

ANNEX 2

VINYLPUS COMMENTS ON ECHA INVESTIGATION REPORT ON PVC AND PVC ADDITIVES – SUMMARY OF DATA GAPS

Topic	ECHA request	VinylPlus commitment
REACH registration dossier related to the 63 additives. Hazard and exposure data of additives <ul style="list-style-type: none"> - Data gaps - DNEL 	Assumptions made due to lack of data	Coordination with members on ongoing compliance checks and substance evaluation for several substances with associated updates of registration dossiers.
Data gaps from REACH registration dossiers for Heat stabilisers, Plasticisers, Flame Retardants	<i>“However, endocrine disrupting properties cannot be excluded due to: 1) potential presence of constituents with shorter backbone alkyl chain, 2) unclear covering of this endpoint in the toxicological studies available for DINP and identified effects on the thyroid observed in toxicological studies available for DPHP. Both DINP and DPDP are currently subject of dossier evaluation”</i>	<ol style="list-style-type: none"> 1) While the DINP REACH dossier has been updated in 2022 to further clarify the substance identify profiles, European plasticisers members are committed to start a dialogue with ECHA to identify the best ways to address any remaining gaps. 2) DINP registrants are waiting for the final decision on a compliance check, yet they already indicated to ECHA that they agree to commission an OECD 414 in rabbits (PNDT), and OECD 471 (Bacterial Mutagenicity) 3) DPHP registrants regard the observed thyroid effects as secondary to liver enzyme induction, mediated via the HPT axis. Though this was not explicitly shown for DPHP,

		it was so far excepted as mode of action by Competent Authorities. DPHP registrants offered ECHA to test this in specific studies during the CoRAP process but were rejected. Instead, a technically unfeasible study was requested.
	<i>“No DNELs were available for other priority additives”</i>	Coordination with members on where there are existing DNELs for other priority additives and update of registration dossiers where needed.
	<i>“Further Information on the composition of Ortho-phthalates, including the presence of constituents with shorter alkyl chain”</i>	While the REACH dossiers of DINP and other ortho-phthalates have been updated in 2022 to further clarify the substance identify profiles, European plasticisers members are committed to start a dialogue with ECHA to identify the best ways to address any remaining gaps.
	<i>“Although they are identified by the registrants as readily biodegradable, flaws in the available data cannot fully support this conclusion. As mentioned above, both DINP and DPDP are currently subject of dossier evaluation also in this regard.”</i>	Dossier updates by registrants in 2023 for DINP addressed questions on readily biodegradation. Clarification on the biodegradation of DIDP has been provided to ECHA as part of the recent dossier evaluation. Currently, DPHP is not subject to dossier evaluation, and biodegradation was not under discussion in the latest dossier evaluation nor is it in the current substance evaluation. European Plasticiser members are committed to start a dialogue with ECHA to identify the best ways to address any remaining gaps

	<p><i>“A potential for PBT/vPvB properties was also identified for medium-chain (C7- C8) ortho-phthalates since they screen as potentially bioaccumulative based on the values for logKow.”</i></p>	<p>There are several higher-level studies including fish feeding studies which have demonstrated the lack of bioaccumulation potential for these substances..</p>
<p>PVC Microparticles</p> <ul style="list-style-type: none"> - Generation - Particle sizes - Environmental Fate - Migration of additives - Toxicity: human health - Ecotoxicity - Exposure of workers to organotin additives and plasticisers during recycling and from landfill sites - Exposure to PVC dust – consideration of need for an EU microplastic dust OELs (OELs for PVC dust already exist in some Member States - Assessment of voluntary action to minimize release of microplastics in recycling operations and from landfill sites. 	<p><i>“This can be done by implementing and improving on-site emission minimisation technologies for PVC microparticle releases, especially at recycling sites and landfills.”</i></p> <p><i>Due to the non-threshold nature of the risk (Section 3.2.3.1), minimisation of the releases of additives should be the focus of regulatory and/or voluntary actions.”</i></p>	<ol style="list-style-type: none"> 1) Need to understand and measure potential release of additives from PVC microplastics, and to understand better estimated/measured release of PVC microparticles. 2) Research on migration of additives from microplastics: 3) Measured and estimated release of additives from PVC microparticles in the environment and in workplaces 4) Info on release of plasticisers to the air – new paper by Wang et al 2023. 5) Biomonitoring in recycling plants and elsewhere: existing measures within limits: VinylLoop Ferrara SpA – Chemical Safety Report on Soft PVC recycle containing DEHP. 6) Organise monitoring campaign for key additives in recycling plant (aligned with PRE) 7) Risk assessment of direct human exposure for co-exposure (especially recycling plants). 8) Mass balance of PVC and (prioritised) additives in circular economy over a 20-year timespan considering selected end-of-life, recycling rate and substitution scenarios. Corresponding temporal development of releases and environmental stock.

		9) Provide exposure data on organotin stabilisers: e.g. Chemical Safety Report on DOTE – compiled for organotin producers REACH consortium.
Dust Exposure (PVC microplastics)	Recycling and landfill operations	Provide data from VinylPlus Production committee. Need to produce data on potential human health and environmental impacts (e.g. Brigid project) and own research.
Recycling: Mass balance assessment for inputs/outputs/recycling/incineration/landfill of PVC articles (PVC resin and additives)	<i>“The key action for reducing environmental releases (beside site specific release reduction management) is to reduce the overall volume of the substance at these life-cycle stages, and in particular in recycling and landfilling.”</i>	Collect data from Conversio Model and Recovinyl to support mass balance assessment. Such mass balance approaches should also be done for alternative materials to PVC. An initial screening done, and the assessment should be further refined. External support to present results may be needed (Conversio & integration with releases evaluation).