically described in terms of the effect of lead on IQ and earnings. It is estimated that the value of one lost IQ point is around €10,000 (with a range between €5000 and €15,000 used for sensitivity analysis). The cost of avoiding lead in jewellery is estimated to equal the benefit alone with regard to loss in IQ if every child in the EU between the age of 6 months and 3 years would have mouthed one of the pieces of jewellery containing lead that would otherwise have been placed on the market in each year without the restriction, for an average of 32 seconds. Based on, albeit highly uncertain, estimates of actual mouthing times for jewellery containing lead for a sample of children in the UK, it would appear that actual mouthing durations may exceed those that would be required to achieve the 'break even' level of mouthing duration per year. Furthermore, a sensitivity analysis on the 'break even' level of mouthing duration indicates that even when more conservative parameters for the cost of the restriction and the value of a lost IQ point are used, the actual mouthing duration (based on a sample of UK children) still surpasses the estimated break-even durations.

Given that there are also other benefits in reducing the risks related to lead (for instance, in the waste phase) it seems reasonable to conclude that the cost of the proposed restriction is not disproportionate to the reduced risk.

It should be underlined that the estimations carried out in this analysis come with a high degree of uncertainty and are based on a number of unverifiable assumptions (as described throughout the analysis).

F.1.2. Other health impacts

Other long-term health effects could be included in a more extensive analysis such as adult hypertension, cardiovascular diseases, osteoporosis or dental caries due to lead poisoning in childhood (Escribano A. *et al.* (1997); Gruber H.E. *et al.* (1997); Landrigan P.J. *et al.* (2002); Moss M.E. *et al.* (1999)). However, including these effects as long-term impacts in children would be incautious because first, the correlation between these effects and lead poisoning in childhood is not surely proved (Landrigan P.J. *et al.* (2002)) and secondly, these effects can be imputed to many other causes. Consequently, they cannot reasonably be quantified but only be mentioned as qualitative (and potential) health benefits of the proposed restriction.

F.1.3. Example of other health impacts analysis implemented in other countries for lead in jewellery

Before implementing the Canadian Children's jewellery Regulation, an assessment of the benefits and costs of such regulation was performed. According to information in the Canada Gazette (2005), the present value of Total Social Costs was estimated to be around $600,000 over the lifetime of the Regulations (based on a 3% discount rate).

Estimated benefits for the Canadian public were based on the values for cost of illness and medical costs as summarized in the Table below.

Table 60: Measures of benefit for lead reduction

STUDY	TYPE OF VALUE	VALUE PER CASE, C$(2000)
Agee and Crocker (1996)	Parental willingness to pay for reduced blood lead levels in children	Low: 43 High: 397
US EPA Lead in gasoline RIAS (1985)	Cost of Illness and increased cost of education	10,784
US EPA Lead in Drinking Water RIAS (1986)	Cost of Illness and increased cost of education	10,241
Mathtech, (1987)	Medical costs, extra education, parental opportunity cost	636 – 6,533 (range is due to varying severities of lead poisoning)
Schwartz (1994)	Medical cost avoided	2,700

The data in this table indicates that the cost of medical treatment combined with the cost for extra education, on average ranges between $6,000 and $10,000 per case.

A true comparison of benefits and costs was not feasible, due to lack of data. However, a break-even analysis, which determines the point at which benefits equal or exceed costs, was used instead. For the Regulations, assuming that costs over the lifetime of the Regulations have a present value of roughly $600,000, and the partial benefits per case range from $6,000 to $10,000, the Regulations were found to be efficient as long as, over their lifetime, 60 to 100 cases of lead poisoning are avoided.

F.2. Economic impacts

This section refers to costs mentioned in the assessment of the proposed restriction presented in section E.2.1. As mentioned in the introduction of section F, this subsection shall include only additional information compared to section E.2.

The actors of the supply chain concerned are represented in the following diagram.

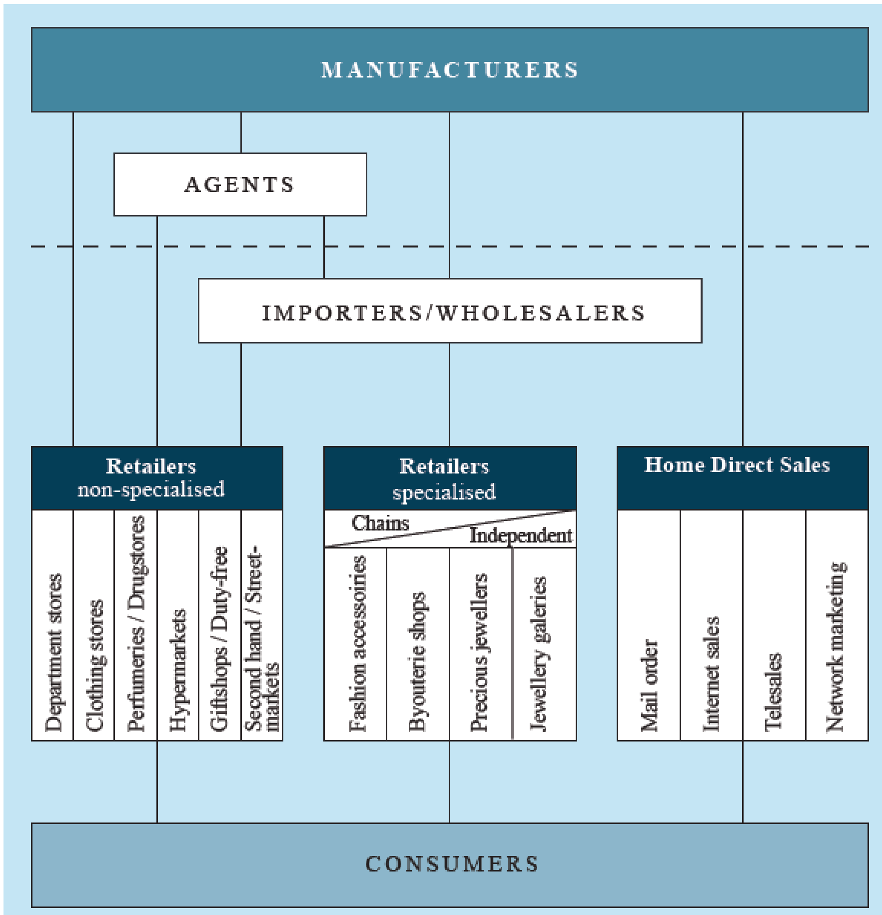

Figure 5: Typical distribution structure for jewellery in EU markets (extracted from CBI (2009))

Agents are independent intermediaries who are sometimes used by industry actors and mostly by the Southern EU countries (CBI (2002)). They operate either between producers and distributors/retailers, either between producers and importers/wholesalers and negotiate prices and quantities. They are mainly used in the precious jewellery sector where exclusive brands are demanded and supplied.

As seen in section B.2, the market of fashion jewellery is very fragmented and mainly composed of small and very small firms. These firms are hardly identifiable, especially if they do not belong to a professional federation or union.

Identified stakeholders who may be affected by economic impacts are:

- Manufacturers/importers/distributors of lead containing alloys
- Manufacturers/importers/distributors of lead-free alloys
- Producers of jewellery:

5,350 European companies were producing fashion jewellery in 2007, employing about 20,000 people.
22,500 European companies were producing precious jewellery in 2007, employing about 94,000 people (CBI (2008)).

- Importers and distributors of jewellery

- Manufacturers/importers/distributors of lead compounds which may be used in jewellery's coatings
- Consumers
- Public authorities

Possible economic impacts which are discussed in this section are the ones proposed in the European Commission's Impact Assessment Guidelines (EC (2009)).

F.2.1. Functioning of the internal market and competition

The restriction is not expected to have an impact on the free movement of goods, services, capital and workers. On the other side, the absence of restriction will have a potential impact on these free movements as it may result in imbalances between different Member States in case they implement specific national regulations.

Because the sector of jewellery, especially of fashion jewellery, is very competitive, is constituted by many different articles using a variety of materials, a reduction in consumer choice as a consequence of the restriction is not foreseen, even though it is recognised that efforts mainly from producers of fashion jewellery will be needed.

F.2.2. Competitiveness, trade and investment flows

The restriction will impact the competitiveness of producers of jewellery, of manufacturers/suppliers of leaded alloys and on manufacturers/suppliers of lead-free alloys.

The part represented by leaded fashion jewellery among the totality of fashion jewellery is not clear. It seems to be widely used as component of metallic alloys. When consulted, BOCI (trade association of producers of fashion jewellery) mentioned that alloys which are used by its members are made of copper or tin, with an average concentration of 6% of lead. A surface treatment is performed using rhodium, palladium, gold and silver. Lead has not been reported to be used in an alloy at a concentration higher than 10% by BOCI members. According to BOCI, other components which contain lead are rarely used. However, the results of the studies which are reported in section B.2.6 imply that lead is used at higher levels.

The restriction will thus impact EU producers of leaded jewellery as it is not expected that the lead concentrations which are presently used can comply with the proposed migration rate. They will have to switch to alternatives and they will also have to put in place procedures in order to control the presence of lead in their products. However, as lead in jewellery is already regulated in the USA and in Canada, such control of the products can be seen as an opportunity to also comply with other international regulations.

As for producers of leaded jewellery, importers and distributors will also have to put in place a process to control the quality of the products that they place on the market. It is possible that importers and distributors of jewellery will be attracted by EU producers who have to comply with the restriction, as it may be more difficult to implement a quality control with non-EU producers who do not need to comply with such restriction in their country. For instance, a fashion jewellery importer reports in Fairclough G. *et al.* (2007) that it may happen that a contract can be obtained by a supplier thanks to a product which complies with all the requirements but that all the following mass production is made of a cheaper lead containing material.

The previous remarks are expected to apply to both precious and fashion jewellery sectors, even though it is expected that the precious jewellery sector will be less impacted than the fashion jewellery one as the use of lead in the former one seems more marginal.

Producers of lead-free jewellery who have already implemented a quality control along their supply chain will probably have a competitive advantage.

Concerning the supply and the production of alloys which contain lead, it will probably be also impacted, but possibly to a lesser extent. First, these alloys are most probably used for other applications in addition to the jewellery sector. It will be up to these actors to decide whether they want to also manufacture/import/ distribute alloys which are free of lead or if they do not need to adapt to the restriction, probably depending on the part of their sales which is dedicated to jewellery applications. Secondly, when consulted for the prices of his products, a manufacturer of alloys (which can be used in fashion jewellery) indicated that, given the fluctuation of the costs of raw materials, costs of alloys are varying and as a result, such alloys are manufactured following customers' demand. As a consequence, it is not expected that these actors will have high stocks of leaded alloys that cannot be sold to the fashion jewellery producers.

Concerning the lead compounds which are used in coatings of jewellery, it is envisaged that actors of this sector deal with different types of lead-free compounds which could be used in replacement of the former ones. Moreover, lead compounds may still be used for applications other than jewellery. For these reasons, impacts on this sector are not expected to be high.

F.2.3. Operating costs and conduct of business/Small and Medium Enterprises

Additional costs are foreseen to be due principally to costs of substitution with lead-free alloys made of more expensive raw materials (see section C for more details on alternatives), new training of workforce, process changes such as possible longer heating for the lead-free alloy casting and adaptation to alternatives' specific properties of equipments and machines, and to the implementation of the restriction (product compliance with the regulation, quality controls along the supply chain). The biggest efforts might be made by micro and small firms which represent the major part of actors in the fashion jewellery sector.
It is difficult to estimate the overall costs of a restriction on lead and its compounds in jewellery since no exact and not sufficiently extensive data was found in order to evaluate these costs quantitatively. Consultation has mainly given information about "higher" production costs which would be due to the adoption of more expensive alternatives.

In the jewellery sector, price is highly dependent on the raw materials used to produce jewellery. In this sector in particular, there is a broad range of materials and articles. With the growing competition from Asian countries' imports (and developing countries' in general) in this sector, prices have decreased since the past few years (CBI (2001); CBI (2002); CBI (2008)). Substitution costs for producers of fashion jewellery are supposed to represent the main cost impacts and it has been estimated above that the contribution of the raw material is around 20 to 30% of the final price of a jewellery article and that substitution would imply an increase of about 7% of the cost of the alloys for jewellery manufacturers who would switch to lead-free alloys (for alloys containing up to 10% lead) (see section C.7 and Annex D).

It can be expected also that during the implementation phase the compliance costs will be higher than when the whole supply chain is fully aware of the regulation.

No more precise cost assessment could be performed as information is lacking concerning among others the costs of adaptation of the industrial processes and the part of the alloys' cost in the final article cost. Moreover, as regards the risks and the results of the cost-benefit analysis provided in Annex D, it does not seem to be proportional to implement further investigation on the assessment of these costs.

F.2.4. Administrative burdens of businesses

For the affected actors, the administrative burden will imply the understanding and the implementation of the regulation proposed. More precisely, the restriction will affect the nature of information obligations placed on businesses as actors will need to have information along their supply chain about the presence of lead and its compounds in the articles and to comply with the new requirements.

Producers will have to be aware of the new regulation and could then make the choice of switching to lead-free alloys or lead-free jewellery. Store owners (and distributors in general) who sell jewellery and importers will not only have to be well informed of the REACH restriction but they will also have to formulate requirements that have to be met by their suppliers (and maybe to control it as well). As indicated by KEMI (2007), this will potentially result in an increase of administrative burden. Indeed, suppliers will have to sell articles which comply with the proposed restriction.

In an information note of 2008 (DGCCRF (2008)), the French Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) alerted on the lack of knowledge of suppliers, importers and actors who sell fashion jewellery to consumers concerning the implemented regulation in France about limitation of nickel and certain lead compounds in several types of products (DGCCRF (2008)). This is an important point as it is crucial that such actors are well informed of the regulation so that risks can adequately be managed. This lack of knowledge is also confirmed by the results presented in INERIS (2009). In this report, it is highlighted that very few actors do actually know the composition of the products which they place on the market.

Actors potentially impacted by administrative burden are producers, importers and distributors of jewellery.

Importers, wholesalers and retailers will need to track the presence of lead in their jewellery products, provide information and training to their overseas manufacturers and suppliers, etc. The exact scale of the associated incremental costs is unclear since, as discussed earlier, some tracking of the presence of lead is already undertaken on a voluntary basis, etc. It has not been possible to undertake any assessment of these costs. However, it seems reasonable to assume that such costs are small, compared to the overall increase in the price of jewellery.

F.2.5. Public authorities

The restriction is not expected to require the creation of new or a restructuring of existing authorities. Each Member State is supposed to have an authority which is in charge of controlling that the regulation is respected. Such authorities will be able to control the proposed restriction.

The restriction will have budgetary consequences for public authorities, but most probably not very high. Indeed, public authorities already have to make sure that jewellery comply with the present regulation and, as such, they are already performing some controls on these articles. Moreover, the method which can be used to control the migration of lead from jewellery is available and already used for the testing of lead migration from toys.

As nickel is a substance which is already regulated in jewellery, it may be foreseen that campaigns to control the compliance with nickel regulation can also address the compliance with this restriction. Consequently, in terms of campaign organisation, the restriction is not expected to result in additional costs. However, public authorities will have to allocate a certain budget to the testing of lead migration rates.

Public authorities have a duty to ensure that jewellery on the national market complies with existing legislation. Some testing is already undertaken on jewellery articles to test for the presence of nickel. Furthermore, recent legislative changes regarding cadmium will mean that market surveillance and testing will be necessary to ensure jewellery complies with the restriction in the cadmium content in jewellery[86]. As discussed earlier, it is known that certain testing methods provide results on the content of several elements, including cadmium and lead.

RPA (2009) reported that testing by authorities for nickel in jewellery articles currently takes place as a result of an incident rather than as an ongoing process. It is reported that such an approach would continue following a ban on cadmium in jewellery, though a more active approach to cadmium testing cannot be precluded, even without an EU wide restriction. It is expected that some additional testing of jewellery may be required by public authorities due to the restriction of cadmium content in jewellery. It is unclear whether any incremental testing will be necessary by public authorities for 'screening' type tests for lead. It can be expected that some incremental costs will be incurred by public authorities for 'follow up' confirmatory testing of jewellery that is found to be in non-conformity with the proposed lead restriction.

Given any product screening and confirmatory testing undertaken by industry in order to ensure compliance with the proposed lead restriction, the level of testing by public authorities likely to be rather small compared to the testing made by suppliers, importers and wholesalers. Furthermore, whilst monitoring and enforcement activities may initially increase to remove non-compliant jewellery, this would be expected to stabilise to a level required on an ongoing basis to ensure compliance. Therefore, it is assumed that the product testing costs described in the previous section include testing carried out for enforcement purposes.

F.2.6. Property rights

Property rights are not expected to be affected by the restriction.

F.2.7. Innovation and research

The restriction is expected to increase the need for research and development to produce jewellery, especially fashion ones, which are free of lead and its compounds. However, because of the growing issue of lead in consumer products and because of recent studies which suggest that no safe threshold level can be derived for lead, such research and development activities might have already been undertaken.

Such activities will probably be necessary to address the loss of quality and of functionality that could concern the jewellery which used to contain lead and which will have to contain other materials with the implementation of the restriction. Indeed, as mentioned in section C, these raw materials might not have the same technical properties as lead and thus might make the "new" jewellery less heavy, more cheap-looking and maybe less attractive for consumers. However, as suggested by RPA (2009), changes in fashion may be a more important driver of innovation in fashion jewellery than chemical substances regulations.

F.2.8. Consumers and households

As reported by KEMI (2007), the only negative impact for consumers would be that the supply of cheap jewellery might be slightly reduced; which may be quite significant for this group as it is expected to be composed of consumers who have low spending possibilities. However, again, as fashion jewellery is constituted by a huge a variety of articles, the consumer might not notice a change in jewellery as some of them which are already placed on the market are supposed not to contain lead.

[86] At the time of writing (February 2011), the restriction in the cadmium content in jewellery was being under the scrutiny reservation of the European Parliament and expected to be decided upon by the Commission during the 2nd quarter of 2011.

On the other side, consumer health protection is the clear advantage of the restriction. Consumers are widely informed about the potential health risks of lead. Consequently, communicating about the absence of this substance and of its compounds in the articles may be a good selling point.
On a consumer point of view, this restriction proposal is not expected to have an impact on the precious jewellery since it is not expected that the selling price of these articles will be impacted.

F.2.9. Specific regions or sectors

As mentioned in this report, the specific sector which is affected by this restriction is the sector of jewellery, and especially fashion jewellery sector. From information which was found in literature and in available studies, all types of fashion jewellery may be affected (rings, necklaces, bracelets, pendants etc.).

It is not expected that the restriction has a specific impact on certain regions in terms of jobs created or lost. However, countries which are among the leading fashion jewellery producers may be foreseen to suffer more from this restriction.

There is no single Member State, region or sector which is supposed to be disproportionally affected by the restriction.

F.2.10. Third countries and international relations

Qualitative impacts of restriction of lead and its compounds in jewellery on third countries and international relations are expected to go in the same ways as the ones of a restriction of cadmium in jewellery, as reported by RPA (2009). As many jewellery articles, and especially fashion ones, are imported from non EU countries, this restriction will affect non EU producers and exporters. The impacts will depend on how broadly lead is used in fashion jewellery, whether this use is intentional or not and on the technical and economic available alternatives.

According to RPA (2009), production of fashion jewellery for EU market occurs both in countries with advanced industrial production (Hong-Kong, China, South Korea and India) and in less industrially developed countries (Thailand, Philippines, Indonesia and Turkey). It is expected that small producers who are not able to be informed and/or to comply with the restriction may not be able to export their products to EU countries anymore. However, it is not possible to assess the quantity of imports which may be affected. As concluded by RPA (2009), this restriction will add to the pressure on non-EU producers to improve their practices if they want to maintain their competitiveness in the EU market.

On the contrary, as already mentioned, complying with EU regulation may help fashion jewellery producers to export their articles in other countries which regulate the content and/or the migration rate of lead in jewellery (such as the USA and Canada).

F.2.11. Macroeconomic environment

The proposed restriction is not envisaged to have overall consequences for economic growth and employment nor direct impacts on macro-economic stabilisation.

F.2.12. Summary and conclusion of economic impacts

Given the costs estimated in the above sections reported in Table 54, Table 55 and Table 56, the total costs of the proposed restriction are summarised below. It should be noted that these costs relate to the higher production costs and testing costs of using more expensive alloys than lead based alloys. Thus, these costs do not include possible price increases if the non-metallic parts of jewellery were subject to a restriction.

Table 61: Summary of total costs per annum

	Total additional cost of substituting lead for imported fashion jewellery (mill €)	Total additional cost of substituting lead for fashion jewellery produced in EU (mill €)	Testing costs (mill €)	Total cost (mill €)
Lower bound	1.9	0.2	0.1	2.1
Central case	**4.0**	**0.3**	**0.3**	**4.6**
Upper bound	5.2	0.6	0.5	6.3

Note that this summary is the same than in Table 57.

F.3. Social impacts

Possible social impacts which are discussed in this section are the ones proposed in the European Commission's Impact Assessment Guidelines (EC (2009)).

F.3.1. Employment and labour markets

As already mentioned, CBI (2008) reports that 5,350 European companies were producing fashion jewellery in 2007, employing about 20,000 people and that 22,500 companies were producing precious jewellery, employing about 94,000 people. The impact of the restriction on employment is difficult to assess. Given the reactivity of the sector of fashion jewellery which always has to adapt to new fashion trends, it is however expected that alternatives will be rapidly available in order to propose other products to consumers. This will result in new products to develop and produce; thus counterbalancing the potential loss of activity with restricted leaded fashion jewellery. The restriction may more impact, as previously mentioned, small entities which have more difficulties in being well-informed about the regulation and in implementing a control quality along their supply chain.

The restriction is not expected to have an impact on particular age groups, on the demand for labour, or on the functioning of the labour market.

Considering manufacturers/importers/distributors of leaded alloys, they also may be negatively impacted by the restriction. However, such actors may also manufacture/import/distribute other types of alloys and consequently they may be able to propose other materials to jewellery' producers.

On the contrary, manufacturers/importers/distributors of lead-free alloys should experience more demand and thus be positively impacted.

The restriction is not expected to have a significant impact in terms of employment on manufacturers/ importers/distributors of lead compounds intended to be used in jewellery' coatings as it is envisaged that such actors are not specialised only in lead compounds and as these compounds may also continue to be used in other applications.

F.3.2. Standards and rights related to job quality

A restriction of lead and its compounds in jewellery can offer health protection to employees who usually use such substances in their work. However, it is unknown how many workers may be exposed to these substances while producing jewellery or manufacturing lead containing alloys. Also, personal protective equipment may already be implemented in order to protect the workers.
If the restriction was to affect workers' health, it would be in a protective way as it would reduce exposure to lead and its compounds.

F.3.3. Social inclusion and protection of particular groups

As reported by RPA (2009), safer fashion jewellery may mostly benefit to EU citizens who have "low" incomes as they are a specific target of the fashion jewellery market. Also, and this is the main purpose of this restriction, it will protect young children, a specially vulnerable and at-risk group, who regularly mouth small articles and who may swallow them accidentally.

Moreover, this restriction may make the public better informed about the particular issue of health risks related to exposure to lead as "free lead" might be used as a selling point on the articles which will not contain lead.

F.3.4. Gender equality, equality treatment and opportunities, non discrimination

Children (equally boys and girls) may mouth and accidentally swallow small articles. From InVS (2009), it seems however that jewellery may be ingested mostly by girls (on 52 patients who had swallowed a piece of jewellery, 36 were girls). Nevertheless, it is expected that this restriction will benefit to both boys and girls, without distinction.

If an increase of the price of jewellery was observed, it may impact more women than men as the former ones are expected to purchase jewellery more frequently than men, even though men also buy some jewellery, for them or as gifts.

F.3.5. Individuals, private and family life, personal data

The restriction is not expected to have impacts on the issues proposed in this section.

F.3.6. Governance participation, good administration, access to justice, media and ethics

The restriction is not expected to have impacts on the issues proposed in this section.

F.3.7. Public health and safety

The restriction is expected to affect the health of the European population especially in terms of morbidity and, to a much smaller extent, in terms of mortality (death related to leaded fashion jewellery is extremely rare but has been reported in the USA as already mentioned in the dossier). Examples of health effects which are envisaged to be reduced from the implementation of the proposed restriction are: dullness, restlessness, irritation, poor power of concentration, headache, stomach cramps, kidney injury, hallucinations, loss of memory, hearing loss, lowered IQ.

As indicated, a particular risk group has been identified as being young children who tend to mouth and possibly swallow small articles.

F.3.8. Crime, terrorism and security

The restriction is not expected to have impacts on the issues proposed in this section.

F.3.9. Access to and effects on social protection, health and educational systems

The restriction is not expected to have impacts on the issues proposed in this section.

F.3.10. Culture

The restriction is not expected to have impacts on the issues proposed in this section.

F.3.11. Social impacts in third countries

Restricting the use of hazardous substances such as lead and its compounds in jewellery will most probably result in a decrease of the workers' exposure to these substances while producing the articles. As a growing part of fashion jewellery is produced in third countries, the restriction is expected to present a health benefit for these workers populations.

As reported by Weidenhamer J.D. and Clement M.L. (2007b) and Weidenhamer J.D. and Clement M.L. (2007c), leaded electronic waste may be a source of materials for the production of leaded fashion jewellery. The restriction may have an impact on such industry in the sense that it may discourage trying to extract lead from waste in order to re-use it in consumer products.

F.4. Wider economic impacts

Not relevant for this proposal.

F.5. Distributional impacts

In the context of this restriction proposal, this section should include:
- (Positive) impacts on children and their family in terms of health protection with, if relevant, distinctions between social and ethnic origins;
- (Negative impacts) on importers, distributors and manufacturers with, if relevant, distinctions between actors' size and/or activity.

However, again, no sufficient information on the structural composition of the market and the changes likely to occur with the implementation of the proposed restriction has been identified to establish a relevant report on exact distributional impacts of the proposed restriction.

F.6. Main assumptions used and decisions made during analysis

The lack of relevant and reliable data on several sections of the market studied herein (costs, detailed composition, etc.) and the concern of proportionality of the analysis which should be taken into account in the elaboration of the restriction proposal lead to limit the socio-economic analysis in this dossier: first, in its degree of details and secondly, in its level of quantification.

F.7. Uncertainties

It has been shown, in the previous sections, that uncertainties are high as far as economic data are concerned in this dossier. These uncertainties impede in some extent the implementation of a detailed and complete socio-economic analysis.

F.8. Summary of the socio-economic impacts

The most relevant health, economic and social impacts are summarised in the following table.

Table 62: Summary of the socio-economic impacts of the proposed restriction

Type of impacts	Quantitative/qualitative results
Health impacts	- Examples of chronic health effects which may be avoided due to the implementation of the restriction: hearing loss, lowered IQ, lead poisoning. Number of children which may experience health benefit: all children across Europe. - Examples of acute health effects which may be avoided due to the implementation of the restriction: dullness, restlessness, irritation, poor power of concentration, headache, stomach cramps, kidney injury, hallucinations, loss of memory, and even death in the worst case. Number of children which may experience health benefit: about 5,000 European children for ingestion of jewellery and possibly any child under 3 years-old across the EU for the mouthing behaviour.
Economic impacts	- Possible decrease of the competitiveness of producers of lead containing jewellery and of manufacturers/suppliers of lead-based alloys. - Possible increase of the competitiveness of producers of lead-free jewellery and of manufacturers/suppliers of lead-free alloys. - Necessity to obtain information along the supply chain about the presence of lead and its compounds in the jewellery in order to comply with the regulation. - Potential increase of administrative burden. - No specific impact for the authorities as measuring campaigns are already undertaken in several MS and as the necessary equipment to measure lead migration rate should be already available to control the compliance with the migration rate of the Toy Directive. - Possible increase of the investment in R&D activities to identify suitable alternatives to lead and its compounds in jewellery. - Economic impacts are expected to be high for small actors. - Potential negative impact for consumers with very low spending possibilities as the placing on the market of very cheap jewellery could be slightly reduced. - Increase of the pressure on the non EU producers of jewellery for an improvement of their practices in order to maintain their competitiveness.
Social impacts	- Possible negative impact on actors which produce/place on the market lead

	containing jewellery or which manufacture/place on the market lead-based alloys used in this sector. - Possible positive impact on actors which produce/place on the market lead-free jewellery or which manufacture/place on the market lead-free alloys used in this sector. - Increase of the health protection of workers who are exposed to lead and its compounds while producing jewellery or while manufacturing lead-based alloys, both in EU and non-EU countries. - Increase of the health protection of consumers of jewellery. - Better information of the public concerning the potential health risks of lead since some articles may have a label indicating "lead-free" as a selling point.

Additionally to this table, Annex D provides a summary of all information (quantitative and mainly qualitative) available on the costs.

G. Stakeholder consultation

During the public consultation 40 comments were submitted to the European Chemicals Agency. The comments received will be available on the ECHA website.

This section presents the stakeholders whom France has been consulted during the elaboration of this restriction proposal:

- the REACH MSCAs;
- other Competent Authorities and stakeholders in countries outside the EU (USA, Canada);
- industry actors of the jewellery market in the EU;
- industry actors involved in the lead-based and lead-free alloys manufacture;
- other stakeholders in France and in Europe such as health, trade, governmental institutes.

The chart below shows when, in the process of preparing the dossier, the different consultations listed above have been carried out.

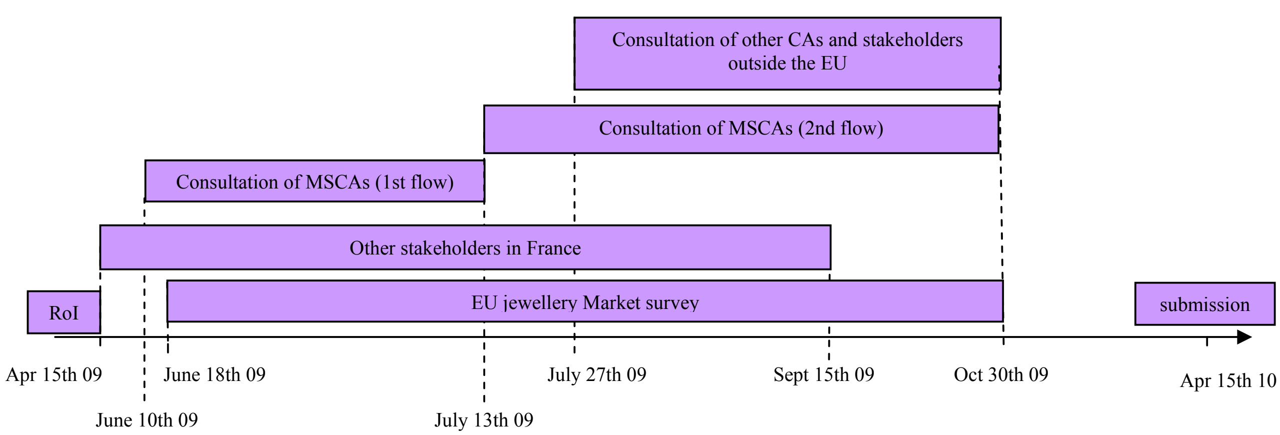

Figure 6: Consultation schedule in the process of preparing the dossier

G.1. Consultation of the REACH Competent Authorities of all Member States

The Competent Authorities of all Member States have been consulted very early in the process. A questionnaire has been sent by email to the contact persons for RAPEX, REACH Regulation, Directive 76/769/EEC and Directive 2001/95/EC. Sometimes, the questionnaire has been steered round to other more relevant persons to answer it and the listing of contact persons has been accordingly updated.

This consultation aimed at collecting information about i) cases of children contamination with lead and its compounds (and their cause) in EU countries, ii) the existence of national measures concerning lead-containing jewellery, iii) the opinion of MSCAs about potential risk management options to reduce this risk and iv) manufacture and imports of lead-containing jewellery in EU countries (the questionnaire is proposed in the original Annex XV report).

This consultation has been carried out through two flows: a first one from June 10th 2009 and July 13th 2009 and a second one from July 13th 2009 and October 30th 2009. The first flow was targeted on the contact persons available from the French Competent Authority network and the second one concerned additional contacts identified later on in the process (supplementary contacts provided by the first consulted bodies and follows-up).

An answer was received from 20 MS, amongst which 15 with at least one returned filled questionnaire (some MS sent back several questionnaires filled by several national competent institutes[87]) and 4 less formal feedbacks from other MS which did not have the precise required information but expressed their feeling about the issue or gave some other contact information. Only one MS replied to our request indicating that no information was available in its country about that issue and sector.

The following tables summarize the information which was collected during this consultation.

[87] Germany sent back 3 questionnaires (from BVL, GIZ-Nord and ChemG) and Greece sent back 2 questionnaires from the Athen's PIC and the Department of Forensic medicine and toxicology division from the University of Athens.

Table 63: Information collected from MSCAs about children contamination to lead and its compounds

MS	Are there some campaigns to measure blood lead levels in your country?	When performing these campaigns, did you collect information on the possible causes of contamination when PbB>100 µg/L ?
SE	1978-2007 measurement around a lead-smelter plant (3789 children)	1 case of blood lead level > 100µg/L => see publi for cause (apparently linked to industrial emission or petrol lead)
NL	_	NVIC: no record of lead poisoning due to ingestion or other kind of exposure of lead in jewellery
DK	no	
DE	GerES campaigns on adults and children GerES IV 2003/2006 children: <100µg/l	no
	no	
	no	no
CY	Annual test for employees of the Cyprus Organization for the Hallmarking of Precious Metals < limit value (WHO, Risk Assessment Report of lead)	_
SK	no	no
EE	no	no
IE	no	no
MT	no on-going campaigns	_
ES	a biomonitoring study is being developped that include the measures of blood lead levels in adults (results end 2010)	no info
IT		no direct news
AT	2005-2006 longitudinal study (cord blood samples)	no
GR		1 fœtus aborted, 2006 (glazed pottery or ceramic dishes) 1 kid 5 years old, 2002, 89 µg/dL (sinker) 1 kid 4 years old, 2005, 60 µg/dL (sinker) 1 kid 11 years old, 2007, 60 µg/dL (small shot) 1 kid 9 years old, 2009, 50 µg/dL (small shot)

	4 or 5 campaigns a year	2 adults, 2008, <40 µg/dL (metal lead in glazed pottery or ceramic dishes) 2 kids (10 and 14), 2005, <70 µg/dL (metal lead in food) 2 kids (6 and 9), 2008, <60 µg/dL (metal lead, other)
HU	no	no
PL	no info	no info

Table 64: Information collected from MSCAs about national measures concerning lead-containing jewellery

MS	**Is there a national legislation on lead in jewellery ?**	**Are there non regulatory actions about lead in jewellery ?**	**Is there a national standard to control lead in jewellery?**	**Is testing routinely conducted on lead in jewellery ?**	**Are there substitution measures currently under development ?**
SE	No legislation A ban has been proposed by the Swedish Chemicals Agency and the Swedish Environmental Agency in 2007	Voluntary actions from sellers of jewellery to phase-out lead	no	Chains report that they do testing…	brass (copper?) (not technically impossible but alternative materials more costly)
NL	No legal requirement in the Netherlands with respect to the presence of lead in jewellery (Regulation on toys (art 11): bioavailability of lead <0,7µg/day) Only one example where, on a voluntary basis, a store chain recalled jewellery containing lead			*EN 71-3 for bioavailability *EN 1811 for migration method => two different methods?	–
DK		no	no	yes (?)	the Danish producers have done a serious job to substitute lead from jewellery and it is possible to substitute. They do have some problems in the soldering.

DE	no	no	EN 71-3 (90mg/kg) cannot be used for jewellery for kids because the swallowable amount of jewellery parts is not comparable with the swallowable amount of toys => use of the standard US CPSC: lead in jewellery < 0,06% = 175µg	*swallowable jewellery for kids *EN71-3 for migration test	–
DE		no	no	no	no
DE	no	no	Norm DIN EN 71-3 which limits bioavailability of lead from use of toys: migration tests are performed on the toy materials and on parts of the toys (see Q6)	RFA (multi-elemental and non-destructive method X-Ray Fluorescence analysis (XRF)) screening migration tests according norm DIN EN 71-3 tests on jewellery, especially from the low price sector or specially designed for children	no
CY	–	The Cyprus Organization for the Hallmarking of Precious Metals control that there is no lead containing jewellery on the market	–	No Tests on imports: XRF	no
SK	no	no	no	no	no
EE	no	no	no	no	no

IE	Electronic jewellery (like watches) max lead content 0,1% in homogenous material (apply for manufacture, import, export and rebrand) = 2005 National law S.I. 341 (Directive 2002/95/EC transposed on restriction of hazardous substances in electrical and electronic equipment) and 2005 National law S.I. 340 (Directive 2002/96/EC transposed on waste electrical and electronic equipment)	no	no	?	?
MT	no	no	no	_	_
ES	_	_	no info	no info	no info
IT	only national laws about annual screening to determine PbB of occupationally exposed workers				
AT	no	no	Only limit value of lead in toys (0,7µg/l) BGBI nr. 823/1994	no	no
GR	-	-	-	-	-
HU	-	no	no, no info	no	no, no info

PL	No national legislation as regards lead in jewellery There is other legislation concerning jewellery as regards noble metals	no	no	no	no

Table 65: Information collected from MSCAs about preferred risk management options and about socio-economic data

MS	Preferred risk management option among the proposed ones?	Socio-economic information	Other information provided/ Other proposed contacts
SE	Favourable to a total ban (less costly and more efficient than partial ban of limitations)	very wide sector (artisanal, non-specialised, etc.) : jewelry sector + hobby sector	_
NL	need more info to say	_	NVIC (national poisons information center) Food and consumer product safety authority (VWA)
DK	Favourable to a total ban (maybe problems with the soldering)	-	GULDSMEDEBRANCHENS LEVERANDØRFORENING T: +45 4583 5211 E: cr@guldsmed.dk W: www.guldsmed.dk
DE	Favourable to a total ban (with problem of determination of lead content) Favourable to a ban for some jewellery (swallowable and leakable)	approximately <1% of jewellery sold may contain lead (rough estimation)	Giftinformationszentralen of germany

	no	-	Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit), Rochusstraße 65, D-53123 Bonn http://www.bvl.bund.de/cln_027/nn_493778/EN/Home/homepage__node.html__nnn=true poststelle@bvl.bund.de Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung) Thielallee 88-92, D-14195 Berlin http://www.bfr.bund.de/cd/template/index_en Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAUA), Friedrich-Henkel-Weg 1-25, D-44149 Dortmund (http://www.baua.de/eindex.htm)
	favourable to a limitation of migration rate of lead and its compounds contained into jewellery (based on a toxicological assessment)	no info	-
CY	favourable to a total ban (second-best would be the limitaiton content)	13 importers 23% of jewellery sold would contain lead	Most of importers don't know the content of lead of their jewellery Usually lead is used in the main part of the jewellery and is coated with other metals
SK	Favorable to limitation of content in jewellery and to limitation of migration rate in jewellery	-	Hospital data (children's faculty hospital with policlinics/DFNsP)
EE	favourable to a total ban (but difficult to enforce, many articles, substitution might be impossible for certain uses like for medals welds)	–	There is no statistics about consumption of lead in Estonia
IE	need more info to say	no data	_
M	_	_	_

T			
ES	_	no info	no info
IT	-	-	Lead is not present in traditional goldsmith and jewellery which are constituted by precious metals. However, lead content is possible in base-metal jewellery (lead alloys). Lead is used to perform weldings. Lead can be used in gold/silver-plated or rhodiated jewellery.
AT	favourable to a ban of *some* jewellery (with the problem of prooving the *unacceptable* risk)	See Austrian Chamber of commerce (contacted Sept 2nd 2009)	
GR	Favourable to a total ban Favourable to a partial ban (little articles like pearls, earrings, etc.)	-	-
	Favourable to a total ban (problem: measure of human exposure) Other RMO: lead free certificate by authorized Lab + better inspections by the State	-	Toxicology and forensic department of Athens University Poison's center couldn't have evidence for lead poisoning from jewellery because there isn't a screening for measuring lead blood levels in children and this type of poisoning is in general unknown to clinicians - suggest that we inform clinicians about the possibility of poisoning from accidental ingestion of jewellery elements and so increase the vigilance for this toxic exposure
HU	Favourable to a total ban	no info	contact : National public health and medical officer service http://www.antsz.hu/portal/portal/antsz_20061010.html They may have statistical data concerning injuries related to lead content in products

PL	Not favourable to a total ban Favourable to a partial ban (as regards elements made of alloys with addition of lead, including brass) Favourable to a limitation of the content of lead and its compounds in jewellery Not favourable to a limitation of migration rate of lead (control and enforcement of migration are difficult, need for testing methods included in the regulation)	no info	contacts: Jewellery and Watch Making Association in Poland (antyk@ipgate.pl) Główny Inspektorat Sanitarny (Chief Sanitary Inspectorate) Ministerstwo Gospodarki (Ministry of Economy)

G.2. Consultation of Competent Authorities and stakeholders in countries outside the EU

G.2.1. US Centers for Disease Control and Prevention (US CDC) and US Consumer Product Safety Commission (US CPSC)

US CDC was contacted by e-mail in order to get more information on the reasons on the limits which are used in the US regulation. US CDC transferred the inquiry to US CPSC who had developed this regulation.
US CPCS indicated that "*the current law which addresses lead content in children's products in the US is the Consumer Product Safety Improvement Act of 2008 (CPSIA). Children's products are defined as consumer products that are designed and intended primarily for children 12 years of age or younger. The law establishes maximum limits for lead content of each part of a children's product and for paint used on consumer products. As of August 14, 2009, the maximum lead content for paint is 0.009% lead by weight in the dried paint film, and for other parts of products, the limit is 300 parts per million (ppm). The limit will be revised to 100 ppm on August 14, 2011, unless the Commission determines that it is not technologically feasible. There are some exclusions from the lead content requirements, such as for inaccessible component parts of product (that is, parts that are not physically exposed). However, paint, coatings and electroplating may not be used as a barrier to make a lead-containing component part inaccessible. In general, products are required to meet these lead content limits; there is no limit for migratable lead for children's jewelry*."

US CPSC also mentioned that "*Prior to this law taking effect, the staff of the U.S. Consumer Product Safety Commission issued an enforcement policy for children's metal jewelry. That policy indicated that metal jewelry products that had lead content less than 600 ppm would not be tested further and no enforcement action would be taken against them. Products that contained lead at levels that exceeded 600 ppm would be subjected to the test for migratable lead. Products with migratable lead of more than 175 micrograms could have been subject to action by the agency, after consideration of a number of other factors. This policy is no longer in effect because of the new law*."

Concerning the reasons of the limits, the following information was obtained: "*The lead limits now in US law were established by the United States Congress (signed into law by President Bush). During development of the legislation, the Congress solicited testimony from various stakeholders, some of whom spoke to the dangers of lead exposure in children and supported setting very low lead content limits. As far as I am aware, however, detailed exposure and risk assessments were not conducted or considered by Congress."* In the opinion of the contacted person, the intent of Congress was to not consider exposure scenarios but to simply mandate maximum lead content limits, forcing reductions in lead content for certain types of products, such as children's metal jewelry. According to this contact, many products and materials do not contain significant levels of lead (i.e., having lead content well below 300 ppm); so the law mostly affects products in which lead might be a constituent - certain metal alloys, some plastics, and pigments used for a variety of materials, etc. As for this contact person, there was no specific analysis of exposure or risk that resulted in the law's limits. Instead, the goal was to reduce the use of lead as much as possible.'

G.2.2. Health Canada

Health Canada was contacted by e-mail in order to get information on the methods which are used in order to control if the implemented regulation is respected. According to their answer, two methods are used:

- Health Canada Method C-02.4 for the determination of total lead in metallic consumer products;

- Health Canada Method C-08 for the determination of migratable lead in consumer products.

Moreover, the same questionnaire as the one which was sent to EU MSCAs has been sent to Health Canada.

The provided information is summarised in the following tables.

Table 66: Information collected from Health Canada about children contamination to lead and its compounds

Are there some campaigns to measure blood lead levels in your country?	When performing these campaigns, did you collect information on the possible causes of contamination when PbB>100 µg/L ?
Not on a routine basis but studies by Statistics Canada.	?

Table 67: Information collected from Health Canada about national measures concerning lead-containing jewellery

Is there a national legislation on lead in jewellery ?	Are there non regulatory actions about lead in jewellery ?	Is there a national standard to control lead in jewellery?	Is testing routinely conducted on lead in jewellery ?	Are there substitution measures currently under development ?
2005 regulation on jewellery and jewellery components for children under 15: 600 mg/kg total lead and 90 mg/kg migratable lead	no (voluntary measures in 1999 and 2000 were not effective)	-	Regular controls of compliance of lead content in jewellery by Health Canada: "enforcement surveys" Tests methodologies: Determination of total lead in metallic consumer products (C02.4) Determination of migratable lead in consumer products (C08) Determination of total lead in surface coating materials in consumer products (C02.2)	Since lead is limited, substitutes must be used but it is industry which is responsible for the choice of alternatives

Table 68: Information collected from Health Canada about preferred risk management options and about socio-economic data

Preferred risk management option among the proposed ones?	Socio-economic information	Other information provided/ Other proposed contacts
Favourable to a total ban ("canadian regulation is efficient to this respect") Not favourable to a partial ban (inefficient as regards the risks)	Most of costume jewellery sold in Canada are imported Marketplaces surveys to check the compliance of the 2005 regulation	For the purposes of enforcing lead content limits, "jewellery" is defined as "decorative items intended for regular wear on the body or on clothing or clothing accessories. Items like watches, eyeglasses, and belt buckles, which have a primary functional purpose, are not classified as jewellery; however, any charms,

Favourable to a limitation of the content of lead Favourable to a limitation of migration rate	are quite satisfactory	beads, or other decorative components on these items must meet the lead content limits for children's jewellery. The range of costume jewellery items sold in Canada is very large and is constantly changing. The number of companies that import and sell costume jewellery is Canada is also very large. This is believed to be a factor in the ineffectiveness of voluntary measures to remove lead-containing children's jewellery from the Canadian marketplace.

G.3. Consultation of industry actors of the EU and French fashion jewellery market

G.3.1. INERIS survey

A need for consultation of European actors of the fashion jewellery market and of the lead market was identified early in the process of this restriction proposal. For this reason, a call for tender was issued in May 2009. Following this call for tender, INERIS (the National Institute for Industrial Environment and Risks) was in charge of this survey and the results are available in INERIS (2009).

Industry actors have been consulted through a web-based questionnaire (the structure of the questionnaire and the type of questions which were included are provided in the original Annex XV report). More than 3000 firms have been surveyed in the EU. These included: manufacturers/importers/ exporters of lead, producers/importer/exporters of fashion jewellery and European federations of these sectors. The questionnaire was available for 3 months: from mid-July to mid-September 2009.
Industry actors were identified and individually contacted directly via e-mail with a formal letter attached to this e-mail explaining the frame and the objective of this consultation. About 130 actors were prior contacted by phone; these were federations and actors which were identified as key players on the market.
Results have not been successful as only about 50 questionnaires have been returned. As reported in INERIS (2009), although these answers are not numerically significant, they still provide some information:
Lead use in the fashion jewellery sector was reported in several EU countries.
Worries about the impacts of a possible modification of the regulation concerning the use of lead and its compounds in fashion jewellery in terms of quality and appearance of the products and in terms of production costs.
A small mobilisation of the consulted actors in the fashion jewellery sector (which may result from the fact that this sector consists of many small and very small companies).

The relatively unsuccessful outcome of this survey may be explained by the reasons mentioned in the introduction of this section: the lack of knowledge of many industry actors regarding their jewellery's composition, especially if jewellery is imported and the difficulty to identify and exhaustively cover all the actors. Another explanation could be added: the reluctance of industry actors to give information or quantitative data about their activities for competition and confidentiality reasons. Besides, these difficulties have been confirmed by several interviews led with industry actors during the survey period.

G.3.2. CETEHOR and BOCI

A phone conference was organised in September 2009 with CETEHOR (Technical Centre for the watch and jewellery industry) and BOCI (trade association of producers of fashion jewellery).
CETEHOR indicated that the most frequently used alloy in fashion jewellery is made of tin and lead with about 8 to 10% lead. Lead is reported to be used especially for decreasing the melting point of the alloy so that it increases malleability. No information could be obtained on the percentage of fashion jewellery which is made of this type of alloy. CETEHOR mentioned that such alloys are always coated and that the lead migration rate depends on the quality of the surface treatment.

BOCI gathers about one hundred members, most of them being small and medium enterprises of less than 10-20 employees. They represent about 65 to 70% of the French market in terms of turnover. BOCI mentioned that it had some feedback from its members about the survey carried out by INERIS and that most of them did not have sufficient knowledge to answer the questionnaire especially on the products' composition and on the risks that they may pose. BOCI estimates that there may be between 800 and 900 companies in the fashion jewellery sector in France.

Concerning alternatives to lead, BOCI reported that the only possible substitute seems to be silver. The companies which have experienced this alternative indicate that the articles have the same quality in terms of hardness. However, they mention that the use of silver would increase production costs of alloys of a factor of 2 or 3 without allowing producers and distributors to sell the jewellery at a higher price. Indeed, the jewellery would remain in the category of "fashion jewellery" because of its mixed content of precious and non precious materials. The loss could be then significant especially because, when an alloy is used for the production of fashion jewellery, it is used for the product scale as a whole, for homogeneity reasons.

BOCI highlighted that the impact of a restriction on the use of lead and its compounds in fashion jewellery would be important, especially for crystal sector. According to BOCI, about 80% of the fashion jewellery would contain crystal and it would be important to have information on the potential release of lead by crystal.

Following this conference call, BOCI sent complementary information:

Alloys which are used in fashion jewellery are made of copper or tin with an average lead content of about 6%.

All articles contain crystal. The percentage of crystal in the whole article depends on the article, but it may be estimated to be comprised between 40 and 70%. Other lead-containing components are rarely used.

Among the proposed restriction options, the companies which gave information to BOCI would rather prefer a limitation of lead migration rate as it is the only one which would be significant in terms of human health impacts. According to them, a limitation of this migration rate is realistic and may be envisaged as long as it does not imply drastic changes of the industrial techniques and processes. A maximal lead content in alloy of 6% would already be synonym of important technical adaptations for the producers.

The use of lead in alloys in a concentration greater than 10% was not reported.

CETEHOR was also contacted in order to get information about the regulations concerning precious jewellery. The aim of this consultation was to know what the minimum levels of precious metals in precious jewellery were and if there were maximum tolerable levels for other metals (such as lead) in this type of jewellery. CETEHOR indicated that, depending on the MS, there is a specific legislation which addresses the production and the placing on the market of articles made of precious metals (in France, gold, silver and platinum are considered as precious metals). In France, it is in the French General Tax Code[88] which stipulates, among others, specific minimum contents for gold, silver and platinum. Depending on the content of these metals, a hallmark is present on the jewellery. If a jewellery has a content of gold which is below 37.5%, it will not be possible to call it "gold jewellery" when it is placed on the market. For other metals which are non-precious, there is no regulation (except the one for nickel) which requires maximum levels. From this information, it can be considered that lead is not regulated in precious jewellery and it may be envisaged that precious jewellery such as "gold" jewellery (which contain a minimum of 37.5% gold) may also contain lead.

G.4. Consultation of the French Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF)

G.4.1. National survey on fashion jewellery articles

DGCCRF was contacted in order to get information on the French regulation about lead compounds in fashion jewellery and piercing and about a survey which had been performed by DGCCRF on fashion jewellery articles.

[88] http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006069577 (accessed in March 2010).

In response to our inquiry, DGCCRF specified that lead compounds were regulated in fashion jewellery and in piercing by the French Arrêté of 1st February 1993 which restricts the import and the placing on the market of imitation pearls which have a coating containing the following lead salts: lead carbonates CAS n°598-63-0 and CAS n°1319-46-6 and lead sulphates CAS n°7446-14-2 and CAS n°15739-80-7 - when the pearls are sold in bulk or used in jewellery and fashion jewellery items.

DGCCRF also sent the results of the survey realised on fashion jewellery articles which are sold in France (DGCCRF (2008)). The main conclusions of this survey are summarised below:
The survey was performed at the end of 2007 and concerned 139 establishments.
The objective of this survey was to assess human health risks for consumers of fashion jewellery articles (mainly). This campaign allowed controlling the respect of the regulations related to nickel and lead compounds in fashion jewellery. 43 samples were taken and 7 of them were not conformed. No sample was qualified as "harmful".

With 66 irregularities noticed in 139 establishments for 445 control actions, this survey highlights that about 32% of the fashion jewellery selling points which were controlled present at least one breach of the regulation. These breaches mainly deal with safety of the products, auto-controls or misleading.
This campaign also highlights that the suppliers, the importers and the actors who place on the market these articles present an important lack of knowledge concerning the regulation related to nickel and that they hardly ever know the one dealing with lead compounds.

The high irregularity rate, the number of non-conformed samples and the observation of an important lack of knowledge of the professionals concerning the regulations applicable in terms of safety of their products are preoccupying considering the consumers' safety. Such situation suggests that this survey should be re-performed later on in order to have a broader scope so that markets could be included since certain sellers who attend this type of exhibition do not always know the composition of the articles that they sell.

G.4.2. SCL

Consultation with the SCL, which is the laboratory of the French Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) and of the French General Directorate of Customs and Indirect Duties (DGDDI) revealed that European standard EN 1811 is contested especially for the part dealing with the measurement of surface area as it seems to lead to a great variation of the results. Consequently, the relevance of expressing the lead migration rate per surface unit is questioned by the laboratory as it is considered that it may lead to dispute.

G.5. The French Institute for Public Health Surveillance (InVS)

InVS was consulted as, at the time of the elaboration of this restriction proposal, this institute was performing a national campaign in order to obtain a distribution of the blood lead levels of children exposed to "unusual" sources of lead. However, InVS indicated that the results of this campaign would be available around May 2010, which is after the deadline of submission of this restriction proposal. As a consequence, this data could not be included in this proposal.

InVS was also contacted regarding EPAC which is a permanent study on home and leisure injuries. A poster from this study about ingestion and inhalation of small objects by children under 5 years-old was identified[89] (InVS (2009)). Jewellery were not specifically mentioned in this poster. Consequently, InVS was consulted in order to obtain information for this type of articles. InVS

[89] http://www.dsi.univ-paris5.fr/AcVC/Publications/Poster%20ingestion%20corps%20etrangers%20SFP%202009%20BAT.pdf (Accessed in March 2010).

indicated that between 2004 and 2007, 52 cases of ingestion of jewellery were registered for children under 5 years-old, in 10 French emergency services.

G.6. OECD

OECD was contacted in order to know if a OECD method for measuring the migration rate of metals from products was available. OECD indicated that no such method was available.

G.7. SCHER (Scientific Committee on Health and Environmental Risks)

The SCHER was requested to provide a scientific opinion on the Danish EPA Survey and Health Risk Assessment of lead in jewellery (Danish EPA (2008)). This opinion has been published in 2010 (SCHER (2010)).

A meeting has been organised, in January 2010, with the members of the working-group of the SCHER who was in charge of this opinion. During this meeting the work undertaken in this restriction proposal was presented and several issues were discussed with the SCHER working-group, based on its opinion about Danish EPA report. The main conclusions of SCHER are available in SCHER (2010).

G.8. General Directorate of Customs and Indirect Duties (DGDDI)

As all articles which are imported in or exported from the EU need to be classified, the General Directorate of Customs and Indirect Duties (DGDDI) was contacted in order to have information on a possible way to categorise fashion jewellery.

DGDDI indicated that such classification is performed using a TARIC code and that the code for “Imitation jewellery” is “7117”[90]. Note 11 of chapter 71 indicates that "for the purposes of heading 7117, the expression 'imitation jewellery' means articles of jewellery within the meaning of paragraph (a) of note 9 (but not including buttons or other articles of heading 9606, or dress-combs, hairslides or the like, or hairpins, of heading 9615), not incorporating natural or cultured pearls, precious or semi-precious stones (natural, synthetic or reconstructed) nor (except as plating or as minor constituents) precious metal or metal clad with precious metal”. Note 9a) states that "... the expression 'articles of jewellery' means: a) any small objects of personal adornment (gem-set or not) (for example, rings, bracelets, necklaces, brooches, earrings, watch-chains, fobs, pendants, tiepins, cuff links, ...)".

H. Other information

Not relevant for this proposal.

[90] http://ec.europa.eu/taxation_customs/dds/cgi-bin/tarchap?Taric=7117000000&Download=0&Periodic=0&ProdLine=80&Lang=EN&SimDate=20100407&Country=----------&YesNo=1&Indent=0&Action=0#OK (Accessed in April 2010).

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Annexes

Annex A - Derivation of chronic DMELs using IEUBK model

Model
The Integrated Exposure Uptake Biokinetic model is a PBPK model developed by US EPA to assess blood lead level of children exposed to different sources (White P.D. *et al.* (1998)).

The software version of IEUBK was 1.1 Build 9.

Methodology

This model has been used to estimate the intake of lead which would result in a blood lead level of 5 µg/L, for a chronic exposure. The choice of the PbB level of 5 µg/L is discussed in Section B.5.11.4.
For the assessment, the following age categories have been taken into account: 3 to 12 months, 12 to 24 months and 24 to 36 months. It is considered that the children are only exposed during the period of the age category. For example: for the age category 24-36 months, it is considered that the exposure of the child only begins when he is 2 years-old and that it stops when he is 3 years-old.

The mouthing of jewellery has been considered as a diet exposure only. All other routes of exposure (air, water, soil/dust, maternal) have been set to 0.
The oral absorption of lead has been set to 50% according to Section B.5.1.1.

In order to assess the intake of lead which would result in a blood lead level of 5 µg/L, a dichotomous process was used: the input of the software called “intake” has been changed until a PbB level of 5 µg/L was reached.

Results

Age of the child (months)	Intake value (µg/d)	Body weight (kg)*	DMELc value (µg/kg bw/day)
3-12	1.66	5.4 to 10.1	0.16
13-24	2.57	10.4 to 12.3	0.21
25-36	3.11	12.5 to 14.4	0.22

* Bodyweights used by IEUBK

As a worst-case approach, the high-end figure of the range of body weights is used to derive a DMELc for each age category.

Annex B - Assessment of the daily intake of lead which would result in a PbB level of 400 µg/L after an acute exposure (2 or 5 days)

The "reconstruction" of the daily intake leading to a PbB of 400 µg/L has been performed by the French National Institute for Industrial Environment and Risks (INERIS (2010)).

PBPK modelling

Toxicokinetic models allow to describe qualitatively and quantitatively the fate of toxic substances within an organism. Among the toxicokinetic models, PBPK models (Physiologically Based Pharmacokinetic), take into account various physiological processes. In PBPK models, different general processes are modelled to describe the kinetics of the substance in different compartments of the body: absorption, distribution, metabolism and excretion. PBPK models have a structure composed of compartments representing tissues or organs and interconnected by flows, like blood flow.

Model

Different models are available in the literature to describe the fate of lead in the body. These models can be distinguished: empirical compartmental models do not take into account the physiology, whereas some models of varying complexity can be based on physiological processes.
The model used for this assessment is an extension of that proposed by Sharma M. *et al.* (2005) completed by equation proposed by O'Flaherty E.J. (1991) to take into account children's growth. The model has been validated by experimental data from two studies (Azar A. *et al.* (1975); Rabinowitz M.B. *et al.* (1976)).

Statistical method

The dose reconstruction performed in this study is based on the principle of Bayesian inference. The Bayesian analysis allows using *a priori* information, to establish distributions of posterior probabilities for different parameters. The dose reconstruction was performed considering the value of blood lead level of 400 µg/L as the maximum reached during each exposure.

Physiological and toxicokinetic parameters (Sharma M. *et al.* (2005)**)**

Parameters	**Notation**	**Values**
Volume of organes or tissues		
Liver	VLI	0.04x(BW)0.86
Kidney	VKI	0.0085x(BW)0.84
Well perfused tissues	VWP	0.01x(BW)0.86-VLI-VKI
Poor perfused tissues	VPP	(BW)0.86-VLI-VKI-VRA-VBO
Bone	VBO	0.039x(BW)1.02
Flow		
Cardiaque flow	Fcard	340x(BW)0.74
Alveolar ventilation	Falv	1.01 x Fcard
Tissular flows (cardiaque flow fraction)		
Liver	FLI	0.25
Kidney	FKI	0.17
Well perfused tissues	FWP	0.44
Poor perfused tissues	FPP	0.09
Bone	FBO	0.05
Partition coefficient		
Liver: blood plasma	PCLI:Pl	100
Kidney: blood plasma	PCKI:Pl	100
Well perfused tissues: blood plasma	PCWP:Pl	100
Poor perfused tissues: blood plasma	PCPP:Pl	20

Bone: blood plasma	PCBO:Pl	1000
Metabolic constants		
Liver excretion	ELI	0.2
Kidney excretion	EKI	0.47
Blood partition		
Bind	BIND	2.7
Kbind	KBIND	0.0075
Absorption		
Oral absorption	Aoral	0.5
Inhalation absorption	Ainhal	0.5

PBPK model (Sharma M. *et al.* (2005)**)**

$$V_{LI}\left(\frac{dC_{LI}}{dt}\right) = F_{LI}(C_{art} - C_{ven,LI}) + A_{oral}S - E_{LI}C_{LI}V_{LI}$$

$$V_{KI}\left(\frac{dC_{KI}}{dt}\right) = F_{KI}(C_{art} - C_{ven,KI}) - E_{KI}C_{KI}V_{KI}$$

$$V_{WP}\left(\frac{dC_{WP}}{dt}\right) = F_{WP}(C_{art} - C_{ven,WP})$$

$$V_{PP}\left(\frac{dC_{PP}}{dt}\right) = F_{PP}(C_{art} - C_{ven,PP})$$

$$V_{BO}\left(\frac{dC_{BO}}{dt}\right) = F_{BO}(C_{art} - C_{ven,BO})$$

$$Cp_{ven,i} = \frac{C_i}{P_i}$$

$$C_{ven,i} = 0{,}55Cp_{ven,i} + 0{,}45Cp_{ven,i} \times \left\{1 + \frac{BIND}{KBIND + Cp_{ven,i}}\right\}$$

$$C_{ven} = \frac{F_{LI}C_{ven,LI} + F_{KI}C_{ven,KI} + F_{WP}C_{ven,WP} + F_{PP}C_{ven,PP} + F_{BO}C_{ven,BO}}{F_{card}}$$

$$C_{art} = \frac{F_{card}C_{ven} + A_{inh}F_{alv}C_{inh}}{F_{card}}$$

With:

S	maximum release threshold of lead in stomach
Ci	concentration in the *i*th organ or tissue
Pi	partition coefficient between blood plasma and the *i*th organ or tissue
Cven,i	concentration in venous blood flow out from the *i*th organ or tissue,
Cpven,i	concentration in venous blood plasma flow out from the *i*th organ or tissue
Cart	arterial blood concentration

Growth over time (O'Flaherty E.J. (1991)**)**

$$BW = 3{,}5 + \left(\frac{BW_{child} \times age}{C_1 + age}\right) + \left(\frac{BW_{adult}}{1 + (C_2 e^{-C3 \times BW \times age})}\right)$$

With:
BW: body weight (kg)
C1 = 3;

C2 = 600;
C3= 0.017;
BWchild = 23;
BWadult = 50.

Results

The assessment has been realised for the minimum age, maximum age and median age of each age category.

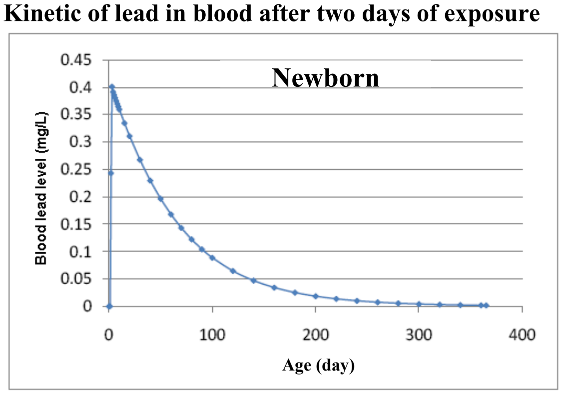
Intake resulting in a PbB of 400 µg/L after 2 days of exposure

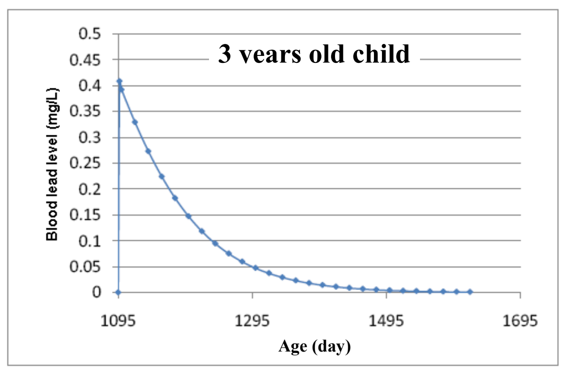
Age categories (months)	Minimum age intake (mg/d)	Median age intake (mg/d)	Maximum age intake (mg/d)
0-3	0.91	1.16	1.35
3-6	1.35	1.55	1.72
6-12	1.72	2.04	2.35
12-18	2.35	2.61	2.82
18-36	2.82	3.41	3.72

Intake resulting in a PbB of 400 µg/L after 5 days of exposure

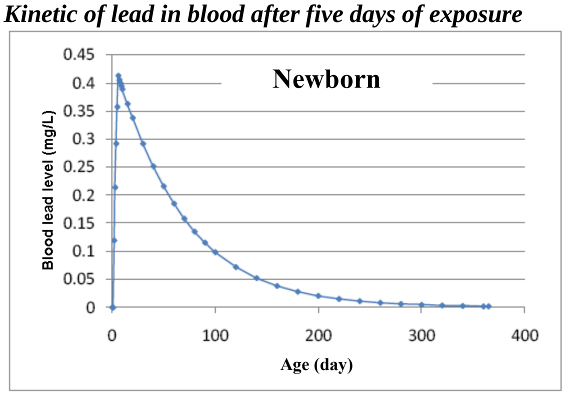
Age categories (months)	Minimum age intake (mg/d)	Median age intake (mg/d)	Maximum age intake (mg/d)
0-3	0.38	0.47	0.56
3-6	0.56	0.64	0.71
6-12	0.71	0.85	0.96
12-18	0.96	1.07	1.17
18-36	1.17	1.32	1.60

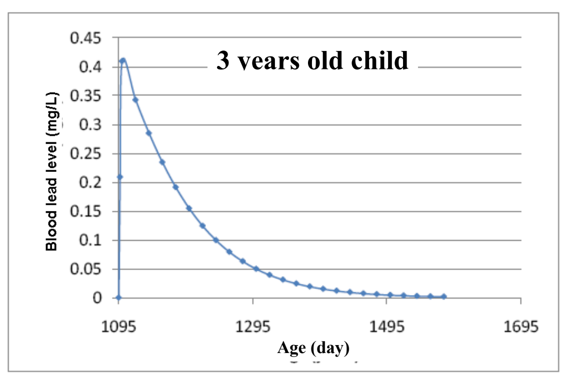
Kinetic of lead in blood after two days of exposure





Kinetic of lead in blood after five days of exposure





Annex C - Option 7: Two-steps option for Restriction on the use and placing on the market of jewellery (fashion and precious) based on the lead content and (under conditions) on lead migration rate

This restriction option would take place in two steps: first, the jewellery articles placed on the market would have to be tested regarding their lead content and then, the articles which would not comply with the first concentration limit set by the authorities would have to be tested regarding their migration potential. The first step would allow a quick and enforceable implementation of the regulation. However, as there is no direct relationship between lead content and lead migration, the second step is necessary in order to further distinguish between 'unsafe' and 'safe' lead-containing jewellery. This second screening aims at allowing lead-containing jewellery without (or "authorized") migration to be placed on the market, while avoiding other jewellery containing (migratable) lead to be legally placed on the market despite their risks for health. To sum up, the first step of this option would consist in a preliminary screening between lead-containing and lead-free jewellery (and between 'first-step-conform' lead-containing jewellery and 'not first-step-conform' lead-containing jewellery) and the second step would consist in testing remaining ('not first-step-conform') lead-containing jewellery.

1. Effectiveness

1.1. Risk reduction capacity

1.1.1. Changes in human health risks/impacts

To the condition that the two limits (content and migration) are set in a conservative way, the level of protection provided by this option is expected to be equivalent to the one provided by option 6 ('Restriction on the use and placing on the market of jewellery (fashion and precious) based on the lead migration rate'), that is, a reduction of the risk of children lead poisoning from both acute exposure (ingestion of jewellery) and chronic exposure (mouthing of jewellery).

1.1.2. Changes in the environmental risks/impacts

Not relevant for this proposal even though it is expected that a reduction of the use of lead and its compounds will have a positive impact on environmental protection.

1.1.3. Other issues

Not relevant for this proposal.

1.2. Proportionality

1.2.1. Economic feasibility

This two-steps approach implies different costs for different actors. Three cases have to be considered:

i. The industry actors <u>who would make the choice to remove any lead compounds</u> from their articles would not have to bear compliance/testing costs but substitution (and related) costs. The substitution costs would result from the switching to alternative (more expensive) raw materials. These costs are examined in section C.7 and Annex D. **They are expected to contribute to an increase of about 20% of the total production cost of a jewellery item**. As regards 'related costs', and as already mentioned above in the assessment of option 1, they are difficult to assess and would be additional operating and adjustment costs due to adaptation to alternatives' specific properties of workers, equipments and machines.

ii. The industry actors who would keep on using lead and/or its compounds in their (manufactured/imported/distributed) articles would have to bear testing costs. As this option is based on two-steps, testing costs are consequently of two kinds. They can be exclusive from one to the other or additional, depending on the situation. If the lead-containing jewellery articles tested comply with the (first) concentration limit set by the regulation, no migration test is then needed. Nevertheless, if the lead content of the articles preliminary tested exceeds the legal limit, the migration has to be tested in order to measure whether the migratable lead is below the second limit set or not. In the first case, the industry actors concerned would have to bear only the lead content testing costs; in the second case, he would also have to bear migration testing costs.

Lead content or migration testing costs differ with the method used. The lead content testing methods and their costs (for some of them at least) are presented in section E.1.2. in the presentation of option 2 ('Restriction on the use and placing on the market of fashion jewellery based on the lead content'). The costs amount between 15 and 40 euros per testing according to the method used and the laboratories (RPA 2009). From this presentation, it has been underlined that the method XRF seems to be cheaper and easier to implement for the industry actors. However, technically, it seems to be limited since it would only allow an analysis of the surface layer of the jewellery articles and have also limited resolution.

As far as the migration testing methods are concerned, they are presented in section E.2.1.2.2. For the reasons set forth in the same section, among the different methods available, the standard EN 71-3 is recommended to test the migration of lead from jewellery articles and according to RPA (2009), the use of this standard would imply a cost of about 22 euros for testing one component, 35 euros if two components are tested, 50 euros for three components and 65 euros for four components or more (as mentioned in section E.2.1. as well).

As a consequence, for the situation ii. previously presented, the industry actors who would succeed the first screening would have to bear a cost comprised between 15 and 40 euros per testing (to test only the lead content) and the others a cost comprised between 37 (15+22) euros and 62 (40+22) euros per (double) testing (on the basis of one component tested: content + migration). All industry actors would not thus bear the same costs. Nevertheless, one can also expect that, knowing that the lead content of their articles would surely exceed the legal limit, some industry actors would thus directly (and only) test their lead migration and thus bear only migration testing costs. These costs would thus be about 22 euros per testing.

Further, next to the question of knowing how much the costs of this option would be is the question of knowing who carries out the test(s). Indeed, one can expect that only manufacturers would have to make the tests required and that importers and distributers would only have to get the guarantee that the jewellery articles they place on the market are in conformity. Such an obligation would imply charges related to the information to be got from suppliers who would have to provide some certification. The testing/certification costs would thus be mainly transferred to manufacturers (who are expected yet to pass their additional costs on importers/distributers).

1.2.2. Technical feasibility

As regards technical feasibility, the present option seems to fulfill this criterion. Indeed, methods for testing lead content and lead migration to be carried out in order to comply with the regulation are available and scientifically recognized. Each method shows advantages and disadvantages. Concerning the measurement of lead content, and such as mentioned in the examination of option 2 in section E.1.2., the XRF method seems to be cheaper and easier to use but is technically limited since it would only allow an analysis of the surface layer of the jewellery articles and seems to have also limited resolution. Concerning the measurement of lead migration, standard EN 71-3 seems to be the most suitable method for the present issue (and for the reasons set forth in section E.2.1.2.2.).

1.2.3. Other issue

Not relevant for this proposal.

Regarding its two-steps approach and by allowing lead-containing jewellery without (or "authorized") migration to be placed on the market, while avoiding other jewellery containing (migratable) lead to be legally placed on the market, this option seems to be proportional.

2. Practicality

2.1. Implementability

As indicated in section E.2.1.2.1. for option 6 only based on migration, industry actors concerned by the option 7 should be capable to comply with its requirements in practice since content and migration tests (and alternatives) are technically available and economically feasible. However, a delay may also be necessary to adapt the production techniques to the alternatives or to implement an adequate control of the lead content and lead migration rate along the supply chain.

2.2. Enforceability

This option can be considered as rather simple to enforce (at least for the first step) given that it is based on an easy and quick first screening based on the measurement of lead content.
As for other options examined, for enforcement purposes, it is recommended that the present option contains a restriction limit so that enforcement authorities can set up an efficient control mechanism. In those circumstances, the present option has to contain two restriction limits: one for the measurement of lead content and one for the measurement of lead migration.

Concerning the second-step limit (migration rate), it is proposed to be in line with the limit proposed for option 6, that is, a migration rate below than **0.09 µg/cm²/hr**.

Concerning the first-step limit (concentration limit) however, the question is challenging. Indeed, in order to be justified for regulatory purposes, this limit should be ideally scientifically based. However, this basis seems to be impossible to determine for the risks targeted herein, since the precise or average lead content of jewellery articles is not known and, in addition to that, and as already mentioned, there is no correlation between the lead content of a jewellery article and the releasable lead contained into it. The limit cannot thus be set on full scientific basis. Still, the limit cannot relevantly be set randomly either. In order to be as much protective as possible, one might thus be tempted to set a very low (very close to zero) concentration limit. However, this choice may face two problems. On the one hand, as there is no correlation between concentration and migration, even such a limit might not guarantee that no lead will migrate from the article which might still cause harm to children. On the other hand, the existing analytical methods to measure lead (and other metals) content are technically limited and all show limits of quantification (LOQ). As a consequence, even if the very low concentration limit chosen was proven to be protective, it might not have much sense (and also not much enforcement efficiency) to set it below these LOQ since the tests would not thus be efficient. In such a situation and despite the absence of full scientific basis, two alternative ‘second-best’ solutions could be envisaged to set the concentration limit for the present option: aligning with the limits set by the world-wide existing regulations on jewellery based on lead content or aligning with the LOQ of available analytical methods.

As already presented in section E.1.2., the existing regulations on that particular issue are the following:

- Denmark with a ban on import and sale of products, including jewelleries, containing more than 100 ppm (mg/kg) of lead (or mercury) in the homogeneous single parts of the product (national Law n°308 of May 17th 1995 and Statutory order n°1082 of Sept. 13th 2007; replacing Statutory order n°1012 of Nov. 13th 2000).
- In the USA, children’s jewellery and other children’s products shall not contain more than 300 ppm lead in any part of the product (with some exceptions, such as inaccessible parts). This limit is expected to be revised to 100 ppm in August 2011, unless the Commission determines that it is not technologically feasible.
- In Canada, a double limit is set via the Children's Jewellery Regulations of May 10th 2005 "on jewellery for children under 15" which authorise their sale, import and advertisement only if the total lead content in the product is below 600 mg/kg (0.06% by weight) (with less than 90 mg/kg (0.009% by weight) of migratable lead).

By opting for this solution, the concentration limit could thus be set at a value **between 100 ppm (mg/kg) and 600 ppm (mg/kg)**.

As far as the second alternative is concerned, the existing analytical methods allowing the measurement of lead content are also presented in section E.1.2. and are comprised **between 81 and 130 mg/kg**.

With these two intervals of values, the choice could be made to opt for a conservative approach and thus to align with the lowest concentration limit, that is, 81mg/kg. This limit is restrictive. The advantages of this choice would be that the level of human health protection would probably be high. However, as the limit is very low, it can be expected that very few lead-containing jewellery articles would succeed the content tests (in the current conditions of the market without substitution) and the number of industry actors who would have also to test lead migration would be high (and so the global cost of testing) (except for the ones previously mentioned who directly test lead migration and thus bear only migration testing costs). Moreover, it can be anticipated as well that some sectors could be more heavily affected than others, such as crystal industry for example, for which it would surely be impossible to comply with the first-step limit (since it is impossible to produce crystal without a rather significant amount of lead) and migration tests would have thus to be systematic.

On the other extreme side, the choice could be made to be rather permissive on the lead content limit for the first screening. The choice could be thus made on 600 mg/kg. Such a solution would allow many lead-containing jewellery articles succeeding the broad first screening and industry actors of whom articles are intrinsically dependent on their lead content (such as crystal industry) would be less inequitably penalized. The number of actors who would have to test migration would then be comparatively low and so would be the global cost of testing. However, the important shortcoming of such a solution would be that a certain volume of lead-containing jewellery articles could be legally placed on the market despite their probable risks for children and human health in general. Indeed, one cannot be sure that a piece jewellery which would contain 600mg/kg of lead would be safe.

A more reasonable 'in-between' choice could thus be more appropriate.

As a consequence, in terms of enforceability, this option is attractive from its two-steps composition viewpoint and since it may be relatively less costly. However, the choice of the first-step concentration limit might be complicated and generate important uncertainties.

2.3. Manageability

For the same reasons set forth for option 6, option 7 is expected to fulfil this criterion in a better way than option 1 since its scope takes into account both fashion and precious jewellery.

3. Monitorability

3.1. Direct and indirect impacts

No significant difference in monitorability is identified compared to options 1 and 6 as it is expected that authorities responsible for the enforcement of option 7 will concentrate more on the fashion jewellery sector than on the precious jewellery sector. However, in the present option, the measures of lead content and lead migration have to be monitored. Stakeholders involved in these monitoring activities are authorities responsible for the enforcement of the REACH restrictions in the different Member States and the laboratories which will be in charge of performing the lead content and migration rate measurements. Here also, monitoring might unequally concern industry actors since micro and SMEs can be more difficult to identify on the market and thus to control.

3.2. Costs of the monitoring

Costs of monitoring relate to lead content and lead migration testing costs that authorities would have to bear in order to control the jewellery articles placed on the EU market. These costs have been presented above in the present Annex and would be comprised between 15 and 40 euros per testing (to test only the lead content) and comprised between 37 (15+22) euros and 62 (40+22) euros per (double) testing (on the basis of one component tested: content + migration). To make the monitoring easier and faster, it can be expected that enforcement authorities would directly test migration on the samples controlled.

As a conclusion, the overall assessment of option 7 concludes on the fact that this option is expected to be rather easy to enforce and implement, at least for the industry actors who would only test the lead content for the first screening, and to monitor. However, the question of the choice of the first (concentration) limit to set is complex and might lead to high uncertainty as regards the risks and the efficiency to mitigate them. From this choice will depend the level of protection which may be guaranteed.

Annex D – Summary of the cost items collected for the socio-economic analysis of the proposed restriction (option 6)

All information is this annex is already presented in the dossier. This Annex aims at gathering information for clarification and presentation purposes.

Quotation (in US $ / tonne) http://www.metalprices.com/ (accessed on 09/02/2010)						
Tin	Antimony	Lead	Cadmium	Copper	Bismuth	Silver
14,925	6,500	1,930	3777.8	6328.5	17222.2	498,020

Compliance/testing cost for all the actors concerned by the restriction proposed	Cost of testing migration: 22 euros for testing one component with method EN 71-3 (according to RPA (2009))

Substitution costs	•The cost of alloys is estimated to represent around 20 to 30% of the final cost of a jewellery article •Lead-containing alloys are estimated to be around 7% cheaper than lead-free alloys (taking into account alloys containing up to 10% of lead)

Other costs for all the actors concerned by the restriction proposed:
•learning of new obligations (administrative burden)
•adjustment costs I: learning of new production processes (workers training) (especially for manufacturers)
•adjustment costs II: purchase of new tools and equipments or conversion/adaptation of existing tools and equipments + R&D activities (especially for manufacturers)
•implementation of quality controls

Other costs for importers of jewellery articles/alloys for jewellery

Costs (qualitative information)
•additional costs due to an increase of the price of imported jewellery articles/alloys for jewellery •the cost increase will depend on the proportion of their cost increase that exporting manufacturers will pass on down the supply chain •cost of acquiring/controlling information on the composition of the products imported (certification/guarantee to be got from suppliers)

Other costs for distributors of jewellery articles

Costs (qualitative information)

•additional costs due to an increase of the price of supplied jewellery articles/alloys for jewellery •the increase of the cost will depend on the proportion of their cost increase suppliers will pass on down the supply chain •cost of acquiring/controlling information on the composition of the products distributed to consumers (certification/guarantee to be got from suppliers)

Other costs for consumers of jewellery articles

Costs (qualitative information)
•Price increase of jewellery articles (depending again on the proportion of the cost increase that suppliers/distributors will pass on the final consumers)

Other costs for public authorities

Costs	**Other costs (qualitative information)**
•costs of controls/monitoring (cost of testing migration): 22 euros for testing one component with method EN 71-3 (according to RPA (2009))	•costs of campaigns: additional budgetary expenses (expected to be moderate)

Other costs for third countries

Costs (qualitative information)
•non-EU producers and exporters of jewellery articles/alloys for jewellery might be affected (compliance costs/substitution costs)

Other costs for labour markets

Costs (qualitative information)
•employment might be affected (conversions/destruction/creation of activities) but the impact is difficult to assess