

## **Guideline on the scope of the Entry 63 (paragraphs 7 to 10) 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 producers, importers, distributors, and users of articles, as well as Member States' competent and enforcement authorities, in understanding and complying with their obligations under the REACH Regulation. However, readers are reminded that only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority. 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 guideline concerns the interpretation of certain aspects of the scope of the restriction provisions<sup>1</sup> in paragraphs 7 to 10 of entry 63 of Annex XVII to Regulation (EU) No 1907/2006 on lead and its compounds in articles supplied to the general public.

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. "accessible part of articles", "normal/reasonably foreseeable conditions of use") and (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 producers, importers and distributors of these types of articles as well as national enforcement authorities of EU Member States. The purpose is to ensure a common understanding of the scope and effective implementation of the restriction.

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<sup>1</sup> Commission Regulation (EU) 2015/628 of 22 April 2015 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. OJ L 104, 23.4.2015, p. 2–5

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 (KEMI 2012).<sup>2</sup>

## **2. Definitions and scope**

### **2.1 Target of the restriction**

The restriction provisions of entry 63, paragraphs 7-10, aim to reduce the risks to consumers, particularly children, caused by repeated 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 interpretation of the scope of this restriction takes particular account of the mouthing behaviour of children and of those consumer articles which may be mouthed by children in the course of their normal or reasonably foreseeable conditions of use.

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<sup>2</sup> KEMI, Swedish Chemicals Agency (2012). Annex XV report, proposal for a restriction of lead and its compounds in articles intended for consumer use. Available from:  
<http://echa.europa.eu/documents/10162/80f7edca-b6c1-4433-8734-854594530db2>

This restriction targets articles and accessible parts of articles which meet all the 3 following conditions:

- (a) are supplied to the general public and contain lead or lead compounds at concentrations of lead, expressed as metal, equal to or greater than 0.05% by weight<sup>3</sup>;
- (b) may be placed in the mouth by small children during normal or reasonably foreseeable conditions of use;
- (c) are not covered by a derogation.

## 2.2 Clarification of general concepts that define the scope of the restriction

### *"Placed in the mouth by children"*

One of the key issues in determining whether an article or an accessible part thereof is covered by the restriction is *if it may be placed in the mouth by children*. This concept was favoured by the Committee for Risk Assessment (RAC) over other options (e.g. "swallowed by children") to properly address situations potentially leading to exposure to children.

The restriction establishes that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension<sup>4</sup> or has a detachable or protruding part of that size.<sup>5</sup>

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<sup>3</sup> This limit does not apply when it can be demonstrated that the rate of lead release from such an article or any such accessible part does not exceed the limit specified in entry 63, paragraph 7, second paragraph, in the terms indicated therein.

<sup>4</sup> If an article is smaller than 5 cm in any of its dimensions (height, length, width) it is considered that it will fit into the mouth of a child, whereas any articles bigger than 5 cm can only be licked but not placed in the mouth.

<sup>5</sup> Placed in the mouth by children" has a precedent in the REACH Regulation, namely in entry 52 of Annex XVII concerning certain phthalates. At the request of the Council and the European Parliament, the Commission issued a guideline on the interpretation of the concept that in 2014 was updated in liaison with ECHA and is now available on ECHA's website as a Q&A No 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." For the purpose of the restriction in entry 63(7) these criteria are fulfilled when the dimensional conditions specified therein are met.

### *Accessible part of an article*

By definition, inaccessible parts of articles cannot be placed in the mouth. Whether a part of an article is accessible can be assessed following the definition and method laid down in clause 8.10 of European Standard EN 71-1<sup>6</sup> on the safety of toys. 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.

### *Normal and reasonably foreseeable conditions of use*

The article as a whole must be available in order for children to mouth it or an accessible part of it. The question is therefore whether during normal or reasonably foreseeable conditions of use of the article, it will be available to a child. The ECHA Guidance on Substances in Articles<sup>7</sup> provides the following interpretations:

- (i) “*Normal conditions of use*” means 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*” means 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 use by children to the extent that the use can be considered likely to occur because of the function and appearance of the article. For example when a small child does not know the function of an article but uses it for any purpose he associates with it, such as biting or licking it<sup>8</sup>.

The notion of “normal conditions of use” is largely unproblematic. Most difficulties in

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<sup>6</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/f?p=204:110:0:::FSP\\_PROJECT:41917&cs=105249A5D7F7CDB15454E2D00E0786F71](http://standards.cen.eu/dyn/www/f?p=204:110:0:::FSP_PROJECT:41917&cs=105249A5D7F7CDB15454E2D00E0786F71))

<sup>7</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))

<sup>8</sup> ECHA Guidance on Substances in Articles can be followed except that within the context of this restriction licking only (not chewing or biting) can be expected from articles or accessible parts of articles bigger than 5cm in one dimension, which are, therefore, out of the scope of the restriction.

interpretation will involve consideration of the “reasonably foreseeable conditions of use”.

An assessment must be made on a case by case basis by considering the nature and function of the article. However, certain characteristics of articles may lead to the conclusion that reasonably foreseeable conditions of use will not lead to the article being available to a small child, because efforts are likely to be made deliberately to keep them out of reach.

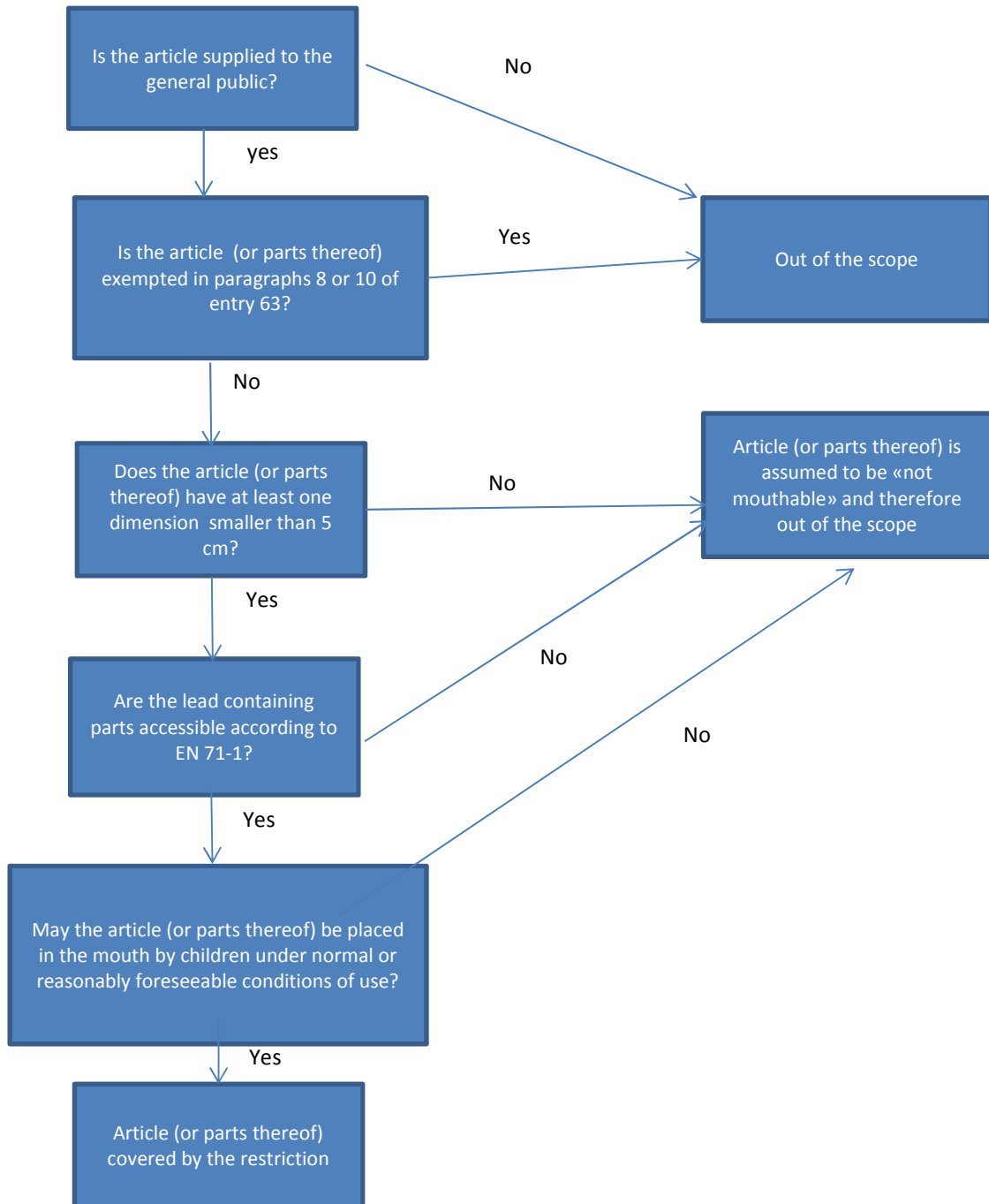
In the context of this restriction, the characteristics of an article that determine “reasonably foreseeable conditions of use” that would make it generally out of the reach of children include:

- a) whether the article is manifestly dangerous (e.g. flammable, etc.)
- b) whether the article is installed at a height or in a location out of the reach of children.

*Stepwise approach*

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

Figure-1. Steps to assess whether articles (or accessible parts there of) are in the scope of the restriction (paragraphs 7 to 10 of entry 63 of Annex XVII):



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

Based on the evaluation presented in the RAC/SEAC opinion<sup>9</sup> on the Swedish proposal for a restriction and in the Background document<sup>10</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 may 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 was the basis for the amendment of entry 63 (“lead and its compounds”) to also cover 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.

Furthermore, the judgement about whether an article is covered by this restriction should be taken after carefully considering the concepts that define its scope, such as mouthability, accessibility of lead-containing parts and/normal or reasonably foreseeable conditions of use. This guideline provides indicative lists of articles which can be considered to fall within (or out of) the scope of this restriction (paragraphs 7 to 10 of entry 63 of Annex XVII).

### **2.3.1 Examples of articles within the scope**

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 during normal or reasonably foreseeable conditions of use by children. The indicative (“non-exhaustive”) lists of articles supplied for the general public include:

- *Clothing categories*, (including metal or plastic details such as: buttons, zippers,
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<sup>9</sup>RAC (Committee for Risk Assessment) /SEAC (Committee for Socio-economic Analysis) compiled opinion available on ECHA’s website: <http://echa.europa.eu/documents/10162/f5a59251-8ef0-4f44-bfd4-95bffca7f807>

<sup>10</sup>Available on ECHA’s website: <http://echa.europa.eu/documents/10162/ab0baa9c-29f8-41e2-bcd9-42af796088d2>

other fastenings or decorative details) (Annex 1-A).

- *Footwear* (Annex 1-B).
- *Sports and leisure articles* (particularly their handles and grips) (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>11</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) 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 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 their mouthability/reachability by children is unlikely as they are incorporated in a permanent manner in construction works. However, for some construction products (e.g. insulation material), it should be assessed whether they would typically be reachable by children once installed and mouthable under reasonably foreseeable conditions of use. Hence construction products that, once installed, are not reachable by children cannot be placed in the mouth under reasonably foreseeable

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<sup>11</sup> Tips of pens: By considering the very small size of the very tip of the pen (where the ink comes out, see Annex 3, picture-a), there is a very low potential for exposure. This part is explicitly exempted from the restriction in paragraph 8(h) of entry 63.



conditions of use and are excluded from the scope of the restriction as indicated in the Annex table 2-C.

(ii) Childcare articles: Although not explicitly mentioned in the initial Annex XV report, it has been clarified in the Background document that childcare articles (e.g. mouthable parts of baby carriages, inflatable mattresses; and similar articles) are clearly covered by the scope of this restriction. 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 out of the scope of this restriction together with the reasons why, such as:

- Articles specifically exempted from the restriction (listed in Annex 2-A). This includes articles which are covered by other European Union legislation specifically regulating lead specified in paragraph 8 (a) and (k) of entry 63 (Annex 2-B).
- Types of articles considered to be outside the scope of the restriction following evaluation of comments submitted by stakeholders during the public consultations (e.g. ammunition, fixed furnishings, etc.) (included in Annex 2-C).

Furthermore, taking into account ECHA's Scientific Committees (RAC/SEAC) evaluation of a number of comments submitted by stakeholders for certain "wide" categories of articles, it is relevant to note that:

- (i) Outdoor items: The evaluation during the opinion making process concluded that outdoor articles should be assessed on a case by case basis. It cannot be excluded that children may place some articles in their mouth that are mainly intended for outdoor use such as: (i) garden hoses, potentially lying on the ground, are often brightly coloured and could be mouthed (in particular their tip) due to their dimensions and appearance; (ii) sport, town and water-proof footwear, since these are used in many everyday activities and can also be stored indoors and within the reach of children. On the contrary, other types of outdoor articles are considered not to be reachable by children under

normal or reasonably foreseeable conditions of use (e.g. garden umbrellas).

- (ii) An overview of examples of outdoor articles, and their status as regards the restriction, is given in Annex 4.

(ii) Coated articles: A few examples of coated articles or parts of articles were considered in the Background Document following the submission of relevant comments in the public consultations. RAC, in its opinion (2014), highlighted the need to specify what the 'coating' is comprised of, as the potential risk 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 therefore such articles would fall outside of the scope of the restriction. The established migration limit will therefore be used for enforcing this restriction for lead containing coated articles such as: spectacle frames, curtain weights, coated decorative items etc.

It must be stressed that not all coated articles containing lead are considered as out of the scope. They should be exempted only if they do not exceed the migration limit in paragraph 7 of entry 63. Therefore a case-by-case judgement should be made.

Two years of wear resistance is considered to be a reasonable indicator of coating integrity, sufficient to prevent migration of lead. This approach is analogous to that used in relation to the migration of nickel in Entry 27 and takes account of European Standard EN 12472<sup>12</sup>.

(iii) Second-hand articles: A derogation was provided for articles placed on the market for the first time before 1 June 2016, in order to exempt second hand articles from the restriction for reasons of enforceability and in line with the Forum advice.

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<sup>12</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 restriction which addresses health risks related to nickel in articles pierced in the human skin or in direct and prolonged contact with the human skin.

## ANNEXES

**ANNEX-1** Indicative lists of examples of articles supplied to the general public within the scope of this restriction (paragraphs 7 to 10 of entry 63)<sup>13</sup>

<b>Table 1-A Examples of clothing items</b>
Rainwear, anoraks, ski-jackets, wind-cheaters, wind-jackets
Trousers and breeches, including those made of cotton, wool, fine animal hair or man-made fibres shorts, bib and brace overalls, dresses, skirts and divided skirts, blouses, and shirts.
Braces, suspenders, garters and similar articles and parts thereof
Nightshirts, nighties and pyjamas, baby garments and clothing accessories, including vests, rompers, underpants, stretch-suits, napkins
Suits ensembles and blazers, tracksuits, ski suits, and jogging suits waistcoats, overcoats, car-coats, capes, cloaks
Gloves (incl. leather sports gloves, mittens and mitts)
Parts of garments or of clothing accessories
Adult/children jerseys, pullovers, sweatshirts, waistcoats and cardigans, of wool or fine animal hair
T-shirts, singlets and vests
Interior textiles and their decorative details (e.g. pillows, blankets etc.)

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<sup>13</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 within the reach of children 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-B Examples of footwear (typical outdoor footwear included in table of Annex 4)</b>
Sandals with rubber or plastic outer soles and leather 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)
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
Articles and equipment for table-tennis (including bats, balls and nets)
Tennis, badminton or similar rackets, whether or not strung
Balls (golf balls, table-tennis balls, punch balls)
Other articles and equipment for sport and open-air games
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>Table 1-D Examples of accessories</b>
Belts and bandoliers and any other type of clothing accessories
Trunks, suitcases, vanity-cases, briefcases, school satchels and similar containers
Handbags, and backpacks of leather plastic sheeting, textile materials or other materials (including those without a handle)
Cases and containers - eg. cigarette cases
Travel sets for personal toilet; sewing; or shoe or clothes cleaning
Manicure or pedicure sets and instruments (including nail files)
Sewing, knitting needle, bodkins of iron or steel, for use in the hand

Iron or steel snuff boxes, cosmetic and powder boxes and cases, and similar pocket articles
Sunglasses <sup>14</sup> , spectacles goggles and the like, corrective, protective or other (if not coated); Plastic and non-plastic spectacle frames and mountings for spectacles
Umbrellas (including sun umbrellas, walking-stick umbrellas)
Hair accessories (such as hair-pins, hair-bands etc.) not falling under the scope of paragraphs 1-6 of entry 63

**Table 1-E Examples of stationery items**

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>15</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, rulers etc. (excluding pencils for medicinal, cosmetic or toilet uses)
Metal or plastic-binder elements (such as spirals, rings, etc.)

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<sup>14</sup> Sunglasses and Spectacle frames: Exposure to lead from the part of the frames where migration 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 during normal and reasonably foreseeable conditions of use.

<sup>15</sup> Writing instruments: Except for the tip, 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 a-Annex 3)

<b>Table 1-F Examples of interior decoration items</b>
Furnishing articles including furniture and cushion covers for car seats (except for fixed furnishings)
Plastic, metals and wooden frames for paintings, photographs, mirrors or similar objects, wooden (painted) articles, candlesticks
Household articles and toilet articles, made of plastics, porcelain or china
Statuettes, mirrors and other ornamental articles made of base metal, plastic, ceramic or porcelain (including photograph, and pictures)
Bells, gongs, etc., non-electric, of base metal
Articles for Christmas, Easter etc. festivities, carnival or other entertainment articles (excluding candles, statuettes, statues and the like used for decoration of places of worship)
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, seats of cane, osier, bamboo or similar materials
Curtains and curtain weights <sup>16</sup> , table cloth weights

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<sup>16</sup> Curtain weights: Curtain weights as such are considered to be accessible, mouthable and within the range of a child so foreseeable use may occur. If the curtain weights are coated in plastic or another material that will prevent lead migration (and thereby fulfil the condition that "if migration can be demonstrated to be below the established limit in the terms of paragraph 7 of entry 63) these can then be considered as exempted from the restriction".

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

Blankets (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) and child car seats
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)

**ANNEX-2** Indicative lists of examples of articles supplied to the general public that fall out of the scope of this restriction (paragraphs 7 to 10 of entry 63)

**Table 2-A Article types exempted from the restriction (as indicated in paragraphs 7-10 of entry 63)<sup>17</sup>**

<i>Types of articles</i>	<i>Justification/conditions as explained in recitals of the restriction ( Commission Regulation (EU) 2015/628)</i>
Keys, locks, padlocks and musical instruments (par.8-e,f)	This derogation is based on socio-economic grounds including lack of suitable alternatives.
Crystal glass, enamels, and precious and semiprecious stones (par.8-b,c,d)	The exemptions were granted as the expected migration level is low.

<sup>17</sup> Please note that according to the paragraph 9 of entry 63 of Annex XVII to REACH, 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 the entry accordingly.

Brass alloys, if the concentration of lead in the brass alloy does not exceed 0.5% (par. 8-g)	This exemption was granted on the basis that migration rate of lead from brass alloys is regarded acceptable for articles with the stated maximum content limit.
Religious articles for consumer use (par.8-i)	They have been exceptionally exempted until a detailed assessment of the potential impact of applying the restriction is performed. Examples of this type of articles (whenever present in a household and not in special places of worship e.g. churches) are icons, crucifixes, rosaries, etc.
Portable zinc-carbon batteries and button cells batteries (par.8-j)	Both types of batteries, which are directly available to consumers, are exceptionally exempted from the scope until a detailed assessment of the potential impact of applying the restriction to them can be performed.
Tips of writing instruments (par.8-h)	This exemption was granted given the small size of the very tip of the ball pen (the part where the ink comes out) (Annex 3, picture-a), therefore there is a very low potential for exposure.
Articles covered by EU specific legislation (par.8-a and 8-k)	A list of articles covered by EU specific legislation under which lead is already regulated is presented in more details in table 2-B.
Articles (coated or not coated) with very low lead release (par.7)	The restriction shall not apply where it can be demonstrated that the rate of lead release from 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.
Articles placed on the market for the first time before 1 June 2016 (par.10)	This exemption indicates that "second hand" articles are not covered by the restriction.



**Table 2-B Article types which are exempted when covered by European Union legislation specifically regulating lead content and specified in the paragraphs 8(a) and (k) of entry 63**

<i>Type of articles</i>	<i>EU specific legislation</i>
Articles intended to come in to contact with food (e.g. kitchen utensils, ceramic articles for food/drinking use etc.) when covered by the specific EU legislation.	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.
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.
Toys	Directive 2009/48/EC on the safety of toys.
Jewellery articles	Paragraph 1(as referred in paragraph 8(a) of Entry 63 of Annex XVII to REACH. Restriction on lead in jewellery articles.
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-reachability under normal or reasonably foreseeable conditions of use**

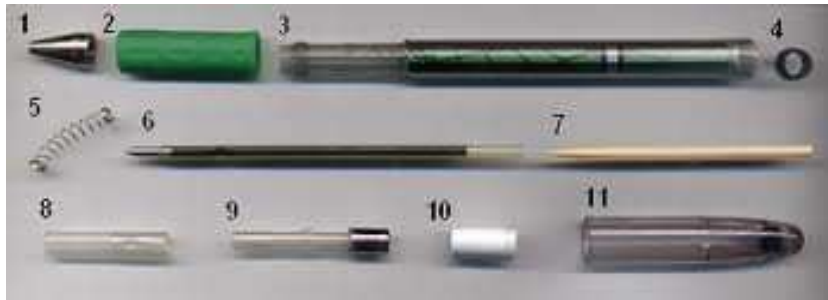
<i>Type of articles</i>	<i>Justification</i>
Ammunition (+fire arms and other weapons)	National legislation implementing Directives 91/477/EEC contains requirements to store ammunition securely in order to prevent unauthorised access, including access by children.
Fixed furnishings	The main part of fixed furniture (e.g. cupboards) is of a size that is assumed too big for mouthing. Furthermore, concerning door furniture the articles may be fixed to the door at such a height or in a manner that they cannot be reached by small children with the mouth (e.g. lever handles, knobs, back plates, roses, knockers). In those cases where they cannot be reached by children they are considered out of the scope of the restriction.
Fishing rods and weights	These have obviously sharp and pointed part of articles such as fishing hooks and are typically out of the reach of children in normal or reasonably foreseeable conditions of use.
Diving weights	Even though possibly mouthable (with side <5 cm in length), these generally will, due to their heavy weight, be out of the reach

	of children, under normal or reasonably foreseeable conditions of use.
Internal hinge mechanisms in frames	These are considered out of scope since due to their placement on the back side of a frame, they are not reachable by children under normal or reasonably foreseeable conditions of use. Internal hinges are not physically accessible when they are placed.
Material and articles for construction and building related applications (e.g. hinge mechanisms/ screws and nails/ pipes and sanitary tapware.).	The mouthability/ reachability of construction products by children is unlikely when these are incorporated in a permanent manner in construction works. Furthermore various articles used in buildings embedded or installed are not easily reachable by children under normal or reasonable and foreseeable conditions of use (e.g. hinge mechanisms, Annex 3 picture-b). Since both construction products and building related applications cover a wide range of articles, a case by case assessment should be performed.
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 not migrating (see table 2-A for the exempted types).
Collectors' tin based figures and ship miniatures	<p>Miniature figures and models, including miniature models of ships (see Annex 3-pictures c and d) made of pewter alloy are excluded from the scope of the restriction when:</p> <ul style="list-style-type: none"> <li>-they meet the definition to be considered as toys under the Toy Safety Directive (in which case the provisions therein apply) or;</li> <li>- they are outside the scope of the Toy Safety Directive because they are "products for collectors", such as "detailed and faithful scale models" or "historical replicas of toys" and each product or its packaging is labelled to indicate that it is</li> </ul>

	<p>"intended for collectors of 14 years of age and above<sup>18</sup> or;</p> <ul style="list-style-type: none"> <li>- these articles are solely used in museums and exhibition centres (e.g. to represent battles/historical events); or</li> <li>- these articles are enclosed in a container so that the figure cannot be reached by children.</li> </ul>
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**ANNEX-3** Pictures<sup>19</sup> of certain articles that fall in or out of the scope of the restriction

(a) Picture of a typical writing instrument (the tip is exempted, while "nose" and "clips" and other parts are considered mouthable , thereby within the scope)



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

<sup>18</sup> According to the Directive 2009/48/EC on the safety of toys, Annex 1, it is required that for certain articles which are products for collectors (thus not regarded as toys), the product or the packaging needs to bear a visible and legible indication that it is intended for collectors of 14 years of age and above. As examples of this category are e.g. detailed and faithful scale models.

<sup>19</sup> Images were provided by the following sources: (a)-(b) by Fotolia (2015), (c) by KLIO (2015) and (d) by Rhenania-Miniaturen (2015).

(b) Picture of a typical hinge mechanism (not mouthable under normal or reasonably foreseeable conditions of use)



(c) Picture of a typical tin-based figure (mouthable; whether reachable by children under normal or reasonably foreseeable conditions of use should be analysed on a case by case basis)



(d) Picture of a typical ship miniature (metal scale 1:1250/1:1200) (mouthable; whether reachable by children under normal or reasonably foreseeable conditions of use should be analysed on a case by case basis)



<b>ANNEX-4</b> <i>Examples of outdoor articles</i>	
<i>Type of articles</i>	<i>Scope clarifications (IN or OUT from the scope)</i>
Garden hoses <sup>20</sup>	IN (can be reached by children, in particular their tips, if left lying on the ground). However, hoses made of coextruded layers could be excluded from the scope if it can be demonstrated that the rate of lead release, including from the tips, does not exceed 0.05 µg/cm <sup>2</sup> per hour in the terms indicated in paragraph 7 of entry 63.
Outdoor shoes: <ul style="list-style-type: none"> <li>- Town footwear with rubber, plastic or leather outer soles and textile uppers</li> <li>- Tennis shoes, basketball shoes, gym shoes, training shoes and the like.</li> <li>- Waterproof footwear, with uppers in rubber or plastics</li> </ul>	IN (can be reached by children under normal or reasonable and foreseeable conditions of use).
Saddlery and harness for non-domestic animals kept outside the house (such as horses, cattle) made from any material (including traces, leads, muzzles, saddle cloths, saddle bags),	OUT (should be normally out of reach of children under normal or reasonable and foreseeable conditions of use).
Dog coats and similar items for other domestic animals/pets.	IN (these items could be reached by children since they are normally located in their proximity in a household).
Ski equipment	OUT (as they are relatively bulky and heavy articles which will normally be

<sup>20</sup> *Garden hoses.* The garden hoses are considered as mouthable and reachable by children, therefore under the scope of the restriction. The question about foreseeable use 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. Information provided by stakeholders have clarified that garden hoses manufactured by using recycled PVC are normally co-extruded, with recycled material sandwiched between two layers of virgin PVC. Hence only the middle layer may contain lead and will only be accessible at the tips of the hose.

	kept out of reach of children).
Garden and beach umbrellas	OUT (Due to their dimensions, weight and bulky nature these will generally not be mouthable under normal or reasonably foreseeable conditions of use).

**Change history**

<b>Revision</b>	<b>Comment</b>	<b>Date</b>
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