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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[(1)], and in particular Article 68(1) thereof,

Whereas:

(1) 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).

(2) Repeated exposure to lead from mouthing of articles containing lead or its compounds 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 placing on the market and use of lead and its compounds in articles that are supplied to the general public, and which can be placed in the mouth by children, should therefore be prohibited if the concentration of lead (expressed as metal) in that article, or part of the article, exceeds a certain threshold.

(3) On 10 December 2013, the Committee for Risk Assessment (hereinafter 'RAC') adopted its opinion, concluding that the restriction is the most appropriate Union-wide measure to address the identified risks posed by lead and its compounds present in

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articles intended for consumer use in terms of the effectiveness in reducing such risks and proposing certain modifications of the scope of the restriction.

(4) On 13 March 2014, the Committee for Socio-Economic Analysis (hereinafter 'SEAC') adopted its opinion in which it concluded that the restriction proposed by the dossier submitter, as modified by RAC and also by SEAC, was the most appropriate Union-wide measure to address the identified risks, in particular in terms of proportionality. This conclusion was reached after analysis of available socioeconomic evidence and on the basis of best available estimates for uncertainty factors, taking into account that there is no threshold for the neurobehavioural and neurodevelopmental effects of lead.

(5) The Agency's Forum for Exchange of Information on Enforcement was consulted during the restrictions process and its opinion was taken into account contributing to a modified description of the scope and exemptions from the proposed restriction.

(6) It has to be concluded that an unacceptable risk to human health arises from the presence of lead and its compounds in articles supplied to the general public exceeding the content limits or, alternatively, the migration rate limit as specified in the opinions. Those risks need to be addressed on a Union-wide basis.

(7) 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.

(8) 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.

(9) 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.

(10) Articles already covered by specific Union legislation regulating lead content or migration should, for reasons of consistency, be exempted.

(11) Guidelines regarding articles that fall within and outside the scope of this restriction should be developed to assist economic operators and enforcement authorities in its implementation.

(12) 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.

(13) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

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.

Done at Brussels, 22 April 2015.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/628. (See end of Document for details)*

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 % 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/cm^2 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. 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.

a	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).
b	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).’