



REACH EU Regulation No. 1907/2006 re: Lead in Jewellery & other products infants mouthe

Extracts from the Official Journal of the European Union (OJEU), 19th September 2012, at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0836> and from OJEU, 23rd April 2015, at <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1582340438535&uri=CELEX:32015R0628>

In summary, the following extracts from a 2012 amendment and a 2015 amendment to the European Union Regulation No 1907/2006 show that jewellery put on the market for the first time since 9th October 2013 and other consumer articles which are small enough for young children to mouthe put on the market for the first time since 1st June 2016 in Europe (with a couple of exceptions) must not contain more than 0.05% lead [equivalent to 500 parts per million or ppm].

COMMISSION REGULATION (EU) No 836/2012 of 18 September 2012

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

THE EUROPEAN COMMISSION, Having regard to the Treaty on the Functioning of the European Union

Whereas:

...On 15 April 2010 France submitted to the Agency a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006, in order to initiate a restriction process in accordance with Articles 69 to 73 of that Regulation. In that dossier, it was demonstrated that due to their mouthing behaviour, children, especially those under 36 months, can be repeatedly exposed to lead released from jewellery articles. Such repeated exposure to lead can result in severe and irreversible neurobehavioural and neurodevelopmental effects, to which children are particularly sensitive given that their central nervous system is still under development. The dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, in order to avoid as much as possible the exposure to lead and its compounds in jewellery articles. Accordingly, the dossier proposes a prohibition of placing on the market and the use of lead and its compounds in jewellery articles if the lead migration rate is greater than 0,09 µg/cm²/h [0.09 micrograms of lead per square centimetre of product surface per hour].

In its opinion of 10 March 2011, the Committee for Risk Assessment (hereinafter 'RAC') considered that the most appropriate Union-wide measure to address the identified risks in terms of the effectiveness in



reducing the risks is the prohibition of the placing on the market and use of lead and its compounds in metallic and non-metallic parts of jewellery articles, if the lead concentration is equal to or greater than 0,05% [0.05%] by weight of the individual part, unless it can be demonstrated that the rate of lead released does not exceed the limit of 0,05 $\mu\text{g}/\text{cm}^2/\text{h}$ (0,05 $\mu\text{g}/\text{g}/\text{h}$ [0.05 micrograms of lead per gram of product per hour])....

In view of the current non-availability of a migration testing method mimicking mouthing conditions, SEAC considered that the restriction should be based on the content of lead in any individual part of jewellery articles, and not on the migration rate of lead released from such articles. In addition, SEAC recommended exemptions to be provided for crystal glass, vitreous enamels, internal components of watch timepieces as well as non-synthetic or reconstructed precious and semiprecious stones....A restriction on the placing on the market of second-hand and antique jewellery would have a significant socioeconomic impact, as such items would lose their marketable value in the Union, and would pose difficulties for enforcement. Therefore, jewellery articles placed on the market for the first time up to 12 months after the entry into force of the restriction as well as imported antique jewellery articles should be exempted from the restriction.



HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006

is amended in accordance with the Annex to this Regulation.



Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry 63 is added:

63. Lead CAS No 7439-92-1; EC No 231-100-4 and its compounds:

1. Shall not be placed on the market or used in any individual part of jewellery articles if the



concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05% [0.05%] by weight.

2. For the purposes of paragraph 1:

(i) "jewellery articles" shall include jewellery and imitation jewellery articles and hair accessories, including:

- (a) bracelets, necklaces and rings;
- (b) piercing jewellery;
- (c) wrist watches and wrist-wear;
- (d) brooches and cufflinks;

(ii) "any individual part" shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles.

3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making.

4. By way of derogation, paragraph 1 shall not apply to:

- (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC;
- (b) internal components of watch timepieces inaccessible to consumers;
- (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances;
- (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.

5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961.

6. By 9 October 2017, the Commission shall re-evaluate 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.

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

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Whereas:

On 21 December 2012, Sweden submitted to the European Chemicals Agency (hereinafter 'the Agency') a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006 (the Annex XV dossier), demonstrating that due to their mouthing behaviour, children, especially those under 36 months, may be repeatedly exposed to lead released from consumer articles containing lead or lead compounds. Lead and lead compounds are present in consumer articles as intentionally added metallic lead, as an impurity or additive of metal alloys (particularly in brass), as pigments, and as a stabiliser in polymers (particularly in PVC).

... On the basis of the established derived minimal effect level of lead, the mouthing behaviour of children and studies on lead migration from metallic parts of jewellery, a limit content for lead should be set which will apply to metallic and non-metallic parts of articles unless it can be shown that the rate of lead release does not exceed a certain threshold. For coated articles, the coating should be sufficient to ensure that this rate is not exceeded for a period of at least two years of normal use of the article.

Exemptions from this Regulation should be made for certain articles in relation to which the expected migration level is low, such as crystal glass, enamels and precious and semi-precious stones, or acceptable provided that a certain content limit is not exceeded, which may be the case for brass alloys, and for specified articles whose small size means that exposure to lead is minimal, namely tips of writing instruments.

... Keys, locks, padlocks and musical instruments can potentially be mouthed by children and therefore may pose a risk to children if they contain lead. However, those articles should be exceptionally exempted as there seems to be a lack of suitable alternatives to lead in the manufacture of those articles, and the possible adverse socioeconomic impact of applying the restriction to them could be significant. Similarly, the impact of applying the restriction to religious articles and certain batteries has not been fully assessed and it is therefore appropriate exceptionally to exempt them from its scope until a detailed assessment can be performed. Therefore, the new paragraphs in this entry should be reviewed after an appropriate period following their date of application, as well as the requirements on coating integrity. Articles already covered by specific Union legislation regulating lead content or migration should, for reasons of consistency, be exempted. Economic operators should be allowed a transitional period to adapt their manufacturing to the restriction laid down by this Regulation and to dispose of their stock not yet placed on the market. Furthermore, the restriction should not apply to second hand articles which were placed on the market for the first time before the end of that transitional period as that would give rise to considerable enforcement difficulties...HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.



Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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 7 to 10 are added:

‘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 % [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.

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/cm² per hour (equivalent to 0,05 µg/g/h [0.05 micrograms of lead per gram of product per hour]), 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.

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 cm in one dimension or has a detachable or protruding part of that size.

8. By way of derogation, paragraph 7 shall not apply to:

(a) jewellery articles covered by paragraph 1;

(b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/EEC;

(c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/87) unless they have been treated with lead or its compounds or mixtures containing these substances;

(d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500°C;



- (e) keys and locks, including padlocks;
 - (f) musical instruments;
 - (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 % [0.5%] by weight;
 - (h) the tips of writing instruments;
 - (i) religious articles;
 - (j) portable zinc-carbon batteries and button cell batteries;
 - (k) articles within the scope of:
 - (i) Directive 94/62/EC;
 - (ii) Regulation (EC) No 1935/2004;
 - (iii) Directive 2009/48/EC of the European Parliament and of the Council [re: toys] ;
 - (iv) Directive 2011/65/EU of the European Parliament and of the Council [re: electrical and electronic equipment]
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.
10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016.