ECHA proposes a restriction on lead compounds in PVC articles[1]

Summary

The European Chemicals Agency (ECHA) has, at the request of the European Commission, submitted a report proposing a restriction on the placing on the market on PVC articles containing lead compounds as stabilisers in concentrations greater than 0.1% by weight. Lead compounds are widely considered as a group of substances (the intrinsic properties of which are defined by the lead cation), which are hazardous for both human health and the environment.

It is well established that exposure to lead can result in severe neurobehavioral and neurodevelopmental effects, even at a low doses. Lead is considered a non-threshold neurotoxic substance associated with adverse impacts on the development of children's central nervous systems.

The public consultation on this proposed restriction will start on 22 March 2017 and end on 22 September 2017. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome any early comments, by 01 June 2017, to assist them in the first discussions of the restriction proposal.

SUGGESTED RESTRICTION

Scope

The proposal is to restrict placing on the market of lead compounds used as stabilliers in articles (or parts of articles) produced from polyvinyl chloride (PVC) if the concentration of lead (expressed as metal) is equal to or greater than 0.1% by weight of the PVC material. The proposal was made on the request of the European Commission. The proposed restriction shall apply 24 months from the entry into force of the restriction.

More specifically, the proposal will restrict the placing on the market of articles in whose production lead compounds have been used as PVC stabilisers. These articles are most commonly produced of rigid PVC and are mainly used in building and construction relevant applications (making up 70-80% of PVC uses in the EU). Examples are:

- window profiles,
- fittings, pipes and tubes,
- rolling shutters and gutters,
- wires and cables,
- roofing and flooring tiles, etc.

It should be noted, though, that the proposed restriction covers all PVC articles (based

[1] The information note has been prepared based on the Annex XV report prepared by ECHA.

on both rigid and soft PVC) and for all applications (consumer, industrial and professional).

The proposal will also restrict the use of lead stabilisers in PVC mixtures that are then used to produce articles. However, the intention of the restriction is not to prevent manufacture of the stabilisers or production of PVC mixtures containing lead stabilisers that are then exported.

The proposed restriction derogates:

- the following article types containing recycled PVC for a period of 15 years from entry into force, if the concentration of lead (expressed as metal) does not exceed 1% by weight of the PVC material:
  - profiles and rigid sheets for building applications;
  - doors, windows, shutters, walls, blinds, fences, and roof gutters;
  - cable ducts;
  - fittings for tubes, furniture etc.;
  - pipes for non-drinking water, if the recycled PVC is used in a multilayer pipe and is entirely enclosed with a layer of virgin PVC in compliance with the general restriction limit.
- PVC-silica separators in lead acid batteries for a period of 10 years.
- Articles that can be placed in the mouth by children (paragraph 7 of Entry 63 of Annex XVII) or articles covered under existing legislation on: food contact materials[2], electrical and electronic equipment[3], packaging[4] and toys[5].
- articles placed on the market prior to the application of the restriction (envisaged two years after entry into force i.e. probably 2021.

Reasons for action

The proposed restriction is targeted at PVC articles produced using lead-based stabilisers that cause risks to human health, by contributing to overall lead exposure via various exposure pathways. The approach used to demonstrate risk in this proposal is inline with other REACH restrictions[6] for substances where it is not possible to establish a threshold (in line with Annex I of REACH, paragraph 6.5). In these cases a comprehensive exposure and risk characterisation of such substances is not required. Instead, releases of lead from PVC articles are used as a proxy for risk.

Total lead emissions from PVC articles placed on the EU market in 2016 were modelled to be between 4.3 and 10.3 tonnes with a central estimate of 6.8 tonnes. Lead released during the disposal phase accounts for approximately 95% of emissions (the remainder being released during service life). Since the European PVC industry has already initiated the phase-out of lead compounds as PVC stabilisers, around 90% of the estimated lead emissions are attributable to PVC articles imported into the EU during 2016. Import data

[2] covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011 on plastic materials;
[3] covered under 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 (RoHS Directive);
[4] Directive 94/62/EC on packaging and packaging waste;
[5] Directive 2009/48/EC on the safety of toy.

6 See e.g. the Annex XV restriction proposals for mercury, phenyl mercury, decaBDE, PFOA and related substances and D4/D5.

from Eurostat (2016) indicate that imports of relevant PVC articles have progressively increased (resulting in a 140% volume increase between 2010 and 2015) and are likely continuing to do so without a restriction in place. This highlights the need for Union-wide action to lower lead emissions to the European environment and to reduce human exposure to lead.

Based on the above, ECHA's assessment concluded that the identified risk to humans from lead stabilisers in PVC articles in the EU is not adequately controlled.

More specifically, the proposed restriction is expected:

- to strengthen the effectiveness of an existing voluntary action by the European PVC industry (the so-called Vinyl Plus agreement), aiming at a complete phase-out of lead-based PVC stabilisers in the EU.
- to further reduce human exposure to lead from PVC articles that are imported from non-EU countries (where lead compounds are still used as PVC stabilisers).

Consequences of the action

The proposed restriction will cost-effectively reduce human exposure to lead in the EU. The reduction in lead emissions to the environment is used as a proxy for the risk reduction capacity of the restriction.

Based on a simulation of the total volume of lead-containing PVC articles placed on the EU market in 2016, the net compliance costs of the proposed restriction have been estimated to be in the range of € 0.9 to 3.3 million per year (with a central value of € 2.1 million). The calculation was made assuming that technically and economically feasible alternatives to lead PVC stabilisers are already available on the EU market with calcium-based systems being the systems of choice for lead substitution in the EU.

The R&D costs for transitioning any remaining uses to the alternative as well the testing and enforcement costs are anticipated to be low for all the actors concerned. In conclusion, it is assumed that the total economic impact in 2021 (indicative year for the proposed restriction to enter into force) should be substantially lower than in 2016, but no quantitative assessment on the development of compliance costs was undertaken. In addition, no significant social impacts (e.g. loss of employment, or impact on consumers) are expected from the implementation of the proposed restriction.

The cost-effectiveness of the proposed restriction is estimated to be between € 100 and € 2 500 per kg of lead emissions avoided with a central cost-effectiveness estimate of roughly € 300 per kg. This value of cost-effectiveness is in the same order of magnitude or lower than previous restrictions under REACH.

As cost-effectiveness is not a welfare economic measure, an additional break-even analysis was performed based on a developed causal lead impairment model. The break-even analysis suggests that the restriction breaks even if 1.24 g or more of the lead emitted per year would be ingested by humans. Based on the cost-effectiveness and the break-even analysis, the proposed restriction is considered to be proportionate in reducing the identified risk.

ECHA's assessment also concluded that the proposed restriction is implementable (technical feasible alternatives exist/sufficiently long transition period provided), enforceable (analytical methods for lead determination available) and manageable for the various industrial actors involved (existing voluntary agreement at EU level).

SPECIFIC INFORMATION REQUESTED

A few specific elements have been addressed in the Public Consultation to gather relevant information if available,, however stakeholders are invited to submit also any other information that they consider relevant for the opinion making

Question-1: How much lower could the proposed 1% limit in recycled PVC be without hindering the recycling process (e.g. could it be lower for some types of products)? What is the current lead concentration in PVC articles made from recyclate? Is it necessary to add supplementary lead-based stabilisers during PVC recycling?

Question-2: If PVC waste is exported outside the EU for recycling, or for other reasons what are the quantities and is there an increasing trend? Please also specify the reason for export (if known).

Question-3: Please provide any available data on the market share of the lead-stabilised PVC articles imported into the EU as well as any other relevant information (e.g. number of importers, size of companies, market trends etc.). If you are an importer we would be interested in the quantity of PVC you import and if it contains lead as a stabiliser (this can be done confidentially).

Question-4: Please provide any additional information concerning possible socio-economic impacts of the proposed restriction. Such information might include, for example, figures on costs or cost savings as well as impacts on employment in any sector potentially impacted (e.g. lead compounds manufacturers, producers of alternatives, PVC convertors etc.). In particular impacts on SMEs (e.g. investment and effort needed to substitute lead-based stabilisers) would be of interest.

Question-5: Are there any PVC articles stabilised with lead compounds, and placed on the EU market, other that those identified in the proposal? Please indicate (i) whether these are produced by soft or rigid PVC (ii) the range of lead concentrations in these PVC applications.

Comments preferably by 01 of June

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 22 March 2017. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 22 September 2017 the rapporteurs of RAC and SEAC would appreciate receiving comments by 01 June to assist them in the early opinion development process.

The final opinions of both Committees are scheduled to be available by March 2018. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

PUBLIC CONSULTATION

Further information on the purpose, objectives, and process of the public consultation on restriction proposals is available in the Public Consultation Guidance http://echa.europa.eu/docu ments/10162/13641/public_consultation_guidance_en.pdf

Please note: Information arriving after the closing date of the PC (via other channels e.g. emails) will not be taken into account by RAC/SEAC.