ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAMES: Lead and its compounds

IUPAC NAME**: LEAD**

EC NUMBER: 231-100-4

CAS NUMBER: 7439-92-1

CONTACT DETAILS OF THE DOSSIER SUBMITTER:
The French Competent Authority

VERSION NUMBER: 1 DATE: 15th April 2010

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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
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 substance(s)

The substances concerned herein are **lead and all its (organic and inorganic) compounds**. Instead of giving an exhaustive list of all lead compounds, only elemental lead is reported below.

Table 1: Identity of the substance

Substance name	IUPAC name	CAS Number	EINEC	Formula	Purity and impurities
Lead	Lead	7439-92-1	231-100-4	Pb	The restriction dossier 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

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.9.1.1). 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 jewels intended for children, as these articles are exempted from the new Toy Safety Directive 2009/48/EC[2].

Lead may be present in jewels 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 jewel. Consequently, both metallic and non-metallic jewels 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)).

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 jewels (i.e. exposure via dermal route) does not seem to result in any health risk. On the contrary, mouthing or accidentally ingesting jewels which contain lead can result in health risks.

[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

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 jewels (mouthing and ingestion) are documented in the international literature (see section B.9.3.1), 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 jewels 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 jewels 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.2.6) 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 10th 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 jewels which are 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 Annexe 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 of restriction

Conditions of the restriction
Jewels which have a lead migration rate greater than 0.09 µg/cm²/hr are prohibited from being produced and placed on the market.

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 jewels, 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 jewels. This choice is mainly based on manageability reasons. Indeed, there is no clear definition for what a fashion jewel is even though fashion jewels may be differentiated in practice from precious jewels, according to RPA (2009) depending on the used material (presence of precious metal alloys in precious jewels and use of a variety of materials in fashion jewels), on the place where they are sold, on the pricing structure (fashion jewels are significantly cheaper than precious jewels) and on the presence of a hallmark which indicates that a jewel is precious (however, the absence of a hallmark does not necessarily mean that the article is a fashion jewel). Moreover, it is acknowledged that the majority of reported cases involve fashion jewels and not precious ones. However, because of a lack of a clear definition, because children can come into contact with adult jewels, and also because it is expected that the use of lead and its compounds is marginal in the sector of precious jewels, decision was made to include both types of jewels. Section E.2.1.2.3 presents more information on the differences between fashion and precious jewels.

It is highlighted that this restriction dossier only deals with jewels 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.
However, many of the reported cases deal with jewels and this is the reason of the targeting of this restriction proposal on this type of articles.

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. The proposal is based on the lead migration rate. Indeed, studies suggest that there is no correlation between the lead content of a jewel and the quantity of lead that migrates from the jewel (BfR (2008); Danish EPA (2008)). Lead content is the quantity of lead that is present in the jewel's composition whereas lead migration rate is the quantity of lead which can be released by the jewel, during a certain time, generally under acidic conditions, simulating the use or misuse of the jewel (e.g. mouthing or ingestion). As a consequence**, the proposed restriction is targeted to the limitation of lead migration rate as it is considered to be the most relevant indicator of potential exposure**.
Several suitable testing methods are available for the measurement of the lead migration rate from a jewel. 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).
The lead migration rate of 0.09 µg/cm²/hr should be considered for each individual part of the jewel. When tests are performed on several parts of an article, the analytical results of each part should be compared to the limit of 0.09 µg/cm²/hr. If a part has a migration rate which exceeds this limit, it should be considered that the article is not allowed to be produced or placed on the market.

It is 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, jewels 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. Secondly, coated jewels should be tested after removal of their coating; in this case, the sum of both migration rates (coating alone and jewel 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.

Derogations
No derogation is proposed.

Delay
A delay should be envisaged for implementation: the restriction may apply 6 months after the entry into force of the amendment of REACH Annex XVII.

Formally transposed in Annexe 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	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.

It is important to consider that consumers may still be exposed to lead in jewels which are 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

A.2. Summary of the justification

A.2.1. Identified hazard and risk

The population targeted in this dossier is constituted by children, and especially children under the age of 3. According to data provided in section B, **children are more vulnerable than adults to lead** as their rate of digestive absorption is approximately three times higher and as their central nervous system is still under development. Organic mental disorders caused by lead are permanent. Studies have shown that individuals poisoned during infancy continue to manifest a cognitive deficiency many years later and beyond, during adolescence and adulthood. Moreover, according to recent publications, it does not seem possible to define a scientific-based threshold for the effects of lead on the central nervous system and on the endocrine system (BfR (2009); Canfield R.L. *et al.* (2003); Lanphear B.P. *et al.* (2005); Schnaas L. *et al.* (2006)). The Human Biomonitoring Commission of the German Federal Environment Agency states that "**the definition of an effect threshold concerning blood lead levels is arbitrary and not justifiable**" (BfR (2009)).
Few information exist on acute poisoning, but 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 blood lead 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. A LOAEL of 800 µg/L (ATSDR (2007)) and a NOAEL of 400 µg/L (TNO (2005)) were identified for acute effects in children.
Concerning chronic exposure, the most important effect in children is a non-threshold effect on the nervous system (effects on the IQ). Concerning other effects, renal effects are also important and could be observed at blood lead levels over 100 µg/L (LDAI (2008a)).

Furthermore, children may also be exposed to lead *in utero*: pregnant women can thus also be considered, to a lesser extent, as an at-risk population since they might also mouth leaded jewels, resulting in an exposure of their unborn child. Concerning the pregnant women, risk of spontaneous abortions, growth retardation and premature delivery may appear when blood lead level is above 250 µg/L.

Living in an old building (with possible lead paints and lead waterworks), in an area which has been contaminated because of industrial activities are generally among risks factors which are currently used to organise campaigns to detect lead poisoning. However, some other unusual sources of lead which may result in lead poisoning of children have been identified. These may be traditional remedies and cosmetic products, materials used for the storage and the preparation of food, professional of hobby activity of the parents and accidental ingestion or mouthing of different products which contain lead (INSERM (2008); InVS (2006b)). **Such lead-containing products with moderate or low exposure potential are more and more recognised as having a significant impact on public health** (Maas R.P. *et al.* (2005)). Weidenhamer J.D. and Clement M.L. (2007b) also suggest that environmental policies would need to address restrictions on lead in consumer goods such as jewellery.

Feedbacks from worldwide studies and surveillance activities for the past few years have highlighted **several serious alerts of children poisoned by lead and/or its compounds resulting from a misuse (ingestion/mouthing) of small articles, such as fashion jewels**. The restriction proposed herein is grounded on these alerts which have been confirmed by the different consultations performed during the preparation of this dossier.

As previously mentioned, lead poisoning by misuse of such articles may be caused by both acute and chronic exposure.

1. Acute exposure may result from the ingestion of an article, such as the case of the child who died in the USA in 2006. Similar cases of ingestion of small items containing lead, not resulting in the death of the child, have been reported in the international literature (Guillard O. *et al.* (2006); InVS (2009)). It is very important to highlight that, in case of ingestion, the behaviour of the child does not necessarily change and consequently, it is possible that the parents are not aware of the accident. This was the case of the child, reported by Guillard O. *et al.* (2006): the child had swallowed a toy money made of pure metallic lead. Its behaviour did not change, he showed no loss of appetite and no specific abdominal pain or vomiting was noted by the attending physician.
2. Chronic exposure can result from mouthing articles as reported by Jones T.F. *et al.* (1999): a two-year-old child had a blood lead (PbB) level of 430 µg/L and the investigation showed that the only possible source of exposure was a necklace with metallic pearls containing lead in a concentration of 2%. The blood lead level of this child was measured because of a routine campaign, as no specific risk factor had been identified. InVS (2008) reports that another child of 9 years old was also lead poisoned with the same necklace (PbB level of 180 µg/L). This study thus indicates that many cases of chronic lead intoxication may remain unknown because of unusual sources of lead. InVS (2008) also reports that ingestion of lead fishing weights and mouthing of metallic articles can be linked to PbB levels from 476 to 820 µg/L. Another case of lead poisoning due to mouthing activity is reported by Health Canada (InVS (2008)) with a child of 5 years old who used to mouth the pendant of a necklace: the pendant was made of pure lead and it was covered with a plastic coating. Due to mouthing of the coating, the metal was accessible and migration tests showed a result of 1 022 mg/kg of migratable lead. Tsuji L.J. *et al.* (2002) measured lead dissolution in saliva in children from northern Ontario (Canada) who place lead pellets in the mouth as a place of temporary storage prior to discharge in air-pellet guns. The authors report significant differences between initial salivary-lead levels (1.5 +/- 1.7 µg/L) and salivary-lead levels after addition of two lead pellets (12400 +/- 5700 µg/L). These results confirm that lead originally present in items which are placed in the mouth can dissolve in saliva.

Since 1998, at least 6 cases of lead poisoning have been clearly identified as resulting from a misuse of fashion jewels 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. They are reported in section B.9.3.1. Moreover, 52 cases of ingestion of jewels for children under 5 years-old were reported in 10 French emergency services, between 2004 and 2007. Based on assumptions described in Section F.1.2, it may be extrapolated that about 5000 children possibly ingest a jewel every year in the EU.

There are many reasons which make think that these few cases reported in the literature clearly constitute an **under-estimation of the actual number of children actually poisoned** by lead from articles and among them, jewels. These cases may be considered as detected by chance. Indeed, the monitoring and surveillance systems are targeted to at-risk populations (e.g. living in contaminated environments, in old houses) and they are not adapted to the detection of lead poisoning resulting from unusual sources. Also, chronic lead poisoning is difficult to detect by doctors. It is often insidious because the patient does not necessarily present any visible symptom and the neurodevelopmental effects might only be diagnosed much later, specifically, once the child has started school, by which time the effects have become irreversible. The symptoms are also not necessarily specific and may easily be attributed to other causes than lead. These issues have led the French Institute for Public Health Surveillance (InVS) to the assumption that *"it is unlikely that a child with lead poisoning linked to ingestion or to sucking a lead object or containing lead would be detected by doctors"* (InVS (2008)).

It has to be emphasised that different studies indicate that lead-containing jewels are still (and significantly) placed on the market and thus, are likely to be (mis)used by children (see section B.2.6). According to Weidenhamer J.D. and Clement M.L. (2007c), despite numerous recalls in the USA, information related by mass media and published papers in per-reviewed scientific literature, a significant part of children's and fashion jewels which are imported to the USA contain a high amount of lead. Like in the USA, many jewellery items are imported in Europe; therefore, the issue of lead in jewels is not anecdotal and it concerns all children across the Community. Given the high number of products which have been recalled from the American market because of their lead concentrations (152 million of jewels sold in vending machines have been withdrawn of the American market between 1990 and 2004 - KID (2004)), it is clear according to InVS (2008) that children have been poisoned even though it has not been detected and that the psychomotor development of these chronically poisoned children has been altered, but without any possibility to detect it. This is also the opinion of Weidenhamer J.D. and Clement M.L. (2007c): "*the accumulating evidence that very low lead exposures can result in significant neurological consequences for children implies that for every child with a life-threatening blood lead level from ingestion of contaminated jewellery, many more may quietly suffer slight but significant intellectual impairment by lead ingested by handling and mouthing of leaded jewellery.*"

Children, especially under the age of 3 years old, naturally show 'hand-to-mouth' and 'object-to-mouth' behavioural routines (RIVM (2008)). This may increase their risk of being poisoned by lead-containing jewels which are small, relatively light, sometimes worn permanently on them, and which may be particularly appealing because of their sweet taste. The occurrence of such behaviours is confirmed by the number of consultations in emergency service of the hospitals. Between 2004 and 2007, inhalation or ingestion of small objects represented 3% of the admissions of children under 5 years old, in 10 French emergency services (InVS (2009)). Nearly 1900 children were admitted for inhalation or ingestion of a small object such as a toy, a food item, a coin, a jewel etc. Such behaviours make difficult the control of the risk due to misuses of these articles. More, as the presence of lead in jewels is difficult to perceive and as lead is often hidden under a decorative or protective coating, it is very difficult for the parents to know that such articles may cause a health risk for their children. According to Weidenhamer J.D. and Clement M.L. (2007c), pewter finish was more prevalent in jewels which had a high lead content, but it proved difficult to differentiate leaded items only by visual inspection.

In light of the situation, and given the fact that it is nearly impossible for consumers to identify jewels which contain lead, the only way to prevent children from being poisoned by these articles is to restrict the exposure to lead from these products.

Contrary to risk management proposals already implemented in certain countries, this restriction proposal does not only focus on jewels intended for children since it is recognized that children can come into contact with adult jewels. This proposal thus concerns all jewels, whether they are intended for children or not.

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

Considering the severity of the effects of lead poisoning and the transnational dimension of the risk, action is required at community-wide basis. Moreover, a community-wide action is necessary because of the negative effects that would be caused by independent national legislations on industry actors on the internal market.

Indeed, effects of lead exposure on children are severe and may be irreversible. For now, no safe threshold can be scientifically determined for the effects on their central nervous system. Further, the risk of poisoning targeted in this proposal is not limited geographically to one country or group of countries. It is not specific and potentially concerns any consumer and any child within the EU.

Children present the same behavioural routines (swallowing, chewing and licking all kind of objects) whatever their origin and nationality are and they are all likely to be in contact with jewels in their homes, recreational areas and more generally in their everyday living environment.

Moreover, fashion jewels are placed on the market and sold all over Europe, in very various shops, of any size and not only (and even rarely) in specialized jeweller's shops. They are manufactured 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. Trade physical flows of these articles are numerous and multidirectional (see details in sections B.2. and F.2). The market of fashion jewellery (from supply and demand sides) is atomistic and dispersed in Europe. Compared to independent and isolated national actions, a community-level action would avoid trade distortions between industry actors of the jewellery supply chain in the different Member States. Uncoordinated and potentially inequitable national measures might indeed be redundant, contradictory and/or unbalanced and thus hinder commercial relations on the internal market.

As a consequence, it is necessary to implement a large-scale and harmonised risk management measure within the EU which adequately allows protecting children's health from this kind of risk related to widely spread articles, while ensuring equal treatment and fair trade relations within the internal market across the EU.

This justification is further developed in section D.

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.).

As developed in section E.2, the options for restriction selected for the assessment are:
- Option 1 – Restriction on the use and placing on the market of fashion jewels based on the lead migration rate, and
- Option 6 (the proposed restriction) – Restriction on the use and placing on the market of jewels (fashion and precious) based on the lead migration rate.
Other options have been examined but set aside from the assessment either because they are not effective (not sufficiently targeted to the exposures and capable of reducing the identified risk) or because they are not proportional to the risk (for further details, see section E.2).

Both options 1 and 6 can be compared as regards the three mentioned criteria and scored in the following table.

Table 2: Comparison of restriction options 1 and 6

	Effectiveness		Practicality			Monitorability	
	Reduction risk capacity	Prop. to the risks	Implement.	Enforc.	Manag.	Direct and indirect impacts	Costs of monit.
Restriction option 1 Restriction on the use and placing on the market of fashion jewels based on the lead migration rate	+++	Economic feasibility ++ Technical feasibility ++ Targeting to the risk +++	++	+(+)	++	+++	++
Restriction option 6 (the proposed restriction) Restriction on the use and placing on the market of jewels (fashion and precious) based on the lead migration rate	+++	Economic feasibility ++ Technical feasibility ++ Targeting to the risk +++	++	+++	++	+++	++

+++ criterion fully met
++ criterion partly met
+ criterion barely met

In conclusion, an amendment to REACH Annexe XVII would allow a stable legal solution to manage the identified risks (lead poisoning of children resulting from the ingestion and the mouthing of leaded jewels) and to provide a secure legal framework for firms producing and placing on the market jewellery articles. This justification is further developed in section E.

B. Information on hazard and risk

B.1. Identity of the substance(s) 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 jewels. 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 exposed.

B.1.1. Name and other identifiers of the substance(s)

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

Table 3: 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 substance(s)

Jewels 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 jewels 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 jewels is available. It is also highlighted that lead itself may be considered as an impurity in the alloys used for the production of the jewels as its presence may be, sometimes, unintentional.

No standard for lead, lead alloys or lead compounds used in jewels 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 4: 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 5: 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 6: 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 globally concerns lead and all its compounds. Indeed, as already mentioned, it 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. As no information was identified concerning the possible lead compounds which can be used in jewellery articles, the restriction proposal covers lead and all its compounds.

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 is available at the time of elaboration of this restriction proposal. 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)

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

Data on production, import and export of **lead-containing jewels** is very difficult to collect. Indeed, first, industry actors often simply do not have the information about the composition of the fashion jewels they place on the market or the precise raw materials composing the parts of the jewels 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 jewels 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 Annex A) to obtain data on the market and uses of lead-containing jewels 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 jewels 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 Annex B). More than 3000 firms have been surveyed in the EU. These included: manufacturers/importers/exporters of lead, producers/importers/exporters of fashion jewels 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 jewels 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 jewels' composition, especially if jewels are 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 jewels 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 jewels, 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 jewels since higher quantities of lead and its compounds are expected to be used in this type of articles compared to precious jewels.

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

B.2.1.1. Production of jewellery articles

Fashion jewels

CBI (2009) indicates that fashion jewellery production is mainly concentrated in Austria, Spain, Italy, France and increasingly Poland (amber), Czech Republic (crystals) and Denmark (Trollbeads). Between 2004 and 2008, the EU production value rose from 1,159 to 1,236 million € (see Table 7). 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, Finland, Belgium and Hungary CBI (2009).

Table 7: EU production of fashion jewellery from 2004 to 2008 in million € (extracted from CBI (2009))

	2004	2006	2008	Average annual % change in value
Total EU	1,159	1,176	1,236	1.6

CBI (2009) reports that, in 2008, in the EU:
- 5,500 companies were producing fashion jewels, employing about 10,000 people.
- 28,000 companies were producing precious jewels, employing about 81,000 people.

Precious jewels

According to CBI (2009), about 90% of the EU produced jewellery is precious jewellery. In 2008, EU accounted for more than 20% of the global jewellery production. Between 2004 and 2008, the value of European precious jewels production decreased from 11.742 to 11.708 billion € with an annual average of 0.1%.

B.2.1.2. Import of jewellery articles[3]

CBI (2009) indicates that EU is among the principal importers of jewellery in the world.

Fashion jewels

Concerning fashion jewels imports, from 2004 to 2008, values rose from 1.5 to 2.3 billion €, whereas volumes fell from 116.6 to 104.6 tonnes CBI (2009). For this period, the volume of Chinese jewellery supplies (mostly consisting of fashion jewels, silver jewels and hair accessories) to the EU almost doubled: from 34.11 to 65.89 tonnes, making China the main volume supplier to the EU. Almost 40% of the EU imports were supplied by EU countries (Germany being the main supplier, followed by Austria).

Table 8: EU imports of fashion jewels from 2004 to 2008 in million €/tonnes (extracted from CBI (2009))

	2004		2006		2008		Average annual % change in value
	Value	Vol.	Value	Vol.	Value	Vol.	
Total EU,	1,500	116.57	2,217	94.44	2,352	104.59	11.9
of which from developing countries	711	38.41	1,166	62.52	1,233	66.75	14.7

CBI (2009) reports that fashion jewellery of base metal represented 650 million € and, in volume, about 22 tonnes. It includes all jewels 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 2008, 243 million € and, in volume, 6.16 tonnes.

Precious jewels

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

Table 9: EU imports of precious jewellery articles from 2004 to 2008 in million €/tonnes (extracted from CBI (2009))

	2004		2006		2008		Average annual % change in value
	Value	Vol.	Value	Vol.	Value	Vol.	
Total EU,	4,777	8.98	5,834	9.56	5,767	12.10	4.8
of which from developing countries	1,560	3.21	1,966	3.18	1,740	3.62	2.8

B.2.1.3. Export of jewellery articles[4]

Concerning export, no information specific to fashion jewellery was available. The data provided in the following table concerns both precious and fashion jewels. CBI (2009) explains high volume increase in 2008 by exports of cheap jewels from large EU countries to Eastern EU countries and, more generally, by an increase of trade between EU Member States because of the EU enlargement.

[3] 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*.'

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

Table 10: EU exports of jewellery 2004-2008 in million €/tonnes (reproduced from CBI (2009))

	2004		2006		2008		Average annual % change in value
	Value	volume	value	volume	value	Volume	
Total EU, of which:	13,657	24.83	15,891	33.41	15,864	105.53	3.8
Intra-EU	3,778	15.48	4,474	23.78	4,618	98.03	5.1
Extra-EU	8,512	5.36	9,371	6.41	8,833	4.43	0.9
Dev. countries	1,366	3.98	2,046	3.22	2,412	3.07	15.3

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

Fashion jewels

Fashion jewellery has a very wide distribution network. According to CBI (2009), it varies from bijouterie shops, fashion accessory chain stores, online jewellery sellers to a wide range of non-specialists such as department stores, clothing stores, gift shops, hypermarkets, perfumeries, market stalls, mail order or telesales companies.

CBI (2009) mentions that the competition is more intense among online sellers, department stores, accessory chain stores, clothing stores and hypermarkets as they offer accessible costume and silver jewellery and change their collections at least two times per year along with the seasonal fashion trends.

In 2008, EU consumption was 23.3 billion € for jewellery (precious and fashion jewels) with an average per capita expenditure of 6.4 € for fashion jewellery (CBI (2009)). Since 2004, fashion jewellery has enjoyed a substantial growth with much cheap jewels 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 a jewel. In 2008, EU costume jewellery sales rose further to 3.1 billion € (see Table 11). It represents 14% of the total jewellery sold in the EU and, in terms of volume, more than half of the jewellery sales.

Differences in consumption are observed between EU countries: consumption per capita is much higher in countries which have a low population and a high expenditure on precious jewels. CBI (2009) reports an increase of sales of costume jewellery especially in Austria, Sweden, Finland, Ireland, Greece, Spain and in many Eastern EU countries. Costume and silver jewels seem to be preferred by consumers who are more conscious on price and less on material composition. CBI (2009) 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 11: EU consumption of fashion jewels in million € (extracted from CBI (2009))

	2004	2006	2008	Average annual % change in value
Total EU	2,795	2,954	3,144	3.0

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

Table 12: French distributional data by price for fashion jewels

Price class	**Placing on the market (domestic distribution and exports on the EU market)**			
	Volume in million of articles		**Value in million euros**[5]	
	2003	**2004**		
< 30 euros	**20.6** (average price of 5 €)	22.2 (average price of 7 €)	111	149
From 30 to 100 euros	4.1 (average price of 49 €)	3.9 (average price of 50 €)	203	195
> 100 euros	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 jewels (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 jewels 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)).

Precious jewels

From CBI (2009), the specialist distribution dominates in most EU countries. The main channels for precious jewels 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 jewels represented 86% of all jewels which were sold in the EU in 2008 and that the value of precious jewels sales decreased by an annual average of 0.7% between 2004 and 2008 (from 20.7 to 20.2 billion €). Such decrease seems to result from the fact that consumers tend to limit their purchase of luxury products because of the recent recession.

B.2.1.5. 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 13: 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)[6]	-
	importers	13 (2002)	
Spain	producers	120 (2000)	-
	importers	12 (2002)	
Italy	producers	120 (2000)	-
	importers	14 (2002)	

5 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.

6 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.

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, jewels are 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 jewels are not identifiable. Therefore, this data only provides a sample of the real number of producers and distributors in EU countries 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 jewels, 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 jewels (and jewels 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)).

Finally, 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 jewels and other jewels. Data which would enable to make this distinction is not available since macroeconomic aggregates and national account systems do not display lead-containing jewels as a specific category. As a consequence, the few data likely to help in the quantification of the amount of leaded fashion jewels 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 jewels

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 jewels 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[7]).

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 jewel**, even though it was specified that 30% of the 37 jewels 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

[7] http://www.douane.gouv.fr/page.asp?id=3258

lead content and the three product categories: gold (which includes jewels coated with gold and golden-like jewels – does not necessarily mean that the jewel contains precious metal), silver-like and non-precious metal. In addition to test for lead content, some jewels were also tested for lead migration. The **results of these tests did not show a direct relation between migration rate and lead content** 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 jewels 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.

Maas R.P. *et al.* (2005) estimated **the probability of purchasing a jewel 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 jewels 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 jewels 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 jewels sold in the USA. They base their hypothesis on the fact that the combined lead-tin-copper content of 6 jewels 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 jewels samples to battery lead supports the hypothesis that some battery lead is recycled into highly leaded jewels (the tested jewels 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 jewels' 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 jewels.

Fairclough G. *et al.* (2007) reports that the owner of a Chinese producer of fashion jewels 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 jewels.

Table 14: Identified studies on the presence of lead in fashion jewels

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 jewels divided in 318 parts) ▪ > 0.01%: 58% of all examined jewels ▪ 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[8] 24 items of children's jewellery bought in London and Birmingham	Test on 24 children's jewels: ▪ 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[9]	17600 fashion jewellery items from one targeted container 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)

[8] 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)
[9] http://www.douane.gouv.fr/page.asp?id=3258

Canada	Canada Gazette (2005) National survey 95 children's jewels examined	Test on 95 pieces of jewellery: ▪ > 0.0065% lead: 94% of the analysed jewels ▪ 50% to 100% lead : 69% of the analysed jewels ▪ < 10% lead: 31% of the analysed jewels (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 jewels 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	A survey of inexpensive jewellery (less than $20) revealed that

	Carolina (2009)	70% of the jewels contained lead. (No available information on the testing method)
	KID (2004)	Over 152 millions 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[10] (No available information on the testing method)

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

B.2.3. Uses advised against by the registrants

As no CSR is 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.5, and on several alerts and cases documented from different countries (see section B.9.3.1).

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[11] of the European Parliament and of the Council and on Commission Regulation 790/2009/EC[12]). 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[13].

[10] At the time of the KEMI report (2007), US Regulation required that the products should have less than 175 µg of migratable lead.
[11] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF
[12] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:en:PDF
[13] 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 STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H351 H360-Df H373** H400 H410
lead(II) methanesulphonate	401-750-5	17570-76-2	Repr. 1A	H360-Df

			Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Skin Irrit. 2 Eye Dam. 1	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. Environmental Fate Properties

Even though lead might have effects on the environment, these are not taken into account in this dossier. As mentioned previously, it is targeted on health effects on children despite the fact that it may be considered that once the jewels are disposed, lead containing jewels might contribute to the environmental pollution. For this reason, it was considered relevant to present some data on the environmental fate properties of lead and its compounds in this section.

In the framework of the European Regulation on Existing Substances, lead industry committed to undertake a Voluntary Risk Assessment (LDAI (2008b)) for lead and inorganic lead compounds produced in the EU or imported into the EU in volumes exceeding 1000 tonnes per year: lead oxide, lead tetroxide, dibasic lead phthalate, basic lead sulphate, tribasic lead sulphate, tetrabasic lead sulphate, neutral lead stearate, dibasic lead stearate, dibasic lead phosphite, polybasic lead fumarate, basic lead carbonate, dibasic lead sulphite.
This Voluntary Risk Assessment was partly validated by the TCNES (Technical Committee on New and Existing Substances) and the complete report is available on ECHA website[14]. The main conclusions are presented in the final opinion of the TCNES (TCNES (2008)).

It was decided to present data extracted from the environment parts of the Voluntary Risk Assessment (LDAI (2008b)) 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 which were discussed and partly validated by consensus at the TCNES.

In addition, to our knowledge, no such complete and synthetic report on the risk assessment of lead and its compounds exists.

B.4.1. Degradation

Metal and metal compounds do not have the same properties as organic compounds. The term "degradation" refers to the decomposition of organic molecules. For inorganic compounds such as metal and metal salts, the concept of degradability, as it has been considered and used for organic substances, has limited or no meaning. Rather, the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Methods used to determine persistence of organic chemicals (hydrolysis, photodegradation and biodegradation) are not applicable to metals and their salts (OECD (2001)). Hence, biotic and abiotic degradations are not relevant for metals and metal compounds.

B.4.2. Distribution

Summarized information on the distribution of lead and its compounds in the environment was extracted from LDAI (2008b) which presents a detailed evaluation of the environmental fate of these substances.

<u>Speciation of lead in the aquatic compartment</u>
"Pb in fresh water can occur in both suspended and dissolved forms and is partitioned over a number of chemical species. In sediments, Pb can occur as dissolved and precipitated form."

[14] http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp (accessed in March 2010)

Speciation of lead in soil
"Lead can be present in soils as free ion (Pb^{2+}) in solution, adsorbed onto soil solids (clay minerals, Fe and Mn oxides and soil organic matter) or in a precipitate (formation of soil minerals, e.g. anglesite, jarosite). The distribution of Pb over these various forms depends on soil properties (e.g. pH, % organic matter, parent material,…), the source of the Pb contamination (lead shot, residues from mining etc) and the time since contamination."

Precipitation
"The solubility of lead is dependent on the physico-chemistry of the medium and precipitation will be more important in alkaline than in acid media. In most surface waters and groundwaters, the concentration of dissolved lead is low because the lead will form complexes with anions in the water such as hydroxides, carbonates, sulfates, and phosphates that have low water solubilities and will precipitate out of the water column. At pH values at or below 6.5 most of the dissolved lead is in the form of free Pb^{2+} ion. At higher pH values, $PbOH^+$ and $PbCO_3$(aq) are both important species. In waters with higher amounts of natural organic matter corresponding to a dissolved organic carbon concentration of 10 mg/L, organically bound lead becomes more important."

Since metals do not have the hydrophobic or lipophilic characteristics of organic compounds, the concept of Kow and Koc is not applicable to describe the distribution. The distribution of metals between aqueous phase and soil/sediment/suspended matter should preferentially be described on the basis of measured soil/water, sediment/water and suspended matter/water equilibrium distribution coefficient (Kd; also called partition coefficient, Kp) (ECHA (2008)).

For lead and some of its compounds, the following partitioning coefficients have been reported in the LDAI (2008b):

Partitioning coefficient in Suspended matter
Kp_{susp} = 295121 L/kg (log Kp_{susp} = 5.47) (50^{th} percentile)

Partitioning coefficient in Sediment and porewater
Kp_{sed} = 154882 L/kg (log Kp_{sed} = 5.19) (50^{th} percentile)

Partitioning coefficient in Soil
Kp_{susp} = 64000 L/kg (log Kp_{soil} = 3.81) (50^{th} percentile)

B.4.3. Bioaccumulation

"Most concepts and tools to assess the bioaccumulation/biomagnification potential of substances were originally developed on the basis of observations made on a fairly limited number of neutral lipophilic organic substances that have shown that their potential to bioaccumulate and/or to biomagnify is directly related to the inherent properties of the substance. However, for naturally occurring substances such as metals, bioaccumulation is more complex, and many processes are available to modulate both accumulation and potential toxic impact. Many biota for example, tend to regulate internal concentrations of metals through (1) active regulation, (2) storage, or (3) a combination of active regulation and storage over a wide range of environmental exposure conditions. Although these homeostatic control mechanisms have evolved largely for essential metals, it should be noted that non-essential metals are also often regulated to varying degrees because the mechanisms for regulating essential metals are not entirely metal-specific. Some species (mostly plants) could also be adapted to a natural enriched environment and as such accumulate high levels of metals. Most often these phenomena are very local and not an overall concern for secondary poisoning and biomagnification.
From the above it is clear that it is not appropriate to apply classical concepts (e.g. use of bioconcentration factors, BCF, or biomagnification factors, BMF) to metals as they are applied to organic substances.
Hence, no data on BCF or BMF is presented in this section."

B.4.4. Secondary poisoning

The following paragraph about secondary poisoning is extracted from LDAI (2008b) and is presented in the final TCNES opinion (TCNES (2008)).

"In total 13 high quality NOECs and L(E)C10s were selected using screening criteria set out in the VRAR (7 for birds and 6 for mammals). Using the TGD methodology of applying an assessment factor to the lowest NOEC in the database resulted in an oral PNEC of 0.5 mg/kg for mammals, which predicts risks at soil concentrations in the natural background range. The toxicity dataset was therefore used in a species sensitivity distribution, resulting in an HC5-50 of 49.1 mg Pb/kg ww (best fit function). A median soil-earthworm BAF value was derived and, using the oral HC5-50, this would predict a risk to mammals and earthworm eating birds above soil lead concentrations of 491 mg/kg. A field validation of the PNECoral was performed by comparing the estimated earthworm concentrations (PECoral) from different field studies with a critical body burden lead in mammals (shrews, moles, rats etc) of 32 µg Pb/g dw (kidney lead concentration). If the critical body burden lead is reached at earthworm lead concentration below the PNECoral of 49 mg/kg, then there is reason for additional concern. Below that value, there are reports of elevated lead exposure to three populations of wildlife with potential adverse effects, out of 77 populations compiled. These exceptions are attributed to the measured extreme earthworm BAF values (i.e. larger exposure than in the '*generic* case') in 2 of these 3 populations and are not a reason for additional concern regarding the level of protection offered by the HC5-50 in the context of setting a generic PNECoral value. This also illustrates that larger BAF values than median values should be used for *site-specific* risk characterization. However, discussions at TCNES raised concerns regarding the degree of remaining uncertainty associated with the HC5-50 as well as with the issue of whether non-classical endpoints such as neurotoxicity should be accounted for. As a result, no discussion on an assessment factor to be applied to the HC5-50 has taken place and it has been agreed that further work is required to derive a robust PNEC."

B.5. 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 blood lead (or PbB) level is considered as the best biomarker for an exposure to lead, but it does not reflect the whole body charge of lead. 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)).

Since lead is an accumulating poison, adverse effects should be related to a cumulated dose; however, no standard assay is able to estimate this cumulated dose.

B.5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

B.5.1.1. Absorption

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

- <u>Oral absorption rate</u>

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)).

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.
Children who ingest more than 5 µg of lead per kilogram body weight per day (kg bw/day) will retain (netto) 32% of the intake, whereas children who ingest less than 4 µg of lead per kg bw/day will excrete more than what is taken in (WHO (2003)).

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

- <u>Inhalation rate:</u>

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.

- <u>Dermal absorption</u>

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.5.1.2. 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.5.1.3. 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)).

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 36 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.

B.5.1.4. 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.5.2. Acute toxicity

B.5.2.1. 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.5.2.2. 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% of lead. At the time of death, the boy had a PbB level of 1800 µg/L (see cases reported in section B.9.3.1).

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.

B.5.3. 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 24h. However, this effect does not lead to any classification (Danish EPA (2008)).

B.5.4. 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.5.5. 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.5.6. 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.5.6.1. 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.5.6.2. 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)).

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.5.6.3. Nervous system effects

In young children, brain is the primary target organ. When PbB level is above 800 µg/L, an encephalopathy can be observed (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 300 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).

WHO (2003) describes a number of studies, which indicate a possible correlation between reduced IQ and a PbB level < 100 µg/dL (PbB level of 56 µg/L).

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

Designation of 50 µg/L as an epistemic threshold and a "societal blood lead target" serves to both provide a population benchmark for blood lead levels in children and to dramatically reduce the probability that individual children might exceed a blood lead level of 100 µg/L. Maintenance of blood lead levels for the majority of the population below 100 µg/L would require average population blood lead levels less than 50 µg/L. For purposes of risk characterisation, in LDAI (2008a), 100 µg/L post-natal lead in blood is considered as a NOAEL for the individual child but a general population blood lead average of 50 µg/L is required to minimize the probability that individual blood lead levels would exceed 100 µg/L (RIVM (1995)).

This approach has been approved by the Scientific Committee on Health and Environmental Risks (SCHER), who has reviewed LDAI (2008a) (SCHER (2009)).

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 16: 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

The threshold of 100 µg/L should probably be lower now, since this value has been established in the 1990s, but a lower threshold has not been taken into account yet. For information, the median of measured blood lead levels for French children is now 15-20 µg/L, the 90th 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.5.7. 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.5.8. 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.5.9. 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)).

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.5.10. Other effects - Specific effects

<u>Lead poisoning in pregnant women</u>

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)).

B.5.11. Derivation of DNEL(s)/DMEL(s) or other quantitative or qualitative measure for dose response

B.5.11.1. 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.

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, but the former WHO value of 3.6 µg/kg bw/d has not been corrected yet.

B.5.11.2. 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 17.
For children in the age of 4-6 years-old, the average intake reported was 9.7 µg/d.

Table 17: Background exposure of lead in Denmark and margin to TDI value (µg/kg bw/d) (Danish EPA (2008))

Background exposure	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). 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 18: 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/d. This value represents a daily intake of 12 µg/d for a child of 1 year (6 kg bw) and 20 µg/d 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).

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.5.11.3. 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, no 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.

B.5.11.4. Chronic DMEL (DMELc)

Concerning chronic exposure, since it has been demonstrated that neurotoxic effects could occur in children without a threshold in 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.
It could have also been possible to choose the same approach as the one used by RIVM (2008), for toys; that is to consider a certain percentage of the TDI to allocate to the specific exposure source of jewels. However, if one wants to use an approach based on a TDI value, it is necessary to define which TDI value to use (the 'old one' of 3.6 µg/kg bw/day from WHO or the 'new one' of 1.8 µg/kg bw/day but not validated yet), which percentage of this value should not be exceeded by the targeted source of exposure and what background level should be taken into account. These choices are very sensitive and the proposed approach, based on the smallest measurable PbB level variation, allows not to have to make such assumptions.

Consequently, it has been chosen to determine the smallest measurable variation of the PbB level and to use a PBPK model in order to calculate a daily intake which will not generate a variation higher than this smallest measurable variation.

- The smallest measurable variation of the PbB level

The smallest measurable variation heavily depends on the range of the blood lead concentration that is measured (called the "target concentration"). In order to select the smallest measurable concentration, a target blood lead level of 20 µg/L was selected as it corresponds to the geometric mean of blood lead level of children of 0 to 6 years-old (Glorennec P. *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.

A recent study (Olichon D. *et al.* (2007)) reports 3 µg/L as the smallest variation between two values usually measured for a target concentration of 20 µg/L. However this value of 3 µg/L is considered to be underestimated, since it has been measured in only one laboratory.
In Labat L. *et al.* (2006), the smallest variation between two measured values is 20 µg/L (for a target concentration of 100 µg/L). However, the target concentration is considered to be too high to be representative of the blood lead level of the general European population.
The selected value is <u>5 µg/L;</u> it is based on the standard deviation determined in a French inter-laboratories analysis for a target blood lead level of 20 µg/L (AFSSAPS (2009)).

- <u>Use of a PBPK model</u>

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 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 PbB of more than 5 µg/L. The following DMELs have been obtained (for more details on the model calculations, see Annex C):

Table 19: Modelled chronic DMELs

Age of the children (months)	DMELc value (µg/kg bw/day)
3-6	0.16
6-12	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 comparative purposes, 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/day, which is very close to the DMELs used in this assessment.

Conclusion:

The following table presents the DNEL and the DMELs which are selected for the assessment.

Table 20: DNEL/DMELs values

DNEL/DMELs	Critical effects	Age (months)	Value	Unit
Acute DNEL (DNELa)	Dullness, irritation, headache, loss of memories, stomach cramps….	0-36	400	µg/L
Chronic DMELs (DMELc)	Effects on the CNS with no threshold	3-12	0.16	µg/kg bw/d
		13-24	0.21	
		25-36	0.22	

B.6. Human health hazard assessment of physico-chemical properties

B.6.1. Explosivity

The substance does not present explosive properties.

B.6.2. Flammability

The substance is not highly flammable.

B.6.3. B.6.3 Oxidising properties

The substance does not present oxidising properties.

B.7. Environmental hazard assessment

Even though lead might have effects on the environment, these are not taken into account in this dossier. As mentioned previously, it is targeted on health effects on children despite the fact that it can be considered that once the jewels are disposed, lead containing jewels might contribute to the environmental pollution. As indicated in SCHER (2010), it can be assumed that several thousands of tons of jewellery items made of non-precious metals may be sold annually in Europe and that a considerable part of them may be discarded as waste.

No data related to effects on organisms due to the use of lead and its compounds in jewels was found.

However, as mentioned previously in this report, in the framework of the European Regulation on Existing Substances, the lead industry committed to undertake a Voluntary Risk Assessment (LDAI (2008a), LDAI (2008b)) for lead and inorganic lead compounds produced in the EU or imported into the EU.

It is not considered appropriate to present the whole environmental risk assessment report (LDAI (2008b)) as the targeted risks of this dossier concern human health.

However, it was considered interesting to present the PNECs derived for the environment in order to provide an idea of the main effects of lead and its compounds in the different environmental compartments.

B.7.1. Aquatic compartment (including sediment)

<u>Freshwater PNEC</u>
In LDAI (2008b), two final HC5-50 were derived “using a species mean NOEC/L(E)C10 dataset ” and “using the lowest NOEC dataset”, which lead to a HC5-50 of 8.0 µg/L and to a HC5-50 of 1.6 µg/L respectively.
Two freshwater PNECs using the HC5-50 of 8.0 µg/L are presented using two different Assessment Factors (AF= 2; AF=3) to account for the remaining uncertainty.
“This results in a freshwater PNEC value of 4.0 µg/L (AF=2) or 2.7 µg/L (AF=3).”
Finally, as stated in TCNES (2008), “the report notes that it was concluded at TCNES II’07 that bioavailability is an important factor in the freshwater toxicity of lead and this effect should be accounted for in the derivation of PNECs. It is noted that a biotic ligand model for lead is expected in 2008.”
Hence, the PNEC for freshwater is still under development.

<u>Freshwater sediment PNEC</u>
In LDAI (2008b), “a Species Sensitivity Distribution (SSD) yielded a log-normal HC5-50 of 245 mg/kg when expressed as bioavailable lead. An assessment factor of 3 was applied, resulting in a sediment PNEC (bioavailable lead) of 81 mg/kg.”

B.7.2. Terrestrial compartment

In LDAI (2008b), “a species sensitivity distribution yielded a lognormal HC5-50 of 333 mg/kg. An assessment factor or 2 was applied, yielding a terrestrial PNEC of 166 mg/kg”.

B.7.3. Atmospheric compartment

No quantitative risk characterisation for exposure of organisms to airborne lead was conducted in the VRAR (2008). Indeed "no useful data on the effects of airborne lead on environmental organisms are available and thus no PNEC for air could be derived. "

B.7.4. Microbiological activity in sewage treatment systems

In LDAI (2008b), a PNECmicro-organisms of 0.1 mg/L for dissolved lead in effluent was derived.

B.7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

See section B.4.4.

B.8. PBT and vPvB assessment

Lead and its compounds are not currently reported as PBT or vPvB under the European Regulation. Lead and lead compounds are reported in the US EPA TRI (Toxic Release Inventory) PBT Chemical List.

References:
http://ecb.jrc.ec.europa.eu/
http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp
http://www.epa.gov/tri/trichemicals/pbt%20chemicals/pbt_chem_list.htm#chemical
(Key words: lead, lead compounds, PBT, vPvP)

B.9. Exposure assessment

B.9.1. General discussion on releases and exposure

B.9.1.1. 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.

<u>A - Regulations related to the use of lead and its compounds in preparations, articles or consumer products</u>

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

Table 21: 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 < 0.005g/l
Annexe 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 = 3.4mg/kg liquid or sticky toy material ▪lead migration limit = 160mg/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 0.02mg/kg by wet weight (cow's milk) and 1.5mg/kg w.w. (mussels)
Directive 98/83/EC on quality of water intended for human consumption	lead content < 10µg/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 < 1mg/kg
Directive 88/388/EEC on flavourings for use in foodstuffs	▪ lead content in flavourings < 10mg/kg

and to source materials for their production	
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.

B - 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[15]).
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.

C - 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 below.

Table 22: 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 EC/1999/45[16] concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous	Paints and varnishes (potentially concern jewels)	Labels of packages of paints and varnishes 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 »

[15] "fashion accessories for children which are not for use in play" is mentioned as an exemption (exemption 19)
[16] 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

	preparations		
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°1082 of 13.09.2007 (replacing Statutory order n°1012 of 13.11.2000) ▪Law n°308 of 17.05.1995	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
Ireland	2005 National law S.I. 341 for electronic jewellery (transposition of Directive 2002/95EC[17])	Electronic jewellery	Lead content should be below 0.1% in homogenous material. This law applies for manufacture, import, export and rebrand of electronic jewellery.
Non EU countries			
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[18]). 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)[19] of total lead and not more than 90 mg/kg (0.009% by weight) of migratable lead[20].

[17] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:037:0019:0023:EN:PDF

[18] 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.

[19] Consistent with the Canadian regulation on the maximum lead limits for surface coating materials under the Canadian Hazardous Products Act

[20] Consistent with the EU migratable lead limit standards for toys (EN 71-3) intended for children under six years of age.

D - 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 jewels, 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.)[21].
Precious jewels are 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.

E - 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 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.9.1.2. Summary of the effectiveness of the implemented risk management measures

As documented in Section B.9.3.1, several cases of lead poisoning due to the misuse by children of lead-containing jewels are reported; implying that the implemented risk management measures are not sufficient. Moreover, as explained in Section A.2.1, 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 a lead-containing jewel 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 jewels).

B.9.2. Manufacturing

B.9.2.1. 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 jewels which contain these substances.

[21] 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.

B.9.2.2. Environmental release

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

B.9.3. Misuse of jewellery articles

B.9.3.1. 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 jewels 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. They are reported in the following table.

Table 23: Cases of children poisonings due to ingestion/mouthing of jewels

Country	Year	Age of the child	Cause of poisoning	Origin of the jewel	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 jewel 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	-	Pendant contained 1022 ppm of lixiviable lead Elevated blood	-	InVS (2008); Canada Gazette (2005)

			covered with a decorative coating		lead level		
	1998	-	Chewing off the decorative coating and sucking on the exposed cores of a child's necklace	-	Test on the jewel: almost 75% lead	-	Canada Gazette (2005)
Japan	-	-	There have been cases of poisoning in Japanese children who have ingested large quantities of lead from jewellery.	-	One of the tested jewels released 56 times the quantity of lead allowed in the USA[22]	-	KEMI (2007)

As already mentioned in sections A.2.1 and B.9.1.2, these cases are an underestimation of the actual children lead poisonings from this type of articles.

Target population

Exposure to lead from jewels can 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.

Pathways of exposure

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 jewels:**

Use 1: Mouthing of a leaded jewel (chronic exposure),

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

Use 3: Accidental ingestion of a leaded jewel (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.

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

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

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

B.9.3.2. Exposure estimation

B.9.3.2.1. Workers exposure

Not relevant for this proposal.

B.9.3.2.2. Consumer exposure

As mentioned above, the 3 following uses have been considered in order to assess the exposure of children (below 36 months) to lead from jewels:

Use 1: Mouthing of a leaded jewel (chronic exposure),

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

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

Migration of lead from the jewel heavily depends on the jewel itself. The presence of a coating, the type of coating, the state of the jewel (whether it is in good condition or not), the other constituents of the jewel – all of these are parameters which may influence lead migration from the jewel. Moreover, there does not appear to be a correlation between the lead content in the jewel and the amount of lead which can migrate from this jewel, i.e. its migration rate (Danish EPA (2008)).
Consequently it is not possible to develop a classical exposure assessment covering all kinds of leaded jewels and therefore a risk assessment.

It is however possible to identify and characterise criteria that jewels must fulfil in order to reduce health risks. This approach is called a reverse exposure assessment. As there is no correlation between lead content in the jewel and the amount of lead which can migrate, the key property for exposure assessment is the quantity of lead that is released by the jewel into the matrix (sweat, saliva or gastric acid), i.e. its migration rate.

The objective of the following exposure assessment is to assess a “safe” lead migration rate or a “safe” total lead content for each of the 3 previously mentioned uses (uses 1, 2 and 3) based on the DNEL/DMELs established in section B.5.11 and which are reminded in the following table.

Table 24: DNELa and DMELc used in the assessment

DNEL/DMELs	Age (months)	Value	Unit
Acute DNEL (DNELa)	0-36	400	µg/L
Chronic DMELs (DMELc)	3-12	0.16	µg//kg bw/d
	13-24	0.21	
	25-36	0.22	

As there is a great variation in the body weight and in the frequency and duration of hand-to-mouth and object-to-mouth activities among children under the age of 36 months, four categories of ages are distinguished. The choice of these categories was made according to the data provided by the software ConsExpo and which are presented in RIVM (2002). Indeed, ConsExpo is considered as a reference at European level concerning consumer exposure, including children (it is a reference model according to REACH guidance Chapter R15 on consumer exposure). The following table describes the age categories and their corresponding body weights. Other age-dependent parameters will be presented later on in the assessment when relevant.

Table 25: Default values for the body weight of children (RIVM (2002))

Age category	Age (months)	BW (kg)
1	3-6	6.21
2	7-12	7.62
3	13-18	9.47
4	19-36	9.85

The age category "0-3 months" is not taken into account for the exposure assessment. Indeed, at this age, it is supposed that the behavior of children is not likely to result in a potential risk regarding mouthing and ingestion of jewels.

Use 1 Mouthing of a leaded jewel (chronic exposure)

As already mentioned, children exposure can arise while mouthing jewels. Indeed, for instance, children may suck pendants of their necklace and thereby directly absorb the migrating lead, as reported in some cases presented in section B.9.3.1.

Mathematical model

The ingested amount of lead while mouthing an article during a defined period of time can be calculated using the following equation:

$$D_{swallowed} = F_{jewel\text{-}saliva} \times T \times S / BW \quad \text{(Eq. 1)}$$

$D_{swallowed}$	Daily dose of ingested lead	µg/kg bw/day
$F_{jewel\text{-}saliva}$	Lead migration rate from the jewel to the saliva	µg/hr/cm²
S	Surface area of the jewel in contact with the mouth	cm²
T	Daily mouthing duration	hr/day
BW	Body weight of the child	kg

For the reasons stated above, estimation of a maximum "safe" lead migration rate into the saliva is done using a reverse reference assessment. In order to do this, the daily dose of ingested lead ($D_{swallowed}$) is set to the DMELc.

The following equation will be used for the assessment:

$$\mathbf{F_{jewel\text{-}saliva} = DMELc \times BW / (T \times S)} \quad \text{(Eq. 2)}$$

Where:

$F_{jewel\text{-}saliva}$	Maximum "safe" lead migration rate from jewel to saliva	µg/hr
DMELc	Chronic derived minimum effect level	µg/kg bw/day
T	Daily mouthing duration	hr/day
BW	Body weight of the child	kg
S	Surface area of the jewel in contact with the mouth	cm²

Exposure parameters

Daily mouthing duration (T)

As no data concerning the specific activity of mouthing a jewel is available, it was decided to use 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). Indeed, this report describes behaviors that could be considered as similar to the mouthing of a jewel.

Table 26: Default mouthing time for children (RIVM (2002))

Age (months)	Default mouthing times (min/day)			
	Pacifier	Toys for mouthing	Other toys	Non toys
3-6	285	11	27	8
7-12	82	21	63	23
13-18	52	0	9	26
17-36	62	0	3	6

In RIVM (2002), the category "toys for mouthing" represents all kinds of teething rings and some rattles. The "non toys" category, defined as piece of cloth, piece of paper, a book for adult, flatware…, covers items which are usually not in the child's environment; whereas the category "other toys", defined as cloth books, plastic books, cuddly toys, refers to items which are not designed to be mouthed but which are available to the child.

Mouthing of jewels may cover mouthing of articles that are not designed for this activity. In this way, "pacifiers" and "toys for mouthing" are not considered. A jewel worn by a child could be assimilated to the "other toys" category as it is always available to him. In addition, a jewel which is not worn but that can be reached by a child may be considered as a "non toy".

As jewels 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 27: Default mouthing times for jewels 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

Surface of jewel in contact with the mouth (S)

This parameter represents the surface of the jewel 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.

Chronic derived minimum effect level (DMELc)

As age classes used for DMELc and mouthing times are different, the most conservative DMELc is selected to match the already defined age classes of mouthing time.

Table 28: Summary of the parameters selected for the assessment of use 1

Age (months)	BW (kg)	Default mouthing times (hr/day)	DMELc (µg/kg bw/d)
3-6	6.21	0.58	0.16
7-12	7.62	1.43	0.16
13-18	9.47	0.58	0.21
19-36	9.85	0.15	0.21

As a reminder, an oral absorption rate of 50% has been taken into account in the calculation of the DMELc.

Results

The mouthing activity is a very common behaviour for children under 36 months, and it reflects their everyday life. Moreover, as lead is not well absorbed during digestion, significant intoxication may result from an exposure which spreads over time: lead is progressively accumulated in the body, resides mostly in bones and is then very slowly eliminated. Consequently, it is very important to consider this use in the assessment.

A “safe” maximum lead migration rate from the jewel to the saliva is calculated for each age category according to Eq. 2 and the results are presented in the following table.

Table 29: “Safe” maximum lead migration rates from jewel to saliva for use 1

Age (months)	“Safe” maximum lead migration from jewel to saliva (µg/hr/cm²)
3-6	0.17
7-12	0.09
13-18	0.34
19-36	1.37

Use 2: Hand-to-mouth activity after hand contacts with a leaded jewel (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 a jewel: lead migrates from the jewel 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 jewels is very scarce, a worst case approach could consist of considering that the child wears a jewel and that he sucks the part of his body which is in contact with the jewel.

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 jewel (acute exposure)

Children may also be exposed to lead because of accidental ingestion of small jewels (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 jewel in the stomach’s gastric fluid. It is however difficult to determine the time the jewel will remain in the stomach: in certain cases, the jewel stays in the stomach and is not eliminated by the body, in other cases, the jewel 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 jewel has to be extracted using an endoscopy or a gastrotomy (InVS (2008)).
As no information on the possible time of residence of a jewel 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)).

Mathematical model
The ingested amount of lead if a jewel is swallowed at once is given by the following equation:

$$Q_{stomach} = F_{jewel\text{-}stomach} \times 24 \quad \text{(Eq. 3)}$$

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

From Equation (3), the following equation is derived to express $\mathbf{F_{jewel\text{-}stomach}}$:

$$\mathbf{F_{jewel\text{-}stomach} = Q_{stomach} /24 \quad (Eq.\ 4)}$$

$Q_{stomach}$	Quantity of ingested lead	µg/day
$F_{jewel\text{-}stomach}$	Lead migration rate from the jewel 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 D.
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 jewel in the stomach: 2 days and 5 days. For more details on the calculations performed with this model, see Annex D. 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 30: 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 a jewel 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. 4.

Table 31: Safe" maximum lead migration from jewel to stomach considering acute effects

Age (months)	"Safe" maximum lead migration rate from jewel to stomach for 2 days of residence (µg/hr)	"Safe" maximum lead migration rate from jewel 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 32: Summary of “safe” migration rates

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

B.10. Risk characterisation

B.10.1. Exposure to leaded jewels

B.10.1.1. Human health

B.10.1.1.1. Workers

Not relevant for this proposal.

B.10.1.1.2. Consumers

Three different uses have been identified (see section B.9.3.2.2 for details). Two of them address chronic exposure: use 1 corresponding to a repeated poisoning from mouthing a leaded jewel and use 2 corresponding to a repeated poisoning from hand-to-mouth activity after repeated or long-duration contacts with a leaded jewel. The third one (use 3) addresses acute poisoning: accidental ingestion of a leaded jewel or a leaded part of a jewel.
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 exposed, “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 summarises these limits.

Table 33: Summary of “safe” lead migration rates for use 1 and use 3

Use 1 - Mouthing of jewel Lead migration limit for saliva (µg/hr/cm²)	Use 3 - Ingestion of jewel Lead migration limit for stomach (µg/hr)
0.09	23.33

B.10.1.1.3. Indirect exposure of humans via the environment

Not relevant for this proposal.

B.10.1.1.4. Combined exposure

As exposure assessments are based on a reverse exposure approach, the different uses, i.e. mouthing and ingestion, cannot be combined.

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 jewel would need to have a surface higher than 255 cm² (=23.33/0.09)**

to reach the lead migration limit for acute exposure (use 3). It seems reasonable to think that most of the jewels which can be ingested have a surface below 255 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 a jewel residence time in stomach of 5 days. However, as modelled in the study from INERIS (2010) (see Annex D), 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 jewel 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: 0.09 µg/hr/cm² (measured in gastric conditions).

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, jewels. In this assessment, the selection of the chronic use as being protective for the acute use is grounded on the same approach.

B.10.1.2. Environment

Not relevant for this proposal, see section B.9.3.2.4.

B.11. Summary on hazard and risk

Exposure to lead and its compounds occurs mostly by the oral and the inhalation route, 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 fashion jewels 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.9.3.2.2 for details), two of them concerning a chronic exposure: use 1 corresponding to a repeated poisoning from mouthing a leaded jewel and use 2 corresponding to a repeated poisoning from hand-to-mouth activity after repeated or long-duration contacts with a leaded jewel. The third one (use 3) concerns acute poisoning: accidental ingestion of a leaded jewel or a leaded part of a jewel.
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 (DNELa) 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 the DNELa have been determined for two exposure durations (duration of residence of the jewel 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 DNELa for acute effects (400 µg/L).

Table 34: 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

Concerning chronic exposure to lead, the most relevant effect is on the CNS. Observational data suggests that no threshold could be determined for such effects in children. Consequently, it was 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 higher than 5 µg/L (corresponding to the smallest measurable variation in blood lead levels). Since one of the parameters of this model is the body weight of the child, four different DMELs have been calculated depending on the age categories.

Table 35: Modelled chronic DMELs

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

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 below).

Table 36: Summary of the "safe" lead migration rates for use 1 and use 3

Use 1 - Mouthing of jewel Lead migration limit for saliva (µg/hr/cm²)	Use 3 - Ingestion of jewel Lead migration limit for stomach (µg/hr)
0.09	23.33

Based on these values and on the fact that both migration rates are expected to be measured with the same test simulating gastric conditions, it has been determined that the lead migration rate derived for chronic exposure is more conservative. Indeed, it appears that the jewel will need to have a surface area higher than 255 cm² to reach the lead migration limit for acute exposure.
It seems reasonable to think that most of the jewels which can be ingested have a surface area below 255 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 a jewel residence time in stomach of 5 days. However, as modelled in the study from INERIS (2010) (see Annex D), 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 jewel would remain 5 days in the stomach. This implies that the child could possibly suffer from chronic effects such as neurotoxic effects which may occur under 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 (measured in gastric conditions): 0.09 µg/hr/cm².

In summary and to conclude, based on two derived toxicological values for both acute and chronic health effects in children, and based on three different uses describing possible exposure of children to leaded jewels, a maximum lead migration rate of 0.09 µg/hr/cm² in gastric conditions has been determined and is selected for the proposed restriction.

C. Available information on alternatives

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 jewels' manufacturers that "lead is absolutely not present in traditional goldsmith and jewellery which are constituted by precious metals" and that, "with regard to jewels 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 jewels 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 jewels. Indeed, it gives a certain quality and appearance to jewels 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 jewels 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[23]. 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 jewels 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

[23] 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.

fashion jewellery. They usually contain the following metals in replacement of lead: tin, bismuth, copper and silver[24].

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 37: 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 38: 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 jewels 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 jewels have increased since the last past years (+ 5% between 2007 and 2008 for example) and are expected to

[24] http://www.contenti.com/products/metals/176-888.html (accessed in March 2010)
http://www.purityalloys.com/Pewter_Alloys.html (accessed in March 2010)

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 jewels are made of massive silver. If silver is used for plating or only in one part of a jewel (chain, pendant, etc.), the jewel 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%)[25].**

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.

Sources of information which were consulted:
http://ecb.jrc.ec.europa.eu/
http://echa.europa.eu/chem_data/transit_measures/vrar_en.asp

[25] 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).

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 39: 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 40: 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 jewels 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[26] 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.

C.4. Assessment of zinc

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

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

Table 41: 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 42: 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)[27].

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.

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.

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

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 about 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 43: 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 44: 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 jewels.

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)[28].

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.

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

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)).

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/73/93 (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.

<u>Freshwater compartment including sediment</u>
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 45: 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 46: 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 jewels.

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[29].

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.

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.
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.

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

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.

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 48. 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 at least 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 jewels. 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 jewels' 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 jewels. 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 jewel at a higher price. Indeed, the jewel 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 a fashion jewel, 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 jewels constituting the set.

In terms of prices, quotation of silver is substantially higher than other non-ferrous metals (see Table 47). 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 jewel. 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 on estimating the price of an alloy based on its composition and on the price of the metal which constitute this alloy is provided in Table 48. It is highlighted that such way of calculating an alloy price is clearly an underestimation it as it only takes account of the price of the constituting metals. However, it may still provide an order of magnitude for comparison purposes. This rough calculation shows that the estimated costs of lead-free alloys containing silver (12€ on average) should be around 20% higher than the lead-based alloys containing less than 10% of lead (10€ on average). If it is considered that the contribution of the raw material is around 20 to 30% of the final costs of the jewel, the impact on final price of the jewel should be moderate.

As already mentioned, according to industry (see section B.3.2), the alloys which are used in fashion jewels do not contain more than 10% of lead. Using the same way of calculation as exposed in the previous paragraph (Table 48), it is estimated that the price of lead-based alloys containing no more than 10% is 10.1€ on average. The estimated price of lead-free is estimated at 10.8€ on average. This would imply an increase of 7% of the cost of the alloy for most jewellery manufacturers.

For jewellery producers using cheaper alloys containing very high amounts of lead (> 70%), the increase in alloys costs is expected to be significantly higher as average price of lead-based alloy containing 70% lead or more is estimated to be 1.9€. This would result in an increase of 570% of the cost of the alloy for such jewellery producers. However, such situation is expected to be exceptional as it was reported by BOCI (trade association of producers of fashion jewels) that alloys which are used by its members have an average concentration of 6% lead.

Then, this extra cost would likely to be passed on down the supply chain. As a result, sales price of the jewels 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 jewels.

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 47: 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 48: Basic calculation of the price 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)[30]***
Contenti[31] (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[32] (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*
		#927	0.92	0.07			0.01			*14.25*	*10.34*
		BM92 - Pewter alloy	0.92	0.08						*14.25*	*10.35*

[30] Using an exchange rate USD / Euro of 1 USD = 0.726 Euros (09/02/2010)
[31] http://www.contenti.com/products/metals/176-888.html
[32] http://www.alchemycastings.com/lead-products/jewelry.htm

		#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[33] (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*

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

D. Justification for action on a Community-wide basis

Given the following points:

A. The **severity** of the risk: chronic exposure can lead to disturbed heame synthesis, peripheral neuropathy, encephalopathy, kidney damage and reproductive toxicity. Also, lead induces **neurotoxic effects** which may be irreversible and children are particularly vulnerable as their brain is under development. Moreover, acute exposure can be **fatal** when it results in very high blood lead levels (as in the case of the child who died in the USA after having swallowed a leaded bracelet's pendant).

B. The **extent** of the risk:

   1.B The population affected is **all potential consumers** and as such, it includes children who constitute a very vulnerable sub-group

   2.B **Children** across all Member States may be exposed to lead from ingestion/mouthing of jewels, because of the wide spread of such articles within the Community

It is necessary to take measures to ensure the protection of children's health through the Community. **Moreover, it can be expected that new tests results and publications will be released about the health risks related to leaded jewels inciting Member States, in the absence of European regulation, to implement national measures. Considering the negative effects that isolated national actions would have on adequate management of the risks across the European countries, on industry actors and on the internal market, an action is then required at a Community level to tackle these identified health risks while insuring equal treatment and fair trade relations within the internal market across the EU.**

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 jewels 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

Jewels are distributed and sold all over Europe, in very various shops, of all size and not only (and even rarely, for fashion jewels) 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 jewels 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 jewels 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.

The risk to be addressed herein is the risk of lead poisoning resulting from a misuse (accidental ingestion/mouthing) of jewels by children. This concern is grounded on several alerts and cases documented in the international literature (see section B.9.3.1). 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 there is no threshold 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 lead-containing jewel 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 very difficult to quantify the exact amount of jewels (and lead-containing jewels) 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: although some EU countries are leaders on the market, all Member States produce, import and distribute jewellery articles. These are current consumption products and future trends show that they are expected to extend even more in Europe due to the development of the internal market and of the imports from non-EU countries.

As a result, in the absence of the proposed restriction or any further RMO, the baseline can be summed up in the following way: *the risk of children lead poisoning from jewels will still be present and even possibly increase in the future with the envisaged extension of the fashion jewellery market (increasing of production inside the EU and of imports from non-EU countries).*

It may be expected that tests for lead in jewels 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

The proposed restriction consists of limiting the lead migration rate from jewellery articles to a maximum of 0.09 µg/cm²/hr. Six alternative options for a REACH restriction of the use of lead and its compounds in jewellery have been considered and are presented in this section.

Option 1: Restriction on the use and placing on the market of <u>fashion</u> jewels 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 jewels. 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 jewels 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> jewels 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 exposed in sections B.9.1.1 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°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.

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.

As explained in the previous sections, such option does not seem relevant as there is no correlation between the lead content of a jewel 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 jewels 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 jewels but with an expected low lead migration rate** (such as jewels made of crystal or glaze) and inversely, might let lower leaded jewels 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.

Option 3: Restriction on the use and placing on the market of <u>fashion</u> jewels 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 jewel 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 jewel: **a measured migration rate on a jewel which is in good condition may be much lower than if it is measured on a used jewel (jewel in bad condition), as some possibly protective coating may be damaged following the repeated uses of the jewel. For this reason, limiting both lead content and migration rate may be relevant for a very conservative approach.**

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 jewels in bad condition, it could be envisaged as part of option 1 to test the migration rate of the jewels 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> jewels which are used and placed on the market

In this option, lead and its compounds would be prohibited from being used in fashion jewels.
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 jewels, 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.
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 jewels, 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 jewels). **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 jewels 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 jewels 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 jewels 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 jewels 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 jewels 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.

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 jewels (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 jewels, this option also affects precious jewels. **The proposition of this option results from the lack of definition for what a fashion jewel is**. With no clear definition of a fashion jewel, it is expected that a restriction only affecting fashion jewels will be very difficult to implement. 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.

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.9.1.1, 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"*[34] (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 jewels. 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 jewel may be ingested. As a consequence, it is not the same approach. However, it is acknowledged that jewels 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 jewel.
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 jewel 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 jewels concerning their lead composition and of warning the consumer about the potential health risks of mouthing such articles. However, in practice, jewels are not kept in their packaging and thus the information concerning lead composition and the warning will not remain with the jewel and it can be expected that the consumer will not remember it. In addition, such labelling would imply that all producers, importers and actors who place the jewels on the market have the information concerning the lead composition of these articles in order to edit proper labels. However, it is not expected that all these actors have this information.

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 jewels; 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 jewels

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

(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 jewels. **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 presented in the previous section have to be evaluated and compared to each others as regards the risk to be addressed and the baseline described in section E.1.1. As a reminder, these options are:

- Option 1: Restriction on the use and placing on the market of fashion jewels based on the lead migration rate
- Option 2: Restriction on the use and placing on the market of fashion jewels based on the lead content
- Option 3: Restriction on the use and placing on the market of fashion jewels based on the lead migration rate AND the lead content
- Option 4: Ban on lead and its compounds in fashion jewels which are used and placed on the market
- Option 5: Ban on lead and its compounds in SOME fashion jewels which are used and placed on the market
- Option 6 (the proposed restriction): Restriction on the use and placing on the market of jewels (fashion and precious) based on the lead migration rate

These options (except for option 3 which is a combination of option 1 and option 2 and except for option 6 which has been identified later on during the preparation of the dossier, once industry consultation had already been performed) have been proposed during the consultation process to MSCAs, national health institutes and industrial actors. The outcome of this consultation is presented in the next tables (more details are available in section G.1 and in INERIS (2009)).

The following table presents the views from different Member States Competent Authorities and health institutes which were contacted via questionnaire. For more information on this consultation process, please refer to Section G.1.

Table 49: Views from different MSCAs and health institutes about the options proposed

Options	EU countries											CA	Specific comments
	SE	CY	SK	EE	DE(1)[a]	DE(2)	AT	DK	PL	HU	GR		
Option 1 Migration (all fashion jewels)			√		√							√	SE: “This approach will be costly both to introduce (requires agreed test methods and limits) and to enforce (requires more complex analysis). Also it will not address added risks to the environment from the waste phase to the same extent as a ban.” CY: “The analysis for the migration rate of lead and its compounds is time and money consuming. A ban or a restriction on the use or the content of lead and its compounds in jewels will be easier to enforce.” DE(1): “It is required that the limitation level is based on a toxicological assessment.” DE(2): “Analytical problems with the determination of the migration rate concerning the reproducibility between different laboratories are expected (according to nickel).” PL: “At present we can not support such option because there is difficult to control and enforcement the migration of lead contained into jewellery and enforcement. In this context we consider that testing methods for determination of migration rate of lead should be included as a part of regulation.”
Option 2 Content (all fashion jewels)		√	√						√			√	SE: “This approach will be more costly than a ban both to introduce (requires agreed test methods and limits) and to enforce (requires more precise quantitative chemical analysis than a ban). Also it will not address added risks to the environment from the waste phase to the same extent as a ban.” CY: “This will be the second easier option to enforce, after the total ban on the use.”
Option 4 Ban on lead and its compounds (all fashion jewels)	√	√		√		√		√		√	√	√	CY: “It will be easier to enforce a ban in all jewels instead of a ban in some kind of jewels.” EE: problems envisaged related to this option concern “jewellery where lead is needed for connecting different details (national honorary medals); complicated to avoid consumption of lead. There are lots of non precious metal jewellery items on the market that have lead in the surface alloy (coated); hard to eliminate from

													the market.” DE(2): “Problems with the determination of the lead content because of inhomogeneous materials and jewellery parts.” DK: “There can be a problem in the soldering.” CA: “The Canadian lead limits for children’s jewellery are low enough to act as an effective prohibition on the intentional use of lead.” GR: problem of the measure of human exposure
Option 5 Ban on lead and its compounds (some fashion jewels)						√	√		√		√		SE: “This approach would be harder to enforce than a ban since the definitions of the relevant jewellery will be hard to do. Also it will not address added risks to the environment from the waste phase to the same extent as a ban.” CY: “It will be difficult to justify for which jewels accidental ingestion is likely to occur.” DE(2): “could apply to jewelleries which can be swallowed and jewelleries (e.g. chains) which are often placed into the mouth without swallowing.” AT: “REACh requires the proof of an unacceptable risk to humans and an economic analysis of alternative management options which might be more cost-efficient.” CA: “1. The greatest risk of lead exposure occurs when jewellery items containing lead are swallowed. However, children can be exposed to harmful levels of lead from sucking or chewing on lead-containing jewellery, whatever its size. 2. Lead is soft and pieces small enough to be swallowed may break off large pieces of lead. 3. With respect to enforcement survey results, we have found pendants to be the jewellery category with highest proportion of non-compliant items.” PL: “We would support such option for every type of jewellery that consists of elements made of alloys with addition of lead (including brass).” GR: Little articles like pearls, earrings, etc.

[a] Two columns are provided for Germany as several filled-in questionnaires were received.

General comment from NL: “At this moment, we cannot indicate whether the Netherlands would support a restriction or not. We need much more information on possible risks, content in jewellery, incidences etc.”

During the consultation, Member States had the possibility to propose other risk management options. Greece proposed that some “lead-free” certificates could be delivered by authorised laboratories.

The following table presents the views from different industrial actors which were contacted via questionnaire. For more information on this consultation process, please refer to Section G3.1 and to INERIS (2009).

Industry actors who answered the questionnaire may be classified according to the following activities:

- production of fashion jewels (or parts of fashion jewels)
- manufacture/extraction of lead and/or its compounds intended to be used into fashion jewels
- manufacture/extraction of other substances intended to be used into fashion jewels
- import of fashion jewels (or parts of fashion jewels)
- import of lead and/or its compounds intended to be used into fashion jewels
- import of other substances intended to be used into fashion jewels
- distribution of fashion jewels (or parts of fashion jewels)
- other activity related to fashion jewellery

Table 50: Views from different industrial actors about the options proposed

Proposed options	Would you support this option?			Comments
	Yes	No	Don't know	
Option 1 Migration (all fashion jewels)	7	3	3	BOCI (trade association of manufacturers of fashion jewels) considers this option to be the only one which is relevant considering the management of human health risks. According to them, a decrease of the lead migration rate is realistic and conceivable as long as it does not imply a drastic change of industrial techniques and process. They mention that a maximal content of 6% of lead in alloys would be synonym of important technical adaptations for the producers. Lead manufacturer/extractor (Yes): "I don't have figures, but this is logical and is beginning to look like a scientific rather than political approach." Lead importer (Yes): "This is my initial proposal with an adapted surface treatment" Lead manufacturer (Yes): "Migration rates given in US regulations." Producer of fashion jewels (Yes): "[The migration rate that could be proposed is] the migration rate according to EN 71-3 European Norm on the Safety of Toys, Migration of Heavy Metals".
Option 2 Content (all fashion jewels)	5	3	3	Lead manufacturer/extractor (No): "It is not a problem of content but of availability." "For information, for this type of application lead crystal contains close to 35% lead and this threshold is necessary to have the brilliance characteristics required for this application. Reducing this threshold to 20% would be an aberration because it would no longer be the same crystal: it would be a bit like wanting Perrier without bubbles. Lead crystal for this application requires between 34 and 35% lead in the silicate…" Lead importer (Don't know): "Why not. It's already done. We exceeded 40% lead a few years ago at less than 10% now (except a few specific applications" "To avoid over-protecting ourselves, I would propose a threshold value of 5 to 10%" "[This would involve] increasing prices for jewels not requiring this measure" Lead manufacturer (Yes): "<0.01%" "IMPORT AUDIT" Lead manufacturer/extractor (Yes): "Max 5% Pb, this would make it possible to have a wide range of alloy suitable for all jewelry applications." "To be verified with the quantity of Pb which can be released by alloys with this content." "The alloys would remain costly because heavily loaded with tin (more expensive than

				Pb)" Manufacturer of other materials (Yes): "Limitation for a content of less than 4%" Manufacturer/extractor of other materials (Yes): "We are not directly concerned" Lead manufacturer (Yes): "Alignment with US legislations or alignment with REACH/RoHS." "Consider time involved with implementation of limits in production. Full conversion to 600 ppm would require about 3 years; full conversion to 100 ppm requires about 5 years or longer." Producer of fashion jewels (No): "Only limits on lead migration really reflect the actual risk of absorption of the human body and therefore negative consequences if derived no effect level is exceeded. A reasonable reduction is feasible as long as production processes and techniques do not need to be changed. Any lead limit below 60 000 ppm lead content already requires considerable change of production processes and techniques."
Option 4 Ban on lead and its compounds (all fashion jewels)	4	9	2	Lead manufacturer/extractor (Don't know): "We stock up with glass stones. It is not technically possible to have a level of 0% regarding lead content." "California and Florida already have sufficient legislation in this matter. It is difficult to do better." Lead manufacturer/extractor (No): "Lead is trapped in the silicate network and is not salted out throughout the life of the jewel. A ban would be completely unfounded." Lead importer (No): "This option would cause an increase in manufacturing costs for jewels. For most [jewels] which undergo a surface treatment, the presence of lead does not cause any problems. I would recommend: 1. Ban on using lead for raw jewels which do not undergo any surface treatment 2. Standardizing the surface treatment to require a minimum thickness, but authorizing lead in the structure of the jewel" Lead manufacturer/extractor (No): "[This option would cause] an increase in costs for a major portion of manufacturing (passage to pure tin alloy)." "In some pieces, we don't achieve the same quality (surface appearance) with leadless substitution alloys." Lead manufacturer (No): "A complete ban would eliminate jewellery industry. The only option are reasonable lead limits (e.g. according to US legislation) with clearly defined measurement methods. also different limits for specific product categories (e.g. children) could be possible." Producer of fashion jewels (No): "A complete ban would eliminate jewellery industry. The only option are reasonable lead limits, based on lead migration rather than lead content, with clearly defined measurement methods."
Option 5 Ban on lead and its compounds (some fashion jewels)	6	6	1	Manufacturer/extractor of other materials (Yes): "It all depends on the percentage. [This would] doubtless [involve] stopping the entire activity." Lead importer (No): "This does not resolve the problem of Pb in jewels which does not integrate" "Is the presence of lead the biggest risk when one ingests a jewel? Lead manufacturer (No): "The final use is decided by our clients. When we manufacture something, we don't always know how our client will use it." Lead manufacturer (Yes): "for children's jewellery.

				Definitions have to be very clearly specified, e.g. definition of "children" (age...), also definition of testing methods have to be very precise." Producer of fashion jewels (Yes): "This can be supported for children's jewellery, only as long as the definition of a child contains an age limit that reflects a real danger of accidental ingestion of jewellery according to experiences in development of children".

The International Lead Association Europe (ILA) mentioned that an EU Voluntary Risk Assessment on Lead and some inorganic lead compounds (VRAR, 2008) was conducted over the period 2000-2008 according the guidance for the Existing Substances Regulation (79/793/EEC). ILA indicated that "The risk assessment report was reviewed by the EU's Technical Committee on New and Existing Substances (TCNES) as well as the European Commission's Scientific Committee on Heath and Environmental Risks (SCHER). The report concluded a potential risk from the use of lead in children's costume jewellery due to the potential for accidental ingestion. However we understand that this use of lead is already banned in the EU through toy safety regulations[35]" … "On the basis of the VRAL conclusions the International Lead Association Europe, representing a significant proportion of EU lead manufacturers, does not support the use of lead in children's fashion jewellery."

[35] The use of lead in children's jewellery is not banned in the EU through the Toy Directive 2009/48/EC as fashion accessories for children which are not for use in play are an exemption of this Directive.

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 jewels.**
- **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 jewels, difficulties are foreseen to determine which jewels 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

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

From the outputs of this comparison, only options 1 and 6 will be assessed in more details in the following sections.

E.2.1. Restriction option 1: Restriction on the use and placing on the market of fashion jewels 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 jewels, it will reduce the risk of children poisoning both from acute exposure (accidental ingestion) and from chronic exposure (mouthing of the articles). The fashion jewels 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

The proposed restriction appears to be economically feasible. 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. More important efforts are expected to be made however from industry actors if they choose or have to switch to alternatives to lead as, from the limit set up for the lead migration rate, it is expected that it will not be possible to use lead as a constituent of the alloys anymore. In this case, additional costs due to more expensive raw materials (see section C for more details on alternatives) and perhaps **additional operating and adjustment costs as well due to adaptation to alternatives' specific properties of equipments and machines**. These costs are also further examined in section F. **The biggest efforts are envisaged to be made by micro and small firms.**

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 jewels are changed according to seasonal fashion trends. This suggests that the stocks of actors who place fashion jewels 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 jewels 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.
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 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 jewels 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 in saliva. 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 jewel 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 **Jewels**	Lead migration rate **Jewels**	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 »	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 solution	Sufficient volume to just cover the toy	Sufficient volume just to cover the sample	50 times the weight of the jewel	- Dish that can be filled: 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	Flame atomic absorption spectrophotometer	ICP	Flame atomic absorption spectrophotometer

	spectrophotometer could be used.	at 283 nm		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 for enforceability of the proposed restriction. However, when using this method one should consider the following adaptations:

A - Concerning the size of the jewel

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" 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 jewels, but also with the mouthing of the jewel. As the latter activity may be performed by the child **whatever the size of the jewel is, it is necessary that all jewels are being tested according to this standard**: indeed, a toy (and, possibly a jewel) which is too large to be swallowed may clearly be mouthed/sucked and may result in chronic lead poisoning (InVS (2008)).

As bigger jewels need to be tested using EN 71-3, it may be necessary to adapt the quantities of aqueous solution of hydrochloric acid. For information, US CPSC (2005) indicates that the amount of acid solution added should be equivalent to fifty times the weight of the jewellery item.

B – Concerning the coating

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 coating of jewellery articles.

Section C.10.1 of EN 71-3 specifies that "glass, ceramic and metallic materials completely coated so that no glass, ceramic or metal is accessible as defined in EN 71-1 are not tested according to this requirement". This point should also be adapted as it is acknowledged that while mouthing the jewels, children will deteriorate the article and thus they will remove some parts of the coating making the underneath material accessible. **Consequently, the jewel should also be tested after removal of any coating in accordance with section 8.1.1 of 71-3 and the coating should also be tested in accordance with section 8.1.2 of EN 71-3. In that case, the sum of the two migration rates (coating alone + jewel without its coating) should not exceed the limit proposed in the restriction.**

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 jewels is however unknown. Analytical tests would probably be needed to assess its relevance.

It should be highlighted that the migration rate is defined in µg/cm²/hr. This implies that the surface of the tested jewel 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. However, given the variability in terms of materials and of forms which are used in the articles of the jewellery sector, it does not seem possible to go from a unit in "µg/cm²/hr" to another one in "µg/kg/hr" even though it is acknowledged that it would make the proposal more enforceable.

The great variety in terms of jewels which are 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 jewels and that the necessary equipment for these tests is already available in the laboratories.**

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 a fashion jewel?". 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 jewels with important differences in terms of their composition, their price and their selling points.

- Concerning their composition, fashion jewels 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 jewels 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 jewels 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"[36] by Health Canada.
- "Any jewel (including hair ornaments) which does not contain massive precious metals" by the French jewellery professional federations Cetehor and BOCI.

Fashion jewels may be differentiated from precious jewels, according to RPA (2009) depending on the used material (presence of precious metal alloys in precious jewels and use of a variety of materials in

[36] 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)

fashion jewels), on the place where they are sold, the pricing structure (fashion jewels are significantly cheaper than precious jewels), the presence of a hallmark (or CCM) which indicates that a jewel is precious (however, absence of a hallmark does not necessarily mean that the article is a fashion jewel).

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 jewels. DGDDI indicated that such classification is performed using a TARIC code and that the code for “Imitation jewellery” is “7117”[37]. 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, ...".
This definition indicates that fashion jewels 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 jewels. However, the previous mentioned definitions indicate that a “fashion jewel” 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 a fashion jewel could be the one used in the TARIC code above mentioned, but an addition should be made in this case concerning jewels which are 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 jewels which have 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 jewels which are 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

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 jewel 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

[37] 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)

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 53. 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 jewels 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 jewels” and to the measurement of the surface area of a jewel.

E.2.2. Restriction option 6 (the proposed restriction): Restriction on the use and placing on the market of jewels (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 jewel) and chronic exposure (mouthing of a jewel).
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 jewels).
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 jewels 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[38] 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 jewel. If a jewel has a content of gold which is below 37.5%, it will not be possible to call it a “gold jewel” 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

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

be considered that lead is not regulated in precious jewels and it may be envisaged that precious jewels such as “gold” jewels (which contain a minimum of 37.5% gold) may also contain lead.
Consequently, including precious jewels in this restriction proposal seems relevant in terms of effectiveness.

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 jewels than in fashion jewels.** This is confirmed by information obtained during consultation of the MSCAs: according to an Italian Federation of precious jewels' 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 jewels 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 jewels on the market are rapidly renewed, alloys intended for use in fashion jewels seem to be manufactured following customers' demand and as such, stocks are not expected to be important. Moreover, concerning precious jewels, 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 jewels 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 jewels, 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 jewel 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 jewels 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 a fashion jewel 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 533.
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 jewels in addition to fashion jewels, 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 jewels (according to an Italian Federation of precious jewels' 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 jewels" 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 jewel.

E.3. Comparison of the risk management options

Restriction options 1 and 6 can be compared as regards the three mentioned criteria and scored in the following table.

Table 53: Overall assessment of restriction options 1 and 6

	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)	+++	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.

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 jewels) and to provide a secure legal framework for firms producing and placing on the market jewellery articles.

E.4. Main assumptions used and decisions made during analysis

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 jewel, surface of a jewel which is in contact with the mouth for the "use 1", time during which the ingested jewel 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 jewel 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 jewel can be measured in order to calculate a lead migration rate in µg/cm²/hr; which may be difficult in practice for jewels with an uncommon shape, as reported during consultation of SCL (see section G.4.2) following experience gained with the nickel restriction in jewels (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 jewel is not considered to be representative of the potential exposure of a child accidentally ingesting or mouthing the jewel, contrary to the lead migration rate.
- It has been assumed that precious jewels contain neither lead nor its compounds. Percentage of lead in precious jewels 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 jewels' manufacturers. Considering this assumption, impact of the proposed restriction on the sector of precious jewels 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 **jewels 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 proposed restriction is considered to be the only adequate tool to manage the risks posed by lead and its compounds in jewels.

As presented in section A., the proposed restriction, its conditions, scope and justifications are the following.

Conditions of restriction

Jewels which have a lead migration rate greater than 0.09 µg/cm²/hr are prohibited from being produced and placed on the market.

Formally transposed in Annexe 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	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.

The scope of restriction

A delay should be envisaged for implementation: the restriction may apply 6 months after the entry into force of the amendment of REACH Annex XVII.

The restriction shall apply to all jewels (**both precious and fashion jewels**) **whether they are intended for children or not.**
No derogation is proposed in this restriction.

The lead migration rate of 0.09 µg/cm²/hr should be considered for each individual part of the jewel. When tests are performed on several parts of an article, the analytical results of each part should be compared to the limit of 0.09 µg/cm²/hr. If a part has a migration rate which exceeds this limit, it should be considered that the article is not allowed to be produced or placed on the market.

It is 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, jewels 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. Secondly, coated jewels should be tested after removal of their coating; in this case, the sum of both migration rates (coating alone and jewel 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.

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 jewels (see Section B.9.3.1). Moreover, many reasons exposed in Section

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.
- This restriction proposal is based on the lead migration rate of the jewels which is considered to be more representative of potential exposure than the lead content.
- 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 jewels (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

As requested in the Guidance for the preparation of an Annex XV dossier for restrictions, this section focuses on the proposed restriction and must document the socio-economic impacts related to it. Whereas section E includes the assessment of proportionality including information on costs and impacts as required in Annex XV, the present section F includes **additional, discretionary information as described in Annex XVI of REACH regulation.**

As presented in section E.1.1., in the absence of the proposed restriction or any other RMO, the baseline can be summed up in the following way: the risk of *children lead poisoning from jewels will still be present and even possibly increase in the future with the envisaged extension of the fashion jewellery market (increasing of production inside the EU and of imports from developing countries).*

With the implementation of the proposed restriction, exposure to lead from jewellery articles will be reduced. This restriction would thus have mainly impacts on human health and on industry actors which will have to comply with it.

This section aims at presenting and assessing qualitatively and quantitatively (when possible) the different impacts induced by the switching from the baseline situation (situation without restriction) to the restriction (hypothetic and future) situation.

An impact is defined as the measurement of the qualitative/quantitative gap between these two situations. The magnitude of the impacts of the proposed restriction depends on:
- the severity of the identified risks
- the vulnerability of the targeted at-risk population
- how wide-spread leaded jewellery items are within the EU
- the type and number of industry actors which would be affected by the restriction
- the extent of the impacts on these industry actors
- the existence and the feasibility of alternatives

Within the focus of this dossier, the following socio-economic analysis will show the important hindrances to the quantitative assessment of the impacts of the restriction proposed, in

particular of the health impacts. These hindrances are mainly due to an important lack of information on: the use of lead and its compounds in jewels, the quantities of such articles which are present on the market, the exposure of the population from this source, the health effects resulting from this exposure, the costs of the products, among others.

F.1. Human health impacts from exposure to lead in jewels

This section aims at evaluating qualitatively and quantitatively (when possible) the impacts that the proposed restriction would have on children's health. As the objective of the proposed restriction is to reduce health risks, these impacts are considered as health benefits.

As presented in section B.5, exposure to lead and its compounds may induce deleterious effects on children and in particular on their central nervous system. Symptoms associated with exposure to lead are broad and go from hyperactivity, headaches, hearing loss and diarrhoeas to kidney injuries, lowered IQ, mental retardation and, in the most extreme cases, to death. Some of these health effects, such as neurotoxic effect, are difficult to detect since they can be linked to low chronic exposure levels. Moreover, some symptoms are also difficult to attribute to lead exposure.

The evaluation of health benefits of the proposed restriction could include two types of assessments:

▪ the assessment of the health effects themselves which consists in giving a monetary value (when possible) to the health effects (from morbidity to mortality) resulting from lead exposure via the use/misuse of leaded jewels.

▪ the assessment of direct and indirect costs of these exposures which consists in calculating the costs of the short-run and long-run curative implemented treatments to tackle the health effects of lead exposure resulting from the use/misuse of fashion jewels. These costs are borne by families or by society.

Both approaches are attempted in the following sections.

F.1.1. Chronic health impact assessment

The aim of this part is to use information on the lead migration rate of jewels which are placed on the EU market. From this data, children exposure to lead resulting from mouthing these articles can be estimated. Based on this exposure estimation, an assessment of the possible resulting health effects will be attempted.

F.1.1.1. Lead migration rates of jewels on the EU market

The only information on EU jewels' lead migration rates was identified in Danish EPA (2008). In this study, 25 jewellery parts of metal jewelleries were used for a migration test for release of lead, among other substances. The analysis method that has been used is "Migration to artificial sweat" according to DS/EN 1811:2000. The aim of this section is to assess exposure via oral route (migration of lead from the jewel to the saliva). As no other data on lead migration test on jewels was identified, the results from these tests will be used, but it has to be highlighted that the matrix is different as its aim is to simulate sweat. Danish EPA mentions that the pH value in the sweat test is higher of a factor of 1.5 than the pH of the saliva. Consequently, using these test outputs will result in a possible under-estimation of the exposure.
Danish EPA (2008) specifies that the jewellery parts were selected so that they cover different types of products (rings, necklaces, bracelets etc.) and different product categories (silver-coated, golden-like, non precious metal etc.) but the major criterion was that the jewel part was supposed to be in contact with the skin. It is important to note that the selected jewels in this study are not supposed to be representative of the EU market. Also, in order to perform the tests, jewels have been cut and the new exposed parts were covered with wax to avoid migration. It may be questioned whether the use of wax

was really efficient in prohibiting the migration from these newly exposed parts as the samples were placed at 40°C during 4 hours. All these limits have to be kept in mind when performing the health impact assessment.
The results of the migration tests performed for 4 hours indicate that the lowest measured migration rate (M_R) was 2 µg/cm² and that the highest one was 280 µg/cm² (only the results which were above the detection limit were considered).

F.1.1.2. Exposure assessment

In order to estimate the amount of lead which is ingested by a child during mouthing activity, it is necessary to use the following parameters: the duration of mouthing and the surface of the jewel which can be placed in the mouth.

The following table presents the default mouthing times which were used in section B.9.3.2.2. For more information on this parameter, please refer to section B.9.3.2.2.

Table 54: Defaults mouthing times for children under the age of 36 months

Age (months)	BW (kg)	Default mouthing time (M_t) (hr/day)
3-6	6.21	0.58
7-12	7.62	1.43
13-18	9.47	0.58
19-36	9.85	0.15

According to RIVM (2008), the surface (S) of a toy which can be placed in the mouth at once is 10 cm². It is proposed to use this value in the assessment.

Using these parameters, the amount of lead which is ingested because of mouthing a lead containing jewel is calculated and presented in the following table for the lowest and the highest migration rates measured in the Danish EPA study:

Table 55: Daily quantity of lead which is ingested by children under the age of 36 months

Age (months)	BW (kg)	Daily quantity of lead which is ingested (in µg/day) = M_R x S x M_t / 4		Daily quantity of lead which is ingested (in µg/kg bw/day)	
		2 µg/cm²/4hrs	280 µg/cm²/4hrs	2 µg/cm²/4hrs	280 µg/cm²/4hrs
3-6	6.21	2.9	406	0.47	65
7-12	7.62	7.2	1001	0.94	131
13-18	9.47	2.9	406	0.31	43
19-36	9.85	0.8	105	0.08	11

No clear dose-response relationship was established for lead effects, except several studies which make a link between PbB level and the loss of IQ points (Bellinger D.C. and Needleman H.L. (2003); Canfield R.L. *et al.* (2003); Lanphear B.P. *et al.* (2005)). However, it is suggested that the loss of IQ points depends on the global blood lead level of the child and not only on the increase of the PbB level (Lanphear B.P. *et al.* (2005)). Consequently, in order to assess the number of lost IQ points, it would be necessary to have the distribution of the PbB levels of the European children.

This exposure assessment is based on many assumptions, among which:
- a migration rate in the sweat which is used instead of a migration rate in the saliva.
- migration results are obtained for only 25 parts of jewels; as a result they are not representative of the EU jewellery market.
- the method that is used to measure the migration rate presents some biases (SCHER (2010)).
- only fashion jewels have been tested.
- 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 (risk assessment is aimed at being protective whereas the objective of health impact assessment is to be realistic).

Considering all these uncertainties, it does not seem relevant to try to assess health impacts using dose-response relationships for lead and IQ effects. Indeed, it is considered that the outputs of the health impact assessment would be too uncertain.

It is however proposed, in order to assess in a very uncertain way the possible health impacts of this exposure, to compare the exposure with the tolerable daily intake of lead, the TDI. It is also proposed to compare the resulting increase in PbB level to information on potential health effects that may occur at such concentrations. Both approaches are exposed in the following section.

F.1.1.3. Health impact assessment

The TDI value for lead is 3.6 µg/kg bw/day. The following table indicates the part of TDI that would be represented by the previously calculated exposures.

Table 56: Part of the TDI of the daily quantity of lead which is ingested

Age (months)	Daily quantity of lead which is ingested (in µg/kg bw/day)		% of the TDI	
	2 µg/cm²/4hrs	280 µg/cm²/4hrs	2 µg/cm²/4hrs	280 µg/cm²/4hrs
3-6	0.47	65	13	1816
7-12	0.94	131	26	3649
13-18	0.31	43	9	1191
19-36	0.08	11	2	296

Data in the previous table shows that the TDI value is largely exceeded (by a factor of more than 3600 for children of 7-12 months) for all categories using the highest migration rate measured in the Danish EPA study. Using the smallest migration rate, the exposure represents 26 % of the TDI for children of 7-12 months, which is already a very important part considering the fact that global exposure to lead results from various other sources of exposure such as air, food, drinking water, soil etc. For information and for comparative purpose, migration limits used in the Toy Directive are calculated so that the exposure from toy does not exceed 5 % of the TDI.

If one wants to go further in the health impact assessment, the PBPK model (IEUBK model) that was already used in section B.5.11.3 can be applied to determine the increase of PbB level that would result from the estimated ingested quantities of lead.

As the model IEUBK is based on age classes different from those used in the calculation of the daily ingested quantity of lead above, the daily intakes of each classes have been time-weighted to correspond to the age classes used in IEUBK.

Table 57: Time weighted daily quantity of lead which is ingested

Age (months)	Time weighted daily quantity of lead which is ingested (in µg/day)	
	2 µg/cm²/4hrs	280 µg/cm²/4hrs
1-12	4.3	603.7
12-24	1.8	256.7
24-36	0.8	105.0

For the PbB level assessment, mouthing of a leaded jewel is considered as the only source of lead exposure and the oral absorption of lead is set to 50%. Children are considered to be exposed to leaded jewels from 1 month to 36 months.

Using IEUBK model, the results of the PbB assessment are presented in the following table:

Table 58: PbB assessment using IEUBK model

Migration rate (µg/cm²/4h)	Blood lead level in µg/L (time weighted average)				
	12 months	24 months	36 months	48 months	60 months
2	12	5	2	0	
280	500	316	167	38	2

The results presented in the previous table can be interpreted in the following way: mouthing a jewel for the duration specified in Table 544 would result in an increase of blood lead level of 500 µg/L at the end of the first year, of an increase of 316 µg/L at the end of its second year etc. for the highest migration rate.

These calculated increases of PbB levels may be compared to information provided in the following table.

Table 59: Toxic effects resulting from a prolonged exposure to lead (reproduced and translated from Garnier R. (2005))

Effects	**PbB level (μg/L)**
Risk of death for adults	
Risk of severe encephalopathy for adults	**2000**
Toni-Debré-Fanconi syndrome	**1500**
Risk of lethal poisoning for children	
Risk of peripheric neuropathy clinically evident for adults	
Increased risk of a severe encephalopathy for children	
Colic due to lead poisoning	**1000**
Anemia	
Risk of severe encephalopathy for children	
Recognized organic mental disorders for adults	**700**
Increase of urinary ALA	
Abdominal cramps and slow down of gastro-intestinal transit	
Risk of glomerulonephritis and tubulointerstitial nephritis after a long-term exposure	**500**
Risk of sub-acute encephalopathy for children	
First signs of a tubular renal impairment	
Decrease of haemoglobin rate	
Defects in sperm	
Decrease of the speed of nerve conduction	**400**
Increase of the ZPP	
Inhibition of vitamin D synthesis	
	200
Cognitive troubles for children	**100**
Hearing loss for children	
Inhibition of ALAD	
Inhibition of growth	

ALA: Delta-aminolevulinic acid; ALAD: Delta-aminolevulinic acid deshydratase; ZPP: zinc protoporphyrin

However, as previously mentioned, it is not possible to assess which of these health effects will be developed and by how many children. Globally, the results of the health impact assessment could show that lead exposure from jewels which are on the market represents, for the age class which is the most at-risk (7-12 months), 26 to 3649% of the TDI. From this data, it can be inferred that such jewels clearly pose a health risk for these children but, considering all the previously exposed weaknesses and uncertainties, it does not seem possible to determine which health effects will result from this exposure.

For all these reasons, it does not seem possible to assess the chronic health impacts of this restriction. As the extent of these health impacts cannot be quantified, it is not possible to make a valuation/monetisation of them. However, the main changes in **chronic** health impacts as a result of the restriction can be qualitatively estimated as follows taking into account the possible health effects and the targeted population (according to the ECHA guidance on Socio-Economic Analysis for Restrictions):

- **Number of children which may experience health benefit: all children across Europe;**
- **Examples of chronic health effects which may be avoided due to the implementation of the restriction: hearing loss, lowered IQ, lead poisoning.**

F.1.2. Acute health impact assessment

Acute exposure from lead containing jewels may result in various symptoms, going from stomach cramps, kidney injuries, poor power of concentration, vomiting to death.

Target population

As exposed in the previous sections, reported cases of poisoning due to misuse of jewels presented in Section B.9.3.1 are clearly under-estimated as this type of articles is not among the common risk-factors which are looked at when considering an exposure to lead. Consequently, it is very difficult to have a precise number of children affected by such health effects in relation to lead containing jewels. The number of cases of ingestion of jewels may be approached using the number of consultations in emergency services of the hospitals (for more information, see Section G.5). Between 2004 and 2007, 52 cases of ingestion of jewels were registered for children under 5 years-old, in 10 French emergency services. In order to be able to derive a national number of cases, information would be needed on the number of children under 5 years-old who were admitted in the other French emergency services. However, such information was not available.
In order to try to assess this national number, a rough assumption is made: it is considered that the number of cases of ingestion of jewels is the same for all French emergency services. From the information presented above, it can be estimated that 1.3 cases of ingestion of jewel are registered each year by a French hospital emergency service [52/(4x10)]. Considering that there exist 622[39] emergency services in France, the total number of French children of this age category who ingest a jewel every year is approximated: 809. Considering the number of children under 5 years-old in France, the percentage of children who possibly swallow jewels can be estimated. As the increase of the number of the French children below 5 years old between 2004 and 2008 is not expected to have a significant impact (3,913,913 in 2004 and 3,973,883 in 2008 according to Eurostat), the figure that is used is the most recent one (from 2008): 3,973,883. The percentage of children below 5 years-old who yearly ingest jewels can thus be estimated: 0.02%. Using the European population of children under 5 years-old in 2008 (25,777,067 for EU27 and 24,358,205 for EU25, according to Eurostat), it may be considered that about:

- **5,150 European children possibly swallow a jewel every year, considering EU27, or**
- **4,870 European children possibly swallow a jewel every year, considering EU25.**

This figure gives an idea of the size of the population which may develop acute health effects due to the swallowing of a jewel. This represents an under-estimation of the targeted population, as reported cases of acute poisoning due to lead in jewels (see section B.9.3.1) show that they result not only from ingestion of the jewel but also from mouthing of a jewel. However, information on the number of children who suffer from acute effects related to mouthing of a jewel is not available.

Health effects

Depending on the quantity of lead which can be released by the jewel, on the time the jewel is mouthed by the child or stays in the child’s stomach, on the time that it takes parents/doctors to realise that the child has been poisoned by a jewel, heath effects may be very diverse and so may be their severity. Examples of such effects are dullness, restlessness, irritation, poor power of concentration, headache, stomach cramps, kidney injury, hallucinations, loss of memory, and even death in the worst case.

[39] Data from 2004.
http://www.sante.gouv.fr/drees/donnees/es2005/17activite-urg.pdf - Accessed in February 2010

Given the lack of information about the size of the affected population, the percentage of jewels which contain lead and its compounds, the variability in the resulting blood lead levels from mouthing/swallowing a lead containing jewel, the variety of health effects which may be suffered from, it is not possible to assess acute health impacts quantitatively.

If such information was available, quantitative valuation of acute health impacts could have been performed by using the costs of measures which can be implemented by families to tackle and (when possible) mitigate the health effects of lead exposures. Measures to care/mitigate these effects can be classified in 2 categories:

Table 60: Measures to care/mitigate health effects of lead exposure

Short-run measures	Long-run measures
medical cares (diagnostic testing, treatment, chelation therapy[40], hospitalization fees, follow-up and monitoring by medical profession and health institutes[41], etc.)	additional[42] educational expenses (educational support, remedial courses, etc)

Publications such as Agee M.D. and Croker T.D. (1996); Garnier R. (2005); Kemper A.R. *et al.* (1998); Landrigan P.J. *et al.* (2002); Rosenblatt N.L. (2007); Schwartz J. (1994); US EPA (1985); US EPA (1986) have examined the costs of exposure to lead and its compounds in terms of medical treatment, education or loss of earnings (children independently of the source of exposure).

In the most extreme case, child's death, strictly talking about "costs" may not be appropriate. However, an approximation of the value of those human losses could be cautiously attempted, using indicators such as the value of statistical life (Gegax D. *et al.* (1991); Leung J. and Guria J. (2006); Commissariat Général du Plan (2001)).

For the reasons previously mentioned, it does not seem possible to assess the acute health impacts of this restriction. As the extent of these health impacts cannot be quantified, it is not possible to make a valuation/monetisation of them. However, the main changes in **acute** health impacts as a result of the restriction can be qualitatively estimated as follows, taking into account the possible health effects and the targeted population (according to the ECHA guidance on Socio-Economic Analysis for Restrictions):

- **Number of children which may experience health benefits: about 5,000 European children for ingestion of jewels and possibly any child under 3 years-old across the EU for the mouthing behaviour;**
- **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.**

F.1.3. 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

[40] Chelation therapy is the use of chelating agents to detoxify poisonous metal agents such as mercury, arsenic, and lead by converting them to a chemically inert form that can be excreted without further interaction with the body.
[41] These costs include lab testing, physician visits, home inspections, etc.
[42] These expenses are considered as 'additional' compared to the current educational expenses required for a healthy child.

causes. Consequently, they cannot reasonably be quantified but only be mentioned as qualitative (and potential) health benefits of the proposed restriction.

F.1.4. 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 has been performed. The following information is extracted from Canada Gazette (2005).

"Background

Most inexpensive jewellery in Canada is sold in general merchandise stores and outlets, rather than in jewellers' shops, which sell mainly fine jewellery. An estimated 95% of children's jewellery containing lead sold in Canada is imported. Canadian manufacturers can meet lead limits for children's jewellery, but this is economically feasible only if imported jewellery is required to meet the same standard. The Regulations will ensure that the same standards are applied for all manufacturers and importers. There may be a slight increase in the average price of children's jewellery if lead substitutes are used since these substitutes are more expensive than lead. The cost of non-toxic substitute metals such as tin, varies considerably. The lead tolerances specified in the Regulations will permit the use of standard-grade substitute metals such as tin.
The white-metal casting industry, which makes alloys for jewellery and other products such as giftware and publicity objects, will also be affected by regulations on lead in children's jewellery. There are approximately 10 white-metal casting companies in Canada. However, the industry can meet the demand for other metal alloys suitable for costume jewellery.

Costs

Only incremental costs, which are costs that arise solely from the proposed control measure and are in addition to the costs for pre-existing activities, are considered. This avoids double counting that could substantially overestimate the costs.

The total cost of a control measure to prevent the importation, sale or advertising of children's jewellery with a high lead content is represented by compliance costs to industry and government regulatory costs. The incremental costs to society of the proposed regulations can be represented by the following equation:
Total Social Costs = Total Incremental Private Costs + Total Incremental Government Costs

Amending the Hazardous Products Act *to limit the total lead and leachable lead content of children's jewellery will make it necessary for manufacturers to make their product from other metals. Substitute metals for children's jewellery include tin, zinc, nickel or low-lead pewter. These metals often contain traces of lead but at levels that would remain below the proposed standard. For example, standard grade tin has a maximum lead amount of 500 mg/kg.*

The average 2001 commodity prices (in American dollars) for lead, zinc and tin were $0.21, $0.41 and $2.12 per pound respectively, suggesting 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. Domestic jewellery manufacturers and manufacturers of white metal alloys indicated that a number of alternates for lead in jewellery manufacture exist, including low-lead zinc and pewter. The base cost of low-lead zinc is about twice the base cost of the lead currently used in jewellery. Manufacturers who were consulted did not anticipate any additional manufacturing costs associated with a switch to non-lead alternatives.

Assuming that a replacement metal would cost twice as much as lead, a single Canadian jewellery manufacturer estimated that costs to them associated with a change of metal would be $15,000 in the first year, and $20,000 in the second and subsequent years. Indications are that there are few (possibly no more than two) Canadian manufacturers of children's jewellery which would be affected by the Regulations. If it is assumed that there are three affected domestic firms, all of a similar size to *the single firm that provided cost data, the cost of the Regulations to domestic producers will be $45,000 in the first year and $60,000 per year in subsequent years.*

Foreign manufacturers of children's jewellery are likely to incur the same cost differential when switching from lead to a nonlead alternative. Similarly, their cheapest and most likely option is a switch to low-lead zinc, which would double the cost of the metal used in the manufacture of the jewellery.

Monitoring, enforcement and related laboratory costs for Consumer Product Safety of Health Canada are estimated at $30,000 in the year after the Regulations are introduced. These costs would tend to decline over time as experience is gained and noncompliant jewellery is removed from the marketplace. After the third year, costs are estimated at an average of $5,000 per year.

The present value of Total Social Costs is roughly $600,000 over the lifetime of the Regulations, at a 3% discount rate.

Benefits

This section evaluates how the Regulations will improve the well being of individuals in society and where possible, express these welfare improvements in monetary terms. It includes the following three steps:
1. Identify and categorize the adverse impacts that will be avoided through the Regulations;
2. Quantify reductions in risk for each of the adverse impacts identified; and
3. Place a monetary value on the quantified reductions.

In this instance, quantifying and monetizing reductions are greatly limited by the availability of data and resources.

Estimated benefits for the Canadian public are based on the values for cost of illness and medical costs found in the valuation literature. These values are summarized in Table below.

Table 61: 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. This range of values will be compared to the costs that are outlined in the next section.

Net Benefit

Since we do not have exhaustive data regarding benefits, a true comparison of benefits and costs is not feasible. However, a break-even analysis, which determines the point at which benefits equal or exceed costs, may be 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 are efficient as long as, over their lifetime, 60 to 100 cases of lead poisoning are avoided.

Distributional Analysis

The preceding analysis of benefits and costs indicates the point at which the control measure is economically efficient, that is, the point at which net benefits become positive. A distributional analysis considers the distribution of costs and benefits, and the fairness of the regulatory outcome.

For the purpose of this analysis, those considered favourably affected by the Regulations include:
- *Users of children's jewellery; and*
- *Family and friends of the users.*

Those considered unfavourably affected would include:
- *Importers, manufacturers and distributors of children's jewellery.*

There is no indication of differences among users of children's jewellery based on such factors as provincial, income or gender disparities. Any child in Canada is thus considered to be as likely as any other to be a user of children's jewellery. Consequently, there is no observable difference in impact among the users who will be beneficiaries of the Regulations. Similarly, there appears to be no significant differences in the potential impact of the Regulations among the importers, manufacturers, and distributors of children's jewellery who bear the costs of the regulations. Furthermore, those employed in the manufacturer/importation/distribution of children's jewellery may also be the parents of users of the jewellery. Thus, members of this group may be both positively (as a consumer) and negatively (as an employee in the manufacture, importation or sale of children's jewellery) affected by the Regulations.

Summary

The benefit-cost analysis based on the available data has indicated that regulations of the lead content of children's jewellery would be an efficient control measure if, over the lifetime of the Regulations, 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.

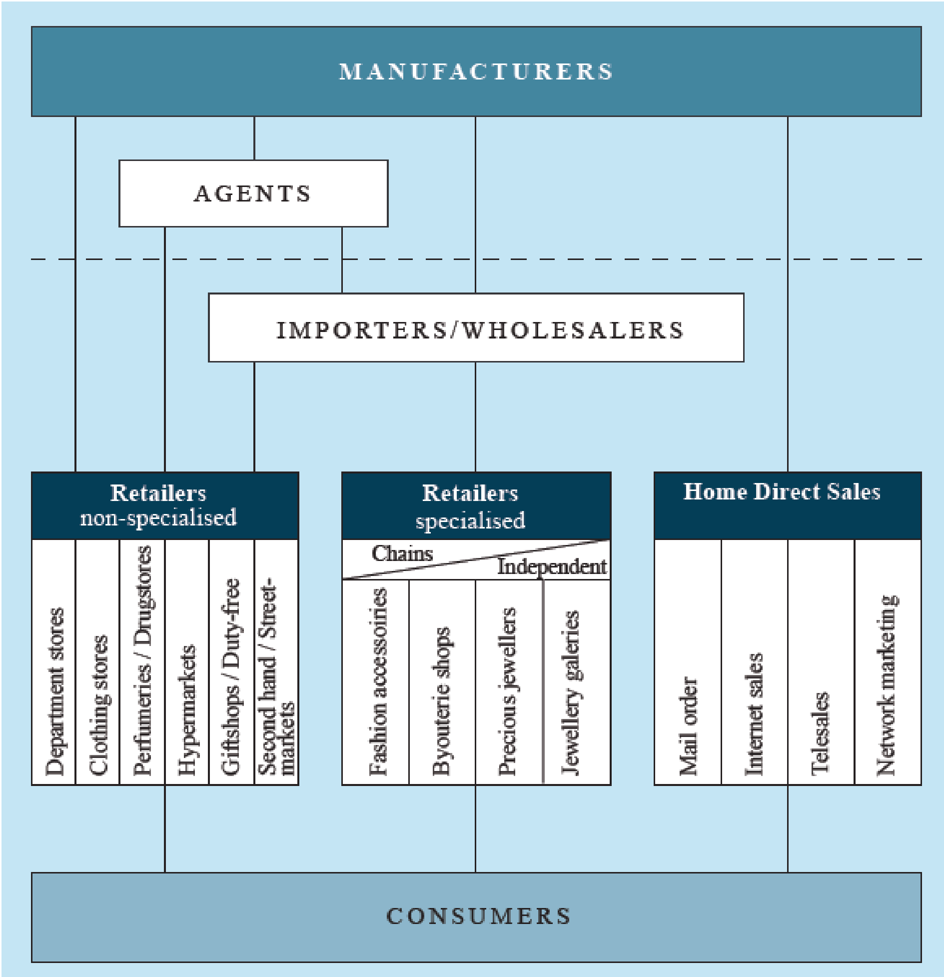

Figure 1: Typical distribution structure for jewellery in EU markets (extracted from CBI (2009))

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 jewels:
    - 5,500 European companies were producing fashion jewels in 2008, employing about 10,000 people.
    - 28,000 European companies were producing precious jewels in 2008, employing about 81,000 people (CBI (2009)).
- Importers and distributors of jewels
- Manufacturers/importers/distributors of lead compounds which may be used in jewels' 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 jewels will be needed.

F.2.2. Competitiveness, trade and investment flows

The restriction will impact the competitiveness of producers of jewels, of manufacturers/suppliers of leaded alloys and on manufacturers/suppliers of lead-free alloys.

The part represented by leaded fashion jewels among the totality of fashion jewels is not clear. It seems to be widely used as component of metallic alloys. When consulted, BOCI (trade association of producers of fashion jewels) 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 jewels 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 jewels 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 jewels, 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 jewels 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 jewel 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 jewels 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 jewels 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 jewels, 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 jewels. 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)). Given the fact that substitution costs for producers of fashion jewels are supposed to represent the main cost impacts, a rough estimation of the additional costs due to switch from lead to tin in alloys used for fashion jewels is presented in Box 1 (all assumptions are exposed in Box 1). From this information, it could be expected that such a substitution would have an additional cost on the alloys of 15,200 € if all imported and produced fashion jewels in the EU initially contained 1% lead and of 152,000 € if they initially contained 10% lead. It is highlighted that such figures are presented only to have an idea of an order of magnitude and are not supposed to represent actual costs.
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.

Box 1: Rough assessment of the additional costs due to use of lead-free alloys in the jewellery articles

The aim of this very rough calculation is to give an order of magnitude of the EU-wide impact on costs due to use of lead-free alloys in the jewellery.

Assumption #1:
The majority of lead which is used in jewels in EU concerns fashion jewels.

Assumption #2:
Additional costs are almost entirely due to replacement of lead by tin, as shown in the available lead-free alloys for jewellery application (presented in Table 48).

Price of lead: 1,930 US $/tonne (see Table 47)
Price of tin: 14,925 US $/tonne (see Table 47)
Cost difference for 1 tonne = 14,925 – 1,930 = 12,995 US $ ≈ € 9,500[43]

Assumption #3:
Lead is presently used in jewellery articles at a concentration comprised between 1 and 10%.

Assumption #4:
Available data (CBI (2009)):
Total EU imports of fashion jewels (2008): 2,352 € million representing 104.59 tonnes (≈ 105 tonnes)
Total EU production of fashion jewels (2008): 1,236 € million (no tonnage available)

As no tonnage is available for the quantities of fashion jewels which are produced in the EU, it is assumed that the relationship between quantity and value of imports is similar to the one for

[43] Using an exchange rate of 1 USD = 0.726 Euros (09/02/2010)

production: consequently, it is assumed that a production of 1,236 € million corresponds to a production of about 55 tonnes of fashion jewels.
Then the total EU volume of fashion jewellery is about 160 tonnes (105 + 55).

Calculation of EU additional costs due to substitution of lead by tin in fashion jewels:

If lead is used at 1% in the total fashion jewellery which is produced and imported in the EU:
Additional cost = 160 x 1% x 9500 = € 15,200

If lead is used at 10% in the total fashion jewellery which is produced and imported in the EU:
Additional cost = 160 x 10% x 9500 = € 152,000

F.2.4. Administrative burdens of businesses

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.
Store owners who sell jewels will have to be aware of the REACH restriction. As indicated by KEMI (2007), this will potentially result in an increase of administrative burden. Such actors will not only have to be well informed about the current regulation but they also will have to formulate requirements that have to be met by their suppliers. 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 jewels 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 jewels. Small and medium enterprises (e.g. independent fashion boutiques) are expected to have a higher administrative burden as they probably do not have internal workforces in charge of looking for information on the latest regulations and of implementing the needed procedures to comply with it, contrary to bigger firms such as fashion accessory chain stores.

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 jewels 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 jewels is available and already used for the testing of lead migration from toys.
As nickel is a substance which is already regulated in jewels, 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.

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 jewels, 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 jewels 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” jewels 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 jewels 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 jewels as some of them which are already placed on the market are supposed not to contain lead. 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 jewels 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 jewels, and especially fashion jewels. From information which was found in literature and in available studies, all types of fashion jewels 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 jewels 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 jewels on third countries and international relations are expected to go in the same ways as the ones of a restriction of cadmium in jewels, as reported by RPA (2009). As many jewels, 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 jewels, whether this use is intentional or not and on the technical and economic available alternatives.
According to RPA (2009), production of fashion jewels 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 jewels producers to export their articles in other countries which regulate the content and/or the migration rate of lead in jewels (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.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

CBI (2009) reports that 5,500 European companies were producing fashion jewels in 2008, employing about 10,000 people and that 28,000 companies were producing precious jewels, employing about 81,000 people. The impact of the restriction on employment is difficult to assess. Given the reactivity of the sector of fashion jewels 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 jewels. 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 jewels' 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 jewels' 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 jewels 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 jewels 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 jewels 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 jewels may be ingested mostly by girls (on 52 patients who had swallowed a jewel, 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 jewels was observed, it may impact more women than men as the former ones are expected to purchase jewels more frequently than men, even though men also buy some jewels, 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 jewels 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 jewels will most probably result in a decrease of the workers' exposure to these substances while producing the articles. As a growing part of fashion jewels 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 jewels. 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 jewels 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 jewels and of manufacturers/suppliers of lead-based alloys. - Possible increase of the competitiveness of producers of lead-free jewels 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 jewels. - 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 jewels. - 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 jewels could be slightly reduced. - Increase of the pressure on the non EU producers of jewels 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 jewels 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 jewels 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 jewels or while manufacturing lead-based alloys, both in EU and non-EU countries. - Increase of the health protection of consumers of jewels. - 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.

G. Stakeholder consultation

This section presents the stakeholders who have 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.

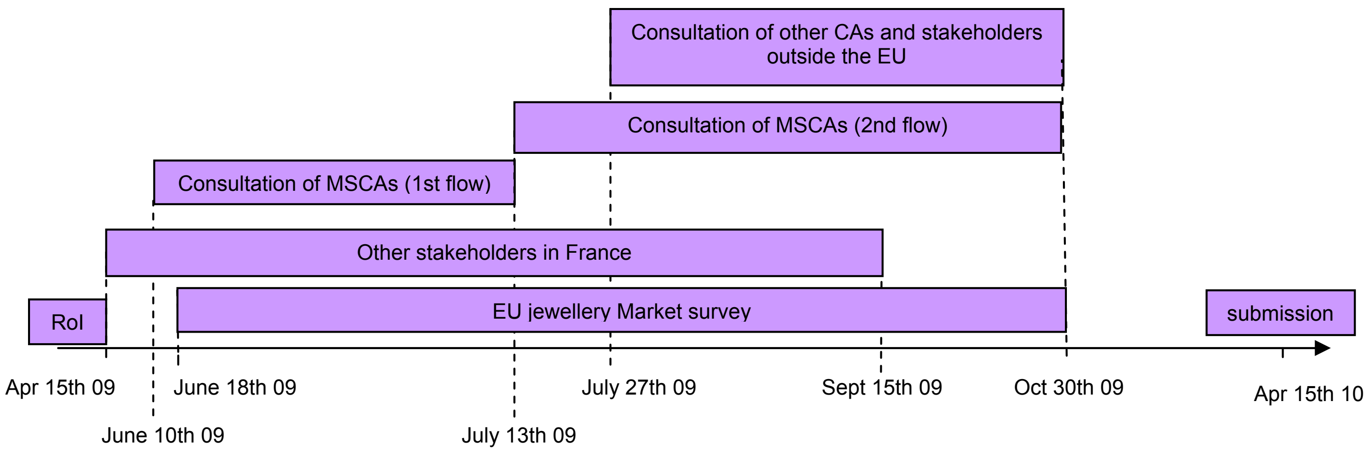

Figure 2: Consultation schedule in the process of preparing the dossier

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 Annex A).

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[44]) 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.

[44] 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	_
		no	no	no	no

	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 jewels, 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 jewels 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 jewels (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 jewels (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 jewels Usually lead is used in the main part of the jewel and is coated with other metals
SK	Favorable to limitation of content in jewels and to limitation of migration rate in jewels	-	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	_
MT	_	_	_
ES	_	no info	no info

IT	-	-	Lead is not present in traditional goldsmith and jewellery which are constituted by precious metalsHowever, lead content is possible in base-metal jewels (lead alloys)Lead is used to perform weldingsLead can be used in gold/silver-plated or rhodiated jewellery
AT	favourable to a ban of *some* jewels (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 jewels 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 jewels 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) Favourable to a limitation of the content of lead Favourable to a limitation of migration rate	Most of costume jewellery sold in Canada are imported Marketplaces surveys to check the compliance of the 2005 regulation are quite satisfactory	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, 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 Annex B). More than 3000 firms have been surveyed in the EU. These included: manufacturers/importers/ exporters of lead, producers/importer/exporters of fashion jewels 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 jewels 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 jewels' composition, especially if jewels are 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 jewels).
CETEHOR indicated that the most frequently used alloy in fashion jewels 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 jewels which are 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 jewel at a higher price. Indeed, the jewel 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 a fashion jewel, 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 jewels 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 jewels 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 jewels. The aim of this consultation was to know what the minimum levels of precious metals in precious jewels were and if there were maximum tolerable levels for other metals (such as lead) in this type of jewels. 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[45] 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 jewel. If a jewel has a content of gold which is below 37.5%, it will not be possible to call it a "gold jewel" 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 jewels and it may be envisaged that precious jewels such as "gold" jewels (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 jewels and piercing and about a survey which had been performed by DGCCRF on fashion jewellery articles.
In response to our inquiry, DGCCRF specified that lead compounds were regulated in fashion jewels 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 jewels.

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

- 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[46] (InVS (2009)). Jewels were not specifically mentioned in this poster. Consequently, InVS was consulted in order to obtain information for this type of articles. InVS indicated that between 2004 and 2007, 52 cases of ingestion of jewels 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)).

[46] http://www.dsi.univ-paris5.fr/AcVC/Publications/Poster%20ingestion%20corps%20etrangers%20SFP%202009%20BAT.pdf (Accessed in March 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 jewels.

DGDDI indicated that such classification is performed using a TARIC code and that the code for "Imitation jewellery" is "7117"[47]. 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.

[47] 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. Questionnaire sent to the REACH Competent Authorities of all Member States (and some countries outside EU)

QUESTIONNAIRE
Lead and its compounds in jewellery

The questionnaire is structured as follows:

Section A	Contact details
Section B	Children contamination with lead and its compounds
Section C	National measures concerning lead-containing jewellery
Section D	Potential risk management options
Section E	Manufacture and imports of lead-containing jewellery

Section A: Contact details

Name: Organisation Name: Address: Country: Telephone number: Fax number: E-mail:

Section B: Children contamination to lead and compounds

Question 1.
Are there some campaigns to measure blood lead levels in your country? ☐**Yes** ☐**No** **If yes, please specify below what is the frequency of these campaigns and when did the most recent one take place?**

Question 2.					
When performing these campaigns, did you collect information on the possible causes of contamination when children (< 15 years old) blood lead level exceeded 100µg/L? ☐**Yes. Please fill in the following table** ☐**No**					
-	**Number of cases**	**Year**	**Child's age**	**Contaminating Substance (if identified)**	**Observed effects (and associated blood lead level if possible)**
Usual sources of contamination					
Wall painting	*1*	*2002*	*3*	*Lead chromate*	*lead concentration in blood > 100 µg/L*
Water					
Polluted soil					
Other					
Unusual sources of contamination					
Accidental ingestion or licking	*2 (jewels)*	*2005*	*3* *5*	*Metal Lead (pendant)* *Metal Lead (clasp)*	*death* *lead concentration in*

of articles (please, indicate the type of article)					*blood > 100 µg/L*
Glazed pottery or ceramic dishes					
Cosmetics					
Parents' occupation (if known, please specify)					
Parents' spare-time (if known, please specify)					
Heating with painted wood					
Food					
Folk remedies					
Other					

Section C: National measures concerning lead-containing jewellery

Question 3.		
Is there currently a national legislation which bans, restricts or controls the production, import, use and/or marketing of jewels containing lead and/or its compounds? ☐**Yes. Please provide the relevant information below** ☐**No**		
Articles/Substances regulated	**Limit concentration of the substance (if relevant)**	**Legal reference**
Lead salts in imitation pearls	*Total lead concentration must be below 90 mg/kg in the product*	*Law n°…*

Question 4.	
Are there currently non-regulatory actions aiming at banning, restricting or controlling the production, import, use and/or marketing of jewels containing lead and its compounds? ☐**Yes. Please provide the relevant information below** ☐**No**	
Articles/Substances considered	**Type of non-regulatory actions and actors involved (year)**
Metal lead in imitation pearls	*Voluntary agreement between metal lead importers (2001) to restrict the concentration of metal lead in imitation pearls below 50 mg/kg*

Question 5.
Is there a national standard in order to control the content and/or the migration rate of lead (and its compounds) in jewellery? ☐**Yes. Please provide details below** ☐**No**
Norm EN 71-3 which limits the bioavailability of lead from use of toys: migration tests are performed on the toy materials and on parts of the toys

Question 6.	
Regarding jewellery, is testing routinely conducted in order to assess composition and/or the migration potential of lead (and/or its compounds)? ☐**Yes. Please provide details below** ☐**No**	
Jewels/part of jewels tested	**Type of testing**
Necklace composed of one chain and two pendants	*Migration test done according norm NF EN 71-3 applied on:* *- the whole jewel;* *- each pendant separately.*

Question 7.
Are there substitution measures currently under development (or already implemented) to replace lead and/or its compounds in jewellery? ☐**Yes. Please provide details below** ☐**No**

Section D: Potential risk management options

Question 8.		
Several possible management options for controlling the risks resulting from exposure to lead and its compounds in jewels are proposed below. Please indicate for each of them whether, in principle, you would support them and whether you envisage problems arising from their implementation (practicability, enforceability, etc.).		
Potential risk management options	**Would you support this option? (Y/N)**	**Problem(s) you envisage arising from the implementation of this option**
Ban on the use of lead and its compounds into jewels		
Ban on the use of lead and its compounds into *some* jewels (those for which accidental ingestion is most likely to happen)		
	If yes, for what type of jewels (pendant, etc.)?	
Limitation of the content of lead and its compounds into jewels		
Limitation of migration rate of lead and its compounds contained into jewels		
Please indicate below if you have other proposals of risk management options:		

Section E: Manufacture and imports of lead-containing jewellery

Question 9.
Where known to you, could you kindly provide the following information:

The number (or approximate number) of manufacturers of lead-containing jewels (or parts[48] of jewels) in your country	
The number (or approximate number) of importers of lead-containing jewels (or parts of jewels) in your country	
The amount (or approximate amount) of jewels containing lead and/or its compounds which are manufactured yearly in your country	(please precise the unit)
The amount (or approximate amount) of jewels containing lead and/or its compounds which are imported yearly in your country	(please precise the unit)
The amount (or approximate amount) of jewels containing lead and/or its compounds which are consumed yearly in your country	(please precise the unit)
The proportion (%) of jewellery sold in your country that may contain lead and/or its compounds? Please also indicate the basis of this percentage (guess, estimate or market data).	

Question 10.
Where known to you, could you kindly provide the names of manufacturers and importers of lead-containing jewellery in your country (including any relevant industry associations):

***

Please also indicate below other relevant national bodies (and their contact information) which could assist us in this study:

Feel free to add any comments on issues raised by this questionnaire in the space below:

We thank you very much for participating to this study

Please return your completed questionnaire by September 14th 2009 to:
Afsset / 253, av. Général Leclerc / 94701 Maisons-Alfort Cedex / France / Email: karine.fiore@afsset.fr

If you need additional time to complete the questionnaire, please let us know as soon as possible.

[48] With " parts " of jewels, we mean pendants, pearls, clasps, etc.

Annex B. Questionnaire sent to industry actors for the EU jewellery market survey

QUESTIONNAIRE
Fashion jewellery sector in Europe – Lead and compounds

The questionnaire is structured as follows:

Part 1	Information about your activities related to fashion jewels	
	Part 1.1	Structure and organisation of your activities
	Part 1.2	Socio-economic information
Part 2	Information about your products and health risks related to lead and its compounds	
Part 3	Potential management options of health risks	
Part 4	Information about alternatives to lead and its compounds	

Should you have any question, please feel free to contact: Aurélien Gouzy, INERIS, Aurelien.GOUZY@ineris.fr.

DEADLINE: 15 days after reception

Firm's Identity

Firm's name: Address: Country: NACE Code: Union, trade association, federation, technical centre, (other) to which the firm is a member: **Contact person:** Name: Position: Telephone number: E-mail address: Position of the person who filled in the questionnaire (if different from the contact person):

Please fill in the following table for the different types of activities that correspond to your company:

Type of activity	Y/N	Percentage of this activity in your whole activity (%)
Manufacturer of the whole or part of fashion jewels		
Producer/extractor of lead or one of its compounds intended to be used into fashion jewellery		
Producer/extractor of other substances intended to be used into fashion jewellery – Please precise what kind of jewels:		
Importer of the whole or part of fashion jewels		
Importer of lead or one of its compounds intended to be used into fashion jewellery		
Importer of other substances intended to be used into fashion jewellery – Please precise what kind of jewels:		

Distributor of fashion jewels		
Other – Please precise:		

If you are a manufacturer/producer/importer/distributor of the whole or part of fashion jewels, please specify if your products contain lead or one of its compounds?
☐ Yes ☐ No ☐ Do not know

- If you answered "yes" to the previous question, please fill in ALL parts of the questionnaire.
- If you answered "no" to the previous question, the reason is that…
  - you substituted at least one of these substances: please fill in parts 1 AND 4.
  - you never used any of these substances and you are not interested in using them: please fill in ONLY part 1.
- If you do not know, please fill in ONLY part 1.

Part 1. Information about your activities related to fashion jewels

1.1. Structure and organisation of your activity

Question 1. Are your activities specialised exclusively in (whole or parts of) " fashion jewels "?
Yes ☐ No ☐
In case of diversification, please indicate:

Type of activity	Category of products/materials/substances	Proportion of each category in the activity (%)
Manufacture/Production	*Example:* *1. fashion jewels* *2. hairstyle articles* *3. clothes*	*Example:* *1. 10%* *2. 10%* *3. 80%*
Importation		
Distribution		

Question 2. Please specify the type of fashion jewels (or parts of fashion jewels) that you import/ manufacture/distribute:

Type of activity	Type of fashion jewels (or part of fashion jewels)	Proportion of this type of jewel/part of jewel in the whole jewels/parts of jewels imported/manufactured/distributed (%)
Manufacture/Production	*Example:* *1. bracelet* *2. necklace catch*	*Example:* *1. 80%* *2. 20%*
Importation		
Distribution		

Question 3. Please specify the country of origin of your suppliers, their activity and the origin and the type of fashion jewels (or part of jewels) they provide you with:

Type of activity of your suppliers	Country of origin of your suppliers	Origin of the fashion jewels (or part of fashion jewels) provided	Type of fashion jewels (or part of fashion jewels) provided
Example: importer	*France*	*China*	*Bracelets*

Question 4. Please specify the country of origin and the type of activity of your customers (inside and outside the EU)?

Type of customers (manufacturers, distributors, etc.)	Country of origin of your customers	If your customers are distributors, please precise (Wholesale distribution, retail trade, etc.)

1.2. Socio-economic information

Question 5. According to your estimation, how much of your total employment volume directly or indirectly depends on activities related to fashion jewels (in number of persons)?

Total employment volume	Employment volume directly dependent on fashion jewels	Employment volume indirectly dependent on fashion jewels

Question 6. Please provide an estimate of the annual average sales revenue and the annual average volume of sales for the activities related to fashion jewels (over the past five years) ?

Annual average sales revenue (€) for the activities related to fashion jewels	Annual average volume of sales (number of articles sold) for the activities related to fashion jewels

Question 7. What is the annual average quantity of fashion jewels (or parts of fashion jewels) that you manufacture/import/distribute (over the past five years)?

Type of activity	Average quantity of fashion jewels (or parts of fashion jewels) (please precise the unit)	Proportion of fashion jewels/parts of jewels containing lead and/or its compounds (%)
Manufacture/Production Importation	*Ex : bracelet*	*0%*
	Ex : catch	*60%*
Manufacture/Production		
Importation		

Question 8. If you are an importer, what are the annual average importation costs of your activities related to fashion jewels/parts of jewels (over the past five years)?

Type of cost	Annual average cost
Purchase of jewels/parts of jewels - *please precise the type (bracelets, etc.)* - -	(€) - - -
Purchase of raw materials - *please precise (iron, lead, etc.)* -	(€/kg) - -
Transport	
Specific custom duty	
Other	

Question 9. If you are a manufacturer of fashion jewels/parts of jewels, what are the annual average manufacturing costs of this activity (over the past five years)?

Type of cost	Annual average cost
Purchase of raw materials - *please precise (iron, lead, etc.)* - -	(€/kg) - -
Purchase of manufactured parts of fashion jewels - *please precise the type (catchs, etc.)* - -	(€) - -
Transport	
Treatment/transformation - *please precise* - -	(€) - -
Consumers Information - *safety data sheets* -	(€) -
Other	

Question 10. If you are a manufacturer of fashion jewels/parts of jewels, please provide an estimate of the average cost of a fashion jewel/part of jewel (as an end-product)?

Type of fashion jewels (or part of jewels)	Average cost (€)
Ex : catch	*0.50*
Ex : Necklace	*8*

Question 11. If you are a distributor, what are the annual average distribution costs of your activities related to fashion jewels (over the past five years)?

Type of cost	Average annual cost (en €)
Purchase of the jewel(s) (end products) - *please precise the type (bracelets, etc.)* - -	 - -
Transport	
Information to consumers - *safety data sheets* -	 -
Other	

Question 12. If you are a distributor of fashion jewels, please provide an estimate of the average sale price of fashion jewels according to their type?

Type of fashion jewels	Average sale price (in €)

Part 2. Information about your products and health risks related to lead

Question 13. For each type of fashion jewel/part of jewel containing lead and/or its compounds that you import/manufacture/distribute, please indicate the content of these substances in the jewel/part of jewel.

Type of fashion jewels/part of jewels	Substance(s) contained (lead and its compounds) (CAS number)	Lead content in mg/kg. Please precise the measurement method.	Is the content homogeneous in the jewel? If not, in which part of the jewel is the substance?
Ex : Necklace composed of one chain and two pendants	*-lead metal (7439-92-1) -lead Acetate (301-04-2)*	*- total lead: 23 mg/kg of jewel (measure done on the whole jewel by Spectrometry ICP-AES) - lead acetate: 54 mg/kg (concentration used in the formulation of the pendants coating)*	*NO Lead metal is contained in the necklace chain Lead acetate is contained in the pendants coating.*

Question 14. For each fashion jewel/part of jewel mentioned in the previous question, please indicate whether a migration test was performed.

Type of fashion jewels/parts of jewels	Substance(s) contained (CAS number)	Has a migration test been done? If so, please specify the experimental conditions and (where applicable) the norm that was followed.
Ex : Necklace composed of one chain and two pendants	*-lead metal (7439-92-1) -lead Acetate (301-04-2)*	*Migration test done according norm NF EN 71-3 applied on: - the whole jewel; - every pendant separately.*

Question 15. Do you have any information about incidents/accidents resulting from the ingestion of lead and/or its compounds due to a misuse of a fashion jewel (e.g. ingestion of a lead-containing pendant by a child)?

Year of the accident	Approximate age of the person	Description of the incident and observed effects

Question 16. Did you read the report published by Danish EPA[49] about the potential risks related to chemicals in fashion jewels?

☐ Yes, please indicate the comments you may have:
☐ No

Part 3. Potential risk management options of health risks

Question 17. Several possible management options for controlling the risks resulting from exposure to lead and its compounds in fashion jewels are proposed below. Please indicate for each of them

[49] Danish EPA (2008): Survey and health assessment of chemical substances in jewelleries: Survey of Chemical Substances in Consumer Products No. 94, Prepared by Strandesen M & Poulsen PB, report by FORCE Technology for the Danish Ministry of the Environment - Environmental Protection Agency, Denmark.

whether, in principle, you would support them and whether you envisage problems arising from their implementation (practicability, enforceability, etc.).

Risk management options	Would you support this option? (Y/N)	Problem(s) you envisage arising from the implementation of this option
Ban on the use of lead and its compounds in *all* fashion jewels		
Ban on the use of lead and its compounds in *some* fashion jewels (those for which accidental ingestion is most likely to happen)		
	If yes, for what type of jewels (pendant, etc.)?	
Limitation of the content of lead and its compounds in fashion jewels		
Limitation of the migration rate of lead contained in fashion jewels		
Please indicate below if you have other proposals of risk management options:		

Part 4. Information about alternatives to lead and its compounds

Question 18. Did you implement a substitution of lead and/or its compounds for an application in fashion jewels?

☐ Yes, please fill in the table below.
☐ No, please go directly to question 23.

Type of fashion jewels/parts of jewels	Substance(s) (CAS number) you used before (lead and/or its compounds)	Substance(s) (CAS number)/process(s) used now for substitution	Information about the substitution : implementation delay, year of implementation, collaboration with external institution/firm, etc.

Question 19. Has an evaluation of the substitution(s) mentioned in the previous table (in terms of efficiency, risks, etc.) been carried out?

☐ Yes. In this case, please provide details on:

- the advantages of the alternative in terms of:

Health	Safety	Environment	Efficiency	Costs	Other

- the shortcomings of the alternative in terms of:

Health	Safety	Environment	Efficiency	Costs	Other

☐ No.

Question 20. If the substitution has a significant impact in terms of costs and/or efficiency, please provide details:

Type of cost and other impacted efficiency indicators	Magnitude of the impact (gain or loss in %)
Ex : supply cost of the new substance *Delay of transformation in end-product*	*-15%* *+20%*

Question 21. Were other solutions different from the ones mentioned in question 19 considered?
☐ Yes. Please indicate the reasons why they were not developed:
☐ No.

Question 22. Are you currently developing other possible substitutions?
☐ Yes. Please indicate these solutions:
☐ No

Question 23. If you did not implement substitution, what are the reasons?
☐ You do not think that your product may cause health risks and therefore you do not think that there is a need for substitution.
☐ For technical reasons, no substitution method can replace lead or one of its compounds in the product. Please feel free to add comments:
☐ For economic reasons, no substitution method can replace lead or one of its compounds in the product. Please feel free to add comments:
☐ Other, Please precise:

Please indicate in the space below any information you would think relevant about lead and its compounds in fashion jewels and/or comments you would like to add on issues mentioned or not mentioned in this questionnaire.

Would you accept to be contacted by Afsset to provide additional useful information to complete this survey on lead and its compounds in fashion jewels?
☐ Yes ☐ No

Annex C - 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 jewel 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 D - 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.

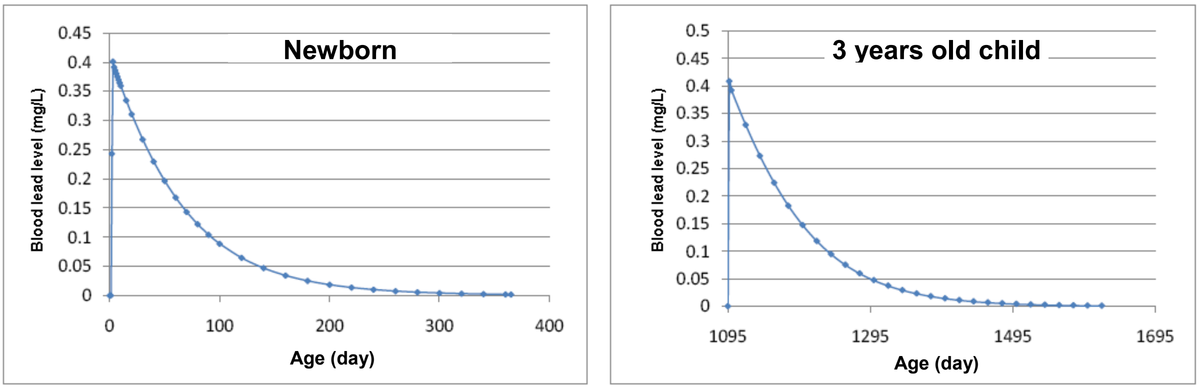
Intake resulting in a PbB of 400 µg/L after 2 days of exposure

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