Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on

Lead and its compounds in articles intended for consumer use

ECHA/RAC/[Opinion No (same as opinion number)]

ECHA/SEAC/[Opinion No (same as opinion number)]

	EC NUMBER	CAS NUMBER
Lead and its compounds in articles intended for consumer use	231-100-4	7439-92-1

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Revision [4]

[08.11.2013]

Change history

Revision n.	Reason for change	Date	Prepared by
1	Background Document	26.6.2013	Dossier Submitter
2	Changes in the wording of the proposal / lists of include / excluded from the scope articles (Sections A.1.2, B.2, E5)	16.08.2013	ECHA-S
3	Changes to reflect the content of the 3rd versions of the draft opinions.	30.09.2013	Restriction team
4	Changes to reflect the content of the 4th versions of the draft opinions.	08.11.2013	Restriction team
5	Changes to reflect the content of the final versions of the RAC opinion as well as the SEAC draft opinion	17.12.2013	Restriction team

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List of acronyms

ALAD	Delta-aminolevulinic acid dehydratase (enzyme)
ATSDR	The Agency for Toxic Substances and Disease Registry
BMDL	Bench Mark Dose Level
bw	Body weight
CA	Competent Authority
CAS number	CAS registry numbers are unique numerical identifiers for chemical elements, compounds, mixtures etc.
CDC	Centers for Disease Control and Prevention
C.I.	Colour Index
CI	Confidence Interval
CLP	Classification, Labelling & Packaging
CMR	Carcinogen/Mutagen/Reproductive toxicant
CoRAP	Community Rolling Action Plan
CPSC	U.S. Consumer Product Safety Commission
CSR	Chemical Safety Report
DKK	Denmark kroner
DMEL	Derived Minimal Effect Level
DMELc	Chronic Derived Minimal Effect Level
DNEL	Derived No Effect Level
DNELa	Acute Derived No Effect Level
DRI	Dietary Reference Intakes
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
GI	Gastro-intestinal
GPSD	General Product Safety Directive
IARC	International Agency for Research on Cancer
IQ	Intelligence quotient
IUCLID	International Uniform Chemical Information Database (software application)
IUPAC	The International Union of Pure and Applied Chemistry
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
KEMI	Swedish Chemicals Agency
kPa	kiloPascal (unit of pressure)
LC_{50}	Lethal Concentration 50%
LD_{50}	Lethal Dose 50%
LME	London Metal Exchange
LOAEL	Lowest Observed Adverse Effect Level
MS	Member State
MSCA	Member State Competent Authority
N/A	Not Applicable
NGO	Non-Governmental Organization
NIOSH	US National Institute of Occupational Safety and Health
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
OJ	Official Journal of the European Union
Pa	Pascal (unit of pressure)
PbB	Blood lead
PBT	persistent bio accumulative toxic chemical

ppm	parts per million
PVC	Poly Vinyl Chloride polymer
RAC	Risk Assessment Committee
RAPEX	Rapid Exchange of Information System
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RFI	Request for Information
RMO	Risk Management Option
RoHS	Restriction of Hazardous Substances Directive
ROI	Registry of Intention
SCHER	Scientific Committee on Health and Environmental Risks
SEAC	SoSocio-Economic Analysis Committee
SME	Small and Medium-sized Enterprise
STOT	Specific Target Organ Toxicity
SVHC	Substance of Very High Concern
TDI	Tolerable Daily Intake
US EPA	United States Environmental Protection Agency
WHO	World Health Organization
vPvB	Very Persistent and Very Bioaccumulable
VRAR	Voluntary Risk Assessment Report
µg/dL	micrograms per decilitre (concentration)

PROPOSAL FOR A RESTRICTION

About this report

The objective of this report has been to develop a proposal for the restriction under REACH Annex XVII of lead and its compounds in articles, which can be placed in the mouth by children, and which are made available for consumers or intended for consumer use. The report comprises the justifications – in terms of risk assessment, practical workability and socioeconomic impact – for such a restriction.

Lead has been deemed a non-threshold toxic substance for neurotoxic and neurodevelopmental effects, in particular in children. This means that it is not possible to establish a “safe” level of lead in the blood of children. Consequently, their exposure to lead should be avoided as far as possible. Since the 1970’s, lead and lead compounds have been subject to several regulations limiting their use in many different products, the most important measure being the phase-out of leaded petrol. With the decreasing use of leaded petrol, and the subsequent additional restrictions, the general human exposure to lead in urban environments has fallen sharply. Because lead is still available in several types of articles, the reduction of lead in our environment has come to a halt before reaching sufficiently low levels. Children’s exposure to lead is still above the highest tolerable level. All additional exposure to lead, from food or non-food sources, should therefore be avoided as far as possible. There is hence a need for further regulation.

Lead and its compounds have a wide use and have been found in a great variety of applications, some of them being articles intended for consumer use. Lead is usually present in metal alloys, in pigments/dyes, and to a lesser extent as stabilisers in plastic and as pure metal. It cannot be determined through a simple analysis which lead compound is present in a specific material. Neither can it be simply established whether lead is present as pigment or as stabiliser in a plastic. Therefore, all lead compounds should be targeted by any further action proposed.

The main route through which children are exposed to lead from these articles seems to be the mouthing (sucking and chewing) behaviour exhibited by small children. Of the consumer available articles that are frequently placed in the mouth by children, and that are not covered by other regulations, around 10% can be estimated to contain lead. The average lead concentration in these articles is around 1%. When children exhibit their normal mouthing behaviour, this lead may cause risk of impaired development of their central nervous system.

The health risk to children who suck or chew lead containing articles has recently been subject to a restriction under REACH, namely that of lead in jewellery (entry 63 of Annex XVII). In the restriction dossier, the submitter (the French CA) noted that the risks described could be mutually valid also for other objects than jewellery. No further assessment was however made of non-jewellery articles, and the resulting restriction only covers jewellery. In this report, it will be shown that the same health risks are indeed mutually applicable also to a wider range of articles, and that they therefore too should be restricted.

In this report, children’s exposure to lead through placing lead containing articles in their mouth, and the resulting risk of IQ deficits, is assessed. Using the same estimates that formed the basis for the restriction of lead in jewellery, a total exposure of 473,900,000 µg/year is calculated, corresponding to a total IQ loss of 76,781 units. This justifies Union-wide action.

The action proposed in this report is a restriction in which articles intended and available for consumer use, which can be placed in the mouth by children, may be placed on the market only if they do not contain lead above a limit value of 0.05% by weight. The limit value, which is supported by the tolerable lead content calculated in this report, should also apply to individual parts of the articles in question. Such a restriction is aligned with the similar restriction of lead and its compounds in jewellery items, which enables a harmonised regulation on lead in the whole range of consumer articles.

A. Proposal

A.1 Proposed restriction

A.1.1 The identity of the substance(s)

The substances concerned herein are all lead compounds used in articles intended for consumer use which might liberate the lead ion. Instead of giving an exhaustive list of all lead compounds, only elemental lead is selected and presented as prototype for all other lead compounds. When using the term 'lead', it includes also all possible lead compounds which contribute to the overall content of lead in articles.

Table 1: Identity of the substance

Name (IUPAC)	CAS No.	EC No.	Formula	Purity and impurities
Lead	7439-92-1	231-100-4	Pb	The restriction shall apply to lead and its organic and inorganic compounds, regardless their concentration in substances.

Reference number for submission to the Registry of Intention: 7416b1ad-8072-4927-b4d0-b72334ec076f

A.1.2 Scope and conditions of restriction(s)

The proposed restriction concerns placing on the market and the use of lead compounds in articles available or intended for use by consumers. The aim of the proposed restriction is to minimise children's lead exposure and body burden from mouthing articles containing lead. It has been stressed in several reports that it is very important to minimise the overall lead exposure of children, because of their vulnerable brain development. Children who place articles containing lead in their mouth are at risk of impaired neurological development. With this restriction, the lead content in articles and hence the potential exposure is controlled.

The proposed restriction is worded as below:

In Annex XVII to Regulation (EC) No 1907/2006, the following entry XX is added:	
‘ XX. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1.Shall not be placed on the market in articles, or accessible parts of articles, which are supplied to the general public and which can be placed in the mouth by children, if the concentration of lead (expressed as metal) in that article, or part of article, is equal to or greater than 0.05% by weight. 2. For the purposes of paragraph 1, an article or part of an article can be placed in the mouth by children if it is smaller than 5 cm in one dimension or has detachable or protruding parts of that size. 3. Paragraph 1 does not apply if an article, or a part of an article, is not accessible by children during normal or reasonably foreseeable conditions of use. European Standard EN71-1, as adopted by the European Committee for Standardisation (CEN), shall be used, where appropriate, as the method to determine “accessible parts” of articles by children. 4. By way of derogation, paragraph 1 shall not apply to: (i) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC[1] (ii) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/87[2]), unless they have been treated with lead or its compound or mixtures containing these substances; (iii) enamels, defined as having vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500°C;

1 Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass OJ L 326 29.12.1969, p 36.

2 Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff. OJ L 256, 7.9.1987, p 1–675.

	(iv) keys and locks, including padlocks, and musical instruments; (v) articles comprising brass alloys if the concentration of lead in the brass alloy does not exceed 0.5% by weight of lead (expressed as metal); (vi) the tip of writing instruments; (see Annex III) (vii) articles covered by European Union legislation specifically regulating lead content or migration. 5. By way of derogation paragraph 1 shall not apply to used articles placed on the market for the first time before ….(12 months after entry into force)
(*) [insert OJ reference]'	

The proposed restriction is to be applied 12 months after the amendment of the REACH Annex XVII comes into force.

A.2 Targeting

Lead is harmful both to human health and to the environment. The specific effect of lead that is focused in this dossier is its neurotoxic effects, especially the impairment of the development of children's central nervous systems. No threshold has been scientifically established for this effect; contrarily, lead causes IQ deficits in children at levels lower than 10 µg/dL. No safe blood lead level has yet been established; hence, lead should be regarded as a non-threshold toxic substance. The highest tolerable exposure level has been determined to 1.2 µg/L (0.12 µg/dL, corresponding to a DMEL of 0.050 µg/kg bw/day). The current blood lead levels are 15–20 µg/L in Western Europe, and 30–40 µg/L have been measured in Central and Eastern Europe. Since these levels are higher than the highest tolerable exposure level, all additional exposure must be avoided.

Children are targeted as a sub-group of the population due to their particular sensitivity to the toxic effects of lead during brain development. The targeting is based on toxicity data and the exposure assessment carried out for this proposal. It relates to the potential exposure, not to whether the articles were intended for children or not. The primary group at risk are children between 6 and 36 months of age; not only are they especially sensitive to the effects of lead, but they also are most exposed to lead in articles due to their mouthing behaviour. Small children, as a result from their normal development, frequently place any kind of object in their mouth to suck and chew on them. These objects can be regulated objects such as kitchen utensils and toys (where lead is already restricted), but also non-regulated articles like clothes, accessories, interior decoration objects, sports and leisure equipment, keys and key rings, stationery, etc. Studies have shown that children spend in average 15-20 minutes a day sucking and chewing on objects, of which 32% are articles where lead can be present but is not regulated.

Lead is restricted in several product groups, including paints (residential and others), electric equipment, toys, food contact materials, packaging and more recently jewellery. Lead and lead compounds, also as carbonates and sulphates in paints, are however still used in the manufacturing of articles outside the EU and imported into EU contained in metal parts, pigments, painted surfaces and to some extent also stabilisers in polymers. These are the uses that will be targeted in this report.

Accidental ingestion of lead-containing articles, as well as inhalation of lead fumes or released lead particles, present a more hazardous type of exposure than does the exposure targeted here. However, exposure through mouthing can be used as a proxy for all other exposure routes that are likely to cause harm, i.e. managing the risk associated with mouthing will simultaneously manage also the other routes of exposure. Likewise, managing the risk for small children will simultaneously manage also the risk for the general public, as children are the most sensitive group. For this reason, the exposure of children to lead from articles through mouthing seems an adequate target for a restriction proposal.

A.3 Summary of the justification

A.3.1 Identified hazard and risk

Chronic exposure to lead can result in severe and irreversible neurobehavioral and neurodevelopmental effects. No threshold has been established for children's reduction in IQ scoring for lead exposure; consequently, any additional exposure to lead should be avoided. Currently, the "background exposure" to lead from food and non-food sources, giving blood lead levels between 15 and 40 µg/L in European children, exceeds the highest tolerable exposure (1.2 µg/L, corresponding to a DMEL of 0.050 µg/kg bw). Thus, any additional exposure should be avoided. Although human exposure to lead has decreased considerably since the 1970's, lead still poses an unacceptable risk. Not only are children especially exposed to lead in articles due to their behaviour – children frequently put things in their mouth and/or suck on them – but they are also particularly vulnerable to the harmful effects of lead and its effect on brain development. This risk is reinforced by the increased availability of lead, including the potential recycling of leaded waste materials into consumer products, and the general increase in consumption trends, which further justify preventive measures in order to restrict known risks.

Lead is present in many articles intended for and available to consumer use. Some of these articles can be placed in the mouth by children, which may cause exposure to lead and potentially impact the child's brain development. Primarily being present in metal alloys and pigments/dyes for plastics, lead has been found in various common articles such as clothes, accessories and shoes, furniture and interior decoration objects, keys and key rings, stationery, and others. This lead may originate from several different lead compounds including elemental lead.

Studies have shown that children spend 15-20 minutes a day sucking and chewing on objects other than food, toys and childcare articles. The articles in scope of the proposed restriction comprise 32% of the total mouthing activity. 10% of these articles are estimated to contain lead, and the average lead content in these articles is 1%. The migration rate of lead from articles under mouthing condition is determined to 0.7 $\mu g/h/cm^2$/(% lead in product), which is the same estimate as established by RAC in course of the lead in jewellery restriction dossier. Using these figures, a total exposure (for all children) of 367000000 µg lead/year has been calculated. This is 7 times higher than the total exposure for lead in jewellery, calculated with data used in their dossier. The total IQ loss resulting from that exposure is 32000 units.

From the risk exposure assessment it is clear that there is a health risk concern which justifies regulatory action. It is thus proposed that a lead threshold value of 0.05% in consumer articles (that can be mouthed by small children) is appropriate. This is supported by the tolerable lead content in consumer articles calculated in this report.

A.3.2 Justification that action is required on a Union-wide basis

Existing legal requirements on lead in articles are sector specific and only target some article categories such as toys, packaging and electric equipment. Still, 32% of the objects frequently mouthed by children remain unregulated with respect to lead. There is accordingly a remaining risk of IQ deficits resulting from the lead exposure of European children aged 6–36 months from mouthing of these articles This is a concern which justifies regulatory action.

The placing on the market of articles containing lead is a global phenomenon which cannot be isolated to any specific country. Children's mouthing behaviour cannot either be geographically isolated, nor can their particular sensitivity to lead. Thus, the risk of lead exposure is not limited to any specific Member State, but affects any consumer and any child within the EU equally. Regulating the risk at Union level is likely to offer the strongest protection all over the EU. Moreover, in the absence of EU regulations it is probable that some Member States will take national measures, which may create a plethora of incoherent, heterogeneous regulations which are less coercive and more difficult to manage. National regulations are more sensitive to influencing activities from strong local interests, which might dilute the restriction and put the protection level at stake. Moreover, national regulations will likely introduce market distortions and thereby create non-harmonisation.

A Union-wide restriction of lead in articles will create a level playground for trade. It will not discriminate between articles produced in the EU and articles imported from third countries, and it will not hinder commercial relations on the internal market. It will create a harmonised, manageable regulatory situation which can reduce the administrative burden and the costs of compliance, and it will prevent the market distortions following from national regulations while still targeting the health concerns. Thus, a Union-wide restriction is found justified.

A.3.3 Justification that the proposed restriction is the most appropriate Union-wide measure

The scope of this restriction is articles that can be placed in the mouth by children and that are made available for consumer use. Of the articles available on the market, the vast majority (77%) are imported to the Union from third countries. The other options under REACH – classification and subsequent identification as SVHC, and the authorisation procedure – can only be applied to articles produced in the EU. A restriction under REACH is the only regulatory option that can be applied to articles imported from third countries. Non-REACH regulations do not seem appropriate for a long-term management of a chronic exposure. As regards other risk management measures than regulation, such as information campaigns, economic policy instruments and voluntary measures from industry, these have for various reasons – mainly the diversity of the articles concerned and the often unintentional occurrence of lead in them – been found insufficient to manage the risk.

Four restriction options have been assessed with respect to their effectiveness in reducing the risk, their proportionality to the risk, their practicality and their monitorability. These restriction options differ from each other as regards the scope, and whether content or migration is restricted. Overall, the scope “can be placed in the mouth by children” has been found sufficiently practical, while any larger scope is impractical. Limiting the scope to a subset of that scope (“clothes, accessories and shoes”) gives a clear, unambiguous and therefore practical alternative. However, this alternative has a low risk reduction capacity and also inferior cost effectiveness. For an adequate risk reduction, it is necessary to involve all articles that contribute to the risk. Again, the scope “can be placed in the mouth by children” has been found effective in reducing exposure and proportional to the risk in terms of costs. Finally, a restriction based on content is more easily enforceable (and hence monitorable) than a restriction based on migration.

The proposed restriction exempts keys, as there seem to be no technically feasible alternatives to lead in keys with respect to the workability of the metal alloy. There is reason to believe that substitutes will be available in the future, and the exemption is therefore subject to a review clause.

Under the proposed restriction the total remaining exposure is calculated to 85,900,000 µg/year, mostly from keys. Compared to the initial exposure, this is a reduction by 82%. The compliance costs are estimated at €34 million, which is deemed economically feasible. Moreover, the proposed restriction is well aligned with existing restrictions, in particular the restriction of lead and its compounds in jewellery in entry 63 of Annex XVII to REACH.

Due to the lack of information on actual exposures in the population, suitable for use in benefits assessment, SEAC proposes to follow the ‘break even’ approach used in the assessment of the Lead in Jewellery restriction in order to consider the proportionality of the restriction. Based on, albeit highly uncertain, estimates of actual mouthing times for articles containing lead for a sample of children in the UK, it would appear that actual mouthing durations may exceed those that would be required to achieve the ‘break even’ level of mouthing duration per year.

It should be noted other effects than solely loss of IQ points is likely impacts of lead exposure to children, e.g. impaired school performance, distractibility, short attention span, impulsivity, perseveration and increased activity. Although linked, these impacts are not all covered by life income impacts which are the basis for the actual analysis of proportionality. Furthermore, the assessment of benefits does not include other potential benefits of reducing lead exposure. These include non-cognitive functioning and other health and non-health related endpoints.

As about 90% of the market affected by the proposed restriction already has substituted lead with other substances or techniques a transitional period of 12 months has been considered reasonable for the remaining 10% of the market to adjust and adopt the requirements. Optional transitional periods of 6, 12 and 18 months have been assessed and lead to this conclusion. The practical activities that follow by an implementation of a new regulation are for example information activities from importers to suppliers outside the EU about the new regulation. A shorter transitional period could therefore imply implementations problems on the EU market. In the assessment it has not been evident with diverge transitional period for different applications. There are especially many advantages due to enforceability and practicality reasons with having a common transitional period. A transition period of 12 months would facilitate for the handling of existing stocks and give time for depletion.

B. Information on hazard and risk

B.1 Identity of the substance(s) and physical and chemical properties

This restriction proposal concerns lead and all its compounds used in articles intended for consumer use, which can be placed in the mouth by children and are not regulated by other EU legislation. The restriction proposal 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 ions during the use or misuse of articles containing them.

Moreover, it is not possible to identify a certain lead compound which has been specifically added to the material in an article. No such methods for analysing lead content have been identified.

This limited opportunity to collect information makes it difficult to propose a limited list of lead compounds used in articles for consumer use as this would possibly result in the non-identification of relevant lead compounds and consequently 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, analogous to the Annex XVII entry for lead in jewellery.

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

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

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

Table 2: Identification of lead

EC number	231-100-4
EC name	Lead
CAS number	7439-92-1
CAS name	Lead
IUPAC name	Lead
Annex I index number	N/A
Molecular formula	Pb
Molecular weight range	207.2 g/mol
Structural formula	Pb

B.1.2 Composition of the substance(s)

Substances containing lead or lead compounds are used for different reasons to produce articles. It may be that these compounds are main constituents, impurities or additives in substances. All substances containing lead or lead compounds contribute to the overall content of lead in the article. As it is technically not possible to identify individual lead constituents, this dossier focuses on lead as such which is present in consumer articles.

Examples of lead compounds are given in the Appendix 1. The list of compounds in the appendix cannot be seen as an exhaustive list of all relevant lead compounds used in the manufacturing of articles for consumer use available on the market in the European Union.

For the reasons previously presented, it is considered that the restriction dossier shall apply to lead and its compounds.

B.1.3 Physicochemical properties

Table 3: Overview of physicochemical properties of metallic lead

Property	Value	Reference
Physical state (20°C; 101,3 kPa)	Solid, silver-grey-bluish metal (powder or massive)	
Melting point	326ºC	Franke 2005b
Boiling point	1740 ºC	LDAI 2008
Density	11.45 g/cm3 at 23.8°C D4R: 11.45	Smeykal 2005b
Vapour pressure	133 Pa at 973 ºC	LDAI 2008
Surface tension	N/A	
Water solubility	185 mg/L [20 °C, at pH = 10.96]	Heintze 2005
Partition coefficient n-octanol/water	N/A	
Flash point	N/A	
Flammability	Non flammable	Smeykal 2005a
Explosive properties	Considered inert – elemental and metallic	
Self-ignition temperature	N/A	

Oxidising properties	N/A	
Granulometry	Mean particle size of representative lead metal powder sample (determined with laser diffraction): D50 = 12.7 µm. Mass median aerodynamic diameter of airborne fraction (determined with rotating drum method): MMAD = 33.7 µm.	Franke 2005a Selck 2003
Stability in organic solvents, identity of degradation products	N/A	
Dissociation constant	N/A	
Viscosity	N/A	
Auto-flammability	N/A	
Reactivity towards container material	N/A	
Thermal stability	N/A	

B.1.4 Justification for grouping

This restriction proposal targets the health effects of lead in children, effects that may result from an exposure to lead which can migrate from materials in articles for consumer use. For that purpose, the proposal globally concerns lead and all its compounds. This grouping is justified by the following facts:

The toxic species which causes the harmful effects is the lead ion itself.

The exact lead compounds present in articles for consumer use are unknown.

There are no methods available to analyse the specific lead compounds in the relevant articles but for lead which poses the concern.

In order to ensure maximum protection, the proposal covers lead and all lead compounds.

B.2 Manufacture and uses

The availability of lead in consumer goods in general is seldom reported as a source from which people are exposed, but still such exposure is a possible risk especially for small children. Lead is often found in different kinds of goods available to consumers for which the use of lead is not restricted today. This has been described e.g. in RAPEX reports listed annually by the Commission (see e.g. RAPEX 2012).

The articles addressed in this restriction proposal are articles intended for consumer use, which are likely to be mouthed by small children, and where those articles contain lead or lead compounds (not regulated by other EU legislation) in any individual material of the article. Examples on such articles are **clothes, shoes, accessories, interior decorations, articles for sports and leisure, stationery and keys**. In section B.9.3.1 the background to the importance to restrict lead in such articles is described. For that reason specific regard has been taken to the mentioned categories of articles in the data collection of market volumes, availability of lead and lead compounds for certain functions, market structure etc.

Examples[3] **of articles that may be**[4] **included** in the scope of the restriction proposal are:

- Clothes (including rainwear and accessories, such as belts) with buttons, zippers or other fasteners;
- Reflective vests, reflective badges, reflective bracelets;
- Key rings, key chains;
- Bags, all sizes;
- Wallets;
- Part of writing instruments (e.g. clips/tops);
- Artificial Christmas trees, Christmas decorations;
- Decorative magnets;
- Inflatable mattresses;
- Childcare articles including mouthable parts on baby carriages;
- Handles of bicycles and similar articles;
- Mouthable parts of furniture;
- Grips, grip coverings and other external parts of racquets; and
- Curtain weights if they are accessible to children i.e. not sown into the curtain or coated.

In addition, certain groups of articles may also be covered under the scope of the restriction:

- *Outdoor items:*

  Children may have an opportunity to mouth some articles that are primarily for outdoor use e.g. garden hoses since they are often lying on the ground after use including filling up pools for bathing. Other articles do not appear to have the same risk of being mouthed. So it is not possible to conclude that there is no risk in general for outdoor articles and since, as described above, any additional exposure to lead should be avoided.

[3] Note: this list is not intended to be exhaustive.

[4] Some of these items may not meet the requirement in paragraph 2 of the restriction proposal.

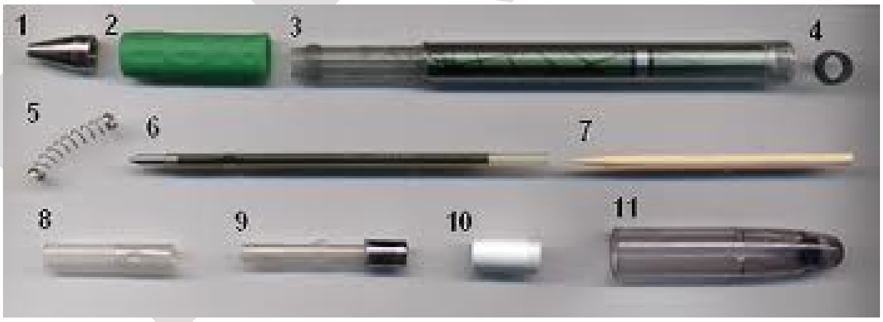
- *Coated articles:*

  In this case it needs to be specified what the 'coating' is comprised of; the potential risk depends on the effectiveness of the coating in preventing migration of lead. In this respect RAC refers to the proposed migration limit of 0.05 µg/cm2 per hr (0.05 µg/g per hr) as a suitable way of dealing with this issue. If the migration of lead from the coated article is below the migration limit value it would fall outside of the scope of the restriction. Any coating would have to be substantial enough to last for a reasonable length of time to be effective in preventing migration of lead if it was mouthed. It is therefore proposed to add a similar condition to that used in the restriction on nickel (entry 27(1)(c)).

Some items were specifically assessed during the opinion making process as being **inside the scope**:

- **Indoor adult shoes**. See also below under outdoor adult shoes.
- **Curtain weights**. Curtain weights as such are considered to be accessible, mouthable and within the range of a child so foreseeable misuse may occur. If the curtain weights are covered with a coating (see above) that prevents lead migration this fulfils the condition that if migration can be demonstrated to be below the limit then the curtain weights are exempted from the restriction.
- **Garden hoses**. These articles are considered to be mouthable and accessible. The question about foreseeable misuse is also answered positively, since there in some cases will be a garden hose lying on the ground (e.g. for filling bathing basins) and it therefore could be mouthed.
- **Writing instruments as such**. Except for the tip, the surface area for the rest of the writing instrument (such as the nose and clip) is much larger and these parts of the article are therefore considered to be within scope.

  The following diagram shows the relevant parts of the pen for clarification:

  (Key: number 1 (nose), number 6 (tip))

- **Spectacle frames**. As with curtain weights, accessibility to the part of the frames where migrating can occur is dependent on whether there is a suitable coating or not. If there is no such protection the spectacle frames will be within the scope since it is mouthable, accessible and foreseeable misuse can be foreseen.

Keys and padlocks In terms of articles, or part of articles that are considered out of scope of the proposed restriction, the following examples have been examined by RAC, in line with above:

Examples of articles that are excluded from the scope of the restriction proposal include (considering the restriction is intended to protect mainly 6 – 36 month old children):

- Articles covered by European Union legislation specifically regulating lead content (proposed column 2 (5)(vi)):
  - o Kitchen utensils, including child care articles, intended for food contact, including crystal glass for beverages

    Regulation (EU) No 1183/2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
  - o Electrical and electronic articles, such as bulbs, light sources etc, and relevant child care articles

    Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment
  - o Toys

    Directive 2009/48/EC on the safety of toys.
  - o Batteries

    Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC
  - o Food wrapping or containers

    Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food Restriction on lead in jewellery articles
  - o Lead in Jewellery

    Entry 63 of Annex XVII to REACH
  - o Packaging materials

    Directive 94/62/EC on packaging and packaging waste
- Articles not intended to be accessible[5] to children during normal or reasonably foreseeable conditions of use such as:
  - o Ammunition

    National legislation implementing Directive 91/477/EEC is assumed to contain a requirement to stored ammunition securely to prevent unauthorised access, including access by children. If ammunition casings are sold as jewellery they are covered by the existing entry in REACH.
  - o Fixed furnishings

    The mouthability of fixed furnishing by children is doubtful as it is assumed that the main part of fixed furniture is of a size that makes them too big for mouthing.

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[5] European Standard EN71 as adopted by the European Committee for Standardisation (CEN) shall be used as method to determine whether inaccessible parts of articles can or cannot be taken into the mouth.

- Fishing sinkers and weights

  It is assumed these are stored and used so as they are not accessible by children in normally foreseeable conditions of use for safety reasons, such as the proximity of fishing hooks to these articles.

- Diving weights

  Even though diving weights are accessible and possibly mouthable (smaller weights could have one side less than 5 cm in length), in most cases RAC considers normal or reasonably foreseeable conditions of use do not exist due to the danger the child would be exposed to in handling such very heavy articles, and therefore adults attention would prevent the contact with these articles.

- Coated articles or articles where the accessible parts are coated, e.g. spectacle frames. It is assumed that any such coating will prevent migration of lead in line with column 2 (iii).

- Outdoor equipment not covered elsewhere, e.g. garden hoses, camping equipment, fishing rods, garden swings and slides

  It is assumed these will not be accessible by children with mouthable parts or that exposures will be limited.

- Adult outdoor shoe soles.

  These parts are accessible and to some extent mouthable by a child, but 'foreseeable misuse' is not assumed to take place as adults wouldn't under normal or reasonably foreseeable conditions of use let a child play with a shoe due to hygienic reasons. For indoor shoes RAC concludes the opposite, these are available for the child to mouth.

- Tip of writing instruments.

  RAC considers the very tip of the ball pen (the part where the ink comes out) as so small (and also covered as interior part), that there is a very low potential for exposure.

- Internal hinge mechanisms.

  These are considered out of scope since they are not accessible according to the EN 71.

- Screws and nails.

  These articles are usually embedded in the articles they are used for. Individual loose nails and screws are considered to be kept out of children's reach due to their size (can easily be swallowed) and for other safety reasons, e.g. sharpness.

There are some kinds of articles that are not put either inside or outside of the scope as it has not been regarded relevant to do so, as the articles are not expected to contain lead. Examples on such articles are books, journals, office papers and pure textile articles made from cotton, wool, linen, polyester etc. There is no evidence that articles made from such materials contain lead in concentrations above a trace level under normal conditions (Göttsching 1996, KemI 2013). In case they should contain lead above the proposed limit, there is no reason to keep them outside the proposed restriction. Note that textiles covered by plastic materials, e.g. in raincoats are analysed for lead content, assessed and listed as articles included in the scope.

Published and unpublished test reports, as described in section B.9.3.1, as well as new testing made by the DS in course of this proposal, show that lead can be present in different materials to give the article a certain function, such as a given colour or mechanical properties during the manufacturing process. However there are also several article groups where the use of lead can be regarded as unintentional. The manufacturer/supplier has not been aware of the lead content in the material and there is no intended function of the lead or lead compound that is requested for the specific article.

The concentration of lead in the identified categories of consumer articles is normally in the range between hundreds of ppm to 40 000 ppm (4%), with an average above 10 000 ppm (1 %). Some articles like fishing sinkers and curtain weights contain more than 70% lead. More details are available in Section 9.3.1, where the origin of data is described in more details.

Clothes and accessories are examples on articles where lead can be found in a variety of materials in the articles. Metallic parts like buttons, buckles and zippers can be manufactured from alloys containing lead. Lead pigments are found to be used for colouring of the textiles or polymer material as well as paints on the surface of metal or polymer details. To some extent lead is still used for stabilising PVC polymers which can be used both for textile prints and in more rigid articles. The same apply to other articles intended for consumer use. Lead can be available both in alloys, pigments and as a stabiliser in different parts of sports, interior and stationery articles. Reports from testing of consumer articles confirm that lead occurs less frequently in articles where it is already restricted (Goldberg 2009).

As a result the availability of lead and lead compounds have been investigated and assessed based on the identified functions, namely:

- Metallic lead
- Additive or impurities in metal alloys
- Pigments
- Stabilisers in polymers

The most frequent of those uses have been identified as **additive/impurities in metal alloys** and **pigments**. Stabilisers were only identified as the probable source of lead in a minor share of the articles for consumer use. A more detailed description of the uses is available in section B.2.2. From a health point of view it does not matter if the lead is added deliberately or if it is present as an impurity in the consumer articles covered by this restriction proposal.

B.2.1 Manufacture, import and export of a substance

Metallic lead, however rare, does occur in nature. Usually, lead is found in ore with copper, zinc and silver, and is extracted together with these metals. The levels of lead in samples of soil, water and food today are affected by human activities, e.g. industries, former use of lead in petrol, air deposits etc. China is the dominant mine producer of lead in the world with nearly one-half of global lead mine production, followed by Australia, U.S.A., and Peru. In Europe, the countries with the largest production are Sweden and Ireland. (USGS 2012)

The global mine production of lead was 4.5 million tons in 2011 (USGS, 2012). The average mine production of lead in Europe (EU34) 2006-2010 was 273 000 tonnes per year (Brown 2012). This is around 6% of the total mine production of lead in the world.

Lead is recycled to a great extent. The world production of secondary (recycled) lead is approximately 40 % of the production of primary lead. The lion's share of this recycling originates from leaded batteries. (USGS 2012)

Further information regarding the extraction and manufacturing of lead in Europe and the rest of the world can be found in Appendix 5.

Import and export

Volumes of international trade with lead raw materials are presented in Table 4.

Table 4: Import, export and intra-EU trade of lead raw materials. Average values 2005-2010. (Eurostat)

	Lead ores and concentrates tonnes per year	**Lead waste and scrap tonnes per year**
Imports to EU27	245,000	264,000
Exports from EU27	124,000	399,000
Intra EU trade	298,000	157,000

Current trends

"The global lead market was in surplus during 2011 owing to the build-up of lead stocks held in London Metal Exchange (LME) and producer warehouses. Global mine production of lead was expected to increase by 9% in 2011 from that in 2010, to 4.52 million tons, mainly owing to production increases in China, India, and Mexico, while it declines in other regions. China was expected to account for nearly one-half of global lead mine production. Global lead consumption was expected to increase by about 6% in 2011 from that in 2010, to 10.1 million tons, partially owing to a 7% increase in Chinese lead consumption." (USGS 2012)

Average lead metal prices the last five years are presented in Table 5.

Table 5: Trends in lead prices (from USGS 2012; prices converted from US cents/pound to €/tonne)

Lead price, average, Euro per tonne	**2007**	**2008**	**2009**	**2010**	**2011**
North American Producer	1994.64	1804.88	1374.53	1811.63	1962.17
London Metal Exchange	1882.04	1425.86	1233.76	1618.83	1788.11

Lead substances manufactured and used in the EU can be found in the REACH registration acts, see Appendix 1. Some of the lead compounds are already included in the Candidate list, subject to authorisation (REACH Annex XIV) or restricted for some uses (REACH Annex XVII). Only compounds with a known use as pigment or stabiliser or elemental lead, for example in alloys, are expected to be used in consumer articles manufactured in the EU. There may also be other lead compounds used in the manufacturing of articles, when the manufacturing takes place outside the EU and the articles are imported. Thus the table in Appendix 1 cannot be seen as an exhaustive list of all relevant lead compounds used in articles for consumer use on the market in the European Union.

Statistical data on production, import and export of the specific lead compounds is not available at a substance level. Nor is the similar data for other possible lead compounds which may be used in imported articles only.

Recycled materials

Recycling of plastics

In 2011, the total production of plastics in EU-27 reached 58 million tonnes (Plastics Europe 2012). The same year, 47 million tonnes plastics were used by the converting and producing industry. Collected post-consumer waste reached 25.1 million tonnes, of which 10.3 million tonnes were disposed of and 14.9 million tonnes were recovered. Recovered plastics may be recycled, i.e. new products are produced from the plastic waste, or used for energy recovery. In the latter case, the plastics are removed from the consumer market. As of today, a greater part of the recovered plastics is used for energy recovery (ca. 9 million tonnes), compared to recycling (ca. 6 million tonnes). This implies that ca. 30% of used plastics were recovered, of which ca. 40% were recycled, in EU-27 in 2011.

Of the plastics produced in EU-27, three quarters of the plastics are used for packaging, building and construction, automotive uses and electronic and electrical goods. The articles covered in this proposal belong to the remaining quarter. This quarter includes products for various uses, such as consumer and household appliances, furniture, agriculture, sports, and health and safety.

In order to use recycled plastic materials in new products, the waste streams must be kept separate for different types of plastics as well as different colours (Österwall, 2013). This is most often not the case; collected plastic waste is constituted of different plastic materials of varying colours. The option for mixed material often involves ‘downcycling’ of plastics for cheaper and less demanding applications. These applications involve e.g. opaque films and bags for the distribution sector and building and construction material.

In conclusion, only a small part of the plastic produced and used in EU-27 is recycled, and most of the recycled material is ‘downcycled’ to cheaper materials. Only a fraction of the plastic materials produced are used for the consumer articles covered in this proposal. This indicates that recycled plastics are rarely used for these consumer articles, and also that there are other sectors where recycled plastics – in case they do not fulfil the lead requirements suggested here – can be used.

Recycling of metals

Metals are recycled to a much larger extent than other materials. This is due to the fact that it is very expensive to extract new metals, that metals are a finite resource and that the profit of recycling is high. Metals can be recycled infinitely, and the recycled product is of the same quality as the virgin material. However, the articles covered in this proposal are probably not recycled to a large extent; the small metal parts in e.g. a shoe or a pen most probably end up in general household waste, and not in the collected metal waste.

In general, the consumer articles covered by the restriction proposed in this document constitute a minor share of total metal use. The market for copper alloys serves as an illustrative example (see Section G for more details). The total amount of copper alloys used in the EU is estimated to be 1.4 million tonnes (2011), which accounts for 32% of the EU copper market. Estimations of use in consumer articles reach ca. 83,000 tonnes, and the estimated use in the consumer articles covered in this document is ca. 10,000 tonnes, i.e. around 0.7% of the total copper alloy market, or 0.2% of the total market for copper. Given that the articles covered by the proposed restriction constitute a very small share of total metal use, there is abundant availability of “lead-free” materials for these products. Industry should be able to direct “lead-free” materials towards use in these articles, even when taking recycled materials into account.

Structure of the EU market of consumer articles

Basic facts about the structure of the manufacturing within the EU borders can for example be found in the “Structural business statistics” from Eurostat. However the statistical data is not organised in a way that shows the manufacturers on a level that corresponds to exactly to the articles addressed in the restriction proposal. The number of companies and number of presented in Table 6 are thus highly overestimated. A major part relates to manufacturing or sales of other articles, for example toys, electronics, cosmetics and several other items for which lead already is restricted in other legal acts.

Table 6: Total number of enterprises and employees in sectors that are partly involved in the manufacturing and sales of articles for consumer use in the EU (Eurostat)

Main sector	Indicator for market structure	Year: 2008	Year: 2009
Manufacturers	Total number of enterprises	543,540	734,939
Manufacturers	Total number of employees	5,778,486	6,338,010
Supply chain	Total number of enterprises	2,098,811	2,684,147
Supply chain	Total number of employees	11,651,427	12,864,647

The share of small and medium sized enterprises is expected to be higher than 99% of the total number of enterprises.

Further information about the market structure of the enterprises can be found in Appendix 6.

B.2.2 Uses

World end uses of lead are presented in Table 7. The uses addressed in this proposal are usually not officially compiled, partly due to the small share of the total lead use these account for.

Table 7: World end uses of lead 2011 (ILA, 2010)

Area of application	Volume 1000 tonnes
Batteries	8500
Pigments and other compounds	560
Rolled and extruded products	360
Miscellaneous	210
Shot and ammunition	140
Alloys	130
Cable sheathing	90
Fuel additives	9

Due to the small share of the total lead use, and partly to the way market statistics are generally aggregated, market data does not give a fair representation of the uses targeted in this proposal. For the full picture, different other sources such as medical reports, enforcement activities and tests on lead concentrations in articles performed by e.g. consumer organizations must be consulted. From such sources, the following functions and other reasons for availability of lead in articles intended for consumer use has been identified for further assessment in this restriction report. Specific regard has been taken to articles most often mouthed by children and in which lead is not yet restricted, e.g. clothes, accessories, furniture, interior decoration objects, stationery, keys and key rings, etc.

Metallic lead

Metallic lead is only used in a minor part of the consumer articles, mainly as weights because of the high density. The lead content is approximately 70% by weight.

Lead in metal alloys

Metal alloys containing lead has been identified mainly in buttons, zippers, rivets and studs in clothes and accessories, keys, key rings, interior decorations and stationery. It may also occur in many other kinds of metal parts in all articles categories.

The use of lead in different metal parts (made from alloys) in consumer articles is often unintentional. The producer/supplier has not always been aware of the lead content in the material. Stakeholders consulted have stated that their aim is to substitute lead in all applications where it is present as an impurity and has not been deliberately added to a material in order to gain a specific function. However, in some alloys lead is needed in order to provide a physical function, e.g. to give a glossy surface or add mechanical workability by acting as lubricant. It should be noted that from a risk point of view, it does not matter whether the lead is added deliberately or if it is present as an impurity.

Brass is a group of lead-containing alloys which are based on a mixture of copper and zinc. According to stakeholders consulted, the lead is added to brass in order to enhance the mechanical properties and to function as a lubricating agent. The proportions of zinc and copper can be varied to create a range of brass qualities with various properties.

The properties can be varied further by addition of other compounds e.g. aluminium, nickel, tin, silicon or lead. Lead is often added in concentrations of around 2% to enhance the machinability of brass. Since lead has a lower melting point than the other constituents of the brass, it tends to migrate towards the grain boundaries in the form of globules as it cools from casting. The pattern the globules form on the surface of the brass increases the available lead surface area which in turn affects the degree of leaching. In addition, cutting operations can smear the lead globules over the surface. These effects can lead to significant lead leaching from brasses of comparatively low lead content.

Due to the variety in the proportions between zinc and copper the amount of brass qualities is high. Some common qualities to produce small articles like buttons etc. are the following:

Alpha brasses with less than 35% zinc

Beta brasses, with 45–50% zinc content, can only be worked hot, and are harder, stronger, and suitable for casting.

Prince's metal, a type of alpha brass containing 75% copper and 25% zinc

Leaded brass is an alpha-beta brass with an addition of lead. It has excellent machinability.

The most common brass quality CW602N has a lead content of 3%. There are other qualities, such as CW612N, which has a lower lead content (2%), but in principle the same characteristics (besides less chip removal when cutting).

Brass has a relatively low melting point and its flow characteristics make it a relatively easy material to cast. Due to their magnetic properties, brass alloys can be easily separated in a recycling process, and today almost 90% of all brass alloys are recycled (European Copper Institute, stakeholder consultation, 2013).

Lead in pigments

Although the use of some of the pigments is restricted in mixtures in REACH annex XVII, they can occur as constituents in articles manufactured both inside and outside the EU. Lead based pigments are available in basic colours like white, red and yellow. Other shades may be obtained by mixing different colouring agents.

Lead based pigments are assumed to be the source of lead in coloured polymers used in the manufacturing of accessories and clothing details, as well as in surface paints in other groups of articles. It is also the probable lead source in some plastic prints on textiles. Since it is not possible to analyse the exact lead compound that has been added to the material, the observation was made by comparing articles and surface prints of different colours. Lead was found in higher concentrations in articles or printed areas in yellow, red and orange colours.

Several recent studies confirm that lead is still used in paints on the surfaces of articles as well as a colouring agent in textiles and polymers. Lead is also used to make paints more durable and corrosion resistant. (Murao and Ono 2012; WHO 2010.) Some common lead pigments are listed in Table 8.

Table 8: Pigment substances containing lead as registered under REACH or already restricted.

EC No.	**CAS No.**	**Name**	**Molecular formula**	**Synonyms / Other information**
215-235-6	1314-41-6	Orange lead	Pb_3O_4	Lead tetroxide
215-267-0	1317-36-8	Lead monoxide	PbO	Pigment Red 105 Red lead Litharge Also used as stabiliser

EC No.	CAS No.	Name	Molecular formula	Synonyms / Other information
232-382-1	8012-00-8	Pyrochlore, antimony lead yellow	$Pb_2Sb_2O_7$	C.I. 77588 Pigment yellow 41
233-245-9	10099-74-8	Lead dinitrate	$Pb(NO_3)_2$	
215-693-7	1344-37-2	Lead sulfochromate yellow	$Pb(Cr,S)O_4$	C.I. 77600 C.I. 77603 Pigment Yellow 34 SVHC Annex XIV:11
231-846-0	7758-97-6	Lead chromate	$PbCrO_4$	Pigment yellow 34 SVHC Annex XIV:10
235-759-9	12656-85-8	Lead chromate molybdate sulphate red	$Pb(Cr,S,Mo)O_4$	C.I. 77605 C.I. Pigment Red 104 Chrome vermilion SVHC Annex XIV:12
209-943-4	598-63-0	Lead carbonate	$PbCO_3$	Annex XVII:16

Although banned in Europe, white lead (CAS No. 37361-76-5, Formula $2PbCO_3 \times Pb(OH)_2$) is reported to be used in Asian countries. (Murao and Ono 2012). It may therefore occur in imported articles. Moreover, 75% of the countries in Asia and the pacific do still use lead in e.g. toys and consumer goods. There is a high level of unavailability of data and specific volumes can therefore not be reported. (Murao and Ono 2012)

Lead stabilisers

Lead based stabilisers for sale today seem to primarily be designed for use in piping and window profiles. They are often not intended for use in materials for smaller consumer goods. Nevertheless, tests made by the Swedish CA indicate that there are lead compounds available in plastics that may be the result of the addition of lead stabilisers.

Lead based stabilisers are assumed to be the source of lead in plastic details in reflective bracelets, interior decoration but also in plastic prints on textiles and polymer materials in clothes and accessories. It might be a source of lead in PVC coated rainwear and other coated textiles, but this has not been confirmed.

In the absence of test methods to determine which lead compound that originally was added to the material, it is not possible to fully determine if the aim was to add a stabiliser. There are also substances that are used both as stabilisers and colorants, which also complicates the analysis when lead is found in a plastic material.

Lead has the longest history as a stabiliser for PVC. The stabilising effects of lead are used for PVC products with long service life and requirements for endurance of longer fabrication (heating) hours. A number of different lead compounds are used in PVC formulations in order to provide the right performance in particular applications. (PVC Europe 2012)

The major properties of PVC compounds incorporating lead stabilisers include (PVC Europe 2012):

- Heat and light stability.
- Good electrical properties.
- Good short and long-term mechanical properties.
- Low water absorption.
- Wide processing range.
- Good cost/performance ratio

In Table 9 lead containing stabilisers identified from Reach registrations are listed.

Table 9: Stabilisers containing lead as registered under REACH.

EC Number	CAS Number	Name	Molecular formula	Other information
215-267-0	1317-36-8	lead monoxide	PbO	Also used as pigment
234-853-7	12036-76-9	lead oxide sulfate	Pb_2SO_5	
235-067-7	12065-90-6	pentalead tetraoxide sulphate	Pb_5SO_8	
235-252-2	12141-20-7	trilead dioxide phosphonate	Pb_3HPO_5	
235-380-9	12202-17-4	tetralead trioxide sulphate	Pb_4SO_7	
235-702-8	12578-12-0	dioxobis(stearato)trilead	$C_{36}H_{70}O_6Pb_3$	
263-467-1	62229-08-7	Sulfurous acid, lead salt, dibasic	$PbSO_3$	
273-688-5	69011-06-9	[phthalato(2-)]dioxotrilead	$Pb_3C_8H_4O_6$	
292-966-7	91031-62-8	Fatty acids, C16-18, lead salts	N/A	

Market volumes of articles for consumer use and lead volumes supplied from relevant consumer articles

Specific regard has been taken to articles frequently mouthed by children. Information regarding the selection of the articles is further described in section B.9.3.1. The articles have been organised into a number of subcategories of mouthed items. Articles covered by existing regulations for lead as well as articles that are not expected to contain lead have been excluded from the assessment parts in this report. The remaining subcategories include clothes, shoes, accessories, interior decorations, articles for sports and leisure, stationery and keys. Child care articles have been evaluated and when possible added to a relevant subcategory which sometimes is covered by an existing regulation and sometimes not.

Statistical data on market volumes for the relevant items has been collected from the Prodcom database (Prodcom, 2012. The market volumes of articles are aimed to match the subcategories of articles identified from the analysis of the mouthing behaviour (see section B.9.3.1). The statistical data was collected and compiled for the corresponding subcategories. See

Table 10. Data covers supplied quantities of articles on the European market on production and foreign trade. Data for the years 2005-2011 was extracted from the database. Only data from 2011 are presented in this report.

Total quantities and economic values for 2011 are summarised in

EUROPEAN CHEMICALS AGENCY

Table 10 -

Table 12. The quantities of the articles in Prodcom are reported in either pieces, pairs, weight or in some cases not reported as quantity, but only available in monetary values. To get comparable figures for all articles with unreported quantity or a quantity apart from pieces has been extrapolated to pieces by using the monetary value and a conversion value from a derived relationship between the quantity and value for such articles. The total quantities are thus presented as an adjusted quantity.

The most accurate way to evaluate the consequences of the restriction proposal would be to evaluate each type of article or small subcategories specifically, matching estimated exposure versus the market volumes and costs for substitution of lead for that subcategory. With the wide group of articles in the proposal it would be inefficient and thus not considered reasonable to evaluate with such high accuracy. A general assessment can however be combined with assessments of certain categories with specific properties at a more detailed level. Two such groups have been identified – keys and t-shirts.

Keys are considered for derogation and are assessed separately for that reason.

T-shirts have been found to constitute an extremely large number of articles compared to the sum of all other articles. T-Shirts represent 17% of the total volume of articles extracted from Prodcom for assessment and as much as 33% of the volume of articles in the group clothes from Prodcom, but only 1.5% of the frequency of articles that children normally use for mouthing (4.5% of the articles in the proposed restriction). Most t-shirts are not expected to contain lead. However, there are findings of lead in printed t-shirts reported in EU Rapex. Thus the t-shirts cannot be totally neglected in the assessment of the proposal.

Childcare articles were examined specifically since they were not highlighted in the first submitted Annex XV report. All identified child care articles (not already regulated through other legislations) except baby carriages were included in the original data sets of articles supplied to the market. Since the baby carriages were found not to fit into any of the original subcategories they are compiled in a separate subcategory.

Table 10 Compiled statistical data for each subcategory of articles in quantity (pieces)

	EU production	Export	Import	Net supply to EU market		EU Production, % of total supply	Import, % of total supply
Clothes	1 204 582 921	674 252 583	9 423 415 315	9 953 745 652		5	95
Shoes	476 523 538	185 981 601	2 509 777 976	2 800 319 913		17	83
Accessories	273 525 101	213 824 927	1 885 300 762	1 945 000 936		4	96
Stationery	5 751 323 652	25 867 169	4 135 899 019	9 861 355 502		47	53
Interiour decorations	720 662 887	73 560 882	199 731 900	846 833 905		76	24
Sports and Leisure	110 000	449 041	7 607 502	7 268 461		-5	105
Child care articles *	3 836 734	1 784 144	7 888 759	9 941 349		21	79
Total	8 045 234 559	3 002 252 431	15 373 116 562	20 411 726 027		**25%****	**75%*****

*) If not reported in any other subcategory, this category includes only baby carriages and parts of such

**) Example on the calculation of market shares. % EU production of total supply = (9,341,328,388 – 3,525,084,168) / 25,087,172,068 = 0.23 = 23%

***) % Import of total supply = 19,270,927,848 / 25,087,172,068 = 0.77 = 77%

Articles produced within the EU for export are not covered by the restriction and thus not included in the share of total supply. However, the total EU production volume has been included in the cost calculations. The reason is mainly that articles for the EU-market are assumed to be produced at the same sites as the articles intended for export and that the producer will, if possible, adapt the articles for all markets when the conditions of the production changes. A change in production conditions is thus expected to affect articles intended for both the EU and non-EU market. This will lead to an overestimation of the substitution cost for articles produced in EU in our assessment.

Table 11: Compiled statistical data for each subcategory of articles in economic value (Euro)

	EU production	Export	Import	Net supply to EU market		EU Production, % of total supply	Import, % of total supply
Clothes	21 346 726 242	12 701 804 490	47 784 387 590	56 429 309 342		15	85
Shoes	12 194 094 989	5 669 517 380	13 514 345 000	20 038 922 609		33	67
Accessories	9 359 863 163	7 347 500 560	5 025 105 200	7 037 467 803		29	71
Stationery	1 162 634 422	555 326 710	707 775 180	1 315 082 892		46	54
Interiour decorations	2 235 536 470	376 854 240	1 103 304 670	-5 045 749 350		63	37
Sports and Leisure	36 112 487	8 503 770	43 207 740	70 816 457		39	61
Child care articles *	512 782 002	169 771 530	382 248 100	725 258 572		47	53
Total	46 847 749 775	26 829 278 680	68 560 373 480	88 578 844 575		23%	77&

Total quantities and economic values for 2011 for all article categories in the proposal are summarised in

Table 12 as described earlier.

Table 12: Market volumes (adjusted to pieces) and sales value (Euro) on articles for consumer use in scope of the propsoal (Prodcom, 2012; Extraction of data for 2011)

	EU production	Export	Import	Supply to the EU market
Quantity, pieces adjusted	8 045 234 559	3 002 252 431	15 373 116 562	20 416 098 689
Value, Euro	46 847 749 775	26 829 278 680	68 560 373 480	88 578 844 575

The data on market volumes are used for cost calculations in chapter E2 (sections E2.1.1.2 and E.2.1.2.2)

Table 13: Market shares of consumer articles in scope produced in the EU and of imported goods, based on figures in

Table 12. Supply to the EU market = 100%

	EU production , % of total supply	**Import, % of total supply**
Quantity, pieces adjusted	25	75
Value, Euro	23	77

Estimated lead volumes from assessed articles for consumer use

In the first screening stage of the cost calculations, the total volume of lead was not used for assessment purposes. At that stage an estimation of the lead content in small parts like metallic buttons, zippers, studs, details on pens plus the surfaces of polymeric parts of e.g. accessories was made. Since the data should not be used for further assessment, no great efforts were made to cover all of the articles in the proposal. The intention was to get a very rough idea of the magnitude of the lead volumes to relate the importance compared to the overall flows of lead available on the market. The total lead supply from the investigated items was then reported to be 74 tonnes for restriction options 1 and 2 and 60 tonnes for restriction option 3.

For the refined cost calculations which are based directly on the lead volumes another approach was necessary in order to cover all possible uses of lead in the relevant articles. The base for this calculation stage was the extracted statistical data per statistical code from Eurostats Prodcom database. For each kind of articles, parts where lead could be available were identified and used for a calculation of a lead volume. The lead volumes were derived in several ways. Small details and parts of materials were weighed on a scale. The number of buttons, studs and the length of zippers were investigated for different pieces of clothes and accessories by ocular studies of the supply in shops in Sweden in the autumn 2012. Heavier items were not possible to put on a small scale. Product information from internet stores and product catalogues were in some cases used to estimate the total weight of an article or parts of articles.

The sum of the calculated lead volumes in the various article categories are presented in Table 14. A more detailed description on how the quantities were derived is presented in Appendix 8 and Appendix 9. More efforts have been spent to find relevant values on article categories with high total lead volumes, in order to refine them further. Articles with lower lead volumes are not considered to have the same impact on the final result. Thus a step by step refining of the data with the highest volumes first has been conducted.

Table 14: Estimated quantities of lead to be substituted, tonnes

(ton)	Material containing lead			
Article group	Pigments	Stabilizers	Metals	Total
Clothes	14	18	81	**114**
of which T-shirts	*1*	*11*	*0*	*11*
Shoes	70	56	23	**149**
Accessories	160	0.2	59	**219**
Stationery	0	0	7.0	**7.0**
Sports and leisure*	0.2	62	22	**83**
Int. decorations	115.	48	130	**288**
Child care articles	0	6.4	4.7	**11**

Total	**360**	**190**	**326**	**876**
of which Imported	*261*	*163*	*200*	*623*
of which EU-prod.	*99*	*27*	*127*	*253*

*Fishing articles are not included
Keys and musical instruments are not included.

B.2.3 Uses advised against by the registrants

The information given by the REACH registrants of lead under the heading "Uses advised against" has been examined. The registrants have not mentioned the use of articles for consumers under this heading, indicating that they either are aware of the use in consumer articles but do not consider it a risk or that they are not aware of this marginal flow of lead.

B.3 Classification and labelling

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

Lead compounds in general are classified under the CLP Regulation as toxic to reproduction, Cat. 1A, with a classification limit of 0.1%. This general classification depends on the lead ion being the harmful species. Elemental lead is not classified. Since also elemental lead can emit lead ions (e.g. through corrosion), the Swedish CA has (February 2012) filed a proposal to ECHA to classify elemental lead accordingly. This proposal is currently pending.

Information on the classification of lead compounds is available in Appendix 10.

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

According to (LDAI 2008), the following health classifications are suggested for lead metal with a particle size of <1mm in diameter:

Repr. 1A – H360. May damage fertility or the unborn child.

STOT Re. 1 – H372. Causes damage to organs. Affected organs: The central nervous system and systems for reproduction.

B.4 Environmental fate properties

Not relevant for this proposal.

B.5 Human health hazard assessment

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.

Oral absorption rate

Gastro-intestinal (GI) uptake of lead occurs in the duodenum. In this mechanism, both active transport and diffusion through intestinal epithelial cells are involved.

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 absorb 3-15% of the ingested amount of lead, whereas those who have not eaten for a period of 24 h absorb about 20-70% (EFSA 2010). The mineral content of food is one contributing factor to the decreased absorption of lead when lead is ingested with a meal. A possible mechanism behind this effect could be competition between lead and the minerals for the binding sites that mediate uptake (LDAI 2008)

Lead absorption is affected by nutritional calcium and iron status (Watson et al. 1986). High levels of calcium and/or iron in the blood stream protect from GI absorption of lead, and a low iron intake and deficient iron status is associated with increased blood lead levels (Cheng et al. 1998; Bárány et al. 2005). This information is important to keep in mind since iron deficiency is very common, especially amongst women of child bearing age.

Concerning children, even though data are more limited, an oral absorption rate of 40–50% for lead and its compounds can be determined for non-fasting children from 2 weeks to 8 years of age (ATSDR 2007; LDAI 2008). Whether fasting might increase lead uptake in young children is not known; uptake rates are only available for dietary lead sources.

There have been a number of clearly identified cases of lead poisoning resulting from the misuse of lead-containing jewels, most often by children who have swallowed or repeatedly mouthed them (CDC 2006; CDC 2004; Levin et al. 2008; Jones et al. 1999; Canada Gazette 2005; InVS 2008; KEMI 2007). The observed symptoms of these cases go from headaches and diarrhoeas to death. One report of a fatal case of lead poisoning describes the death of a 4 year old boy in the USA after he ingested a bracelet charm containing 99 % lead (CDC 2006). The initial symptoms of poisoning manifested as vomiting, abdominal pain and fatigue, and the child had a final PbB level of 180 µg/dL at the time of death.

Inhalation absorption rate

For the very small particles (up to to 0.5 µm), a dissolution occurs in the lungs and the lead will be available for systemic absorption. More than 90% of these very small particles are completely absorbed after deposition in the lower respiratory tract (LDAI 2008).

Particles between 0.5–10 µm are partially absorbed in the lung; the non-absorbed parts will be transported up to the mouth via the respiratory tract and then swallowed.

Larger particles over 10 µm will mainly be swallowed and then absorbed via the GI tract.

Dermal absorption

The dermal absorption of lead trough unabraded (non irritated) skin has been established as less than 0.1% (ranging from 0.01% to 0.18% in studies), and is considered to be of much less significance than absorption via the respiratory or gastro-intestinal routes (LDAI 2008).

Lead is a soft metal that can easily “rub off” on to the skin in the case of dermal contact.

Even though absorption directly through the skin is considered negligible, the lead can become systemically available through hand-to-mouth behaviour (LDAI 2008). This route of exposure is feasible for both children and adults that come in contact with lead containing articles, both at home and in the work place. Especially older and thus oxidised lead surfaces can transfer significant quantities (potentially hundreds or thousands of µg's) of lead to the hands via dermal contact (Klein and Weilandics 1996). In the workplace, personal habits such as frequent hand-to-mouth activity, smoking, and eating all provide opportunities for lead ingestion. The intensity of exposure resulting from such habits varies as a function of personal hygiene (e.g. hand washing frequency) and the magnitude of direct lead contact and lead contamination (e.g. dust) on surfaces (LDAI 2008).

B 5.1.2 Metabolism

The inorganic lead ion is not known to be metabolised or biotransformed in the body though it does form complexes with a variety of proteins and non-protein ligands. It is primarily absorbed, distributed, and then excreted, often in form of a complex.

Inorganic lead is not converted in the body. Unabsorbed lead which is ingested orally is expelled through the faeces, while absorbed lead that is not retained in the body is released again 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 mineralizing 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 stored in skeletal tissue. 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 2008).

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 (ATSDR 2007).

Lead concentration is related to calcium status; stored lead can therefore be released from bone tissue into the blood stream in situations where a person suffers from calcium deficiency or osteoporosis (LDAI 2008).

It should be noted that lead is easily transferred to the foetus via the placenta during pregnancy. The foetal/maternal blood lead concentration ratio is approximately 0.9 (Carbone et al. 1998; Goyer 1990; Graziano et al. 1990).

B 5.1.4 Elimination

Lead has a different half-life in different tissue pools. Blood lead and lead in soft tissue is considered the most labile compartment with a half-life of approximately 40 days, while bone lead is very stable with a half-life of several decades (ATSDR 2007).

In lead exposed infants and children, lead is progressively accumulated in the body and is mainly stored in skeletal tissue. As mentioned previously, lead is eliminated from bone very slowly; the half-life can be 10 to 20 years or more. In this way, lead can lead to an internal exposure long after the external exposure has ended, by redistribution between different tissue pools (LDAI 2008).

Elimination takes place mostly via urine (>75%), and 15–20% is excreted via bile and faeces (TNO 2005).

B 5.1.5 Summary and discussion on toxicokinetics

Lead is most easily taken up into the body through inhalation or ingestion, dermal uptake makes a negligible contribution to systemic lead levels. The efficiency of oral uptake of lead can vary depending on e.g. particle size and shape (surface area), amount of time spent in the GI tract, concurrent food intake and the iron- and calcium status of the individual. A number of case reports prove that even one larger piece of lead ingested orally can create sufficient systemic exposure to produce clinical lead intoxication or even death. Therefore lead of all particle sizes should be considered a potential health hazard. As a worst case assumption, one can assume that the bioavailability of metallic lead is equivalent to that of soluble lead compounds such as e.g. lead acetate.

Once taken up into the body, lead is not metabolised. However, it will distribute to various tissue compartments such as blood, soft tissue and bone. The half-life of lead in the body varies depending on body compartment. Blood lead has a half life of around 40 days and measurement of lead in blood can thus provide an estimate of average lead exposure (via all routes) over the preceding month.

Lead is retained far longer in bones, up to several decades. Such lead can both serve as a source of endogenous lead exposure and as a cumulative index of exposure over a time frame of years. Lead excretion takes place primarily via the urine.

B 5.2 Acute toxicity

B 5.2.1 Non-human information

After oral administration in the rat; lead oxide, lead tetroxide, lead phthalate dibasic and lead sulphate tribasic all have a LD_{50} > 2000 mg/kg bw (LDAI 2008).

By the dermal exposure 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 Human information

Very limited data are available describing acute poisoning. Most human data for “acute toxicity” actually describe effects after exposure to lead over a period of weeks or years – exposure time-frames that are more accurately regarded as being sub-acute or chronic in duration.

The US National Institute of Occupational Safety and Health (NIOSH) estimated the acute lethal dose for an adult to be approximately 21 grams (equivalent to 450 mg/kg bw) by the oral route, and 21,000 mg/m^3 for 30 minutes via inhalation (LDAI 2008).

Acute lead intoxication in children has been reported following the ingestion of lead paint chips containing 1% or higher of lead (NAS 1972, ATSDR 1999, Marino et al. 1990, Sand et al. 1985 and Lin-Fu 1992). Acute lead intoxication is serious and can be fatal, especially in children. In 2006, a four year old boy in the USA died after swallowing a bracelet charm containing 99% lead. The boy’s blood lead level was 180 µg/dL at the time of death (CDC 2006).

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

Symptoms of acute lead poisoning include but are not limited to: dullness, restlessness, irritation, poor concentration, muscle “vibration” and weakness, headaches, abdominal discomfort and cramping, diarrhea, memory loss and an altered mental state including hallucinations. These effects can occur at PbB levels of 800–1000 µg/L in children (TNO 2005). Furthermore, the US EPA has 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.

Due to the long elimination half-life of lead in the body, chronic toxicity should generally be considered a greater risk than acute toxicity.

B 5.3 Irritation

In general, lead and its compounds can be considered non-irritating. Out of nine animal studies investigating dermal and eye irritation, eight were negative. One rabbit study was positive for dermal irritation caused by lead oxide, but this study can only be found in an undocumented IUCLID entry (lead oxide), for which there is no experimental verification.

In humans, no studies were found that document eye-, skin- or respiratory irritation resulting from exposure to lead or its compounds.

In conclusion, lead and its compounds should be considered non-irritating.

B 5.4 Corrosivity

No studies were found that document corrosivity to the eye, skin or lung in humans or animals following exposure to lead or its compounds (LDAI 2008). Thus lead and its compounds should be considered as non-corrosive.

B 5.5 Sensitisation

Animal studies indicate an absence of skin sensitizing potential for lead and its compounds (LDAI 2008). No human studies were found documenting sensitization to lead or its compounds. In view of the large number of workers that historically have been occupationally exposed to lead and its compounds, the lack of reports on sensitization strongly suggests lead is non-sensitizing in humans.

B 5.6 Repeated dosed toxicity

According to the group entry in annex IV, all lead compounds are classified according to CLP as STOT RE 1 or 2; causes or 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, fatigue, 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 considered to be adverse. As exposure rises, greater impact on haematological parameters can be expected. At higher blood lead levels, impacts upon haeme synthesis can be observed which can be considered as an adverse effect.

At blood lead levels <100 µg/L an inhibition of enzymes such as ALAD is observed, ALAD is an enzyme involved in the synthesis of haeme. These enzymatic effects are not considered 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 2008).

B 5.6.2 Renal effects

The kidneys are a target organ for lead, and effects can begin to be observed at a PbB level of 100 µg/L. (LDAI 2008). One of the symptoms of lead poisoning is colic, which can occur at a PbB-level from 1000 µg/L (SCOEL 2002).

The effects of lead on kidneys are similar in animals and in humans; the cells brush border in proximal tubules is affected. These effects could lead to nephropathy with tubular atrophy.

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

B 5.6.3 Effects on the central nervous system (CNS)

The most sensitive effect of lead is its ability to cause IQ deficits in the developing brain[6]; this serious effect is the main objective for submitting this restriction dossier. Lead causes IQ deficits in children at *very* low blood lead levels; under 10 µg/dL and since no safe blood lead level has yet been established, lead should be regarded as a non-threshold toxic substance.

The central nervous system is still under development well over a decade after birth; therefore the IQ effects in children should be considered a developmental effect and will therefore be discussed in further detail under section B.5.9.2.

At higher blood lead levels, lead can cause other neurotoxic effects, and children are especially vulnerable. When the blood lead level reaches 80 µg/dL, encephalopathy can often be observed which is characterised by ataxia, coma and convulsions (LDAI 2008). This condition can be fatal.

B 5.7 Mutagenicity

Occupational exposure to lead has been shown to be associated with increased mitotic activity in peripheral lymphocytes, increased rate of abnormal mitosis and increased incidence of chromosomal aberrations and sister chromatid exchange. These effects occur at PbB levels ranging from 220 – 890 µg/L (TNO 2005). However, these results reporting chromosomal aberrations are contradictory since other studies performed with

[6] 0.1 IQ point on an individual level is not likely to be clinically significant. However, the consequence needs to be viewed in a public health context where a low impact effect with a high frequency may contribute significantly to population burdens. In the case of lead, as it is a non-threshold substance, every child affected contributes at least a little to the population effect and thus the cumulative result is substantial and is likely to have an influence on the overall productivity of the population. Consequently, any action to reduce lead exposure is likely to lead to decrease the burden on the population.

similar PbB ranges did not demonstrate such effects.

Moreover, it has been demonstrated that lead exposure can lower the ability of DNA to repair itself, and is therefore responsible for an increase in DNA damage (Karakaya 2005; Mendez-Gomez 2008).

B 5.8 Carcinogenicity

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

According to the CLP-legislation, lead acetate is classified and listed in annex VI as Carc. 2 (H351), since carcinogenic effects have been observed in animal studies. LDAI (2008) 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

B 5.9.1 Effects on fertility

B 5.9.1.1 Non-human information

Impacts of lead upon reproduction have been evaluated in a large number of animal studies documenting the negative effects of lead upon fertility. Lead acetate has been used to create lead exposure in a majority of the animal studies mainly because of its ease of use; e.g. it dissolves easily in water that the animals can drink and has good oral bioavailability. Well in the body, it is the actual lead ion itself that is toxic; making it unimportant which type of lead source is really causing the exposure. What matters is the actual lead concentration in blood/soft tissue/bone or whatever compartment that is of interest.

Animal studies have mainly been conducted to confirm the results of observational studies in humans and for elucidation of mechanisms of action. Extrapolation from experimental animal data to humans is generally unnecessary since large amounts of human data are already available.

Sokol et al. (1994) found that lead exposure could negatively affect the ability of sperm to penetrate and fertilise the egg. Male rats were given 0.3% lead acetate in drinking water with *ad libitum* access, this produced PbB levels of 33, 36 and 46 µg/dL after 14, 30 or 60 days respectively. Sperm was harvested from lead-exposed male rats and eggs from non-exposed females were fertilised *in vitro*. Lead exposure significantly decreased the number of eggs penetrated and fertilised compared to controls (p=0.001). Epididymal sperm counts were also significantly decreased (p=0.02) in the lead-treated group (though sperm counts were controlled for and adjusted prior to *in vitro* fertilization).

Chowdhury et al. (1984) found pronounced testicular atrophy along with cellular degeneration in the testes of rats fed lead acetate; 90 mg/kg BW/day which produced a blood lead level of 143 µg/dL. The lead acetate was administered via the drinking water and the animals were exposed for 60 days. Rats in the 45 mg/kg BW/day dose group (blood lead 72 µg/dL) had significantly decreased Leydig cell numbers. Spermatid- and spermatocytes were also significantly reduced in number and found to be in a degenerative condition.

The effect of lead exposure on sperm production and damage to testicular tissue has also been studied in primates. Exposure from infancy (blood lead 35 µg/dL) was associated with ultrastructural changes affecting the architecture of tissues within the testes during adulthood (Foster et al. 1998).

The combined animal evidence strongly suggests that lead will have negative impact upon sperm production and cause histopathological changes in testicular tissue.

B 5.9.1.2 Human information

A large number of studies have been conducted in occupationally exposed workers to assess the negative impacts of lead on male reproductive function. Common work places with potential lead exposure are e.g. lead-acid battery plants, metal foundries and smelters. Research on lead exposure and male fertility has also been conducted on study populations from fertility clinics, hospitals and firing ranges.

Alterations in semen quality are the most commonly observed effects in the occupational setting and can be documented with precision. The decrements in semen quality associated with high blood lead levels are expected to have an impact upon the fertility of normal, healthy individuals.

The following conclusions can be made:

The available data show that moderate to high lead exposure can have a marked adverse impact upon semen quality. Aberrant sperm morphology, decreased sperm count and decreased sperm density have all been demonstrated in exposed individuals.

Bonde et al. (2002) conducted a cross sectional study of 503 men employed by 10 different companies in the UK, Italy and Belgium. Among other things, semen volume and sperm concentration were measured. The study group was of sufficient size to model dose-effect relationships and indicated a threshold for an effect upon semen quality at 45 µg/dL of concurrent PbB. As blood lead levels increase above 50 µg/dL, progressively greater impact on fertility can be expected.

Some studies have not found an adverse effect of lead upon male fertility. In these studies, the measured blood lead levels are generally relatively low and below the threshold effect level of 45 µg/dL blood lead suggested by Bonde et al. 2002 for effects on male fertility. In addition, many of the negative studies have been conducted using very small study populations and confounders have not always been taken into account which can further compromise the study results.

Female fertility: Historical human data, and animal data, suggest fertility effects in females are probable as well, but fertility effects in women can not be estimated with precision.

Effects of lead on female reproduction have been observed in numerous animal species. These effects include alterations in sexual maturation, hormone levels, reproductive cycles, impaired development of the fertilised egg as well as decreases in fertility (LDAI 2008). Effects on female reproduction in animal studies are usually not apparent at the blood lead levels that impair male fertility; higher blood lead levels are generally needed to see an adverse effect on the fertility of females. In addition, human data are inconsistent and can not be estimated with precision.

B 5.9.2 Developmental toxicity

B 5.9.2.1 Non-human information

The developmental toxicity of lead has been extensively characterised in humans, therefore animal studies are only briefly summarised below.

As a short summary; a large number of animal studies support the human findings in this area. In primates, rats and mice with *in utero* lead exposure; learning disabilities, altered activity levels, effects on social behaviour and visual and spatial discrimination have been demonstrated. In addition, other developmental effects have also been found in the offspring such as decreased birth weight and size, delayed sex organ development and puberty onset, and delayed sexual maturation (LDAI 2008).

B 5.9.2.2 Human information

The nervous system is the main target organ for lead toxicity. The developing foetus and young children are most vulnerable to lead induced neurotoxicity, their nervous system is still under development and therefore more vulnerable to toxic insults. The immaturity of the blood-brain barrier may contribute to the vulnerability, as well as the lack of high-affinity lead binding proteins in the brain that trap lead ions in adults (Lindahl et al. 1999). Young children often exhibit hand-to-mouth behaviour and also absorb a larger percentage of orally ingested lead than adults, thus leading to a greater systemic exposure (EFSA 2010).

Several epidemiological studies have been conducted examining the impacts of peri-natal lead exposure upon birth outcome and neurobehavioral development in children.

Regarding lead exposure, negative impact on IQ is the most sensitive end-point and no safe blood lead level has yet been established (JECFA 2010, EFSA 2010, Lanphear et al. 2005). Therefore lead should be regarded as a non-threshold toxic substance. The central nervous system is still under development well over a decade after birth; therefore lead-induced IQ deficits in children should be considered developmental in nature.

The relationship between blood lead levels in children and IQ deficits has been evaluated in several studies.

Lanphear et al. (2005) examined data collected from 1,333 children who participated in seven international population-based longitudinal cohort studies. This meta-study is a highly valued key study and is put forward by EFSA (2010) as being of great importance when investigating lead’s toxicity on the developing nervous system.

The children in the cohorts were followed from birth or infancy until 5–10 years of age. The objective of the study was to examine the association between intelligence test scores and blood lead concentration, especially for children who had blood lead levels under 10 µg/dL. The full-scale IQ score was the primary outcome measure. The geometric mean blood lead concentration of the children peaked at 17.8 µg/dL and declined to 9.4 µg/dL by 5–7 years of age; 244 (18%) children had a maximal blood lead concentration < 10 µg/dL, and 103 (8%) had a maximal blood lead concentration < 7.5 µg/dL. After adjustment for covariates, the authors found an inverse relationship between blood lead concentration and IQ score. Using a log-linear model, they found a 6.9 IQ point decrement [95% confidence interval (CI), 4.2–9.4] associated with an increase in concurrent blood lead levels from 2.4 to 30 µg/dL. The estimated IQ point decrements associated with an increase in blood lead from 2.4 to 10 µg/dL, 10 to 20 µg/dL, and 20 to 30 µg/dL were 3.9 (95% CI, 2.4–5.3), 1.9 (95% CI, 1.2–2.6), and 1.1 (95% CI, 0.7–1.5), respectively. For a given increase in blood lead, the lead-associated intellectual decrement for children with a maximal blood lead level < 7.5 µg/dL was significantly greater than that observed for those with a maximal blood lead level ≥7.5 µg/dL ($p = 0.015$).

The larger sample size of the pooled analysis permitted the authors to show that the lead-associated intellectual decrement was significantly greater for children with a maximal blood lead of < 7.5 µg/dL than for those who had a maximal blood lead of ≥7.5 µg/dL. The authors conclude there is no evidence of a threshold for negative effects caused by lead exposure, thus no level of lead exposure can be considered as safe.

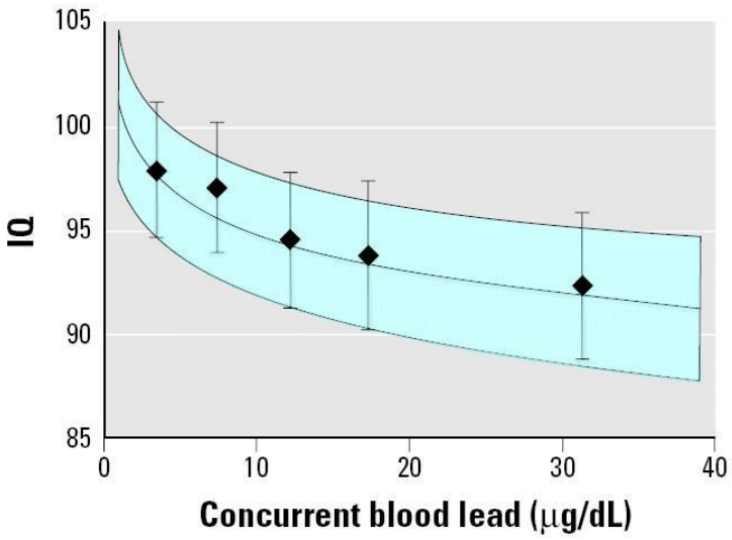

Figure from Lanphear et al. 2005; *Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environmental Health Perspectives, 113, 894-899.*

Log-linear model (95% CIs shaded) for concurrent blood lead concentration, adjusted for HOME score, maternal education, maternal IQ, and birth weight. The mean IQ (95% CI) for the intervals < 5 µg/dL, 5–10 µg/dL, 10–15 µg/dL, 15–20 µg/dL, and > 20 µg/dL are shown.

Figure 1. Log-linear model for concurrent blood lead concentration

B 5.9.3 Summary of Reproductive Toxicity – Developmental Effects on the CNS

Negative effects of perinatal lead exposure upon neurobehavioral performance have been demonstrated both in experimental animals as well as in human prospective studies. The nervous system is the main target organ for lead toxicity and the developing foetus and young children seem to be the most vulnerable to lead induced neurotoxicity.

Several prospective studies have been conducted examining the impacts of pre- and perinatal lead exposure upon neurobehavioral development in children, and impairment of IQ is the most sensitive effect that occurs at the lowest blood lead levels. It appears that lead-associated IQ deficits are significantly greater at lower blood lead concentrations and there is no evidence of a threshold for negative effects. This concludes that there is no safe exposure level for lead induced developmental neurotoxicity.

B 5.10 Other effects

Not relevant for this proposal.

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

B.5.11.1 Tolerable Daily Intake (TDI)

In 1995, a TDI value of 3.6µg/kg bw/day was established for both children and adults by the WHO. This value was established based on the assumption that an intake of 3–4µg Pb/kg bw/day does not affect the Pb levels in blood (PbB) in children or increase the body burden of lead. In 2003, the WHO (World Health Organization) reported a possible correlation between PbB levels below 100 µg/L and a reduction in IQ. EFSA (European Food Safety Authority) reported in 2010 that no TDI value could be placed upon lead exposure for children due to the fact that no known threshold for the decrease in IQ scores in relation to lead exposure has been found.

B.5.11.2 Background levels

The table below is an overview of the estimated dietary and non-dietary lead exposure for children under the age of 36 months taken from EFSA (2010).

Table 15: Lead background exposure for children under the age of 36 months

	Daily intake of lead for children (36 months) µg/kg bw/day	
	Min	**Max**
Food	1.1	5.51
Soil and dust	0.18	0.8
Outdoor air	0.001	0.003
Environmental tobacco smoke	0.012	0.052

For children aged one to three years of age, EFSA (2010) reported an average lead dietary estimates range from 1.10 to 3.10 µg/kg bw/day. These dietary estimate values were based on lower and upper bound assumptions. EFSA also reported an estimated lead exposure range for high consumers, aged one to three of 1.71 to 5.51 µg/kg bw/day. Dietary exposure is the main source of lead exposure for adults as well as children, although high soil intake can be a factor for children especially in contaminated areas.

B.5.11.3 Chronic DMEL (DMELc)

No exposure threshold has been determined for chronic exposure to lead in regards to neurotoxic effects in children. EFSA (2010) proposed a BMDL (benchmark dose level) based on the smallest measurable variation of the PbB level expressed as daily intake (BMDL is equivalent to a derived minimum effect level; DMEL). EFSA reported that "for changes in full scale IQ score a BMDL value of 12 µg/L was derived from the PbB levels in 6 year old children". This value corresponds to an exposure of 0.50 µg/kg bw/day. The EFSA concluded that 10% contribution from toys to the BMDL level should be sufficed to produce no appreciable risk for children (0.05 µg/kg bw/day). The RAC was also in agreement with this conclusion as they reported in the background document to RAC and SEAC opinions on a restriction proposal on lead and its compounds in jewellery (2011). The CSR (Lead registrant 2010) for lead metal reported a DNEL of 5 µg lead/dL blood as a benchmark that the average blood lead level in a large population of children should not exceed, and 10 µg lead/dL blood for an individual child. We are in agreement with both EFSA and RAC that the appropriate DMEL for chronic exposure is 0.050 of children µg/kg bw/day.

B.6 Human health hazard assessment of chemical properties

Not relevant for this proposal.

B.7 Environmental hazard assessment

Not relevant for this proposal

B.8 PBT and vPvB assessment

Not relevant for this proposal.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

B.9.1.1 Summary of the existing legal requirements

Lead has been a substance of concern for many years. This is reflected in the large number of sector specific Union legislative acts which restrict the use of lead. Mixtures, articles and consumer products are regulated through several EU directives with regard to their risk to human health and, in some cases, the environment. None of these acts covers the whole scope of articles available to consumer use, but specialise in specific priority product types.

Sector specific legislation setting limits to lead content or lead release include:

- Toys
- Electric and electronic equipment (EEE)
- Cosmetic products
- Packaging
- Materials intended to come into contact with foodstuffs
- Cars and goods transport vehicles
- Fuel for motor vehicles
- Paints (lead carbonates and sulphates only)
- Chemical preparations intended for consumer use (lead compounds only)

The majority of articles available on the consumer market still remain unregulated with respect to lead.

A more comprehensive (yet non-exhaustive) inventory of existing requirements related to lead in articles, including the legal references, can be found in Appendix 2.

B.9.1.2 Summary of the effectiveness of the implemented operational conditions and risk management measures

Since the 70's, human exposure to lead has decreased significantly in Western countries. In the U.S.A., the geometric mean blood lead level in children has decreased from 150 µg/L in 1976 to 16 µg/L in 2002. (CDC 2012.) In Sweden, the levels have decreased from 60 µg/L in 1978 to 25 µg/L in 1996 and further to 13 µg/L in 2009. (EFSA 2010, Skerfving et al, 2011.) There is an obvious correlation between the decreased blood lead levels in children and the introduction of lead poisoning prevention policies. Of these, the single most important measure has been the elimination of lead in petrol. Other regulatory measures such as the restriction of lead in toys and lead solder in food cans, the restriction of lead in residential paint, and regulations on industrial emissions, also seem to have had an impact. Waste related lead restrictions (packaging waste, electric and electronic equipment, etc.) mainly seem to have been effective to reduce occupational exposure and environmental risk. (EFSA 2010, US CDC 2012, WHO 2009)

Recently, the effects seem to have worn off. According to EFSA (2010), WHO (2009), CDC (2012) and Skerfving et al, (2011), blood lead levels in children seem to have reached a steady state level at 15–20 µg/L in Western countries, whereas in Central and Eastern Europe levels at 30–50 µg/L have been measured. As will be shown in the coming section, this exposure still exceeds the highest tolerable exposure with respect to the neurodevelopmental effects of lead. (EFSA 2010.) Thus, any additional exposure from food and non-food sources should be avoided. A feasible way of achieving further exposure reduction would be the introduction of new restrictions of lead.

B.9.2 Manufacturing

Not relevant for this proposal

B.9.3 User Scenario – Exposure from mouthing

B.9.3.1 General information

This section accounts for the lead contents of the articles in scope of this restriction report. These lead contents form the basis for the exposure scenarios and hence for the risk characterisation.

The mouthing behaviour of small children

The exposure scenario in this restriction report is based on articles articles containing lead, which are likely to be mouthed by small children. Only articles which children have access to in their daily lives are considered in the exposure scenario, as only these articles can be considered to pose a risk to the children. However, articles not covered in the exposure scenario may pose other risks to human health or the environment. Even though a particular article does not appear in the referred study, it should not be assumed that this type of article is not occasionally mouthed by children. The absence of an article in the referred study should therefore not be used as an argument for exclusion of items from the restriction.

Children's mouthing behaviour has been studied and recorded in several studies, but few of them give detailed information on the mouthed articles. The most comprehensive study found in this area in Europe was published by DTI (2002).

In the study published by DTI, mouthing time for consumer articles was recorded specifically. Articles/items mouthed were classified into four categories: a dummy/soother, fingers, toys, and other objects. **Only selected items in the category "other objects" has been regarded in the further assessment of this Background Document.** The category "other objects" can be split into smaller categories, because all the items that were observed are specified in Table 11 (page 26) and in Appendix G (page 71 and forward) in the DTI report (DTI 2002). Table 11 and Appendix G differ in detail, where more detailed information is available in Appendix G. Thus Appendix G has been used to compile data for our assessment.

In Table 16 below, all objects reported by DTI (2002) have been grouped in several sub-categories based on:

- Area of use
- If the articles already are covered by any legislation where lead is restricted
- The probability to find lead in the article

For each sub-category the share of the mouthing time compared to the total mouthing time in the overall category “other objects” was derived. Most articles made from paper like books, colouring books, notebooks, office papers are unlikely to contain lead and thus excluded from further assessment. A category “Other not assessed” contains mainly articles made from “clean” textiles, with no expected lead content. The remaining articles that were selected for further assessment are categorised as clothes, shoes, accessories, stationery (non paper), interior decorations, articles for sports and leisure, childcare articles, t-shirts, and keys. T-shirts and keys are assessed separated from the other articles. T-shirts are reported specifically due to the extremely large amount of articles with the aim to avoid the most obvious skewed distributions in data. This is described in more details in section B.2.2 where the market volumes are presented. Keys are assessed specifically due to a possible need for derogation. The main part of articles reported from the mouthing study in the sub-group non-paper stationery is parts of pens and pencils.

The share of total mouthing time on “other objects” for the described selection of articles, t-shirts and keys excluded, is 32% (31,6). This figure can be used for modelling in two different ways, based either on mouthing time or on certain number of children mouthing. The latter has been used in order to assess the risk to children. In the model it is estimated that 32% of the children mouth items from the categories defined above (clothes, shoes, ….) during the periods of the day they spend mouthing at items in the category “Other objects”.

The Dossier Submitter has made a selection of articles based on the scope of the proposal as it was proposed in the Annex XV report. On the basis of that scope the Dossier Submitter has made an evaluation of the articles in the PRODCOM (PRODuction COMmunautaire) database and included those articles in the cost calculation.

During the development of the opinion the wording of scope was modified a) in order to better define what mouthing is and b) to react to requests for exemptions that were put forward in the Public Consultation

Due to these revision fo the scope, the relevant mouthing frequency is approximately 22% of the items

Thus, the time children are expected to spend mouthing dummies/soothers, fingers, toys, paper, construction details, jewellery, kitchenware, packaging materials, electrical equipment, hygiene articles or natural objects <u>is not included</u> in the further assessment.

Only the time a single child is expected to mouth at clothes, shoes, accessories, non-paper stationery, interior decorations, and articles for sports & leisure is included in the following assessment.

From the DTI report it is not possible to split the mouthed articles into more narrow age groups, neither to identify the material (polymers, metal, paper etc.) for other objects separated from materials in mouthed toys.

<u>Additional investigations to check the relevance of the choice of article categories</u>

There is a relation between choking incidents and commonly mouthed items (DTI 2002) which indicates that it is relevant to consider data regarding objects and incidence frequency from choking studies. These studies are referred to in this report only with the aim to strengthen the inclusion of certain articles in the assessment. The reason is that no other studies with relevant data on mouthing times combined with mouthing frequency on items specified at that detailed level have been identified.

DTI has also published a study on choking incidents (DTI 1999). Other objects (i.e. non toys, non-food) were responsible for around 30% (27,7-32,1%) of such accidents for children in ages 3 years or younger. Buttons and pen tops accounted for 3% and 2% respectively of the choking accidents. Items that are reported from the choking accident but not in the mouthing studies are categorized as “piece of ceramic/vase/plate.

Table 16: Article sub-categories and mouthing frequency for children in the ages 1 months–5 years according to the DTI report Appendix G (DTI 2002)

Sub-categories of articles	**Current restriction including lead for this sub-category of articles**	**Mouthing frequency, no of items mouthed by children in the studied group**	**Mouthing frequency, share of total mouthing time in the category "Other objects", %**
Clothes	none	**180**	**11.1**
Shoes	none	**36**	**2,2**
Accessories	none	**31**	**1.9**
Stationery (non paper)	none	**99**	**6.1**
Interior decorations	none	122	7.5
Sports and leisure	none	35	2.2
Childcare articles*	none	**10**	**0.6**
Total for further assessment in the annex XV report		*(513)*	*(22%)*
T-shirts	none	25	1.5
Other – keys	none	9	0.6
Paper (part of stationery)	none	87	5.4
Other not assessed	none	175	10.8
Other Miscellaneous	Not defined	56	3.5
Construction details	National regulations	33	2.0
Jewellery	REACH annex XVII e 63	20	1.2
Kitchenware	Food contact material framework regulations	218	13.4
Packaging materials	Packaging directive	195	12.0
Electrical	RoHS	121	7.5
Hygiene articles	Cosmetics regulation	138	8.5
Natural objects (stones, flowers etc)	Not relevant	32	2.0

TOTAL		**1 622**	**100**

*) If not reported in any other subcategory inside or outside the scope of the proposal.

Overall exposure of children and availability of lead in the mouthed articles

The assessment of this restriction report was initiated by reports in journals and the RAPEX list on findings of lead in consumer articles like children’s clothes, shoes and bags. (Rapex 2012; Testfakta 2011; CEH 2012) Lead in articles poses a risk only if the release of lead ions and the frequency of exposure in combination are high enough. The expected mouthing time was available from data presented above. All articles in the various sub-categories are not expected to contain lead, only a limited share of the articles on the market. Thus the lead exposure of a child is a combination of mouthing time, share of articles containing lead and lead concentration in the mouthed article.

Even assuming the total exposure to lead follow the relationship between mouthing time, market share of articles containing lead and average lead content, the impact is not evenly distributed between children. Articles with lead content can be assumed to be randomly present in some homes, but not in others. This will be further assessed in Section B.10.1.1.2.

Lead is most often not present in all parts of assembled articles, but rather in certain parts, e.g. buttons, zipper flaps, sewn or printed decorations or in the basic material of the article. In several cases lead has been found in more than one material during analyses of the same article. One example is a raincoat with lead findings in both plastic surfaces of the buttons and in the textile material. Another example is a belt where lead was discovered both in the metallic buckle and in the fake leather material of the belt. According to the reported data on market share of articles containing lead, Table 17 show a market share of 11,3% for articles with a lead content above 500 ppm in any part. Including articles with a lead content below 500 ppm in the total market share, would result in a higher share. Such articles contribute to children's total exposure to lead, but have been omitted in order to simplify the calculations in the assessment. On the other hand a child can put a lead-free part of a lead-containing article in its mouths. It is impossible to make an exact quantification of these two uncertainties, but they have been highlighted in a sensitivity analysis in Section B 10.1.1.2..

There is a proportionality in the calculations of costs and benefits as the market share of articles containing lead is a parameter in all specific parts of the cost benefit analysis. It is therefore not expected to be meaningful to improve the market share data if there are requests for further improvements in the evaluation of restriction options.

In section B.2. it was indicated that the concentration of lead in the identified categories of consumer articles has an average above 10 000 ppm (1%, only test results 500 ppm or higher were included).

Published data on lead content in different articles indicated that the lead may be present in consumer articles and could thus be a risk for mouthing children. Additional data on availability of lead in articles was received from other MSCA during the consultation periods. Reports to both the European RAPEX and recalls by the U.S. Consumer Product Safety Commission have been studied to identify subcategories that are likely to contain lead in relevant concentrations.

To confirm reported lead findings, the Swedish CA has carried out own tests of various articles in the sub-categories identified in Table 17. Examples of details containing lead that were found in the tests are:

- Accessories – Key rings (lead in both metal and colored parts)
- Accessories – Bags, purses and cases (lead in both colored polymer materials and metal details such as buckles)
- Clothes (lead in metal buttons, zippers, rivets etc., plastic buttons*, textile and polymer materials)
- Interior decorations** (lead in both metal parts and polymers)
- Stationery (lead in metal parts)
- Sports and leisure (lead in metal parts; in polymers only content below 500 ppm)
- Keys (lead in alloy)

*) Not clear whether lead was added as a stabiliser to the polymer or as a pigment on the surface of some buttons and zipper flaps.

**) Christmas decorations and plastic flowers were tested.

It should be noted that metallic lead was not identified in the mouthed articles in the DTI report (DTI, 2002), despite its current usage in e.g. weights. This does not mean that there is no risk associated with the use of lead in such articles. There are several reports available from the health care sector regarding children having swallowed pieces of lead, e.g. fishing sinkers (Foltran, 2012).

The test results have been used to determine both the market share of articles that contain lead and the concentration of lead in the articles. Test results below 500 ppm (0.05%) have been regarded as lead free and are included neither in the calculation of the average market share, nor the average lead concentration. The limit of 500 ppm chosen in the assessment does not reflect the detection limit, which is around 20 mg/kg, as described in section E.2.1.2.2. The limit was chosen in order to get comparable figures for lead content and market shares of lead containing articles for the subsequent assessment.

A summary of all test results, both from external testing and own testing, can be found in Table 17. More information regarding the test series carried out by the Swedish Chemicals agency is documented in Appendix 4. The average market share of articles containing lead was found to be 11,3% and the average lead content about 11,000 ppm (1.1%). For further assessments a market share of 10% and a lead content of 1% have been chosen with the aim to not overestimate the exposure of lead to children.

The average market share and average lead content of the tested articles were calculated from data given in Table 17 using the following formulas

Weighted average market share: $\frac{\sum_i \frac{Bi}{Ai} * Di}{\sum_i Di}$

Weighted average lead content: $\frac{\sum_i Ci * Bi * Ei}{\sum_i Bi * Ei}$

A substitution of lead in keys seems hard to obtain at present, due to technical difficulties. Thus the data for keys will in some parts of the assessment be treated separately. Test results from the Swedish CA show a market share of 67% and a lead content of 0,6% in the examined keys. Information from stakeholders indicate that the lead content in keys normally is higher than 0.6%. Functional use of lead in keys is reported by the European Cupper Institute to range between. Assa Abloy has reported a lead content of 1.5% in keys, while a value from 1.5-2.5% is reported in the literature (Kondrashov, 2005; Burnett, 2013). No literature value of the market share of keys with/without lead has been found. For the assessment **a market share of 67% and a**

lead content of 1.5 % have been chosen for keys, when evaluating the total risk reduction capacity (cf. section E.2.1.1.1 and E.2.1.2.1 for the respective restriction options).

Table 17: Summary of tests performed by Swedish CA and published by other organisation.

Only test results 500 ppm or higher reported. Weighted average market share: 11,3%. Weighted average lead content: 11 000 ppm = 1.1%.

Article sub-category	Article group	Geographic region	Total no of tested items [A]	Number of lead findings [B]	Market share articles containing lead, %	Minimum lead conc ppm	Maximum lead conc ppm	Average lead conc ppm [C]	Weight for calculation of the market share (0-100) [D]	Weight for calculation of the lead content (0-100) [E]	Ref.
Clothes	Children's rainwear * Buttons, zipper pullers	EU	11	1	9%	11 000	11 000	11 000	100	100	Testfakta 2011
Clothes	Children's rainwear Button	EU	12	1	8%	2 100	2 100	2 100	100	100	Testfakta 2012
Clothes	Bibs (child care articles)	US	n.d.	5	-	-	>600		0	0	Cox, 2007
Shoes	Shoes, Plastic	World	27	3	11%	915	2 220	1488	10	10	SNF 2009
Accessories	Handbags , material	US	300	42	14%	550	58 700	11 840	50	50	CEH 2012
Accessories	Handbags	Sweden	10	3	-	2 400	23 000	9 800	0	100	Testfakta2012

Article sub-category	**Article group**	**Geographic region**	**Total no of tested items [A]**	**Number of lead findings [B]**	**Market share articles containing lead, %**	**Minimum lead conc ppm**	**Maximum lead conc ppm**	**Average lead conc ppm [C]**	**Weight for calculation of the market share (0-100) [D]**	**Weight for calculation of the lead content (0-100) [E]**	**Ref.**
Sports & Leisure	Pool cue chalk	US	23	3	13%	-	7 000	-	10	0	Goldberg 2009
Sports & Leisure	Dog accessories	US	n.d.	6	-	-	>600		0	0	Cox, 2008
Clothes	Clothes	Sweden	8	3	38%	N.A.	N.A.	N.A.	10	0	Jegrelius 2011
Accessories	Accessories	Sweden	6	1	17%	N.A.	N.A.	N.A.	10	0	Jegrelius 2011
All	Consumer products in the US **	US	8 000	800	10%		N.A.		10	0	Goldberg 2009
Clothes	Belts, material	EU	9	3		1573	3024	1231	0	100	own
Clothes	Belts, metal details	EU	9	3	33%	1392	17200	7398	100	100	own
Clothes	Children’s clothes, metal details	EU	22	2	9%	639	6200	3420	10	100	own
Clothes	Children’s clothes, material	EU	4	2	50%	940	4822	2881	100	100	own
Clothes	Adults’ clothes, metal	Sweden	21	0	0%				100	100	own

Article sub-category	**Article group**	**Geographic region**	**Total no of tested items [A]**	**Number of lead findings [B]**	**Market share articles containing lead, %**	**Minimum lead conc ppm**	**Maximum lead conc ppm**	**Average lead conc ppm [C]**	**Weight for calculation of the market share (0-100) [D]**	**Weight for calculation of the lead content (0-100) [E]**	**Ref.**
	details										
Accessories	Bags and cases, material	Sweden	11	3	27%	632	2 386	2 128	10	100	own
Accessories	Reflective bracelets, Polymer	Sweden	20	6	30%	601	16 614	4151	100	100	own
Accessories	Wallets, material	EU	28	5		1202	1926	1395	0	100	own
Accessories	Wallets, metal details	EU	28	0	0%				100	100	own
Accessories	Key rings	EU	26	4	15%	7312	160 000	50028	20	100	own
Stationery	Pens/pencils	Sweden	23	5	22%	1 809	24 000	9846	10	100	own
Stationery	Other stationery	Sweden	29	2	7%	755	11 300	6028	100	100	own
Interior decorations	Christmas decorations	UK	14	6	43%	731	387 000	45489	50	100	own
Other –	Keys	Sweden	51	34	67%	776	11 900	6006	100	100	own

Article sub-category	Article group	Geographic region	Total no of tested items [A]	Number of lead findings [B]	Market share articles containing lead, %	Minimum lead conc ppm	Maximum lead conc ppm	Average lead conc ppm [C]	Weight for calculation of the market share (0-100) [D]	Weight for calculation of the lead content (0-100) [E]	Ref.
keys											

* Another 4 findings >100 ppm ** Mouthable articles with lead at levels exceeding 300 ppm

“own” denotes tests made by the Swedish CA in course of the development of this dossier

The reliability of a market share of over 10% of articles containing lead in the identified sub-categories has been discussed. Only test series were articles were expected to give an adequate representation of the market have been used to calculate the weighted average. In some cases articles have been collected because they were all suspected to contain lead, e.g. the purchase of 30 wallets in red and yellow colours. Such tests results have not been included in any evaluation of a market share. Still the weighted average value of the market share of articles containing lead (in the selected sub-categories) from the remaining test series is higher than 10%. It could also be discussed if it is relevant to include test results from the US, e.g. 8000 items reported by Goldberg. All overseas test results are given a lower weight in averaging. The final outcome if they were to be removed would be even higher than 11,3%. Regarding the test of handbags from the US, it was also checked and confirmed that several tested brands are available on the European market.

The number of items in each group of articles may seem to be low. Professional statisticians have been consulted for discussions about sampling methods. Their advice was that 25-30 items in one group are enough for the statistical evaluation, if the origin of the samples is chosen from sources that represent the market. Purchased articles have therefore been chosen to represent different market segments with regard to company size, shop size, shop location, internet stores, country of purchase, and price range. The eastern parts of EU are however underrepresented in the material both for tests performed by the Swedish CA and for reported tests.

Well over 60% of all buttons and zippers used in the world are produced in a very limited part of China, in a town named Qiaotou, where purchasers can choose their products amongst a plethora of articles and companies (Watts, 2005). Even if we the efforts to spread the purchases of articles, whose small metal parts have been analysed, over a larger geographical area, the majority of the parts would still have originated from the same region.

Some additional data is available in Appendix 3. Tests performed by the Swedish CA are further described in Appendix 4.

Lead that is used in polymer materials is often stated to be unavailable for human exposure. Some random samples of articles made from polymer materials and analysed for lead by an XRF instrument was sent for migration analysis by the Swedish CA. The test results showed that there was a migration of lead from the tested samples of polymers with an identified content of lead inside, see Appendix 4. Some of the materials had a lead migration that exceeded the migration limit of lead in the Toys directive. Those materials were samples from accessories like bags, wallets and belts. There are also medical reports indicating that lead substances in polymers migrate when people misuse them by chewing (Franco 1994). Migration studies received from the stakeholder consultation confirm that there is a migration of lead ions from both metal and polymeric materials, although none of the reports were covering a situation that could be compared to the mouthing behaviour.

B.9.3.2 Exposure estimation

B.9.3.2.1 Workers exposure

Not relevant for this proposal.

B.9.3.2.2 Consumers exposure

There are two different oral exposure scenarios for consumers in regard to these consumer products where consumers can come into contact with lead. Scenario one is repeated chronic exposure of small children from mouthing lead containing items (such as a button, zipper flap, print on clothing etc.). For the assessment of this potential exposure, the following information and assumptions have been used:

- The sensitive subpopulation is small children likely to mouth items with brains still developing.
- The daily mouthing time for different types of consumer products has been based on three published studies.
- Information on lead content in different consumer products (e.g. key rings, buttons, zippers, pens, bags, wallets and raingear) comes from analyses performed by the Swedish CA and other published data on the occurrence of lead in consumer products.
- A migration rate of 0.7 µg/h/cm^2/(% lead in product), based on an assessment of migration of lead from jewellery made by the RAC (2011).

The data and the assumptions used are further described below.

Scenario two is repeated exposure of children from hand to mouth behaviour, caused by handling consumer products containing lead. However, although contamination of hands with lead from articles is likely to occur, it has not been possible to quantify the resulting oral exposure via the hands. We can only suggest that this additional exposure may exist, but no quantitative risk assessment has been performed for the hand to mouth behaviour.

Target population

Lead exposure from consumer articles can occur in the entire general population, both adults and children. Amongst the general population, children (especially children under the age of 36 months) have been identified as the subpopulation at the highest risk for exposure (RIVM 2008). This risk is due to these children's high frequency of mouthing activities and their hand to mouth behaviour. The mouthing behaviour in children is very common and is part of everyday life. The time spent on mouthing varies amongst children and during the various stages of the child's development.

Daily mouthing time

The daily mouthing times have been assessed based on four studies (Juberg et al., 2001; DTI 2002; RIVM 1998; Greene 2002). These studies all show a total mouthing time up to a few hours per day. However, most mouthing concerns the own body, especially concerning young children.

Additionally, mouthing pacifiers and toys are quite common. In this assessment, the time spent on mouthing body parts, pacifiers or toys, have not been considered. Only the time spent on mouthing "other types" of consumer articles, e.g. parts of clothes, handbag materials, key rings or decorative items has been considered. The estimated amount of time for ages up to 36 months are presented in **Table 18** below. Many estimates are based on observational studies of mouthing behaviour over relative short periods of the day scaled up to give an estimated total mouthing time in min/day. It should be noted that the study observations are representative for the daytime. Short observational periods should not necessarily be seen as a disadvantage. With long periods of observation, it is more likely that the observer's attention falls and the reported results therefore deviate more from the real situation.

Juberg et al. (2001):

This study utilised parental observations with 107 US children aged zero to 18 months old. Mouthing duration and mouthing frequency was recorded by a one day standard diary form. The mouthing time for "other objects" (other objects are items such as clothes etc., that were mouthed that was not a toy or item used for mouthing such as a pacifier or teething ring or body parts such as hands) was nine minutes for all children but 22 minutes for the children that actually displayed mouthing behaviour. For ages 19–36 months of age, 110 children were observed and these children spent two minutes on mouthing other objects. The children that displayed mouthing behaviour within this age group had an average mean of 15 minutes. Only the children that displayed mouthing behaviour have been taken into consideration for the exposure assessment.

This study seems to be well known and is cited with details in many literature reviews, probably due to the high number of participating children. From the information given in the report it has not been possible to verify the relevance of the reported mouthing times. There is information missing regarding the instructions given to the observing parents, rounding principles to the nearest minute, the number of mouthing events. The large share of children with zero minutes mouthing time during the entire day seems not to be realistic. "The observation time was the entire day …". The results have thus not been used in our final assessment.

DTI (2002):

Parental observations were also employed in this study. Both mouthing frequency and mouthing duration was recorded for a total of five hours, split into 20 fifteen minute observation sessions spread over a two week period. A total of 236 children were observed in this study. In this study both the average mean mouthing time and the maximum mouthing time was presented.

RIVM (1998):

Mouthing duration and frequency was recorded by parental observers in this study. The observation lasted for 15 minutes and was repeated ten times over a course of two days. A total of 42 Dutch children were observed in this study.

The results could not be verified since the original study seems not to be possible to get from the organisation where it was made and has not been available elsewhere. The results have thus not been used in the final assessment but are dealt with in the sensitivity analysis in section B.10.1.1.2.

Greene (2002)

A total of 169 children were included in the observational study where professional observers watched and recorded children's mouthing activities for two hours on two days. The exposure time (when the child was not eating or sleeping) was extrapolated from the four hours of mouthing to an average exposure of about ten hours for children under the age of 36 months per day. The mean values presented in the Greene study were obtained by bootstrapping.

The information from these four studies combined provides a base to make an estimate for a realistic exposure mouthing time. The time chosen was the median value of 20 min for the ages 6–24 months and 15 min for children of the ages 24–36 months. Children 0–6 months of age were not considered further due to a decreased range of mobility and ability to frequently come into contact with objects other than toys, pacifiers and teething rings. For a reasonable worst case exposure, the median value of 80 min was chosen for children 6–12 months of age, 65 min for children of the ages 12–24 months and 120 min for children 24–36 months of age for the maximum mouthing times.

Table 18: Summary of published estimates of mouthing times (minutes/day) for "other objects" in young children.

Reference	Description	Age (months)	Mean mouthing time (min/day)	Maximum (min/day)
Juberg et al. (2001)	1 day parental observation Other objects	0–18 (n=46)	22	
		19–36 (n=18)	15	
DTI (2002)	Parental observation Other objects	1–3 (n=9)	5.2	28.2
		3–6 (n=14)	12.5	36.7
		6–9 (n=15)	24.5	70.4
		9–12 (n=17)	16.4	91
		12–15 (n=16)	12.0	63
		15–18 (n=14)	23.0	98
		18–21 (n=16)	19.8	66.4
		21–24 (n=12)	12.9	40.3
		24–36 (n=39)	21.8	178
RIVM (1998)	Parental observation Non toys	3–6	2.8	
		7–12	9.4	
		13–18	7.2	
		17–36	4.0	
Greene (2002)	Parental observation Other Items	3-12 (n=54)	25.3	
		12-24 (n=66)	20.6	
		24-36 (n=49)	16.8	

The range of average mouthing times (min/day) taken from the above studies come out to 9.4-25.3 min/day for children 6-12 months of age, 7.2-23.0 min/day for children 12-24 months of age and 2.0- 21.8 min/day for children 24-36 months of age. The median value for the four studies comes out to 16.8 minutes for children 6-36 months of age. The range of average mouthing times (min/day) taken from the above studies come out to 9.4-25.3 min/day for children 6–12 months of age, 7.2-23.0 min/day for children 12–24 months of age and 4–21.8 min/day for children 24–36 months of age. The median value for the three studies comes out to 16.8 minutes for children 6–36 months of age.

Based on the studies by DTI and RIVM, it is obvious that the youngest children, i.e. babies of age 0–6 months, have very limited mouthing of “other consumer articles”. Due to the limited mobility of children under the age of six months, and taken into consideration the types of objects containing lead for this proposal and the accessibility we have focused on children 6–36 months of age.

Table 19: Summary of realistic and reasonable worst case mouthing time for mouthing “other objects” in young children

Age (Months)	Realistic Mouthing time (min)	Reasonable Worst case Mouthing Time (min)
6–12	20	80
12–24	20	65
24–36	15	120*

The maximum mouthing time was only recorded for the DTI study. The median value from the DTI study was 70.4 minutes for children aged 6–36 months. The median value of the average mouthing times for children aged 6–12 months was 20 (22) minutes and the median of the maximum mouthing times was 80 (80.7) minutes. For children aged 12–24 months of age the median value of the average mouthing times was 20 (19.8) minutes and the median value of the maximum mouthing time was 65 (64.7) minutes. The median value of the average mouthing time for children 24–36 months of age was 15 (15.9) minutes and the maximum median value was 180 (178) minutes. There is a large variation amongst the maximum mouthing time, especially the time for ages 24–36 months; this raises doubt as to the presence of out layers. Information concerning the distribution of the maximum time could not be obtained, due to the lack of information concerning the distributions. Due to this concern the value of 180 min has been substituted with a value of 120 min (*) which is presented in Table 19. This value comes from (ECHA, 2012b). The median value gives a better indication of the maximum amount of time children spent on mouthing other objects than the average of averages taken from different groups. This is due to the differences in group size and distribution amongst the subgroups in this study, a median value is just essentially the middle value and is not dependent on these variations.

Considering the uncertainties in the available data, RAC concluded that 20 min is a realistic daily mouthing time for all three age categories, for articles that potentially contain lead as derived from relevant studies (such ‘as other objects’ in the DTI (2002) study).

Whereas the studies by Green (2002), Juberg et al (2001) and Groot et al (1998)/RIVM (1989) help to evaluate realistic mouthing times the DTI (2002) study also allows evaluation of the realistic worst case mouthing times of articles. The study includes 152 children between 1 and 36 months of age and determined mouthing times for “other objects” (mouthing excluding body parts, pacifiers or toys). The estimated 95th percentile mouthing time is 54 min.

Based on this analysis RAC concluded that a realistic worst case mouthing time of 1 hr is representative for all three age categories. This value is consistent with the mouthing time used in the lead in jewellery opinion and is used in the calculation of the limit value for lead in the relevant consumer articles.

Exposure

The exposure assessment should be based on the quantity of lead that is released by the articles in question into saliva, sweat or gastric acid. The migration rate used in this restriction dossier (0.7 µg/h/cm^2) is taken from the migration data presented by the Danish EPA survey (2008) and re-evaluated by RAC for the background document to RAC and SEAC opinions on lead and its compounds in jewellery (2011). In the Danish EPA survey a clear linear trend correlates lead content and migration at the highest lead content. RAC and SEAC conclusions from the reassessment of this rapport indicated a good correlation between migrations based on surface, and in addition a slope of 0.7 µg/cm^2/h per % was consistently observed. Despite the available information on migration rates at low lead concentrations having a lower accuracy level, based on RAC (2011), the migration rate of 0.7 µg/h/cm^2/(% lead content) has been used for the exposure assessment.

Lead exposure (µg/kg bw/day) for a realistic case and for a reasonable worst case can be estimated by using the median times for these cases and for the corresponding age groups. The lead exposure can also be calculated for different lead contents. In the **Error! Reference source not found.** lead exposure was calculated for lead contents 0.05–6%, this provides us with information on the changes in lead exposure for the different lead contents and also for different mouthing episodes.

Table 20: Estimated lead exposure (µg/kg bw/day) in young children associated with mouthing articles.

Age Weight Average mouthing time Max. mouthing time	Lead content (%)	Lead exposure (µg/kg bw/day)	
		Realistic case	Reasonable worst case
6-12 months, 9.2 kg	0.05	0.01	0.06
	0.1	0.026	0.1
20 min	1	0.26	1
	3	0.8	3.1
80 min	6	1.5	6.2
12-24 months, 11.4 kg	0.05	0.01	0.04
	0.1	0.02	0.07
20 min	1	0.2	0.7
	3	0.6	2
65 min	6	1.2	4
24-36 months, 13.8 kg	0.05	0.008	0.08
	0.1	0.015	0.15

	1	0.15	1.5
15 min	3	0.4	4.6
120 min	6	0.8	9

The exposure was calculated by using the following formula:
Lead exposure (µg/kg bw/day) = (Surface (cm^2) × mouthing time (h) × migration rate (µg/h/cm^2/% lead) / body weight (kg)

Migration rate is 0.7 µg/h/cm^2/%lead; this value is taken from the background document from RAC and SEAC opinions on a restriction proposal on lead and its compounds in jewellery (2011).

Surface of items in contact with mouth has been set at 10 cm^2 as this is the value proposed by RIVM (2002, 2008). This surface correlates to the surface that can be placed in a child's mouth.

The weight values of children at different ages was taken from Existing default values and recommendations for exposure assessment (Norden, 2011).

The uncertainties surrounding the exposure assessment are caused by certain assumptions. The migration rate is calculated based on studies on metallic jewellery, so it seems relevant for articles like key rings. It is not clear how representative this value is for other types of materials, such as polymeric materials or lead pigment but the few migration studies performed by us indicate that the migration rate for non-metallic materials might be higher than the assumed migration rate of 0.7 µg/h/cm^2/% (Appendix 4). The migration rate in the saliva is extrapolated from a migration rate estimated in sweat and the method used to measure the migration rate contains biases (SCHER (2010)). In addition the migration rates used for the calculations are based on 4 h migration values and therefore may in fact be an underestimation if most lead migration occurs during the initial phase of the migration testing. There are also uncertainties concerning the surface default value of 10 cm^2, depending on the particular consumer object in question for example buttons and zipper flaps are smaller than this size and would in turn create an overestimation of exposure due to size. However due to the differences in size and shape of the consumer objects such a key or key chain a value of 10 cm^2 would be valid and in some other cases objects such as the surface of a handbag/wallet underestimate of surface.

The exposure potential of consumer objects containing lead (0.05 to 6 %) for children 6-12 months of age for a realistic exposure is 0.01 µg/kg bw/day to 1.5 µg/kg bw/day and for a reasonable worst exposure 0.06 µg/kg bw/day to 6.2 µg/kg bw/day. The exposure potential for children aged 12-24 months mouthing at objects with a lead content of 0.05 to 6% is 0.01–1.2 µg/kg bw/day and 0.04–4 µg/kg bw/day for the realistic and worst case exposure respectively. For children aged 24–36 months the calculated exposure potential for a realistic case is 0.008–0.8 µg/kg bw/day and for the reasonable worst case 0.08–9 µg/kg bw/day.

Hand to mouth activity

Exposure to lead due to hand to mouth activity can occur when lead is present on the hands. A possible scenario resulting in this type of exposure is when a child handles an object containing lead and the lead rubs off the object onto the hands (through sweat) and is ingested by hand to mouth activity creating an oral exposure. The Center for Environmental Health (CEH) made the following statement concerning hand to mouth activity in conjunction to lead present in handbags 2012: “We do allege that lead can come off of vinyl through touching, and we did wipe testing of a few purses at the early stages of our work. Unfortunately the test data is confidential (as part of our lawsuits), but the tests did show that lead can come off at levels above the state safety standard (0.5 micrograms of lead per day).” Exposure from hand to mouth does occur even from materials such as vinyl; however we are unable to quantify this exposure and thus must concentrate our efforts to quantify oral exposure as a consequence of mouthing behaviour.

In contrast, direct dermal exposure is considered negligible since dermal absorption of lead is very low (0.1%).

B 9.3.2.3 Indirect exposure of humans via the environment

As indicated in Table 15, food is likely to be the most important source of lead. EFSA has assessed the background exposure of 36 months old children to quite considerable (1.1-5.5 µg/kg/day), with some minor additional exposure from soil and dust, outdoor air, and environmental tobacco smoke.

B.9.3.2.4 Environmental exposure

Not relevant for this proposal.

B.9.4 Other sources (for example natural sources, unintentional releases)

Not relevant for this proposal.

B.9.5 Overall environmental exposure assessment

Not relevant for this proposal.

B.9.6 Combined human exposure assessment

Not relevant for this proposal.

B.10. Risk characterization

B.10.1 Exposure to consumer objects containing lead

B.10.1.1 Human health

B.10.1.1.1 Workers

Not relevant for this proposal.

B.10.1.1.2 Consumers

In section B.9.3.2.2, it was previously described that two different scenarios have been identified. These scenarios are hand-to-mouth (chronic exposure), and mouthing (also chronic exposure) of lead containing articles. However, only for mouthing scenario, there is a quantitative exposure assessment and risk characterization.

The lead background exposure for children taken from the EFSA report (2010) and presented in section B.4.11.2 (1.3 to 6.4 µg/kg bw/day) exceeds the BMDL of 0.5µg

Pb/kg bw/day. Therefore, any additional lead exposure beyond the background will contribute to an increase of risk. EFSA (2010) has argued that the highest additional lead exposure via single sources to ensure no appreciable risk is 0.05 µg/kg bw/day. This value was endorsed by RAC (2011), and is used in this dossier as a relevant DMEL for lead exposure via consumer articles.

Tolerable lead content in articles

Since no known threshold has been found for the reduction in IQ scores as a result from lead exposure in children a tolerable lead content for consumer articles has been calculated. To preform the calculations the daily realistic mouthing times were used for the three different age groups of children. In addition to this information the weight in kg for the different ages groups were used and the migration rate of 0.7 µg/cm^2/h per % lead provides the basis for the calculation. These calculations will show the lead content that will cause a lead exposure of 0.05 µg/kg bw/day. By that follows, that at higher lead contents, the lead exposure will exceed the DMEL of 0.05 µg/kg bw/day.

For children aged 6-12 months, the calculated tolerable lead content % is 0.2 (0.05 µg/kg bw × 9.2kg/ (0.7 µg/cm^2 h% × 10 cm^2 × 20 min) = 0.2%).

For children 12-24 months of age, the calculated tolerable lead content % is 0.2 (0.05 µg/kg bw × 11.4kg/ (0.7 µg/cm^2 h% × 10 cm^2 × 20 min) =0.24%).

For children aged 24-36 months, the calculated tolerable lead content % is 0.4 (0.05 µg/kg bw × 13.8kg/ (0.7 µg/cm^2 h% × 10 cm^2 × 15 min) = 0.39%).

A calculated tolerable exposure for a reasonable worst case mouthing time at an exposure value of 0.05 µg/kg bw/day together with a migration rate of 0.7 µg/cm^2/h per % lead gives a calculated tolerable lead content in %.

For children aged 6-12 months, the calculated tolerable lead content % is 0.05 (0.05 µg/kg bw × 9.2kg/ (0.7 µg/cm^2 h% × 10 cm^2 × 80 min) = **0.049%**).

For children 12-24 months of age, the calculated tolerable lead content % is 0.08 (0.05 µg/kg bw × 11.4kg/ (0.7 µg/cm^2 h% × 10 cm^2 × 65 min) = **0.075%**).

For children aged 24-36 months, the calculated tolerable lead content % is 0.03 (0.05 µg/kg bw × 13.8kg/ (0.7 µg/cm^2 h% × 10 cm^2 × 120 min) = **0.049%**).

The calculations show that for a daily realistic exposure that the tolerable lead content in articles is 0.2% (for children aged 6-12 months), and for the reasonable worst case daily exposure the tolerable lead content is 0.05% (for children aged 6-12 and 24-36 months). The differences are explained by a 4-fold longer daily mouthing time on consumer articles in the worst case scenario as compared to the realistic scenario.

This is the basis for the proposed maximum lead content of 0.05% in this restriction proposal.

During the public consultation the European Copper Institute presented new migration rate studies based on work by the Chilenian Mining & Metallurgy Research Center. To support their request for a derogation for brass alloys containing lead, migration rates of 3 alloys with different lead content were determined. Based on their analysis (which assumed a 20 min mouthing time) a content limit of 1.7% was proposed by the consultee. Evaluation of these studies indicated the methodology, including using standard discs of material, was plausible. The results are given in the following Table:

Table 1: Lead migration data of 3 samples of alloys of different lead contents normalized

to 1 hr incubation (mouthing) time and 1 cm^2 surface area (2nd column). The 3rd column indicates the lead concentration, which leads to a migration of 0.05 µg/cm^2 per hour.

Sample	Pb content % (average)	Migration rates µg/cm^2 per hr	Pb content % leading to 0.05 µg/cm^2 per hr
M57	0.1-0.2 (0.15)	0.041	0.18
Z45	1.7-2.2 (1.95)	0.173	0.56
Z33	3.1-3.5 (3.3)	0.243	0.68

Since the average lead concentration in the 3 alloy samples, which releases 0.05 µg/cm^2 per hr (4th column), was 0.47%, it was proposed that a tolerable Pb content in such material of 0.5%. The RAC considered it appropriate to use a 1 hour mouthing time (reasonable worst case mouthing time) for this evaluation, as with the calculation of the 'general' limit value of 0.05%, and did not agree with the industry's proposal to use a mouthing time of 20 min (realistic mouthing time), which would result in a concentration limit of about 1.5%.

Migration Limit

The original proposal from the Dossier Submitter targets lead content, whereas the actual risk emanates from lead migration. The relationship between content and migration has been questioned, in particular whether it is linear or not, for example in the opinion of RAC and SEAC on lead in jewellery. In their original proposal for that restriction, the French CA (2010) suggested a migration limit, based on the premise that there is no correlation between the lead content of an article and the quantity of lead which can migrate from the same article. This premise was based on a survey made by the Danish EPA (2008). However, when RAC re-evaluated that survey, a linear association was found between lead migration and lead content for the metallic parts of jewellery. RAC also concluded that in the absence of data that the same association could be used for non-metallic parts and therefore the same concentration limit could be used in order to ensure the same level of protection.

Whilst there still is a lack of a validated method for measuring migration which mimics mouthing, there have been developments within industry that would allow a migration limit, to play a part in the conditions of the restriction. Specifically, the data used in determining the higher content limit from brass alloys illustrates these developments. The test used was based on ASTM 5517 'extractability of metals from art materials', amongst others, but used with artificial saliva and a standardised shape and surface treatment of the material with a known lead content, and therefore allowed the determination of lead migration in way that is repeatable and comparable. According to industry this test results in highly repeatable data sets with small observed coefficient of variation (CV) (< 20%) and shows consistent time-dependent release data. The data collected by industry, allowing a lower migration rate from certain articles to be established to the satisfaction of RAC, could be used as an example of how compliance with the proposed migration limit could be demonstrated.

However, even though developments have been made, there would be substantial benefits in agreeing a standardised test method, for example by CEN, where the issues mentioned above could be independently validated.

Migration rate studies detailed in appendix 4 and other relevant information received during the stakeholder consultation, confirm that there is a migration of lead ions from both metal and polymeric materials, although the number of reports is very limited and most covered situations that could be directly compared to exposure via mouthing (i.e. migration in saliva).

In RAC's opinion on lead in jewellery, the migration limit of 0.05 µg/cm^2 per hr was derived from a Danish survey, which showed linearity in the migration of lead from different metal parts of jewellery containing concentrations above at or above 1%. Assuming that below 1% there is also linearity, RAC made the following calculation: Since at 1% the migration rate was 0.7 µg/cm^2 per hour and assuming that a 10 kg child mouths 10 cm^2 for 1 hour, this results in a total exposure of 7 µg or 0.7 µg/kg bwt. Since 0.7 µg/cm^2 per hour results in an exposure of 0.7 µg/kg, a migration limit of 0.05 µg/cm^2 per hour is equivalent to the acceptable exposure of 0.05 µg/kg bw per day from an article.

During public consultation, the migration of lead from polymers was questioned by some stakeholders. In Appendix 4 migration data from 16 samples of polymeric materials containing lead are presented. Six of them showed migration rates that exceeded the toys directive limit value of 90 mg Pb/kg[7]. The migration limit of 90 mg/kg is based on a daily ingestion of 8 mg of the material with a lead content that contributes 10% to the accepted daily intake (CSTEE 2004)[8]. Thus, the data provided in the Background document only indicate that there is a migration of lead from the tested samples. Whether these data support the proposed limit value of 0.05% for non-metallic articles cannot be concluded on the basis of the available information but the fact that lead migrates from the samples has been established. Concerning other than metallic or polymer material, the PC yielded an info from industry that lead migration from crystal material is much lower in the order of 0.08 µg/kg bw/day.

In the absence of any further specific data it seems reasonable to refer to RAC's previous opinion[8] (lead in jewellery) where it was concluded that the limit value of 0.05% for the metallic parts may be sufficient for protecting children from exposure to non-metallic parts.

The Dossier Submitter concluded it is reasonable to include a migration limit in the proposed elements for the legal text of the restriction and RAC agreed to this conclusion. SEAC however, in their Draft Opinion, considers that taking into account that a standard test method mimicking mouthing conditions is not yet available, and also bearing the conclusions made in the context of the restriction proposal concerning lead in jewellery in mind, the restriction should be based on content (w/w). More information is anticipated during the Public Consultation of the SEAC Draft Opinion and the conclusion will be reconsidered in the preparation of the SEAC Final Opinion if necessary.

Lead exposure impact on IQ due to mouthing articles

The estimation of lead exposure's impact on IQ due to mouthing articles containing lead has been calculated. The calculation is based upon the assumption of a linear correlation between lead content and lead migration and it is also based on the estimated IQ impact for a dose response that assumes a reduction of six IQ points at a lead blood concentration increase from 10 to 100 µg/L (EFSA 2010, Jusko et al. 2005). EFSA (2010) described a two step process that requires a description of the dose-response

7 Value is currently under revision.

8 CSTEE (2004). Opinion of CSTEE on the assessment of the bioavalaibility of certain elements in toys. (http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out235_en.pdf)

relationship between IQ and blood lead level, followed by a description of the relationship between lead intake and blood lead levels. In accordance with the conclusion of RAC in the background document for the restriction of lead in jewellery, the dose-response relationship for low-level lead exposures and IQ is derived from the findings of Lanphear et al (2005). The estimated relationship is given in terms of an inverse log-linear model, for the quantitative relationship between IQ score and concurrent blood lead level. This relationship is expressed as the formula: IQ = α – 2.7 log (concurrent B-Pb) + γ confounders. Based on this relationship, average IQ loss per 1 µg/L is estimated at 0.0513 IQ points for blood lead exposures below 100 µg/L (assuming an even distribution of IQ loss in the range below 100 µg/L). This also follows the approach of Gould (2009). This converts to an expected loss of 1 IQ point per 19.48 µg/L blood lead level. Likewise, the DMEL of 0.05 µg/kg bw/day has been calculated to correspond to an IQ loss of 0.1 units.

The calculations below are based on a migration rate of 0.7 µg/kg bw/day/(% lead in the article), and a surface of 10 cm^2 and provide an estimation for the reduction in IQ scores that can be associated with a realistic mouthing exposure and different lead concentrations in the article.

Table 21: Estimated IQ reduction (points) in young children associated with a realistic exposure case for mouthing articles.

Age, Weight, Mouthing time	Lead content (%)	Lead exposure (µg/kg bw/day)	Increase of blood PB level (µg/l)	IQ reduction (points)
6-12 months 7.4 kg 20 min	0.05	0.01	0.24	0.02
	0.1	0.026	0.62	0.05
	1	0.26	6.17	**0.5**
12-24 months 11.4 kg 20 min	0.05	0.01	0.24	0.02
	0.1	0.02	0.48	0.04
	1	0.2	4.8	**0.4**
24-36 months 13.8 kg 15 min	0.05	0.008	0.19	0.016
	0.1	0.015	0.36	0.03
	1	0.15	3.6	**0.3**

The bold numbers in the table show the estimated lead exposure values that exceed an IQ reduction of 0.1 points.

The above table shows that for children 6-36 months of age, 0.1 points of IQ reduction occurs at a lead content of 1 %, for a realistic mouthing exposure (15-20 min). The IQ reduction at a lead content of 1 is higher than 0.1 points and therefore is seen as a risk. These calculations are in agreement with the calculated tolerable lead content of 0.2% for a realistic mouthing exposure.

Table 22: Estimated IQ reduction (points) in young children associated with a reasonable worst case exposure case for mouthing articles.

Age, Weight	Lead content (%)	Lead exposure (µg/kg bw/day)	Increase of blood PB level (µg/l)	IQ reduction (points)
6-12 months 9.2 kg	0.05	0.06	1.44	**0.12**
	0.1	0.1	2.4	**0.2**

80 min	1	1	24	**2**
12-24 months 11.4 kg 65 min	0.05	0.04	0.96	0.08
	0.1	0.07	1.68	**0.14**
	1	0.7	16.8	**1.4**
24-36 months 13.8 kg 120 min	0.05	0.05	1.2	**0.1**
	0.1	0.12	2.4	**0.2**
	1	1.0	24.0	**2.0**

The bold numbers in the table show the estimated lead exposure values that exceed an IQ reduction of 0.1 points.

The Table 22 above shows that for the reasonable worst case exposure, the loss in IQ score will exceed 0.1 IQ units when the lead concentration roughly exceeds 0.05%. This implies that a 0.05% lead content might be a suitable threshold for worst case exposure conditions, as higher concentrations of lead will lead to concern. This is in accordance with the calculated tolerable lead content of 0.03%–0.08%.

Estimation of IQ impact from mouthing objects containing 1% lead for different time periods and at different frequencies

In the analysis of consumer articles, lead has been found in many of them, at an average concentration of roughly 1%. Based on this "average" consumer article, we have below tried to illustrate how different mouthing habits could affect IQ. Thus, in order to assess the consequences of mouthing articles containing 1% lead for different durations and at different frequencies, the impact on IQ scoring has been estimated at this lead content in the consumer articles. The durations chosen are 5 minutes, the realistic mouthing times (15–20 minutes), and the worst-case mouthing times (65–120 minutes). The frequency chosen for this estimation were on a daily, weekly and monthly basis. The impact on IQ at these different conditions is given in the tables below.

IQ impact exceeding 0.1 points are high-lighted below in bold print. Impacts below 0.1 IQ points are considered sufficiently low to ensure no appreciable risk.

Table 23: Mouthing time 5 minutes

Age, Weight	Lead content (%)	Exposure duration		
		Daily	Weekly	Monthly
6–12 months, 9.2 kg	1	**0.13 points**	0.02 points	0.005 points
12–24 months, 11.4 kg	1	**0.1 points**	0.014 points	0.004 points
24–36 months, 13.8 kg	1	0.09 points	0.01 points	0.003 points

Table 24: Mouthing time 4-9 minutes

Age, Weight	Lead content (%)	Exposure duration		
		Daily	Weekly	Monthly

6–12 months, 9.2 kg (9 min)	1	**0.23 points**	0.03 points	0.008 points
12–24 months, 11.4 kg (7 min)	1	**0.14 points**	0.02 points	0.005 points
24–36 months, 13.8 kg (4 min)	1	0.07 points	0.01 points	0.002 points

Table 25: Mouthing time realistic case (15-20 minutes)

Age, Weight	Lead content (%)	Exposure duration		
		Daily	Weekly	Monthly
6–12 months, 9.2 kg	1	**0.5 points**	0.07 points	0.02 points
12–24 months, 11.4 kg	1	**0.4 points**	0.06 points	0.014 points
24–36 months, 13.8 kg	1	**0.3 points**	0.04 points	0.01 points

Table 26: Mouthing time reasonable worst case (80, 65, 120 minutes for 6-12, 12-24, and 24-36 months old children respectively)

Age, Weight	Lead content (%)	Exposure duration		
		Daily	Weekly	Monthly
6–12 months, 9.2 kg	1	**2 points**	**0.29 points**	0.07 points
12–24 months, 11.4 kg	1	**1.4 points**	**0.2 points**	0.05 points
24–36 months, 13.8 kg	1	**2.0 points**	**0.29 points**	0.07 points

The Table 23 above shows that a daily exposure to an object containing 1% lead could lead to an IQ reduction ≥ 0.1 points from a five minute mouthing time for children 6-24 months of age. However exposure to lead at 1% on a weekly or monthly basis for five minutes does not induce an IQ reduction of concern. Impacts on IQ following a twenty minute mouthing exposure to a 1% containing lead object are greater than 0.1 points for all the children aged 6-36 months if it occurs on a daily basis, but not for a weekly or monthly basis (**Table 25**).

Table 26 shows that for the reasonable worst case mouthing durations, both daily and weekly mouthing episodes lead to IQ losses much greater than 0.1 IQ points in all age categories. According to these estimations, also monthly mouthing episodes could affect the IQ, but not with more than 0.1 IQ units.

Based on these calculations, it can be concluded that a lead content of 1%, which seems to be common in consumer articles, can result in unacceptable effects on the IQ of children already after very short mouthing episodes (5 minutes), **if** it occurs on a daily basis. Since many articles have been found to contain this concentration of lead, short daily mouthing of different types of consumer articles may result in unacceptable lead exposure. For children with more extreme mouthing habits (>1 hour episodes), effects on IQ can be foreseen even if the episodes only occur on a weekly basis.

Total number of children

The total number of children in the EU in 2011 has been calculated using Eurostat data. An adjustment of the data was made to get a representative figure of the age group from 6 – 36 months. Data extracted from Eurostat is presented in Table 27. Since children 0-6 months are excluded from the exposure assessment, only 50% of the children in the youngest age group are included in the total. 50% of 5,341,475 is 2,670,738. The total number of children aged 6–36 months in the EU was in 2011 13,437,880.

Table 27: Number of children in EU aged 6-36 months 1 January 2011,

Data is from Eurostat, Database Table: Population on 1 January by age and sex [demo_pjan], Geographic area: European Union (27 countries); Extracted on 19.10.2012; Last update (of data on day of extraction) 05.10.2012

Age of children	No of children reported by Eurostat	No of children in ages 6-36 months
Less than 1 year	5,341,475	2,670,738 *
12-24 months	5,383,155	5,383,155
24-36 months	5,383,987	5,383,987
	16,108,617	**13,437,880**

*) The number of children in ages 6-12 months is approximated by half the number of children up to 1 year

Modelling of the aggregate exposure of children in the EU

Articles containing lead can be assumed to be randomly present in some homes, but not in others. Thus, a child mouthing an article containing lead one day is more likely to mouth the same article the next day, compared to a child who has a similar lead-free article in its home.

In an extreme scenario, some children will mouth only lead containing articles, while other children never are exposed to leaded articles. Input data for mouthing frequency and market share of articles containing more than 500 ppm lead were derived in section B.9.3.1. Keys are calculated separately due to a possible need for derogation.

In reality the articles that contain lead are more evenly distributed between children, a larger number of children will be exposed for a shorter time. Still, an individual article can only be available in one home and thus the 10% of articles containing lead should not be distributed completely evenly throughout the mouthing time for all children. The use of a certain number of children is a technical solution to perform the calculations. If the reasoning above is differentiated into smaller age groups and mouthing on both keys and other articles is regarded, the total lead exposure can be derived as in the following table. It was taken into account that keys are expected to contain 1,5% lead and not 1%.

Exposure (µg/kg bw, day) x Body weight (kg) x Fictive no of children x 365 (days/year)

Table 28: **Risk to be addressed – total exposure to lead from articles in scope**

mouthing time	mins/day	20	20	20	
mouthing time(hrs)	h/day	0.33	0.33	0.33	
migration	µg/cm^{2}/h /%	0.7	0.7	0.7	
surface	cm^{2}	10	10	10	
lead content	%	1	1	1	
articles with lead	%	22%	67%	10%	
proportion of articles covered by proposal	%	10%	2%	16%	
Number of children (0.5 - 3 years)		13 437 880	13 437 880	13 437 880	total exposure:
exposure		251 781 078.27	115 018 174.39	180 824 592.57	366 799 252.66
risk reduction capacity		69	31	49	
total exposure / year					
	intake factor per IQ loss	1.08	1.08	1.08	
	bw child	11.57	11.57	11.57	
	year' factor	2.5	2.5	2.5	
					total IQ points
loss of IQ point based total exposure / year		22 081.73	10 087.34	15 858.70	32 169.07

This is the realistic scenario with respect to mouthing time. In this scenario, the yearly exposure to lead for children aged 6–36 months is 367 000 000 µg. A worst case scenario would assume a maximum mouthing time from 65 minutes for children aged 12-24 months to 120 minutes for children aged 24–36 months, i.e. a three to eight-fold increase.)

The worst case scenario is calculated on the basis that that an average number of children aged 6-36 months in one cohort is to 5,369,539. The weighted average of IQ-loss in the realistic case is 0.38 and the number of exposed children in the modelled scenario is (22% × 10% + 0.6% × 67% × 1.5) x 5,369,539 = 191,263. Thus this exposure scenario represents a total IQ loss of 191,263 x 0.38= 76,781 units.

Unlike the direct uptake of lead where the exposure can be described with an accumulation from all mouthing occasions over time, the potential IQ loss is proportional to a prolonged increase in the blood lead levels. When people are exposed to lead, part of the lead dose is transferred to and stored in the bones. When the external exposure is interrupted the blood lead levels does not level out at the same rate as it is secreted from the body as lead is released from the bones into the blood again.

To determine the effects on a population level a cohort of children with exposure over 2.5 years was chosen. Data from Table 25 is used to calculate the potential total IQ-loss.

The yearly exposure to lead from the articles targeted in this report is 367 g. This corresponds to a potential IQ loss of 32000 IQ units per cohort of children in ages 6-36 months

Sensitivity analysis of the exposure scenario

The chosen model of the aggregate exposure scenario is based on a set of input parameters, including several developed in the comprehensive analysis by expert groups. The reliability of these parameters should be considered as high. Other parameters, like the market share of articles containing lead are specific for this assessment. A sensitivity analysis on some of the input parameters was made. The results are presented in **Table 29**.

Table 29: Sensitivity analysis of input parameters in the exposure scenario

Set of parameters	**Total yearly exposure, µg**	**Potential IQ loss**
Central estimate, realistic mouthing time. Mouthing time 20-20-15 minutes Market share of articles containing >500 ppm lead: 10%	**366 799 252**	**approx 32000**
Low Exposure time Mouthing time 9-7-4 minutes		approx 10000
Low market share Market share of articles containing >500 ppm lead: 5%	240 908	approx 22000
High daily lead intake per IQ loss Ratio daily lead intake per unit IQ loss: 1.22 µg/kg bw, day	366 799	32 000 (including keys, exl uding keys: 22 000)

In the background document for lead in jewellery (ECHA, 2011) a ratio between daily lead intake and unit IQ loss of 1.23 µg/kg bw, day was used in the socioeconomic analysis for assessment of a central estimate. That figure is based on the Lanphear dose-response relationship between blood lead levels and IQ deficits in the entire range up to 100 µg/L and derived from a modelled value of a blood lead level at 57 µg/L before exposure to jewellery containing lead.

According to EFSA (EFSA 2010, EFSA 2013) the $BMDL_{01}$ for developmental neurotoxicity is received at a dietary intake value of 0.5 µg/kg bw, day which corresponds to a blood lead level of 12 µg/L and a IQ loss of 1 unit. Measured blood lead levels in European children are in the range 10-40 µg/L with an average value close to 20 µg/L (Figure 2). The value used for evaluation of the impacts on IQ deficits for lead in jewellery, derived from model calculations, is thus outside the range of the measured values that is published (Figure 3). Although it is relevant to perform a sensitivity analysis, the upper values used for lead in jewellery seem to be outside the range of today´s realistic values. Values of the potential total IQ loss based on the ratio between daily lead intake and unit IQ loss of 1.22 (see section) µg/kg bw, day is however reported in **Table 29** for comparison.

The Dossier Submitter and RAC use a daily intake factor of 0.5 µg/kg bw per day as the intake factor for loss of 1 IQ point. The factor is based on the work done by EFSA (2013). Whilst this intake factor is appropriate for deriving a risk assessment based limit value for the restriction, it requires adjustment for the purposes of socioeconomic impact assessment. In accordance with the procedure outlined in the Lead in jewellery restriction, SEAC use a daily intake factor for loss of 1 IQ point of 1.22 µg/kg bw per day (range 1.08 1.23 µg/kg bw per day).

The exposure value of 1.22 µg/kg bw per day is a median value calculated using the IEUBK model (as in the lead in jewellery restriction) using a 1.1 µg/kg bw/day lower bound daily dietary intake for an average child consumer of 1-3 years. These parameters are based on EFSA (2013).

No attempt has been made to develop another value for the relationship between dietary intake of lead and IQ deficits at values below 57 mg / L. The aim from the society is to reduce children's blood lead levels further. Without a restriction of lead in the proposed consumer articles, they will over time constitute an increasing share of the children's burden of lead, which further justifies the use of 0.5 µg/kg bw, day as the realistic value for the assessment.

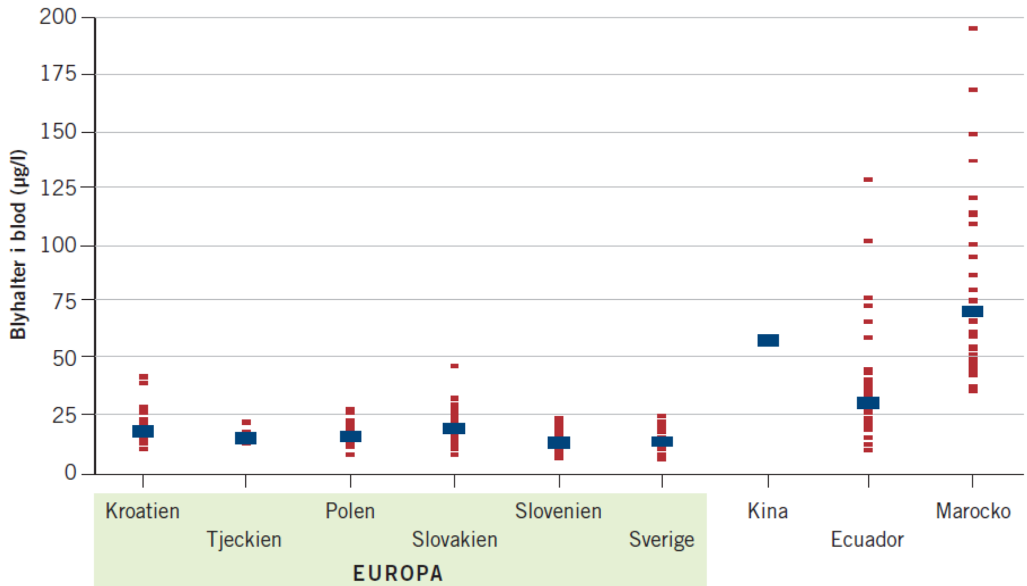

Figure 2, Lead levels in the blood (µg/l, y-axis) of urban children in some European countries, and in some overseas countries.

The levels are much higher for overseas children. (Naturvårdsverket, 2013)

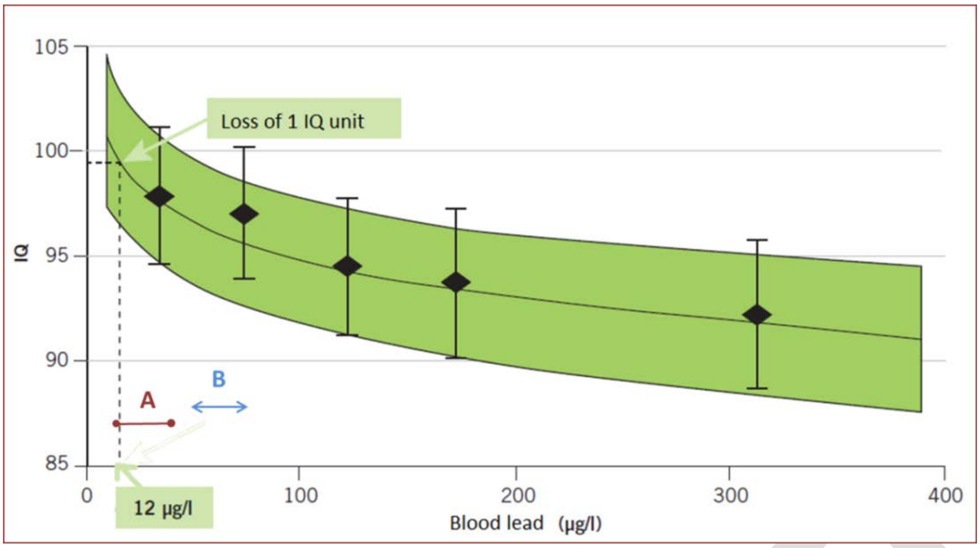

Figure 3, Relationship between the range of measured blood lead levels in children in the EU and the levels used for modeling a daily lead intake for use in the sensitivity analysis.

A: Measured blood lead levels in European children are in the range 10- 45 µg/L, (see Figure 2)

B: The range of blood lead levels where the ratio 1.23 µg/kg bw between daily lead intake and unit IQ loss was derived according to the explanation given in the background document for the restriction of lead in jewellery page 127 (ECHA, 2011).

B.10.1.2 Environment

Not relevant for this proposal.

B.11 Summary on hazard and risk

The aim of the proposed restriction is to minimise children's lead exposure and body burden from mouthing articles containing lead. It has been stressed in several reports that it is very important to minimise the overall lead exposure of children, because of their vulnerable brain development (ATSDR 2007, EFSA 2010, Skerfving et al 2011, and RAC 2011). EFSA has assessed that, on a population level, an exposure of small children to lead at a level of 0.5 µg/kg bw/day will result in a reduction of IQ by 1 unit. They also propose that chronic lead exposure from specific sources should not exceed 0.05 µg/kg bw/day for children aged 6–36 months. This exposure corresponds to an IQ score reduction of 0.1 points. We are in agreement with both EFSA and RAC that this exposure level from specific sources is not acceptable.

The background exposure to lead (via food, water and air; estimated by EFSA to 1–6 µg/kg bw/day) is currently assumed to affect European children and their IQ, and all efforts should be taken to minimise this environmental exposure. Any additional exposure from other sources is therefore likely to contribute negative effects on the brain development of children. However, in contrast to the "background exposure" via food, which is difficult to quickly reduce, exposure from consumer articles is much easier to avoid (and regulate).

The additional exposure to lead from consumer articles may under worst case scenarios (higher lead concentrations, longer mouthing episodes) reach the exposure levels obtained from food, and thus clearly constitute a health risk for children.

Based on three studies on mouthing behaviour of children (Juberg et al., 2001; DTI 2002; RIVM 1998) it can be concluded that small children do mouth the types of articles which has been analysed in this restriction dossier. Realistic mouthing times are 15–20 minutes/day, and they seem quite reliable. For consumer articles containing 1% lead, which is a rather common finding, realistic mouthing times lead to an exposure of approximately 0.2 µg/kg bw/day. This exposure will result in an IQ of 0.4 units, which is not acceptable. Even shorter daily mouthing times (5 minutes) at 1% lead, leads to concern for some age groups.

The data that can be used for assessing the worst case mouthing times is more limited (only the DTI 2002 study). Furthermore, the data is expressed as maximum mouthing times (among 9–39 children per age group) and are more variable between the different age categories (maximum varied between 28–178 minutes). Based on these data, worst case mouthing times of 80, 65, and 180 minutes were calculated for the age groups 6–12, 12–24, and 24–36 months of age, respectively. Since the worst case data is calculated from maximum mouthing times, 65 minutes (as calculated for the 12–24 months old children) is felt as the most appropriate realistic worst case mouthing time. Thus, based on the data for the 12–24 months old children (65 minutes mouthing), lead concentrations above 0.05% leads to IQ losses of >0.1 units.

It is thus proposed that a lead threshold value of 0.05% in consumer articles (that can be mouthed by small children) is appropriate. The calculated tolerable lead content in consumer articles (see section B.10.1.1.2) is supporting this threshold value.

C. Available information on alternatives

As the risk of lead exposure has been known for a long time, several alternatives to lead have been developed, and are available on the market to a reasonable cost. This chapter aims to describe the variety of possibilities for the broad group of consumer articles rather than to scrutinise every possible alternative in every application. For the applications where lead is not added to a material in order to gain a certain property, the alternative is to choose another quality of the material which does not contain lead, or another material altogether.

Information regarding the function of lead in different articles/materials as well as information regarding alternatives has been provided by stakeholders in the stakeholder consultation.

The function of lead in consumer articles

Lead has different functions in different consumer articles; it may act as a pigment in plastics, a lubricant in brass or provide weight in e.g. diving weights. However, in many articles, lead has no function at all, but is present as an impurity in the material. Alternatives to the following applications will be evaluated in this report: metallic lead, additives/impurities in metal alloys, pigments and stabilisers in polymers.

Lead and lead compounds are used in plastics as stabilisers or as pigments. The use as stabilisers is not identified as an important source of lead, as the use has decreased over the years, see **Table 34** and **Table 35** (Vinyl 2010). The use of lead in pigments is however still frequent. The typical lead pigments are white, red or yellow, and are integrated in the plastic.

In alloys, lead may be present as a functioning metal or as an impurity. The most frequently used lead containing alloy is brass. Lead is added to brass in order to increase the workability. The lead also functions as a lubricant, which increases the working years of the equipment. For many uses, it is possible to replace the leaded brass with a lead-free alloy. There are, however, certain uses where a substitution of lead may be more difficult to obtain due to the enhanced workability of leaded brass. One such use is in keys and locks. The industry has aimed to lower the lead content as much as technically possible, and research in the area is continuously being performed.

Metallic lead is used only in specific articles where the density of lead is needed, for example in diving weights. The alternative to lead in these applications is another high density substance or material.

Since lead is used for various functions, the alternatives depend on the original function of the lead compound. In this chapter, the alternative substances are assessed based on the intended function. For each function the most commonly used alternatives are described.

The use of lead in crystal glass is not assessed specifically in this report. According to companies and trade organizations that participated in the stakeholder consultation, there are lead-free alternatives to full lead crystal. However, some stakeholders have stated that the workability of the alternative glasses is limited compared to lead containing crystal. This is especially the case for crystal that is processed manually.

C.1 Identification of potential alternative substances and techniques

Alternatives to metallic lead

Metallic lead has only a limited use in mouthable consumer articles, mainly as weights because of its high density. The alternatives are metallic materials based on other element, for example iron, steel, zinc and bismuth, but also non-metallic materials as concrete.

Alternatives to lead in metal alloys

According to stakeholders consulted, most copper alloys contain lead, either as a functional element or as an impurity. Each alloy has a defined composition and unique characteristics, which means that there are no "lead-free" and "lead-containing" varieties of the same alloy. Which alternative substances that can substitute lead in a specific alloy depend on whether the lead is present as an impurity or as a functioning element in the alloy. In the former case, the substitution of lead involves a replacement of the lead containing alloy with another, lead-free, alloy. In the latter case, the substitution might be more problematic, since the substitute must have certain functions.

In the stakeholder consultation, many of the consulted parties stated that they have already substituted lead in, for example, buttons and zippers by requiring lead-free products from their suppliers.

Lead-free alternatives are being developed mainly for free cutting brass for use in drinking water applications. There are currently no alternatives for leaded nickel silver. Alternatives include brasses containing silicon (up to 0.1% lead) or bismuth (up to 0.25% lead). The producers state that the main problems with these alternatives include higher prices and separate scrap cycles.

Materials that can be used to replace leaded brass include bronze, steel and other lead-free alloys.

Alternatives to lead in pigments

More than 13,000 different pigments are known and most of them are also available on the market. This implies that there should be alternatives to lead based pigments.

Among the available reported alternatives, there are pigments containing cadmium and chromium. Due to the hazards to health and the environment associated with these substances, they are not considered appropriate as substitutes to lead . Such pigments are therefore not evaluated in the following sections, but one cannot completely ignore the possibility that they will appear as a substitute to lead based pigments in imported articles if a restriction of lead is implemented.

Lead based pigments are available in basic colours like white, red and yellow. A selection of pigments in those colours has been evaluated. The selection of red and yellow pigments is based on common pigments reported in the Swedish products register (Swedish Chemicals Agency, 2011). The evaluation should not be regarded as recommendations for any specific use. The intention is merely to show that alternative substances are available, to give an indication of the price levels and to show that the alternatives, to the most part, have less impact on health and the environment, compared to lead.

Alternatives to lead in stabilisers

Calcium/zinc stabilising systems and tin-organic compounds are reported to be the most common substitute to lead stabilisers. Due to the high risk profile for health and the environment for tin-organic compounds, the calcium/zinc systems are preferred, but it is not unlikely that the tin-organic compounds may appear as a substitute to lead in imported articles.

Materials containing substances that are already restricted are not evaluated in this dossier. Restricted substances that may act as substitutes to lead in stabilisers include di-and tri substituted tin stabilisers, which are restricted in articles in concentrations over 0.1% (REACH annex XVII, entry 20) and chromium compounds (REACH Annex XVII, entry 23).

Barium/zinc systems seem to more often be designed for use in e.g. synthetic leather than the calcium/zinc system. Barium compounds are not approved for food contact applications, toys or medical applications, but it is not unreasonable to expect barium to appear in other articles for consumer use as an alternative to lead stabilisers.

C.2 Assessment of alternatives in metallic materials

Lead as the major constituent in a metal is only used in articles where a high weight is requested. Lead may also be present in alloys. Possible alternatives to lead or leaded materials are summarised in Table 30.

Table 30: Alternatives to lead metal or as an additive in brass alloys

Substance	CAS no	Function		
		Weights / Dense articles	Main constituent in alloys	Additive in alloys
Concrete	e.g. 65997-15-1	X		
Tin	**7440-31-5**	X		
Iron	**7439-89-6**	X	X	
Zink	**7440-66-6**	X	X	
Copper	**7440-50-8**	(X)	X	
Bismuth	**7440-69-9**	X		X
Silica	7440-21-3			X

In general, one single alternative metal cannot meet all the possible functions of lead when used in applications where the weight is important as different applications may require different properties from the material. The alternatives have different physical properties; iron is heavy but corrosive, while zinc is corrosion resistant but fragile at high temperatures. Bismuth is heavy and has good processing properties. The different properties of the alternatives can affect the economic feasibility in specific cases, but one should be aware that metallic lead only is used in a minor part of the consumer articles evaluated in this restriction report. If the aim is to replace lead as a weight in consumer articles, iron, zinc or concrete may in most cases have sufficient properties for this function.

As mentioned in section B.2.2, brass is the most common, but not the only alloy that is used in the articles addressed in this restriction report. In section B.2.2 some common brass qualities containing lead were presented. Lead may also be available in other alloys and certain qualities of steel. Lead-free brass is normally defined as a quality with "not more than 0.25 per cent lead content". Special brass qualities with a lead content of 0.05% are defined according to CEN standards. Bronze, steel and other alloys are also available in lead-free qualities – often from the same manufacturers as the lead free brass. They are more commonly available with lead content below 0.05% according to information from the stakeholder consultation. Particularly bismuth and silicon replace lead in the lead free alloys. Federalloy is a patented brand in which lead is completely replaced by bismuth. (federalmetal.com, 2012; concast.com, 2012). This was confirmed in an investigation published by the Swedish EPA (Naturvårdsverket, 2006).

C.2.1 Availability of alternatives in metallic materials

All identified alternatives among the materials are accessible on the market. Details on market volumes reported in REACH registrations are available in Appendix 11.

C.2.2 Human health risks related to alternatives in metallic materials

Information on human health hazards of the alternative metals, silica and concrete is reported in Appendix 12.

C.2.3 Environment risks related to alternatives in metallic materials

Information on environmental classification of the alternative , silica and concrete is reported in Appendix 12. The conclusion is that the suggested alternatives have less severe environmental hazard properties compared to lead.

C.2.4 Technical and economic feasibility of alternatives in metallic materials

Technical feasibility

Silicon and bismuth are alternatives to lead in brass. However, from the stakeholder consultation information was given that when these metals are used in brass alloys, the scraps cannot be mixed with leaded brass scrap because of contamination and safety problems.

The technical feasibility and the economic impact of a substitution of lead were discussed with stakeholders representing manufacturing of clothes, accessories and furniture. There are no technical hindrances for substitution of lead additives in brass. However, some changes in the production process may be needed. Adjustments in the machinery are needed initially because of other properties of metallic shavings from the process, but no new investments will be necessary. There was no information if this makes the process less effective – only that it works differently.

For a manufacturer of, for example, clothes or accessories, a change from alloys with lead to lead-free alloys in metal details does not cause any technical investments. The price difference is reported to be of a marginal value. There can be initial changes for administrative reasons, like multiple article numbers, multiple articles in the warehouse, revision of documents, and residual stocks.

Stakeholders state that the technical features of keys are difficult to achieve with lead-free alloys. There is an on-going work going on in the industry in order to substitute lead, but at present it seem not possible to completely substitute lead from the alloys used for keys. In order to drive innovation for substitution, an exemption with limited validity could be a possibility.

Economic feasibility of alternatives to lead metal

Lead is a relatively cheap metal, which can be used to produce fairly cheap alloys. The main drawback from substituting lead metal to other metals, identified in the background document for lead in jewellery, were negative impacts on the supply cost of alternative metals and consequently on the sale price of jewellery (ECHA 2011). The additional costs for production that could be a result from substituting lead metal would likely to be passed on down the supply chain even for the articles of concern in this dossier. As a result, the sales price of consumer articles containing/manufactured from these alternatives would be slightly higher.

The market price for lead metal is currently around 1.5 EUR/kg, but has varied in the range 0.7-2.2 EUR/kg over the last five years[9] (www.metalprices.com Accessed 2013-05-28.). Alternatives to lead are – with some exceptions (e.g. zinc and steel) – often more costly (**Table 31**). Market prices for copper has during the last five years been in the range 2.5-7.5 EUR/kg, while antimony prices were 3-14 EUR/kg, tin prices were 8-25 EUR/kg, and bismuth prices were 12-25 EUR/kg. Overall, the price difference between lead and some of the most common substitutes have over the last five years been in the range 1-25 EUR/kg. This is an indication of likely substitution costs, in the cases where lead can be directly replaced by an alternative metal.

Substituting lead from alloys where it has a functional property is more problematic, and more costly. An example is free cutting brass (e.g. CuZn39Pb3), where alternatives exist in the form of brass alloys containing silicon or bismuth. The silicon based alloy is – according to stakeholder consultations – around 40% more expensive than the alloy based on lead. Assuming a brass price of 5.3-5.7 EUR/kg (as indicated by www.metalprices.com for brass types C83600, C84400, and C85400 in April 2012 (last available data point, accessed 2013-05-28)), and 40% higher costs for lead-free alternatives, indicate that the alternatives costs 2.1-2.3 EUR/kg more than the lead containing brass. Assuming a lead content of 3% (as in CuZn39Pb3), the substitution cost per kg lead is 70-80 EUR/kg lead. (Wieland, stakeholder consultation)

Substitution of lead in articles has been on-going for some years. Therefore, an increase in purchase prices for substitutes is not to be expected if a restriction was implemented. The cost of raw material is assumed to represent about 30% of the production cost and of the final cost of the article (TemaNord, 1995).

Contact with various stakeholder groups indicate that no price difference is passed down the supply chain. However, there has been conflicting information regarding whether it is economically feasible to completely replace lead in fishing gear.

[9] Prices reported in US$/lb. Converted to EUR/kg using factors 2.2 lb/kg and 0.775 EUR/USD

Table 31: Overview of the cost of alternative metals. Most of the prices assessed below are FOB prices (Free on Board)

Metals/substances:	Price range 2008-2013(EUR/Ton) (metalprices.com 2013-05-28)	Price (EUR/Ton) infomine.com 2012)
Lead metal for comparison	700-2,200	1,467
Copper	2,500-7,500	4 809
Antimony	3,000-14,000	
Zinc	900-2,000	
Steel (Benchmarker)	300-1,200	
Tin	8,000-25,000	11,341
Bismuth	12,000-25,000	13 087

(Use of exchange rate 1 USD =0.775 EUR, 9/12-2012)

In conclusion, direct substitution of lead by another metal would cost 1-25 EUR/kg, based on metal market prices of the last five years. Substituting functional lead in brass alloys is more costly. One estimate indicates a substitution cost of 70-80 EUR/kg lead. These estimates will be used in total substitution cost calculations in Chapter E.

C.3 Assessment of alternatives to lead in pigments

Lead based pigments are available in basic colours like white, red and yellow. A selection of pigments in those colours has been evaluated. The evaluation should not be regarded as recommendations for any specific use. The intention is to merely show that alternative substances are available, give an indication of the price levels and that the intrinsic properties of the alternative substances are preferable to those of lead.

An evaluation of a specific alternative solution has to be performed on case by case basis. The manufacturers must search for solutions that suit the conditions in their specific production process. In that context it does not differ from ordinary production changes due to seasonal fashion trends and to variations in colours.

Examples on alternative pigments are listed in Appendix 13.

C.3.1 Availability of alternatives to lead in pigments

Several alternatives, accessible on the market, have been identified by the Swedish CA during the work with this dossier. There are hundreds of different pigments available in each colour segment (white, red, yellow). In order to find possible alternatives to red and yellow lead containing pigments, a search in the Swedish Products Register (Swedish Chemicals Agency, 2012 was performed. The register contains information on chemical products (mixtures) manufactured, imported or brought into Sweden, if the quantity of a product is 100 kg or more per year. A list of red and yellow pigments is reported in Appendix 13. This list should not be regarded as a complete list of all available pigments. One should also be aware that all the red (or yellow) pigments are not fully interchangeable. To obtain a desired shade, only certain combinations of colouring agents work, but the availability of various options to achieve a certain shade are still considered to be sufficiently large.

The most used white pigments are calcium carbonate, titanium dioxide and zinc oxide. For red and yellow pigments a couple of examples were chosen for assessment from some of the most common pigments that were found in the Swedish Products Register, see **Table 32**. The selected substances are not meant to be a complete list of possible lead-free pigments; as the number of suitable pigments is high and many other substances can be relevant to use it is not proportional to examine all possibilities. The list merely demonstrates that lead-free red and yellow colouring agents are already being used.

Titanium dioxide is an alternative that still is used as a substitute for the pigment lead white. (Clark et al., 2006, 2009). (WHO, 2010) Titanium oxide is included in the Community Policy Action Plan (CoRAP) to be evaluated by France in 2014 due to its properties as a suspected respiratory sensitiser, CMR and suspected vPvB.

A risk assessment on zinc oxide was carried out by the Netherlands in the context of Council Regulation (EEC) No. 793/93. The risk assessment report is notified on the ECHA webpage (http://echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation/-/substance/2743/search/1314-13-2/term)

Table 32: Examples of lead free pigments for use in the assessment of alternatives.

Pigments	**CAS No**	**EC No**
Red pigment (examples, common substances)		
C.I. Pigment Red 2	6041-94-7	227-930-1
C.I. Pigment Red 4	2814-77-9	220-562-2
C.I. Pigment Red 53	5160-02-1	225-935-3
C.I. Pigment Red 57	5281-04-9	226-109-5
C.I. Pigment Red 122	980-26-7	213-561-3
Yellow pigments (examples, common substances)		
C.I. Pigment Yellow 12	6358-85-6	228-787-8
C.I. Pigment Yellow 17	4531-49-1	224-867-1
C.I. Pigment Yellow 73	13515-40-7	236-852-7
C.I. Pigment Yellow 74	6358-31-2	228-768-4
C.I. Pigment Yellow 184	14059-33-7	237-898-0
White pigments (examples, most used substances)		
calcium carbonate	471-34-1 13397-26-7 14791-73-2	207-439-9
Zinc oxide (Zinc white)	8051-03-4 1314-13-2	
Titanium dioxide	13463-67-7 1317-70-0 1317-80-2	236-675-5 215-280-1 215-282-2

Through the public consultation additional information on safe leadfree alternatives has been provided by a pigment manufacturer.

Inorganic alternatives	
Bismuth Vanadate	PY.184
Mixed Metal Oxide	PY.53

Mixed Metal Oxide	PBr. 24
Iron Oxide	PR. 42
Iron Oxide	PR.101
Organic alternatives	
Azo Diarylides	PO.13 7 PO.34 8 PY.13 9 PY.14 10 PY.83
Azo Dianisidine	PO.16
Azo Benzimidazolones	PO.36 13 PY.151 14 PY.154 15 PY.194
Monazo	PY.65 17 PY.74 18 PY.97
	PY.61 20 PY.62 21 PY.168 22 PY.183 23
Metal Azo	PY.191
Specialty Azo	PO.64 25 PO.67 26 PY.155
Specialty Other	PO.73 28 PY.110 29 PY.138 30 PY.139
DPP	PR.254

Industry provided information that for the purposes of consumer articles all of the above mentioned pigments are suitable and can replace pigments that contain lead.

C.3.2 Human health risks related to alternatives to lead in pigments

Information on human health classification of the chosen selection of alternative colouring agents is reported in Appendix 12.

C.3.3 Environment risks related to alternatives to lead in pigments

Information on classification of the environmental risks of the alternative pigments is reported in Appendix 12. The conclusion is that the alternatives have less severe environmental impacts compared to lead based pigments.

C.3.4 Technical and economic feasibility of alternatives to lead in pigments

Technical feasibility

In order to change colouring agents in a process, investments in new equipment are normally not needed. However, it has to be taken into account that it is not only the colouring agent itself that needs to be replaced. In order to make the colouring agent permanent and to achieve other required technical characteristics, a new set of chemical additives may be needed. The introduction of a new pigment will therefore normally lead to a change to a new set of other additives as well.

Economic feasibility of alternatives to lead pigment

Plastic products containing lead based pigments are articles of international trade. As been assessed in section C3.1, lead pigments may be substituted with a number of alternative colouring agents, either inorganic or organic. According to a study from WHO there is, despite a wide range in retail price, no correlation between price and lead content in paints. If so, price is not a deterrent for paint companies to shift to lead-free alternatives in order to remain competitive (WHO, 2010). From the information on prices in **Table 33Table 5**, this correlation is confirmed for colouring agents as well. Any impacts on the price of articles for consumer use manufactured with lead-free pigments have not been reported on sales to end customers at the retail level during the public consultation carried out by the Swedish CA.

Table 33: An overview of the prices for lead free pigments (marketpublishers.com 2012; alibaba.com 2012; chemicalland21.com 2012; aliexpress.com 2012). Use of exchange rate 1 USD =0,775 EUR, 9/12-2012

Pigments	**Price range in 2012 (EUR/Ton)**
Lead pigment for comparison	775 – 77489
Red pigment (examples, common substances)	
C.I. Pigment Red 2	2053
C.I. Pigment Red 4	23247
C.I. Pigment Red 53	3487 – 4262
C.I. Pigment Red 57	2247
C.I. Pigment Red 101	N/A
C.I. Pigment Red 122	2053
Yellow pigments (examples, common substances)	
C.I. Pigment Yellow 73	N/A
C.I. Pigment Yellow 184	N/A
C.I. Pigment Yellow 12	2 248
(C.I. Pigment Yellow 13	1 473
C.I. Pigment Yellow 42	930
C.I. Pigment Yellow 83	3 178
White pigments (most used)	
Titanium dioxide	1394- 2324
Zinc oxide (Zinc white)	1208-1286
Calcium carbonate	N/A

According to a study carried out by Nordic Council of Ministers on the opportunities and costs of substituting lead the cost of substituting lead in pigments for plastic can roughly be estimated to 0–33 EUR[10] per kg lead substituted. The following assumptions were made; the alternatives typically substitute leaded master batches in a weight ratio of 1:1 and master batches with lead pigments typically contains 30% of lead. The content of

[10] 0-180 DKK in 1995 translated to 2011 terms by using Eurostat data on HICP (Harmonised indices of consumer prices), and the average exchange rate for 2011 (7.46 DKK/EUR)

lead in plastic products due to pigments varies from about 1% for injection-died articles to 3% for thin plastic film and up to 5% relative to the production price of injection-moulded plastic items respectively 23% for extruded products. (TemaNord 1995)

Manufacturers within the EU have for several years substituted lead based pigments in plastics for example to be used for toys, kitchenware and food containers. But for plastic products on the international market that are affected by a strong competition on price and high demand of pigment per unit of products lead based pigments are assumed to be more common due to the lower price.

In conclusion, consultation with stakeholders and recent publications indicate no, or very low, additional costs for replacing lead in pigments. This is in line with the rough overview of prices presented in **Table 33**. A study from the Nordic Council of Ministers (TemaNord 1995) estimate lead substitution costs to be 0-33 EUR/kg of lead substituted. This estimate is used in the substitution cost calculations in Chapter E. Even though these estimates are rather old by now, they can be seen as indicative approximations. It is likely that, due to technological developments and industrial experience from using the alternative substances, the substitution costs have decreased since that study was published. These values are therefore probably over-estimations.

C.4 Assessment of alternatives to lead in stabilisers

Stabilisers are used to stabilise polymeric materials. Calcium/zinc stabilising systems and tin-organic compounds are reported to be the most common substitute to lead stabilisers. They are already widely used by manufacturers of plastic. As mentioned in the introduction, cadmium based stabilisers are not assessed as an alternative, due to their effects on health and the environment.

The replacement of lead in PVC has resulted in a rapid growth of calcium/zinc (Ca/Zn) and Calcium-organic stabiliser systems. For example, calcium acetylacetonate and zinc acetylacetonate are used as ingredients for these stabiliser systems. (AkzoNobel, 2012)

From internet sales sites, barium zinc systems more often seem to be designed for use in synthetic leather than the calcium/zinc system. Barium compounds are classified as “harmful” and this type of product is not approved for food contact applications, toys or medical applications. Lead stabilisers seem to be a minor source of lead in consumer articles on the EU market. Which kind of stabilisers that are most frequently used in polymers in consumer articles has not been fully evaluated.

The volumes and the most common groups and substances used in calcium/zinc stabilising systems are listed in Appendix 11. (Eurolex, 2012)

It is quite difficult to sort out from the information on stabilisers what function that really is referred to – if the name refers to a synonym name, if it is an intermediate substance or if it is the active stabilising substance. A mixture of calcium acetyl acetonate and zinc acetyl acetonate has been chosen as an example for the assessment of the hazards for health and for the environment.

C.4.1 Availability of alternatives to lead in stabilisers

Several alternatives which are accessible on the market have been identified. Details on registered market volumes are available in Appendix 11. For instance, there are zinc compounds registered under REACH (CAS numbers 67701-12-6 and 91051-01-3). Calcium stabilising systems are not registered, or at least not found under the names and CAS-numbers in this report. Nevertheless, their availability at the market is confirmed. (Vinyl 2011)

Market overviews have also been reported by sector organizations. For example the ones in **Table 34** and **Table 35** on European production and sales of stabilisers published by the Vinyl Plus program.

Table 34: European Production Data on stabilisers for the EU-27. (Vinyl 2010).

Tonnes of Stabiliser Systems	2007	2010
Formulated lead stabilisers	99 991	37 545
Formulated calcium organic stabilisers e.g. Ca/Zn systems	62 082	91 948
Tin stabilisers	16 628	12 162
Liquid stabilisers –Ba/Zn or Ca/Zn	19 000	14 000

Table 35: Sales of stabilisers in EU-15 plus Norway, Switzerland and Turkey. (Vinyl 2010).

Tonnes of Stabiliser Systems	2000	2010
Formulated* calcium organic stabilisers e.g. Ca/Zn systems	17 579	77 750
Tin stabilisers	14 666	11 622
Liquid stabilisers –Ba/Zn or Ca/Zn	16 709	13 229

Sales of formulated calcium based stabilisers in Western Europe and Turkey, including calcium/zinc, have increased from 18 ktonne in 2000 to 56 ktonne in 2007. Further growth is expected as a result of the phasing out of lead-based systems. In the sector of flexible foils where the main stabiliser used is a barium/zinc soap, substitution by calcium/zinc materials is also taking place, although, again, there are technical issues which need to be overcome. (PVC Europe 2012)

C.4.2 Human health risks related to alternatives to lead in stabilisers

According to the Commission Green Paper on “Environmental issues of PVC”, calcium/zinc compounds have a less severe risk profile compared to lead and cadmium compounds, and are currently not classified as hazardous. (EC, 2000)

C.4.3 Environmental risks related to alternatives to lead in stabilisers

According to the Commission Green Paper on “Environmental issues of PVC” calcium/zinc compounds have a less severe risk profile compared to lead and cadmium compounds, and are currently not classified as hazardous. (EC, 2000)

C.4.4 Technical and economic feasibility of alternatives to lead in stabilisers

Technical feasibility

The calcium-zinc stabilisers can be purchased either as a powder or in a ready to use liquid solution. They can readily be used by the formulators of the material.

The stakeholder consultation verifies that a change of stabilisation systems in a polymer material does not normally imply a need to invest in new equipment. However, it has to be taken into account that other additives may also have to be replaced. Technically, there seems to be no major differences between lead stabilisers and alternative stabilisers. This is confirmed by other actors stating that "the processing conditions while using calcium-zinc stabilisers are almost the same with lead systems" (Plastics online 2012). Comments at a public hearing before the decision about 100 ppm lead content limit for children's products in the US confirm that applying such a limit to materials such as plastics do not cause any practical problems. (cpsc.gov, 2012)

Stabilisers for some applications may require enhancement from supplementary additives. For example, organic co-stabilisers will often be added to formulations of calcium/zinc. These materials include polyols, epoxydised soya bean oil, antioxidants and organic phosphites. (pvc.org 2012) This is valid also for lead stabilisers. It has not been investigated during the project if the additives are the same or not for the lead and the lead-free stabilisers.

Economic feasibility of alternatives to lead in stabilisers in PVC

Substitution of lead in stabilisers for PVC has been going on for many years. Lead stabilisers can be substituted with a number of different alternative compounds as can be seen in **Table 36**. PVC articles are, however, items of international trade. According to Vinyl Plus, the replacement of lead stabilisers is progressing, even though it is affected by the cost of lower production output and higher scrap volumes. (Vinyl 2010) In the report from the Nordic Council of Minsters it was concluded that the higher material costs and the total estimated costs for substituting lead in stabilisers might be overestimated due to the on-going substitution taking place. However, lead in stabilisers is still detected in consumer articles available on the EU market. The cost of substitution of lead in stabilisers reported by TemaNord (1995) was evaluated to be between 4–15 EUR[11] per kg lead for soft PVC product and about 46 EUR (250 DKK in 1995) per kg lead for rigid PVC.

[11] 20-80 DKK in 1995 translated to 2011 terms by using Eurostat data on HICP (Harmonised indices of consumer prices), and the average exchange rate for 2011 (7.46 DKK/EUR)

Table 36: An overview of the cost of substances used for alternative stabilisers in PVC (alibaba.com 2012) Use of exchange rate 1 USD =0,775 EUR, 9/12-2012

Stabilisers in PVC:	Price range in 2012 (EUR/Ton)
Lead stabiliser for comparison	1046–1565
Fatty acids, C14-18 and C16-18-unsatd., zinc salts	0.775- 1.162
Fatty acids, C16-18, zinc salts	N/A
Calcium Acetylacetonate	5153–6935
Zinc acetylacetonate	775–6935

As can be seen in the table above, alternatives to lead stabilisers are available on the market. These alternatives have been identified as technically feasible. Any impact on the price of articles for consumer use manufactured from lead-free alternative to lead stabilisers or on sales to end customers at the retail level has not been reported during the public consultation.

In conclusion, consultation with stakeholders indicates no, or very low, additional costs for replacing lead in stabilizers. A study from the Nordic Council of Ministers (TemaNord 1995) estimate lead substitution costs to be 4-15 EUR/kg of lead substituted in soft PVCs and around 46 EUR per kg in rigid PVCs. These estimates are used in the substitution cost calculations in Chapter E. Even though these estimates are rather old by now, they can be seen as indicative approximations. It is likely that, due to technological developments and industrial experience from using the alternative substances, the substitution costs have decreased since that study was published. These values are therefore probably over-estimations.

C.4.5 Other information on alternative 3

The VinylPlus programme is a commitment from the European PVC industry for Lead replacement in the EU-27 by end 2015. (Vinyl 2012)

According to the stakeholder consultation, the involved producers cover about 80% of the produced volumes of PVC in the EU. Producers of PVC and articles containing PVC outside the EU are not covered by this commitment.

C.5 Overall conclusion for the alternatives

The most frequent uses of lead in articles for consumer use have been identified to be **pigments and additive/impurities in metal alloys**. Stabilisers were only identified as the probable source of lead in a minor share of the articles. Metallic lead is only used for specific articles where the density of lead is important. **Alternatives have been identified** for all those function. The **alternatives are already available on the EU market and substitution is technically feasible**.

The effects on human health and/or the environment from the available alternatives, is expected to be less severe than the effects of lead.

No major investment cost has been identified for a change to the alternatives in the part of the supply chain where the articles are manufactured and assembled, e.g. **no investments in new machinery has been identified** on an article level.

Some of the alternatives available on the market are less expensive in terms of purchase price. The alternatives, however, already stand for a broad use in the consumer articles of concern. The alternatives to lead as metal, pigment and stabilisers in PVC are therefore **considered as economically feasible as they are already available and used on the EU market**.

D. Justification for action on a Community-wide basis

From the information presented in Chapter B, it is clear that articles well exceeding the lead content considered as safe according to the exposure assessment presented in section B.9.3 can be found on the EU market. The existing legal requirements, as described in section B.9.1.1 and Appendix 2, are sector specific and only target some article categories such as toys, packaging and electric equipment. Consequently, there is a remaining risk of lead exposure resulting from children's use of articles not in scope of the existing requirements. The recently passed restriction of lead in jewellery, originally proposed by France, partly targets this concern. Still, the reasons behind the restriction of lead in jewellery are mutually valid for a number of non-jewellery items which share some key properties (consumer availability, lead content, and the proneness of children to put them in their mouths) with jewellery. These include clothes, shoes, accessories, interior decorations, articles for sports and leisure, stationery and keys (DTI 2002.)

Lead can have severe and irreversible impact on the development of children's central nervous systems. No lower threshold has been scientifically established for these impacts; consequently, any additional exposure to lead should be avoided. This is reinforced by the increased availability of lead and the general increase in consumption trends, which further justify preventive measures in order to restrict known risks.

As this concern is not limited geographically or nationally, but should be similar in all Member States, Community wide action is justified. Moreover, regulating lead in articles on a national level will likely introduce market distortions. As the same articles will in many cases be available on the market in many Member States, the Community level should be appropriate for material restrictions on these articles.

D.1 Considerations related to human health and environmental risks

From the available information it is clear that articles well exceeding the lead content considered as safe according to the exposure assessment presented in section B.9.3 can be found on the EU market. Furthermore, the world production of lead is growing (USGS 2012), as is the general material consumption across Europe (EEA 2010). These two trends indicate a potential increase in the amount of lead-containing articles available on the consumer market. There is obviously a risk of lead poisoning resulting from accidental ingestion and/or mouthing[12] of articles or parts of articles by children. This risk is present for any article that is not covered by a sector specific regulation setting limits to lead content or lead release.

Although human exposure to lead has decreased considerably since the 1970's, this specific type of poisoning remains an unacceptable risk. Not only are children especially exposed to lead in articles due to their behaviour – children frequently put things in their mouth or suck on them – but they are also particularly vulnerable to the harmful effects of lead. Repeated exposure to lead can result in severe and irreversible neurobehavioral and neurodevelopmental effects, even at a low exposure. Currently, the "background exposure" to lead from food and non-food sources exceeds the highest tolerable exposure (EFSA 2010). Thus, any additional exposure should be avoided. As shown by the risk assessment in section B.10.1, it is clear that there is a health risk concern which justifies regulatory action.

The placing on the market of articles containing lead is a global phenomenon which cannot be isolated to any specific country. Children's mouthing behaviour cannot either

[12] As defined in the EN-71 guidelines

be geographically isolated, nor can their particular sensitivity to lead. Thus, the risk of poisoning is not limited to any specific Member State, but affects any consumer and any child within the EU equally. This justifies a Community wide restriction.

Although the risk can be managed on a national level, leaving regulatory action to national legislation are likely to create a plethora of incoherent, heterogeneous regulations which are less coercive and more difficult to manage. National regulations are more sensitive to influencing activities from strong local interests, which might dilute the restriction and put the protection level at stake. Regulating the risk at Community level is likely to offer the strongest protection all over the EU.

D.2 Considerations related to internal market

The market for articles is, partly due to the wide scope, highly fragmented and dispersed. A great part of the articles concerned are imported from third countries, notably from Asia, by a diversity of actors. Trade flows are numerous and multidirectional, both between Member States and as regards import to the EU. The same articles will in many cases be available on the market in many Member States. Regulating lead in articles on a national level will likely involve internal market distortions. For instance, industry actors in one MS will need to conform to strong requirements imposed by that government, whereas their competitors in neighbouring countries will face less strict national regulations or no regulations at all. Whatever the content of national regulatory actions could be, regulated firms might be disadvantaged and lose markets shares. Meanwhile, 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 regulated countries).

The EC competition law states that flows of working people, goods, services and capital shall be free in a borderless Europe and that firms shall be equally treated on the common market. Isolated and non-harmonised national measures against lead in articles, no matter how they are constructed, will likely constitute barriers to trade and be incompatible with the spirit of that law and single market principle.

Despite their drawbacks, national measures are a real option to Member States. As there is no harmonised legislation covering the general concept of articles, it is legally possible to restrict lead in articles on a national level. Such national requirements already exist, e.g. the general lead ban in Denmark and the restriction of lead in textiles in Poland. Since there is a clear concern over human health risks associated with lead in articles, more national measures are probable to follow unless Community wide action is taken. The likelihood of this will probably increase, following influencing activities by green and consumer groups and further reports of lead poisoning.

A Community wide restriction of lead in articles will create a level play field for trade. It will not discriminate between articles produced in the EU and articles imported from third countries, and it will not hinder commercial relations on the internal market. It will create a harmonised, manageable regulatory situation which can reduce the administrative burden and the costs of compliance, and it will prevent the market distortions following from national regulations while still targeting the health concerns.

When formulating a restriction, or any other legal action, due care needs to be taken to its proportionality. In this context this relates mainly to the definition of the scope. Various scopes can be conceived for a potential restriction, ranging from “all articles on the market” to “specific article categories”. The different impacts of these upon the internal market and for individual market actors and authorities will be discussed in Chapter E and F.

E. Justification why the proposed restriction is the most appropriate Union-wide measure

E.1 Identification and description of potential risk management options

E.1.1 Risk to be addressed – the baseline

The risk addressed in this restriction dossier is the risk of lead exposure resulting from mouthing or ingestion of articles containing lead. As shown in section B.9, this concern is well grounded, in particular with respect to the effects of lead on children's central nervous systems. Each lead containing article may contribute to these effects. As the risk occurs in the consumption stage of the article's life cycle, relevant risk management options may affect all actors in the supply chain.

Since the 70's, human exposure to lead has decreased significantly in Western countries. In the U.S.A., the geometric mean blood lead level in children has decreased from 150 µg/L in 1976 to 16 µg/L in 2002. (CDC 2012.) In Sweden, the levels have decreased from 60 µg/L in 1978 to 25 µg/L in 1996 and further to 13 µg/L in 2009. (EFSA 2010, Skerfving et al, 2011.) Recently, the decrease seems to have worn off. Swedish figures indicate the same blood lead levels in children from 2005 through 2009 (Skerfving et al, 2011). German surveys show median levels at 16 µg/L in children aged 3 to 14 years, with higher levels among the youngest children. (EFSA 2010.) In the U.S.A., the levels remain more or less constant at approximately 16 µg/L since 2001. (CDC 2012.) Belgium and France report similar figures around 20 µg/L during the early 00's. (WHO 2009). To summarise, the trend in Western countries seems to be a steady state at 15–20 µg/L. In Eastern Europe, the levels are also decreasing but yet a bit higher: 31 µg/L was reported from the Czech Republic in 2003, >50 µg/L from Poland in 2003, and 40 µg/L from Hungary still in 2007. (EFSA 2010, WHO 2009.) There is reason to believe that the trend will continue until the levels reach the same steady state as in Western Europe.

There is a historical correlation between the decreased blood lead levels in children and the introduction of lead poisoning prevention policies. Of these, the single most important measure has been the elimination of lead in petrol. Other regulatory measures such as the restriction of lead in toys and lead solder in food cans, the restriction of lead in residential paint, and regulations on industrial emissions, also seem to have had an impact. (EFSA 2010, US CDC 2012, WHO 2009)

Recently, blood lead levels in children seem to have reached a "baseline" level at13–50 µg/L. This exposure, probably originating both from food and non-food sources, still exceeds the highest tolerable exposure with respect to the neurodevelopmental effects of lead. (EFSA 2010.) Thus, any additional exposure from food and non-food sources should be avoided. A feasible way of achieving further reduction would be the introduction of new restrictions of lead.

As follows from the reasoning in section B.9.3.1, the principal exposure driver is not the total number of articles on the European market or even in European homes, but the likelihood that children will choose to mouth the articles containing lead. From the mouthing studies described in section B.9.3.2 (Juberg et al 2001, DTI 2002, Greene 2002), the median mouthing time of a non-toy, non-food article by a child aged 6–36 months is estimated to 20 minutes a day. 22% of the total mouthed articles are in scope of this report. Of these, 10% are expected to contain lead, except for keys for which the share is 67% as reported in section B.9.3.1. 0.6% of the total mouthed articles are keys and the lead content per article is assumed to 1% (1.5% for keys).

Articles containing lead can be assumed to be randomly present in some homes, but not in others. Thus, a child mouthing an article containing lead one day is more likely to mouth the same article the next day, compared to a child who has a similar lead-free article in its home.

The total number of children between the ages of 6–36 months in the EU was in 2011 13,437,880. See the derivation of data in Table 27 Section B10.1.1.2.The exposure of the children in the realistic scenario with respect to mouthing time was estimated in section B.10.1.12. resulting in a yearly exposure of 367 g From the exposure assessment presented in section B.10.1, this exposure represents a total IQ loss of 32000 units.

Altogether, some European children are at risk of being exposed to lead at levels that impact their neurological development. The total exposure including keys is **367** g/year (if excluding keys the total exposure is251 g/year).

How the existing use of articles that already have been put on the market and already are being used by consumers further affect the baseline exposure has not been possible to quantitatively assess. The scope of the proposed restriction concerns a long variety of articles and materials. The time for how long these articles remain in consumer should vary accordingly. This is however a field where few reliable and relevant references have been found during the work on this proposal. One study indicates that most clothes are used for 5-10 years (including second hand use) before being disposed of (Nordic Council of Ministers, 2012). Some articles (e.g. shoes and accessories) covered by this restriction proposal probably has a shorter product life, while other articles (e.g. furniture) probably remain in use for a longer period of time. In general the use of articles is increasing as long as the GDP increases. It can also be assumed that the share of articles containing lead will be the same in the future without further regulatory actions taken to limit the use. The trend is therefore expected to be fairly stable or slightly increasing without further risk management actions taken. The existing stock of articles among consumers will eventually be replaced with new articles. The existing articles will however be a (declining) source of exposure for a transitional period after the implementation of the proposed restriction. Full risk reduction will not be reached until this transition has been completed. In order to enable a comparative assessment of the restriction measures presented in this chapter, a business as usual (BAU) scenario needs to be assessed. In the BAU scenario, no further actions are taken except for the ones that have already been initiated, decided upon or implemented. The scenario is based on the current and predicted future use of lead and its compounds in the absence of further regulation.

In the BAU scenario, the following measures are considered:

The sector specific legislative acts imposing restrictions on the use of lead, such as the Toy Safety Directive, the RoHS Directive and the Regulation setting maximum limits for contaminants in foodstuffs (cf. Appendix 2)

The existing restrictions of lead in REACH, namely:

- the restriction of lead based pigments in paints in Annex XVII, entry 16,

- the restricted use of lead compounds in mixtures for consumer use in Annex XVII, entry 30,

- the restriction of lead in jewellery in Annex XVII, entry 63

- the harmonised classification and labelling of lead compounds under the CLP Regulation (1272/2008)

- the proposal for harmonised classification and labelling on elemental lead that the Swedish CA submitted to ECHA in February 2012 (the public consultation has now been finalised)

Since the Swedish CA submitted its ROI for this restriction proposal in April 2011, a number of additional measures have been proposed. This includes proposals for the identification as SVHC of 21 different lead compounds, which were prepared by ECHA upon request from the Commission. If these lead compounds are identified as SVHC, they may be subject to the authorisation procedure in REACH. Such a requirement would likely bring changes to the occurrence of lead in articles available to consumers, and needs therefore also be accounted for in the BAU scenario.

None of the legal measures are expected to provide a significant decrease of children's exposure to lead through consumer articles. The sector specific regulations, while being effective to regulate lead within their scope, have been around for a long time without eliminating lead in non-regulated articles. Theoretically, the requirements in e.g. the Toy Safety directive could help promote lead-free raw materials and therefore "spill over" lead-free alternatives also to non-toy articles, but the Toy Safety Directive dates back to 1988 and there is still lead present in articles. If it has had any positive effect on the lead content in articles, this effect has probably worn off. The other REACH options, such as authorisation (which is dealt with in section E.1.3), target the production and use of lead and its compounds in the EU, rather than the occurrence of articles on the EU market, and consequently exempt all imported articles from the requirements. If authorisation was implemented for the lead compounds recently proposed by ECHA as SVHC, which would be the ultimate outcome of that proposal, the lead compounds would be phased out from EU produced goods but may still be present in imported articles. The same principle applies to the current requirements, e.g. the restriction of lead paints in entry 16-17 of Annex XVII. These restrict paints in the EU, but articles that were painted in third countries may still enter the EU market. Although the current restrictions certainly have meant a historic decrease in lead exposure, this trend will probably not continue, especially not when taking into account that approximately 72% of the articles on the Union market are imported from third countries. (Section B.2.2, Table 11)

Voluntary measures by market actors have been suggested as a driver for the elimination of hazardous substances. An often cited example is the Vinyl Plus initiative referenced in Chapter C, with the objective of phasing out lead stabilisers in European produced PVC. While this probably has a positive impact on the occupational exposure to lead in European plants, the articles targeted by the scope of this dossier are generally not made of European raw materials but imported into the Union from third countries. Hence, Vinyl Plus and similar initiatives are not likely to have any impact on the exposure.

Consumer concerns also tend to be less significant. In order to drive the phase-out of lead, consumer awareness needs to be broad and not only restricted to the "eco-niche" consumers that constitute only a minor fraction of the general consumer population.

Market research has suggested that the “eco-niche” or “LOHAS” (“Lifestyles of health and sustainability”) consumer segment accounts for between 5 and 20% of the consumer market, depending on business. (P&G 2012, Rogers 2011.) A considerable larger fraction, around 75%, belongs to the “sustainable mainstream” segment. Given its size, this segment has been highly attractive to companies and therefore a significant driver of change into environmentally friendly products and services. However, these are not as dedicated to environmentally sound consumption and will likely not refrain from consumption for environmental reasons. (P&G 2012, Rogers 2011.) Compared to all other environmental and health aspects of everyday consumer goods, lead content in non-food, non-toy articles is not likely to be a priority concern to the “sustainable mainstream” consumer. This also impacts the willingness of enterprises to take their own measures, in particular as the presence of lead is often not known to the actors in the supply chain. Occasionally, enterprises may be prompted to take measures by media alerts and tests commissioned by green or consumer groups. However, even these alerts should have little to no effect. Media alerts tend to be stochastic and locally based, and also calm down quickly as the media spotlights move on; these should not have any significant effect on the EU market as a whole. Altogether, voluntary measures by enterprises will likely not decrease the fraction of articles containing lead, or the levels of lead in these articles, and should therefore not impact human exposure to lead.

Instead, the main impact on human exposure should come from the trends in use of lead. Here, two separate and opposite trends can be anticipated. First, due to increased awareness, the lead may be eliminated in all applications where it is not intentionally added to perform a specific function. This can be driven by market actors in Europe, who apply stricter requirements to their Far East suppliers, but it can also be initiated in the countries of produce, e.g. due to higher working environment standards. Following this trend, metallic lead as well as lead pigments may be reduced in consumer articles. However, higher standards usually bring higher costs, and it cannot be excluded that some enterprises will choose to move their production to new countries where costs and environmental concerns are lower. (Dinh 2012.) This trend is thus not unambiguous.

The opposite trend is more worrisome. Global production and consumption of lead is currently increasing, mainly due to the growing demand for energy-efficient vehicles which require lead-acid batteries. (WHO 2010.) The global mine production of lead was expected to increase by 9% in 2011 from that in 2010, reaching a total tonnage of 4.52 million tons. China was expected to account for nearly one half of global lead production. (USGS 2012.) While this lead mainly goes to batteries, construction products, and other applications out of the scope (cf. section B.2), During the Public Consultation of the Annex XV dossier however, information was submitted implying that leaded waste materials actually are usually recycled to articles out of scope of the proposed restriction (e.g., construction materials).

It is difficult to forecast which of the opposite trends will have the greatest impact on the presence of lead in articles. There is however nothing to suggest that there will be a spontaneous risk reduction in the absence of regulation. A reasonable estimate is therefore that the BAU exposure – at least – resembles the situation of today. This gives a baseline exposure of **367 g**/year The exposure affects European children in the age range 6–36 months. This is the risk to be addressed herein.

E.1.2 Options for restrictions

The objective of this approach is to limit the risk to human health, especially children, by the restriction of lead and its compounds in articles available to consumers. A key challenge to this approach is the definition of a practically implementable scope for the restriction. A restriction could focus on lead content, migration of lead or a combination.

It could target the article as whole, accessible parts of the article (following different definitions presented below) or specific materials in the articles. It could target articles depending on how they expose children to lead, and/or how it is made available on the market. At a first screening step, the number of possible restriction options can be visualised in the following matrix.

Table 37: Matrix of possible restriction options

Restricted property	**Article scope**		
	By part of article	**By size**	**By market**
Content	*The whole article*	Can be swallowed	*Articles sold to/intended for consumers*
Migration	*Accessible parts*	*Can be put in the mouth*	*Specific article categories*
Content and migration	Specific materials	All articles	All articles

Taking into account the discussion of different limit values, the number of possible combinations easily exceeds 100. It is not feasible to consider all these combinations separately, not even in the screening phase. Instead, the screening considers each parameter individually; based on to what extent it fulfils the following requirements:

- It should address the identified risk sufficiently
- It should be proportionate to the identified risk
- It should appear feasible from an implementability and enforceability point of view

From these criteria, the Swedish CA has identified four restriction options that seem reasonable to assess in detail in section E.2:

Restriction of lead content in articles and part of articles that are sold to the general public and that can be mouthed by children

Restriction of lead migration in articles and part of articles that are sold to the general public and that can be mouthed by children

Restriction of lead content in (all accessible parts of) clothes, accessories and shoes

Restriction of lead migration in all articles and part of articles that are sold to the general public

These options take into account the parameters marked in *italics* in the matrix above.

In the following sub-sections, the reasoning behind choosing these four restriction option for further assessment will be explained.

Restriction of content or migration:

A lead restriction could either limit the content of lead in an article or the rate of migration of lead from the article. As illustrated by the table below, existing Union legislative acts (cf. Appendix 2) employ both types of limits.

Table 38: Some legislative acts that set maximum levels for lead (for full references see Appendix 2)

Legislative act	Restriction by	Limit
RoHS directive	Content	0.1 % by material
Toy Safety directive	Migration	Current directive (until 2013): 90 mg/kg Recast directive: 13.5 mg/kg (brittle or pliable material) 160 mg/kg (scraped-off material)
Packaging and Packaging Waste directive	Content	100 ppm
End-of-Life Vehicle directive	Content	0.1% by material
Food contact material framework (several directives cf Appendix 2)	Migration	Different by directive and material
REACH Annex XVII, restriction of lead in jewellery	Content	0.05% in each individual part of the jewel (derogations apply)

All these directives have been in force for a while and are generally considered to work well, meaning that the industries involved have successfully implemented the restrictions and that the infrastructure for internal control and market surveillance function. There are obviously successful precedents to both approaches, which have created an infrastructure for compliance that can be reapplied also to this subject matter. **Hence, content and migration both seem reasonable to assess further.**

Another option which has been previously discussed is to restrict content and migration together. This option is implemented in the Canadian legislation on lead in jewellery for children (Canada Gazette 2005). Jewellery items intended for children must not contain more than 600 mg/kg (0.06 %) total lead, and no more than 90 mg/kg (0.009 %) of migratable lead. This “double restriction” is based on a precautionary approach and may therefore be seen as more restrictive. The main drawback is that each article would have to be tested twice, which would double the costs compared to measuring either content or migration. These added costs and the corresponding administrative burden are believed to outweigh the potentially added risk reduction capacity, and this option is therefore not assessed further.

A modification of the “double restriction” is the two-step approach that was proposed by RAC in course of the French proposal to restrict lead in jewellery (ECHA 2011). In this option, the articles are first tested regarding their lead content. Manufacturers whose products fail the set content limit will then have to demonstrate that the product complies with a complementary migration limit. This two-step approach would allow for a quick and enforceable implementation, while still distinguishing between “safe” and “unsafe” lead-containing articles. However, when put into practice this restriction would be virtually identical to a restriction of migration only, in terms of which articles would pass or fail the limit. The only difference would be a cost saving in the enforcement and compliance control, as not all articles would have to be tested for migration but would only need the cheaper content screening. This method is however already used by European enforcement agencies as well as enterprises, e.g. for control of the Toy Safety directive, and it is deemed redundant to explicitly require it by law. Since a simple migration limit yields the same results, the two-step option is not assessed further in the spirit of “better regulation”. **Hence, combinations of content and migration should not be further assessed.**

From this review, the conclusion can be made that **a restriction based on content and a restriction based on migration both seem appropriate to assess further**.

Scope restraints and clarifications

For legal purposes there is a need for a clear, workable scope definition that will not be subject to multiple interpretations and the creation of grey areas. The scope also needs to be proportionate to the risk, i.e. articles which do not pose any risk should not be regulated. This is particularly important if lead content is restricted, as content is less directly related to exposure than is migration. Workable scope restraints can be based on article size, on how the articles are placed on the market or target specific article categories or specific materials. It also needs to address the issue of complex articles.

To start with article size, **Table 37** shows three different article size definitions that conform to the clarity and workability requirement. The scope “Articles that can be swallowed by children” has a clear dimensional definition, e.g. in the toy safety standard EN 71 (which employs a “small part cylinder” designed to imitate a throat). Likewise, “All articles regardless of size” leaves no room for interpretation. However, the former scope does not cover the whole concern and is therefore suboptimal from a risk reduction perspective, while the latter can be viewed as disproportionate, in particular if lead content is restricted. **These two options are therefore eliminated and will not be assessed further.**

The preferable option would therefore be “Articles that can be placed in the mouth by children”. While this option is not as distinct as the other two alternatives, it has a precedent in the REACH regulation, namely in entry 52 of Annex XVII, which restricts three phthalates in toys and childcare articles. By request from the Council and the European Parliament, the Commission has issued a guideline on the interpretation of the concept. (EC 2005) This guideline, which is also illustrated with practical examples, states the following:

“Placing in the mouth” means that the article or parts of the article can be brought to the mouth and kept in the mouth so that it can be sucked and chewed. If the object can only be licked, it is not regarded as “placed in the mouth.”

Articles which exceed a size of 5 cm in all three dimensions can not be placed in the mouth. If the article in question has detachable or protruding parts with at least one dimension smaller than 5 cm, these parts can be placed in the mouth.

Inaccessible parts of articles can not be placed in the mouth. Accessibility can be assessed following the definition and method laid down in the European Standard on the safety of toys, EN 71-1.

The final assessment must be made on a case-by-case basis. (EC, 2005)

The exposure scenario identified in this dossier is comparable to the phthalate scenario regulated in entry 52. Although the guideline still leaves room for interpretation, it provides a workable guidance which can be applied also to this case. **The concept “articles that can be placed in the mouth by children” is therefore considered sufficiently distinct for a restriction proposal.**

Moving on to the market availability of the articles, scope restraints could be applied to different subsets of the article market. The main distinction here is that between the consumer (B2C) and the professional (B2B) market. Restrictions could be applied to “articles sold to consumers” or to “articles regardless of who the intended buyer is”. This is e.g. implemented in the entries 28–30 in Annex XVII to REACH, where CMR substances in categories 1A and 1B – including lead compounds but not metallic lead – are restricted in mixtures sold to the general public. **Reapplying this restriction, and thus levelling mixtures with articles with respect to lead, seems to be an obvious alternative.**

It is however not the only alternative. Children are not only found in homes, but also in kindergartens, schools, hospitals, etc. where also articles which are not sold to the general public may be present. A conservative approach would then be to restrict all articles, regardless of whom they are intended to be sold to. This would also solve definition issues such as how to define concepts as “sold to” or “intended for”, which could have several meanings. On the other hand, it would create other scope issues, as there are articles where the occurrence of lead is unproblematic (e.g. where the lead is encapsulated) or even necessary (such as in radiation protection equipment). It is also very likely that a scope this wide will be disproportionate to the identified risk, especially if considering limits to lead content. Most probably, it will also have significant socioeconomic impact, also upon economic operators who were never intended to be regulated this way. **The option of restricting also articles sold for professional or institutional use is therefore eliminated.**

The opposite approach could also be feasible. In this approach, lead is only restricted in some product categories which are sold to consumers. These categories would be those which usually contain lead at risk levels, <u>and</u> which children usually put in their mouths. Clothes, shoes and accessories have been identified as such priority categories. They make up a substantial part of articles sold to consumers, and account for approximately 37% of the non-regulated articles that can potentially be mouthed by children (DTI 2002). Lead has been detected e.g. in buttons, zippers, buckles and rivets, in plastic screen print and other plastic details, and in leather imitation wallets, bags and purses. Moreover, unlike many other products where lead has been detected, these are distinctly defined categories which would leave no grey areas if they were subject to a lead restriction. They are therefore deemed a reasonable subset of the scope “articles that can be placed in the mouth by children”, in case a smaller scope should be needed for manageability and economic reasons. Despite the obvious disadvantage of not targeting the whole exposure identified in section E.1.1

Finally, the question of how to deal with complex articles needs to be resolved. Articles are often complex, insofar they may consist of different components and of several different materials of which only some may contain lead. This creates a dilution effect which has to be considered. Targeting the whole articles may in these cases fail to regulate the risk; the article as a whole may well comply with the restrictions while certain parts or materials in the article still pose risk.

The definition of articles is not either fully resolved within the Union, in particular regarding how to consider complex articles made from parts that are themselves articles in their own right. The articles targeted in this dossier usually belong to this group. (Consider for instance the common case of clothing buttons. These have once been manufactured as articles, and they can therefore be viewed as still being articles even though mounted upon a garment.) There is an on-going regulatory discussion about these kinds of articles, and a regulation restricting lead in “articles” would certainly be subject to different interpretations. If the buttons in the example contain high concentrations of migratable lead, while the rest of the garment does not, the regulatory compliance of the garment will be judged differently in different Member States. This creates a legal uncertainty which undermines the harmonisation of the internal market.

It may therefore seem appropriate to also consider parts of articles. The concept “parts of articles”, although not entirely unequivocally defined, has two precedents in REACH: the entries 44–45 targeting polybrominated diphenylethers, and entry 63 on lead in jewellery (the latter analogous to the restriction presented herein). It can be viewed to represent “parts” like buttons, but also protruding parts which are not distinguishable by function. **A restriction targeting “articles and parts of articles” would likely resolve the definition issue and address the risk sufficiently.**

There is another opportunity which does not require the ambiguous concept of “parts”, namely to tie the restriction to specific materials in the article. This has a precedent in the RoHS directive, where all materials of the article, also in the interior, have to comply with the substance limits. As the presence of lead is associated with certain materials, such as metal alloys and PVC plastic, the restriction could be targeted to these materials. This approach would possibly limit the scope and hence the impact on economic operators, while still addressing most of the risk. It would also point clearer at the raw materials suppliers, where the actual substitution work has to be made. However, experiences from enforcing material based restrictions (such as that of cadmium in entry 23 to Annex XVII) give reason to raise questions on the practical enforceability. The enforcement of a material based restriction requires knowledge of where these materials are present in articles. When judging a plastic article, in particular a smaller one, it may be difficult to distinguish plastic materials with a lead restriction from those without one. This is not only an issue to enforcement officers, but also for the internal compliance control, which would likely require smaller enterprises to bring in external expertise. Overall, this means added costs and added administrative burden. For these reasons, **a material based restriction is deemed less practical than a restriction in “articles and parts of articles”, and is therefore not considered further.**

Following this reasoning, a number of parameters have been found appropriate to use as a basis for a lead restriction in articles, while others have been eliminated from the matrix of potential restriction options. Combining the remaining parameters, the Swedish CA consequently finds the following four options suitable for further assessment:

Restriction of lead content in articles and part of articles that are sold to the general public and that can be mouthed by children

Restriction of lead migration in articles and part of articles that are sold to the general public and that can be mouthed by children

Restriction of lead content in (all accessible parts of) clothes, accessories and shoes

Restriction of lead migration in all articles and part of articles that are sold to the general public

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

Health risks for children caused by lead in articles could potentially be managed through two different routes: regulations on lead and regulations on product safety. (Regulations targeted specifically at children's products are unlikely to have any real effect, as children's mouthing behaviour takes no notice whether the mouthed article is intended for children or not.) As shown by Appendix 2, the existing sector specific product safety regulations only cover some groups of articles, while the lion's share of articles remain unregulated with respect to lead. This leaves mainly two routes: general chemical regulations as REACH and CLP, or the General Product Safety Directive. In addition, non-regulatory measures such as economic policy instruments or voluntary schemes could be considered.

The Swedish CA finds the following other risk management options to consider:

Harmonised classification under CLP and subsequent identification as SVHC

Following entry 30 in Annex XVII to the REACH regulation, compounds classified as toxic to reproduction in category 1 or 2 are restricted in mixtures for consumer use. These include lead compounds, which are classified as toxic to reproduction in category 1A. Articles that can be regarded as mixtures, such as crayons or cast alloys, could therefore already benefit from a restriction. As elemental lead is not yet classified (in February 2012, Sweden submitted a CLH dossier to ECHA with a proposal to classify elemental lead as Reprotoxic 1A or H360:DF), this restriction would however not cover articles where lead is present as a metal and not as a compound. The public consultation for this CLH dossier has now been finalised.

Classification will in itself not decrease the exposure to lead. Classified substances may however be suggested as substances of very high concern (SVHC) under Article 59(1) of the REACH regulation. If lead and its compounds were identified as SHVC and included in the Candidate List, companies would be obliged to inform their customers on lead content in all articles where the lead content exceeds 0.1 % by weight.

There are three reasons why this measure is deemed unviable. First, the lead content of articles is usually limited to specific materials. The lead content of a complex, multi-material article is therefore usually below 0.1 % although the lead content in a specific material gives rise to concern. In these cases, the information would not be given. Second, consumers have the right to be informed only by their own request, and the information may be delayed up to 45 days. Due to long supply chains and the fact that lead in many cases is not intentionally added, it is likely that the transfer of information to the end consumer will mostly be ineffective. Third, it is not clear how an informed consumer could remove or avoid the lead without posing a risk to exposure.

Following this reasoning, classification and identification as SVHC will likely not sufficiently address the risk identified in this dossier. This measure is therefore not further assessed.

Authorisation under REACH

The authorisation procedure under REACH Title VII (Articles 60–66) could be a feasible way to ensure that hazardous substances are not used. Lead and its compounds meet the criteria laid down in Article 57 and could therefore be included in Annex XIV, meaning that they would be subject to authorisation. An authorisation requirement for lead and its compounds would address the risk for the use within the EU.

The authorisation option shares some advantages with the restriction route. It can easily be monitored and enforced, as there already is an infrastructure and established systems in place for monitoring and enforcing substances and uses subject to authorisation. It is practical as there are alternatives available on the market, and it could provide incentives for further research and substitution activities that would further enhance the practicality. The system with downstream users taking advantage of their suppliers' authorisations could help organise and streamline the rather haphazard supply chains, which would be practically helpful for all economic operators involved.

Although the economic impact to industry largely can be compared to the restriction option, a drawback with the authorisation option is the added cost and administrative burden imposed on the manufacturers ("users") by the requirement to apply for authorisation. In the authorisation procedure, the burden of proof is with the applicant, and many applicants may experience severe difficulties in gaining relevant information. The large number of applications that will likely result will also put an extra administrative burden on the competent authorities.

The major disadvantage with the authorisation option is however that it can only be applied to use within the EU. As the mere distribution or consumption does not qualify as use, it does not cover the vast amount of articles being imported into the EU from third countries (estimated to 77% of the consumer market, cf. section B.2.2 and Table 13). For the case of these articles, the risk remains unregulated. Manufacturers who produce articles at volumes below 1 tonne/year are also exempt from the authorisation requirement. Compared to restriction, authorisation would not address the identified risk to the same extent as would restriction. Adding the time perspective – the authorisation procedure is generally slower than the restriction procedure with regard to the implementation times – the restriction option once again seems favourable. For these reasons, the authorisation route is discarded.

Restriction under REACH Article 68(2)

In addition to the ordinary restriction procedure laid down in Articles 69–73, the REACH regulation allows for a "fast track" restriction under Article 68(2). This article reads:

"For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply."

The final result from this option is expected to be the same as from the ordinary restriction procedure. Theoretically, the procedure is faster as no Annex XV dossier has to be submitted and assessed by RAC and SEAC. This allows for a restriction being applied earlier – with the drawback that the shorter implementation time also means higher conversion costs – and is therefore ideally suited for substances that pose a particularly severe risk.

In this case, the "fast track" restriction under Article 68(2) is not considered suitable. This is mainly because elemental lead is not yet classified; such a restriction would only apply to lead compounds and not to lead metal. Furthermore, the procedure for such a restriction is not yet clarified, and there are still no precedents or guidelines as to what documentation is needed to support a restriction under Article 68(2). So far, only one actual restriction has been proposed under this article, namely a restriction of polycyclic aromatic hydrocarbons initiated by Germany. The original proposal was submitted in June 2010 and has been deemed by ECHA (2012) to fulfil the requirements of a full Annex XV dossier. Evidently, the Article 68(2) route is not yet a real "fast track".

Amendments to the General Product Safety Directive

The General Product Safety Directive (2001/95/EC), henceforth "GPSD", provides an opportunity to implement community wide restrictions for products that pose a risk to consumer health and safety. This includes content of hazardous substances. Currently 19% of the dangerous products notified to the RAPEX alert system, which is introduced by the GPSD to facilitate rapid exchange of information between Member States and the Commission, concern hazardous substances. This is the second most common type of risk. (EC 2012)

The GPSD targets all articles intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them. It also singles out children as a particularly sensitive category of consumers. It may therefore be a suitable legal route to follow. The GPSD has been in force for a number of years and is considered to work well. Consumer products that contain lead have also been the subject of attention previously in the RAPEX system, for example in 2006 when a voluntary recall applying to lead in an item of jewellery was reported following a fatal accident in the United States (notification number 0191/06). The Swedish CA has earlier (KEMI 2007) pressed for a restriction under Article 13(2) of GPSD upon some lead containing articles, including jewellery, clothing accessories, crayons, candle wicks, and cast alloys. For these articles, a concentration limit of 0.1 % by weight was proposed, except for functional metal parts in jewellery where a concentration limit of 0.3 % by weight was suggested.

Article 13 of the GPSD states that:

"*1. 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

I 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.

2. The decisions referred to in paragraph 1 shall be valid for a period not exceeding one year and may be confirmed, under the same procedure, for additional periods none of which shall exceed one year."

The measures listed in Article 8(1) include mandatory labelling, sales bans, and product recalls. The Commission may thus adopt a decision requiring Member States to issue temporary bans and even recalls of products deemed unsafe.

It can be considered that the risk identified in this dossier 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. Like a restriction under Article 68(2) of the REACH regulation, this would be a “fast track” option. However, the duration of a restriction under the GPSD is limited to a year, although it may be extended for additional periods of one year. Obviously, restrictions under the GPSD are temporary interim solutions, and aim to restrict unsafe products until a corresponding restriction has been implemented in another, sector specific regulation. A current case involving substances in articles is the ban on the corrosive and allergenic anti-mould agent dimethylfumarate, which is restricted in articles and parts of articles above 0.1 mg/kg. This restriction was originally introduced under the GPSD in 2009, but has recently (Commission Regulation 412/2012) moved to Annex XVII of the REACH regulation.

In this case the need for risk reduction is not acute, but needs to be managed on a long term basis. For this reason, a restriction under REACH seems more adequate as a risk management option than does an amendment to the GPSD, and this option will thus not be further assessed.

Voluntary agreements

A voluntary agreement could be established with manufacturers, importers and distributors of articles to ensure that only articles, that do not pose a risk to consumers by exposure of lead by inhalation or ingestion, are placed on the market. This option would however not be feasible or effective in terms of risk management, due to:

The large differentiation of the scope “consumer articles”, and the vast number of economic operators making such articles available on the EU market, would make it virtually impossible to bring together the whole market in order to make the agreement. In reality, there would be different agreements within different trades and in different Member States. This option would therefore not bring harmonisation of the EU market.

Voluntary actions undertaken in this field have generally given unsatisfactory results. While retailers seem able to promptly replace lead in specific articles following an inspection or an alert, proactive phase-outs of lead have had a very limited impact according to findings from Sweden (KEMI 2007) as well as Canada (Canada Gazette 2005).

Monitoring of a voluntary agreement would be difficult, as it would require sampling and chemical analysis done by competent authorities, accreditation bodies or other third parties. With no regulatory basis to do so, such monitoring would probably not take place, leaving own declarations made by economic operators as the only *de facto* “monitoring”. This option is therefore not considered further.

Labelling and other information

Information to consumers, through product labelling or targeted campaigns, has in some cases proved efficient in order to raise consumer awareness and thus reduce risk. Some successful cases include the Danish skin allergy campaign (Danish EPA 2011), the Swedish campaign on indoor pest management (KEMI 2011), and the British aerosol industry campaign against volatile substance abuse (BAMA 2007). Voluntary product labelling is also common, e.g. in the detergent industry (AISE and Cefic 2009).

In this case, information as the single risk management option seems not effective or economically feasible. Targeted campaigns would not enable consumers to identify precisely which articles may contain lead. Besides this leading to the risk not being adequately addressed, the consumer response to a campaign could be anything between no notice at all and alarmist overreaction. An information campaign would also be difficult to monitor and follow up. Hence this measure implemented alone is not sufficient to address the risk, and has therefore not been considered further. This option can however be effective in combination with another risk management option such as restriction. As for labelling, it is unlikely that this would address the risk from the vast group of articles where the lead is not intentionally added. The much diversified market would also make it difficult to implement practically. This option is therefore not considered further.

Economic policy instruments

An option to regulation could be the introduction of a fee or tax to reduce the use of lead in articles with the purpose to stimulate the use of alternative materials. This could be a possible option since there is a market for alternatives.

Economic policy instruments act through price signals. The effectiveness of such measures therefore depends on how much the demand changes when the price changes. The willingness to substitute to alternative substances or techniques also varies depending on how effective and how expensive the alternatives are. Factors that are significant for when economic control are to be considered favourable is when price sensitivity is high, there are big differences in readjustment costs between regulated participants, the number of participants (economic operators) involved are low and when there is a high potential for finding and developing alternative substances and technologies.

The case of lead in articles is however different. The scope is very broad with a high number of participants, many of them unknowing as lead is sometimes present only as a contaminant. The amount of lead in articles varies heavily depending on the specific use, which means that the influence of the price of lead on the price of the article also will vary significantly. In those cases where the lead is intentionally added to perform a function, the cost of substitution may outweigh the cost added by the fee or tax. The impact of an economic policy instrument would likely hit different article groups very different, which makes it insufficient to address the risk for the broad scope of articles of concern.

Economic policy instruments are more likely to be implemented as a supplementary measure for a single use of lead in combination with a restriction for other uses. For the scope of this dossier, such measures show little or no potential and will therefore not be further assessed.

E.2 Assessment of risk management options

E.2.1 Restriction option 1: Lead content in articles that can be mouthed

This restriction option is intended to accurately target all those articles where the exposure scenario is applicable. It employs the same scope as the phthalate restriction in entry 52 to Annex XVII to REACH, and could hence benefit from the guideline (EC 2005) developed to implement that restriction. It restricts lead content and therefore assures a high level of protection, as lead can never migrate from lead-free products. For practical reasons, it is tailored to be aligned with the existing restriction of lead in jewellery (entry 63).

E.2.1.1 Effectiveness

Criteria for effectiveness are described in Annex XV to REACH: "the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk." The assessment of the effectiveness needs to combine the risk reduction capacity and the proportionality of the proposed restriction. In order to assess proportionality, the costs of the restriction should also be estimated. Altogether, the effectiveness assessment should show that the proposed restriction adequately controls the risks identified, while balancing costs and benefits and minimises inadvertent impacts.

E.2.1.1.1 Risk reduction capacity

In this restriction option, articles that may not be placed on the market if they contain lead at levels above 0.05% by weight expressed as metal, is assessed. The limit value is derived from the RAC re-evaluation of the Danish EPA study (see below), and also aligned with the limit value in the restriction of lead in jewellery. This restriction applies to entire articles as well as to parts of articles, provided that these parts are protruding, detachable or by other means accessible to be placed in the mouth by children, following the definition of accessibility as laid down in the European standard EN 71-1.

This restriction option targets lead content, whereas the actual risk emanates from lead migration. The relation between content and migration has been questioned, in particular the linearity of this relation. However, the recent process to pass a restriction under REACH of lead in jewellery has presented arguments for a content restriction. In the original proposal, the French CA (2010) suggested a migration limit, based on the premise that there is no correlation between the lead content of an article and the quantity of lead which can migrate from the same article. This premise was based on a survey made by the Danish EPA (2008). When RAC re-evaluated that survey, linear association was indeed found between lead migration and lead content for the metallic parts of jewellery, and RAC accordingly suggested the use of a content limit for these metallic parts. Further assessment by RAC showed that the same limit value applied also to non-metallic parts ensured the same level of protection. SEAC furthermore considered this restriction to be practical and easy to implement and enforce. (ECHA 2011.) The committees consequently found a content restriction more appropriate than a restriction based on migration, and this was also reflected in the final restriction adopted in Commission Regulation 836/2012. From this process, the conclusion can be made that the committees under REACH have found a content based restriction relevant and appropriate for the purpose of reducing children's exposure to lead. This reasoning seems valid also in the context of articles in general; hence, the lead restriction in jewellery can act as a precedent.

In the description of the risk to be addressed (section E.1.1), it has been assumed that 10% of the articles in scope contain lead and that the lead content of these articles is 1%

by weight (except for keys; see below). Assuming that all manufacturers comply precisely with the requirements and lowering lead levels to 0.05%, and assuming a linear content–migration relation, the risk reduction would be 95%.

It is however plausible that many manufacturers would respond to the restriction not by lowering lead levels, but by completely removing lead through a switch to lead-free raw materials, provided that it is economically feasible. Assuming that 50% of the manufacturers do that, the risk is reduced further to a total 97.5%.

Altogether, under the premises above, and assuming full compliance, this restriction option reduces children's exposure to lead by 69%. In addition, it pre-empts any potential increase in the use of leaded raw materials in articles. The figure is largely based on estimates and therefore associated with uncertainties, and should therefore primarily be used as an indication. Nevertheless, even taking these uncertainties into account the figure is high enough to estimate that this restriction option indeed reduces the risk significantly. For **this reason, this restriction option is deemed fully appropriate as regards risk reduction capacity.**

E.2.1.1.2 Costs

The analysis of cost concerns the costs related to the restriction of lead in articles in order to discuss the proportionality of costs and benefits. The analysis does not cover all elements of costs. It has also been necessary due to certain lack of data to rely on assumptions in the calculations. The following annual costs are included in the assessment carried out in E2:

- **Compliance and product testing costs** for all the actors concerned by the proposed restriction. The costs for product testing for companies are assessed under the heading "costs" and the costs for analysis and testing of products for public authorities are assessed under the heading "enforceability".

- **Substitution costs and cost of lead free alternatives.**

The Dossier Submitter proposes two different methods for the calculation of substitution costs in the Background Document, one method that is based on the total value of the article and one method that is based on the substitution of lead in those parts of articles that contain lead. The latter approach is based on a methodologically sound cost assessment technique. Therefore, SEAC has based its opinion on the method based on substitution costs for parts of articles that contain lead. With this method the substitution costs have been estimated at 12 (5.2-18) M€ per year. However, it should be noted that there are significant uncertainties in some of the assumptions used, as well as incomplete accounting for all costs associated with the restriction. As such there is considerable uncertainty about both the magnitude and direction of error in the estimate of costs.

The estimation of substitution costs in the method based on substitution of lead in those parts of the article that contain lead is based on the following factors:

- Selection of article categories/ types included in scope
- Number of relevant articles per category
- Number of parts containing lead per category (Assumption 1)
- Weights of parts containing lead per category (Assumption 2)
- The share of total articles that are assumed to contain lead (Assumption 3)
- The percentage content of lead in articles (Assumption 4)
- Additional cost per tonne of lead in relevant applications

SEAC has analysed the reliability and suitability of these key parameters:

Selection of article categories/types included in scope

The Dossier Submitter has made a selection of articles based on the scope of the proposal as it was proposed in the Annex XV report. On the basis of that scope the Dossier Submitter has made an evaluation of the articles in the PRODCOM (PRODuction COMmunautaire) database and included those articles in the cost calculation.

During the development of the opinion the wording of scope was modified a) in order to better define what mouthing is and b) to react to requests for exemptions that were put forward in the Public Consultation. For the definition of mouthing the EN-71 guidelines were used along with the relevant guidance related to entry 52 of Annex XVII of REACH as a basis (see section 2.2.) and the derogations and exemptions that were asked for are listed under scope as presented in section 2.2. Annex 1 to this opinion indicates to what extent this has impacted the selection of articles as proposed by the dossier submitter e.g. it lists the articles selected by the dossier submitter considered to be in scope in accordance with the definition of mouthing.

The cost estimation in this opinion is based on this set of articles. The total number of articles included in the analysis is around 20 000 million.

Number of relevant articles per category (PRODCOM selection)

The Dossier Submitter has attempted to use the PRODCOM database to quantify the number of mouthable articles on the market that might contain lead in either metal parts, pigments, painted surfaces and to some extent polymers. The PRODCOM database contains statistics on production of manufactured goods together with related external trade data. The Dossier Submitter has sought to match the categories of articles mouthed by children in a study of children's mouthing behaviours (Department of Trade and Industry, 2002) with the available statistical information in the PRODCOM database, so as to provide a proxy of the volume of kinds of articles that are mouthed and which might contain lead. SEAC is of the view that this approach has significant limitations, including:

1. The relevance for mouthing can be questioned for a number of articles: although many of the articles could potentially contain lead, it is questionable whether or not some of the articles can be mouthed according to the EN-71 guidelines that have been deemed to be applicable for this proposal.

2. The mouthing behaviour observed in the DTI study has been established only for those articles that were available to children at the time of the study. Although the list of articles that can be mouthed, according to the DTI study, is extensive it is questionable whether or not the mouthing times can be extrapolated to all consumer articles.

3. The estimation of number of articles per PRODCOM category is based on assumptions regarding a specific relationship between monetary value and weight, for which there is no empirical evidence or other support.

SEAC has reviewed the articles evaluated by the Dossier Submitter and has tried to identify where mouthing seems to be applicable on the basis of the EN-71 guidelines using the criteria of dimensions, availability and reasonably foreseeable use for those articles selected by the Dossier Submitter which are in scope of this restriction proposal.

SEAC has made an interpretation on the categories that could be considered to be affected by the proposed restriction. This selection has been used as the basis for the cost estimation underlying this opinion and is presented in Annex I to this opinion.

SEAC would like to point that the list provided in Annex I is indicative. It is the rapporteurs interpretation of the application of EN-71 to the articles analysed by the Dossier Submitter for the purposes of defining the analytical scope of the cost assessment. It is not in any way a definite list of articles relevant for the legal scope of this restriction. Any decision on whether an individual article falls within the scope of this restriction should be based on the criteria indicated in the section on scope of this restriction proposal.

Given the above mentioned limitations and interpretations, SEAC is unable to confirm that the approach taken by the Dossier Submitter gives an accurate estimate for the number of articles that could be affected by the proposed restriction and also cannot provide bounds on the degree of uncertainty in the analysis.

Assumption 1: number of parts per article

To further quantify the amount of lead to be substituted in articles that are relevant for this proposal the Dossier Submitter has, where relevant for the product category of PRODCOM, estimated the number of parts of articles that could contain lead. The Dossier Submitter has described what parts of the articles have been counted per product category and documented this in appendices 8 and 9 in the BD. The methodology used and the values that are derived seem plausible: e.g. the number of buttons and zippers in the textile categories is appropriate and accords with expectations from casual observation. It seems therefore reasonable to use these results in the cost calculation.

Assumption 2: weights of parts per articles

To quantify the total amount of lead to be replaced the Dossier Submitter has purchased certain articles, separated those parts of articles that could potentially contain lead and weighed them. The Dossier Submitter has reported the weight per part of articles that they found in appendices 8 and 9 of the Background Document. It is unclear whether the coverage of articles sampled encompasses all of the relevant population.

Assumption 3: proportion of relevant articles on the market assumed to contain lead

With the previous 2 assumptions the Dossier Submitter has derived the total volume of articles in scope of this proposal. However only a certain percentage of these articles contain lead. This market share of articles that are suspected to contain lead is assumed to be 10%. This percentage is a weighted average that is based on testing by the Dossier Submitter and on reported test results from other sources (see table 23). The information on testing can be found in chapter B 9.3.1 of the BD with additional information in appendices 3 and 4. The weights that the Dossier Submitter has assigned to these studies are apparently based on whether or not articles are independently chosen, representative for the EU market, whether the sampling process is adequately described, and the total number of articles reported, and whether test results on lead concentration are available. SEAC has been unable to establish that the weights do indeed reflect these criteria or are analytically meaningful. Moreover, SEAC wishes to underline the following shortcomings with the studies used to provide the market shares, with the consequence that the 10% assumption for articles containing lead cannot be confirmed as valid:

1. The sample sizes are small which makes extrapolation of the findings to the entire range of consumer articles in scope of the proposal problematic.

2. The Dossier Submitter claims to have taken care to test articles from different market segments (company size, shop size, shop location, internet stores, and country of purchase and price range). For example the articles that are reported to contain lead (testfakta 2012, testfakta 2011) are available on the EU market and that they cover a wide price range and are available in shops of any size. However SEAC cannot establish that the sample is representative and generalisable to the population since the surveys appear to be based on a non-probability sampling approach.

3. SEAC finds that the variety of articles that were tested compared to the variety of articles that are in scope is rather small which makes SEAC question whether the value of 10% can be applied to the whole range of consumer articles. In other words the heterogeneity of the articles in scope (all consumer articles) makes the applicability of the 10% found by the Dossier Submitter questionable.

Assumption 4: lead content

The lead content in consumer articles within the scope of this restriction was assumed by the dossier submitter to be 1%. This is again a weighted average of values found in literature and in values found in tests performed by the Dossier Submitter. SEAC is again unable to verify the validity of the estimate. Although the assumption is subsequently used in the cost calculations, SEAC again has concerns regarding the representativeness and generalisability of the samples.

Cost per tonne of lead replaced in relevant applications

The costs per tonne that are used to derive the total cost of substitution are based on the TemaNord study (TemaNord, 1995), recent prices of alternatives to metallic lead, lead pigments and lead stabilizers, and on recent stakeholder consultations.

For metallic lead the cost per kg to substitute lead is based on information from the stakeholder consultation and the prices per tonne of alternative metals is derived from the London Metal Exchange. The Dossier Submitter has assumed a 1:1 ratio of substitution in those applications where lead has no function in the alloy and has used more recent information from the stakeholder consultation to assess the cost of substituting functional lead in alloys.

SEAC agrees the prices reported and the assumptions and information on substitution seem to be applicable for this proposal.

The cost per kg lead to be substituted in pigments is based on the TemaNord report (TemaNord 1995). The Dossier Submitter claims that these prices can still be used as it is likely that due to technological development and industrial experience substitution costs have decreased since that study was published. The inclusion of lead based pigments in Annex XIV (for professional use) is likely to stimulate further substitution of lead based pigments with lead free alternatives and hence make alternatives more feasible in the (near) future.

The cost per kg lead to be substituted in stabilizers is also based mainly on the information in the TemaNord study. As there are on-going industry initiatives (Vinyl 2010) it is likely that lead free alternatives for plastic will become more available and hence less costly. These assumptions are confirmed by the Vinyl plus own reporting. (Vinyl plus, 2012[13])

No facilities or equipment costs are anticipated, neither are any costs expected related to reformulation or redesign, as the substitution usually will merely be a switch to lead-free materials. Enforcement costs are covered in section E.2.1.2.2. In addition, damage costs directly associated with the impact of lead to human health should be taken into account. These are related to the current risk situation and not to any specific restriction option, and are therefore analysed in Chapter F.

It is assumed that the price differences are small and that firms or consumers would not reduce the overall number of pieces of articles sold or bought due to an introduced restriction. In other words, the income or price elasticity of articles is not taken into account as their impact is conjectured to be small.

The average lead concentrations in consumer articles are according to the studies and analysis carried out by the Swedish CA estimated to be 1%. In the assessment a lower and an upper bound is also used for the purpose of conducting a sensitivity analysis. The upper bound used is 1.5%, this is not the highest measured content but a more common value in consumer articles according to the analysis and tests carried out by the Swedish CA. The lower bound used for the sensitivity analysis is 0.5% and is a level that has been monitored in clothing. According to the analysis carried out it is assumed that 10% of the articles that are put on the EU market contain lead. Based on the statistic information this would mean that the number of articles containing lead that are available for consumers on the EU market is 2 012 222 158 . See more information about EU production, import and export presented in chapter B and **Table 39** below.

Table 39: Number of items of consumer articles placed on the market annually that will be affected by the proposed restriction

Imported articles	**EU produced articles**	**Exported articles**	**Total**	**Of which articles contains lead**
15 373 116 562	8 045 234 559	3 002 252 431	20 122 221 588	2 012 222 159

<u>Substitution costs and cost of lead free articles</u>

Any restriction may during a shorter timeframe bring higher production costs for concerned companies due to the use of alternatives with a high price. These costs will initially be met by manufacturers who most likely will pass these costs onto importers, retailers and further down the supply chain to consumers.

<u>Method based on lead content to be substituted</u>

This method uses estimates of substitution costs per unit of lead and total quantity of lead to be substituted. Based on the conclusions in C.2.4, C.3.4 and C.4.4, Table 40 summarizes estimated substitution costs per kg for lead in pigments, stabilizers and metals.

13 http://www.vinylplus.eu/uploads/Progress_Report_2012/VinylPlus_ProgressReport_2012.pdf

Table 40: Additional cost for substitution of lead in articles produced in, and imported to, the EU. Estimation based on lead content

(Euro per kg lead)	Lower bound	Central case	Upper bound	Comments – see Chapter C for more details
Pigments in plastics	10	20	30	0-33 Euro/kg indicated in TemaNord (1995)
Stabilizers in plastics	10	20	30	4-15 for soft PVCs and around 46 for rigid PVCs. Central estimate based on 75% soft PVCs (at 10 Euro/kg) and 25% rigid PVCs. Low = 50% lower; High = 50% higher
Metals	20	50	80	1-25 Euro/kg for direct replacement of lead by other metals; 70-80 Euro/kg for replacement of functional lead in alloys, this is also used as an estimate for impurities in alloys; Central estimate is based on a 50/50 mix of the two cost types, but with a "conservative margin"; Lower bound based on primarily direct replacement; Upper bound based on primarily functional lead and impurities in alloys

Using these cost per kg estimates and the quantities of lead to be substituted from the different product groups in Table 14 allows us to calculate an indicative value for total substitution costs. The results from this calculation procedure are presented in Table 41. Fishing articles are not included in this estimation.

Table 41: Additional cost for substitution of lead in consumer articles produced in, and imported to, the EU. Estimated through the lead content based method.

Total substitution cost (000 €)				
Central case	Pigments	Stabilizers	Metals	**Total**
Clothes	0.287	0.147	4.065	**4.499**
Shoes	0.385	0.231	0.260	**0.876**
Accesories	2.616	0.000	0.902	**3.518**
Stationery	0.000	0.000	0.331	**0.331**
Sports and leisure	0.000	0.000	0.000	**0.000**
Intrerior decorations	0.322	0.123	1.544	**1.990**
Child care articles	0.000	0.128	0.233	**0.361**
T-shirts	0.000	0.211	0.000	**0.211**
Total	**3.611**	**0.840**	**7.336**	**11.787**

Lower bound	Pigments	Stabilizers	Metals	**Total**
Clothes	0.144	0.073	1.626	**1.843**
Shoes	0.192	0.115	0.104	**0.412**
Accesories	1.308	0.000	0.361	**1.669**
Stationery	0.000	0.000	0.132	**0.132**
Sports and leisure	0.000	0.000	0.000	**0.000**
Intrerior decorations	0.161	0.062	0.618	**0.840**
Child care articles	0.000	0.064	0.093	**0.157**
T-shirts	0.000	0.106	0.000	**0.106**
Total	**1.805**	**0.420**	**2.934**	**5.160**
Upper bound	Pigments	Stabilizers	Metals	**Total**
Clothes	0.431	0.220	6.504	**7.155**
Shoes	0.577	0.346	0.416	**1.340**
Accesories	3.924	0.000	1.444	**5.368**
Stationery	0.000	0.000	0.530	**0.530**
Sports and leisure	0.000	0.000	0.000	**0.000**
Intrerior decorations	0.483	0.185	2.470	**3.139**
Child care articles	0.000	0.192	0.373	**0.565**
T-shirts	0.000	0.317	0.000	**0.317**
Total	**5.416**	**1.261**	**11.738**	**18.414**

*Fishing articles are not included

Product testing costs for companies

As an effect of the restriction companies that supply, retail, sale or import products will have to ensure that these products are in compliance with the legislation and therefore the use and presence of lead needs to be traceable along the supply chain. Manufacturers will request information from their suppliers in order to make sure that their products are in compliance. Whenever such information is not available the option that remains will be to test article samples. Tests can be carried out by suppliers or by laboratories and will generate product testing costs.

The total cost for testing as calculated by the Dossier Submitter was obtained by multiplicating

- the number of articles assumed to contain lead after implementation by
- the share of articles to be tested and
- the average cost per test.

Following comments from the Public Consultation SEAC has concluded that it is not sufficient to take into account only the above factors in the estimation of testing costs. The following elements should be accounted for as well:

1. The number of tests per article is higher: more than one test are needed to estimate and verify the actual lead content of an article

2. When a test for lead content gives a positive result, additional testing needs to be done which usually is done via destructive testing

3. The lost value of the tested articles needs to be taken into account

The suggestion made in the Public Consultation that 65% of testing is done via XRF and 35% via destructive testing has been taken into account in the estimation carried out by SEAC. Subsequently the suggestion that a percentage of articles that undergo XRF testing still need to undergo destructive testing has also been taken into account. In the analysis carried out by SEAC it has been assumed that 10 % of all tested articles will undergo follow-up destructive testing, in line with the assumption on the proportion of articles that contain lead it is a high-side conservative estimate by SEAC.

For those manufacturers, importers, distributers and wholesalers which are not in full control of their supply chain, testing is the only option to ensure compliance with the proposed restriction. It is expected that large well-known retailers may be particularly proactive in ensuring conformity and may they choose to test their products, or update their procurement requirements. This seems to be confirmed in the consultation with stakeholders whilst preparing the proposal (as documented in Appendix 15 of the BD). Further evidence of this can be found in the AFIRM[14] guidelines, which recommend[15] buying metal parts, pigments, plastics etc. from known suppliers that are certified lead-free. In other cases, testing may be undertaken further upstream by wholesalers and distributors.

In addition, it should be noted that a more stringent restriction has been implemented in the US. According to the Consumer Product Safety Improvement Act (CPSIA) of 2008, products that are designed or intended primarily for use by children 12 years of age or younger may not exceed more than 100 ppm (0.01 percent) of total lead content in any accessible component part of the children's product. This is lower than the limit in the proposed restriction.

Evidence, either in the form of statements on the websites of companies or publications of external certification of their products (see table 6)[16], suggests that bigger companies which export globally already test their products to ensure compliance with the requirements on lead content of the Consumer Product Safety Improvement Act (CPSIA) of 2008 of the US.According to the CPSIA, products that are designed or intended primarily for use by children may not contain more than 100 ppm (0.01 percent) of lead in any accessible component part of the product. Companies exporting to the US seem to have applied this content limit to all articles, as statements and published certificates of lead content tests and/or compliance with standards for lead-free products mention compliance for all articles.

Company name	Source	statement
YKK	http://www.ykkfastening.com/quality/standard/laws.html	**1) Lead content in surface coating and substrates** > Lead content in products manufactured by YKK, except TZN airtight / watertight zippers and zippers with lead

[14] Apparel and footwear industry group: http://www.afirm-group.com/
[15] http://www.afirm-group.com/rsl-guidance/

		crystals/ rhinestones, does not exceed the lead content requirements of the CPSIA, as confirmed through internal testing.
Prym	Corporate website	Metals: http://www.prym-fashion.com/static/0H0500AlN.pdf Plastic: http://www.prym-fashion.com/static/0H0500Alg.pdf
Scovill	http://www.scovill.com/about-us/quality-assurance/)	Automotive, Aerospace and Medical are just a few examples of industries that must adhere to stringent regulatory demands. Scovill products meet or exceed regulatory standards to ensure durability and prevent product failure. We also offer full compliance of EU and USA regulations. The CPSIA (US Consumer Product Safety Improvement Act) of 2008 provides for a maximum allowable lead content of 100ppm, however, Scovill's internal standard is 60ppm or less. In other areas, we exceed regulations set for separation strength- once again going beyond what is required by industry standards.
Berning	http://www.berning-net.de	http://www.berning-net.de/en/fashion_style/umwelt_verantwortung/certificates/oeko_tex.html
JN zippers	http://www.jnzipper.com/New/index.html	Effective from 10 February 2009, the CPSIA requires that the lead content for children's products cannot exceed 600 parts per million (ppm). The standard will be tightened to 300 ppm on 14 August 2009. Unless the CPSC determines that the 100 ppm standard is not feasible for a product or product category, the lead content ban will be further reduced to 100 ppm on 14 August 2011.

Table 42: evidence on existing testing

It should also be noted that similar tight restrictions apply to the Canadian market where currently a 300 ppm limit exist for consumer articles that can be mouthed. This limit is lowered to 90 ppm for children's articles[17].

It is therefore logical to assume that testing for lead is already applied to a large amount of articles regardless of their intention for children or adults and irrespective of their products being exported to the US, Canada, Europe or other parts of the world.

[17] http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2010/2010_203fsb-eng.php

SEAC therefore considers it reasonable to assume that no major extra costs are to be expected for such manufacturers. The testing cost estimations made by the Dossier Submitter and elaborated by SEAC is intended to account for new testing triggered by the proposed restriction.

The analysis of testing costs is as follows

Number of articles assumed to contain lead after implementation

The number of articles to be tested is based on both the total amount of articles and the proportion of articles that are assumed to contain lead.

The derivation of the number of articles from the PRODCOM database has been described in the section under substitution costs. In the calculation made by the Dossier Submitter, the proportion of the articles on the market that are assumed to contain lead is discussed under the substitution costs.The proportion of articles assumed to contain lead after implementation of the proposed restriction has been estimated at 1-3% by the Dossier Submitter.

Share of articles to be tested

The Dossier Submitter assumes a testing rate (0.1-1%) to the proportion of articles assumed to contain lead. This results in an overall testing rate of 1-3% x 0.1-1% = 0.001%[18]-0.03[19]%, or 1 in 3300-100000 articles.

The testing rate of 0.1%-1% had been suggested during the Public Consultation whilst preparing the dossier. However, according to the Dossier Submitter, it was also indicated during the consultation that this testing regime might be an overestimate as in reality far fewer items per batch might be tested. Information on testing regimes has been obtained from guidelines from the AFIRM-RSL, who recommend buyers to test random batches if the supplier is known and generally well performing. AFIRM recommends testing all batches only for new suppliers or for poorly-performing suppliers.

SEAC does not agree with the approach set out by the Dossier Submitter as it implies that a priori knowledge on the share of articles that contain lead exist. This does not seem to be logical as it is exactly the share of articles that contain lead that is still to be established before testing.

Within the framework of the US Consumer Product Safety Improvement Act[20] of 2008, recommendations have been made on the testing and certification requirements. As regards the frequency of testing, a recommendation is made *inter alia* to test articles for their lead content with a testing rate of 1 out of 10000 articles. Follow up questions to industry have confirmed that this value is not unreasonable to use and SEAC proposes to use this latter value.

Number of tests per article

[18] Lower bound of testing regime proposed by DS (0.1%) * lower bound of proportion of articles that contain lead after implementation (1%) = 0.001* 0.1 = 0.0001

[19] Lower bound of testing regime proposed by DS (0.1%) * lower bound of proportion of articles that contain lead after implementation (1%) = 0.001* 0.3 = 0.0003

[20] http://cs.cpsc.gov/ConceptDemo/SearchCPSC.aspx?query=http://www.cpsc.gov/library/foia/foia10/brief/102testing.pdf&OldURL=true&autodisplay=true

The approach as developed by the Dossier Submitter took into account only one test per article. Information from the Public Consultation has indicated that several tests per articles are actually performed. SEAC agrees to this and has applied a higher number of tests per article. Furthermore articles can consist of multiple components for which separate testing might be needed.

Average cost per test

The average cost per test used in the calculations by the Dossier Submitter is based on the cost of tests for XRF testing known to the Dossier Submitter in the context of their own duties as a CA. This was a price range of about 20-40 € per analysis using XRF screening. Consequently the Dossier Submitter has based its values on the costs of testing on the prices offered to them. Following comments from the Public Consultation the prices for XRF testing have in the assessment by SEAC been adjusted downwards to 5 euro per test,

The Dossier Submitter assumes all testing is done using XRF screening. The Dossier Submitter claims that most of the larger retailers and most enforcement agencies have this equipment. It is however not likely that all testing will be performed using this method as the equipment is rather expensive. Therefore, some testing will be performed using wet-tests, which are destructive.

Average price per article

The Dossier Submitter uses an average price per article that is based on the value of all articles and the volume of articles. This is not likely to be a correct estimate: in reality the original scope of the proposal is very broad and the prices will vary within that scope to the extent that it is questionable to use such a measure. With the refined scope (based on EN-71) using such an approach becomes more credible. On the basis of the refined scope the average price per article is estimated to be around 6 euro.

Table 1 gives an overview of the derivation of the testing costs.

	unit		low number of xrf test, low value of destructive test	medium number of xrf test, medium value of destructive test	high number of xrf test, high value of destructive test
Number of articles assumed to contain lead (10% of total articles in scope)	nr	a	2012222159	2012222159	2012222159
share of articles tested		b	0,0001	0,0001	0,0001
Number of articles		c = a*b	201222	201222	201222

tested					
number of xrf tests per article		d	1	3	6
cost per test	€	e	5	5	5
average cost per article	€	f = d*e	5	15	30
share of articles that are tested with XRF		g = 65%	0,65	0,65	0,65
cost of XRF testing	€	h = f*g*c	653972	1961917	3923833
cost per destructive test	€	i	30	60	90
number of tests per article		j	1	3	6
average cost per article	€	k = i*j	30	180	540
rate of destructive testing		l = 35%	0,35	0,35	0,35
cost of destructive testing	€	m = c*k*l	2112833	12677000	38030999
% follow up test for xrf tested articles		n = 15%	0,15	0,15	0,15
cost of follow-up tests		o = c*g*i*n	588575	1177150	1765725
value of article	€	p	6,95	6,95	6,95
loss of value of tested article	€	q = c*l*p+ c*g*n*p	625826	625826	625826
total testing costs	€	r=h+m+ o+q	**3 981 207**	**16 441 892**	**44 346 383**

Table 43: testing costs

Overall the assumptions made by the Dossier Submitter and the following adjustments to the approach on the basis of information submitted via the Public Consultation on testing costs for companies seem to be valid: the price of testing is based on values which have been confirmed during the Public Consultation. The testing regimes were confirmed by the stakeholder consultation and follow the recommendation set within the framework of the CPSIA. It is worth noting that the cost of obtaining information on lead content of articles is not known and it can therefore not be compared to the costs of testing. It is however likely that a number of companies will shift to lead free articles on the basis that the costs of shifting supplier can be lower as the costs of testing.

Using the abovementioned assumptions the total testing cost is estimated to be 16 M€ (4 M€ - 44 M€).

The costs per test are taken from section E.2.2.1.2 on enforceability. As will be shown in that section, costs may in many cases be significantly reduced by the use of non-destructive X-ray fluorescence (XRF) testing. The costs given from the table are therefore likely to overestimate the actual cost somewhat.

The Dossier Submitter did not assess these kinds of costs in their proposal. It did take this into account to some extent by basing the higher bound prices on the industry feedback on expected substitution costs for functional lead and by discussing the economic feasibility of alternatives (chapter C). SEAC agrees that there might be costs associated with re-engineering articles due to the need to use new materials in order to be compliant.

Costs due to redesign and re-engineering

Pigments

The Dossier Submitter presents a (non-exhaustive) list of possible alternatives. During the stakeholder consultation for preparing the proposal the Dossier Submitter was informed that a) there are no consumer articles where lead is still needed and b) no major adjustments had to be done to change from lead stabilisers to lead free stabilisers.

The Dossier Submitter therefore concludes that (especially) not all pigments are fully interchangeable, and to obtain a certain shade a certain combination of pigments is necessary. This information was confirmed on the Public Consultation where information was provided that lead containing pigments were no longer in use in consumer articles.

Plastics

Through the Vinyl Plus Programme major achievements to replace lead in stabilisers have already been achieved. Furthermore, on the basis of comments received during the Public Consultation, re-engineering is not considered to be necessary as the lead containing recycled raw material will no longer be used and has been indicated that this material will rather be used in construction materials and will not be used for (mouthable) consumer articles.

Metals

Re-engineering might be an issue for some of the alloys, especially for those alloys where lead constitutes a functional addition to the metal. This is in particular the case in some metal alloys where lead is added for functional reasons.

For the articles currently in scope of the restriction (after having revised the scope based on EN-71) re-engineering does not seem to be a key issue, anecdotal evidence suggests that clothing manufacturers are willing to pay the higher price for lead-free articles as parts of assurance of quality of the overall final product[21].

During the Public Consultation information on several applications was provided that copper alloys in consumer articles, which could be mouthed by children, have a lead content above 1-2% by weight. The presence of lead fulfils a technical function, critical for the fabrication of precision articles such as keys, locks, musical instruments and writing instruments. No adequate substitutes are available and exemptions for such uses are needed.

As a follow up of questions to industry on the impact of the brass derogation, industry indicated that extra costs will be endured in the order of 6 M€/year when the listed exemptions under point four of the opinion are recognized. The reason additional costs will be incurred is that by reducing the maximum lead limit to 0.5 % means that copper alloys, which contain lead for technical reasons, can't be used for the current applications in consumer products and have to be substituted by other copper alloys (or other materials offering acceptable performance). Consequently larger amount of copper will have to melted. Additional costs are then foreseen:

a) due to the operating cost of the smelter

   These additional operating costs are composed of refining charges and treatment charges which both depend on the copper content of the scrap. The refining charge depends on the copper content and the treatment charge depends on the volume of scrap.

b) increased material and processing costs at the semi-fabricator's site

   Prices depend on the difference between the pure metal and the scrap prices, prices are global prices which are volatile.

c) and the impact on scrap recycling.

   It is expected that due to lead restrictions, scrap collectors cannot sell their scrap to semi-fabricators for re-melting and that therefore the scrap will have to be sold to the smelter. As a consequence, the value of the scrap will drop and only the copper content of the scrap is paid for. The value of the scarp and the extent to which that value drops depend on the copper content, taking into account minor losses of copper during the process.

The exact figures for reach steps have been claimed to be confidential by industry.

Based on the industry information it can be concluded that regardless of the cost scenario, 6 M€/year will be incurred by the recycling sector.

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http://www.slate.com/articles/business/branded/2012/04/ykk_zippers_why_so_many_designers_use_them_.html

Total compliance costs for companies

Adding together the costs from the tables above, the total annual compliance costs for the central case as well as lower and upper bound is shown by the below table. Total compliance costs are calculated using the lead content method. This method is considered to be the more accurate of the two, since it is related to actual amounts of lead to be substituted and also due to the more thorough data analysis applied in this method. The total compliance costs are now 81% lower than previously anticipated. Note however that fishing articles are not included in the method used.

Table 44: The total compliance costs per annum (M€)

	Lower bound	**Central case**	**Upper bound**
Substitution cost lead content method	5	12	18
Costs for testing	4	16	44
Costs for testing	4.6	17.1	46
Costs for redesign and re-engineering	6	6	6
Total using lead content method	15	34	68

The overall additional costs and increase in costs that a restriction in option 1 would pose to different actors in the supply chain.

No major additional costs for consumers or society are expected since alternatives are already available on the market and some of them also at a competitive price.

The annual compliance costs for affected companies are expected to decrease over time, as procedures for ensuring compliance will be established, including the possibility of reducing testing costs using XRF. The presence of lead-free articles at competitive prices on today's market also indicates a potential rationalisation; lead-free alternatives do not necessarily bring about higher costs other than during the initial transition.

Overall SEAC supports the methodology based on the substitution of lead in those parts of articles that contain lead and considers it fit for the purpose of the analysis, SEAC however notes that several of the assumptions used in the model are rather weak. The Public Consultation has given information on categories where substitution is not feasible due to the availability of alternatives or their economic feasibility. These applications are discussed in the section on derogations.

SEAC notes that several problematic issues frame the analysis of substitution costs.

E.2.1.1.3 Proportionality

The proportionality of a restriction option is roughly a qualitative weighting of the risk reduction capacity and the costs, also taking into account the non-intended impact of the restriction option in question. It can be used as an indicative statement of the cost-benefit balance, although it is not intended as a cost-benefit analysis.

This restriction option has been found capable of removing 69% of the total exposure of lead from articles, at an initial yearly cost of 34 M€ (which is likely to decrease over time). Of the four restriction options assessed here, this is the option giving the highest added value in terms of risk reduction or "the highest risk reduction for the money". Moreover, it is targeted to the risk and impacts only those article categories where exposure can be expected. The non-intentional impact is likely low; although a lot of articles which cannot be presumed to contain lead are in the scope, these articles could be easily identified and their manufacturers will not need to take on any compliance work. The additional costs of alternatives are estimated to be low, if any (in some cases the lead-free alternatives even seem cheaper), and the costs for compliance and product testing seem bearable. Finally, as will be shown in Chapter F, this risk reduction can also be transformed into an economic benefit, as the absence of neurodevelopmental damage to children is related to socioeconomic benefits.

Given these costs to society and estimated health benefits, this restriction option is considered fully appropriate as regards proportionality.

E.2.1.2 Practicality

According to ECHA (2007), practicality means that the proposed restriction must be implementable, enforceable and manageable. "Implementability" implies that the actors must be technically capable to comply with the restriction within the set timeframe. "Manageability" means that the proposed restriction should be clear and understandable to the actors involved, the relevant information accessible, and the administrative burden proportional. The term also involves taking into account the characteristics of the sectors concerned, including the number of SME's. "Enforceability" is the ability of MSCA's to check the compliance with the proposed restriction. All three terms imply proportionality with respect to resource management.

E.2.1.2.1 Implementability and manageability

As has been demonstrated from Chapter C, the replacement of lead from raw materials used to manufacture the articles in this dossier seems to be economically and technically feasible. Consequently, the actors involved in the supply chain for the articles should be capable of complying with the proposed restriction simply by switching to lead-free raw materials. With the exceptions mentioned below, the market actors consulted during the consultation process have not indicated any foreseeable difficulties with complying with a lead restriction based on content. No changes in production techniques, machinery, or training of staff are anticipated; compliance can be achieved simply through switching to lead-free raw materials. As such raw materials already exist on the market, there is no need for a longer transition period from this perspective and the restriction could enter into force immediately.

This restriction option employs a wide scope, and its implementability as well as manageability is likely to benefit from the introduction of derogations. During the consultation process a few applications have been singled out as candidates for derogation, as lead seems to be necessary for the function of the material and hence of the article. This applies to metallic lead only. One article category where metallic lead may be required is keys and locks, where lead adds workability including acting as lubricant.

In the work carried out by the DS the need for derogation concerning second hand market and recycling has also been assessed. The resources for carrying out inspection activities are already limited for articles on the first-hand market. Additional inspection activities concerning the second-hand market would therefore neither be implementable nor be manageable for the authorities. The additional costs for carrying out inspections would not be proportionate to the achieved risk reduction. The number of years the articles remain in the supply chain vary. For clothing and shoes it has been estimated that a common time before being phased out is 5-10 years (Tema Nord, 1995). For accessories the time is shorter and for interior decorations the time is longer. SEAc in their opinion assumes that for any new articles item added to the circulation each year, an old articles items is removed from circulation, and that the lifetime of an item of an articles is 3 years (i.e. the items in circulation will be completely renewed every 3 years).

A more efficient and implementable measure for the second hand market would be to carry out targeted information activities about the present lead content in certain articles and how this can be monitored and tested. It is therefore recommended that the second hand market is derogated from the proposed restriction.

For recycling there are already restrictions that have been put into practice within the EU. According to some consulted actors there is however technical constraints when sorting out metal containing lead from metal not containing lead in the recycling stage. The handling of hazardous waste, that includes lead containing waste, may never cease to be handled as hazardous waste according to the end-of waste criteria.

In comparison to the case of cadmium in PVC a higher content was implemented/accepted for recycled materials (0,1%) than for new/virgin materials (0,01%). The DS is of the opinion that the principle of equivalence should be applied and gives guidance for new regulation. Following this principle it would not be possible to implement a risk management option that would result in a regulation that allows further use of lead containing zippers made of recycled materials but not in zippers manufactured from virgin materials. The same limits should therefore be implemented for recycled materials as for virgin materials. The lifecycle should be efficient with resources and as far as possible be free from hazardous substances.

The brass industry has during the consultation addressed the need for a derogation for recycled materials since the produced brass from non recycled materials is of lower quality. Consultation with the recycling industry indicates that the industry themselves does not want recycled materials to be considered as a less favorable alternative.

The following categories should therefore be exempted from restriction in this option:

- Second hand market

The use of lead in crystal glass was not assessed specifically in the Annex XV report. According to companies and trade organizations that participated in the stakeholder consultation, there are lead-free alternatives to full lead crystal. However, some stakeholders have stated that the workability of the alternative glasses is limited compared to lead containing crystal. This is especially the case for crystal that is processed manually.

Many objects made of crystal fall outside the scope of this dossier, e.g. glassware. Crystal ornamentals, however, are consumer articles, which could be accessible to children. The stakeholders consulted, both companies and trade organizations, state that there are lead in the glass and possibly also in metal parts of their products.

Full lead crystal contains lead oxides, PbO or Pb3O4, and the lead concentration is at least 24%. The amount of lead oxides used to produce lead crystal glass is 3000 t /year (7% of the total market of this substance). The lead is bound in a molecular network and thereby integrated in the crystal. The stakeholders state that crystal should not be regarded as a preparation, but rather as a substance of its own. Since crystal must contain at least 24% lead in order to be called crystal, it is not possible to replace the lead. There are however other glass materials which are comparable in optical and visual properties, to which no lead has been intentionally added. These glasses could substitute the crystal itself. The stakeholders are however of differing opinions regarding whether these materials can be regarded as satisfactory alternatives. Apparently, the alternative glasses are not as workable as crystal, if the glass is processed manually. On the contrary some stakeholder responses state that crystal glass does not require lead for its function including optic properties.

SEAC notes that most articles containing crystal glass are often typically not accessible for children, or already covered under specific EU legislation, where lead is restricted (e.g., food contact materials, jewelry), and that those kinds of articles are considered to be out of scope of the proposed restriction. However, during the Public Consultation of the Annex XV dossier it was raised that a similar approach to crystal glass, precious and semi-precious stones, and enamels should be taken as in the lead in jewelry restriction using a similar justification. RAC has not objected to the derogation of crystal glass, precious and semiprecious stones, and enamels. SEAC is therefore of the opinion that granting of the requested exemptions would align the proposed restriction with E-63 provisions and would avoid problems of enforceability for the relevant “borderline” items (which are anyway very limited in number).

Beside the derogations, the principal scope restraint is that only articles that can be placed in the mouth by children shall be within scope of this restriction. This restraint is also used in entry 52 of Annex XVII to REACH, and a guideline for compliance has been developed (EC 2005). Although the final assessment is made on a case-by-case basis, the legal precedent and the existence of a guideline justifies that the suggested scope is manageable. To most actors in the supply chain, it should be self-evident whether they market articles that can be placed in the mouth by children or not.

In practice, the actors in the supply chain will need to make sure that they market only lead-free articles. This will not be a new requirement. Article 33 in REACH states that producers, importers and other suppliers of articles containing candidate list substances (SVHC’s) above 0.1% must provide information on the content of these substances to their customers. This requirement already applies to some lead compounds. ECHA has recently proposed another 21 lead compounds to be identified as SVHC. If these proposals are accepted, all lead compounds that are actually used will be subject to the information requirement. Market actors must then be knowledgeable of the content of lead compounds in their products. The same requirement applies to a number of other hazardous substances. Thus, testing for lead and other substances must already be done by all actors in the supply chain. The only incremental information requirement imposed by this restriction is that also metallic lead should be subject to testing. Hence, the added administrative burden of this restriction option is believed to be small. The practical means of implementation will be compliance testing (see section E.2.1.2.2), material declarations and supplier declarations. These procedures are normal to trade and should not provide any additional difficulties. As will be shown in the next section, compliance testing (i.e. determination of lead content) is standardised and comparatively easy to achieve.

Small and medium sized enterprises (SME's) more frequently encounter difficulties in managing regulatory requirements, mainly due to smaller budgets and lack of specialised knowledge. The sectors affected by this restriction proposal are likely to contain a fair extent of SME's. It is therefore important that the restriction is manageable as regards costs (which are dealt with in section E.2.1.1.2) and comprehensibility. Content based substance restrictions are legion in the article market, be they regulatory or market requirements, and are easily understandable without room for interpretation. They enable market actors to make concrete and easily verifiable requirements on their suppliers. This is especially useful to market actors with little knowledge in chemistry, and when trading across language barriers. It is therefore believed that a content based restriction will benefit SME's. In order to further increase manageability for SME's, MSCA's may need to provide information or training for some of them (notably the smallest ones and the distributors).

Altogether, the proposed restriction is easily understandable for all affected parties and access to the relevant information is relatively easy. Substitutes are readily available and substitution is economically feasible. **Thus, this restriction option is considered to be implementable and manageable for all parties within the product chain.**

E.2.1.2.2 Enforceability

In order to be enforceable, a restriction needs two properties. First, it needs to be properly limited so that it is clear to the enforcement authorities which products are in scope of the restriction and which are not. This property is dealt with in section E.2.1.2.1. Second, the restriction needs a limit value that can be subject to supervision mechanisms. In order to be implementable within a reasonable time frame, the restriction should also be designed so that an existing supervision mechanism exists and is practically workable for enforcement authorities. A number of current EU legislative acts set content limits for heavy metals (cf. Appendix 2), including the RoHS directive and the Packaging and Packaging Waste Directive. Moreover, national restrictions of lead content apply in several countries, e.g. in Denmark (all articles) and the U.S.A. (children's products). Taking into account the technical need for knowing the chemical composition of metal alloys for specific applications, it is clear that standardised analytical methods are already available.

Table 45: Overview of analytical methods of lead content in different matrices

Reference	**Matrix**	**Method**	**Comments**
IEC 62321	Metal alloys (based on Fe, Al, Sn, Zn, Cu) Plastics (ABS, PE, etc.) Glass Electronics	XRF (screening) ICP-OES ICP-MS Flame AAS	Designed for use on electric and electronic equipment. Used for the purposes of the RoHS directive, i.e. to enforce the limit of 0.1 % by weight in each material. The wet chemical methods are accurate within ± 20% at 10 mg/kg and above.
Health Canada C02.2–C02.5	Surface coatings PVC and similar Metal Wax and similar	Flame AAS	Used on consumer products. Preparation methods and LOQ differ somewhat depending on matrix. LOQ's range from 32 to 86 mg/kg, i.e. below the 0.05% limit relevant for this proposal.
U.S. CPSC (1) U.S. CPSC (2)	Metal Non-metal	XRF (screening) ICP-OES (ICP-MS and GF-AAS can also be used)	Used on children's products for enforcement of U.S. regulation on lead in children's products.
ASTM F 2617-081	Polymeric materials	XRF	Referenced in the U.S. CPSC standards above. No LOQ is reported, but the method has been found applicable from 20 mg/kg.

In addition to these methods intended for use on consumer products, numerous analytical standards exists for the determination of lead and other elements in raw materials like various metal alloys, rubber, paints and polymers. These methods include European standards, ISO methods and corresponding ASTM standards for use in the U.S.A, and mainly use AAS and ICP for the determination.

The wet chemical methods (AAS and ICP) are destructive and are used for a reliable determination of the full lead content. Both the actual determination methods and the methods for sample preparation (microwave digestion and dry ashing) are widely available, based on routines, and employed by virtually all commercial laboratories. There should be no need for further standardisation or method adaptation in order to enforce this restriction option, which enhances the immediate implementability of the method.

In addition to the wet chemical methods, X-ray fluorescence (XRF) spectroscopy can be used to detect elements in the relevant matrices. XRF is already used for screening purposes by European enforcement agencies in order to enforce e.g. the RoHS directive and the Toy Safety directive, and is also acknowledged by the U.S. CPSC for enforcing the lead restriction in children's products. The XRF method has several advantages. First, it is non-destructive and gives immediate answers, and also does not require sample preparation. This facilitates the enforcement process significantly and also supports manufacturers' internal control for compliance. Second, it is considerably cheaper than sending all samples off to wet chemical analysis (cf. section E.2.1.1.2). Field-portable

XRF instruments have already been purchased by several European enforcement agencies for the purposes of enforcing other regulations. This allows for a cheap and efficient in-house testing.

The XRF method has three major technical drawbacks. First, it does not allow for an analysis of the interior of the articles, but only the surface layer. Second, it is not feasible to use on soft and low-density materials such as textiles, but require a certain hardness and density. Some of the articles targeted here will require wet chemical analysis even for screening. Third, its resolution can be questioned; in those cases where an article has a lead content close to the restriction limit, a wet chemical analysis will be required to determine the compliance of the article. For these reasons, the XRF method can not completely replace wet chemical methods, but only used as a means of screening (and hence reduce the number of destructive wet chemical analyses).

Testing lead content is already carried out widely both by industry actors (for compliance) and by authorities (for market surveillance). The methods are widely available, commonly used and a non-destructive, immediate-answer screening method can be utilised. No modification of existing analytical methods is anticipated from this restriction option. It can therefore be implemented rather quickly. It can also be noted that that the methods for lead content analysis can be used for the simultaneous enforcement of other restrictions in REACH, which makes the enforcement cheaper and more efficient. These restrictions include the one of lead in jewellery (entry 63), and that of cadmium in various applications, including many plastic materials (entry 23). Lead and cadmium are usually regulated and therefore analysed together, and the standards overviewed above can typically be used also for the determination of cadmium.

The cost of analysis for public authorities seems to vary between laboratories and between Member States. As for wet chemical analysis (cf. section E.2.1.2.2), RPA (2009) reports a cost between 16 and 40 € per testing, with a marginal cost between 6 and 10 €. The costs offered to the Swedish CA upon queries to laboratories (as part of the stakeholder consultation) range between 30 and 60 €, with discounts if many articles or several elements are analysed at the same time. The cost figures are indicative only. It should also be noted that due to overlapping with other legislative requirements, like the restriction of cadmium in most consumer articles, only a fraction of this cost can be attributed to this restriction.

For XRF screening (cf. section E.2.1.2.2), RPA (2009) reports a cost of 15€. The costs offered to the Swedish CA range from 25 to 40 €. All these costs are lower than the corresponding costs for wet chemical analysis, but are reported by the same traditional laboratories. Prices could be further lowered. In the U.S.A., the introduction of the lead restriction in articles in the Consumer Product Safety Improvement Act has spawned a market for consultancies offering XRF testing services to companies for regulatory screening. These charge per hour or per test, and the prices offered by such consultancies range from 2.50–15 US$ per test or 100–200 US$ per hour, depending on the firm and the number of tests (or hours) hours purchased. Portable XRF devices can also be rented, at prices 300–400 US$ per day or 1200–1500 US$ per week. Moreover, field-portable XRF instruments are available on the market at costs between 20,000 and 40,000 €. Such instruments have already been purchased by several enforcement agencies and major retailers, which allows for an even cheaper and more efficient in-house testing. Experiences from the Swedish CA show that with an in-house XRF device, the number of element (lead and others) analyses in articles can be multiplied without any additional costs.

Personnel costs could also be included in the calculation. Currently, enforcement activities very similar to those described here are carried out regularly by MSCA's in course of other regulations. For RoHS enforcement, MSCA's spend approximately 300-400 working days annually according to a questionnaire sent out as part of the stakeholder consultation. The respondents generally represent MSCA's in Northern and Western Europe, where a full time equivalent can be assumed to cost 50,000 € annually. (Gross charge). It is commonly estimated that lead accounts for more than half of these costs, as non-compliances generally relate to lead. This gives an annual cost of 6,000 €. MSCA's who also enforce other regulations, MSCA's who also enforce other regulations, like the Packaging and Packaging Waste Directive or the Danish national lead ban, tend to spend equally on these regulations. Here, the personnel costs are roughly proportional to the number of inspections. In those cases where several restrictions can be enforced simultaneously, as would be the case with this restriction and e.g. the cadmium restriction under REACH, the costs for each inspection can be split over these restrictions. However, it is not likely that MSCA's will hire additional personnel only to enforce this single restriction. They would rather try to find opportunities for rationalisation, e.g. by testing all requirements applicable to an article simultaneously, or simply by expanding the range of articles in which they enforce. While the latter in practice might lead to a weakening of the enforcement pressure per article category (e.g. less RoHS inspections) these costs for public authorities will be minor compared to business compliance.

Hence, the conclusion can be drawn that the incremental cost of enforcing this specific restriction equals the sheer cost of analysis. This is deemed a reasonable burden to MSCA's compared to the reduced risk.

Altogether, the combination of XRF and wet chemical methods such as ICP and AAS, and the opportunity to enforce many regulations simultaneously and thus decrease the incremental cost and workload of this specific restriction, makes a lead restriction based on content fully appropriate in terms of enforceability.

E.2.1.3 Monitorability

Following the ECHA (2007) guidelines, monitoring may cover any means to follow up the effect of the proposed restriction in reducing the exposure. This may include the monitoring of blood lead levels in children, to see if the exposure decreases following the restriction. However, the current blood lead levels are the result of many different routes of exposure, and it might be difficult to attribute changes in blood lead levels to this specific restriction.

Another means to follow up this restriction option is to monitor the evolution of the fraction of articles with a lead content above the proposed limit, i.e. the percentage of non-compliant articles over time. Reliable methods for this measurement have been presented in section E.2.1.2.2. This means of monitoring is essentially identical to enforcement, but can also comprise actions undertaken by industry actors to comply with the proposed restrictions, as well as measurements carried out by independent test institutes, media, or green and consumer groups. Unlike the measurement of blood lead levels, this means of monitoring will be directly related to this restriction.

The costs of monitoring are assumed identical to the enforcement costs reported in section E.2.1.1.2. No further costs for monitoring are anticipated.

E.2.1.4 Overall assessment of restriction option 1

This restriction option is intended to accurately target all those articles where the exposure scenario is applicable. It employs the same scope as the phthalate restriction in entry 52 to Annex XVII to REACH, and could hence benefit from the guideline (EC 2005) developed to implement that restriction. It restricts lead content and therefore assures a high level of protection, as lead can never migrate from lead-free products. Moreover, it is tailored to be aligned with the existing restriction of lead in jewellery (entry 63) and can therefore be applied consistently in the whole range of mouthable articles including jewels.

As shown from this review, a content restriction is practically feasible and has a good capacity of reducing exposure at a reasonable cost. It is easy to understand for all involved parties and enables even importers and distributors without any particular chemical knowledge to impose the relevant requirements upon their suppliers. The necessary analytical methods are commonly used by commercial laboratories globally, and the potential of non-destructive, field-portable XRF as a screening measure further facilitates compliance control as well as enforcement. Adding the existence of lead content restriction in other countries, including the U.S.A., it can be expected that the restriction can be implemented without the need for a longer transition period.

The main drawback of this restriction option, which it also shares with other options, is the need for derogations in order to be workable. From the information provided during the stakeholder consultation derogations may be needed. One example is the need for derogating keys. Keys are particularly worrisome as they are relatively frequently mouthed by children, and contribute largely to the exposure remaining after a restriction would be in place. It does not appear unrealistic that lead can be substituted from keys in the future; contrarily, possible future substitutions have been indicated by one major lock and key manufacturer. For this reason, the derogations are suggested to be subject to a revision. The Commission should therefore perform an evaluation of the derogations after five years, looking at the availability and the reliability of the alternatives to lead in these applications. This evaluation could be linked with the evaluation of the lead in jewellery restriction in entry 63.

Overall, this restriction option has been found effective, practical and possible to monitor. Compared to the other identified options, it offers the best balance between a high level of protection and a practical and workable regulation. For these reasons, **this is the proposed option.**

E.2.2 Restriction option 2: Lead migration in articles that can be mouthed

This restriction option is tailored to be identical to restriction option 1 in terms of scope, but apply to lead migration instead of lead content. Thus, it targets the exposure more directly, but might be more difficult to work with in practice. The comparative assessment of this option and restriction option 1 is intended as an evaluation of whether a migration restriction is applicable.

E.2.2.1 Effectiveness

Criteria for effectiveness are described in Annex XV to REACH: “the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk.” The assessment of the effectiveness needs to combine the risk reduction capacity and the proportionality of the proposed restriction. In order to assess proportionality, the costs of the restriction should also be estimated. Altogether, the effectiveness assessment should show that the proposed restriction adequately controls the risks identified, while balancing costs and benefits and minimises inadvertent impacts.

E.2.2.1.1 Risk reduction capacity

In this restriction option, articles which have a lead migration rate equal to or greater than 0.05 mg/kg in a standard extraction test are prohibited from placed on the market. This migration limit was determined by ECHA (2011) to be the equivalent of the content restriction given in restriction option 1. The risk reduction capacity of this option should therefore be equal to that of restriction option 1, and the reasoning presented for that option in section E.2.1.1.1 is on all accounts mutually valid also for this option.

Compared to a content restriction, the principal advantage of a migration restriction is its direct relation to the actual exposure. As only migratable lead is bioavailable and hence capable of causing harm, a migration restriction will always be directly proportionate to the risk. Moreover, it will likely be more accurate than a content restriction, as the relation between content and migrations are not always linear. Although RAC found association between lead migration and lead content for metallic jewellery parts (ECHA 2011), the link is weak and may be questioned. Indeed, this questioning is implied in paragraph (6) of entry 63 to Annex XVII, where it is stated that the Commission shall *"re-evaluate this entry in the light of (…) and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly"*. Apparently, lead content is not a flawless indicator for potential exposure. Instead, migration seems slightly preferable.

To summarise, the risk described in section E.1.1. is in this option reduced by 69 as regards the potential exposure. Also, this option is possibly slightly more accurate than restriction option 1. **Thus, this restriction option is considered fully capable of reducing the targeted risk.**

E.2.2.1.2 Costs for companies

Since this restriction option has the same scope as restriction option 1, no differences in substitution costs are expected for this option compared to the ones assessed in section E.2.1.1.2. The testing costs will however differ, due to a price difference between a content analysis and a migration analysis. The cost of migration testing varies between 20 and 60 € and is hence slightly more expensive than content testing (cf. section E.2.2.2.2). Performing the same calculation as for restriction option 1 yields the following costs:

Table 46: Testing costs for restriction option 2

Number of articles			2012222159	2012222159	2012222159
testing rate			0.0001	0.0001	0.0001
number of articles tested			201222	201222	201222
cost of destructive testing	€	a	30	60	90
number of test per article		b	3	6	12
value of article	€	c	6.00	6.00	6.00
total testing costs	€	d =a*b+a&c	19 317 333	73 647 331	218 527 326

This will in turn affect the total compliance costs:

Table 47: The total compliance costs per annum for restriction option 2. (00000€)

	Lower bound	**Central case**	**Upper bound**
Substitution cost lead content method	**5**	**12**	**17**
Costs for testing	19.3	73	218
Total using lead content method	24.3	85	235

For the central case, the cost difference between this restriction option and restriction option 1 is 50 M€. In other words, the total cost associated with restriction option 2 is more than double the costs associated with restriction option 1.

E.2.2.1.3 Proportionality

In theory, this restriction option is even more targeted to the risk than is restriction option 1, as restriction option 1 assumes a linear relation between content and migration which yet has been seen only for metallic materials. It is possible that restriction option 1 in some cases would require the elimination of such lead that does not contribute to exposure. This restriction option will never do that, but solely target actual risk. In this matter, it can be considered even more proportionate than restriction option 1. The reasoning on costs and benefits, and on the low additional costs for substitution, reported in section E.2.1.1.3 is mutually valid for this restriction option, due to the virtually identical scope. **Altogether, this restriction option is not considered equal to restriction option 1 in terms of proportionality.**

E.2.2.2 Practicality

According to ECHA (2007), practicality means that the proposed restriction must be implementable, enforceable and manageable. "Implementability" implies that the actors must be technically capable to comply with the restriction within the set timeframe. "Manageability" means that the proposed restriction should be clear and understandable to the actors involved, the relevant information accessible, and the administrative burden proportional. The term also involves taking into account the characteristics of the sectors concerned, including the number of SME's. "Enforceability" is the ability of MSCA's to check the compliance with the proposed restriction. All three terms imply proportionality with respect to resource management.

E.2.2.2.1 Implementability and manageability

As has been demonstrated from Chapter C, the replacement of lead from raw materials used to manufacture the articles in this dossier seems to be economically and technically feasible. Consequently, the actors involved in the supply chain for the articles should be capable of complying with the proposed restriction simply by switching to different raw materials (lead-free or with a low lead migration rate). With the exceptions mentioned below, the market actors consulted during the consultation process have not indicated any foreseeable difficulties with complying with a lead restriction based on content. No changes in production techniques, machinery, or training of staff are anticipated; compliance can be achieved simply through switching to lead-free raw materials. As such raw materials already exist on the market, there is no need for a transition period but the restriction can enter into force immediately upon the development of a suitable analytical method (see the next section).

Just like restriction option 1, this option targets articles that can be placed in the mouth by children. As reported in section E.2.1.1.1, ECHA (2011) has established a relationship between lead migration and lead content for metal alloys. The article categories that are exempt in restriction option 1 contain lead in metal alloys, which are also accessible for children and therefore migratable in this context. For this reason, this restriction option will need the same derogations as restriction option 1. Thus, the scope of this option is identical to the scope of restriction option 1.

This restriction option does not offer the same opportunities of data sharing with other legal requirements, that restriction option 1 does. Article 33 in REACH will require market actors to provide information on the content of hazardous substances, not on their migration rates. This restriction will need separate testing and separate material declaration. The information systems developed in course of that requirement can therefore not be readily used for this restriction. It is likely that many market actors will choose lead-free materials in order to make sure that no migration may occur. In these cases, the potential proportionality advantages of a migration restriction will not be realised. Moreover, migration limits may be more difficult to manage when purchasing raw materials, especially across language barriers and especially where the purchasing party lacks specific knowledge in chemistry. This would particularly disadvantage SME's, who may also lack the budget to run confirmatory compliance spot checks. This difficulty should not be overestimated – migration limits are successfully dealt with in the toy market, and initial confusion may be overcome by information campaigns – but remains a weakness compared to a restriction based on content.

Altogether, this restriction option is considered implementable and manageable. Substitutes are readily available and substitution is economically feasible and requires only a change of raw materials. However, the provisions of this option are slightly less understandable for the affected parties, compared to restriction option 1. A migration restriction will not be able to share information systems built to deal with other requirements, and may therefore mean an increased administrative burden which could be particularly cumbersome to SME's. **Therefore, this restriction option is deemed less manageable than restriction option 1.**

E.2.2.2.2 Enforceability

In order to be enforceable, a restriction needs two properties. First, it needs to be properly limited so that it is clear to the enforcement authorities which products are in scope of the restriction and which are not. This property is dealt with in section E.2.1.2.1. Second, the restriction needs a limit value that can be subject to supervision mechanisms. In order to be implementable within a reasonable time frame, the restriction should also be designed so that an existing supervision mechanism exists and is practically workable for enforcement authorities. A number of current EU legislative acts set migration limits for heavy metals (cf. B.9.1.1 and Appendix 2), including the Toy Safety Directive and the food contact material framework legislation. The restriction of nickel in entry 27 to Annex XVII of REACH also sets migration limits. (Cf. Appendix 2.)

SCHER (2010) recommends performing repeated discontinuous extractions separated by a "dry spell" of the metal in order to mimic the mouthing behaviour of children, which is a dynamic process. However, no such method is currently available and no method is available for the measurement of the lead migration rate which mimics mouthing. Nevertheless, several methods have been developed and are used for the measurement of lead migration rate in acidic conditions which simulate the gastric compartment. Although these methods are not suitable to assess migration in the saliva, they could be used in a protective approach, as the gastric conditions are more acidic compared to the saliva and therefore should increase the migration rate of lead.

The methods listed below, all based on a leaching with weak acid and subsequent content analysis of the leachate, allow for the measurement of the quantity of migratable lead regardless of the original form of the lead. They have been proven useful both for enforcement authorities and for internal control carried out by industrial or retail actors in course of their respective legislation. The resemblance among the methods can be viewed as an indicator of their effectiveness and practical workability.

Table 48: Methods for lead migration analysis

	EN 71-3	**Health Canada C.08**	**US CPSC (3)**	**DIN 54233-4 (draft)**	**EN 1388-1**	**Health Canada C.10**
Product	Toys	Jewellery	Jewellery	Textiles	Ceramic ware in contact with foodstuffs	Ceramic and glassware in contact with foodstuffs and lip and rim
Sample size	Fitting to “small parts cylinder”	Fitting to “small parts cylinder”	N.A.	1 cm^2	Distinction between flat and shallow dish	Distinction between different dish designs
Extraction	0.07 M HCl	0.07 M HCl	0.07 M HCl	Synthetic saliva, adj. to pH 2.5	0.07 M Hac	4% Hac
Volume of extraction solution	Sufficient volume to cover the toy	Sufficient volume to cover the sample	50 times the weight of the jewel	250 mL (wool and felt) 100 mL (other textiles)	Sufficient to fill or cover the dish	Sufficient to fill or cover the dish
Extraction duration	2 h	2 h	1 h + 2 h + 3 h	1 h (with agitation)	24 h	24 h
Separation	Decantation and filtration	Filtration	N/A	N/A	N/A	N/A
Analysis	Not indicated, but ICP or flame AAS could be used.	Flame AAS at 283 nm	ICP	Refers to other standards employing ICP and/or AAS	Flame AAS at 283 nm	Flame AAS at 283 nm

In addition to the wet chemical methods, this option gives the enforcement opportunity to use X-ray fluorescence (XRF) spectroscopy for a non-destructive screening of lead content in an article. This allows for many items to be tested in a short time, and will secure that only articles actually containing lead are sent off to wet chemical migration analysis. In this respect, this option does not differ from restriction option 1.

Of the wet chemical methods, EN 71-3 stands out by being a European standard already used for a similar restriction, namely that of lead and other elements in toys. Just like the articles targeted in this dossier, toys come in many different designs and are made of many different materials; a standardised method that is applicable to toys should hence be applicable also in this context. The determination methods – ICP and AAS – are the same as for content analysis, only with different sample preparations (extraction instead of digestion), and therefore share the commercial availability and hence the manageability with restriction option 1.

A few modifications needs however to be made to EN 71-3 in order to be fully appropriate for this restriction. Of these, the most important is the need to mimic the mouthing conditions concerned by this restriction. The weak hydrochloric acid used in EN 71-3 mimics gastric fluid, which is more acidic and therefore likely to overestimate the amount of migratable lead in the mouthing scenario. Although the extraction solution in EN 71-3 may be used as a worst case scenario until a suitable synthetic salivary solution has been established and standardised, this remains a weakness that was pointed out by RAC as a major drawback with the French proposal for lead in jewellery. In the same process, SEAC suggested another restriction option than migration for the same reason.

The German national standard DIN 54233-4, which is employed in the Oeko-Tex 100 standard for voluntary chemical control in textiles, provides a synthetic salivary solution used for extraction of lead and other metals. This standard has been qualified by comparison to other analytical standards, and could well be integrated into the EN 71-3 framework for use in this restriction proposal. However, the extraction solution in DIN 54233-4 is also more acidic than actual saliva, and may therefore also overestimate lead migration. It may therefore be considered insufficient without further adaptation. Moreover, DIN 54233-4 is a national standard which is also at hand only as a draft, which calls for more standardisation work to be carried out at European level. An implementation time is therefore anticipated before full applicability is reached.

Other minor modifications may also be needed. One concerns the larger sample size following from a restriction targeting mouthing instead of swallowing; in this restriction, the samples will be larger than fitting into the “small parts cylinder” as defined in the standard EN 71-1 A9. This calls for an adaptation of the quantities of migration solution, or alternatively, revised directions for sample preparation. Another modification concerns the need to take wear into account. As shown by Yost and Weidenhamer (2008), high levels of lead have been measured in the coating of inexpensive plastic jewellery items, and there is reason to believe that similar lead levels may be present also in plastic non-jewellery items. The potential exposure to this lead may depend on the level of wear of the article. In order for a migration limit to be fully applicable, the analytical method should take wear into account. The standard EN 12472, which simulates wear and corrosion of coated items, may be suitable for this purpose. This however is yet to be confirmed by analytical results.

The cost of analysis seems to vary between laboratories and between Member States. RPA (2009) reports a cost of about 22€ for testing one component with method EN 71-3. If two components are tested (for instance, authorities can test an article for both lead and nickel migration rates), the cost is reported to be about 35€. For three components, it is of about 50€ and for four components or more, around 65€. These costs, reported from a UK laboratory, are considerably lower than the costs known to the Swedish CA following own enforcement and queries made to laboratories. The costs per analysis seem rather to range between 40 and 60 €. If the determination of the elements is made using ICP, several element analyses (such as lead and cadmium) can be carried out to the same price. Questionnaire answers provided by several European enforcement agencies generally support this view. The costs given here should therefore only be seen as indications; in reality, costs may range between 20 and 60 € per analysis. Generally, migration analysis seems to be slightly more expensive than content analysis.

Just as in restriction option 1, substantial cost savings could be made by screening articles using XRF spectroscopy prior to wet chemical analysis, and only send articles actually containing lead to the laboratory. This is the same procedure as with restriction option 1, (cf. section E.2.1.2.2), and does not change the above comparison.

In terms of enforcement, the only difference between this restriction option and restriction option 1 is the analytical methods used. The inspection activities will likely follow exactly the same routines. Consequently, the reasoning on personnel costs in section E.2.1.2.2 is mutually valid also for this option, i.e. no additional personnel costs are anticipated for this restriction option.

Altogether, the necessary adaptations of EN 71-3 makes it reasonable to believe that a new standard, building on the mentioned standards, needs to be developed in order to ensure full and harmonised enforceability of this restriction option. While this is probably a fairly straightforward task for the standardisation community, it still requires an implementation time and an added administrative burden. **For this reason, this restriction option is deemed less favourable than option 1 in terms of enforceability.**

E.2.2.3 Monitorability

Following the ECHA (2007) guidelines, monitoring may cover any means to follow up the effect of the proposed restriction in reducing the exposure. This may include the monitoring of blood lead levels in children, to see if the exposure decreases following the restriction. However, the current blood lead levels are the result of many different routes of exposure, and it might be difficult to attribute changes in blood lead levels to this specific restriction.

Another means to follow up this restriction option is to monitor the evolution of the fraction of articles with a lead migration rate above the proposed limit, i.e. the percentage of non-compliant articles over time. Reliable methods for this measurement have been presented in section E.2.2.2.2. This means of monitoring is essentially identical to enforcement, but can also comprise actions undertaken by industry actors to comply with the proposed restrictions, as well as measurements carried out by independent test institutes, media, or green and consumer groups. Unlike the measurement of blood lead levels, this means of monitoring will be directly related to this restriction.

The costs of monitoring are assumed identical to the enforcement costs reported in section E.2.2.1.2. No further costs for monitoring are anticipated.

E.2.2.4 Overall assessment of restriction option 2

This restriction option is tailored to be identical to restriction option 1 in terms of scope, but apply to lead migration instead of lead content. Thus, the assessment of this option is largely an evaluation of whether a migration restriction is equally applicable compared to a restriction based on lead content.

The principal advantage of a migration restriction is its direct relation to the actual exposure. As only migratable lead is bioavailable and can cause harm, a restriction on lead migration will always be proportionate to the risk. It will likely be more accurate, as the relation between content and migration cannot always be assumed linear especially for non-metal materials, while still enabling “safe” use of lead in those articles where lead is necessary. This does however not dismiss the need for derogations. The derogations suggested under restriction option 1 will be needed also in this option, as the lead in e.g. keys is indeed migratable and causes human exposure. Contrary to what might be anticipated, there are no obvious practical advantages to this restriction option in terms of scope definition.

The main drawback of a migration restriction is the practicality, in particular the enforceability (including businesses' own compliance control). Analytical standards for lead migration do exist, but these are specific to their respective contexts and not as easily applicable to the articles relevant in this context, as are the corresponding standards for content analysis. Moreover, a migration restriction may be more difficult to translate into supplier requirements, in particular to SME's that might lack specific chemical knowledge. Migration based restrictions are therefore likely to be more difficult to implement and enforce, and may also bear higher costs. In an overall assessment, **this restriction option is therefore deemed less favourable than the proposed option.**

E.2.3 Restriction option 3: Lead content in (all accessible parts of) clothes, accessories and shoes

This restriction option is a subset of restriction option 1. It has been identified as a fall-back option, in case the first option is not found proportionate and further scope restraints are needed. Following section E.2.1, restriction option 1 has indeed been found appropriate, making this option somewhat redundant. For transparency reasons, this option is nevertheless evaluated according to the ECHA (2007) criteria.

E.2.3.1 Effectiveness

Criteria for effectiveness are described in Annex XV to REACH: "the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk." The assessment of the effectiveness needs to combine the risk reduction capacity and the proportionality of the proposed restriction. In order to assess proportionality, the costs of the restriction should also be estimated. Altogether, the effectiveness assessment should show that the proposed restriction adequately controls the risks identified, while balancing costs and benefits and minimises inadvertent impacts.

E.2.3.1.1 Risk reduction capacity

Just like restriction option 1, this restriction option targets lead content, but in a considerably narrower scope than that restriction option. In this option, the scope is limited to clothes, shoes and accessories. All articles in these categories are assumed possible to be placed in the mouth by children, following the guideline issued by the European Commission (2005) in the context of the phthalate restriction in entry 52 of Annex XVII to REACH.

The reasoning on the relevance of a content restriction in section E.2.1.1 is mutually applicable also to this restriction option. However, the narrower scope has a direct impact on the risk reduction capacity. With a restriction imposed only on clothes, shoes and accessories, only exposure from these articles will be reduced. Following the same procedure as in section E.1.1 and in the assessment of restriction option 1 (section E.2.1.1.1), the total exposure from these articles has been calculated to 192, g g/year. / This should be related to the total exposure as defined in section E.1.1, i.e. 367 g /year. The remaining exposure is therefore 178g/year or 31% of the initial exposure, Hence, the risk reduction capacity of this restriction option is only 51%, which is considerably lower than the other options.

Just like in the assessment of the restriction options 1 and 2, the figure is associated with uncertainties. The uncertainties are however of a similar nature and probably of a similar magnitude. The result, that this restriction option has clearly lower risk reduction capacity than options 1 or 2, is therefore not disputed by uncertainties. Hence, **this restriction option is therefore deemed less appropriate from a risk reduction perspective**.

E.2.3.1.2 Costs for companies

As this restriction option employs the smallest scope of the options considered here, the substitution and compliance costs for this option are naturally lower than for the other options. The value of imported clothes, accessories and shoes into the EU is €70,842,695,110. Based on the number of articles imported into the EU estimated at 13,818,494,053 articles per annum, the average **value of an imported** articles is 5.13€. Using the same assumption as previously, namely that 10% of the articles contain lead, the following data is obtained:

Table 49: Number of items of clothes, shoes and accessories for consumer use placed on the market annually in the EU 2012

Imported articles	**EU produced articles**	**Export**	**Total**	**Of which articles contains lead**
13,818,494,053	1,954,631,559	1,082,615,001	14,690,510,611	1,469,051,061

<u>Substitution costs and cost of lead free articles</u>

As assessed for restriction option 1 a restriction may during a shorter timeframe bring higher production costs for concerned companies due to the use of alternatives with a high price. These costs will initially be met by manufacturers who most likely will pass these costs onto importers, retailers and further down the supply chain to consumers.

Any additional costs will depend on the current percent of articles containing lead. The number of articles is estimated to be around 10%. The average lead concentration in the articles of concern is assumed to be around 1%.

<u>Method based on lead content to be substituted</u>

This method uses estimates of substitution costs per unit of lead and total quantity of lead to be substituted. Based on the conclusions in C.2.4, C.3.4 and C.4.4, Table 40 summarizes estimated substitution costs per kg for lead in pigments, stabilizers and metals. Using these costs per kg estimates and the quantities of lead to be substituted from the different product groups in Table 14 allows us to calculate an indicative value for total substitution costs in the product groups covered by this restriction option (Table 50).

Table 50: Additional cost for substitution of lead in clothes, accessories and shoes produced in, and imported to, the EU**. Estimation based on** lead content.

Total substitution cost (000 €)				
Central case	Pigments	Stabilizers	Metals	**Total**
Clothes	0.287	0.147	4.065	**4.499**
Shoes	0.385	0.231	0.260	**0.876**
Accesories	2.616	0.000	0.902	**3.518**
	3.288	0.378	5.228	8.894
Lower bound	Pigments	Stabilizers	Metals	**Total**
Clothes	0.144	0.073	1.626	**1.843**
Shoes	0.192	0.115	0.104	**0.412**
Accesories	1.308	0.000	0.361	**1.669**
	1.644	0.189	2.091	3.924
Upper bound	Pigments	Stabilizers	Metals	**Total**
Clothes	0.431	0.220	6.504	**7.155**
Shoes	0.577	0.346	0.416	**1.340**
Accesories	3.924	0.000	1.444	**5.368**
	4.933	0.566	8.365	13.863

Product testing costs for companies

For the product testing and compliance costs, the same assumptions and calculations are made as for restriction option 1 (section E.2.1.1.2). That is, it is assumed that 65 % of articles tested are tested using the xrf method and 35 % through wet chemical methods. Value of destructed articles has been taken into account. It is assumed that 1 in 10000 articles will be tested and that in 10 % of the cases there will be need for follow-up testing. . This gives the following costs:

Table 51: Testing costs for restriction option 3

Number of articles with lead after implementation	nr	a	146905106	146905106	146905106
share of articles tested		b	0.0001	0.0001	0.0001
Number of articles tested		c = b*d	14691	14691	14691
number of xrf tests		d	3	6	12
cost per test	€	e	5	5	5
average cost per test	€	f = d*e	15	30	60

share of articles that are tested with XRF		g = 65%	0.65	0.65	0.65
cost of XRF testing	€	h = f*g*c	143232	286465	572930
cost of destructive testing	€	i	30	60	90
number of test per article		j	3	6	12
rate of destructive testing		k = 35%	0.35	0.35	0.35
cost of destructive testing	€	l = c*i*j*k	462751	1851004	5553013
value of article	€	m	6.00	6.00	6.00
% follow up test		n = 15%	0.15	0.15	0.15
loss of value of tested article		o = n*c*m + k*c*m	39664	39664	39664
total testing costs	€	p	645 648	2 177 134	6 165 607

Total compliance costs

Adding together the costs from the tables above, the total annual compliance costs for the central case as well as lower and upper bound is shown by the below table. Total compliance costs are calculated using both substitution cost methods described above.

Table 52: The total compliance costs per annum in option 3 (000€)

	Lower bound	**Central case**	**Upper bound**
Substitution cost lead content method	4	9	14
Costs for testing	0.6	2.2	6.2
Total using lead content method	5	11.2	20.2

Just as for restriction option 1, the overall additional costs and increase in costs that a restriction in option 1 would pose to different actors in the supply chain depending on the proportion of costs increase that the suppliers would pass on down the supply chain. No additional costs for consumers or society are expected since alternatives are already available on the market and some of them also at a competitive price.

Due to the narrower scope, this restriction option would bring lower costs than would restriction option 1. Altogether, for the central case the difference is €15,899,000. As restriction option 1 has been considered feasible from a cost perspective, this must also apply to this restriction option.

E.2.3.1.3 Proportionality

This restriction option has a narrower scope than the previous two options, and is therefore highly unlikely to unduly affect users or actors in the supply chain which are not associated with lead exposure. It is considered economically feasible as alternatives are available on the market at insignificantly higher costs. Furthermore, it brings on the lowest total compliance costs.

The main drawback of this option is its low risk reduction capacity. It concerns 1,469,051,061 articles, compared to the 2,508,717,207 articles targeted in option 1. The estimated lead exposure that would be reduced in option 1 is 251/year at an (initial) annual compliance cost of M€9..

E.2.3.2 Practicality

According to ECHA (2007), practicality means that the proposed restriction must be implementable, enforceable and manageable. "Implementability" implies that the actors must be technically capable to comply with the restriction within the set timeframe. "Manageability" means that the proposed restriction should be clear and understandable to the actors involved, the relevant information accessible, and the administrative burden proportional. The term also involves taking into account the characteristics of the sectors concerned, including the number of SME's. "Enforceability" is the ability of MSCA's to check the compliance with the proposed restriction. All three terms imply proportionality with respect to resource management.

E.2.3.2.1 Implementability and manageability

As has been demonstrated from Chapter C, the replacement of lead from raw materials used to manufacture the articles in this dossier seems to be economically and technically feasible. Consequently, the actors involved in the supply chain for the articles should be capable of complying with the proposed restriction simply by switching to lead-free raw materials. With the exceptions mentioned below, the market actors consulted during the consultation process have not indicated any foreseeable difficulties with complying with a lead restriction based on content. No changes in production techniques, machinery, or training of staff are anticipated; compliance can be achieved simply through switching to lead-free raw materials. As such raw materials already exist on the market, there is no need for a transition period but the restriction can enter into force immediately.

The scope of this restriction option is a subset of the scope of restriction option 1. The implementability and manageability of this option is therefore largely comparable to restriction option 1. However, this scope is considerably narrower than the scope of restriction option 1. This leads to a few differences as regards manageability. First, the scope does not need to be restrained the way option 1 does. All clothes, shoes and accessories meet the definition of "can be placed in the mouth by children" as defined by the guideline to entry 52 (see section E.1.2); hence, this provision is redundant. The same applies to the derogations: this restriction option does not target any article categories where lead is necessary to maintain the function of the constituent materials. Therefore, it does not need any derogations.

Second, the scope of this option comprises fewer actors compared to restriction option 1. While option 1 affects all businesses involved with consumer articles, regardless of their categories, the actors involved here all belong to a specific branch of trade. The fashion industry has its own specific infrastructure for regulatory matters, which can be used to channel information about the restriction and provide guidance and training to individual companies. This will enhance awareness and therefore also compliance, in particular among SME's, which will in turn improve manageability.

Just like restriction option 1, this option is easily understandable for all affected parties and access to the relevant information is relatively easy. Substitutes are readily available and substitution is economically feasible. In addition, the scope is narrow and well defined, and will mainly affect only one branch of enterprise. **Thus, this restriction option is considered slightly more manageable than restriction option 1.**

E.2.3.2.2 Enforceability

The scope of this restriction option is a subset of restriction option 1, the only difference between the options being the number of articles in the scope. This is not believed to have any impact on the enforceability. The enforcement methods for this restriction option are identical to those used to enforce restriction option 1. Hence, the assessment of the enforceability of option 1, as reported in section E.2.2.2.2, is therefore applicable also to this restriction option.

E.2.3.3 Monitorability

No difference in monitorability is expected between this option and option 1.

E.2.1.4 Overall assessment of restriction option 3

This restriction option is a subset of restriction option 1. It was originally intended as a fall-back alternative to restriction option 1, in case that option would be found not proportionate. As the assessment of restriction option 1 showed that option to be fully appropriate, this option seems redundant. From the assessment made, the scope of this restriction does not even seem to be the most adequate subset. Clothes, accessories and shoes to not appear to contribute more to the exposure than any other article categories, and another scope restraint such as "accessories and interior decoration objects" would likely be just as successful as this one. While a clearly defined scope is always an advantage from a practicality point of view, in particular when it primarily affects a single branch of business, this restriction option is simply insufficient to reduce the identified risk. Moreover, it seems to induce almost as high costs as pursuing the "full" scope of restriction option 1, and is therefore considerably less effective. Altogether, **this restriction option is considered not appropriate** to manage the risks identified in this dossier.

E.2.4 Restriction option 4: Lead migration in all articles

This restriction option is an attempt to evaluate whether a more precautionary approach than the scope in restriction options 1 and 2 can be viable. It targets lead migration, as a content restriction in all articles would be clearly disproportionate with respect to all those articles where lead is encapsulated or otherwise inaccessible to children. The scope is chosen to be all articles that are sold to or intended for use by consumers, as no suitable "middle scope" has been identified. This restriction option can be viewed as an expansion of restriction option 2 and should therefore primarily be compared to that option.

E.2.4.1 Effectiveness

Criteria for effectiveness are described in Annex XV to REACH: "the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk." The assessment of the effectiveness needs to combine the risk reduction capacity and the proportionality of the proposed restriction. In order to assess proportionality, the costs of the restriction should also be estimated. Altogether, the effectiveness assessment should show that the proposed restriction adequately controls the risks identified, while balancing costs and benefits and minimises inadvertent impacts.

E.2.4.1.1 Risk reduction capacity

This restriction option resembles restriction option 2 inasmuch as it prohibits articles with a lead migration rate equal to or greater than 0.05 mg/kg in a standard extraction test from being placed on the market. The difference from restriction option 2 is that it not only targets articles that can be placed in the mouth by children, but all articles regardless of their size and their accessibility. Thus, it represents a conservative approach which takes into account also the possibility of exposure to lead from articles that can only be licked or come into contact with the skin (and potentially be ingested through hand to mouth behaviour, cf. section B.9.3.2). This is the only restriction option which also targets these exposure routes.

In the risk assessment, cf. section B.9.3.2, these exposure routes have not been quantified, which means that there is currently no data to support any estimates on this incremental risk reduction. The risk to be addressed, as identified in section E.1.1, is also solely based on those articles that children are actually mouthing. The increment (compared to restriction option 2) would therefore consist of a reduction of a risk not described in this dossier, and should consequently be viewed as hypothetical or at least unquantifiable. It is therefore possible, but not certain, that this restriction option provides an additional risk reduction.

Altogether, this restriction option has at least the same risk reduction capacity as restriction option 2. **Thus, this restriction option is considered fully capable of reducing the targeted risk.**

E.2.4.1.2 Costs for companies

The costs for compliance and testing for this restriction option should be higher than the costs for restriction option 2, owing to the larger scope. These incremental costs are however considered marginal for the concerned companies, as the additional costs for testing will be proportional to the additional number of articles within the scope of the restriction. Hence, from a strict cost perspective (i.e. not taking into account the manageability issues which will be dealt with in section E.2.4.2.1) employing the same assumptions as in the assessment of the previous options, this restriction option is deemed equally feasible to restriction option 2.

E.2.4.1.3 Proportionality

This restriction option roughly shares the same risk reduction capacity as restriction option 2. Moreover, it brings about approximately the same costs. It would therefore be reasonable to conclude that also the proportionality of this restriction option resembles that of restriction option 2. There is however a difference which weakens this restriction option as regards proportionality, namely the considerably larger scope. In this option, all articles regardless of their size are subject to the restriction. Articles that cannot be placed in the mouth by children can only hypothetically contribute to the exposure, as there is not sufficient data to support that licking only will lead to exposure. This restriction option is therefore less targeted, which increases the risk of unduly affecting uses or actors in the supply chain which are not associated to the identified risks. While the restriction may not be unjust per se – it only applies to those articles that have an actual migration – it will require a considerably larger number of actors than necessary to assess whether they are concerned or not. This will bring an added administrative burden, and hence a cost, not related to any added risk reduction. **For this reason, this restriction option is considered less appropriate as regards proportionality.**

E.2.4.2 Practicality

According to ECHA (2007), practicality means that the proposed restriction must be implementable, enforceable and manageable. "Implementability" implies that the actors must be technically capable to comply with the restriction within the set timeframe. "Manageability" means that the proposed restriction should be clear and understandable to the actors involved, the relevant information accessible, and the administrative burden proportional. The term also involves taking into account the characteristics of the sectors concerned, including the number of SME's. "Enforceability" is the ability of MSCA's to check the compliance with the proposed restriction. All three terms imply proportionality with respect to resource management.

E.2.4.2.1 Implementability and manageability

This restriction option has the widest scope, and comprises all articles that are sold to consumers regardless of their size and use. This means that it impacts all actors involved in production, import and distribution of material goods intended for use by consumers, the only exception being those specific article categories that are covered by separate legislations. As demonstrated from Chapter C, the replacement of lead from raw materials used to manufacture articles generally seems to be economically and technically feasible. In the previous three restriction options assessed, the conclusion as made that the actors involved in the supply chain should be capable of complying with the proposed restriction simply by switching to lead-free materials. However, in this case there is a lack of knowledge as regards certain products that are likely classified as articles. Construction products, leisure equipment including larger constructions like boats, furniture, etc. have not been fairly represented in the stakeholder consultation process, and there might therefore be difficulties that are not fully known to the Swedish CA. These difficulties might also (but does not necessarily) include changes in production techniques. Although it is believed that compliance also in this option is a mere question of choice of raw materials, this is yet to be confirmed. Neither is it entirely clear that suitable and reliable substitutes are available for all applications in this scope; it may need additional derogations in order to be fully implementable. These additional derogations are yet not identified.

Due to the vast number of actors involved in this option, additional administrative burden will be imposed on a substantially larger share of enterprise. The wide scope may also demand more from MSCA's in terms of information campaigns and guidance to enterprise, in order to ensure manageability. The actors new to this restriction option compared to restriction option 2 are generally believed to have trained staff and information systems on chemicals. The administrative burden added by this restriction option (compared to restriction option 2) is therefore likely not linear to the scope expansion, but smaller than if a linear relation is assumed.

In addition, this restriction option shares the same drawbacks as does restriction option 2 (cf. section E.2.2.2.1). For this reason, **this restriction option is deemed the least favourable option in terms of implementability and manageability.**

E.2.4.2.2 Enforceability

The enforcement methods for this restriction option are the same as those used to enforce restriction option 2. The assessment of the enforceability of that option, as reported in section E.2.2.2.2, is therefore largely applicable also to this option.

Compared to restriction option 2, in this option any article regardless of size will be subject to enforcement. This will require further modifications to the standard EN 71-3 in order to encompass also larger objects, likely through revised directions for sample preparation. Compared to restriction option 2, the adaptation of EN 71-3 may be slightly different. No additional implementation time is anticipated compared to restriction option 2, as the necessary adaptations have comparable magnitude for both options. The enforceability of this restriction option is therefore considered virtually identical to that of restriction option 2.

E.2.4.3 Monitorability

No difference in monitorability is expected between this option and option 2.

E.2.4.4 Overall assessment of restriction option 4

Of the assessed alternatives, this restriction option provides the highest level of safety, as all potential exposure to lead is restricted – even where there is no robust evidence of an actual exposure. It hence applies a precautionary approach. However, this restriction option has been found difficult to work with, e.g. when identifying the concerned actors and practical alternatives. There is little data to support any conclusions on the implementability and manageability of this restriction option, including the technical feasibility, which is itself an indication of its principal weakness. Nevertheless, this restriction option is anticipated to lead to significant manageability issues, which are likely not balanced with a sufficient increase in risk reduction. The mere precautionary principle is not considered to outweigh the practical difficulties, at least as long as there is no clearer indication of actual exposure from licking articles which cannot be mouthed. Therefore, **this restriction option is found not appropriate.**

E.3 Comparison of the risk management options

Quantifiable parameters from the assessment of the risk management options are compared in Table 53. The **overall assessment of** the restriction options, as presented in the previous sections, are summarised in Table 54. The ranking is qualitative and indicative only.

Table 53: Comparison of quantifiable parameters for the assessed restriction options. Central case estimates for costs and benefits assumed.

	Option 1 (proposed)	**Option 2**	**Option 3**	**Option 4**
Total exposure from articles covered by the proposed restriction, g lead/year	251	251	192	> 251
Risk reduction capacity, %	69	69	51	N.A.
Risk reduction capacity, IQ units	22000	22000	16900	N.A.
Substitution cost, M Euro/year	11.8	11.8	9	>NA
Estimated testing costs, M Euro/year	**16,4**	73	2	>NA
Cost for redesign M Euro/year	6	6	6	
Total quantified costs for implementation, M Euro/year	34	91	17	>40

N.A. Not available

Table 54: Overview over the assessed restriction options

	Option 1 (proposed)	**Option 2**	**Option 3**	**Option 4**
Effectiveness	**++**	**++**	**+**	**++**
Risk reduction capacity	++	++	(+)	++(+)
Costs	++	++	++(+)	++
Proportionality	++	++	+	+
Practicality	**++**	**+**	**++**	**+**
Implementability and manageability	++	+	+++	(+)
Enforceability	++	+	++	+
Monitorability	**++**	**+**	**++**	**+**
OVERALL ASSESSMENT	**++**	**+(+)**	**+**	**+**

(+) Criterion barely met
\+ Criterion partly met
++ Criterion met
+++ Criterion met with excellence

The restriction options assessed differ from each other as regards the scope and whether content or migration is restricted. Overall, the scope "can be placed in the mouth by children" has been found sufficiently practical, while any larger scope is impractical. The limited scope "clothes, accessories and shoes" is clear, unambiguous and therefore the most practical alternative. As for effectiveness, however, it is clear that the limited scope does not yield the desirable risk reduction. For an adequate risk reduction, it is necessary to involve all articles that contribute to the risk. Finally, a restriction based on content seems more enforceable (and hence monitorable) than a restriction based on migration.

From the assessment presented in the previous sections, the conclusion can be drawn that restriction option 1 presents a workable and appropriate restriction. It has a satisfactory reduction of exposure to lead, it is economically feasible and can be managed and enforced without a longer transition period or other implementation conditions. It is also well aligned with existing restrictions, in particular the restriction of lead and its compounds in jewellery in entry 63 of Annex XVII to REACH. For this reason, **restriction option 1 is the restriction to be proposed in this dossier.**

The suggested proposal is presented in section E.5.

E.4 Main assumptions used and decisions made during analysis

The main assumptions and own decisions forming the basis for the analysis are as follows:

The market share of articles containing lead has been estimated to 10%, and the lead content of these articles is estimated to 1%. These estimates, which lay the foundation for the assessment in Chapter E, are backed up by data from own measurements as well as reports compiled from other sources (cf. section B.2.2 and Appendix 3 and 4). The articles analysed are mainly purchased in Western Europe and the U.S.A., with a particular bias to Sweden and the U.K. These products may not be fully representative for all articles on the EU market. Deviations may therefore occur.

The selection of articles for testing has been limited to certain article categories, mainly clothing metal details such as buttons, zippers and rivets, as well as keys, key rings, pens, selected interior details, and imitation leather wallets and purses. These are not fully representative for the article market. The selection has been weighted in order to compensate for this non-representability, i.e. the values used in the estimates are deliberately lower than the measured values in order not to overestimate the calculated risk (cf. Appendix 3). Deviations may however still be present. This may affect this estimated market share of articles containing lead (10%), as well as the estimated average lead content in such articles (1%). It may also impact the estimated tonnage of lead supplied to the article market, as this is calculated from analysed lead levels. However, as this tonnage is not the principal driver of exposure (which is the mouthing behaviour of children), uncertainties in this matter should be of lesser importance.

The stakeholder consultation has been an important source of data. Although some industry organisations representing the EU market participated in the consultation, the majority of participants were Swedish enterprises. Also, SME's have been underrepresented in the consultation. These enterprises are more sensitive to additional costs and administrative burden. However, as price differences have been found small, it is assumed that they can be borne also by SME's, and that firms and/or consumers would not reduce the overall number of pieces of articles sold or bought due to an introduced restriction.

Mouthing exposure times for this proposal are based on observational studies of mouthing behaviour over relative short periods of the day scaled up to give an estimated total mouthing time in min/day. It should be noted that the study observations are representative for the daytime and any mouthing activity during sleep is not accounted for. These studies (Juberg et al 2001, DTI 2002) all utilised parental observation for relatively small groups of children at different age groups. The data on frequently mouthed objects may therefore be dependent on the presence of articles in these specific homes, and may in that case differ somewhat with different home environments. The difficulties to fin representative data for this type of assessment has also been proven, when two of the studies used for the Annex XV report were excluded by the DS at a late stage, while the results could not be verified by the information in the available publications.

The uncertainties surrounding the exposure assessment are caused by certain assumptions. For instance, the migration rate in the saliva is extrapolated from a migration rate estimated in sweat and the method used to measure the migration rate contains biases (SCHER 2010). In addition the migration rates used for the calculations are based on 4 h migration values and therefore may in fact be an underestimation if most lead migration occurs during the initial migration testing. There are also uncertainties concerning the surface default value of 10 cm^2, depending on the particular consumer object in question for example buttons and zipper flaps are smaller than this size and would in turn create an overestimation of exposure due to size. However, the sizes and shapes of consumer objects vary heavily. In the case of a cylinder lock key, a value of 10 cm^2 is more accurate, and for the surface of a handbag it likely represents an underestimation. Overall, the default value should therefore be usable.

The migration rate used for this restriction proposal is a value taken from the background document to RAC and SEAC opinions on lead and its compounds in jewellery (ECHA 2011), where a clear linear trend correlates lead content and migration at the highest lead content. Linear relations have been assumed between content and migration, based on the RAC evaluation (ECHA 2011), as well as between exposure to lead and IQ losses at low lead levels, based on several studies (e.g. Lanphear et al 2005, Gould 2009, EFSA 2010).

The migration rate is calculated based on studies on metallic jewellery, so it seems relevant for articles like key rings, zippers and similar. It is not clear how representative this value is for other types of materials, such as polymeric materials or lead pigment but the few migration studies performed by the DS indicate that the migration rate for non-metallic materials might be higher than the assumed migration rate of 0.7 $\mu g/h/cm^2$ (Appendix 4).

In the assessment of alternative materials, the specific choice of alternative alloys and colouring agents has not been possible to identify for specific articles. Thus, the information on the alternative substances is just indicative to show that substitution is feasible.

The baseline scenario used to assess the risk management options in Chapter E is assumed unchanged from today's situation. No reduction (or increase) of lead exposure is expected in the absence of regulation. Also, the lead concentrations in articles are assumed to be constant over the test report period (2005-2011), forming a linear added amount of lead in the article supply.

When calculating the total exposure in section E.1.1 (BAU scenario), as well as the risk reduction capacities of each restriction option, the figures obtained are associated with uncertainties resulting from the underlying assumptions and estimates accounted for above. Likewise, the risk reduction capacities calculated from the total exposure are associated with the corresponding uncertainties. The percentages calculated are therefore indicative rather than definitive.

The scope of the cost analysis of each respective restriction option has been narrowed to include compliance and product testing costs, substitution costs and cost of lead free alternatives, and administrative burden such as learning of new obligations. Thus it is assumed, that there are no expected adaption costs of facilities or equipment, nor costs related to reformulation or redesign.

The price differences resulting from the assessed risk management options have been assumed small. Income or price elasticity has not been taken into account.

Due to lack of accurate data on actual production costs of consumer articles sold on the EU market, production input substitution costs have been estimated from the average value of a consumer article imported to the EU.

The assessment of product testing and compliance costs is based on the assumption that 1/10000 of the articles will be tested, i.e. ten times less often than the recommended testing frequency for quality control.

E.5 The proposed restriction(s) and summary of the justifications

Considering:

- The severity and irreversibility of risks associated with an exposure to lead, in particular for small children;
- The fact that articles with a high exposure potential can be placed on the market without any control;
- The fact that the health risks cannot be managed by other policy options than the restriction under REACH;
- The comparative assessment of restriction options in section E.2;

This restriction is deemed the only adequate tool to manage the risks posed by lead and its compounds in articles available to consumers and accessible to be placed in the mouth by children. As presented in Chapter A, the proposed restriction, its conditions and scope are as follows:

In Annex XVII to Regulation (EC) No 1907/2006, the following entry XX is added:	
‘ XX. Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be placed on the market in articles, or accessible parts of articles, which are supplied to the general public and which can be placed in the mouth by children, if the concentration of lead (expressed as metal) in that article, or part of article, is equal to or greater than 0.05% by weight. 2. For the purposes of paragraph 1, an article or part of an article can be placed in the mouth by children if it is smaller than 5 cm in one dimension or has detachable or protruding parts of that size. 3. Paragraph 1 does not apply if an article, or a part of an article, is not accessible by children during normal or reasonably foreseeable conditions of use. European Standard EN71-1, as adopted by the European Committee for Standardisation (CEN), shall be used, where appropriate, as the method to determine “accessible parts” of articles by children. 4. By way of derogation, paragraph 1 shall not apply to: (i) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC[22] (ii) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/87[23]), unless they have been treated with lead or its compound or mixtures containing these substances; (iii) enamels, defined as having vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500^{o}C; (iv) keys and locks, including padlocks, and musical instruments; (v) articles comprising brass alloys if the concentration of lead in the brass alloy does not exceed 0.5% by weight of lead (expressed as metal); (vi) the tip of writing instruments; (see Annex III) (vii) articles covered by European Union

[22] Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass OJ L 326 29.12.1969, p 36.

[23] Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff. OJ L 256, 7.9.1987, p 1–675.

	legislation specifically regulating lead content or migration. 5. By way of derogation paragraph 1 shall not apply to used articles placed on the market for the first time before ….(12 months after entry into force)
(*) [insert OJ reference]’	

The proposed restriction is to be applied 12 months after the amendment of the REACH Annex XVII comes into force.

Justification:

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 in Europe and the rest of the world have reported several serious alerts related to a misuse (ingestion and/or mouthing) of small articles. These alerts include acute poisoning, but also chronic effects such as negative impact on the neurological development of children. The cases documented seem to be the tip of the iceberg.

Recently, these effects justified a restriction of lead in jewellery under REACH. However, the same reasons justify also non-jewellery articles to be restricted. As shown in Chapter B, non-jewellery articles that contain lead and that can be placed in the mouth by children account for at least a comparable risk than does jewellery, although each article typically contain lower levels of lead than a jewellery article may do. From the baseline calculations presented in section E.1.1, the total exposure to lead from non-jewellery articles is 8.5 times higher than that from jewellery. This calls for action also for non-jewellery articles.

Because of the severity and the extent of the risks, and the negative effects independent national measures would have on enterprise and the free movement of goods, action is required at Union-wide basis in order to effectively manage risks. As shown in the previous sections, a restriction under REACH has been considered the most adequate Union-wide measure as regards effectiveness, practicality and monitorability. Four different restriction options have been assessed with respect to these parameters, and the proposed restriction has been found the most appropriate.

Finally, several studies have indicated that leaded waste materials such as lead battery waste and solder materials might be recycled in consumer products. This caused the committees under ECHA to call for a “responsible management of recycling of leaded wastes” in the adequate regulations. Although responsible waste management is of paramount importance, another means to avoid leaded waste being recycled in consumer products is to simply restrict the use of lead in such products. The proposed restriction pre-empts such a development and secures a lead-free everyday environment for small children.

Justification for proposing a transitional period of 12 months

In general the proposed restriction can be implemented, managed and enforced without any transition period or other implementation conditions taken. Optional transitional periods of 6, 12 and 18 months have however been assessed in order to analyse whether there is any need for a transition period in order to limit the impacts that the restriction might bring to certain actors. As about 90% of the market affected by the proposed restriction already have substituted lead with other substances or techniques a longer transitional period than 18 months is not relevant to assess.

Manufacturers, importers, wholesalers and retailers may be economically affected due to the implementation of the restriction and the limited possibility to sell out any existing stocks of articles. From a risk management perspective it is however important in order to reduce the risk and limit the exposure to also limit the companies possibilities for building up large stocks.

A 6 months transitional period was originally proposed in the restriction on lead in jewelry. In the original proposal references were made to the 6 months transitional period implemented in the cadmium restriction. The 6 months transitional period for jewelry was concluded to be reasonable due to the fact that the production changed according to seasonal fashion trends and that the actors are used to a market that is rapidly renewed. The consultation with concerned actors also indicated that it would not be likely that these actors would keep high stocks of for example leaded alloys that would be unsold because of the implementation of the proposed restriction. SEAC later found a longer transitional period justified for adjusting the production process and the storage of intermediates and final jewelry by the importers and producers. Of importance for SEACs opinion was also the modified proposal based on content and that established test methods are available. It was however recognized that retailers ordering jewelry 9-12 months in advance could face problems if they would not make the necessary precautions. The transition period that was later implemented for lead in jewelry was 12 months.

In the French dossier it was recognized that the fluctuation of the costs of raw materials and the varying costs of alloys has resulted in a manufacturing of alloys following customers' demand. These production processes are also applied for many of the concerned applications in this dossier.

The proposed restriction in this dossier has however a wider scope than the French dossier on lead in jewelry had. Therefore it is advised and justified to implement a longer transitional period than in the restriction proposal for lead in jewelry. The concerned companies are mainly small and medium sized companies that import articles within the scope of the proposed restriction. The practical activities that follow by an implementation of a new regulation are for example information activities from importers to suppliers outside the EU about the new regulation. A shorter transitional period could therefore imply implementations problems on the EU market. There will also be a need for more focused information and training activities in relation to the businesses of smaller companies and especially distributors in order to secure an effective and practical restriction. The proposed restriction does not involve a major change in production processes and techniques for the remaining 10% of the use on the EU market. The adaption of the proposed restriction still involves some time for implementation of limits in production for all uses within the scope of the proposal. The concerned actors therefore need some time to adapt after the regulation has entered into force due to mainly practical and regulatory reasons.

From the consultations carried out by the Swedish Chemicals Agency it can be concluded that a restriction is reasonable and feasible as long as some time is given to the concerned actors in order to adapt to the new regulation even after it has entered into force. Therefore a transitional period of 12 months is proposed that enables the actors to adjust to the new regulation and to take relevant actions so that the restriction can be put into practice.

The assessment of alternatives shows that a substitution of lead is possible in most applications. The concerned companies are expected to be able to replace lead within a transitional period of 12 months without affecting for instance the quality of products. No additional costs in order to find or develop alternatives have been identified.

In the assessment it has not been evident with diverge transitional period for different applications. There are especially many advantages due to enforceability and practicality reasons with having a common transitional period.

An 18 months transition period would give concerned actors even more time to adapt to the implemented restriction. The practical effects such as information and necessary preparations in terms of responsibilities for authorities and industry does not justify the need for a 18 months long transitional period. The alternatives are already dominating the market and therefore a shorter transitional period than 18 months is justified.

The conclusion from the assessment is however that due to the variety of the service period for the concerned articles where some articles have longer service periods and some have shorter service periods a longer transition period would in total prolong the exposure of the children of concern. A transition period of 12 months is therefore considered reasonable for the remaining 10% of the market to adjust and adopt the requirements of the proposed restriction. A transition period of 6 months could according to the assessment and the consultation with industry imply implementations problems on the EU market. A transition period of 12 months would also facilitate for the handling of existing stocks and give time for depletion. The restriction concerns the placing on the market of articles and is not a ban for use therefore.

F. Socio-economic assessment of proposed restriction

The objective of this report has been to develop a proposal for a restriction under REACH Annex XVII of lead and its compounds in articles, which can be placed in the mouth by children and, which are made available for consumers or intended for consumer use. Lead can be available in different articles as a metal, an additive in alloys, a pigment in several materials or stabilisers in polymers. The most frequent of those uses have been identified as additive/impurities in metal alloys and pigments. Stabilisers were only identified as the probable source of lead in a minor share of the articles for consumer use. From the available information on the incidence of lead compounds the risk evaluation has shown that the content of lead in the articles within the scope of this dossier is of concern for children with a mouthing behaviour. The assessment in chapter E also concludes that the proposed restriction would effectively reduce this risk.

In the background document of the restriction on lead and its compounds in jewellery (Annex XVII in REACH, entry 63) a partial CBA (cost-benefit-analysis) was carried out in order to compare the benefits of restricting the manufacture and sale of articles containing lead with the costs of such a restriction. The analysis was meant to be illustrative and not necessarily an exact reflection of reality. The analysis is partial and does not cover all elements that might be covered in a more realistic evaluation. The analysis only takes into account the effects on lifetime earnings related to cognitive ability (IQ) impacts as a result of children's mouthing (non-ingestion) behaviours between the ages of 0.5 to 3 years. A number of other benefits of reducing lead exposure are not included in this analysis (for example non-cognitive functioning and other health related endpoints etc.). The analysis does not consider possible benefits in relation to ingestion (swallowing of jewellery), exposure to older children, and worker protection during manufacture. A number of cost elements are not estimated or analysed.

F.1 Human health and environmental impacts

F.1.1 Human health impacts from exposure to lead in consumer articles

The analysis in this section will use two different approaches when presenting the results of the partial CBA conducted. The first approach is based on the 3-step model used in the background document on jewellery, where break-even levels (i.e. where net benefit equals 0) of mouthing are derived. The second approach is to calculate the net benefit of the suggested restriction based on the avoided IQ losses derived in Section B.10.1.1.2, and the compliance costs in Section E.2.1.1.2. The two approaches compare the estimated annual compliance costs with the lifetime benefits of children arising from reduced exposure in one year in the first case and two and a half years in the second case. Both approaches will be subjected to a sensitivity analysis, where uncertainties in compliance costs and benefits from the restriction are taken into account. In order to do these calculations, we will first need an estimate of the effect of IQ on lifetime productivity.

<u>Reduction in Lifetime Productivity per IQ Point Decrement</u>

The partial CBA conducted here rests on the assumption that cognitive ability, measured by IQ, affects lifetime productivity. Wage income is a recognized measure of productivity. Estimates of reductions in lifetime earnings due to IQ losses are derived in two steps. First the percentage effect on income from a 1 point change in IQ is estimated based on a literature review of previous studies. The second stage is to multiply this percentage with estimates of lifetime earnings.

The relationship between cognitive ability and lifetime earnings has been analyzed in a number of studies. The causal links are both direct and – via schooling and labour force participation – indirect. Analysis of the relationship is complicated by the various covariations between family characteristics, socio-economic conditions, schooling, individual ambition, cognitive abilities, and income. A key question in the literature on the subject is which covariates are appropriate to include. The range in the results reported in the studies in **Table 55** is largely due to different conclusions on this issue. The studies that take age and gender into account conclude that the effect of IQ on income is larger for women than for men, and that the effect increases by age/work experience.

Table 55: Overview of studies on the effect of a 1 point IQ difference on income

Study	Effect on income	Comment
Schwartz (1994)	1.8%	
Salkever (1995)	1.7-1.9% 3.2-3.6%	For men For women
Zax & Reese (2002)	0.3-0.8% 0.7-1.4%	For men at age 35 For men at age 53
Heckman et al (2006)	0.6-0.9%	For men at age 30. Effect on hourly wages

The estimates derived by Schwartz (1994) and Salkever (1995) have been used extensively by the US EPA (Grosse 2007), and in several other studies (Muir & Zegerac 2001; Rice & Hammitt 2005; Trasande et al 2005; Griffiths et al 2007). These estimates are high relative to more recent estimates and to the estimates from the labour economics literature (e.g. Bound et al 1986). More recent studies (Gould, 2007) use the same methodology as a basis to present updates of the values found by Grosse (Grosse, 2003)

Zax & Reese (2002) look at a cohort of male students who graduated from high-school in Wisconsin in 1959. This cohort is analysed at two points in time: at age 35 in 1974, and at age 53 in 1992. Four econometrical models are analysed. The explanatory variables are individual traits and socio-economic characteristics at age 17. The high end results (0.8% at 35 and 1.4% at 53) of the effects of one extra IQ point on income are obtained by using IQ as the only explanatory variable. Introducing family and community characteristics and estimates of individual effort as additional explanatory variables reduces the estimated impact of IQ on income later in life. The authors conclude that the true effect of cognitive ability (measured by IQ) is most probably somewhere within the reported range. Explanations (given by Zax & Reese) for the larger effect of IQ on income at higher age are that intelligence has a larger income effect for more experienced labour and/or that the labour market has changed over time to give a relatively larger benefit to more high-skilled labour.

Grosse (2007) argues that some of the additional explanatory variables used by Zax & Reese are endogenous with respect to cognitive ability. Previous economic studies on characteristics of parents, biological children and adopted offspring suggest that shared genes are responsible for most of the association between parents and biological children, indicating that inclusion of family characteristics as covariates results in substantial underestimation of cognitive ability on income. Grosse therefore suggest that the high end estimates are more likely to be the true effects of IQ on income, than the estimates including the other explanatory variables.

Heckman et al (2006) finds that a 1% difference in cognitive ability (comparable with a 1 point IQ change) affects hourly wages by 0.6% for men at age 30. When the effects of cognitive ability on schooling and of schooling on wages are included the impact on income is estimated at 0.9%. Taking into consideration that this study does not include effects on labor force participation, and that it analyses men at a relatively low age, these results are probably underestimates.

The literature reviewed here indicates that the impact of a 1 point IQ difference affects lifetime earnings by around 1%. This estimate is however uncertain and should be treated with caution. In a sensitivity analysis a range of 0.3–1.5% will be used. One element of uncertainty is that all the studies referenced in Table 56 are based on data from the US, where labor market conditions and wage dispersion differ substantially from most EU member states.

To transform this effect of IQ on income into monetary values we need an estimate of lifetime earnings for an average EU citizen. There are, to our knowledge, no such estimates available from previous studies. Instead we have used an estimate from Grosse (Appendix I in Haddix et al 2003) on lifetime income in the US. Grosse's estimate is based on US income levels in the year 2000, and assuming that real income will increase by 1% annually. Earnings are comprised of labor market income and household production, where the latter refers to the uncompensated – but still valuable – work carried out within a household and in other informal sectors.

Table 56: Discounted lifetime productivity at birth (Grosse in Haddix et al 2003), $\$_{2000}$ in the US in 2000

Discount rate / Earnings	0%	2%	3%	5%
Labor market earnings	2 489 019	1 039 134	691 830	323 974
Labor market earnings and household production	3 620 505	1 452 315	955 895	443 145

The choice of discount rate is very important. A discount rate of 5% gives lifetime earnings estimates that are less than half of those given by a 3% discount rate. A simple definition of the discount rate – recommended in ECHA's guidance on Socio-Economic Analysis (ECHA 2008) – is that it is the sum of the pure time preference rate and the expected real growth in income. ECHA (2008) states that the pure time preference rate is usually estimated around 1.5%. Since annual income growth in Grosse's lifetime income estimates is set at 1%, a pure time preference rate of around 1.5%, indicates that a discount rate of 2–3% is a reasonable assumption.

This discount rate is relatively low compared to the rates of 3–5% commonly used in socio-economic analyses. This is due to the relatively low assumption of income growth (1%) used by Grosse. As long as the pure time preference rate is fixed, the assumed income growth rate has marginal implications on the present value of lifetime income. A higher income growth assumption would be compensated by the increase in the discount rate, and would not affect the present value of lifetime income.

In Table 57**:** Deriving discounted lifetime productivity at birth, €$_{2011}$ in the EU in 2011

Grosse's lifetime earnings estimates for the US in 2000 are converted to EU estimates for 2011 based on official Eurostat data on GDP, currency exchange rates, and CPI-deflators. If we only consider labour market earnings and use a discount rate of 3%, we get conservative estimates of the impact of IQ on lifetime income. Using the central estimate (1%) of the effect of a 1 point change in IQ on income, the cost per IQ point lost is around €8,000. For the sensitivity analysis the lower end cost is around €2,400, given by 0.3% of labour market earnings at a discount rate of 3%. The high end cost estimate is €25,000, given by 1.5% of labour market earnings and household production at a discount rate of 2%.[24]

Table 57: Deriving discounted lifetime productivity at birth, $€_{2011}$ in the EU in 2011

Discount rate	Earnings	$\$_{2000}$ in US in 2000	$€_{2000}$ in US[1] in 2000	$€_{2000}$ in EU[2] in 2000	$€_{2011}$ in EU[3] in 2000	$€_{2011}$ in EU[4] in 2011
2%	Labour market earnings	1 039 134	1 125 091	698 586	911 281	1 208 647
	Labour market earnings and household production	1 452 315	1 572 450	976 358	1 273 626	1 689 230
3%	Labour market earnings	691 830	749 058	465 101	606 709	804 688
	Labour market earnings and household production	955 895	1 034 966	642 626	838 284	1 111 829

[1]In 2000 the exchange rate was 0.92 US$/€; [2]In 2000 PPP-adjusted GDP per capita was 1.61 times larger in the US than in EU27; [3]EU 27 CPI 1.30 times higher in 2011 than in 2000; [4]GDP in the EU was 1.33 times larger in 2011 than in 2000

In conclusion, the review of previous studies indicates that a 1 point increase (decrease) in IQ leads to an increase (decrease) in lifetime productivity of 0.3-1.5%, with a central estimate of 1%. In combination with the estimates of lifetime labour market earnings, the benefit (cost) per IQ-point gained (lost) is around €8,000, with an uncertainty range of €2,400-25,000[25]. These estimates will subsequently be used in break-even and net benefit calculations.

[24] It should be noted that willingness to pay (WTP) studies suggests slightly lower, but uncertain, estimates of the value of lead reduction. Lutter (2000) estimates parents' WTP for treatments that reduce lead levels (and indirectly increase IQ) in their children. The study, based on Agee and Crocker (1996), estimates this WTP to US$ 1100-1900 per IQ point. Converting this estimate to current EU income levels, as in Table 57, gives €1,300-2,200 per IQ point.

[25] The upper bound includes informal household production

Break-even calculations

These calculations will identify levels of mouthing exposure that will generate break-even (i.e. net benefit equal to zero) scenarios based on the rate of migration of lead from consumer articles to children, the relationship between blood lead level and IQ, the effect of IQ on lifetime income, and the costs for complying with the proposed restriction. This calculation is conducted in three steps:

Step 1: calculate on the basis of the reduction in lifetime earnings per IQ point lost, the break-even level of cognitive ability (IQ) impacts that would equate with the total additional cost of restricting the use of lead in the consumer articles concerned in this report.

Step 2: calculate the aggregate lead intake in the population of children that would result in such a break-even level of IQ impacts.

Step 3: calculate a number of exposure profiles that would give rise to the lead intake calculated in Step 2, and compare these profiles with corresponding benchmarks of actual mouthing exposure behaviours related to articles containing lead.

The first step is described in the three first rows in

Table **58**. Total compliance cost was in E.2.1.1.2 estimated to be €15-69 million, with a central estimate of €34 million. In combination with the estimated reduction in lifetime earnings from a 1 point IQ loss (€2,400-25,000), the total IQ loss within the EU that would lead to a break-even is 606-28650 points, with a central estimate of 4279 points.

The daily lead intake per kilogram of body weight (kg bw) that would generate a one point loss in IQ is approximated to 1.22 µg/kg bw and day (range 1.08-1.23 µg/kg bw and day) (B.10.1.1.Accounting for that the average body weight of children aged 6-36 months is 11.57 kg[26], imply that the daily lead intake required to meet break-even is 60395 µg (range 7568-404411 µg).

[26] Calculated as (7.4*2,670,738 + 11.4*5,383,155 + 13.8*5383155)/13,437,880 = 11.57 kg bw/child

Table 58: Break-even calculations

Break even calculation of lead in articles starting from four different calculations of costs					
	unit		low cost -High IQ value, low dos repsonse	Central estimate	high cost - low IQ value-low dose/response
Total cost for one year, €	€	a	15 141 179	34 229 075	68 760 778
Value of loss of one IQ point, €	€	b	25 000 €	8 000 €	2 400 €
Number of IQ to be lost to break even	points	c=a/b	606	4279	28650
Daily lead intake pr IQ-point loss	µgram	d	1.08	1.08	1.22
Contribution of each years exposure to IQ	factor	e=	1.0	1.0	1.0
One day lead intake pr IQ loss	µgram	f=e*d	1.08	1.22	1.22
Lead intake pr kg bw pr day required to equal cost	µgram	g=c*f	654	5220	34953
Lead intake (pr child (11.57 kg) pr day) required to equal cost	µgram	h=g*10	7 568	60 395	404 411
Migration rate for 1 % lead content	µg/cm^2	j	0.7	0.7	0.1
Migration rate for 3 cm2	µg/cm^2	k=j*3	2.1	2.1	0.2
Migration rate for 1% lead content, 10 cm2	µg	l=k*10	7.0	7.0	0.8
mouthing hours to result in required microgram lead intake (daily)	hours/	m=i/l	1 081	8 628	505 513
Number of children per age group EU (0.5-3 years age)		n	5 375 152	5 375 152	5 375 152
Secondsper day required to reach break even / per European child		p=m*3600/n	0.7	5.8	338.6
minutes per year			4	35	2 060
second per day			0.72	5.78	338.57

The realistic average mouthing time of a non-toy, non-food article by a child aged 6-36 months is estimated to be 20 minutes per day, and approximately 22% of the mouthing events concerns lead containing articles covered by this restriction proposal (B.10.1.1.2). This means that we can assume that every day, each European child will have to mouth for six seconds on a lead containing article in order for the benefits to break even with the costs.

The total number of articles items mouthed relevant for the scope of this proposal was thus 356 out of 1665 items in the ‘other objects’ category (22% of items). Assuming that the total amount of time spent mouthing an object is proportionate to the frequency that the item is mouthed, then the total amount of time spent mouthing articles items by the 236 children is estimated to be (22% of 3728 minutes) 820 minutes per day (or 3.47 minutes per child).

Since it is estimated that only 10% of articles contain lead, then the total amount of time spent by the 236 children mouthing articles items containing lead is estimated to be (2.2 % of 3728 minutes) 82 minutes per day (or 0.348 minutes per child). The number of minutes of mouthing articles containing lead per child per year is thus estimated at [0.348 x 365=] 126.85 minutes. It should be noted that this is the time spent mouthing the total number of such item which are already in circulation, rather than the additional items that come into circulation each year (which is the appropriate comparator to make with the ‘break even’ level.

However, it is not possible to estimate the mouthing time for the additional articles that come into circulation each year, without making some assumptions about what proportion of the total articles in circulation is made of up the additional articles items that come into circulation each year. In order to simplify the analysis, it is furthermore assumed that for any new articles item added to the circulation each year, an old articles items is removed from circulation, and that the lifetime of an item of an articles is 3 years (i.e. the items in circulation will be completely renewed every 3 years).

On this basis then, the number of minutes of mouthing articles containing lead per child per year for additional articles items that come into circulation per year is estimated at 42.3 minutes (2537 seconds) or 6.95 s per day.

Net benefit calculations

The net benefit of restricted lead content in consumer articles is given by the difference between the benefits related to productivity gains arising from avoided losses in IQ, and the costs related to compliance with the proposed restriction.

In E.2.1.1.2 the annual compliance cost was estimated to be €15-68 million per year, with a central estimate of €34 million per year. The proposed restriction will – through lower lead exposure of children aged 6-36 months – result in lower losses in cognitive ability (IQ) than what would otherwise be the case.

From the risk assessment presented in B.10.1.1.2 we have that the total exposure represents an IQ loss of 22000 points per year. The risk reduction capacity in Section E.2.1.1.1 indicates that the proposed restriction will reduce this loss by 69%. Based on the impact on lifetime productivity from a change in IQ (€2,400-25,000/point), a net benefit from the proposed restriction can now be computed.

Table 59: Annualized net benefit of the proposed restriction

	Low cost & High IQ income effect	**Central case**	**High cost, Low IQ-effect & Low IQ income effect**
Substitution costs (M€)	**5.2**	**11.8**	**18.4**
Product testing costs (M€)	**3.9**	**16.4**	**44.3**
Redesign & Recyling costs (M€)	**6**	**6**	**6**
Total compliance costs (M€)	**15**	**34**	**69**
Risk reduction (IQ-points)	**22000**	**22000**	**19547**
Reduction in lifetime productivity per IQ loss(€/IQ)	**25000**	**8000**	**2400**
Total benefit (M€)	**552**	**176**	**52**

Net benefit (M€)	**537**	**142**	**-17**
Benefit/Cost-ratio	**36.80**	**5.18**	**0.75**

The central estimates indicate that the restriction will generate a net benefit of €139 million per year. The benefits are about 4 times larger than the costs. Based on the uncertainties regarding the different parameter values given in this report, a range of net benefits can be calculated. The lower bound, given by the highest compliance cost and the lowest impact of IQ on productivity, is negative by €20 million per year. The higher bound, given by the lowest compliance cost and the highest effect of IQ on productivity, is €535 million per year.

The negative result in the sensitivity analysis arises when extreme values for the three varying parameters – i) Compliance costs; ii) Risk reduction; and iii) Reduction in lifetime productivity per IQ loss – are assumed. Estimates for net benefit and benefit/cost ratio have been derived for various combinations of parameter values (see Table 60).

Table 60: Net benefit and benefit-cost-ratio with different parameter assumptions

	i) High **ii) Low** **iii) Central**	**i) High** **ii) Central** **iii) Low**	**i) Central** **ii) Low** **iii) Low**
Net benefit (M€)	Cost= 69, Benefi= 155 net benefit = 86	Cost = 69, Benefit = 55 net benefit = -14	Cost =34, Benefit= 48 net benefit = 14
Benefit/Cost-ratio	2.4	0.8	1.4

i) Total compliance costs; ii) Risk reduction; iii) Reduction in lifetime productivity per IQ loss

The estimate of avoided losses in IQ, due to the proposed restriction, comes with considerable uncertainties. These are discussed in Section E.4, where the general conclusion is that the chosen estimate should be considered as indicative rather than definitive.

It should be noted that the costs and benefits of the proposed restriction have very different time characteristics. The costs will generally appear early on, and the annual costs are likely to decrease with time (Section E.2.1.1.2). The benefits, on the other hand, will not come until the children affected by the decreased lead exposure enter working age, meaning that the benefits will only start to come into effect around 20 years after the restriction is implemented. These time characteristics mean that the choice of discount rate is of high importance. As mentioned previously, these results are based on a social time preference rate of around 1.5%, which is in line with the ECHA guidelines on discounting in socio-economic analysis (Appendix D in ECHA 2008).

In conclusion, the net benefit calculations indicate that the proposed restriction will probably generate benefits that are 3 times larger than the compliance costs. Net benefit is expected to be €139 million per year.

F.1.2 Other health impacts

Apart from effects on IQ, human health impacts of concern are also related to the impacts on reproduction, the immune system, blood pressure, kidneys, the nervous system, and other organs. Other long-term health effects include 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); WHO (2009)).

Lead exposure can also give rise to a vast assortment of effects; dizziness, fatigue, irritability and nausea (Werbach (1997); Silbergeld (1992); Fischbein (1992)) to more severe health impacts such as paralysis, convulsions, and cerebrovascular diseases ((Rempel (1989); Royce (1992); NRC (1993)). These stated “other” health impacts can not be quantified for the purpose of this restriction proposal; however they can be mentioned as qualitative and potential health benefits of the proposed restriction. Even for these other health impacts children under 6 years old and pregnant women whose developing foetus can be exposed are especially vulnerable.

F.1.3 Overall conclusions of the human health impacts

Lead exposure can give rise to a range of human health effects (Section F.1.2). These effects would be affected by decreased lead exposure. This analysis has, however, only focused on the benefits related to cognitive abilities, as measured by IQ.

A literature review indicates that a 1 point decrease in IQ leads to a decrease in lifetime productivity of 0.3–1.5%, with a central estimate of 1%. In combination with estimates of lifetime earnings, the benefit per avoided IQ-point loss is around €8,000, with an uncertainty range of €2,400–25,000.

The CBA indicates that a break-even will occur if all children aged 6-36 months mouth lead containing articles for 6 seconds per day. According to the reasoning in E.1.1, children aged 6-36 months mouths non-toy, non-food articles for 20 minutes per day, and approximately 22% of the mouthing events concerns lead containing articles.. The risk reduction capacity of the proposed restriction is approximately 69% (Section E.2.1.1.1), which indicates that the restriction will have a positive net benefit.

The net benefit calculations indicate that the proposed restriction will probably generate benefits that are 4.6 times larger than the compliance costs.. The net benefit is expected to be €139 million per year, with an uncertainty range of minus -20 to plus 535 million Euro per year. The negative result in the sensitivity analysis arises when extreme values for the three varying parameters – i) Compliance costs; ii) Risk reduction; and iii) Reduction in lifetime productivity per IQ loss – are assumed. Assuming the central estimate for either of these, while keeping the other two at the extreme value, will generate positive net benefit estimates.

The costs and benefits of the proposed restriction have very different time characteristics. The costs will generally appear early on, and the annual costs are likely to decrease with time. The benefits, on the other hand, will not come until the children affected by the decreased lead exposure enter working age. These time characteristics mean that the choice of discount rate is of high importance. The discount rate used here for the central estimate (3%) is relatively low compared to the rates commonly used in socio-economic analysis (3-5%). This choice is motivated by the relatively low growth rate assumption (1%) used in the lifetime productivity estimates (Section F.1.1).

F.2 Economic impacts

In this section the main economic impacts that the proposed restriction could result in are assessed. This includes costs for society and other costs that are mostly assessed qualitatively.

Some direct economic impacts of importance for the companies of concern have been estimated in the assessment carried out in chapter E.2, such as compliance, testing costs and substitution costs. Other costs assessed in E.2 where enforcement costs and administrative burdens. In chapter F.1 the damage costs related to direct and indirect impacts on human health have been assessed such as effects on lifetime earnings, impacts on job attainment and performance, reduced educational attainment and change in labor market participation. In the remaining parts of chapter F other economic impacts that might affect the companies and/or the society as a whole are discussed. A few examples of such economic impacts are maintenance costs such as labor costs and cost differences between various alternatives due to different market price or raw material cost.

The identified stakeholders (dealing with either lead-free and/or lead containing consumer articles) that may be affected by any economic impacts are:

- Producers
- Manufacturers and importers
- Retailers, distributors and suppliers
- Agents and wholesalers
- Consumers
- Public authorities

Companies that have not already substituted lead compounds in their articles are most likely to be affected by the proposed restriction. Based on the information from stakeholders the following impacts could follow when substitution of lead compounds is carried out. Marketing costs, training costs, information costs and costs of new alternative substances.

The SMEs in both trade and industry sector represents 99 % of the companies on the EU market. A majority of the companies, including SMEs, have already substituted lead compounds in their articles and therefore the impacts on SMEs are not expected to be great. As the intentional addition of lead in the supply chain has already been reduced the economic impacts for SMEs from a restriction will also be lower than would otherwise have been the case.

The additional cost of compliance will most likely be passed on down the supply chain, and as a result sales price of the consumer articles containing alternatives to lead would be slightly higher. The alternatives to lead has been assessed to be technically feasible but with the economic drawback of an increased supply cost – a cost that will initially result in a higher sales price.

The compliance costs assessed in Chapter E will be higher during and shortly after the implementation, relative to a longer time perspective. As a result of the restriction all companies including importers, producers and suppliers will have to control the quality of their products also in relation to the content of lead compounds. When all companies in the supply chain have full knowledge of the restriction and pass the product information further down the supply chain the compliance cost will however be lower than during the implementation.

As reported in the French dossier about lead in jewellery the costs of raw materials vary. This is reported to lead to manufacturing by demand. Because of this it can be concluded that the stocks that wouldn't be compliant with new regulation would be relatively low and therefore not causing a problem due to an introduced restriction. Companies would be able to sell out their stocks before the restriction would enter into force.

Additional costs, in terms of increased production costs, can initially be expected for companies switching to other alternatives that have a higher raw material cost. But as the lead compounds would not be restricted in all consumer articles available on the market, nor in professional use, lead compounds would still be available for use in other articles. Therefore the impacts on concerned actors will be lower due to the possibility to shift to other output markets.

Economic impacts in terms of administrative burdens that the companies would meet due to the proposed restriction are mainly related to obtaining knowledge about the scope of the restriction and about actions taken in order to implement the restriction. The most important administrative burden that would follow implementation is the obligation for information in the supply chain. All companies in the supply chain will need information about the presence of lead and its compounds in the articles in order to assess whether or not these comply with the regulation. The magnitudes of these costs have not been assessed during the work on this dossier. These administrative burdens would in particular be laid on producers, importers and distributors of consumer articles within the scope of this dossier. The administrative burdens will however also be of importance for wholesalers and retailers as well as other companies in the supply chain who have to make sure that the articles meet the requirement of the restriction. The consultation with industry carried out during the work on this dossier however indicates that the information requested on the content of lead as well as testing is already carried out by some of the concerned companies. Therefore the Swedish CA assumes that the additional burden in the long run due to the increased demand for information in the supply chain would be less than the compliance cost and the substitution cost.

The proposed restriction is not expected to result in a need for increased research activities. Substitution has already been carried out by many companies so therefore producers already are expected to have the knowledge on how to produce lead-free articles.

The proposed restriction is not expected to bring any major additional administrative burden on public authorities in terms of cost for inspection and enforcement. Some of the consumer articles within the scope of the proposed restriction are already objects for control and enforcement due to other EU regulations. Furthermore the methods for testing and analysis of content in these articles already exist and are already used for other consumer articles. The increased cost for testing and analysis that the public authorities would meet are expected to be lower than the costs for testing and analysis carried out by companies in order to make sure that their products meet the requirements of the regulation.

The consumers are initially expected to meet some increase in purchase cost but not for the majority of the articles for which substitution has already been conducted. But these increased costs are likely to be met by acceptance because of the higher level of security in terms of risk.

The proposed restriction is not expected to have an impact on the free movement of goods, services, capital and workers. Furthermore there is no single member state, region or sector that will be affected in particular by the proposed restriction. The restriction would neither bring any overall impacts on economic growth nor the employment.

F.3 Social impacts

Restricting the use of lead compounds in articles for consumer use could affect a large number of manufacturers and suppliers of articles for consumer use in the EU. Indirectly a restriction would also affect the employment of those who are currently producing and manufacturing these articles. Based on the information presented in chapter B the number of staff employed in the EU manufacturing consumer articles were 6,338,010 in 2009 and 12,864,647 at supplying companies. The number of manufacturing companies was 734,939 in 2009 and the number of suppliers was 2,684,147.

Neither the numbers of companies that import or produce, nor the number of employees that could be affected by a restriction, have been possible to quantify, based on the available statistics. Therefore neither the total number of companies nor the number of employees at these companies that produce, market and supply the 10% of the consumer articles that contain lead compounds have been estimated. Most of the companies that produce and import the concerned consumer articles are however assumed to deal with both lead containing articles and parts of articles, as well as articles without lead, and the social impacts on their businesses are expected to be minor.

Based on the information given during the public consultation and the assessment carried out by the Swedish CA there is no reason to assume any negative social impacts in terms of redeployment or temporary unemployment of staff, or any other adjustment costs, as a result of the restriction proposal. Any impacts on employment are mainly distributional impacts, if any, and not a cost to the society. Any negative impacts on employment in the supply chain should mainly be offset by positive impacts in other sectors.

The restriction of lead in consumer articles will not involve any changes in labour inputs required in the production or import of lead containing articles and its alternatives. However the restriction will give a higher safety to employees working for companies that produce lead containing articles. The exposures of workers have not been assessed in the work on this dossier but safety equipment is expected to be used at workplaces already. These assumed positive social impacts due to the implementation of the proposed restriction are expected to be greater in third countries where most of the consumer articles are produced.

Based on indications from a few stakeholders at least some companies have both lead and lead-free alternatives in their portfolio. Most importers are for example assumed to import both articles containing lead and articles that are lead-free. The increased demand for lead-free articles will also bring positive economic impacts on the companies that can produce, supply and deliver such articles. Therefore the DS concludes that the reduction in copper alloys and the limited use for copper alloy scraps will not affect a wide range of labour within the EU.

Based on the assessment carried out by the Swedish CA there is no reason to assume that there will be any social impacts for consumers or the general public within the EU in terms of changes in availability or quality of products or welfare changes. Although the social impacts on third countries have not been assessed in this dossier it can be assumed that a restriction on the use of lead and its compounds in consumer articles will result in positive social impacts in third countries producing these articles especially for the general public and the environment in these countries.

F.4 Wider economic impacts

No wider economic impacts such as overall impacts on the economic growth or development, changes to competition within the EU or direct impacts on the macro-economic stabilisation have been identified by the DS if the proposed restriction were to be implemented.

The European Copper Institute has however in its socio economic analysis identified that the proposed restriction would reduce competitiveness in the European copper industry. The restriction requires according to the European copper industry a redefinition of the lead-free alloys as well as review of the protocols and standards that have been developed by industry. The restriction would therefore require an increase in information reporting and auditing inside and outside of Europe.

F.5 Distributional impacts

As already stated the proposed restriction would affect different actors in the supply chain, including manufacturers and producers, resellers and the users of these articles. In addition, some of the actors in the supply chain of alternative articles will be affected. The costs and benefits are not expected to be spread equally within the supply chain. However the distributional impacts are not simply a cost to society as the eventual negative impacts on for instance importers of articles will be compensated by impacts on the importers of alternative articles.

Many of the affected actors are small and medium size enterprises (SME). Companies who are not already importing or using alternatives to lead have to adapt their business if a restriction is introduced. This will involve some negative impacts for these companies in the short run. These adoption costs will be higher for SME companies than for larger enterprises. During the work on this dossier no information has indicated that this adaption of businesses would result in severe negative impacts. Alternatives are available on the market and the market value of the lead containing articles could also meet a reduced market value on alternatives if a restriction was introduced.

Most likely to benefit from the restriction proposal are children and their families in term of reduced potential lead exposure that may result in loss of IQ points. These benefits may be of different magnitude for different socio-economic groups and, as concluded in section F.1, the benefits are likely to be higher for women than for men.

Other actors that will benefit from the proposed restriction are companies that already have substituted lead in their articles and especially companies that have reliable information and data that verifies that their articles are lead-free. The companies that have substituted lead in the articles represent a majority of the EU market, based on the assumption that 10% of the available consumer articles on the EU market contain lead.

Distributional impacts that have been identified by the copper industry during the consultation is decrease in production and market share for copper alloys, higher production costs to meet the reduced limit for lead for EU smelter and manufacturing companies within the EU. Other distributional impacts are the increased availability of raw materials from EU scrap that would benefit the non EU smelters and manufacturers.

No further information concerning distributional impacts on the market has been identified that could occur if the proposed restriction was implemented. Whether or not a single sector, section of society or geographical area would be more affected has not been possible to assess during this work based on the available information and data.

F.6 Main assumptions used and decisions made during analysis (including uncertainties)

In this section the main assumptions and uncertainties made in chapter F, as well as the decisions made during the analysis are summarised. The main assumptions that were done up to (and including) chapter E – including assumptions regarding compliance costs – have been presented in section E.4. The most central assumptions and uncertainties of importance for the assessment in chapter F are:

Cognitive ability (IQ) is assumed to affect lifetime production. The magnitude of this effect is – based on a literature review – assumed to 1.0% per IQ point. One element of uncertainty is that most of this literature is based on data from the US, where labour market conditions and wage dispersion differ from many EU countries. A range of 0.3-1.5% is included in sensitivity analysis to allow for the uncertainty described in the literature.

Lifetime wage income is used as a proxy for lifetime production. This only includes production in the formal economy, and can thus be considered an underestimate. In the sensitivity analysis, informal household production is included when calculating the upper bound of the effect of IQ on lifetime production.

Lifetime income estimates based on data from the US in the year 2000 are assumed to be transferable to current EU conditions based on differences in purchasing power adjusted GDP, currency exchange rates, and consumer price index (CPI) deflators, as stated in Table 53.

The costs and benefits have very different time characteristics. The costs will generally appear early on, while the quantified benefits will not come into effect until the children affected by the decreased lead exposure enter productive age. This means that the choice of discount rate is of high importance. The discount rate chosen here is 3% (2% for the upper bound in the sensitivity analysis). This discount rate is relatively low compared to the rates of 3-5% commonly used in socio-economic analyses. The reasoning behind this choice is that the discount rate can be defined as the sum of the pure time preference rate and the expected growth in real income. This definition is recommended in ECHA's guidance on Socio-Economic Analysis (ECHA 2008). These guidelines also state that the pure time preference rate is usually estimated around 1.5%. Since annual income growth in lifetime income estimates is set at 1%, a pure time preference rate of around 1.5% indicates that a discount rate of 2–3% is a reasonable assumption.

F.7 Summary of the socio-economic impacts

The proposed restriction is considered to be proportional as it effectively reduces the identified risks associated with lead and its compounds in articles whilst keeping the societal costs at a lower level than the societal benefits. Furthermore, alternatives to lead compounds are already available on the market. A complete analysis of benefits and costs was not feasible to carry out due to lack of data mostly related to the economic impacts. It was further concluded that it would not be proportionate to carry out further assessment of the economic impacts with respect to the estimated risk that would be eliminated as well as the benefits that would be a result of a restriction.

The analysis carried out in chapter F show that the overall impacts are positive and that the benefits with a restriction outweigh the costs by a factor of nine. The net benefit of the proposed restriction is estimated to be €135 million per year. The benefits from the restriction are estimated to be 3 times larger than the costs of compliance.

According to the central estimates the costs of the proposed restriction are €41 million per year, and the break-even point of mouthing leaded articles is estimated to be 5116 IQ points. The costs of avoiding lead would equal the loss in IQ if every child aged 6-36 months in the EU mouths a piece of leaded article that would otherwise have been placed on the market for 37 minutes per year (6.1 seconds per day). This does not include or account for the additional number of other potential health and environmental benefits that could be gained as a result of reducing the exposure of lead.

The associations between lead and different measures of cognitive abilities are typically described in terms of the effect of lead on IQ and earnings. It is estimated that the value of one lost IQ point is around €8,000 (with a range between €2,400 and €25,000 used for sensitivity analysis).

The total compliance costs are estimated to be €41 million per year (with a range of €14 to €102 million) and are primarily made up of testing costs. The use of alternatives is likely to increase the total production costs initially because of a higher raw material cost. Other costs that would be expected to increase initially are compliance costs in term of testing and analysis. All companies down the supply chain will also initially have increased costs in relation to the work on product information. The increased costs are expected to be passed down the supply chain to consumers. The total compliance costs are expected to decrease over time.

A sensitivity analysis indicates a probable range of net benefits from minus 55 million € per year to plus 550 million € per year. This means that the upper bound compliance costs are larger than the lower bound benefits. The negative result in the sensitivity analysis arises when extreme values for the three varying parameters – i) Compliance costs; ii) Risk reduction; and iii) Reduction in lifetime productivity per IQ loss – are assumed. Assuming the central estimate for either of these, while keeping the other two at the extreme value, will generate positive net benefit estimates. This indicates a margin of safety with respect to the uncertainties in the estimated benefits and compliance costs.

In Table 61 the main socio-economic impacts identified in Chapter E and F are summarised.

Table 61: Qualitative summary of the socio-economic impacts of the proposed restriction

Type of impact	Actor	Costs	Benefits
Health impacts	Children and the Society		Avoided loss of IQ and lifetime production per child. (This is the only benefit that is quantified in monetary terms.)
			Other health effects that can be reduced due to the implementation of a restriction and a reduction of consumers exposure to lead.
	Adults and the Society		Avoided costs of illness and of education
			Indirect benefits: Higher level of

Type of impact	Actor	Costs	Benefits
			safety for adult customers. Less negative effects from lead exposure with less negative health impacts as a result
	Workers		Indirect benefit: Protection of workers involved in the manufacturing process
Economic impacts	Importers	Additional costs of substituting lead containing articles	
	Producers	Additional costs of substituting lead containing articles per year	
		Testing costs	
		Administrative burden to adopt to new regulation	
	Producers/Manufacturers	Training of workforce adjustment costs for learning a new production processes	
		Adjustment cost: Purchase of new tools and equipment or adaptation of existing equipment	
		Costs related to implementation of quality controls and gathering product	

Type of impact	Actor	Costs	Benefits
		information	
		Decrease in research for recovery and re-use of copper scrap	
		Decrease in production of copper alloys in the EU	Increase in production of substitutes
		Decrease of economic value of copper recovery and recycling industry	
	Consumers	Price increase: Additional costs due to an increase in the prices of lead free articles	
	Companies in the supply chain	Information initiatives and costs for gathering reliable product information	
	Public Authorities	Cost for enforcement and monitoring	
	Non EU producers and exporters	Costs for compliance and substitution	

G. Stakeholder consultation

During the entire work with this dossier the Swedish Chemicals Agency tried to have an open and interactive dialogue with a broad circle of interested parties in order to ensure that different views of interest were accounted for.

Stakeholder contacts included REACH MSCAs, ECHA and the Commission, industry actors at different levels of the supply chain, sector organisations (mainly at EU level), NGOs, as well as other authorities.

Several methods have been used in the consultation; questionnaires, targeted telephone calls and emails to selected stakeholders, a project website, stakeholder meetings, written consultation including targeted periods for specific consultation with stakeholders on certain issues (2 periods for MSCA's and 2 periods for other stakeholders), media contacts on request and an email address to the project group.

The chart below shows when, in the process of preparing the dossier, the different consultations listed above have been carried out.

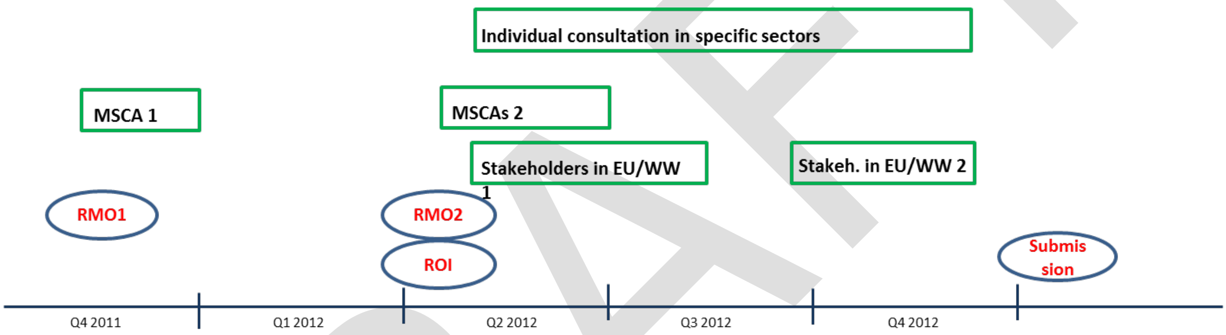

Figure 3: Consultation during the preparation of the report.

Project webpage

An official webpage with information regarding the restriction proposal was published in Swedish and English under the Swedish CA's webpage. The English part of the webpage could be reached through the shortened URL: www.kemi.se/leadinarticles. The webpage was published in May 2012 and is still available.

The webpage contains information about:

- The plan for the consultation process including a timetable for all planned activities and for the work on the dossier.
- Background information
- Requests for information during the two open written consultations and request for other kind of communication initiatives.
- Invitation to the stakeholder meeting

Stakeholder meeting at the Swedish Chemicals Agency

Stakeholders were invited to a meeting held in Stockholm in June 2012. Only two stakeholder representatives came to this meeting. The aim of the meeting was to:

- Inform about the intentions for further restrictions of lead and lead compounds
- Discuss data gaps concerning the occurrence of lead and lead compounds in articles intended for consumer use.
- Collect information regarding innovations and available alternatives to lead and lead compounds in articles intended for consumer use
- Exchange views on the working process and procedure

Due to the low number of participants at the first meeting, no additional stakeholder meetings were held.

Request for information in a written consultation process

A first consultation period was arranged during June-September 2012. A Request for information (RFI) was sent to a wide number of stakeholders for consultation. The request for information included the following issues:

- Consumer awareness of the availability of lead in consumer articles
- Information about lead content in articles
- Market volumes of lead in articles
- Technical and economic feasibility of substitution
- Alternatives/lack of alternatives to lead in the materials
- Experience of substitution of lead and lead compounds in articles
- Data on release of lead ions from specific materials/matrices/compounds
- Data on exposure and impacts on human health

The entire list of stakeholders is presented in Appendix 14. The full Request for information (RFI) is enclosed in Appendix 16.

A second consultation period was arranged during October–November 2012 with a new request for information that was sent to the stakeholders for consultation. These questions were also published on the webpage and included the following issues:

- Information about lead content in articles
- Comments or views on possible restriction options
- Opinions on the restriction options with regard to risk reduction capacity, feasibility, practicality, monitorability and socioeconomic impacts
- Preferences for any specific restriction option
- Performed tests and data on presence of lead in articles

The full RFI is enclosed in Appendix 17.

19 answers were received from the first consultation period, of which twelve gave input to the requested issues or other issues related to lead in consumer goods.

From the second written consultation, five answers were received with input to the requested issues. Totally three answers actively supported one or more of the given restriction options.

Requests for information were submitted to the other member states CA in November 2011 and April 2012, each time accompanied with an RMO report. Nine answers were received on the first RFI and two answers during the second RFI. The main information received from those two consultations were test results on articles containing lead, that confirmed previous findings, but also new references like recently published reports. Data on lead content in relevant articles is included in Appendix 4.

Direct contact with stakeholders

Besides the consultations period's bilateral contacts has also been taken, by email or phone calls, with companies and organisations that have knowledge in specific areas. All contacted stakeholders are listed in Appendix 14.

Issues discussed included:

- Availability of lead-free materials and articles
- Experience from the use of alternative substances/materials
- Future market trends
- Possibilities to substitute lead
- Testing frequency of goods deliveries
- Test methods and results
- Previous and new test reports of various article categories (mostly accessories and clothes)
- Impacts (technical and economic)

Media contacts

A couple of media made telephone calls, in order to get more information for publication of short news, immediately after the publication of the registry of intention at ECHAs webpage and the project information on the web site of the Swedish CA. These media contacts were of help in order to reach even more stakeholders with information about the project.

Feedback on comments

Stakeholders who have sent written comments have gotten feedback by email with information about the progress of the project. Further feedback about how the provided information and views from stakeholders have been considered when finalising the Annex XV report will be sent. Stakeholders that participated at the meeting in June 2012 preferred not to be cited in specific meeting notes, why their information is included directly in this report. A list of consulted stakeholders can be found in annex XX.

Summary of the stakeholder consultation

A summary of the information gathered during the stakeholder consultation can be found below and also in Appendix 15. The consultation has focused on consumer articles that appear in studies of children's mouthing of objects. The information provided by the stakeholders has been used as a basis for the socio-economic analysis, and for the evaluation of alternatives.

Alloys

Producers of brass were targeted since brass contains lead, and is also used for articles accessible to children (e.g. keys, handles on furniture, ornamentals).

According to producers of copper and brass, most copper alloys contain lead, either as a functional element or as an impurity. Each alloy has a defined composition and unique characteristics, which means that there are no "lead-free" and "lead-containing" varieties of the same alloy.

The most frequently used copper alloy is brass. The most frequently used brass contains lead. The yearly production of leaded brass in Europe reaches ca. 800,000 tonnes. The main leaded alloys are free cutting brass with up to 3.5% lead and leaded nickel silver, which contains up to 2.5% lead.

The volume of copper alloys in consumer products reaches 83,000 tonnes (2011), of which the use in the articles covered by the proposed restriction is around 10,000 tonnes. It is used in a great variety of applications and materials, cf. Table 62.

Table 62: Copper alloys in consumer products (modified from input from stakeholder)

Market segment	Content of the alloy
Clothing	Mainly lead-free copper-zinc alloys (<0.1% lead) (Voluntary industry initiative, Oeko-tex© 100 standard)
Fitting and hinges	Mainly free cutting brass with up to 2.5% Pb and 3.5% Pb (significantly smaller volume)
Keys and locks	Mainly free cutting brass (up to 3.5% Pb)
Other metal goods (doorhandles, touch surfaces)	Mainly free cutting brass with up 3.5% Pb
Musical instruments	Lead-free copper tin alloys and lead-free copper zinc alloys, leaded brass with up to 3.5% Pb
Spectacles parts	Mainly lead-free nickel silver 8<0.1% lead) and leaded nickel silver (ca. 1% lead) (often coated due to nickel content)
Writing instruments	Mainly free cutting brass with up 3.5% Pb and leaded nickel silver (up to 3.5% lead)

Lead in alloys functions as a lubricant and chip breaker, which increases the machinability and gives better dimensional control. It also increases the lifetime of the cutting tools. The stakeholders states that the advantages of lead leads to lower emissions of CO_2 and less use of emulsifiers and oils.

Lead-free alternatives are being developed mainly for free cutting brass for use in drinking water applications. There are currently no alternatives for leaded nickel silver. Alternatives include brass containing silicon (up to 0.1% lead) or bismuth (up to 0.25% lead). The producers state that the main problems with these alternatives include higher prices and separate scrap cycles.

One stakeholder, who produces brass articles, stated that requirements regarding brass purchased from suppliers are mainly based on the shine of the brass. This stakeholder also finds it hard to purchase lead free brass.

Apparel / accessories / details on apparel

Companies selling apparel and accessories were targeted since these kinds of products have been demonstrated to sometimes contain lead, e.g. in buttons, zippers and other metal parts, as well as in materials such as fake leather. These products are also easily accessible for children.

The companies that participated in the consultation already have requirements for lead free materials in place. The requirements are mainly based on hazard; the effects associated with lead are well-known. All companies stated that there are lead-free products available on the market, and that they require these materials in procurements. Products are tested for lead and some of the companies monitor the production sites themselves. All of the companies that participated in the consultation stated that a restriction will not affect their business, as they have already substituted lead. An increase in costs due to more testing of the product was anticipated by some companies. Also, discard of products that have been tested positively for lead might lead to increased costs. The larger companies stated that it is not very hard to put down requirements in procurements, whereas the smaller ones stressed the importance of dialogue with the suppliers.

Furniture

Manufacturers of furniture were contacted since furniture is a possible source of lead, to which children may be exposed. Furniture is easily accessible to children. Only one stakeholder provided information regarding substitution of lead. The stakeholder stated that there are already requirements regarding lead content in articles in place, and the substitution of lead has already taken place. In order to substitute lead, the company performed an analysis to ensure that it was possible to substitute lead in the materials and the production chains of the suppliers. A mapping of alternative materials was also performed. The analysis showed that it was indeed possible to substitute lead and an internal plan for substitution was set up. The company states that the main cost of the phase-out of lead, was the conversion of the production. The cost of the raw material differs only marginally. Also, the administration of two separate stocks and the update of internal documentation, added to the cost of substitution, as well as the discard of the stock still present at the time of the deadline.

Lead was originally present in the products due to the enhanced machinability. The friction between the tool and the material is decreased, which leads to a better breaking of the chips and thereby an increased life-span of the machinery.

Keys and locks

Producers of keys and locks were targeted since these products are made from leaded brass. The lead enhances the machinability and acts as a lubricant. The friction between the tool and the material is decreased, which leads to a better breaking of the chips. According to the one of companies that participated in the consultation, it has not been possible to find an alternative material that function for keys and locks, even though research in the area is performed. Instead, the lead concentration in the brass has been lowered as far as technically possible. The lock itself contains 2-3% lead and the keys 1.5% lead. An alternative to lead containing brass in keys and locks would be other techniques that have not yet been developed.

It is, according to one of the consulted stakeholders, possible to substitute lead in manufacturing of keys and locks as lead-free alternatives are available on the market. The costs for substitution are however high and the performance of the locks and keys manufactured from the alternatives is not well known.

With the present available technique and machinery for manufacturing of keys and locks and the maintenance of keys and locks in use a short transitional period would have major technical and economical impact on the manufacturers.

Lead is used because of its cutting, corrosive and wearing qualities. Parts of locks and keys that can be manufactured without cutting don't usually contain lead according to one stakeholder (such as handles, cylinder rings). Brass with very low lead content is stiffer which results in a higher strain and wear on machinery and tools.

According to another stakeholder the entire lock, including the handle, is made from brass. The parts accessible for children are, however, coated. The risk that a child would be exposed to lead from the lock is therefore limited. Keys and padlocks, on the other hand, are accessible to children, and may act as a source of lead.

Manufacturing of keys is carried out by many SME companies such as locksmiths and heel bars. These companies would need to invest in new machinery in order to work with both lead-free alternatives and lead-containing materials. Machinery for manufacturing and processing of keys made of other alternatives are not available on the market and would have to be developed.

Crystal

Many objects made of crystal fall outside the scope of this dossier, e.g. glassware. Crystal ornamentals, however, are consumer articles, which could be accessible to children. The stakeholders consulted, both companies and trade organizations, state that there are lead in the glass and possibly also in metal parts of their products.

Full lead crystal contains lead oxides, PbO or Pb_3O_4, and the lead concentration is at least 24%. The amount of lead oxides used to produce lead crystal glass is 3000 t /year (7% of the total market of this substance). The lead is bound in a molecular network and thereby integrated in the crystal. The stakeholders state that crystal should not be regarded as a preparation, but rather as a substance of its own. Since crystal must contain at least 24% lead in order to be called crystal, is it is not possible to replace the lead. There are however other glass materials which are comparable in optical and visual properties, to which no lead has been intentionally added. These glasses could substitute the crystal itself. The stakeholders are however of differing opinions regarding whether these materials can be regarded as satisfactory alternatives. Apparently, the alternative glasses are not as workable as crystal, if the glass is processed manually.

All stakeholders further states that lead is not intended for children.

Musical instruments

Some musical instruments may according to one of the consulted stakeholders require lead-containing alloys to maintain their acoustic properties. According to the stakeholders consulted, these alloys cannot be manufactured from the lead-free brass varieties currently available. The intended use of lead and lead compound in music instruments that has been verified by published articles and consultations with representatives for colleges, research centers and manufacturers is mainly in organ pipes and as a weight in piano keys. These uses are not considered within the scope of the proposed restriction. Any use of lead in wind instrument has not been verified during the work carried out by the dossier submitter.

According to a company that produces and repair wind instruments, brass instruments are made of brass and silver. The solder used for brazing of brass instrument is often tin. Mouthpieces for wind instruments are manufactured in rubber (ebonite), metal and wood materials. The metals used are exempt for brass silver or gold plated finish.

The company is not familiar with any intended use of lead in brass instruments. According to the European Copper Institute “lead-free” copper tin alloys and “lead-free” copper zinc alloys are used for manufacturing of musical instruments. The lead content in these instruments is <0.1%. According to the same Institute leaded brass with up to 3.5% lead is used in some music instruments.

Rubber industry

The rubber industry was targeted since lead may be present in the products produced, either as pigments or as stabilizers. These products can be used in a variety of articles, including different plastic articles, faux leather in bags and shoes and accessories. Such articles may be accessible to children.

According to the stakeholders consulted, lead stabilizers are not present in consumer articles made of chloroprene rubber. The stakeholders further put forward that there currently are no consumer articles where lead stabilizers are needed. No major adjustments to the process have been necessary in order to substitute lead stabilizers with alternatives.

Fishing sinkers

Fishing sinkers are targeted since they are often made of lead and could be accessible to children. According to the stakeholders consulted, it is hard to substitute lead in fishing sinkers. An alternative substance could be tungsten, although a substitution would lead to increased costs. Other materials are not deemed to be able to replace lead in sinkers, due to technical reasons.

The stakeholder further claims that sinkers, to a large part, are purchased online. Also, people are making their own sinkers/baits at home, using scrap lead. It has also been put forward by the stakeholders, that Denmark’s national ban on lead in sinkers has led Danish sport fishers to purchase sinkers from Sweden. This claim has however not been supported by any underlying data.

Recycling

In the process of recycling, lead may be transferred to new materials and articles. However, the same requirements apply to recycled and to virgin materials. This implies that it may be complicated to recycle materials which contain lead.

According to producers of brass, a restriction would complicate recycling of metals. As of today, there are well-established scrap cycles for metals. Introducing new alloys would be problematic and lead to increased costs since more material would need to be sent to smelters in order to recycle the metals. Alloys containing bismuth may also contaminate regular brass and make the recycled product brittle.

According to consulted authorities recycled plastic most often is downcycled to products such as waste bins, plastic bags and pallets.

Test results

In order to be able to estimate both the share of articles containing lead and the lead concentration in these articles, organizations and authorities that perform tests were contacted in the consultation.

The stakeholders provided both test results and descriptions of how tests are conducted.

Test results were reported from USA and Sweden. Both concerned findings in handbags and wallets. An Indian test laboratory provided information regarding products exceeding limit values for lead. According to the company, failures have been observed in metal zippers, metal buttons, plastic buttons, certain coated fabrics, rhinestones/beads, sequins, fashion jewelry, leather belts/accessories, other miscellaneous accessories. Failure equals a lead content > 100 mg/kg. The highest content found was in a metal button which contained 4.2 % lead.

G.2 Public consultation on the Annex XV restriction report (21 March- 21 September 2013)

After submission of the Annex XV restriction report, ECHA organised a six-month public consultation on the restriction dossier on lead and its compounds from 21 March until 21 September 2013. During the consultation, 55 comments were received from stakeholders, representing industry, individuals and Member State Competent Authorities. The comments received, as well as the responses from the dossier submitter (Sweden) and from the rapporteurs of the Committees for Risk Assessment and Socio-economic Analysis are to be made available on the ECHA website.

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Appendices

Appendix 1. Lead and lead compounds registered or restricted under REACH

Lead substances manufactured or imported in the EU can be found in the REACH registration acts, see table A1.1. Lead compounds registered as intermediates are included in the table since the lead ion will not be consumed during a chemical reaction of the intermediates. In the table, there is also information on lead substances included in the Candidate list (SVHC), subject to authorisation in Annex XIV or restricted for any uses in Annex XVII (in addition to the lead substances falling under entry 30). Only lead compounds with a known use as pigment, stabiliser or elemental lead, for example in alloys, are expected to be used in the manufacturing of consumer articles in the EU. However, there may also be other lead compounds used in the manufacturing of articles, when the manufacturing takes place outside the EU and the articles are imported. Thus table A1.1 cannot be seen as an exhaustive list of all relevant lead compounds used in articles for consumer use on the market in the European Union.

Table A1.1: Substances containing lead as registered under REACH or elsewhere mentioned in REACH legislative acts

EC Number	CAS Number	Name	Volume per year registered to ECHA (tonnes)	Current measures under REACH; SVHC, Annex XIV or Annex XVII
231-100-4	7439-92-1	lead	1,000,000 - 10,000,000	
201-075-4	78-00-2	tetraethyllead	1,000 - 10,000	
206-104-4	301-04-2	lead di(acetate)	1 - 10	
208-908-0	546-67-8	lead tetraacetate	10 - 100	
215-235-6	1314-41-6	orange lead	10,000 - 100,000	
215-267-0	1317-36-8	lead monoxide	100,000 - 1,000,000	
231-845-5	7758-95-4	lead dichloride	1 - 10	
232-382-1	8012-00-8	pyrochlore, antimony lead yellow	10 - 100	
233-245-9	10099-74-8	lead dinitrate	10 - 100	
234-363-3	11120-22-2	silicic acid, lead salt	100 - 1,000	
234-853-7	12036-76-9	lead oxide sulfate	100 - 1,000	

EC Number	CAS Number	Name	Volume per year registered to ECHA (tonnes)	Current measures under REACH; SVHC, Annex XIV or Annex XVII
235-038-9	12060-00-3	lead titanium trioxide	10 - 100	
235-067-7	12065-90-6	pentalead tetraoxide sulphate	100,000 - 1,000,000	
235-252-2	12141-20-7	trilead dioxide phosphonate	100,000 - 1,000,000	
235-380-9	12202-17-4	tetralead trioxide sulphate	1,000,000 - 10,000,000	
235-702-8	12578-12-0	dioxobis(stearato)trilead	100,000 - 1,000,000	
235-727-4	12626-81-2	lead titanium zirconium oxide	100 - 1,000	
237-486-0	13814-96-5	lead bis(tetrafluoroborate)	10 - 100	
244-073-9	20837-86-9	lead cyanamidate	1 - 10	
263-467-1	62229-08-7	sulfurous acid, lead salt, dibasic	100 - 1,000	
272-271-5	68784-75-8	silicic acid (H2Si2O5), barium salt (1:1), lead-doped	10 - 100	
273-688-5	69011-06-9	[phthalato(2-)]dioxotrilead	100 - 1,000	
292-966-7	91031-62-8	fatty acids, C16-18, lead salts	10,000 - 100,000	
614-455-3	68411-07-4	copper lead resorcylate salicylate complex	1 - 10	
257-175-3	51404-69-4	acetic acid, lead salt, basic	10 - 100	

EC Number	CAS Number	Name	Volume per year registered to ECHA (tonnes)	Current measures under REACH; SVHC, Annex XIV or Annex XVII
297-907-9	93763-87-2	slags, lead-zinc smelting	100,000 - 1,000,000	
215-693-7	1344-37-2	lead sulfochromate yellow	1,000 - 10,000	SVHC, Annex XIV:11
235-759-9	12656-85-8	lead chromate molybdate sulfate red	1,000 - 10,000	SVHC, Annex XIV:12
236-542-1	13424-46-9	lead diazide	10 - 100	SVHC
239-290-0	15245-44-0	lead 2,4,6-trinitro-m-phenylene dioxide	10 - 100	SVHC
215-290-6	1319-46-6	trilead bis(carbonate) dihydroxide	10 - 100	Annex XVII:16
401-750-5	17570-76-2	lead(II) bis(methanesulfonate)	Confidential	SVHC
231-846-0	7758-97-6	lead chromate	Not registered	SVHC, Annex XIV:10
239-831-0	15739-80-7	PbxSO4	Not registered	Annex XVII:17
232-064-2	7784-40-9	lead hydrogen arsenate	Not registered	SVHC
229-335-2	6477-64-1	lead dipicrate	Not registered	SVHC
222-979-5	3687-31-8	trilead diarsenate	Intermediate use only	SVHC
209-943-4	598-63-0	lead carbonate	Intermediate use only	Annex XVII:16
231-198-9	7446-14-2	lead sulphate	Intermediate use only	Annex XVII:17
215-246-6	1314-87-0	lead sulphide	Intermediate Use Only	

EC Number	CAS Number	Name	Volume per year registered to ECHA (tonnes)	Current measures under REACH; SVHC, Annex XIV or Annex XVII
215-247-1	1314-91-6	lead telluride	Intermediate Use Only	
235-109-4	12069-00-0	lead selenide	Intermediate Use Only	
243-310-3	19783-14-3	lead hydroxide	Intermediate Use Only	
257-175-3	51404-69-4	acetic acid, lead salt, basic	Intermediate Use Only	
273-701-4	69011-60-5	lead alloy, base, Pb,Sn, dross	Intermediate Use Only	
273-791-5	69029-45-4	lead, dross, antimony-rich	Intermediate Use Only	
273-792-0	69029-46-5	lead, dross, bismuth-rich	Intermediate Use Only	
273-795-7	69029-51-2	lead, antimonial, dross	Intermediate Use Only	
273-796-2	69029-52-3	lead, dross	Intermediate Use Only	
273-800-2	69029-58-9	slags, lead reverbatory smelting	Intermediate Use Only	
273-809-1	69029-67-0	flue dust, lead-refining	Intermediate Use Only	
273-825-9	69029-84-1	slags, lead smelting	Intermediate Use Only	
273-925-2	69227-11-8	Lead, dross, copper-rlch	Intermediate Use Only	
282-356-9	84195-51-7	matte, lead	Intermediate Use Only	
282-366-3	84195-61-9	speiss, lead	Intermediate Use Only	

EC Number	CAS Number	Name	Volume per year registered to ECHA (tonnes)	Current measures under REACH; SVHC, Annex XIV or Annex XVII
293-314-4	91053-49-5	leach residues, zinc ore, lead-contg.	Intermediate Use Only	
305-411-1	94551-62-9	calcines, lead-zinc ore conc.	Intermediate Use Only	
305-445-7	94551-99-2	wastes, lead battery reprocessing	Intermediate Use Only	
305-449-9	94552-05-3	waste solids, lead silver anode	Intermediate Use Only	
308-011-5	97808-88-3	lead, bullion	Intermediate Use Only	
308-765-5	98246-91-4	speiss, lead, nickel-contg.	Intermediate Use Only	
310-050-8	102110-49-6	residues, copper-iron-lead-nickel matte, sulfuric acid-insol.	Intermediate Use Only	
310-061-8	102110-60-1	slimes and Sludges, battery scrap, antimony- and lead-rich	Intermediate Use Only	
931-607-7		lead bullion, Platinum Group Metals rich	Intermediate Use Only	
931-722-2		reaction product of lead chloride or lead sulphate with alkaline solution	Intermediate Use Only	

Appendix 2. Existing legal requirements

Mixtures, articles and consumer products containing lead are regulated through several EU directives with regard to their risk to human health and, in some cases, the environment. As can be seen from Table A2.1, none of these directives covers the whole scope of articles available to consumer use, but specialise in specific priority product types such as toys, electric and electronic equipment, packaging and materials that come into contact with food. The majority of articles available on the consumer market remain unregulated with respect to lead.

A number of regulations that do not contain explicit restrictions on lead may also be relevant in this context. Some of these are listed in Table A2.2.

Finally, some Member States have adopted national regulations imposing restrictions upon the use of lead in articles beyond the Community level requirements. Analogous regulations exist also in non-EU countries. Some of these restrictions that may be relevant for this proposal are summarised in Table A2.3. (Food related regulations are omitted.)

Table A2.1: List of regulations setting maximum concentration limits or otherwise restrict the use of lead and its compounds in preparations, articles or consumer products. The list is non-exhaustive.

Legislative act	**Requirement**
REACH Regulation (1907/2006/EU)	*Annex XVII, entry 16 + 17:* Lead carbonates and lead sulphates must not be used in preparations intended to be used as paints. *Annex XVII, entry 30:* Substances classified as toxic to reproduction, Cat 1A or 1B, may not be made placed on the market and made available to consumers, neither as pure substance or in preparations, at higher concentrations than the classification limit. This affects all lead compounds but not metallic lead. *Annex XVII, entry 63:* Jewellery may not contain lead or its compounds at levels ≥ 0.05 % by weight (expressed as lead metal) of any individual part of the jewellery. This includes *inter alia* bracelets, wrist watches, cufflinks, and hair accessories. The restriction is not applicable to crystal, enamel, precious stones or internal components of timepieces.
Cosmetics Regulation (1223/2009) (*replaces Cosmetics Directive 76/768/EEC*))	Cosmetic products must not contain lead or its compounds.

Legislative act	**Requirement**
Fuel Quality Directive (98/70/EC)	Fuel for motor vehicles may not contain lead or its compounds at levels > 0.005 g/L. Aircraft fuel is out of the scope of the directive.
RoHS Directive (2011/65/EU, replacing 2002/95/EC) *(on the restriction of the use of certain hazardous substances in electrical and electronic equipment)*	Electric and electronic equipment must not contain lead at levels > 0.1 % by weight of each homogeneous material in the equipment. Several exclusions and exemptions apply (e.g. can copper alloys contain up to 4 % lead, and lead in solders are exempt in various applications)
ELV (End-of-life Vehicle) Directive (2000/53/EC)	Cars and goods transport vehicles < 3.5 tons must not contain lead at levels > 0.1 % by weight of each homogeneous material in the vehicle Several exemptions apply, e.g. for alloys, batteries and various components.
Toy Safety Directive (2009/48/EC) *(N.B. The requirements in the old directive 88/378/EEC are still valid for metals. The chemical requirements in the new directive apply from July 2013.)*	Toys must not contain substances classified as CMR, Cat 1A, 1B or 2, at higher concentrations than the classification limit. This affects all lead compounds but not metallic lead. Cf. section C. Migration of lead from toys is limited to: ▪ 13.5 mg/kg from dry, brittle, powder-like or pliable toy material ▪ 3.4mg/kg from liquid or sticky toy material ▪ 160mg/kg from scraped-off toy material (N.B. In the current directive 88/378/EEC, which applies for metals until 20 July 2013, the maximum migration limit of lead is 90 mg/kg regardless of material.)
Packaging and Packaging Waste Directive (94/62/EC)	Packaging and packaging components must not contain lead and its compounds at levels > 100 mg/kg.
Directive 86/278/EC on Sewage sludge in agriculture	Sludge containing > 1000–1750 mg lead / kg dry matter may not be used in agriculture.

Legislative act	**Requirement**
Commission Regulation (1881/2006) setting maximum levels for certain contaminants in foodstuffs *(under the framework Regulation (1935/2004) on materials and articles intended to come into contact with food)*	Lead content in 17 categories of food must not exceed specified limits, ranging from 0.02 mg/kg (milk) to 1.5 mg/kg (mussels).
Directive 98/83/EC on quality of water intended for human consumption *(last revised in 2011)*	Lead content in water for human consumption must not exceed 10 µg/L.
Directive 88/388/EEC on flavourings for use in foodstuffs and to source materials for their production	Lead content in flavourings must not exceed 10 mg/kg.
Commission Regulation (10/2011, amended by 1282/2011) on plastic materials and articles intended to come into contact with food *(under the framework Regulation (1935/2004) on materials and articles intended to come into contact with food)*	Restriction only for one specific plastic material, whose raw components must not contain more than 2 mg/kg lead. Migration limits are however set for other metals.
Directive 84/500/EEC on ceramics articles intended to come into contacts with foodstuffs *N.B. This directive is currently being reviewed. New maximum levels are expected by early 2013. EFSA (2010) suggested maximum levels 1000 times lower.*	Migration limits for lead are (as of April 2012): ▪ 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, ▪ 4.0 mg/L for other articles.

Table A2.2: List of other regulations related to lead in articles. The list is non-exhaustive.

Legislative act	Requirement
CLP Regulation (1272/2008/EU)	Lead compounds are classified as toxic to reproduction, Cat 1A, i.e. with a classification limit of 0.1 %. Sweden has filed a proposal to classify metallic lead accordingly.
Battery Directive (2006/66/EC)	Labelling, collection and recovery targets for lead containing batteries and accumulators apply. Lead is not restricted in batteries and accumulators due to lack of available substitutes. At next directive recast 2016 lead might be restricted. Restrictions already apply for mercury and cadmium.
General Product Safety Directive (2001/95/EC)	Allows measures, including product recalls and temporary bans, against products deemed unsafe for consumers. Such measures have been taken due to health risks resulting from lead content or migration.
Crystal Directive (69/493/EEG)	Prescribes that only glass containing lead may benefit from the term “crystal”. For “full crystal glass, category 1” a lead content of > 30% is required.

Table AI.3: National regulations restricting lead in articles. The list is non-exhaustive.

Country	Restriction
Denmark	Restriction of lead compounds in all articles above 0.01 %. Some exemptions apply, e.g. discharge lamps, elevator cables, crystal glass, radiation protections, electronic components, and others. Restriction of metallic lead above 0.01% in a number of applications, including hobby articles, candles, fishing tackle, decorative objects, and others. (Blybekendtgørelsen of 2009.)
Poland	Total ban (no maximum limit given) of lead in textiles that can come into contact with skin. (Decree of the Council of Ministers, April 2004. Dz.U. 2004 nr 81 poz. 743.)
The Netherlands	Ban on lead and its compounds in fireworks intended for consumer use.

Country	Restriction
Norway	Recently proposed a national ban on lead in consumer articles, analogous to the Danish ban. The proposal is currently pending.
Non-EU countries	
U.S.A.	Products intended for children must not contain more than 100 ppm (0.01 %) total lead in accessible parts. For paints and similar surface coatings, the limit is 90 ppm. These limits have been successively lowered from 600 ppm and were last amended in 2011. (Consumer Product Safety Improvement Act of 2008)
Canada	Jewellery items intended for children must not contain more than 600 mg/kg (0.06 %) total lead, and no more than 90 mg/kg (0.009 %) of migratable lead.
Australia	Children's toys may not contain lead above the migration limit of 90 mg/kg toy material. For finger paints, the migration limit is 25 mg/kg. (Consumer Protection Notice No. 1 of 2009.) Candles with wicks that contain lead in a quantity greater than 0.06% are banned. (Consumer Protection Notice No. 7 of 2002.)
New Zealand	Children's toys may not contain lead in their accessible parts at a migration level above 90 mg/kg of toy material. (Unsafe Goods (Lead in children's toys) Indefinite Prohibition Notice 2009.)

Some of the EU directives listed in Table A2.1, e.g. the RoHS directive, have also spawned "mirror regulations" in non-EU countries like Canada, India and China. Furthermore, many countries have regulations on lead in toys, and on lead contaminants in foodstuff and materials that come into contact with food. These are not considered relevant in the context of this proposal.

Appendix 3. Additional data on lead analysis of articles intended for consumer use

In the table some single samples of lead findings in consumer articles are presented.

Table A3.1: Reports of single findings of lead in articles

Article description	Part containing lead	Lead concentration ppm	Reference
T-shirts	Print	554 – 5844 a)	EU Rapex (Poland)
Backpacks	N.A.	2 600	Norweigan CA
Purses	N.A.	2 100 – 12 400	Norweigan CA
Wallet	N.A.	12 000	Norweigan CA
Rainwear	N.A.	15 000	Norweigan CA
Scooter handle	N.A.	8 900	Norweigan CA
Garden hoses	N.A.	4 500	Norweigan CA
Elastic strap	Fastening hook	34 000	own

Release rate 5630 units

Data from the stakeholder consultation confirm the figures e.g. lead content up to 4,2% has been identified in metal buttons and writing instruments may contain up to 3,5% lead.

Appendix 4. Lead testing of articles intended for consumer use

There are only a few reports published where the lead content in articles for consumer use have been tested. The Swedish CA has therefore performed test series to further evaluate the presence of lead in selected groups of consumer articles.

There has been more than one aim with the test series made by the Swedish CA, namely to earn knowledge on:

The presence of lead in certain materials and article groups

The market share of lead containing articles in total and in selected sub-categories of articles

The concentration of lead in articles containing lead

Migration of lead from polymer materials

Screening tests with a variety of articles but with few articles in each group as well as test series with a larger number of articles in each selected sub-category were performed. A couple of articles with identified lead content were also sent for lead migration tests.

As the worst case daily exposure of lead leads to the conclusion that the tolerable lead content should not exceed 0.05%, only test results above 0,05% have been used from the test series. Test results lower than 500 ppm (0,05%) have been regarded as lead free and are not included either in the calculation of the average market share or the average lead concentration. The choice to only report test results above 500 ppm does not reflect the detection limit of the analyses, which is around 20 mg/kg as described in section E.2.1.2.2, but it is merely a simplification that was made in order to get comparable figures for lead content and market shares of lead containing articles for the subsequent assessment. It also means that the assessed risk in the proposal has not been overestimated.

The results about the market share of lead content in various sub-categories of articles are presented in the report, section 9.3.1.

XRF Screening tests

Totally 155 articles were screened with an XRF-instrument. Lead was found in 55 of the 155 articles. Lead concentration ranged from 601 - 42 500 ppm (0,06 – 4,25 %). Only test results of 500 ppm or higher were reported. In addition, the lead content of three fishing sinkers was measured. The lead concentration in the fishing sinkers ranged from 68 – 75%.

The screening tests cannot be used for evaluation of the market share of articles that contain lead as many of the articles were not randomly chosen, but rather chosen because they were suspected to contain lead.

The screening tests did reveal that accessories like bags and belts often contained lead in the textile or polymer materials. It is assumed that the measured levels of stem from coloring agents that are added to the material. Since there is no method available to identify specific lead compounds in a textile or polymer matrix, the assumption could not be verified by chemical analysis. The test results have influenced the work of assessing possible alternatives for the substitution of lead compounds.

Test of selected articles and subcategories of articles

Some example articles were chosen to represent a broader group of articles commonly used by consumers. The chosen articles were such articles that are reported to be commonly mouthed by children such as clothes, pens and keys/key rings. Wallets, mainly in red and yellow colours, were also chosen for testing since they were considered to be able to represent the broader category accessories.

Accessories are quite often mouthed by children, but they are not on top of the list in the DTI report (DTI 2002). Wallets were however identified as a strategic sub-category to represent several other categories. They were also chosen to verify findings from tests published on purses available on the US market.

A summary of the test results on article level are presented in table A4.1.

Table A4.1: Summary of test results for various sub-categories of articles

Article group	Total no of samples	Samples containing lead	Range lead concentration, ppm *)	Average lead concentration, ppm / (%) *)
Clothes	56	7	632 – 17 200	4970 (0,50%)
Accessories	85	18	601 – 160 000	13 243 (1,3%)
Stationery	52	7	755 – 24 000	8 754 (0,87%)
Interior decorations	14	6	731 – 380 000	45 489 (4,5%)
Keys	51	34	776 – 11 900	6026 (0,60%)

*) Only test results of 500 ppm or higher are included.

As the category accessories include several types of articles, the test results for the specific articles (wallets, bags and key rings) are reported in table A4.2.

Table A4.2: Test results of lead content in polymer and textile materials in wallets, bags and cases.

Article group	Total no of samples	Samples containing lead	Range lead concentration, ppm *)	Average lead concentration, ppm / (%) *)
Wallets, polymer material	26	7	1202 – 1926	1667 (0,17%)
Bags and cases	11	3	632 – 2 386	2 128 (0,21%)

*) Only test results of 500 ppm or higher are included.

Key rings are often used together with keys, which have been recorded in the mouthing studies. In table A4.3 results from tests on different subsets of key-rings are presented.

In this report the key rings are categorised as an accessory. Note that it is only the key rings from Sweden that are reported in the sub-category accessories in Table 17

Like jewellery, many key rings were found to contain high levels of lead.

Table A4.3: Test results of lead content in various subsets of key rings.

Item	Total no of samples	Samples containing lead	Range lead concentration, ppm *)	Average lead concentration, ppm *)
Sweden	26	4	7312 – 160 000	50 028
EU	32	11	6 300 - 354 000	131 282
World	31	17	655 – 64 900	20 415
Total	89	31	655 – 550 000	62 228

*) Only test results of 500 ppm or higher areincluded.

Migration tests

A third screening test was performed to verify if lead in polymer materials is bound to the material without migrating during normal mouthing behaviour. It is often stated from different stakeholders that for example lead stabilizers are not available for human exposure, but reports that verifies that were not available or at least not found while preparing this restriction proposal.

16 samples with identified lead content and one reference sample without lead were sent for test of migration (EN 71-3). The testing time is 2 hours. The test results are presented in table A4.4. Six of the samples had a migration level exceeding the limit in the Toys directive.

The analyses were performed by Eurofins on request from the Swedish CA in October 2012.

Table A4.4: Test results from migration tests.

No	Article	Part of the article sent for testing	Migration Pb (mg/kg)
1	Garden glove	Green plastic dots	22
2	Reflective cat collar	Mixed materials	29
3	Green textile bag	Outer layer	2,0
4	Spectacle case	Front layer	18
5	Reflective bracelet orange	Inner layer	15
6	Reflective bracelet yellow	Inner layer	70
7	Grey purse	Front layer (silver)	13
8	Purse orange	Front layer (orange)	290*
9	Strap purse in red polymer	Back and front layer	28
10	Purse in red polymer	Front layer (red)	3,2
11	Wallet in red polymer	Front layer (red)	180*
12	Belt coral (Lead free reference)	Inner layer (white)	1,3
13	Belt coral	Front layer	130*
14	Belt coral	Back layer	140*
15	Plastic flower	Outer layer	0,27
16	Belt orange	Front layer	270*
17	Belt orange	Back layer	220*

*the limit value for migration in the Toys directive is 90 mg/kg.

Overall conclusions from the test series

The presence of lead in metal details of clothes and accessories were not found as frequently as expected from the screening tests and test reports from other organisations.

On the other hand, lead was found in textile and polymer materials in clothes, but even more frequently in accessories like purses and wallets.

Lead in metal alloys were found in high concentrations in key rings and decoration articles, while keys and stationery had a somewhat lower content but still at a level of concern if the article should be used for mouthing by small children.

There is a migration of lead from the tested samples of lead containing polymers.

Appendix 5. Detailed lead mining and manufacturing data

Table A5.1: Mine production of lead in EU34, tonnes metal content (Brown 2012)

Country	2006	2007	2008	2009	2010
Bulgaria (a)	19 571	17 768	14 577	12 981	12 705
Greece	11 400	13 400	14 000	10 000	12 200
Ireland	61 800	56 800	50 200	49 500	39 100
Italy	6 000	3 000	3 000	2 000	3 000
Macedonia	11 531	36 039	49 877	46 788	41 300
Poland	77 450	61 330	67 070	62 910	44 200
Romania	6 269	784	-	-	-
Spain	-	-	-	1 000	300
Sweden	55 644	63 224	63 489	69 293	67 697
Turkey	11 000	20 800	31 800	21 600	39 000
United Kingdom	400	300	300	243	251
EU34 Total	261 100	273 400	294 300	276 300	259 800

Metal content of ore

Table A5.2: World Mine Production and Reserves: Reserve estimates for Australia, Canada, China, Peru, Poland, and the US were revised based on information derived from Government and industry sources.

(USGS 2012) (Data in thousand metric tons of lead content)

	Mine production	**Mine production**	**Reserves**
	2010	2011	
United States	369	345	6,100
Australia	625	560	29,000
Bolivia	73	85	1,600
Canada	65	75	450
China	1,850	2,200	14,000
India	95	120	2,600
Ireland	45	50	600
Mexico	158	225	5,600
Peru	262	240	7,900
Poland	70	40	1,700
Russia	97	115	9,200
South Africa	50	55	300
Sweden	60	70	1,100
Other countries	320	340	5,000
World total (rounded)	**4,140**	**4,500**	**85,000**

Appendix 6. Detailed information on statistical data of the enterprises in manufacturing and trade of articles for consumer use

Table A6.1: Number of enterprises involved in the manufacturing of articles for consumer use; Sum of national reported values

Statistical code	Sector	2008	2009
B072	Mining of other non-ferrous metal ores	142	344
C2443	Lead, zinc and tin production	206	233
C2012	Manufacture of dyes and pigments	472	613
C2016	Manufacture of plastics in primary forms	2 449	3 070
C2229	Manufacture of other plastic products	25 398	28 856
C2341	Manufacture of ceramic household and ornamental articles	8 293	10 836
C2572	Manufacture of locks and hinges	8 773	8 892
C323 + C3230	Manufacture of sports goods	3 794	3 863
C3299	Other manufacturing n.e.c.	23 457	26 988
C13	Manufacture of textiles	62 149	79 981
C14	Manufacture of wearing apparel	129 790	182 120
C1411	Manufacture of leather clothes	2 490	3 540
C1413	Manufacture of other outerwear	67 161	110 131
C1419	Manufacture of other wearing apparel and accessories	17 979	20 617
C1420	Manufacture of articles of fur	2 614	4 369
C1439	Manufacture of other knitted and crocheted apparel	7 909	10 549
C151	Tanning and dressing of leather; manufacture of luggage, handbags, saddlery and harness; dressing and dyeing of fur	16 311	18 011
C1511	Tanning and dressing of leather; dressing and dyeing of fur	3 828	4 374
C1512	Manufacture of luggage, handbags and the like, saddlery and harness	11 776	12 806
C1520	Manufacture of footwear	23 063	26 904
C2599	Manufacture of other fabricated metal products n.e.c.	37 508	41 331
C3102	Manufacture of kitchen furniture	12 560	22 643
C3103	Manufacture of mattresses	2 185	2 323
C3109	Manufacture of other furniture	73 233	111 545
	Total sum (batteries excluded)	**543 540**	**734 939**

Table A6.2: Number of persons employed in enterprises involved in the manufacturing of articles for consumer use; Sum of national reported values

Stat. code	Sector	2008	2009
B072	Mining of other non-ferrous metal ores	12 641	21 418
C2443	Lead, zinc and tin production	17 553	15 675
C2012	Manufacture of dyes and pigments	28 732	22 340
C2016	Manufacture of plastics in primary forms	171 448	154 691
C2229	Manufacture of other plastic products	482 615	465 613
C2341	Manufacture of ceramic household and ornamental articles	59 899	52 769
C2572	Manufacture of locks and hinges	119 509	114 829
C323 + C3230	Manufacture of sports goods	35 545	35 071
C3299	Other manufacturing n.e.c.	118 730	129 973
C13	Manufacture of textiles	718 204	929 974
C14	Manufacture of wearing apparel	1 254 124	1 494 304
C1411	Manufacture of leather clothes	13 451	23 357
C1413	Manufacture of other outerwear	701 663	798 175
C1419	Manufacture of other wearing apparel and accessories	131 718	122 284
C1420	Manufacture of articles of fur	6 980	9 185
C1439	Manufacture of other knitted and crocheted apparel	81 342	84 067
C151	Tanning and dressing of leather; manufacture of luggage, handbags, saddlery and harness; dressing and dyeing of fur	127 051	125 050
C1511	Tanning and dressing of leather; dressing and dyeing of fur	46 867	49 447
C1512	Manufacture of luggage, handbags and the like, saddlery and harness	74 765	71 504
C1520	Manufacture of footwear	314 421	311 005
C2599	Manufacture of other fabricated metal products n.e.c.	376 284	365 147
C3102	Manufacture of kitchen furniture	114 963	133 024
C3103	Manufacture of mattresses	38 874	42 602
C3109	Manufacture of other furniture	731 107	766 506
	Total sum	**5 778 486**	**6 338 010**

Table A6.3: Number of companies in the supply chain of articles for consumer use; Sum of national reported values

Stat. code	Sector	2008	2009
G4615	Agents involved in the sale of furniture, household goods, hardware and ironmongery	41 587	44 216
G4616	Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	46 333	48 018
G4618	Agents specialised in the sale of other particular products	92 669	103 586
G4619	Agents involved in the sale of a variety of goods	117 601	129 666
G4641	Wholesale of textiles	21 653	41 119
G4642	Wholesale of clothing and footwear	65 369	74 036
G4644	Wholesale of china and glassware and cleaning materials	14 962	21 126
G4647	Wholesale of furniture, carpets and lighting equipment	18 539	23 006
G4649	Wholesale of other household goods	72 418	79 591
G4711	Retail sale in non-specialised stores with food, beverages or tobacco predominating	399 823	572 000
G4719	Other retail sale in non-specialised stores	105 242	115 785
G4751	Retail sale of textiles in specialised stores	60 438	100 608
G4759	Retail sale of furniture, lighting equipment and other household articles in specialised stores	112 748	156 130
G4764	Retail sale of sporting equipment in specialised stores	43 909	54 443
G4771	Retail sale of clothing in specialised stores	327 623	387 140
G4772	Retail sale of footwear and leather goods in specialised stores	73 454	92 557
G4778	Other retail sale of new goods in specialised stores	175 142	252 907
G4782	Retail sale via stalls and markets of textiles, clothing and footwear	87 911	122 218
G4789	Retail sale via stalls and markets of other goods	72 273	98 983
G4791	Retail sale via mail order houses or via Internet	41 821	67 272
G4799	Other retail sale not in stores, stalls or markets	107 296	99 740
	Total sum	**2 098 811**	**2 684 147**

Table A6.4: Number of persons employed in of companies in the supply chain of articles for consumer use; Sum of national reported values

Statistical code	Sector	2008	2009
G4615	Agents involved in the sale of furniture, household goods, hardware and ironmongery	62 339	65 783
G4616	Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	76 655	79 429
G4618	Agents specialised in the sale of other particular products	164 161	170 368
G4619	Agents involved in the sale of a variety of goods	196 639	190 647
G4641	Wholesale of textiles	109 591	174 064
G4642	Wholesale of clothing and footwear	332 079	399 650
G4644	Wholesale of china and glassware and cleaning materials	84 908	115 180
G4647	Wholesale of furniture, carpets and lighting equipment	114 559	124 582
G4649	Wholesale of other household goods	400 837	471 808
G4711	Retail sale in non-specialised stores with food, beverages or tobacco predominating	4 683 901	5 413 050
G4719	Other retail sale in non-specialised stores	988 824	945 489
G4751	Retail sale of textiles in specialised stores	152 461	209 078
G4759	Retail sale of furniture, lighting equipment and other household articles in specialised stores	640 300	694 227
G4764	Retail sale of sporting equipment in specialised stores	241 047	246 413
G4771	Retail sale of clothing in specialised stores	1 751 680	1 829 517
G4772	Retail sale of footwear and leather goods in specialised stores	383 317	420 096
G4778	Other retail sale of new goods in specialised stores	634 954	758 130
G4782	Retail sale via stalls and markets of textiles, clothing and footwear	115 028	129 179
G4789	Retail sale via stalls and markets of other goods	92 167	90 416
G4791	Retail sale via mail order houses or via Internet	195 992	159 554
G4799	Other retail sale not in stores, stalls or markets	229 988	177 987
	Total sum	**11 651 427**	**12 864 647**

Appendix 7. Statistical codes from Eurostat Prodcom for the calculation of market volumes of articles for consumer use

Table 7.1 Clothing categories, available for consumers/children (PRODCOM)

PRCCODE	Description	In scope
14131110	Men's or boys' overcoats, car-coats, capes, cloaks and similar articles, of knitted or crocheted textiles (excluding jackets and blazers, anoraks, wind-cheaters and wind-jackets)	In
14131120	Men's or boys' anoraks, ski-jackets, wind-cheaters, wind-jackets and similar articles, of knitted or crocheted textiles (excluding jackets and blazers)	In
14131230	Men's or boys' jackets and blazers, of knitted or crocheted textiles	In
14131260	Men's or boys' suits and ensembles, of knitted or crocheted textiles	In
14131270	Men's or boys' trousers, breeches, shorts, bib and brace overalls, of knitted or crocheted textiles	In
14131310	Women's or girls' overcoats, car-coats, capes, cloaks and similar articles, of knitted or crocheted textiles (excluding jackets and blazers)	In
14131320	Women's or girls' anoraks, ski-jackets, wind-cheaters, wind-jackets and similar articles, of knitted or crocheted textiles (excluding jackets and blazers)	In
14131430	Women's or girls' jackets and blazers, of knitted or crocheted textiles	In
14131460	Women's or girls' suits and ensembles, of knitted or crocheted textiles	In
14131470	Women's or girls' dresses, of knitted or crocheted textiles	In
14131480	Women's or girls' skirts and divided skirts, of knitted or crocheted textiles	In
14131490	Women's or girls' trousers, breeches, shorts, bib and brace overalls, of knitted or crocheted textiles	In
14132110	Men's or boys' raincoats	In
14132120	Men's or boys' overcoats, car-coats, capes, etc	In
14132130	Men's or boys' anoraks, ski-jackets, wind-jackets and similar articles (excluding jackets and blazers, knitted or crocheted, impregnated, coated, covered, laminated or rubberized)	In
14132210	Men's or boys' suits (excluding knitted or crocheted)	In
14132220	Men's or boys' ensembles (excluding knitted or crocheted)	In
14132300	Men's or boys' jackets and blazers (excluding knitted or crocheted)	In
14132442	Men's or boys' trousers and breeches, of denim (excluding for industrial or occupational wear)	In
14132444	Men's or boys' trousers, breeches and shorts, of wool or fine animal hair (excluding knitted or crocheted, for industrial or occupational wear)	In
14132445	Men's or boys' trousers and breeches, of man-made fibres (excluding knitted or crocheted, for industrial or occupational wear)	In
14132448	Men's or boys' trousers and breeches, of cotton (excluding denim, knitted or crocheted)	In

PRCCODE	Description	In scope
14132449	Men's or boys' trousers, breeches, shorts and bib and brace overalls (excluding of wool, cotton and man-made fibres, knitted or crocheted)	In
14132455	Men's or boys' bib and brace overalls (excluding knitted or crocheted, for industrial or occupational wear)	In
14132460	Men's or boys' shorts, of cotton or man-made fibres (excluding knitted or crocheted)	In
14133110	Woman's or girls' raincoats	In
14133120	Woman's or girls' overcoats, etc	In
14133130	Women's or girls' anoraks, ski-jackets, wind-jackets and similar articles (excluding jackets and blazers, knitted or crocheted, impregnated, coated, covered, laminated or rubberized)	In
14133210	Women's or girls' suits (excluding knitted or crocheted)	In
14133220	Women's or girls' ensembles (excluding knitted or crocheted)	In
14133330	Women's or girls' jackets and blazers (excluding knitted or crocheted)	In
14133470	Women's or girls' dresses (excluding knitted or crocheted)	In
14133480	Women's or girls' skirts and divided skirts (excluding knitted or crocheted)	In
14133542	Women's or girls' trousers and breeches, of denim (excluding for industrial or occupational wear)	In
14133548	Women's or girls' trousers and breeches, of cotton (excluding denim, for industrial or occupational wear)	In
14133549	Women's or girls' trousers and breeches, of wool or fine animal hair or man-made fibres (excluding knitted or crocheted and for industrial and occupational wear)	In
14133551	Women's or girls' bib and brace overalls, of cotton (excluding knitted or crocheted, for industrial or occupational wear)	In
14133561	Women's or girls' shorts, of cotton (excluding knitted and crocheted)	In
14133563	Women's or girls' bib and brace overalls, of textiles (excluding cotton, knitted or crocheted, for industrial or occupational wear) and women's or girls' shorts, of wool or fine animal hair (excluding knitted or crocheted)	In
14133565	Women's or girls' shorts, of man-made fibres (excluding knitted or crocheted)	In
14133569	Women's or girls' trousers, breeches, bib and brace overalls, of textiles (excluding cotton, wool or fine animal hair, man-made fibres, knitted or crocheted)	In
14141230	Men's or boys' nightshirts and pyjamas, of knitted or crocheted textiles	In
14141310	Women's or girls' blouses, shirts and shirt-blouses, of knitted or crocheted textiles	In
14141430	Women's or girls' nighties and pyjamas, of knitted or crocheted textiles	In
14142100	Men's or boys' shirts (excluding knitted or crocheted)	In
14142230	Men's or boys' nightshirts and pyjamas (excluding knitted or crocheted)	In
14142300	Women's or girls' blouses, shirts and shirt-blouses (excluding knitted or crocheted)	In

PRCCODE	Description	In scope
14142430	Women's or girls' nightdresses and pyjamas (excluding knitted or crocheted)	In
14142570	Braces, suspenders, garters and similar articles and parts thereof	In
14191100	Babies' garments and clothing accessories, knitted or crocheted including vests, rompers, underpants, stretch-suits, napkins, gloves or mittens or mitts, outerwear (for children of height <= 86 cm)	In
14191210	Track-suits, of knitted or crocheted textiles	In
14191230	Ski-suits, of knitted or crocheted textiles	In
14191300	Gloves, mittens and mitts, of knitted or crocheted textiles	In
14192100	Babies' clothing and accessories, of textiles, not knitted or crocheted (for children of height <= 86 cm) including vests, rompers, underpants, stretch-suits, napkins, gloves, mittens and outerwear	In
14192210	Other men's or boys' apparel n.e.c., including waistcoats, tracksuits and jogging suits (excluding ski-suits, knitted or crocheted)	In
14192220	Other women's or girls' apparel n.e.c., including waistcoats, tracksuits and jogging suits (excluding ski-suits, knitted or crocheted)	In
14192230	Ski-suits (excluding of knitted or crocheted textiles)	In
14192370	Gloves, mittens and mitts (excluding knitted or crocheted)	In
14192395	Parts of garments or of clothing accessories, of textiles (excluding bras, girdles and corsets, braces, suspenders and garters, knitted or crocheted)	In
14193175	Gloves, mittens and mitts, of leather or composition leather (excluding for sport, protective for all trades)	In
14193180	Belts and bandoliers, of leather or composition leather	In
14391031	Men's or boys' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of wool or fine animal hair (excluding jerseys and pullovers containing <=50% of wool and weighing <=600g)	In
14391032	Women's or girls' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of wool or fine animal hair (excluding jerseys and pullovers containing <=50% of wool and weighing <=600g)	In
14391033	Jerseys and pullovers, containing <= 50% by weight of wool and weighing <= 600 g per article	In
14391061	Men's or boys' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of cotton (excluding lightweight fine knit roll, polo or turtle neck jumpers and pullovers)	In
14391062	Women's or girls' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of cotton (excluding lightweight fine knit roll, polo or turtle neck jumpers and pullovers)	In
14391071	Men's or boys' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of man-made fibres (excluding lightweight fine knit roll, polo or turtle neck jumpers and pullovers)	In
14391072	Women's or girls' jerseys, pullovers, sweatshirts, waistcoats and cardigans, of man-made fibres (excluding lightweight fine knit roll, polo or turtle neck jumpers and pullovers)	In
14391090	Jerseys, pullovers, sweatshirts, waistcoats and cardigans, of textile materials (excluding those of wool or fine animal hair, cotton, man-made fibres)	In

PRCCODE	Description	
14143000	T-shirts, singlets and vests, knitted or crocheted	In

Table 7.2 Categories of accessories (PRODCOM)

PRCCODE	Description	
14193180	Belts and bandoliers, of leather or composition leather	In
14193190	Clothing accessories of leather or composition leather (excluding gloves, mittens and mitts, belts and bandoliers)	In
15121210	Trunks, suitcases, vanity-cases, briefcases, school satchels and similar containers of leather, composition leather, patent leather, plastics, textile materials, aluminium or other materials	Out
15121220	Handbags of leather, composition leather, patent leather, plastic sheeting, textile materials or other materials (including those without a handle)	In
15121230	Articles normally carried in pocket or handbag	In
15121250	Cases and containers, n.e.c.	Out
15121270	Travel sets for personal toilet; sewing; or shoe or clothes cleaning (excluding manicure sets)	Out
25711350	Manicure or pedicure sets and instruments (including nail files)	Out
25931800	Sewing, knitting needles, bodkins... of iron or steel, for use in the hand	Out
25992927	Iron or steel snuff boxes, cigarette cases, cosmetic and powder boxes and cases, and similar pocket articles	Out
32504250	Sunglasses	In
32504290	Spectacles, goggles and the like, corrective, protective or other (excluding sunglasses)	In
32504350	Plastic frames and mountings for spectacles, goggles or the like	In
32504390	Non plastic frames and mountings for spectacles, goggles and the like	In
32992130	Umbrellas, sun umbrellas, walking-stick umbrellas, garden umbrellas and similar umbrellas (excluding umbrella cases)	Out
32992150	Walking-sticks, seat-sticks, whips, riding-crops and the like	Out

Code 14193190 was accounted for in both Clothes and Accessories categories in the submitted report.

Table 7.3 Shoes (PRODCOM)

PRCCODE	Description	
15201100	Waterproof footwear, with uppers in rubber or plastics (excluding incorporating a protective metal toecap)	Out
15201210	Sandals with rubber or plastic outer soles and uppers (including thong-type sandals, flip flops)	Out
15201231	Town footwear with rubber or plastic uppers	Out
15201237	Slippers and other indoor footwear with rubber or plastic outer soles and plastic uppers (including bedroom and dancing slippers, mules)	In
15201330	Footwear with a wooden base and leather uppers (including clogs) (excluding with an inner sole or a protective metal toe-cap)	Out
15201351	Men's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)	Out
15201352	Women's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)	Out
15201353	Children's town footwear with leather uppers (including boots and shoes; excluding waterproof footwear, footwear with a protective metal toe-cap)	In
15201361	Men's sandals with leather uppers (including thong type sandals, flip flops)	In
15201362	Women's sandals with leather uppers (including thong type sandals, flip flops)	In
15201363	Children's sandals with leather uppers (including thong type sandals, flip flops)	In
15201370	Slippers and other indoor footwear with rubber, plastic or leather outer soles and leather uppers (including dancing and bedroom slippers, mules)	In
15201380	Footwear with wood, cork or other outer soles and leather uppers (excluding outer soles of rubber, plastics or leather)	Out
15201444	Slippers and other indoor footwear (including dancing and bedroom slippers, mules)	In
15201445	Footwear with rubber, plastic or leather outer soles and textile uppers (excluding slippers and other indoor footwear, sports footwear)	Out
15201446	Footwear with textile uppers (excluding slippers and other indoor footwear as well as footwear with outer soles of rubber, plastics, leather or composition leather)	Out
15202100	Sports footwear with rubber or plastic outer soles and textile uppers (including tennis shoes, basketball shoes, gym shoes, training shoes and the like)	Out
15202900	Other sports footwear, except snow-ski footwear and skating boots	Out
15203200	Wooden footwear, miscellaneous special footwear and other footwear n.e.c.	out

Shoes for professional use are not included.

Table7. 4 Stationery (PRODCOM)

PRCCODE	Description	
22197321	Erasers, of vulcanized rubber	In
25711330	Paper knives, letter openers, erasing knives, pencil sharpeners and their blades (including packet type pencil sharpeners) (excluding pencil sharpening machines)	Out
25992370	Office articles such as letter clips, letter corners... of base metal	In
32991210	Ball-point pens	In
32991230	Felt-tipped and other porous-tipped pens and markers	In
32991250	Propelling or sliding pencils	In
32991330	Indian ink drawing pens	In
32991350	Fountain pens, stylograph pens and other pens (excluding Indian ink drawing pens)	In
32991510	Pencils and crayons with leads encased in a rigid sheath (excluding pencils for medicinal, cosmetic or toilet uses)	In

Several paper categories are excluded due no expectance and no test results indicating a content of lead in relevant concentrations for the proposal.

Table 7.5 Interior decorations (PRODCOM)

PRCCODE	Description	
13921660	Furnishing articles including furniture and cushion covers as well as cushion covers, etc for car seats (excluding blankets, travelling rugs, bed linen, table linen, toilet linen, kitchen linen, curtains, blinds, valances and bedspreads)	Out
16291420	Wooden frames for paintings, photographs, mirrors or similar objects	Out
22292340	Household articles and toilet articles, of plastics (excl. tableware, kitchenware, baths, shower-baths, washbasins, bidets, lavatory pans, seats and covers, flushing cisterns and similar sanitary ware)	In
22292620	Statuettes and other ornamental articles of plastic (including photograph, picture and similar frames)	Out
23411150	Household and toilet articles, n.e.c., of porcelain or china	Out
23411330	Statuettes and other ornamental articles, of porcelain or china	Out
23411350	Ceramic statuettes and other ornamental articles	Out
25992400	Statuettes, frames, mirrors and other ornaments of base metal	Out
25992982	Bells, gongs, etc, non-electric, of base metal	Out
32995130	Articles for Christmas festivities (excluding electric garlands, natural Christmas trees, Christmas tree stands, candles, statuettes, statues and the like used for decorating places of worship)	Out

32995150	Festive, carnival or other entertainment articles, n.e.c.	In
32995500	Artificial flowers, foliage and fruit and parts thereof	In
32995980	Globes, printed (excluding relief globes)	Out
31001170	Upholstered seats with metal frames (excluding swivel seats, medical, surgical, dental or veterinary seats, barbers or similar chairs, for motor vehicles, for aircraft)	Out
31001190	Non-upholstered seats with metal frames (excluding medical, surgical, dental or veterinary seats, barbers or similar chairs, swivel seats)	Out
31001210	Seats convertible into beds (excluding garden seats or camping equipment)	Out
31001230	Seats of cane, osier, bamboo or similar materials	Out
31001250	Upholstered seats with wooden frames (including three piece suites) (excluding swivel seats)	Out
31001290	Non-upholstered seats with wooden frames (excluding swivel seats)	Out
31001300	Other seats, of HS 9401, nec	Out
31021000	Kitchen furniture	Out
31091100	Metal furniture (excluding office, medical, surgical, dental or veterinary furniture; barbers' chairs - cases and cabinets specially designed for hi-fi systems, videos or televisions)	Out
31091230	Wooden bedroom furniture (excluding builders' fittings for cupboards to be built into walls, mattress supports, lamps and lighting fittings, floor standing mirrors, seats)	Out
31091250	Wooden furniture for the dining-room and living-room (excluding floor standing mirrors, seats)	Out
31091300	Other wooden furniture (excluding bedroom, dining-, living-room, kitchen office, shop, medical, surgical, dental/veterinary furniture, cases and cabinets designed for hi-fi, videos and televisions)	Out
31091430	Furniture of plastics (excluding medical, surgical, dental or veterinary furniture - cases and cabinets specially designed for hi-fi systems, videos and televisions)	Out
31091450	Furniture of materials other than metal, wood or plastic (excluding seats, cases and cabinets specially designed for hi-fi systems, videos and televisions)	Out

Table 7.6 Sports and leisure (PRODCOM)

Items a such are out but buttons and zippers shodul be lead free

PRCCODE	Description	
13922270	Pneumatic mattresses and other camping goods (excluding caravan awnings, tents, sleeping bags)	Out
13922430	Sleeping bags	Out
15121100	Saddlery and harness for any animal made from any material (including traces, leads, knee pads, muzzles, saddle cloths, saddle bags, dog coats and the like)	Out
32301131	Skis, for winter sports	Out
32301137	Ski-bindings, ski brakes and ski poles	Out
32301150	Ice skates and roller skates, including skating boots with skates attached; parts and accessories therefor	Out
32301200	Snow-ski footwear	Out
32301510	Leather sports gloves, mittens and mitts	In
32301530	Golf clubs and other golf equipment (including golf balls)	Out
32301550	Articles and equipment for table-tennis (including bats, balls and nets)	Out
32301560	Tennis, badminton or similar rackets, whether or not strung	Out
32301580	Balls (excluding golf balls, table-tennis balls, medicine balls and punch balls)	Out
32301590	Other articles and equipment for sport and open-air games, nec	Out
32301600	Fishing rods, other line fishing tackle; articles for hunting or fishing nec	Out
32404210	Articles and accessories for billiards (excluding mechanical counters, time meters and cue racks)	Out

Table 7.7 Childcare articles (PRODCOM)

PRCCODE	Description	
30924030	Baby carriages	In
30924050	Parts of baby carriages	In

Most of the child care articles are included in other subcategories, mainly as part of other statistical codes in the subcategory Interior decorations. Childcare articles may also be reported in statistics for categories not relevant for this proposal like electrical articles or articles in contact with food

Table 7.8 Keys and locks (PRODCOM)

Whole category was out of scope as it was referred to being out of scope during public consultation.

PRCCODE	Description	In scope	Mouth - able
25721130	Base metal padlocks	x	
25721350	Base metal keys presented separately (including roughly cast, forged or stamped blanks, skeleton keys)	x	
25721230	Base metal cylinder locks used for doors of buildings	x	
25721250	Base metal locks used for doors of buildings (excluding cylinder locks)	x	
25721270	Base metal locks (excluding padlocks, motor vehicle locks, furniture locks and locks used for doors of buildings)	x	

Appendix 8. Description of the calculation of lead volumes in different articles for consumer use

Depending on size and availability of the articles the weights of relevant parts on them were derived in different ways. A scale with an accuracy of 1 gram was used, except for boots where the accuracy of the scale was 0,1 kg. The descriptions below show some examples of how the workflow was in order to calculate the amount of lead in all categories of articles. Weights which are not reported in this appendix can be found in the tables in Appendix 9.

Buttons on clothes

Metallic buttons were cut from the clothes. All accessible textile parts were removed to make the buttons clean. The buttons were weighed either one by one or several together to get an as good as possible value, compensating for the lowest accuracy of the scale. The average weight of a button was determined to 2 grams. There are also plastic parts of buttons containing lead.

Buttons on small handbags, wallets etc

Metallic buttons were cut from the surrounding material. All accessible surrounding parts were removed to make the buttons clean. The buttons were weighed on the scale. The average weight of a button was determined to 1 gram.

Studs

Metallic studs were cut from the clothes. All accessible textile parts were removed to make them clean. The studs were weighed in groups of four or ten to get an as good as possible value, compensating for the lowest accuracy of the scale. The average of weight of a stud was determined to 0,5 grams.

Zippers

Metallic zippers were cut from the clothes. The textile parts of the zippers were removed as close as possible to the hooks. The zippers were weighed. The weight of a short zipper for trousers was determined to 6 grams and of longer zippers for jackets to 20 grams.

T-shirts

Plastic prints from a t-shirt is normally not possible to remove. As a proxy for a thin PVC print a piece of plastic film was weighed.

Gloves and mittens

The possible presence and weight of metal details, decorations and prints have been estimated based on knowledge of occurrence and weight of such details in other articles of clothing.

Belts

Belt buckles and belt material were weighed separated from each other on the scale.

Bags

The average number of buttons, studs and zippers on a couple of bags were counted in shops and on samples bought for testing.

Umbrella.

A handheld umbrella was weighed on the scale. The total weight was approximately 200 grams. The metal parts were estimated to weigh less than 150 grams. A small amount of plastic which represents small PVC prints has been used in this data set. It could be discussed whether all metal parts are available for mouthing or not. No account has been taken to the fact that large garden parasols, that are far more inaccessible to children, are included in this statistics group. Umbrellas for baby carriages, i.e. a child care article, are included.

Key rings

Around 20 key rings were weighed. The average weight of one key ring+ was 20 grams. By simply looking at the key rings it was concluded that 50% of them were based on polymers and 50% on metallic materials.

Pen parts

A couple of pens were disassembled and the metallic parts were weighed. The average weight of pen tops and nozzles was determined to 2 grams. One of the statistical codes included sets of pens, why the weight was multiplied by 2.

Sunglasses

Three pairs of glasses and sunglasses were weighed. They were estimated to consist of 50% polymers and50% metallic frames.

Shoes

Both weighing and looking at material declarations for shoes on the internet determined the total weight of one shoe to be 200 grams. Around 20% of the sole was considered to fulfil the definition of a mouthable piece.

Boots

Vinyl boots have been used as a representative for this group as they are expected to contain the highest volumes of PVC, and thus the highest volumes of lead, in the group. A pair of vinyl boots, adult size, was weighed on a scale. Their weight was determined to 2,0 kg. The outer plastic layer accounted for almost 50% of the total material volume. 5-10% of the coating was estimated to fulfil the definitions "mouthable" and accessible. 2000 grams *0,5*0,1 = 100 gram of plastic material with a possible lead content.

Baby carriages

The total weight of chassis and seats was estimated from product information for baby carriages on internet sites.

Frames

It is estimated that 95%, corresponding to the the largest items, hang on the wall and are not available for mouthing. Smaller items can be placed on a shelf or table etc, and are available for gripping and mouthing by children.

Decorations, globes

The articles in this group may to a great extent be electrical articles. If there are non-electric articles in this group, metal fittings may be used in some parts of the article. A guess is that 50 grams can be used as a high estimate. This group is not large enough to provide a significant contribution to the total volume.

Statuettes and ornamental articles in metal or plastics

It is somewhat unclear to the DS exactly what kind of articles that are included in the statistical data in Prodcom for these groups. Both small and big items can be expected. Artificial flowers and fruits are included in another group and were not accounted for here. An average weight of 100 gram per item have been chosen, with the view that most items are even smaller e.g. souvenirs and other small decorative items.

Statuettes and ornamental articles in ceramics and porcelain

A small volume is estimated to represent a possible content of lead pigments. In is unlikely that lead is widely used. This group is not large enough to provide a significant contribution to the total volume of lead.

Household and toilet articles

Not included in the exposure assessment, but could contain child care articles for hygienic purposes. No value of weight given due to no expected lead content.

Entertainment articles

This group is expected to include a variety of quite small articles of varying materials. A mix of materials at a relatively low weight has been estimated to represent various materials.

Artificial flowers

A small bouquet of artificial flowers was weighed on the scale. As both large and small items can be expected to occur in this group, the value from the scale was multiplied by a factor of 10.

Christmas trees and Christmas decorations

The maximum share of artificial Christmas trees was assumed to be 15 % of this group. The market for Christmas tree in Europe is approximately 60 million trees a year. The figure is based on the following input data: 200 million households in EU. 50% use an artificial Christmas tree. The service life of the tree is 6 years.
Sources: http://www.pickyourownchristmastree.org/facts.php
http://www.ellipsos.ca/site_files/File/Christmas%20Tree%20LCA%20-%20ellipsos.pdf

Furniture

Total weights and weights of specific parts have been taken from information on shipping weights from internet stores. Legs on upholstered seats (sofas) were regarded as exceeding the size of 5 cm in the definition of an article that could be mouthed by children, and thus regarded as not accessible to children for mouthing.. The weight of surface covering materials (textile, artificial leather, leather) was determined by estimating an area weight of 200 g/m2, and by measuring the area on a normal article that fulfils the dimension limits for an article that could be mouthed by children. The articles in categories for upholstered seats was assumed to consist of 50% sofas and 50% chairs.

Pneumatic matresses

Weights were taken from shipping weights from internet stores . Average weights were determined to 4 kg per item. 50% of the material in a pneumatic mattress is expected to be PVC and 50% to be textile.

Golf clubs

The weight of a golf club is around 1,5 kg. Clubs, balls and other items are mixed in this group. Balls and pegs are expected to be sold in packages with more than one piece each. The share of purchased clubs vs other items are estimated to be 1:9 of the total number of pieces for this statistical code.

Other articles for sports and leisure

Weights of different materials that could be of relevance for the restriction have been estimated based on personal experience on the design and dimensions of articles for different uses.

Saddlery and harnesses

Weights were estimated from personal experiences of articles used for horses. The group contains for example also dog and cat collars. Articles designed for smaller animals than horses were, due to misunderstanding of which articles that belong to the product category, not taken into account.

Keys

About 20 house keys were weighed on the scale. The average weight of one key was determined to 15 grams.

Appendix 9. Input data for the calculation of lead volumes in selected articles for consumer use

Below is a list of input data used in the calculation of total market volumes of lead in articles covered by the restriction proposal. A description of article specific details is available in Appendix 8.

The articles in the tables are not always named exactly as in the statistical codes. Each data set may be used for estimation of the lead volume of more than one statistical code.

In the statistical database clothes for adults and children are reported separately. Unless otherwise stated, the clothing categories are estimated for adult sizes.

In the estimations below, there is not a clear distinction between pigments and stabilisers in plastic materials. Both columns are used to indicate a lead volume, but without counting the samba amount twice. The indicator print is for example used to get all volumes of stabilisers, unless they are expected to occur as real prints or in other parts of the articles.

Trousers, Jeans, Adult & Children				**Total weights, gram**		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button	Metal	2	1	2	0	0
Zipper, short	Metal	6	1	6	0	0
Studs	Metal	0,5	4	2	0	0
Total				**10**	**0**	**0**

Jackets				**Total weights, gram**		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button	Metal	2	5	10	0	0
Zipper, Long jacket	Metal	20	1	20	0	0
Studs	Metal	0,5	2	1	0	0
Decorations, reflective materials	Plastic	2	4	0	8	0
Total				**31**	**8**	**0**

Suits, blazers

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button *	Metal	1	2	2	0	0
Total				**2**	**0**	**0**

*) Buttons are more often made from hard plastic materials. This is handled by underestimation of the number of buttons per item.

Shirts, blouses

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button *	Metal	1	1	1	0	0
Total				**1**	**0**	**0**

*) Buttons are more often made from hard plastic materials. This is handled by underestimation of the number of buttons per item.

Dresses, Skirts

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button	Metal	2	1	2	0	0
Zipper, short	Metal	6	1	6	0	0
Total				**8**	**0**	**0**

Pyjamas, nightshirts, jumpers etc

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button	Metal	2	1	2	0	0
Plastic prints	Print	6	1	0	0	6
Total				**2**	**0**	**6**

Jogging dresses

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Zipper, short	Metal	6	1	6	0	0
Studs	Metal	0,5	4	2	0	0
Plastic prints	Print	2	2	0	0	4
Total				**8**	**0**	**4**

Pullovers, sweatshirts

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button	Metal	2	1	2	0	0
Zipper, short	Metal	6	0,25	1,5	0	0
Plastic prints	Print	6	0,25	0	0	1,5
Total				**1,5**	**0**	**1,5**

Zippers and prints are not expected to occur on every item. This is handled by lowering of the number of articles per item.

Clothes for babies (for children of height <= 86 cm)

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal details	Metal	1	1	1	0	0
Plastic decorations	Plastic	1	1	0	1	0
Plastic prints	Print	1	1	0	0	1
Total				**1**	**1**	**1**

Most clothes in this category have few or none additional details. The weights are added to avoid a total zero report in this row.

Gloves and mittens

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal details	Metal	2	1	2	0	0
Plastic decorations	Plastic	1	1	0	1	0
Plastic prints	Print	1	1	0	0	1
Total				**2**	**1**	**1**

Metal details, decorations and prints are not expected to occur on every item. Thus the values are expected to be overestimated. Gloves and mittens are always reported as a pair.

T-shirts

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Plastic prints	Print	3	1	0	0	3
Total				**0**	**0**	**3**

Belts

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Buckle	Metal	10	1	10	0	0
Studs	Metal	0,5	2	1	0	0
Belt material	Plastic	10	1	0	10	0
Total				**11**	**10**	**0**

Key rings, Spectacles

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Key rings	Metal	20	0,5	10	0	0
Key rings	Plastic	20	0,5	0	10	0
				0	0	0
Total				**10**	**10**	**0**

Expected 50% metellic, 50% plastic

Handbags

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button	Metal	1	5	5	0	0
Zipper,	Metal	6	2	12	0	0
Studs etc	Metal	0,5	4	2	0	0
Outer material	Plastic	200	1	0	200	0
Total				**19**	**200**	**0**

Trunks, suitcases

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button	Metal	2	6	12	0	0
Buckles	Metal	30	4	120	0	0
Outer material	Plastic	500	1	0	500	0
Total				**132**	**500**	**0**

Travel sets, cases etc

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Button	Metal	1	2	2	0	0
Zipper,	Metal	6	1	6	0	0
Outer material	Plastic	20	1	0	20	0
Total				**8**	**20**	**0**

Umbrellas

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	150	1	150	0	0
Outer material	Print	1	1	0	0	1
Total				**150**	**0**	**1**

Walking sticks etc

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	30	1	30	0	0
Total				**30**	**0**	**0**

Shoes adults

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts, studs etc	Metal	1	8	8	0	0
Sole	Print	20	1	0	0	20
Outer material *	Plastic	20	1	0	20	0
Total				**8**	**20**	**20**

*) It is not meant to be prints, but merely a way to get the result in the stabiliser column

Shoes children

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts, studs etc	Metal	1	4	4	0	0
Sole	Plastic	50	1	0	50	0
Outer material	Plastic	10	1	0	10	0
Total				**4**	**60**	**0**

Shoes boots

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts, studs etc	Metal	1	8	8	0	0
Outer material	Plastic	100	1	0	100	0
Total				**8**	**100**	**0**

Wooden footwear

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts, studs etc	Metal	0,5	10	5	0	0
Outer material	Plastic	50	1	0	50	0
Total				**5**	**50**	**0**

Pens pencils

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts, studs etc	Metal	2	1	2	0	0
Total				**2**	**0**	**0**

Other stationery

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts, studs etc	Metal	50	1	50	0	0
Plastic materials, erasers	Plastic	1	1	0	1	0
Total				**50**	**1**	**0**

Erasers

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Polymeric material *	Print	2	1	0	0	2
Total				**0**	**0**	**2**

*) It is not meant to be prints, but merely a way to get the result in the stabiliser column

Baby carriages

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts, Chassi *	Metal	400	1	400	0	0
Plastic parts chassi, grip	Print**	500	1	0	0	500
Metal parts, seat	Metal	20	4	80	0	0
Plastic material covering seat***	Print**	150	1	0	0	150
Total				**480**	**0**	**650**

*) 5% of chassi weight is expected to be available to the child. Calculated from a total chassi weight of 8 kg.

**) It is not meant to be prints, but merely a way to get the result in the stabiliser column

***) 50 times the area compared with a t-shirt

Parts of Baby carriages

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts, seat	Metal	20	4	80	0	0
Plastic covering material seat *	Print	150	1	0	0	150
Total				**80**	**0**	**150**

*) 50 times the area compared with a t-shirt. It is not meant to be prints, but merely a way to get the result in the stabiliser column.

Wooden furniture, kitchen, bedroom, living room

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts for assembly	Metal	25	4	100	0	0
Varnish and paint	Plastic	30	1	0	30	0
Total				**100**	**30**	**0**

Wooden furniture, Chairs

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts for assembly	Metal	10	4	40	0	0
Varnish and paint	Plastic	30	1	0	30	0
Total				**40**	**30**	**0**

Wooden furniture, other

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts for assembly	Metal	10	4	40	0	0
Varnish and paint	Plastic	20	1	0	20	0
Total				**40**	**20**	**0**

Metal furniture

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal frames and sides	Metal	500	1	500	0	0
Varnish and paint	Plastic	5	1	0	5	0
Total				**500**	**5**	**0**

Each item is estimated to be 10 times heavier. Most metal furniture is designed for locker rooms, and not private homes.
Thus only 10% is estimated to be sold to private users, which is here handled with a lower total weight per item instead.

Plastic furniture

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Furniture material	Plastic	2000	0,5	0	1000	0
Total				**0**	**1000**	**0**

It cannot be proven how much of the articles that are used for private homes compared to public environments like cafés, restaurants and similar. 50% is estimated to be used in private homes. Articles produced in EU are not expected to contain pigments based on lead compounds. This is taken into account in the calculations of the total lead volumes in other parts of the cost assessment.

Upholstered seats with metal frames

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts on cushions (zippers)	Metal	20	6	120	0	0
Covering material	Plastic	300	1	0	300	0
Legs **	Metal	0	0	0	0	0
Varnish and paint	Plastic	0	0	0	0	0
Total				**120**	**300**	**0**

*) Not expected to be accessible (inside and under a sofa)
**) Not expected to be mouthable

Non-upholstered seats with metal frames

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Legs, Frames	Metal	160	1	160	0	0
Varnish and paint	Plastic	30	1	0	30	0
Total				**160**	**30**	**0**

*) Not expected to be accessible (inside and under a sofa)

Seats convertible into beds (excluding garden seats or camping equipment)

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts on cushions (zippers)	Metal	20	6	120	0	0
Covering material	Plastic	500	1	0	500	0
Varnish and paint	Plastic	20	1	0	20	0
Total				**120**	**520**	**0**

Seats of cane, osier, bamboo or similar materials

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Varnish and paint	Plastic	20	1	0	20	0
Total				**0**	**20**	**0**

*) Not expected to be accessible (inside and under a sofa)

Upholstered seats with wooden frames (including three piece suites) (excluding swivel seats)

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts on cushions (zippers)	Metal	20	6	120	0	0
Covering material	Plastic	300	1	0	300	0
Varnish and paint (on legs)**	Plastic	20	0	0	0	0
Total				**120**	**300**	**0**

Non-upholstered seats with wooden frames (excluding swivel seats)

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Varnish and paint	Plastic	20	5	0	100	0
Total				**0**	**100**	**0**

Other seats

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts for assembly	Metal	30	1	30	0	0
Possible covering material, varnish and paint	Plastic	30	1	0	30	0
Total				**30**	**30**	**0**

Globes

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	50	1	50	0	0
Total				**50**	**0**	**0**

Christmas articles

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Plastics in Christmas trees	Print	2200	0,15	0	0	330
Metal in small decorations	Metal	10	0,85	8,5	0	0
Polymers in small decorations	Plastic	10	0,85	0	8,5	0
Total				**8,5**	**8,5**	**330**

Maximum 15 % of the articles are artificial Christmas trees

Frames for paintings, photos etc

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts for assembly, hanging etc	Metal	10	0,05	0,5	0	0
Varnish and paint	Plastic	3	0,05	0	0,15	0
Total				**0,5**	**0,15**	**0**

Metallic statuettes, frames etc

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	100	1	100	0	0
Total				**100**	**0**	**0**

Plastic statuettes, frames etc

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Plastic parts	Plastic	100	1	0	100	0
Total				**0**	**100**	**0**

Ceramic statuettes, frames etc

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Caramic parts	Plastic	5	1	0	5	0
Total				**0**	**5**	**0**

Possible pigments on the surface.

Bells, gongs etc

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	200	1	200	0	0
Total				**200**	**0**	**0**

Sleeping bags

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Zipper flaps	Metal	1	2	2	0	0
Total				**2**	**0**	**0**

Tennis racquets and similar

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Grip coverings, Other plastic details Zipper flaps	Print	30	1	0	0	30
Total				**0**	**0**	**30**

Golf clubs and other golf equipment (including golf balls)

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	750	0.,1	75	0	0
Grip coverings	Print	3	0.1	0	0	0.3
Warnish, paint on pegs	Plastic	1	0.9	0	0	0.9
Total				**75**	**0**	**1.2**

Pneumatic mattresses

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Polymer (PVC)	Print*	4000	0,5	0	0	2000
Total				**0**	**0**	**2000**

*) It is not meant to be prints, but merely a way to get the result in the stabiliser column

Saddles and harnesses

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Buckles and fastenings, several	Metal	100	1	100	0	0
Possible pigments	Plastic	5	1	0	5	0
Plastic materials	Print	5	1	0	0	5
Total				**100**	**5**	**5**

Ski bindings, ski poles

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	500	1	500	0	0
Total				**500**	**0**	**0**

The relevance of such articles for mouthing can be questioned. Thus probably a source for overestimation of the total lead volumes.

Ice skates, roller skates

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	700	1	700	0	0
Total				**700**	**0**	**0**

The relevance of such articles for mouthing can be questioned. Thus probably a source for overestimation of the total lead volumes.

Articles for table tennis

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	50	1	50	0	0
Linding on handles	Print	1	1	0	0	1
Total				**50**	**0**	**1**

Other articles and equipment for sport and open-air games

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts	Metal	50	1	50	0	0
Colored parts	Plastic	1	1	0	1	0
Grip coverings	Print	1	1	0	0	1
Total				**50**	**1**	**1**

Articles for billiard				**Total weights, gram**		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Metal parts e.g. on ques	Metal	20	1	20	0	0
Linding on handles	Print	1	1	0	0	1
Total				**20**	**0**	**1**

Balls (excluding golf balls, table-tennis balls, medicine balls and punch balls)

				Total weights, gram		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Plastic materials	Print	100	1	0	0	100
Total				**0**	**0**	**100**

Keys				**Total weights, gram**		
Articles	**Material**	**Weight per piece, gram**	**No of pieces**	**Metal**	**Pigments**	**Stabilisers**
Keys	Metal	15	1	15	0	0
Total				**15**	**0**	**0**

Appendix 10. Classification of a selection of lead compounds

Several lead compounds are classified in Annex VI to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Dangerous Substances and Mixtures. Lead compounds that are not specified elsewhere have an aggregate classification entry. One can notice that elemental lead is not classified.

Table A10.1: Classification of lead compounds according to Regulation (EC) No 272/2008 Annex VI Table 3.1

Identification	EC number	CAS number	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
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 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
Silicic acid, lead nickel salt	-	68130-19-8	Carc. 1A Repr. 1A STOT RE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H360Df H372** H317 H400 H410

Identification	**EC number**	**CAS number**	**Classification**	
			Hazard Class and Category Code(s)	**Hazard statement Code(s)**
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

Identification	**EC number**	**CAS number**	**Classification**	
			Hazard Class and Category Code(s)	**Hazard statement Code(s)**
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

Identification	EC number	CAS number	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
Lead(II) methanesulphonate	401-750-5	17570-76-2	Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Skin Irrit. 2 Eye Dam. 1	H360-Df H332 H302 H373** H315 H318
Lead sulfochromate yellow; C.I. Pigment Yellow 34; [This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77603.]	215-693-7	1344-37-2	Carc. 1B Repr. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H350 H360-Df H373** H400 H410
Lead chromate molybdate sulfate red; C.I. Pigment Red 104; [This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77605.]	235-759-9	12656-85-8	Carc. 1B Repr. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H350 H360-Df H373** H400 H410

Identification	**EC number**	**CAS number**	**Classification**	
			Hazard Class and Category Code(s)	**Hazard statement Code(s)**
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
Barium calcium cesium lead samarium strontium bromide chloride fluoride iodide europium doped	431-780-4	199876-46-5	Acute Tox. 4 * STOT RE 2 * Aquatic Chronic 2	H302 H373** H411
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

Identification	**EC number**	**CAS number**	**Classification**	
			Hazard Class and Category Code(s)	**Hazard statement Code(s)**
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

Appendix 11. Availability of alternatives

Tonnage data from REACH registrations at ECHA

Metals and metal additives

Compound	**Cas number**	**EC number**	**Tonnage band** (tonnes per annum)
Lead (for comparison)	7439-92-1	231-100-4	1,000,000 - 10,000,000
Copper	7440-50-8	231-159-6	1,000,000 - 10,000,000
Zinc	7440-66-6	231-175-3	1,000,000 - 10,000,000
Iron	7439-89-6	231-096-4	100,000,000 +
Tin	7440-31-5	231-141-8	10,000 +
Bismuth	7440-69-9	231-177-4	1,000 - 10,000
Silicon	7440-21-3	231-130-8	1,000,000 +

Pigments

Compound	**Cas number**	**EC number**	**Tonnage band** (tonnes per annum)
Red pigments (examples, common substances)			
C.I. Pigment Red 2 4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-phenylnaphthalene-2-carboxamide	6041-94-7	227-930-1	Preregistered
C.I. Pigment Red 4 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol	2814-77-9	220-562-2	Preregistered
C.I. Pigment Red 53 barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]	5160-02-1	225-935-3	Preregistered
C.I. Pigment Red 57 calcium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate	5281-04-9	226-109-5	10,000 - 100,000
C.I. Pigment Red 122 5,12-dihydro-2,9-dimethylquino[2,3-b]acridine-7,14-dione	980-26-7	213-561-3	1,000 - 10,000

Compound	**Cas number**	**EC number**	**Tonnage band** (tonnes per annum)
Yellow pigments (examples, common substances)			
C.I. Pigment Yellow 12 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[3-oxo-N-phenylbutyramide]	6358-85-6	228-787-8	10,000 - 100,000
C.I. Pigment Yellow 17 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methoxyphenyl)-3-oxobutyramide]	4531-49-1	224-867-1	100 - 1,000
C.I. Pigment Yellow 73 2-[(4-chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	13515-40-7	236-852-7	Preregistered
C.I. Pigment Yellow 74 2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	6358-31-2	228-768-4	1,000 - 10,000
C.I. Pigment Yellow 184 bismuth vanadium tetraoxide	14059-33-7	237-898-0	1,000 - 10,000
White pigments (examples, common substances)			
Calcium carbonate	471-34-1	207-439-9	1,000,000 - 10,000,000
Zinc oxide	1314-13-2	215-222-5	100,000 - 1,000,000
Titanium dioxide	13463-67-7	236-675-5	1,000,000 - 10,000,000

Stabilizers in PVC (examples)

Compound	**Cas number**	**EC number**	**Tonnage band** (tonnes per annum)
Fatty acids, C14-18 and C16-18-unsatd., zinc salts	67701-12-6	266-936-9	1,000 - 10,000
Fatty acids, C16-18, zinc salts	91051-01-3	293-049-4	10,000 - 100,000
Calcium acetylacetonate	19372-44-2	243-001-3	Preregistered
Calcium stabilization systems, calcium carboxylates			No registrations. The substances are probably registered or pre-registered under other names and CAS no.

Appendix 12. Human health and environmental hazards of the alternatives

When lead is substituted, it is important that the substitutes are less toxic and have a better hazard profile than the original lead or lead compounds. . In the following sections, the classifications of the alternatives are shown next to the classification of lead and lead compounds. This is to clearly illustrate the superior health and environmental hazard profiles of the alternatives compared to lead and its compounds. The current classifications were obtained from ECHA's C&L Inventory Database.

When classification data is lacking it cannot be regarded that the substance is non-hazardous. That a substance is not classified may be due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification.

Table 12.1: Summary of harmonised or non-harmonised classification (as notified by a majority of manufacturers and importers) of human health hazards for lead based compounds and their alternatives

Substance	**Cas number**	**Classification**		**Notes**
		Hazard Class and Category Codes	**Hazard statement Codes**	**Harmonized or non-harmonized classification**
Lead	7439-92-1	Acute Tox. 4 Acute Tox. 4 Repr. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H360-Df H373 H400 H410	Non-harmonized classification Specific concentration limits: STOT RE 2: C ≥ 0,5% Repr. 2: C ≥ 2.5% Classification according to 292 notifiers. Not classified by 217 notifiers.*

Substance	**Cas number**	**Classification**		**Notes**
		Hazard Class and Category Codes	**Hazard statement Codes**	**Harmonized or non-harmonized classification**
Lead compounds with the exception of those specified elsewhere in the CLP regulation		Repr. 1A Acute Tox. 4 Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H360-Df H302 H332 H373 H400 H410	Harmonized classification
Tin	7440-31-5	STOT SE 3 Eye irrit. 2	H335 H319	Non-harmonized classification Classification according to 23 notifiers. Not classified by 304 notifiers.*
Iron	7439-89-6	STOT SE 3 Eye irrit. 2	H335 H319	Non-harmonized classification Classification according to 40 notifiers. Not classified by 1156 notifiers.*
Zinc	7440-66-6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	Harmonized classification.
Bismuth	7440-69-9	Aquatic chronic 4	H413	Non-harmonized classification Classification according to 15 notifiers. Not classified by 166 notifiers.*

Substance	**Cas number**	**Classification**		**Notes**
		Hazard Class and Category Codes	**Hazard statement Codes**	**Harmonized or non-harmonized classification**
Copper	7440-50-8	Acute Tox. Acute Tox. 2 STOT SE 3 STOT RE 1 Eye irrit. 2 Aquatic Acute 1 Aquatic chronic 1	3 H301 H330 H335 H372 H319 H400 H410	Non-harmonized classification Classification according to 273+ 51 notifiers. Not classified by 1303 notifiers.*
Silica	7440-21-3			Non-harmonized classification Not classified by 1737 notifiers.*
Concrete	e.g. 65997-15-1	Skin Irrit. 2 Skin Sens. 1 Eye Dam. 1 STOT SE 3	H315 H317 H318 H335	Non-harmonized classification Classification according to 127 notifiers. Other classifications by 391 notifiers.*
C.I. Pigment Red 53	5160-02-1	Acute Tox. 4 Acute Tox. 4	H302 H332	Non-harmonized classification Classification according to 36 notifiers. Not classified by 379 notifiers.*

Substance	Cas number	Classification		Notes
		Hazard Class and Category Codes	Hazard statement Codes	Harmonized or non-harmonized classification
C.I. Pigment Red 57	5281-04-9	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Aquatic Chronic 3	H319 H335 H315 H412	Non harmonized classification Classification according to 23 (health) + 34 (environment) notifiers. Not classified by 545 notifiers.*
C.I. Pigment Red 4	2814-77-9			Not classified by 371 notifiers.*
C.I. Pigment Red 122	980-26-7	Eye Irrit. 2 Aquatic Chronic 3	H319 H412	Non harmonized classification Classification according to 27 (health) + 86 (environment) notifiers. Not classified by 639 notifiers.*
C.I. Pigment 2	6041-94-7			Not classified by 297 notifiers.*
C.I. Pigment Yellow 73	13515-40-7			Not classified by 50 notifiers.*
C.I. Pigment Yellow 184	14059-33-7	STOT RE 2	H373	Non harmonized classification Classification according to 1004 notifiers. Not classified by 161 notifiers.*

Substance	**Cas number**	**Classification**		**Notes**
		Hazard Class and Category Codes	**Hazard statement Codes**	**Harmonized or non-harmonized classification**
C.I. Pigment Yellow 12	6358-85-6			Not classified by 392 notifiers.*
C.I. Pigment Yellow 74	6358-31-2	Eye Irrit. 2 Skin Irrit. 2	H319 H315	Non harmonized classification Classification according to 62 notifiers. Not classified by 599 notifiers.*
C.I. Pigment Yellow 17	4531-49-1			Not classified by 276 notifiers.*
Zinc oxide	1314-13-2	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	Harmonized classification
Titanium dioxide	13463-67-7	Acute Tox. 4 Carc. 2	H332 H351	Non harmonized classification Classification according to 42 notifiers. Not classified by 2434 notifiers.*
Calcium carbonate	471-34-1	Eye Irrit. 2 Skin Irrit. 2	H319 H315	Non harmonized classification Classification according to 131 notifiers. Not classified by 1770 notifiers.*

* This may be due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification.

Alternatives to lead based stabilisers

To identify the substances used as substitutes for lead stabilizers is difficult which has resulted in uncertainty regarding the hazard profiles of these alternatives. With regards to the Green Paper on “Environmental issues of PVC”, Calcium-zinc compounds have a more favourable risk/hazard profile compared to lead and cadmium compounds, and are currently not classified as hazardous (EC 2000).

Appendix 13. Lead free red and yellow pigments searched for in the Swedish Products Register

Possible alternatives to lead containing pigments were searched for in the Swedish Products Register. The register contains information on chemical products (mixtures) manufactured, imported or brought in to Sweden, if the quantity of a product is 100 kg or more per year.

The screening in the register was done by first sorting out red and yellow pigments by their name, i.e. substances having a synonym containing the fragment “pigment red” or “pigment yellow”, from the register’s database of substance names. From these the lead-, cadmium-, mercury- and arsenic containing names were removed. The remaining substance names (listed below) were then screened for in the registered chemical compositions of products (mixtures) reported to have a function as **coloring agent** (including pigments to glazing materials, enamels and glass, pigments to paint and printing inks, pigment pastes, regenerator to colours and colouring agents, other), **raw materials for production of rubber products**, **raw materials for production of plastics**, **printing inks** and “**paints and varnishes”**. The quantities of the substances were monitored in order to select high volume substances (2010) for the assessment.

The list presented in section C3.1 is not meant to be a complete list of possible lead free pigments, but shows that several lead free red and yellow pigments are being used. There could thus be more lead free pigments available than the ones found in the Swedish Products Register. Substances not having a synonym fragment “pigment”, or substances that the Swedish chemicals agency not yet have registered in their database are for example not included.

Name fragments giving substances searched for in in the Swedish Products Register

A name may have several cas numbers, or several names may have the same cas number. The cas numbers are not shown due to possible trade secrets.

Table A13.1: Name fragment *Pigment red*

C.I. Pigment Red 1
C.I. Pigment Red 10
C.I. Pigment Red 101
C.I. Pigment Red 102
C.I. Pigment Red 107
C.I. Pigment Red 109
C.I. Pigment Red 11
C.I. Pigment Red 112
C.I. Pigment Red 114
C.I. Pigment Red 115

C.I. Pigment Red 119
C.I. Pigment Red 12
C.I. Pigment Red 120
C.I. Pigment Red 122
C.I. Pigment Red 123
C.I. Pigment Red 13
C.I. Pigment Red 14
C.I. Pigment Red 144
C.I. Pigment Red 146
C.I. Pigment Red 147
C.I. Pigment Red 148
C.I. Pigment Red 149
C.I. Pigment Red 15
C.I. Pigment Red 150
C.I. Pigment Red 151
C.I. Pigment Red 16
C.I. Pigment Red 166
C.I. Pigment Red 168
C.I. Pigment Red 169
C.I. Pigment Red 17
C.I. Pigment Red 170
C.I. Pigment Red 171
C.I. Pigment Red 172
C.I. Pigment Red 173
C.I. Pigment Red 174
C.I. Pigment Red 175
C.I. Pigment Red 176
C.I. Pigment Red 177

C.I. Pigment Red 178
C.I. Pigment Red 179
C.I. Pigment Red 18
C.I. Pigment Red 181
C.I. Pigment Red 183
C.I. Pigment Red 184
C.I. Pigment Red 185
C.I. Pigment Red 187
C.I. Pigment Red 188
C.I. Pigment Red 189
C.I. Pigment Red 19
C.I. Pigment Red 190
C.I. Pigment Red 191
C.I. Pigment Red 193
C.I. Pigment Red 194
C.I. Pigment Red 195
C.I. Pigment Red 196
C.I. Pigment Red 2
C.I. Pigment Red 200
C.I. Pigment Red 200, strontium salt
C.I. Pigment Red 202
C.I. Pigment Red 206, part of
C.I. Pigment Red 207, part of
C.I. Pigment Red 208
C.I. Pigment Red 209
C.I. Pigment Red 21
C.I. Pigment Red 210
C.I. Pigment Red 210, part of

C.I. Pigment Red 212
C.I. Pigment Red 214
C.I. Pigment Red 216
C.I. Pigment Red 22
C.I. Pigment Red 220
C.I. Pigment Red 221
C.I. Pigment Red 224
C.I. Pigment Red 226
C.I. Pigment Red 229
C.I. Pigment Red 23
C.I. Pigment Red 230
C.I. Pigment Red 231
C.I. Pigment Red 232
C.I. Pigment Red 233
C.I. Pigment Red 235
C.I. Pigment Red 236
C.I. Pigment Red 242
C.I. Pigment Red 243
C.I. Pigment Red 245
C.I. Pigment Red 247
C.I. Pigment Red 251
C.I. Pigment Red 252
C.I. Pigment Red 253
C.I. Pigment Red 254
C.I. Pigment Red 255
C.I. Pigment Red 258
C.I. Pigment Red 260
C.I. Pigment Red 261

C.I. Pigment Red 264
C.I. Pigment Red 266
C.I. Pigment Red 268
C.I. Pigment Red 269
C.I. Pigment Red 271
C.I. Pigment Red 3
C.I. Pigment Red 31
C.I. Pigment Red 32
C.I. Pigment Red 37
C.I. Pigment Red 38
C.I. Pigment Red 4
C.I. Pigment Red 40
C.I. Pigment Red 41
C.I. Pigment Red 42
C.I. Pigment Red 48
C.I. Pigment Red 48, barium salt (1:1)
C.I. Pigment Red 48, calcium salt
C.I. Pigment Red 48, disodium salt
C.I. Pigment Red 48, manganese complexes
C.I. Pigment Red 48, strontium salt (1:1)
C.I. Pigment Red 48:1
C.I. Pigment Red 48:2
C.I. Pigment Red 48:3
C.I. Pigment Red 48:4
C.I. Pigment Red 49
C.I. Pigment Red 49, metal salts
C.I. Pigment Red 49, barium salt
C.I. Pigment Red 49, barium salt (2:1)

C.I. Pigment Red 49, calcium salt (2:1)
C.I. Pigment Red 49, sodium salt
C.I. Pigment Red 49, strontium salt (2:1)
C.I. Pigment Red 49:1
C.I. Pigment Red 49:2
C.I. Pigment Red 49:3
C.I. Pigment Red 5
C.I. Pigment Red 50:1
C.I. Pigment Red 51, barium salt (2:1)
C.I. Pigment Red 52
C.I. Pigment Red 52, barium salt (1:1)
C.I. Pigment Red 52, calcium salt (1:1)
C.I. Pigment Red 52, strontium salt
C.I. Pigment Red 52:1
C.I. Pigment Red 52:2
C.I. Pigment Red 53
C.I. Pigment Red 53, barium salt
C.I. Pigment Red 53:1
C.I. Pigment Red 53:2
C.I. Pigment Red 53:3
C.I. Pigment Red 54
C.I. Pigment Red 54, calcium salt
C.I. Pigment Red 57
C.I. Pigment Red 57, barium salt (1:1)
C.I. Pigment Red 57, calcium salt (1:1)
C.I. Pigment Red 57, calcium strontium salt
C.I. Pigment Red 57, disodium salt
C.I. Pigment Red 57:1

C.I. Pigment Red 58
C.I. Pigment Red 58, calcium salt (1:1)
C.I. Pigment Red 58, strontium salt (1:1)
C.I. Pigment Red 58:1
C.I. Pigment Red 58:2
C.I. Pigment Red 58:4
C.I. Pigment Red 6
C.I. Pigment Red 60
C.I. Pigment Red 60, barium salt (2:3)
C.I. Pigment Red 62
C.I. Pigment Red 63
C.I. Pigment Red 63, metal salts
C.I. Pigment Red 63, calcium salt (1:1)
C.I. Pigment Red 63:1
C.I. Pigment Red 63:2
C.I. Pigment Red 64, calcium salt (2:1)
C.I. Pigment Red 64:1
C.I. Pigment Red 66
C.I. Pigment Red 67
C.I. Pigment Red 68
C.I. Pigment Red 68, calcium sodium salt (2:1:2)
C.I. Pigment Red 69
C.I. Pigment Red 7
C.I. Pigment Red 8
C.I. Pigment Red 81
C.I. Pigment Red 81:1
C.I. Pigment Red 81:2
C.I. Pigment Red 82

C.I. Pigment Red 83
C.I. Pigment Red 88
C.I. Pigment Red 89
C.I. Pigment Red 9
C.I. Pigment Red 90, Al salt
C.I. Pigment Red 90:1
C.I. Pigment Red 95

Table A13.2: Name fragment *Pigment yellow*

C.I. Pigment Yellow 1
C.I. Pigment Yellow 10
C.I. Pigment Yellow 100
C.I. Pigment Yellow 101
C.I. Pigment Yellow 104
C.I. Pigment Yellow 108
C.I. Pigment Yellow 109
C.I. Pigment Yellow 110
C.I. Pigment Yellow 111
C.I. Pigment Yellow 113
C.I. Pigment Yellow 115
C.I. Pigment Yellow 116
C.I. Pigment Yellow 117
C.I. Pigment Yellow 119
C.I. Pigment Yellow 12
C.I. Pigment Yellow 120
C.I. Pigment Yellow 123
C.I. Pigment Yellow 124
C.I. Pigment Yellow 126

C.I. Pigment Yellow 127
C.I. Pigment Yellow 128
C.I. Pigment Yellow 129
C.I. Pigment Yellow 13
C.I. Pigment Yellow 137
C.I. Pigment Yellow 138
C.I. Pigment Yellow 139
C.I. Pigment Yellow 14
C.I. Pigment Yellow 147
C.I. Pigment Yellow 148
C.I. Pigment Yellow 15
C.I. Pigment Yellow 150
C.I. Pigment Yellow 151
C.I. Pigment Yellow 152
C.I. Pigment Yellow 153
C.I. Pigment Yellow 154
C.I. Pigment Yellow 155
C.I. Pigment Yellow 157
C.I. Pigment Yellow 158
C.I. Pigment Yellow 159
C.I. Pigment Yellow 16
C.I. Pigment Yellow 160
C.I. Pigment Yellow 161
C.I. Pigment Yellow 162
C.I. Pigment Yellow 163
C.I. Pigment Yellow 164
C.I. Pigment Yellow 168
C.I. Pigment Yellow 169

C.I. Pigment Yellow 17
C.I. Pigment Yellow 170
C.I. Pigment Yellow 171
C.I. Pigment Yellow 174
C.I. Pigment Yellow 175
C.I. Pigment Yellow 176
C.I. Pigment Yellow 177
C.I. Pigment Yellow 179
C.I. Pigment Yellow 18
C.I. Pigment Yellow 18 (fugitive), benzoate
C.I. Pigment Yellow 18, phosphotungstate
C.I. Pigment Yellow 18, tannic acid salt
C.I. Pigment Yellow 180
C.I. Pigment Yellow 181
C.I. Pigment Yellow 182
C.I. Pigment Yellow 183
C.I. Pigment Yellow 184
C.I. Pigment Yellow 185
C.I. Pigment Yellow 188
C.I. Pigment Yellow 191
C.I. Pigment Yellow 192
C.I. Pigment Yellow 194
C.I. Pigment Yellow 2
C.I. Pigment Yellow 213
C.I. Pigment Yellow 24
C.I. Pigment Yellow 3
C.I. Pigment Yellow 31
C.I. Pigment Yellow 32

C.I. Pigment Yellow 33
C.I. Pigment Yellow 36
C.I. Pigment Yellow 36:1
C.I. Pigment Yellow 38
C.I. Pigment Yellow 4
C.I. Pigment Yellow 40
C.I. Pigment Yellow 42
C.I. Pigment Yellow 43
C.I. Pigment Yellow 49
C.I. Pigment Yellow 5
C.I. Pigment Yellow 53
C.I. Pigment Yellow 55
C.I. Pigment Yellow 57
C.I. Pigment Yellow 6
C.I. Pigment Yellow 60
C.I. Pigment Yellow 61
C.I. Pigment Yellow 61:1
C.I. Pigment Yellow 62
C.I. Pigment Yellow 62:1
C.I. Pigment Yellow 63
C.I. Pigment Yellow 65
C.I. Pigment Yellow 7
C.I. Pigment Yellow 73
C.I. Pigment Yellow 74
C.I. Pigment Yellow 75
C.I. Pigment Yellow 77
C.I. Pigment Yellow 81
C.I. Pigment Yellow 83

C.I. Pigment Yellow 87
C.I. Pigment Yellow 9
C.I. Pigment Yellow 93
C.I. Pigment Yellow 94
C.I. Pigment Yellow 95
C.I. Pigment Yellow 97
C.I. Pigment Yellow 98

Appendix 14. List of contacted stakeholders

This list contains stakeholders that have been contacted for consultation and organisations that have contacted the Swedish CA due to the consultation. In addition, MSCA's, ECHA and the European Commission have been noticed.

AB Lindex

ABUS Scandinavia AB

ALS Scandinavia AB

ARGE; Svenskt sekr: FLB

ASSA Abloy AB

BEUC; Bureau Europeen des Unions Consommateurs

BicWorld

BMW Group

Brinell Centre at KTH Royal Institute of Technology

Businesseurope

CEA-PME; European Confederation of Small and Medium-sized Enterprises

CEFIC; The European Chemical Industry Council

CEH; Center for Environmental Health

CEPE; European Council of the Paint and printing ink and artists colours

COFACE; Confederation of family organisations in the European Union

Comercial Del Sur de Papelera S.L.

Consumers International

Daniel Swarovski Corporation AG

Didriksons AB

Ecolabel scheme, general environmental NGO representation in criteria development:

EEB European Environmental Bureau

EFR c/o BIR; European Ferrous Recovery & Recycling Federation

Epson Europe B.V.

ETUC European Trade Union Confederation

EU Ecolabel

EuPC; European Plastic Converters

Euratex; The European Apparel and Textile Confederation

Eurocommerce

Eurofins Environment Testing Sweden AB

Eurometaux European Association of Metals

Eurometrec c/o BIR; European Metal trade and recycling federation

European Copper Institute

The European Council of Vinyl Manufacturers (ECVM)

European Plastics Converters

Faber Castell International

FEAD; European Federation of Waste Management and environmental services

FECC; The European Association of Chemical Distributors

Fédération des Cristalleries et Verreries

SWESEC, Svenska Säkerhetsföretag

Friends of the Earth

FTA; Foreign Trade Association

Gina Tricot AB

Greenpeace, European Unit

H&M

Herlitz PBS AG

Honda Motor Europe Ltd

ICF/EDG Technical Working Group

IKEA Group

ILA; International Lead association

ILZRO; International lead zinc research organization inc

ILZSG; International Lead and Zink study group

INDISKA Magasinet AB

Inditex Group

Ineos Group Ltd

Intertek Group plc.

IPEN; The International POPs Elimination Network

Jegrelius - institutet för tillämpad Grön kemi

Karolinska Institutet

Karstadt

Konsumentverket Swedish Consumer Agency

KTH Royal Institute of Technology

Lindex Sverige AB

Lund University

Lyra-Bleistift-Fabrik GmbH & Co. KG

NimkarTek Technical Services Pvt Ltd

Grupo ACCS

Öko-tex Association

Orgalime; The European Engineering Industries Association

Pb Reach Consortium Manager

Pentel Europe

Pilot Pen Sverige AB

Plast- & Kemiföretagen

Polarn och Pyret, RNB Retail and Brands

PVC Europa

Råd och rön

Skultuna

SP Technical Research Institute of Sweden

Spofa Spöfiske

Stabilo International GmbH

Staedtler Mars GmbH & Co. KG

Swedish Agency for Economic and Regional Growth - Tillväxtverket

Swedish Consumer Agency

Swedish Consumers' Association

Swedish Environmental Protection Agency

Swedish Society for Nature Conservation (SSNC)

Swedish Trade Federation

Swerea AB

Testfakta

Textil & Läderlaboratoriet

The Swedish Plastics and Chemicals Federation

Trelleborg AB

TÜV SÜD Hong Kong

University of Gothenburg

VCI; Verband der Chemischen Industrie e.V.

Verband TEGEWA

VinylPlus / The European Council of Vinyl Manufacturers (ECVM)

WWF; World Wildlife Fund

YKK Fastening Products Group

Appendix 15. Summary of answers from stakeholders

The stakeholder consultation was focused on companies, NGOs, trade organizations, member states, etc. at the EU-level.

Contact was made by questionnaires, which were distributed to many actors at a time, as well as targeted telephone calls and e-mails. Furthermore, stakeholder meetings have been held at KemI.

Below a summary of the stakeholder consultation can be found.

Organisation	Description	Summary
Companies		
Didriksons	Apparel	The company buys the entire garment, that is, zippers and buttons are not purchased individually. Therefore, the company has to rely on their suppliers. The environmental work is performed via a dialogue with the suppliers, in which the company states which requirements that the suppliers must fulfill. The company has compiled a list of chemicals which should not be present in the products, and which the suppliers must comply with. Lead is included in this list. The company finds that it is hard to guarantee that a product is completely lead-free as mistakes can be made. The company thinks that it is important to know what goes in the product to begin with, as it is much more expensive to investigate the constituents afterwards. Testing is performed on a spot-check basis. Suppliers must provide test reports from laboratories with accreditation. The company has an office in China, where most garments are produced, from where the producing factories are monitored.
H&M	Multinational company, apparel	The company sets the chemical requirements for their products based on the most stringent requirements in the countries where the company is active. All requirements regarding procurement can be seen on the company's homepage. Testing of the products is performed by third party laboratories. A restriction of lead in consumer products will not affect the company, since stringent requirements regarding lead content in the

		products are already in place.
RNB Retail and Brands	Apparel	The company states that there are lead free alternatives (e.g. buttons/zippers) available on the market, but that these are more expensive. The company performs tests on chemicals, including metals, on a certain part of all orders in the production, as well as spot-checks in stores every 6 months. There are also requirements regarding chemical content to be followed in procurements. The company has a list of chemicals that should not be found in their products. As the company requires lead-free products, they are not aware of the price difference, compared to products/articles which are not guaranteed lead-free. Increased cost due to substitution has mainly come from an increase of the number of tests. In order to substitute lead, the company has educated and provided information for the suppliers, as well as clarified the requirements regarding lead. A restriction of lead would not affect the company itself, since they already have requirements in place. However, a restriction would clarify as well as justify the requirements for lead-free products. The reason that the company has substituted lead is based on security – since children put most things in their mouths, and there are health implications associated with lead, the company does not want lead in their products.
IKEA	Multinational company, furniture	The company has not had any trouble finding lead free materials. The suppliers are faced with requirements that must be fulfilled before a deal is closed. One of these requirements concerns lead, i.e. which concentration of lead that is considered acceptable in the products. In order to substitute lead, the company performed an analysis to ensure that it was possible to substitute lead in the materials and the production chains that the suppliers worked with. A mapping of alternative materials was also performed. The analysis showed that it was indeed possible to substitute lead. An internal plan for

		substitution was set up. The company states that the main cost of the phase-out of lead, was the conversion of the production. The cost of the raw material differs only marginally. Also, the administration of two separate stocks and the update of internal documentation, added to the cost of substitution, as well as the discard of the stock still present at the time of the deadline. The company states that they do not want lead in their products based on the intrinsic properties of the substance. Lead was originally present in the products due to the enhanced machinability. The friction between the tool and the material is decreased, which leads to a better breaking of the chips and thereby an increased life-span of the machinery.
YKK	Multinational company, zippers and buttons	The company is multinational, and is active on all continents. The products are adapted to the market to which they are sold. Due to the company's size, it is easy to put down requirements in procurements. The company adapts its requirements in line with all new regulations and certificates. The raw materials, from which the products are produced, are required to be free from lead (öko-tex certified). All materials are sampled. A restriction on lead in consumer products would lead to increased costs for the company, as all products would have to be tested once more. In case lead would be found in any product (however unlikely), the product would have to be discarded, which would lead to even more increased costs.
ASSA Abloy	Multinational company, keys and locks	According to the company, all brass contains lead, due to the production technique. Lead affects the machinability and also functions as a lubricant. The company has tried to use other materials in the production, but the function has been affected. The company states that they are now using the brass with

		the lowest lead concentration technically possible. An alternative to lead containing brass would be other techniques, not yet developed. The company cannot estimate how far ahead in the future these techniques may be. The entire lock, including the handle, is made from brass. The parts accessible for children are, however, coated. The risk that a child would be exposed to lead from the lock is therefore limited. The lock itself contains 2-3 % lead and the keys 1.5 % lead.
SEM group ASSA AB	Company that manufacture and sell keys and locks	With the present available technique and machinery for manufacturing of keys and locks and the maintenance of keys and locks in use a short transitional period would have major technical and economical impact on the manufacturers. There are available lead- free alternatives on the market but the costs for substitution are high and the performance of these locks and keys is not well known. When lead is used it is because of its cutting, corrosive and wearing qualities. Parts of locks and keys that can be manufactured without cutting don't usually contain lead (such as handles, cylinder rings). Brass with very low lead content is stiffer which results in a higher strain and wear on machinery and tools.
Skultuna	Brass	The company states that their demands on the brass they purchase from suppliers are mainly based on the shine of the brass. It also states that it is hard to purchase lead free brass. The lead function as a lubricant for the machinery.
Wieland	Copper/brass	The company states that most copper alloys contain lead, either as a functional element or as an impurity. Each alloy has a defined composition and unique characteristics, which means that there are no "lead-free" and "lead-containing" varieties of the same alloy. The most important alloy is brass, and the most important brass contains lead. The

		yearly production of leaded brass in Europe reaches ca. 800,000 tonnes. The main leaded alloys are free cutting brass with up to 3.5% lead and leaded nickel silver, which contains up to 2.5% lead. The volume of copper alloys in consumer products reaches 83,000 tonnes (2011). It is used in a great variety of applications and materials. Lead in alloys functions as a lubricant and chip breaker, which increases the machinability and gives better dimensional control. It also increases the lifetime of the cutting tools. The stakeholders states that the advantages of lead leads to lower emissions of CO2 and less use of emulsifiers and oils. Lead-free alternatives are being developed mainly for free cutting brass for use in drinking water applications. There are currently no alternatives for leaded nickel silver. Alternatives include brasses containing silicon (up to 0.1% lead) or bismuth (up to 0.25% lead). The producers state that the main problems with these alternatives include higher prices and separate scrap cycles.
Brass Specialisten	Company that manufacture, sell and repair brass instruments.	Lead was used historically for soldering of parts of brass instrument. Today lead-free solders are used. The mouthpieces for brass instruments are made of brass usually with a silver finish. Older brass instruments are still in used with mouthpieces with other finishes then silver. Other materials used for mouthpieces are plastic, and perspex. On the companies website information about plastic trombone's can also be found painted in different colors both for professional and beginner use.
Windcorp (Wind Instrument Corporation)	Company that manufacture, sell and repair wind instruments.	Brass instruments are made of brass and silver. The solder used for brazing of brass instrument is often tin. Mouthpieces for wind instruments are manufactured in rubber (ebonite), metal and wood materials. The metals used are exempt for brass silver or gold plated finish. The company is not familiar with any intended use of lead in brass instruments.

Saint-Louis	Multinational company, crystal	The company has offered information regarding the use of lead in crystal glass, possible substitution and human exposure to lead from crystal glass. The company states that its products consist of 100% full lead crystal and possibly metal parts. Lead and lead compounds are not used in metal parts. The crystal contains about 27% lead. The company states that, in order to substitute lead in crystal, exhaustive studies of composition must be carried out. It is not possible to simply substitute lead in crystal – if lead is replaced, the resulting glass is a completely new glass product. There are alternative glasses that can substitute crystal in literature. There is, however, no complete study or publication aiming to demonstrate economic feasibility covering both product and process. The company itself has tried in the past to substitute lead containing crystal with lead-free crystal without consistent results and economic evidence.
Swarovski	Multinational company, crystal, glass, accessories etc.	The company stated that the concentration limit for consumer products should be the same as for the restriction of lead in jewelry. The company further stated that the implementation time should be sufficient (minimum 12 months), that there should be a clear and limited definition for the product categories, products and materials that fall under the scope of the restriction. The company also stressed the importance of clear guidance on implementation. The company offered input on the questionnaire sent out by KemI. The company states that lead and lead compounds can be found in many parts of the articles – in base metals, surface coatings, lead crystals, plastics, textiles etc. The lead compounds used in the company's products include lead oxides and metallic lead. In the crystal glass the lead concentration can reach up to 30 %, in parts made of metal alloys, the lead concentration can reach 10 %. Regarding substitution, the company states that it for certain base metals and solder

		materials is not technically possible to substitute lead. To the company's experience, a minimization of lead to a limit of 0.05% by weight is however possible. Full lead crystal is not a preparation, but rather a substance on its own, in which lead is bound in a molecular network. It is therefore not possible to substitute lead in full lead crystal. There is however lead-free glass products, with the optical and visual properties of full lead crystal, to which no lead has been intentionally added. Lead in crystal can thus be substituted by the use of alternate glass. For metals, there are lead-free or very low-leaded (< 500 ppm) alloys. The company has actively worked to reduce or eliminate the use of lead in its products. The company monitors laws and regulations, invests research on alternative materials, adapts the production, has increased supply chain communication, works with testing in internal/external laboratories along the value chain.
Ineos Sverige AB	Plastics industry	Provided input on the history, function and former necessity of lead stabilisers, and current alternatives. Says that there are no consumer articles where lead stabilisers still are needed. No major adjustments had to be done to change from lead stabilisers to lead free.
Trelleborg Industri AB	Rubber industry	Lead stabilisers are not present in consumer articles made of chloroprene rubber.
Honda Motor Company	Multinational company, vehicles	The company provided information on lead content in different parts of motorcycles. The company is of the opinion that motorcycles should not be included in the restriction.
Trade organizations		
European Copper Institute	Trade organization	Has provided a socio economic analysis concerning copper alloy articles intended for consumer use.
Federation des cristalleries	Trade organization	The organization answered the questionnaire from KemI, offering input on the use of lead in crystal, substitution etc. According to the organization, the lead

		concentration in lead crystal glass is at least 24% lead. However, crystal is a homogenous material, made by a combination of raw materials reacting together. Lead is present in all articles made of crystal, in the form of PbO and Pb_3O_4. The production of crystal glass in France is 1200 tonnes per year. The organization states that it is not possible to substitute lead in crystal, due to the properties of lead (optical properties, workability). The organization has no experience wit h a fully satisfactory substitute for lead in crystal. There are lead-free alternatives, but these are not optimal for manual work. The organization states that lead is not available in crystal glass (or to a very smaller extent), and that crystal glass is not intended for children.
ICF	Trade organization	The organization answered the questionnaire from KemI, offering input on the use of lead in crystal, substitution etc. According to the organization, lead crystal glass is used to manufacture a wide range of articles – tableware, drinkware, lightning, jewelry etc. The crystal contains lead oxides, PbO or Pb_3O_4, and the concentration of lead is at least 24%. The organization stresses that there is no lead oxide as such present in the articles; the lead is integrated in the crystal. According to the International Lead Association, the amount of Lead Oxides used to produce Lead Crystal Glass is 3000 t /year (7% of the total market of this substance). According to the organization, there are no viable lead-free alternatives on the market today, due to the special properties of crystal glass. The organization further states that crystal is not intended for children.
International Copper Organization	Trade organization	The organization has offered input regarding the use of lead in brass, uses where lead is regarded as vital for production, as well as a mapping of the life cycle of brass. The organization also informed KemI about different brass qualities.

VCI	National trade organization	The organization states that it is not hard to find lead free products. Its members follow the öko-tex standard.
Spofa /EFTTA	Trade organizations, sport fishing	According the organizations, it is hard to substitute lead in fishing sinkers. An alternative substance could be tungsten, although a substitution would lead to increased costs. Other materials are not deemed to be able to replace lead in sinkers, due to technical reasons. The organizations further claim that sinkers, to a large part, are purchased online. Furthermore, the organizations claim that Denmark's national ban on lead in sinkers has led Danish sport fishers to purchase sinkers from Sweden and to make their own fishing sinkers at home, using scrap lead.
Test institutes/labs		
NimkarTek Technical Services Pvt Ltd	Indian lab	The company provided information regarding products that have exceeded limit values for lead. According to the company, failures have been observed in metal zippers, metal buttons, plastic buttons, certain coated fabrics, rhinestones/beads, sequins, fashion jewelry, leather belts/accessories, other miscellaneous accessories. Failure equals a lead content > 100 mg/kg. The highest content found was in a metal button which contained 4.2 % lead.
Testfakta	Test institute	The test institute provided test results for handbags and wallets.
Authorities		
Swedish Environmental Protection Agency	National Agency	The Agency provided information regarding hazardous waste, waste management and recycling of hazardous waste.
COM DG Enterprise and Industry	European Commission	COM posed questions regarding fishing sinkers and diving weights.
Institutes		
GoArt – Göteborg Organ Art Center	Research center for interdisciplinary studies of the	Information about research studies and different EU projects about corrosion of organ pipes and reconstruction of historical alloys

	organ and related keyboard instruments. (At the University of Gothenburg)	for organ pipes.
Jegrelius	Environmental institute	The institute provided background data based on sampling in the homes of five Swedish families.
The Royal College of Music in Stockholm (KMH)	College for artistic learning and development.	Teachers at the college are not aware of any use and lead content in the wind instruments used at the royal college of music in parts of the instrument that can be mouthed. The mouthpieces for instruments used are made of wood, plastics, silver, gold or platinum.
Ökotex/SWEREA	Standardization	Limit value for lead in apparel: 90 mg/kg
NGO´s		
CEH	American consumers' organization	The organization has provided test results for handbags.
SSNC	National environmental organization	Provided test results.
Memberstates		
The Netherlands	MS	The MS provided information on how they gather data on the use of lead in articles, as well as information on in which articles lead may be found.
UK	MS	The MS offered input on the RMO for Pb in consumer products.

Appendix 16. Stakeholder consultation Request for information 1

REQUEST FOR INFORMATION FROM STAKEHOLDER ORGANISATIONS

(This document is published on the webpage of the Swedish Chemicals Agency, http://www.kemi.se/leadinarticles as part of the stakeholder consultation for an intended proposal on a restriction for lead and lead compounds in articles intended for consumer use. There is also a background paper available at the website, which describes the reasons why the Swedish Chemicals Agency considers that a restriction is necessary)

The Swedish Chemicals Agency has registered to ECHA its intention to work for further restrictions of the use of lead in articles intended for consumer use. The main reason for restriction is protection of human health, especially the health of children, from risks due to exposure from lead and lead compounds in articles intended for consumer use. The definition of the group of articles as well as the kind of lead compounds they contain are described in the background paper mentioned above.

Uses of lead that are already restricted in existing legislation, such as use in toys, electric and electronic equipment, vehicles etc., are excluded from the scope. This also applies to use in jewellery, where France has already submitted a restriction proposal, which is under consideration by the relevant authorities.

For the upcoming work with an intended restriction proposal we invite you to share your information, knowledge and experience. In particular, we would like your perspective on the following issues:

Articles for the EU market, containing lead and lead compounds

Lead and lead compounds are available in various materials and articles intended for consumer use. The content of lead in these materials and articles might be unknown to retailers and end consumers.

- *According to your judgment, to what extent do you expect consumers to be aware of the lead content in the articles, including awareness of which part of the articles may contain lead?*
  If you refer to any specific group of article/articles, please specify which.

From reports, e.g. from enforcement activities, it is often difficult to conclude where in an article lead/lead compounds have been found. Do you have any detailed information about the occurrence of lead in articles intended for consumer use? In such cases, please specify the article/articles you refer to:

- *In what part of the article is lead and lead compounds used?*
- *In what material in the article is lead and lead compounds used?*
- *Which lead compounds are used in the material?*
- *What is the concentration of lead and lead compounds in the material?*
- *Other information?*
- *Do you have any information of relevant market volumes of lead or lead*

compounds contained in the intended group of articles or a certain subgroup of articles?

Technical and economic feasibility of substitution

- *Are there any articles put on the market, intended for consumer use, for which it is not possible to substitute the use of lead and lead compounds? Why?*

- *Do you have any information on alternatives for lead/lead compounds in articles intended for consumer use?*
  In such cases, please specify the article/articles/material you refer to

- *Do you have any experience of substitution of lead and lead compounds in articles intended for consumer use?*
  (e.g. through voluntary measures or compliance with sector specific legislation such as RoHS and toy safety)

Data on exposure and impacts to human health

- *Do you have any information about the release of lead ions, e.g. from mouthing by children, where the materials/matrices/compounds are defined?*

- *Do you have any other information related to lead exposure from articles and impacts on human health?*

Any other information

In the invitation for a stakeholder meeting in June, a distribution list can be found.

- *If you find that it is not complete, please suggest other stakeholders who you think we should contact.*

- *Do you have any other information about the use of lead and lead compounds in articles intended for consumer use that you want to share with us?*

Thank you in advance for your assistance.
Please send your input to the questions above, or any other information which you consider relevant, by e-mail to ***kemi@kemi.se*** (reference no H12-00789). In order to process your input, we need it by **10 of September 2012**.

There will be a stakeholder consultation meeting the 18 of June. If you have the possibility to submit comments before the meeting in June, there will be an opportunity to discuss them already at that meeting.

Appendix 17. Stakeholder consultation Request for information 2

Request for information Part 2

Stakeholder consultation about the preparation of a restriction on lead in articles for consumer use

The Swedish Chemicals Agency intends to work for further restriction of the use of lead in articles intended for consumer use. In this specific work, we intend to restrict lead in articles due to the risk of chronic neurotoxic effects in children, in particular in children aged 0-36 months.

Lead in consumer articles - performed tests

In order to support this work we need to confirm the presence of lead in common consumer articles, preferably by identifying tests performed by other parties.

A. We would be very grateful if you could guide us towards any kind of test in which lead has been found in articles such as clothes, bags, accessories etc. Please note that toys and articles intended for food contact are exempted from the proposed restriction, since the use of lead in such articles is already regulated.

B. We are also interested in any other information you may have regarding the presence of lead in articles

Restriction proposals

For the intended purpose, we have identified five possible restriction proposals for lead in articles that are sold to the general public (i.e. made available to consumers):

1. Restriction of lead migration in articles that can be mouthed by children

2. Restriction of lead content in articles that can be mouthed by children

3. Two-step restriction of lead content and migration in articles that can be mouthed by children: lead content is restricted, unless the manufacturer can demonstrate that lead does not migrate from the article

4. Restriction of lead migration in all articles sold to the general public

5. Restriction of lead content in plastic and metal details in all articles sold to the general public

These restriction options will be assessed with respect to their:

- Effectiveness (risk reduction capacity and feasibility)

- Practicality

- Monitorability

Particular consideration will be given to the socioeconomic impacts of each option.

In order to successfully assess the different options, there is a need for further information. We therefore invite you to share your information, knowledge and experience on, in particular, the following issues:

A. How would each restriction option affect your business or area of expertise?

B. This answer may include any kind of impact: administrative, practical, economical, competition, competence and knowledge, resource changes, environmental, health, reduction of risk, etc. The costs and benefits involved may be direct or indirect and also relate to a transitional period. Please do also reflect on the impacts from a shorter and a longer time perspective, as well as the importance of the impacts.

C. Which restriction option would, according to you, be the most efficient in terms of risk reduction capacity and why?

D. Which restriction option would, according to you, be the most technically and economically feasible? Why?

E. For monitoring purposes, which option(s) would, in your opinion, be preferable? Why? This answer may also include the costs of monitoring the restriction(s) in question.

F. All in all, which option(s) do you favour?

Multiple options may be supported. You may also add another restriction option.

Restriction option	**Would you support this option?**		**Comments**
	Yes	**No**	
1. Lead migration from articles that can be mouthed by children			
2. Lead content in articles that can be mouthed by children			
3. Two-step restriction of content and migration in articles that can be mouthed by children			
4. Lead migration from all articles			
5. Lead content in plastic and metal details			
(add your own preferred option)			

A. Within what time frame could the different restriction options be implemented?

B. Do you see any uses or articles where an exemption from the restriction(s) would be justified? Which uses? What are the reasons for this?

C. Do you have any further information or comments that you would like to share?

Whenever possible, please provide existing data and examples in order to illustrate your answers.

Please submit your input to the questions above, or any other information which you consider relevant by e-mail to:
reachrestriction@kemi.se no later than **November 20 2012**.