# EEB Comments on the proposal of the restriction of Lead compounds-PVC

## *Background*

The EEB strongly supports ECHA's proposal to restrict the use of lead in PVC. We thank the COM for their attention to this issue and ECHA for preparing the dossier. This proposal would restrict the use of lead-stabilised PVC, whether manufactured in the EU or imported, setting a limit of 0.1% lead by weight.

The restriction is plainly feasible and affordable. Previous efforts to remove lead from PVC have been widely successful, and today most or all PVC sold in the EU is lead-free.[1] ECHA rightly concludes that the investment, development, and testing costs associated with the restriction are "negligible".[2]

EU-wide action is necessary. The EU PVC industry has today almost entirely phased out lead stabilisers. Most lead emissions from PVC sold in the EU today and in the future – around 90% – can be attributed to imported PVC articles. [3] Although most human exposure to lead is due to historical sources including leaded gasoline and paint, abrasion of PVC articles like window frames, contact with PVC fittings including shutters and blinds, and leaching of lead from PVC pipes into drinking water each represent potential exposure routes to consumers.[4] Emissions due to disposal, especially by incineration, are also important.

The use of recycled PVC made of lead contaminated legacy PVC is also a source of human and environmental exposure to lead.

## *Lead toxicity*

Lead is a potent toxic substance with a complex and widely varied toxicity. Lead exposure impairs neurobehavioral function, particularly as a result of childhood, fetal, or occupational exposure. Lead has effects on nearly every organ system, including cardiovascular,

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1 Tauw 2013, Impact of lead restrictions on the recycling of PVC, http://www.vinylplus.eu/uploads/Modules/Documents/2013_07_13-impact_lead-restrictions_pvc_recycling-tauw.pdf, p28

2 Annex XV Restriction Report: Lead compounds - PVC, p39

3 Annex XV Restriction Report: Lead compounds - PVC, p4

4 Annex XV Restriction Report: Lead compounds - PVC, p12-13

hemopoietic, and renal impacts.[5] As an element, lead is persistent in the global environment.

Inorganic lead compounds have been identified by IARC as "probably carcinogenic to humans" (Group 2A). Organic lead compounds are listed as Group 3 ("Not classifiable"), but are metabolised into ionic lead with carcinogenic properties of inorganic lead.[6] A substantial body of data indicates that lead is likely to be an endocrine disrupter, with effects including delayed puberty/menarche, steroidogenesis, altered and delayed spermatogenesis, decreased fertility, and possible changes to the sex ratio of births.[7]

As with other carcinogens and endocrine disrupters, there is no safe threshold for lead exposure. In fact, there is evidence that lead's impacts on children's neurodevelopment are greatest at the very lowest doses.[8]

### *Goal: Reduce lead in PVC recycling loops, reducing exposure not just via the covered articles but into the recycled future.*

The purpose of this restriction is not clearly stated in the Annex XV dossier, and requires clarification. The proposal "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 phrasing "targeted at PVC articles... that cause risks to human health" may be unclear. The restriction is not (and should not be) intended to reduce immediate consumer exposure to lead via PVC articles placed on the market. Recycling of PVC materials is significant and is increasing; in 2015, over half a million tonnes of PVC was recycled.[9] Therefore, any use of lead in PVC is problematic, since PVC, when recycled, may continue to contribute to overall lead exposure. Given the non-threshold neurotoxicity of lead, it's critical to keep lead out of the supply and recycling chains. As the EU moves towards a circular economy, any lead introduced has the potential to contaminate the supply chain far into the future.

We concur with the advice of ECHA's Enforcement Forum that the phrase "as stabilisers" should be omitted from the restriction text.[10] It is true that the function of lead added to PVC is to stabilize PVC; but the goal of the restriction is to reduce the amount of lead in PVC, regardless of use. Inclusion of the phrase "as stabilisers" adds unnecessary specificity. It might, for example, lead to a situation where a regulating authority is required to prove that stabilisation is the purpose of added lead. We recommend striking this phrase throughout, referring simply to "PVC articles containing lead compounds".

### *Closed loops must be clean loops*

As we begin to approach the circular economy, it is critical to make sure that the closed loops are clean.

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5 HSDB: lead compounds. https://toxnet.nlm.nih.gov/

6 IARC. http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf

7 Dyer. (2007.) "Heavy Metals as Endocrine-Disrupting Chemicals." In Endocrine-Disrupting Chemicals, 111–33. Contemporary Endocrinology. Humana Press. doi:10.1007/1-59745-107-X_5.

8 Canfield et al (2003). "Intellectual Impairment in Children with Blood Lead Concentrations below 10 µg per Deciliter." New England Journal of Medicine 348(16): 1517–26. doi:10.1056/NEJMoa022848.

9 VinylPlus (2016). http://www.vinylplus.eu/mediaroom/53/55/VinylPlus-announces-more-than-500-000-tonnes-of-PVC-recycled-in-2015

10 Enforcement Forum (2017). Advice on Enforceability on Restriction proposal regarding LEAD IN PVC. Final version–June 2017.

More recycling is often an appropriate goal. However, it is as important to have a clean closed loop as it is to increase recycling rates.

The comment during public consultation by Federchimica makes a typical argument: "We need to decrease as much as possible incineration and landfill (both are unsustainable habits going against the Circular Economy principle), and promote as much as possible re-use and recycling".[11] This comment ignores the very potent and non-threshold nature of lead toxicity. Recycling is a priority, but recycling of toxic materials will contaminate the entire circular economy into the future. In the interests of keeping recycling loops clean, contaminated products should be placed in specific hazardous waste landfills (not incinerated) instead of recycled, unless they can be decontaminated ahead of recycling.

This point indicates the urgency of setting stringent thresholds for lead in PVC. With a completely persistent (i.e., elemental) hazard like lead, phasing out use as fast as possible is the only good option, since neither recycling (of a toxic material) or disposal (landfilling or incinerations) are sustainable approaches.

### *Thresholds must be kept low, and derogations and exemptions minimized*

Keeping recycling loops as clean as possible ensures their viability into the circular economy. It is critical that thresholds for lead in PVC be kept as low as feasible.

ECHA proposes to derogate the 0.1% threshold for 15 years for a wide range of building materials, allowing up to 1% Pb use in these applications. But no clear justification is given for this derogation or for why the 1% threshold was chosen.[12] Section 2.3.3.1 of the Annex XV dossier says, "PVC recyclers/converters highlighted [that] in order to comply with a limit of 0.1%, only 10% of an article could be made from (the cheaper) recycled PVC, therefore, PVC recycling would no longer be economically viable and would have to stop". Yet no data is supplied to justify this statement, or to describe the level of recycling that would be required in order to make recycling economically viable. In fact, an analysis from VinylPlus says only that "such low rates usually do not justify" the co-processing of recycled PVC [13], whereas comments from Sweden demonstrate that 10% recycling is a typical value for recycled window frames[14] – so the idea that this is a minimum for economic viability is clearly not the case.

ECHA estimates that if recycling were to stop in 2020, additional lead releases (from incineration and landfilling "would be approximately 23 tonnes (between 9-43 tonnes considering the 10-90 percentile)."[15] (Most of this emission is due to incineration; see Annex XV table 7.) But this comparison is invalid, since ECHA assumes that recycled lead has zero emission. In fact, recycled leaded PVC remains in the use phase, during which it still has appreciable emission to the environment (see Annex XV Table 7). Furthermore, depending on efficiency of PVC recycling, much or all of this material will ultimately be disposed of through landfilling or incineration. Current PVC recycling rates are around 10%, and industry hopes to reach 20% by 2020; in either case, most of this leaded PVC will ultimately be disposed.[16] Recycling of leaded PVC postpones, but does not prevent, these emissions.

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11 Lead in PVC public consultation, comment #1521.

12 One comment (#1513) requested a 2% threshold for this derogation; but since leaded PVC is typically less than 2%, this amounts to a blanket allowance for full use of lead stabilisers as long as the derogation applies.

13 Tauw 2013, Impact of lead restrictions on the recycling of PVC, p9 [emphasis added]

14 Lead in PVC public consultation, comment #1539.

15 Annex XV, p35

Moreover, the numbers do not support this analysis of recycling rates. Given PVC raw material uniformly stabilised with 1% Pb, a mix of 10% recycled material (with 0% Pb virgin PVC) could be used to meet a 0.1% threshold. However, not all PVC products use lead stabilisers. The Annex XV dossier gives 30% as an average share of lead stabilisers for exported PVC items, and estimates that 20 to 60% of PVC imported into the EU (in 2016) was lead-stabilised.[17] Depending on the fraction of leaded PVC in a recycling batch – which in some cases can be estimated by product category – a much larger proportion of recycled PVC can be included while still meeting the 0.1% threshold. Enabling a 1% threshold for recycling could lead to dilution and further diffusion of lead in applications embedding recycled material.

Ensuring compliance with any standard, whether 1% or 0.1%, will require batch testing (except when the leaded PVC recycled content is precisely known). Fortunately, testing costs are anticipated to be "insignificant" and "negligible".[18] One comment made during public consultation is that testing costs might be high (the cited cost is €200 per sample) if the threshold value is set "too low".[19] This is misleading, as 0.1% is the same threshold required for testing of electronics components under RoHS. Such tests are easily performed with handheld XRF, a robust and mature nondestructive test technology that can accurately detect lead in seconds. Handheld XRF is widely available for the specific purpose of testing lead at the 0.1% threshold for RoHS compliance. Applying this technology to batch recycling processing would add very little time, effort, or cost, allowing for rapid and accurate adjusting of recycling mixtures as necessary to comply with the lower 0.1% threshold.

The estimates of leaded PVC given above apply to exports and imports; but EU-produced PVC sold in the EU is now largely lead-free. With implementation of the current restriction proposal, a large and growing fraction of the total PVC stock in the EU will be lead-free. As the overall lead content of PVC in use declines, and leaded PVC articles become rarer, less and less adjustment will be necessary to keep recycled PVC under 0.1%. Thus, a long derogation period is not necessary. By contrast, keeping the threshold for recycled PVC at 1% only postpones the problem until the next generation of PVC recycling.

### *Exports must also be covered*

The proposed restriction has clear benefits for public health at little or no cost. As such, it must also be applied to exports. As drafted, the restriction is not intended to apply to exported lead stabilisers or lead-stabilised PVC, a limitation with which we strongly disagree.

The Commission has the clear and explicit power under REACH to restrict the EU-based manufacture of lead stabilisers and lead-stabilised PVC, "even if those substances are exported".[20] The EU has a moral responsibility to apply the same standards to the health of non-EU citizens. Indeed, the RoHS standard already restricts lead to 0.1% in electronics, and is intended in large part to protect non-EU citizens during recycling and disposal, allowing a higher content of lead in exported PVC would be a clear case of double standards.

The transition of the EU PVC industry to alternative stabilisers is now largely complete; to require that this restriction be applied to exported PVC adds little cost or difficulty. Moreover, exported leaded PVC may still have health impacts on EU residents: via lead

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16 Tauw 2013. Impact of lead restrictions on the recycling of PVC. http://www.vinylplus.eu/uploads/Modules/Documents/2013_07_13-impact_lead-restrictions_pvc_recycling-tauw.pdf A.2.3.1, Appendix 2 p4.

17 Annex XV, Table 16

18 Annex XV p5; p40

19 Lead in PVC public consultation, comment #1513.

20 REACH text, paragraph 7

exposure to workers within EU industry; via the global trade in PVC and recycled goods, and the continued globalisation of supply chains and recycling loops; and even via globalisation of elemental lead from leaded-PVC disposal (particularly via incineration).

It is in the best interest of EU citizens and workers, and their non-EU counterparts, to apply the restriction to all EU-manufactured lead stabilisers and PVC articles. Given the non-threshold nature of lead toxicity, no risk characterisation is required to support this argument.

### *Further comments and clarifications*

- Definitions of materials and articles in the restriction text are not always clear. We recommend that the Agency adopt some of the language and practice of RoHS, which addresses a nearly identical concern in the specific context of electronics. For example, RoHS language makes it clear that the 0.1% threshold applies to "homogeneous material", rather than to the product as a whole.

- Derogation #1 applies to articles "containing recycled PVC". We support Sweden's comment (#1535) that this language is unclear and must be clarified in order to avoid creating a recycling loophole.

- One earlier comment (#1518) takes issue with the idea that lead is a non-threshold contaminant. We strenuously object to this comment. The evidence for low-dose effects of lead is very strong; in fact, some studies have found stronger effects (that is, steeper dose-response) at very low exposures.[21] In fact, the NHMRC document cited by the commenters summarizes a great deal of data indicating no threshold for safe lead exposure, pointing out that "it appears that no threshold can be identified for developmental neurotoxicity, vascular toxicity and other systemic effects".[22]

  As is the case in many epidemiological studies, it is possible that residual confounding could explain some part of the apparent association. However, the possibility of residual confounding is not itself evidence that there is a threshold. The low-dose effects of lead have repeatedly been identified for many endpoints, and they remain largely consistent with both the magnitude and the biology of the effects found at larger doses. The argument for reverse causality has been made for many decades with respect to lead specifically – sometimes with tragic consequences – and it has never held up.[23] Furthermore, the commenters attempt to discredit the importance of small effects on individuals, saying, "blood lead levels less than 10µg/dL may have subtle effects that can only be detected when comparing large groups of people" – but this is tantamount to an acknowledgment that even subclinical effects of lead can have extremely significant population-level impacts, as has been very well documented. The commenters provide little or no evidence that ECHA's classification of lead as a non-threshold substance should be reconsidered. Finally, we object to ECHA's question 5: "Are there any PVC articles stabilised with lead compounds, and placed on the EU market, other than 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." This question gives the unfortunate impression that ECHA is fishing for more products to derogate. Instead,

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21 E.g., Canfield 2003; see footnote (7).

22 NHMRC. 2015. Evaluation of evidence related to exposure to lead. https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/nhmrc_evaluation_of_evidence_related_to_exposure_to_lead_May_2015_0.pdf

23 Markowitz and Rosner. 2003. Deceit & Denial. University of California Press.

ECHA should be asking a more appropriate question: Are there any uses of lead-stabilised PVC that cannot be replaced by non-leaded PVC? Considering the EU PVC industry's clear commitment to non-lead PVC, we can only assume that the answer to this question is "no".

## *Conclusion*

The proposed restriction will significantly reduce the use of lead in the stock of PVC used in Europe. This is important not just for human exposures from the products discussed above – for example, building materials – but because these products are increasingly likely to be recycled into other products, which may have a much wider variety of consumer exposures. As the EU approaches the circular economy, it is critical to prevent toxins like lead from entering the supply chain in the first place. In particular, a proposed derogation allowing for 1% lead in some building materials should not be accepted, as this will allow for continued contamination of the future (increasingly closed-loop) supply chain far into the future, greatly weakening the effect of the restriction. It is true that strict limits on lead in recycled materials may, in some cases, necessitate disposal rather than recycling of existing PVC stocks, but the available data indicates that this is likely to be a minor effect. Furthermore, it is far more urgent to keep closed recycling loops free of toxics than it is to increase recycling of products that include significant amounts of non-threshold substances like lead.

The nearly complete transition of EU-based PVC producers away from lead-based stabilizers is clear indication that the alternatives are available, and are technically and economically feasible. The restriction has the potential to significantly reduce lead exposure in Europe, with little or no added difficulty or expense.

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