



New Requirement on Lead in Products Accessible to Children in Annex XVII to REACH Regulation

Date : 2015-04-29

In entry 63 of Annex XVII to REACH Regulation, lead limit was officially amended in accordance with Regulation (EU) 2015/628 of European Commission on 22 April 2015 and published on Official Journal of the EU on the next day.

For amendment to entry 63, the concentration of lead of the products that can be placed in the mouth by or accessible to children shall not exceed 0.05%, among which the products with rates of lead release that lower than $0.05 \mu\text{g}/\text{cm}^2 / \text{hour}$ or $0.05 \mu\text{g}/\text{g}/\text{h}$ can be derogated. The limit will take into effect on 1 June 2016. Refer to the following for detailed entries.

Time Line:

- (1) Sweden submitted a dossier of Annex XV on 21 December 2012
- (2) The limit proposal officially passed after review of RAC (Committee for Risk Assessment) on 10 December 2013
- (3) SEAC had proposed to accept public consulting from 11 December 2013 to 14 February 2014
- (4) European Commission and REACH Commission Conference passed the entry for such limit on 3 December 2014
- (5) EU informed WTO of the entry draft on 25 September 2014
- (6) [Regulation \(EU\) 2015/628](#) of the commission was officially signed by President of European Commission, Jean Claude-Juncker on 22 April 2015
- (7) Official Journal of the EU published (EU) 2015/628 on 23 April 2015. >>[Official Journal](#)

In Annex XVII to Regulation (EC) No 1907/2006, column 2 of entry 63 is amended as follows: 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.'
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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 $0,05 \mu\text{g}/\text{cm}^2$ per hour (equivalent to $0,05 \mu\text{g}/\text{g}/\text{h}$), 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.
	8. By way of derogation, paragraph 7 shall not apply to: (a) jewellery articles covered by

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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 % 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(*); (iv) Directive 2011/65/EU of the European Parliament and of the Council(**)

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.

(*) 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).

(**) 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).'

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