



REACH 法规附件 XVII 新增儿童接触

产品中铅含量的要求

Date : 2015-04-29

REACH 法规附件 XVII 条款 63, 铅含量的要求于 2015 年 4 月 22 日由欧盟委员会法规(EU) 2015/628 正式修订, 并于次日在欧盟官方公报 (Official Journal of the EU) 中发布。

此次, 针对条款 63 的修订, 要求儿童可入口及可接触产品的铅含量不得高于 0.05%, 对铅释放量低于 $0.05 \mu\text{g}/\text{cm}^2/\text{hour}$ 或 $0.05 \mu\text{g}/\text{g}/\text{h}$ 的产品可以豁免, 限量将于 2016 年 6 月 1 日开始生效。详细条款请参见下文。

时间表:

- 2012 年 12 月 21 日, 瑞典递交 Annex XV 卷宗
- 该限制提案, 由风险评估委员会 (RAC, Committee for Risk Assessment) 于 2013 年 12 月 10 日正式审核通过。>> [详情](#)
- 2013 年 12 月 11 日-2014 年 2 月 14 日, SEAC 意见接受公众咨询
- 2014 年 12 月 3 日, 欧盟委员会, REACH 委员会会议通过该限制条款 >> [详情](#)
- 2014 年 9 月 25 日, 欧盟委员会通知 WTO 该项委员会条例草案>> [详情](#)
- 2015 年 4 月 22 日, 委员会法规(EU) 2015/628 由欧盟委员会主席 Jean Claude-Juncker 正式签署
- 2015 年 4 月 23 日, 欧盟官方公报发布(EU) 2015/628>> [官方公报](#)

具体修订内容如下:

REACH 法规 (Regulation (EC) No 1907/2006) 附件 XVII 第 63 条第 2 列修订情况如下:

(1) 第 6 段替换如下:

6.2017 年 10 月 9 日之前, 委员会应该就 1-5 段内容结合最新的科学信息对其替代品以及第 1 段中的限值进行重新评估, 如果有必要, 根据相关信息修订本条款。

(2) 新增以下 7-10 条:

7.在正常合理可预计的条件下, 能被放入儿童口中的产品以及可接触部件中的铅含量 (以铅计) 大于等于 0.05%的, 不得在投放市场或在供应给公众的产品中使用。该限量不适用于: 产品以及其任何可接触部件的铅释放量低于 $0.05 \mu\text{g}/\text{cm}^2/\text{hour}$ (或 $0.05 \mu\text{g}/\text{g}/\text{h}$) 的, 不管是否带涂层; 另外要求带涂层的物品, 至少保证在正常使用情况下, 两年内其铅的释放量不得超过以上限量。

物品及其可接触部件可被儿童放入口中的判别依据为: 产品某一维度的尺寸小于 5cm, 或者其某一可分离部件或突出部位的尺寸小于 5cm。

8.作为条款 7 的豁免, 以下产品不受管控

(a)第 1 段中已经管控的珠宝类产品;

(b)理事会指令 69/493/EEC 的附件 I (1, 2, 3 和 4 类) 中定义的水晶玻璃;

(c)非合成或再生的贵重宝石和装饰性宝石 (CN 码 7103, 归于条例(EEC)No 2658/87 中), 除非其用铅或铅化合物或者经含有此类物质的混合物处理;

(d)珐琅, 被定义为至少在 500°C 的温度下矿物融化、玻璃化或烧结而得到的玻璃化混合物;

(e)包括挂锁在内的钥匙和锁;

(f)乐器;

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(g)物品或者物品的某部分由黄铜组成,其黄铜部件的铅浓度(以铅计)不得超过 0.5% (质量分数);

(h)书写工具的尖端;

(i)宗教产品;

(j)便携式锌-碳化学电池以及纽扣电池;

(k)以下范围内的物品:

(i)Directive 94/62/EC 欧盟包装指令

(ii)Regulation (EC) No 1935/2004 欧盟食品接触材料法规

(iii)Directive 2009/48/EC 欧盟玩具安全指令

(iv)Directive 2011/65/EU 欧盟 RoHS 2.0

9. 在 2019 年 7 月 1 日前,委员会应根据最新科技信息,对第 7 段和第 8 段(e), (f), (i) 和 (j)条款的替代物的适用性、以及第 7 段中提到的铅迁移量,以及涂层的完整性要求进行重估,若合适,则应据此进行修订。

10.首次投放市场日期在 2016 年 6 月 1 日之前的,不受第 7 段管控。

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希科检测

实验室依据 ISO/IEC 17025 建立实验室管理体系,并持续有效运作,希科检测在继承原瑞旭技术检测项目部精良设备和精锐人才的同时,不断增配更先进的人才、设备及技术,现已成为全球知名的专业性、综合性、国际性的独立第三方检测机构,专业开展产品测试及认证服务,涉及电子电器、玩具、纺织品、汽车、家具、化妆品、食品接触材料、环境及化工等多个行业,能够满足全球不同地区和市场的相关监管要求。



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

Date : 2015-04-29

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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