

## **Draft Guideline on the scope of the upcoming amendment of Entry 63 of Annex XVII to REACH on: Lead and its compounds in articles supplied to the general public that can be mouthed by children.**

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

### **1. Introduction**

This document aims at providing a guideline concerning the interpretation of certain aspects of the scope of the new upcoming provisions<sup>1</sup> (listed in Annex 5) of entry 63 of Annex XVII to REACH Regulation (EU) No 1907/2006 on lead and its compounds in articles supplied to the general public. Note that it does not apply to the restriction of lead in jewellery.

It has been drawn up in response to a request of the Commission to ECHA to (i) clarify certain terms that define the scope of the restriction (e.g. "accessibility", "normal/reasonably foreseeable conditions of use") (ii) provide a non-exhaustive list of article types (and examples of sub-types) which fall within (or out of ) the scope of the restriction.

The guideline is focused on providing a description of article types that are covered by (or are out of) the scope of this restriction entry by giving general guidance on the scope and providing respective lists of examples. The target audience of this guideline is constituted by producers, importers and distributors of these types of articles as well as by national enforcement authorities of EU Member States. The purpose is to ensure a

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<sup>1</sup> The adoption of the referred measure is envisaged to take place in the second quarter of 2015. The new restriction proposal (on lead and its compounds in articles supplied to the general public) as uploaded in the Comitology register is indicated in Annex 5

common understanding of the scope of the restriction in view of an effective implementation of this provision.

Lead and its compounds are present on the EU market in different materials which are part of various consumer articles. They are used in the production of the articles to provide a certain function, such as a specific colour or desired mechanical properties. However there are also several article groups where the presence of lead in their composition can be regarded as unintentional. The different forms of lead that can be found in consumer articles have been investigated and assessed based on their identified functions, namely:

- Metallic lead
- Additives or impurities in metal alloys
- Pigments
- Stabilisers in polymers (PVC)

Lead found in articles is most frequently the consequence of its presence in additives or as impurities in metal alloys and also as a constituent of pigments. Stabilisers were only indicated as the probable source of lead in a minor share of the articles for consumer use studied.

## **2. Definitions and scope**

### **2.1 Targeting of the restriction.**

The restriction provisions of entry 63 (new paragraphs) aim to reduce the risks to consumers, particularly to children, caused by chronic exposure to lead via articles, which can result in severe and irreversible neurotoxic effects. The primary group at risk are children between 6 and 36 months of age. They are especially sensitive to the neurodevelopmental effects of lead exposure, with decline of Intelligence Quotient (IQ) as the critical effect. Small children are at the same time the most exposed to lead in articles due to their 'mouthing behaviour'. Therefore, the definition of the scope of this restriction takes particular account of the mouthing behavior of children and of those consumer articles which can be reasonably expected to be available to be mouthed by children.

To achieve the maximum risk reduction capacity, this restriction targets articles which meet all the 3 following conditions:

- (a) are supplied to the general public and contain lead or lead compounds in any

accessible part of the article at concentrations equal to or greater than 0.05% by weight;

(b) are likely to be placed in the mouth by small children;

(c) are not already covered by any other EU specific legislation where lead is regulated.

The following broad categories of mouthable consumer articles have been identified in the EU market:

- **Accessories** – Key rings (lead in both metal and coloured parts), bags, purses and cases (lead in both coloured 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, including coatings);
- **Stationery** (lead in both metal parts and polymers, including coatings);
- **Sports and leisure** (lead in both metal parts and polymers, including coatings);
- **Keys**<sup>2</sup> (lead in alloy used to make keys).

It must be stressed that clothes and accessories are examples of articles where lead can be found in a variety of materials in the article. Metallic elements such as buttons, buckles and zippers can be manufactured from alloys containing lead. Lead pigments are found to be used for colouring textiles or polymeric material as well as in coatings 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 as well as in more rigid articles.

Following extensive testing<sup>3</sup> by the Swedish Chemicals Agency (KeMI) of a large number

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<sup>2</sup> It should be noted, though, that keys, locks, padlocks and musical instruments are exempted from the restriction, based on socioeconomic grounds including lack of suitable alternatives and for enforcement reasons (RAC/SEAC compiled opinion, April 2014, available on: <http://echa.europa.eu/documents/10162/f5a59251-8ef0-4f44-bfd4-95bffca7f807>

<sup>3</sup> KEMI, Swedish Chemicals Agency, 2013. Hazardous substances in textiles – report of a government assignment. Available from: <http://www.kemi.se/en/This-is-Kemi/Government-assignments-in-2011/Reported-commissions-2010-2011/Hazardous-substances-in-textiles/>

of samples taken from the EU market for the estimation of lead content, Sweden concluded that: *Of the consumer articles available in the EU market 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 (at equal to or greater than 0.05% by weight, which is the restriction threshold), with an average lead concentration at least of 1%.*

## **2.2 Clarifications on general concepts that define the scope of the proposal**

One of the key issues in determining if an article is covered by the restriction is *if the article can be placed in the mouth by children*. This concept was favoured by the Committee for Risk Assessment among other options (e.g. “swallowed by children”) to properly address the situations potentially leading to lead exposure of children. “Placing in the mouth” has a precedent in the REACH Regulation, namely in entry 52 of Annex XVII concerning non-classified phthalates. By request from the Council and the European Parliament, the Commission has issued a guideline on the interpretation of the concept<sup>4</sup> that in 2014 was updated in liaison with ECHA and is now available on ECHA’s website as a Q&A No ID 748. This guideline states that:

*“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.”*

Applying this guideline, by analogy, to all consumer articles (rather than only to toys and childcare articles as for Entry 52), an article supplied to the general public may be included within the scope of this restriction, if:

- (a) It does not exceed a size of 5 cm in all of its three dimensions, so that it can be placed in the mouth;
- (b) It has accessible parts, *detachable or protruding parts with at least one dimension smaller than 5 cm, that can be placed in the mouth.*

Further to the dimensions of the article, two additional criteria need to be considered for the scope definition in terms of “mouthability”:

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<sup>4</sup> Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006 ([https://echa.europa.eu/documents/10162/13645/guideline\\_interpretation\\_concept\\_mouth\\_en.pdf](https://echa.europa.eu/documents/10162/13645/guideline_interpretation_concept_mouth_en.pdf))

- (1) Accessibility: By definition, inaccessible parts of articles cannot 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<sup>5</sup>. The general principles of this standard are considered to be appropriate for application in the context of this restriction and for the definition of its scope.
- (2) Normal or reasonably foreseeable conditions of use: In addition to the physical layout and dimensional considerations on accessibility described above, an article must be available for children to their mouth during normal or reasonably foreseeable conditions of use in order to be considered in scope. For the purposes of this Guideline, the relevant definitions of the terms provided by the ECHA Guidance on Substances in Articles<sup>6</sup> are taken into account; in particular:
- (i) "*Normal conditions of use*" mean the conditions associated with the main function of an article". It is explicitly not a "normal condition of use" if the user of an article uses an article in a situation or manner that the supplier of the article has clearly recommended in writing to avoid, e.g. in the instructions or on the label of the article.
  - (ii) "*Reasonably foreseeable conditions of use*" mean conditions of use that can be anticipated as likely to occur because of the function and appearance of the article (even though they are not normal conditions of use). That would cover misuse by children to the extent that the use can be considered likely to occur because of the function and appearance of the article.

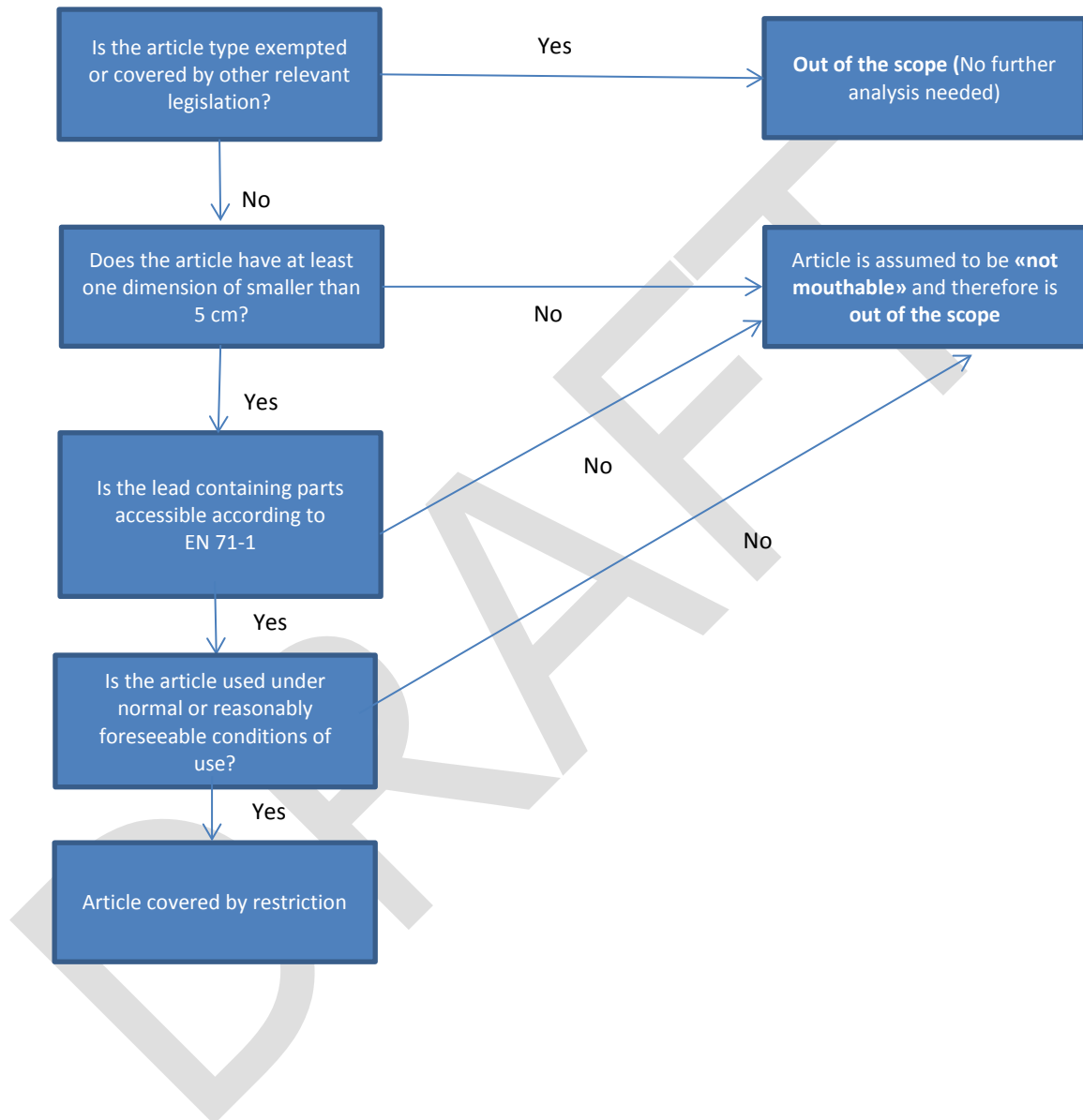
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<sup>5</sup> EN 71-1: European standards within the field of safety of toys on mechanical and physical properties, flammability chemical properties and graphical symbols  
[http://standards.cen.eu/dyn/www/?p=204:110:0:::FSP\\_PROJECT:41917&cs=105249A5D7F7CDB15454E2D00E0786F71](http://standards.cen.eu/dyn/www/?p=204:110:0:::FSP_PROJECT:41917&cs=105249A5D7F7CDB15454E2D00E0786F71)

<sup>6</sup>ECHA Guidance on Substances in Articles (2011)  
[http://echa.europa.eu/documents/10162/13632/articles\\_en.pdf](http://echa.europa.eu/documents/10162/13632/articles_en.pdf)

Figure 1 reflects a “stepwise approach” for assessing whether an article is within or outside the scope of this restriction on a *case-by-case* basis.

Figure-1. Steps to assess whether articles are in the scope of the restriction:



## **2.3 Indicative lists of examples of articles which fall in or out of the scope of this restriction**

Based on the analysis presented in the RAC/SEAC opinion and in the Background document<sup>7</sup> on “Lead and its compounds in articles supplied to the general public” it is overall concluded that: *The articles addressed in this restriction are articles supplied for the general public, which are likely to be mouthed by small children, and where those articles contain lead or lead compounds (not regulated by other relevant EU legislation) in any of their accessible parts.*

This conclusion has been the basis for the amendment of entry 63 (“lead and its compounds in jewellery”) to also cover the articles intended for consumer use. It has to be noted that any articles intended exclusively for professional/industrial uses are excluded from the scope of this restriction, although some careful assessment needs to be made for those of which a consumer use cannot be reasonably excluded (i.e. some tools likely to be used indoors, etc.).

Furthermore, in line with the discussion in section 2.2, the judgement about whether an article is covered or not by this restriction should be taken after carefully considering the concepts that define its scope, such as mouthability/accessibility/normal and foreseeable conditions of use. This guideline provides indicative lists of articles which can be considered to fall in (or out) of the scope of this restriction.

### **2.3.1 Examples of articles within the scope (Annex-1)**

Annex 1 of this guideline provides examples of the broad types of consumer articles which are considered to be potentially within the scope of the restriction, as a consequence of being mouthable and accessible to children. The indicative (“non-exhaustive”) lists of articles supplied for general public include:

- *Clothing categories*, (including metal or plastic details such as: buttons, zippers or other fastenings) (Annex 1-A).
- *Footwear* (Annex 1-B).

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<sup>7</sup> Available on ECHA’s website: <http://echa.europa.eu/documents/10162/ab0baa9c-29f8-41e2-bcd9-42af796088d2>

- *Sports and leisure articles* (particularly their handles and grips, external parts of racquets etc.) (Annex 1-C).
- *Accessories* (bags, badges, but excluding items covered by the paragraphs 1 and 2 of the entry 63) (Annex 1-D).
- *Stationery* (rubber erasers, writing instruments etc.<sup>8</sup>) (Annex 1-E).
- *Interior decoration items* (Christmas decorations, decorative magnets, figurines, etc.) (Annex 1-F).

For a few articles of the above indicated categories (e.g. curtain weights, writing instruments, spectacles) a number of comments were received from stakeholders during the public consultation process. The reasoning for their inclusion in the scope of the restriction is briefly presented in specific footnotes of the relevant Annex-1 lists.

In addition, the following “wide” categories of articles were considered to also be within the scope of the restriction:

(i) Articles made of recycled materials: A number of comments were submitted by stakeholders to ECHA during the public consultations, proposing exemptions from the general scope of the restriction based on the recycled nature of some plastics and metal alloys. It was claimed that some residual (“legacy”) lead may still be present in articles made from recycled PVC, at levels exceeding the limit of 0.05 % by weight. *However, as reflected in the compiled RAC/SEAC opinion, such articles have the same risk profile and thereby pose the same risk as articles made of virgin (not recycled) materials, if falling within the scope of the restriction.*

Furthermore, examination of the relevant comments led to the conclusion that articles manufactured from recycled (lead-containing) PVC material are mainly used in construction applications and are therefore not typical consumer products. Overall construction products are not commonly supplied to consumers and, even those which are bought by consumers (e.g. insulation material), will not typically be accessible to children. Hence these articles are excluded from the scope of the restriction as indicated in the Annex table 2-C.

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<sup>8</sup> Tips of pens: By considering the very small size of the very tip of the ball pen (where the ink comes out, see figure c-Annex 3), there is a very low potential for exposure. This part is explicitly exempted from the restriction.



(ii) Childcare articles: Although not explicitly mentioned in the initial Annex XV report, it has been clarified in the Background document<sup>9</sup> that childcare articles (e.g. mouthable parts of baby carriages, inflatable mattresses; and similar articles) are clearly covered by the scope of this restriction. It is reminded that a definition of childcare articles as well as examples of articles that can be mouthed by children in the context of Entry 52, are given in the previously mentioned ECHA guideline on phthalates. As clarified in a recent restriction Q&A (No [983] available on ECHA's website: <http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/restrictions>) this definition of childcare articles can be considered as valid for all the entries of Annex XVII. In this guideline, a list of examples of childcare articles is provided in the Annex table 1-G.

### **2.3.2. Examples of articles totally or partially excluded from the scope (Annex-2)**

Annex 2 of this guideline provides examples of articles being out of the scope of this restriction for various reasons such as:

- Article categories exempted from the restriction (listed in Annex 2-A along with a brief reasoning behind their exemption).
- Article categories which are covered by other European Union legislation specifically regulating lead content (Annex 2-B).
- Types of articles for which requests for exemptions were submitted by the stakeholders during the public consultation along with a brief explanation about why these have been considered to fall out of the scope of the restriction (e.g. ammunition, fixed furnishings, etc.) (Annex 2-C).

Furthermore, following analysis of a number of comments submitted by stakeholders for the following "wide" categories of articles, ECHA's Scientific Committees (RAC/SEAC<sup>10</sup>) have concluded that:

(i) Outdoor items: These are commonly found outside the household and therefore are

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<sup>9</sup> Available on ECHA's website: <http://echa.europa.eu/documents/10162/10a7006f-1342-40ad-8aa3-c28365d0faca>

<sup>10</sup> Where, RAC: Committee for Risk Assessment; SEAC: Committee for Socio-economic Analysis

not considered to be accessible to small children, at least in their immediate environment. In general, in considering the technicalities and the reasonable worst case scenario for what a child will be likely to mouth both indoors and outdoors, it has been assumed that there is a higher probability of exposure via this route to consumer articles primarily intended for indoor use. However, it cannot be excluded that children also may place some articles in their mouth that are mainly intended for outdoor use, e.g. garden hoses which may be lying on the ground, are often brightly coloured and could be mouthed due to their dimensions and appearance (see figure (a), Annex-3). With some exceptions, most outdoor articles are considered not to be accessible to children under normal or reasonably foreseeable conditions of use, assuming a due level of parental care for reasons of safety (e.g. concerns for heavy or sharp potentially harmful garden tools/fishing gear, etc.) or hygiene (e.g. snow/ski footwear, flower pots, garden decorations). An overview of examples of outdoor articles is given in Annex 4.

(ii) Coated articles: A few examples of coated articles or part of articles have been examined following the submission of relevant comments in the Public Consultation (e.g. spectacle frames, curtain weights). It needs to be considered that the potential risk from coated lead-containing articles depends on the effectiveness of the coating in preventing migration of lead. In this respect, the established migration limit of  $0.05 \mu\text{g}/\text{cm}^2$  per hr ( $0.05 \mu\text{g}/\text{g}$  per hr) is considered as a suitable way of addressing this issue. If the migration of lead from the coated article is below the migration limit value after being subjected to a wear test simulating a period of at least two years of normal use of the article, this is considered as sufficiently protective and thereby such articles would fall outside of the scope of the restriction. It must be noted however, that not all coated articles containing lead are considered as out of the scope, therefore a case-by-case judgement should be made to conclude as appropriate.

Two years of wear resistance has been considered to be a reasonable indicator of coating integrity, sufficient to be effective in preventing migration of lead. This approach has been used by analogy to that used in relation to the migration of nickel in Entry 27 and by reference to the existing European Standard EN 12472<sup>11</sup>.

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<sup>11</sup> A European standard, EN 12472, is available for the simulation of wear and corrosion of coated items. [http://standards.cen.eu/dyn/www/f?p=204:110:0:::FSP\\_PROJECT,FSP\\_ORG\\_ID:33166,413439&cs=13D26AD110CAFC3FDC2AB7BEB14DD3173](http://standards.cen.eu/dyn/www/f?p=204:110:0:::FSP_PROJECT,FSP_ORG_ID:33166,413439&cs=13D26AD110CAFC3FDC2AB7BEB14DD3173)). It was originally developed for the regulation which addresses health risks related to nickel in articles pierced in the human skin or in direct and prolonged contact with the human skin.

(iii) Second-hand articles and articles in stock: A derogation was provided for articles placed for the first time before 1 year after the entry into force, therefore in order to exempt second hand market articles and stocks from the restriction for reasons of enforceability and in line with the Forum advice.

There are many other consumer article types, not mentioned as excluded in this section, or in the annexes of these guidelines, for which no evidence has become available throughout the process leading to the current restriction about the presence or absence within them of lead in relevant amounts. Examples of such items are consumer articles made of paper or pure textile. In the event of concern or suspicion about the presence of lead compounds, for articles meeting the narrative scope of the restriction, the relevant investigations to determine lead content or migration are potentially applicable.

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## ANNEXES

**ANNEX-1** *Indicative lists of examples of articles supplied to the general public within the scope of this restriction<sup>12</sup>*

<b>Table 1-A Examples of clothing items</b>
Adult/children overcoats, car-coats, capes, cloaks
Adult/children anoraks, ski-jackets, wind-cheaters, wind-jackets
Adult/children blazers
Adult/children suits and ensembles
Adult/children trousers, breeches, shorts, bib and brace overalls
Women or girl dresses, skirts and divided skirts
Men or boy trousers and breeches, of cotton, wool, fine animal hair or man-made fibres
Adult/children nightshirts, nighties and pyjamas
Women or girls blouses, shirts and shirt-blouses
Braces, suspenders, garters and similar articles and parts thereof
Baby garments and clothing accessories, including vests, rompers, underpants, stretch-suits, napkins, gloves or mittens or mitts, outerwear
Tracksuits, and ski suits
Gloves, (incl. leather sports gloves mittens and mitts)
Other adult/children apparel, including waistcoats, and jogging suits
Parts of garments or of clothing accessories, of textiles

<sup>12</sup> Articles within the scope: Please note that the listed examples concern types of consumer articles for which there is an understanding that they will generally meet the inclusion criteria that define the scope of this restriction as discussed under section 2.2 (and presented in figure 1). Therefore, these are articles commonly being accessible and potentially mouthable by small children under reasonably foreseeable conditions of use. In addition, it must be noted that for an article to be within the scope it should also contain lead at a concentration higher than the thresholds given in the restriction.

<b>Table 1-A Examples of clothing items</b>
Adult/children jerseys, pullovers, sweatshirts, waistcoats and cardigans, of wool or fine animal hair
T-shirts, singlets and vests.

<b>Table 1-B Examples of footwear</b>
Sandals with rubber or plastic outer soles and uppers (including thong-type sandals, flip flops)
Slippers and other indoor footwear with rubber or plastic outer soles and plastic uppers (including bedroom and dancing slippers, mules)
Adults'/children's sandals with leather uppers (including thong type sandals, flip flops)
Footwear with wooden base, cork or other outer soles and leather or textile uppers (including clogs)

<b>Table 1-C Examples of sports and leisure items</b>
Pneumatic mattresses
Sleeping bags
Skis, for winter sports
Golf clubs and other golf equipment
Articles and equipment for table-tennis (including bats, balls and nets)
Tennis, badminton or similar rackets, whether or not strung
Balls (excluding golf balls, table-tennis balls, punch balls)
Other articles and equipment for sport and open-air games, n.e.c.
Articles and accessories for billiards
medals used for sports/awards purposes (with the exemption of those considered as jewellery or used for religious purposes)

<b><i>Table 1-D. Examples of accessories</i></b>
Belts and bandoliers and any other type of clothing accessories
Trunks, suitcases, vanity-cases, briefcases, school satchels and similar containers
Handbags of leather plastic sheeting, textile materials or other materials (including those without a handle)
Cases and containers
Travel sets for personal toilet; sewing; or shoe or clothes cleaning
Manicure or pedicure sets and instruments (including nail files)
Sewing, knitting needles, bodkins of iron or steel, for use in the hand
Iron or steel snuff boxes, cigarette cases, cosmetic and powder boxes and cases, and similar pocket articles
Sunglasses <sup>13</sup> , spectacles, goggles and the like, corrective, protective or other
Plastic and non-plastic frames and mountings for spectacles, goggles and the like
Umbrellas (including sun umbrellas, walking-stick umbrellas, garden umbrellas and similar ones)
Hair accessories (such as hair-pins, hair-bands etc.) not falling under the scope of paragraphs 1-6 of entry 63.

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<sup>13</sup> Sunglasses and Spectacle frames: 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 they are mouthable and accessible and foreseeable misuse can be foreseen.

<b><i>Table 1-E Examples of stationery items</i></b>
Erasers, of vulcanized rubber
Pencil sharpeners and their blades (including packet type pencil sharpeners)
Office articles such as letter clips, letter corners
Ball-point pens (except for the tip which is exempted <sup>14</sup> )
Felt-tipped and other porous-tipped pens and markers
Propelling or sliding pencils
Fountain pens, stylograph pens and other pens, indian ink drawing pens
Pencils and crayons with lead encased in a rigid sheath (excluding pencils for medicinal, cosmetic or toilet uses)
Drawing compasses, protractors, rulers, etc
Metal or plastic-binder elements (such as spirals, rings, etc.)

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<sup>14</sup> Writing instruments: Except for the tip, the surface area for the rest of the writing instrument (such as the nose and clip) is larger and these parts of the article are therefore considered to be within scope (see picture c Annex 3).

**Table 1-F Examples of interior decoration items**

Furnishing articles including furniture and cushion covers for car seats (except for fixed furnishings)
Plastic, metal wooden frames for paintings, photographs, mirrors or similar objects
Household articles and toilet articles, made of plastics, porcelain or china
Statuettes, frames, mirrors and other ornamental articles made of base metal, plastic, ceramic or porcelain (including photograph, picture and similar frames)
Bells, gongs, etc., non-electric, of base metal
Articles for Christmas festivities (excluding candles, statuettes, statues and the like used for decoration of places of worship)
Festive, carnival or other entertainment articles.
Artificial flowers, artificial fruits, foliage and parts thereof
Upholstered and non-upholstered seats with metal frames (excluding swivel seats, medical, surgical, dental or veterinary seats, barbers or similar chairs, for motor vehicles, for aircraft)
Seats convertible into beds (excluding garden seats or camping equipment)
Seats of cane, osier, bamboo or similar materials
Curtains and curtain weights <sup>15</sup>

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<sup>15</sup> 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 sufficiently sheathed in a textile or plastic envelope that is assumed to prevent lead migration and thereby fulfil the condition that "if migration can be demonstrated to be below the established limit then these are exempted from the restriction".



**Table 1-G. Examples of childcare articles**

Blankets, mattresses protectors (if placed above sheets or cannot be tightly fixed to the mattress)

Articles which are used for the hygienic care of children (articles for the bath such as bathtubs, bathtub mats, hairbrushes, bath thermometers, or nail cutters)

Part of baby carriages (upper surface of side arms, uppermost part of sides and straps and front edge of the tray)

Changing table pillow (edges)

Carrying sling with parts of plastic (accessible parts on the upper side)

Breast-feeding pillow (external parts)

Parts of pushchairs (surfaces of bumper bar, seat sides and braces, straps or belts)

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**ANNEX-2** Indicative lists of examples of articles supplied for the general public that fall out of the scope of this restriction

**Table 2-A Article types exempted from the restriction**

<i>Types of articles</i>	<i>Justification/conditions (as explained in RAC/SEAC opinion)</i>
Keys, locks, padlocks and musical instruments	This derogation is based on socioeconomic grounds including lack of suitable alternatives and for enforcement reasons.
Crystal glass, enamels, and precious and semiprecious stones in articles	Exemptions so as to align with the provisions of Entry 63, while also supported during the public consultation via comments of associated stakeholders and supported by RAC and SEAC. A very low migration of lead from crystal material (e.g. ~100 times lower than from metal) was communicated by the related comments.
<i>Brass alloys</i> , if the concentration of lead in the brass alloy does not exceed 0.5%	This exemption was granted on the basis of a lower migration rate of lead from brass alloys after the assessment of studies using saliva simulant based migration testing provided by European Copper Institute. <sup>16</sup>
Religious articles for consumer use	Normally these type of articles (whenever present in a household and not in special places of worship e.g. churches) should not be accessible to children considering parental care and given their special valuable nature and intended use. Certain types of articles may also be large in size and therefore outside the mouthing range.
Portable zinc-carbon batteries and button cells batteries	Both types of batteries, which are directly available to consumers, are exceptionally exempted from the scope until a detailed

<sup>16</sup> Responses to this comment (along with any other comments received from stakeholders) on the restriction report available on: <http://echa.europa.eu/documents/10162/ab0baa9c-29f8-41e2-bcd9-42af796088d2>

	assessment can be performed.
Tips of writing instruments	This exemption was granted given the small size of the very tip of the ball pen (the part where the ink comes out). In addition, this is also mainly an interior part of the writing instrument (Annex 3-picture c), therefore there is a very low potential for exposure.
Articles covered by EU specific legislation	A list of articles covered by EU specific legislation under which lead is already regulated is presented in more details in table 2-B.

**Table 2-B Article types which are exempted as covered by European Union legislation specifically regulating lead content**

Type of articles	EU specific legislation
1. Articles intended to come in to contact with food (e.g. kitchen utensils, ceramic articles for food/drinking use etc.)	Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
2. Electrical and electronic articles, such as bulbs, light sources etc.	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
3. Toys	Directive 2009/48/EC on the safety of toys.
4. Jewellery items	Paragraphs 1 and 2 of Entry 63 of Annex XVII to REACH. Restriction on lead in jewellery articles.
5. Packaging materials	Directive 94/62/EC on packaging and packaging waste.

**Table 2-C Article types which are considered out of the scope of the restriction due to non-mouthability/non-accessibility**

Type of articles	Justification
Ammunition (+ fire arms and other weapons)	National legislation implementing Directives 91/477/EEC contains requirements to store ammunition securely in order to prevent unauthorised access, including access by children.
Fixed furnishings	The main part of fixed furniture is of a size that is assumed too big for mouthing.
Fishing sinkers and weights (figure b- Annex 3)	These are stored for safety reasons and thereby not accessible by children in normal or reasonably foreseeable conditions of use.
Diving weights	Even though accessible and possibly mouthable (with side <5 cm in length), should be out of the reach of children, considering adults attention.
Internal hinge mechanisms	These are considered out of scope since due to their installation they are not accessible under normal or reasonably foreseeable conditions of use (Annex 3 –picture d).
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 the risk of choking that they pose for children (can easily be swallowed) and for other safety reasons, e.g. sharpness.
Recycled PVC based Construction products	The mouthability/ accessibility of construction products by children is unlikely as these are incorporated in a permanent manner in construction works.
Batteries containing lead	Most of batteries containing lead, covered by the Directive 2006/66/EC, are not within the scope of the restriction (i.e. automotive batteries or industrial batteries). Small sealed lead-acid batteries used by the consumers will often be out of scope if the casing ensures the lead contained within is inaccessible (see table 2-A for the exempted types)

**ANNEX-3** Pictures of certain articles that fall in or out of the scope of the restriction

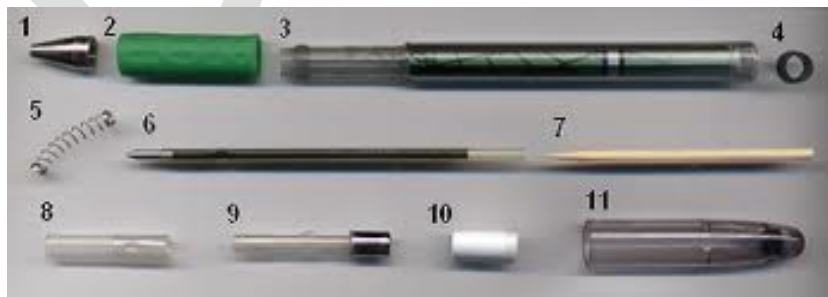
- (a) Picture of a typical garden hose (it can be considered mouthable and accessible to children in particular when lying on the grass)



- (b) Picture of typical fishing weight (out of the scope due to safety reasons)-to be inserted



- (c) Picture of a typical writing instrument ("tip" is exempted, while "nose" and "clips" are parts within the scope of the proposal)



Number 1 (nose), number 6 (tip), number 11 (clip)

(d) Picture of a typical hinge mechanism (not mouthable under normal or reasonably foreseeable conditions of use) to be inserted



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<b>ANNEX-4</b> <i>Examples of outdoor articles (In or out of the scope of the restriction)</i>	
<i>Type of articles</i>	<i>Scope inclusion/exclusion</i>
Garden hoses <sup>17</sup>	YES (can be accessible by children, if lying on the ground)
Town footwear with rubber, plastic or leather outer soles and textile uppers	YES (could be accessible by children if left lying around)
Tennis shoes, basketball shoes, gym shoes, training shoes and the like	NO (should be normally kept out of reach of children for hygienic reasons)
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)	NO (should be normally kept out of reach of children for hygienic reasons)
Ski poles, snow-ski footwear	NO (should be normally kept out of reach of children for hygienic and safety reasons)
Camping equipment, fishing rods etc.	NO (not accessible by children in normal/reasonably foreseeable conditions of use).
Garden umbrellas	NO: Not mouthable mainly due to size dimension
Waterproof footwear, with uppers in rubber or plastics	NO (a type of footwear usually wet and muddy that children would not be allowed to mouth)

<sup>17</sup> *Garden hoses*. These articles are considered to be mouthable and accessible therefore under the scope of the restriction. 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 (see figure (a), Annex-3).

**ANNEX-5** Restriction Proposal of lead in on lead and its compounds in articles supplied to the general public) as uploaded in the Comitology register



Brussels, XXX  
D035742/03  
[...] (2014) XXX draft

ANNEX 1

**ANNEX**

**to**

**COMMISSION REGULATION (EU) No .../..  
of XXX**

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") as regards lead and its compounds**



## ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, column 2 of entry 63 is amended as follows:

(1) paragraph 6 is replaced by the following:

“6. By 9 October 2017, the Commission shall re-evaluate paragraphs 1 to 5 of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly.”

(2) the following paragraphs are added:

“	<p>7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05% by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.</p> <p>That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0.05 µg/cm<sup>2</sup> per hour (equivalent to 0.05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.</p> <p>For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 centimetres in one dimension or has a detachable or protruding part of that size.</p> <p>8. By way of derogation, paragraph 7 shall not apply to:</p> <ul style="list-style-type: none"><li>a. jewellery articles covered by paragraph 1.</li><li>b. crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC<sup>18</sup>;</li><li>c. non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Council Regulation (EEC) No 2658/87<sup>19</sup>) unless they</li></ul>
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<sup>18</sup> 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).

<sup>19</sup> 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).

	<p>have been treated with lead or its compounds or mixtures containing these substances;</p> <p>d. enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500°C;</p> <p>e. keys and locks, including padlocks;</p> <p>f. musical instruments;</p> <p>g. articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0.5% by weight;</p> <p>h. the tips of writing instruments;</p> <p>i. religious articles</p> <p>j. portable zinc-carbon batteries and button cell batteries</p> <p>k. articles within the scope of :</p> <ul style="list-style-type: none"> <li>i. Directive 94/62/EC;</li> <li>ii. Regulation (EC) No 1935/2004;</li> <li>iii. Directive 2009/48/EC of the European Parliament and of the Council*;</li> <li>iv. Directive 2011/65/EU of the European Parliament and of the Council**</li> </ul> <p>9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8 (e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly.</p> <p>10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before [first day of the 13<sup>th</sup> month after the entry into force].</p> <hr style="width: 20%; margin-left: 0;"/> <p>* Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).</p> <p>** Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).</p>
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### Change history

Revision	Comment	Date