

## ECHA investigation into PVC and its additives

ESPA (the European Stabiliser Producers Association), which represents eight companies who produce >95% of the PVC stabiliser needs in Europe, would like to update you on the current ECHA investigation into PVC and its additives.

ECHA was mandated by the European Commission in May 2022 to produce a report investigating the environmental impact of PVC and its additives within one year, from their inclusion in the REACH Restrictions Roadmap published in April 2022 and based on the outcomes of the one-year long study *The use of PVC in the context of a non-toxic environment* published in January 2022 by the consultancy company Ramboll. The broad scope of the mandate<sup>1</sup> covers PVC production, waste management of articles and the potential environmental risks and costs associated with the use of PVC and its additives. In November, ECHA published a prioritisation list<sup>2</sup> of 63 substances which in addition to plasticisers and flame retardants, contained a small number of substances which are components of PVC heat stabilisers.

### ESPA does not support this inclusion for the following reasons:

The entire PVC value chain and ESPA are not aware of any new scientific evidence nor risk analysis which supports the roadmap inclusion, which is justified due to the open dossier/restriction on the permitted level of Lead (Pb) embedded in the matrix of recycled PVC, open since 2017 and with the European Chemical Agency's (ECHA) own recommendations from 2019 to the European Commission rejected by the European Parliament in early 2020.

With three calls for evidence in a short time frame, ECHA continues to reassure stakeholders that they are conducting an investigation and are not preparing an Annex XV restrictions mandate, although potential replacement substances and alternative plastic materials to replace PVC are being considered, in parallel.

During ECHA's first call for evidence, which was focused upon PVC additives, specifically flame retardants and plasticisers were cited to be prioritised. ESPA, together with partner associations within VinylPlus, have fully co-operated with ECHA to provide data that counters the results of the inaccurate information contained within the Ramboll report<sup>3</sup> and in early September 2022 provided ECHA with a current list of circa 500 substances used today in PVC in EU-27.

ESPA is deeply concerned that the stated basis for closer scrutiny from this list of substances is based on ECHA's Assessment of Regulatory Needs (ARNs) which are informal grouping assessment documents

<sup>1</sup> [https://echa.europa.eu/documents/10162/17233/mandate\\_pvc\\_and\\_additives\\_rev\\_en.pdf](https://echa.europa.eu/documents/10162/17233/mandate_pvc_and_additives_rev_en.pdf)

<sup>2</sup> <https://echa.europa.eu/documents/10162/41c8dc37-8d1c-8308-3614-49ebbc882c53>

<sup>3</sup> The Ramboll report included many inaccuracies plus outdated and misleading information with regard to PVC stabilisers' use in EU-27: [https://pvc.dk/wp-content/uploads/2022/05/VinylPlus-comments-on-Ramboll-report-by-chapter\\_final.pdf](https://pvc.dk/wp-content/uploads/2022/05/VinylPlus-comments-on-Ramboll-report-by-chapter_final.pdf)

prepared by ECHA staff without any opportunity for input from other stakeholders. In several cases the conclusions are inconsistent with REACH registration dossiers (the stated basis for the ARN's), and in some cases directly contradict the outcome of formal REACH regulatory processes, such as the ECHA RAC CLH process. The paradoxical effect of the substance grouping, the so called "family approach" which has been selected by ECHA, is anti-scientific and contradicting the REACH law itself. Here below, three self-explanatory examples, specifically related to heat stabilisers:

*Example 1:*

Inclusion of two phenyl 1,3-diones, dibenzoyl methane (DBM, (EC) No. 204-398-9) and stearoyl benzoyl methane (SBM, EC No. 261-257-4), which based on robust testing data and assessments: DBM is a skin sensitiser and SBM substance is not. Robust study summaries are included in the REACH registration dossiers conducted on these substances with a reliability score of 1 (highest possible), yet both are listed in the group of 63 substances. There is no ARN document for these substances so the basis for their inclusion is not transparent and ESPA requests that they be removed from the list. The only reason for inclusion, is that they are named "benzoyl" (phenol-derivative).

*Example 2:*

MOTE (EC No. 248-227-6), in contrast to DOTE (EC No. 239-622-4 which is included in the Authorisation list with a phase-out date of May 2025), has a robust 2-generation study in rats and developmental studies which lead to the conclusion that classification for reproductive effects is not required. MOTE as produced and registered under this EC number (<0.3wt% DOTE) is therefore not classified and hence a further request is made that they be removed from the list for closer scrutiny. There appears to be confusion in that MOTE is also sold by some producers with 6% DOTE and hence this would be classified as a Category 1B reproductive agent due to the presence of DOTE. Hence the warning statement in the substance information card on the ECHA website for MOTE should be reserved for those substances with more than 0.3wt% DOTE. Again, not all the "organotin" show similar toxicity (if any). Not all "family members" are equally hazardous.

*Example 3:*

1,2-Benzenedicarboxylic acid, di-16-18-alkyl ester (EC No. 290-580-3). Used as a lubricant (and not a plasticiser, as ECHA indicated), it is a (non-classified) component of several Calcium Organic Stabilisers (COS), included into the 63-substance list only because contains the word "phthalate" into its common name (Cetyl-Stearyl Phthalate).

## **Next steps**

ESPA and its customers consider that this inclusion of substances in ECHA's published priority list may result in punitive commercial consequences for its members and PVC convertors. As such, ESPA will seek, using all available means, to defend the safe and sustainable use of legally regulated substances in EU-27 and would caution against stakeholders proposing alternative substances which may find themselves 'grouped' at a later stage of the ECHA investigation or having not been adequately or scientifically assessed.

ESPA representatives will continue to actively and intensively participate in the VinylPlus Steering Board, VinylPlus Advisory Board, VinylPlus Advocacy Task Force and the VinylPlus PVC Additive workgroup continuing to support ECHA's investigation and would urge that the ARN's being applied are subject to thorough and balanced scientific analysis.

Should you need any further information please feel free to contact ESPA. We remain at your disposal for any further clarifications.

### **ESPA's commitment to sustainability**

ESPA has always been proactive in anticipating potential regulatory changes which could impact upon any safe and sustainable use of substances included in PVC stabiliser formulations, closely monitoring and supporting the thorough scientific scrutiny within the legal frameworks of CLP and REACH.

Proactively engaging with PVC convertors across the planet, not only in Europe, ESPA members are heavily invested in the substitution of any substances of concern by more sustainable alternatives which has been normal practice for our member companies and their customers for many years. Adopting the Additive Sustainability Footprint (ASF) methodology<sup>4</sup>, developed by VinylPlus with the support of The Natural Step (TNS) ONG, provides ESPA with the most advanced way to completely assess the sustainability of Plastics Additives. The adherence to these criteria is granted by the VinylPlus Supplier Certificate (VSC)<sup>5</sup>, through external audits by top accredited certification bodies.

*ESPA (the European Stabiliser Producers Association) is a sector group of Cefic (the European Chemical Industry Council). The following eight companies are full members of ESPA: Akdeniz Chemson Kimya San. Tic. A.Ş.; Asúa Products S.A.; Baerlocher GmbH; Galata Chemicals GmbH; PMC Organometallic, Inc.; Reagens SpA; Valtris Specialty Chemicals Ltd.*

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About Cefic  
Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 16% of world chemicals production.

<sup>4</sup> <https://www.vinylplus.eu/sustainability/our-contribution-to-sustainability/additive-sustainability-footprint/>

<sup>5</sup> <https://productlabel.vinylplus.eu/vinylplus-supplier-certificates/>