**Detailed Explanation**

**accompanying draft COMMISSION REGULATION (EU) No …/.. of XXX**

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards lead and its compounds in PVC**

Article 73(1) second subparagraph of the REACH Regulation requires the Commission to give a detailed explanation of the reasons why the draft amendment to Annex XVII diverges from the original proposal (‘Annex XV dossier’) of the dossier submitter or does not take the opinions from the European Chemicals Agency’s (‘the Agency’) scientific committees into account.

1. ***Divergences from the original Annex XV dossier proposal***

During the opinion-making process on the Annex XV dossier, the Agency’s scientific Committees – the Committee for Risk Assessment (‘RAC’) and the Committee for Socio-economic Analysis (‘SEAC’) – and the Forum for the Exchange of Information on Enforcement (‘the Forum’) recommended several changes to the restriction wording proposed in the Annex XV dossier. The Commission decided to include the following recommended changes in the draft amendment to Annex XVII:

* In the derogation for articles containing recovered rigid PVC, different provisions are laid down for articles used in:

- exterior applications in buildings and civil engineering works;

- interior building applications;

- parts of buildings, external or internal, which are accessible by people during normal use (e.g. because they face the occupied areas of a building);

- parts of buildings, external or internal, which are inaccessible by people during normal use (e.g. because placed in concealed spaces or voids);

the rationale is to reflect the different potential of those articles to result in human exposure during their service lives, both indirectly (via the environment) and directly (through the potential to form dusts from polymer degradation and abrasion); “occupied” is interpreted to mean any part of a building that is intended to be occupied by people (e.g. residential, commercial, industrial, etc.); civil engineering works include bridges, dams, etc., that are not specifically designed for occupancy as such, but which could use PVC materials in their construction;

* The condition that the recovered PVC must be fully encapsulated by newly produced PVC or other material is added to the derogation for articles containing recovered rigid PVC for use in areas of buildings accessible by people during normal use; the rationale is to prevent human exposure to lead possibly leaching out of the article or to lead-containing dusts forming during article service life; encapsulation technology is already widely practiced by manufacturers of PVC windows and other PVC profiles;
* The scope of the derogation for fittings containing recovered PVC was expanded to all fittings, except those for pipes for drinking water; it is assumed that they have limited potential for human exposure during their service life, as they are either not accessible to users under normal conditions of use (e.g. if they are present in internal parts of a more complex product) and/or these are small articles, implying a limited potential for exposure;
* A requirement for labelling using a pictogram is removed (as it only indicated that recovered material was used, rather than that the recovered material contained lead).
1. ***Divergences from the ECHA Committees opinions***

Furthermore, in drafting the proposed amendment to Annex XVII, the Commission adapted, or deviated from, the opinions of RAC and SEAC in a number of points:

* In an effort to reduce the carry-over of legacy lead into new PVC articles, the proposed derogation allowing higher lead content in recovered flexible PVC is not included;
* To reflect up-to-date information from industry on the current lead content of PVC recyclate, and in an effort to reduce the carry-over of legacy lead into new PVC articles while still preserving some recycling of PVC waste, the conditions of the proposed derogation for recovered rigid PVC are tightened as follows:
	1. the maximum allowed lead concentration is decreased from 2% to 1.5% of the weight of the PVC material;
	2. the duration of the derogation is reduced from 15 to 10 years;
	3. a review of the derogation is to be carried out after 5 years at the latest; the review should verify the trends regarding the lead concentration in the recyclate, the availability of adequate decontamination techniques and the socio-economic impact of removing the derogation.
* On the basis of comments received from industry during the public consultation done by the Agency, and of further information submitted by industry to the Commission, the wording regarding the coating material to be used to encapsulate the derogated recovered rigid PVC is modified to allow the use of any material containing less than 0.1% lead that would equally limit lead migration and dust release from the recovered PVC; this is done not to limit, without due justification, the possibility of the convertors to encapsulate the recovered PVC with other appropriate materials;
* In the context of the proposed derogation for recovered rigid PVC, a provision is laid down requiring that rigid PVC recovered from profiles and sheets in buildings and civil engineering works (e.g. windows, doors, shutters, etc.) and containing more than 0,1 % of lead only be used to produce new PVC profiles and sheets for the same applications; the rationale is to limit the presence of higher lead concentrations to certain known articles, thereby facilitating their traceability and future decontamination; according to information from industry, the EU PVC profile industry has already in place the necessary infrastructure to implement this requirement;
* A provision is introduced requiring PVC articles containing recovered rigid PVC to indicate if they contain lead in a concentration above 0,1 % by weight of the PVC, in order to ensure that professionals and consumers are adequately informed of possible risks and facilitate enforcement, in particular in relation to imports; this provision should also facilitate the separate collection of lead-containing waste;
* Considering the difficulties for enforcement authorities to determine if PVC in articles, especially imported articles, is of recovered origin, a provision is laid down requiring suppliers of PVC articles benefitting from the derogation for recovered rigid PVC to prove the recovered origin of the material by presenting documentary evidence; for PVC articles produced in the Union, existing schemes providing proof of traceability and recycled content may be used to prove the recovered origin of the material; for imported articles, claims on the recovered origin of the material are to be substantiated via independent third party certification;
* The derogation proposed for the use and placing on the market of the lead pigments "lead sulfochromate yellow" and "lead chromate molybdate sulfate red" is not included, in view of recent case law[[1]](#footnote-1) and the Agency’s intention to submit a new restriction dossier pursuant to Article 69(2) of Regulation (EC) No 1907/2006 related to the risks stemming from the use of those pigments in articles.
1. <https://curia.europa.eu/juris/liste.jsf?language=en&num=C-389/19> [↑](#footnote-ref-1)