



**EUROPEAN COMMISSION**

DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP  
AND SMES

Directorate F - Ecosystems I: Chemicals, food, retail

DIRECTORATE-GENERAL FOR ENVIRONMENT

Directorate B - Circular Economy

**The Directors**

Brussels,  
GROW.F.1/PT/nt  
grow.f.1(2022) 3933014

**NOTE FOR THE ATTENTION OF  
MR SHAY O'MALLEY, ACTING EXECUTIVE DIRECTOR, ECHA**

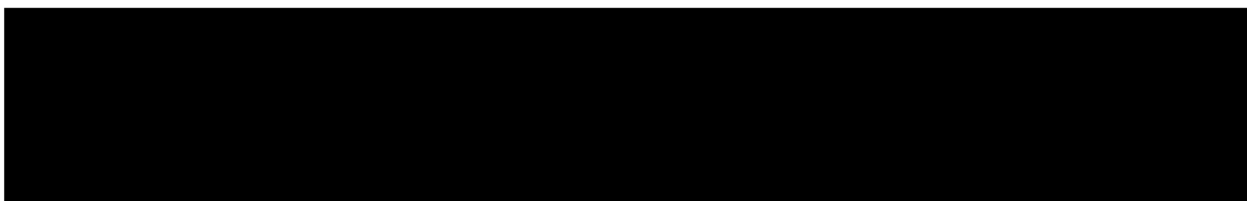
**Subject: Request to the European Chemicals Agency to prepare an investigation report on PVC and PVC additives**

As you are aware, polyvinyl chloride (PVC), a polymer used in many applications, needs to be combined with specific additives before it can be transformed into products. PVC additives are crucial to determine the flexibility, stability, colour, clarity and electrical properties of PVC products. In the past decade, certain additives used in PVC, such as cadmium- and lead-based stabilisers and certain phthalates, have been demonstrated to pose an unacceptable risk to human health and the environment and are now restricted under REACH. In addition, the risks posed by other additives, namely medium-chain chlorinated paraffins and flame retardants, are currently under investigation.

There are growing concerns that the alternative substances used to replace the restricted additives, particularly plasticisers and flame retardants, may themselves pose risks. Furthermore, there is preliminary evidence that there is a potential risk from the use of vinyl chloride during PVC manufacturing and from the generation of furans and dioxins during the disposal of PVC waste through incineration or uncontrolled burning. However, prior to embarking on specific risk management activities, more information is needed to better understand whether the risk, stemming from PVC additives and PVC itself, is significant, and whether there are adequate control measures in place.

In addition, the circular economy aspects of PVC should be further investigated. For example, while recycling seems to be happening for some waste streams (for example, PVC profiles and flooring in construction industry), there is evidence that many uses of PVC follow a linear model with disposal at the end of life. The socio-economic implications of this fact, in particular the additional disposal costs and other costs to society this implies, should be better understood.

Against this background, the Commission hereby requests ECHA to collect information on the potential risk to human health and the environment posed by PVC additives and



PVC itself, the socio-economic impact of a possible restriction and the need for a European Union-wide action beyond any measures already in place.

The investigation report should appraise the availability, reliability and significance of the collected information in relation to the requirements of an Annex XV dossier, including key uncertainties, assumptions and information gaps. The report should clarify if there is sufficient evidence of risk from uses of PVC additives and PVC itself to justify additional regulatory measures.

Based on this report, the Commission will consider whether to request ECHA to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend Annex XVII to REACH. The report should include an assessment on possible legal instruments that could be used in addition to, or instead of, action under REACH to address any identified risk that is not adequately controlled.

During the preparation of the investigation report, information should be gathered on the potential risk posed by PVC additives, when used in PVC and in materials used as alternatives to PVC, as well as PVC itself, throughout the complete life cycle of PVC articles, i.e. manufacture (of PVC itself and PVC products), service life and end-of-life/waste phase, including recycling. The report should include considerations of the potential for human, environmental and animal toxicity, combined exposure of the general population to chemicals sharing the same hazard, persistence in the environment, long range transport and mobility, potential to contaminate natural resources, and exposure/emissions from recycled materials. Attention should be paid, where possible, to address data gaps identified in the recent report “The use of PVC in the context of a non-toxic environment”<sup>1</sup>, such as, but not limited to, the bioavailability of additives, the capacity of additives to leach from the PVC matrix and factors influencing their leaching. Finally, attention should also be paid to socio-economic considerations, such as the availability of suitable alternative substances and materials with comparable technical performance and costs, possible comparatively higher costs of PVC waste management due to the presence of chlorine, constraints in recycling also for the presence of legacy additives, as well as the impacts of a potential restriction on the PVC supply chain.

The choice of the methodology to gather information about the possible risks posed by the different types of PVC additives is left to ECHA, but, given the large number of substances concerned, a grouping approach is encouraged. ECHA should exploit the synergies with the ongoing work on groups of substances, such as on phthalates and flame retardants.

We also acknowledge that it may be difficult to address all substances in the scope of the mandate with the same level of thoroughness in the time specified (see next section). While we encourage ECHA to do its utmost to address the full scope of the mandate in the investigation report, if necessary ECHA may decide to focus its information gathering work on the (groups of) substances with the worse hazard/exposure profile. A possible order of priority is indicated below:

- 1) plasticisers and flame retardants;
- 2) other PVC additives;
- 3) PVC itself.

The order of priority may be further discussed with DG GROW and DG ENV in view of the preliminary results of ECHA’s work.

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<sup>1</sup> <https://op.europa.eu/en/publication-detail/-/publication/e9e7684a-906b-11ec-b4e4-01aa75ed71a1>

Should the above prioritisation be necessary, the report should clearly indicate the (groups of) substances of the mandate that could not be adequately addressed in the time given, and provide an indication of the additional time needed to complete the collection of information and publish a supplementary report.

Any aspect related to the contamination of food and related exposure to consumers should be discussed also with the specific service of the Commission, i.e. DG SANTE, and the European Food Safety Agency.

### *Timing*

We would invite the agency to complete the information gathering work within 12 months of receipt of this letter. The information should then be published in the form of an investigation report that should be clear and concise and make use of the format of an Annex XV dossier adapted as necessary to the scope of the task requested. The timing and content of the report may be further discussed with DG GROW and DG ENV.

We would appreciate receiving a confirmatory letter from ECHA that our request has been accepted.

*(e-signed)*

Kristin Schreiber  
DG GROW

*(e-signed)*

Aurel Ciobanu-Dordea  
DG ENV