

Sweden proposes a restriction on Lead and its compounds in articles intended for consumer use¹

SUMMARY

Sweden has submitted a proposal recommending a restriction on the placing on the market or use of lead and its compounds in articles (or individual parts of articles), which are supplied to the general public and can be placed in the mouth by children, if the concentration of lead (expressed as metal) in the article is equal or greater than 0.05% by weight.

Lead and its compounds have a wide use and have been found in a great variety of applications, some of them being articles for consumer use. Lead is usually present in metal alloys, in pigment/dyes, and to a lesser extent as pure metal and as stabiliser in plastic.

All lead compounds are classified as category 1 or 2 reprotoxic. Elemental lead is not yet classified but has been shown to cause non-threshold neurotoxic and neurodevelopmental effects, in particular for children. The restriction proposal targets the health effects of lead in small children, that may result from an exposure to lead which can migrate from materials in articles for consumer use. The main route through which small children (six to 36 months) are exposed to lead from the consumer articles is by mouthing, which results to the impairment of their developing central nervous system. This is the most sensitive effect.

According to the proposal the benefits of the restriction would be nine times higher than the compliance costs. Therefore, the proposed restriction is considered to be proportional as it effectively reduces the identified risks and has increased health impacts whilst having relatively low costs.

ECHA today starts the public consultation on the restriction report, which will end on 21 September 2013. However, the interested parties are invited to provide any comments by 1 June 2013 in time for the first discussion of the restriction proposal in the committee's meetings of June 2013.

SUGGESTED RESTRICTION

Sweden has submitted a report (a so called Annex XV report) proposing a restriction of lead and its compounds in articles intended for consumer use. In the report, it is proposed that: *lead and its compounds shall not be placed on the market or used in articles or individual parts of articles, which are supplied to the general public and which can be placed in the mouth by children, if the concentration of lead (expressed as metal) in that article or part of article is equal to or greater than 0,05% by weight.*

The proposed restriction will apply 12 months after the amendment of the REACH Annex XVII comes into force.

¹ The information note has been prepared based on the Annex XV report prepared by Sweden.

PUBLIC CONSULTATION

By the way of derogation, the proposed restriction shall not apply to keys, locks and music instruments. A re-evaluation of the exemptions is recommended 5 years after the entry into force, in light of the technical information, including the availability of alternatives.

LEAD AND ITS COMPOUNDS IN ARTICLES INTENDED FOR CONSUMER USE

Lead is often found in different kinds of goods available to consumers for which the use is not restricted today. This has been described, for instance in RAPEX (Rapid Alert System for non-food products posing a serious risk) reports listed annually by the Commission. Lead is usually present in metal alloys (notably brass), in pigments/dyes, and to a lesser extent as stabilisers in plastic and as pure metal.

The articles addressed in this restriction proposal are those intended for consumer use, which can be placed in the mouth by children, and where those articles contain lead or lead compounds in any individual material of the article. Examples on such articles are clothes, shoes, accessories, interior decorations, articles for sports and leisure, stationery and keys.

According to published studies and testing applied by the Swedish Competent Authority (KemI), 10% of the consumer articles that are frequently placed in the mouth by children, (and are not covered by other regulations), contain lead at an average concentration of around 1%.

REASONS FOR ACTION

Under the CLP Regulation, ((EC) 1272/2008 on Classification, Labelling and Packaging of substances and mixtures) the lead compounds (but not elemental lead) are classified as reprotoxic category 1 and 2. Lead, however, has been shown to cause non-threshold neurotoxic and neurodevelopmental effects. The most sensitive effect of lead, in particular in children, is its ability to negatively impact their developing central nervous system. The restriction proposal globally concerns lead and all its compounds, since the toxic species causing the harmful effects is the lead ion itself and the exact lead compounds in consumer articles cannot be identified and quantified with the existing analytical methods.

The restriction report assesses children's exposure to lead through placing lead containing articles in their mouth, and the increased risk of IQ reduction. According to the exposure estimations, for consumer articles containing 1% lead, realistic mouthing times led to an exposure of approximately 0.2 µg/kg bw/day resulting in an IQ loss of 0.4 units. This exposure already exceeds the DMEL (Derived Minimal Effect Level) value of 0.05 µg/kg bw/day² agreed by RAC in 2011 (that corresponds to IQ loss of 0.1 unit) and is therefore not acceptable.

In spite of the implemented measures (other EU legislation), altogether between 5% and 18% of European children aged 6–36 months are at risk of being exposed to lead from consumer articles at levels that impact their neurological development. In addition, a Union wide restriction of lead in consumer articles would treat equally imports and domestic production.

² Based on the BMDL (Benchmark Dose Level) value proposed by EFSA (European Food Safety Authority), scientific opinion on lead in food, 2010.

CONSEQUENCES OF THE ACTION

The action proposed in this report is a restriction in which articles intended and available for consumer use, which can be placed in the mouth by children, may be placed on the market only if they do not contain lead above a limit value of 0.05% by weight.

This restriction option is intended to accurately target all those consumer articles for which the exposure scenario (based on the mouthing behaviour of small children) is applicable. It restricts lead content and therefore assures a high level of protection, as lead can never migrate from lead-free products. Moreover, it is tailored to be aligned with the existing restriction of lead in jewellery (entry 63 of Annex XVII of REACH) and can therefore be applied consistently in the whole range of mouthing articles including jewels.

The proposed restriction is expected to have a high risk reduction capacity by reducing children's exposure to lead by 87%, as compared to the baseline situation. It is also concluded that the overall health benefits (related to cognitive abilities as measured by IQ) are 9 times higher than the compliance costs.

Altogether, the proposed restriction is considered to be proportional as it effectively reduces the identified risks associated with lead and its compounds in articles whilst keeping the societal costs at a lower level than the societal benefits.

COMMENTS PREFERABLY BY 1 JUNE 2013

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 21 March 2013. Interested parties can comment on the proposal and the restriction report using the ECHA website. Although the public consultation concludes on 21 September 2013, ECHA would appreciate receiving comments by 1 June 2013 to assist the Committees in the detailed discussion of the restriction proposal in June 2013.

The final opinions of both Committees are scheduled to be available by 21 March 2014 (RAC opinion scheduled for December 2013 and SEAC opinion for March 2014). ECHA will send these two opinions to the European Commission, which will take the decision whether to include new restrictions in Annex XVII of the REACH Regulation.