

ANNEX 1

VINYLPLUS COMMENTS ON ECHA INVESTIGATION REPORT ON PVC AND PVC ADDITIVES – SUMMARY OF KEY ASSUMPTIONS IN THE REPORT

<h3>Assumption 1 - Hazards</h3> <p>3.2 Risks PVC Additives – Tables 1, 2, and 3</p>	
Nature of assumption	
<p>Hazards – For over half (51%) of the 63 prioritised additives severe hazards assumed (CMR, ED HH, ED Env, PBT, vPvB) contrary to actual data/robust read across. In the case of DINP, the assumption that it is “Reprotoxic, ED HH, ED Env, PBT” contradicts actual data, the REACH registration dossier and the ECHA RAC opinion (2018).</p>	
ECHA Report – Basis for assumption	
<p>Read-across is being used indiscriminately for over half (51%) of the prioritised additives and for 71% of the plasticisers, even when there is actual data on a substance not consistent with the read-across).</p>	
VinylPlus comment	
<p>It is not justified to use read across in this way. A robust science-based read-across approach should be followed, i.e. data on a substance should not normally be superseded by read across from another substance, which is classified, especially when structure activity based on data is also available as well as detailed mode of action information.</p>	
Proposal to address assumptions	
<p>Ongoing testing under REACH dossier compliance check, REACH Substance Evaluations, and harmonized classifications are being actively worked on by regulators and industry. Consistent with legal predictability these processes should be allowed to run their course. Tests and assessments done under these processes should address some of the concerns raised by ECHA. Until such tests and assessments are concluded, read-across should not be used indiscriminately.</p>	

<h3>Assumption 2 - Release</h3> <p>3.2 Risk PVC Additives – page 8</p>	
Nature of assumption	
<p>Use of PLASI model (based on polyethylene) for additives release.</p>	
ECHA Report – Basis for assumption	
<p>The PLASI model was previously used for all plastics in a broad screening project to assess plastics additives used broadly in all plastics i.e. not designed for a more specific assessment of a single plastic material such as PVC.</p>	
VinylPlus comment	
<p>The PLASI model is not appropriate for PVC which has a completely different structure to polyolefins and hence a completely different capacity to retain and utilise additives.</p>	

<p>Proposal to address assumptions</p> <p>The PLASI model should be replaced by actual data on migration of additives. These data are available in the VinylPlus submission to the ECHA CfEs and are referenced in the ECHA report as showing “very low migration and compliance.” ECHA states that “the transfer of these results....is not straightforward.” However, VinylPlus believes concrete evidence and data should be used, rather than a tool which is not appropriate. New data become available on an ongoing basis, and needs to be integrated. New data is now available to address inhalation concerns raised in the ECHA report (re: Wang et al 2023 – see detailed comments).</p> <p>The biomonitoring data on plasticisers which shows safe use of current plasticisers captures total exposure and should be used to a much greater degree in the ECHA report. These biomonitoring data are added to on an ongoing basis. The ECHA report again dismisses these data, yet previously, these data were used and recognised. The 2013 ECHA evaluation of new data on DINP/DIDP used the biomonitoring data to a significant degree to reach the conclusion of “No further risks identified” – there is a section on biomonitoring and one on risk characterisation using these data.</p>

<p>Assumption 3- very Persistent vP</p>
<p>3.2.1 Hazard assessment</p>
<p>Nature of assumption</p> <p>PVC microparticles are assumed to be vP. The fate of additives is assumed to be the same as that of PVC microparticles i.e. vP – very persistent</p>
<p>ECHA Report – Basis for assumption</p> <p>Intentional microplastics concluded to be vP (RAC opinion) – read across to PVC assumed with no documentation in line with ECHA's own guidance (Read across framework). Additives in association with PVC microplastics are then also assumed to be vP.</p>
<p>VinylPlus comment</p> <p>Polymers are designed to be durable. vP was always intended for substances, not polymers. It does not seem scientifically coherent to state that additives are also vP because of their association with PVC microplastics. Additives have their own properties, and if an additive is biodegradable when tested as a substance, it will be biodegradable if/when released from a microparticle. Utilizing vP in this way contradicts the REACH regulation in that PBT or vPvB criteria are required to be met to assume severe hazard which leads to non-threshold conclusions.</p>
<p>Proposal to address assumptions</p> <p>For the additives, the actual data on the substances should be used e.g. many plasticisers and additives are “readily biodegradable” by the REACH required tests. PBT assessments by marine environment authorities have concluded substances are NOT PBT. These data and assessments should be fully referenced. Further data can be generated where needed for substances as part of compliance checks.</p>

<p>Assumption 4- Accumulation</p>
<p>3.2.1. Hazard assessment</p>
<p>Nature of assumption</p> <p>Based on Assumption 3 of vP then accumulation in the environment is assumed</p>
<p>ECHA Report – Basis for assumption</p> <p>vP substances can accumulate in the environment since they are not biodegraded</p>
<p>VinylPlus comment</p>

This assumption neglects the processes of physical degradation and weathering, biodegradation, photodegradation, and sorption (particularly for additives). The facts whereby PVC is ~3% of total microplastics, and microplastics are ~0.09% of total particulates are not considered. VinylPlus agrees that more information is needed on the generation, effects, and fate of PVC microplastics. Similarly, for the additives present in the PVC microparticles, additional data on migration rates, amounts, effects, and fate are needed. But based on the current information showing lack of bioavailability, there is no cause to make conclusions on regulatory action specific to PVC microplastics.

Proposal to address assumptions

For many additives, the data shows that they are not very Persistent. Simply by association with PVC the intrinsic properties of the additives do not suddenly change. Concerning PVC microparticles – polymers such as PVC are intended to be durable – this brings sustainability and resource efficiency benefits. PBT and vP are intended to be applied to substances and not to polymeric materials, which by definition are durable (to varying degrees depending on the polymer). All polymers are subject to weathering and breakdown.

Assumption 5- Co-exposure of additives

3.2.1. Hazard assessment

Nature of assumption

Similar leaching rates are assumed for all additives, particularly for environmental exposures. It is then assumed that there are co-exposures which could lead to additive or synergistic effects.

ECHA Report – Basis for assumption

No robust basis or specifics given, other than this is “a further concern” and can lead to additive/synergistic effects.

VinylPlus comment

ECHA assumes leaching of additives at similar rates which is not necessarily the case, and seemingly ignores low solubility of additives, biodegradation, photodegradation, hydrolysis, sorption to sediment, as well as the need for a common mode of action for additive/synergistic effects, and possible inhibitory effects of different additives.

Proposal to address assumptions

Co-exposure can be relevant and be assessed where there is an identified common mode of action (e.g. low molecular weight phthalates – REACH restrictions for DEHP, DBP, BBP and DIBP are in place based on a common mode of action for adverse reproductive effects). Further work is needed on modes of action, and also on comparative leaching of additives from PVC microplastics in order to assess whether co-exposures are taking place. Work from ARCHE 2023 shows that migration of DINP in landfills is very small, and for the small amount of DINP which is released studies have shown it is biodegradable.

Assumption 6- Non-threshold (no safe limit)

3.2.1. Hazard assessment

Nature of assumption

Combining Assumptions 1,2, 3,4 and 5 leads to the final assumption of “non-threshold” i.e. no safe limit. Although it should be noted that several of the major additives have no classified hazard and are biodegradable, and do not even require exposure assessments under the REACH regulation (re:

<p>Registratio dossiers). So, for these the question arises no threshold for which adverse effect (hazards are of course being assumed – see Assumption 1).</p>
<p>ECHA Report – Basis for assumption</p>
<p>A combination or partial combination of particularly Assumptions 1, 3, and 5 means no threshold (no safe limit). Implication – risk assessment not appropriate and safe use not possible is the potential consequence of such assumptions.</p>
<p>VinylPlus comment</p>
<p>Combining several assumptions to make a final assumption of “non-threshold” (safe use not possible) is not scientifically justified. The correct scientific process should be to first establish the true hazard based on a robust weight of evidence assessment and then, where potential non-threshold hazards are identified, to consider/develop data on mode of action to determine threshold or no threshold. Such a determination has major repercussion for a substance and should be based on solid data and an expert assessment.</p>
<p>How to address assumptions and data gaps</p>
<p>The assumption of non-threshold depends largely upon the nature of the hazard (re: CMR, ED, PBT, vPvB) – i.e. Assumption 1. So further data is needed in this regard via the ongoing REACH processes. As already noted, vP is not sufficient to conclude “non-threshold” – under REACH a PBT or vPvB determination is required to conclude that Authorisation is not possible based on risk control but only then on socio-economic grounds.</p>

Implications of ECHA key assumptions

The broad and severe nature of the assumptions which are not based on scientific evidence has led to recommendations for regulation in the ECHA Report (see Section 2. Conclusions).

The logic of these assumptions also seems to be that any new additive proposed as a substitute for use in PVC (or other plastics) could not be considered to have a threshold and, therefore, would also not have the potential for safe use since, in this logic, any additive in association with PVC microplastics is very Persistent (vP).

If Assumption 1 on hazards was not applied, then many additives would not meet the requirements to recommend restriction. Ongoing testing and REACH dossier compliance checks would then be allowed to run the legally specified course with the relevant outcomes, and the expert robust weight of evidence assessment of the hazard.

Similarly, if Assumption 2 (that the PLASI model applies to the PVC matrix) was not applied then the estimated release of the additives would be significantly reduced, potential exposure of humans and the environment (and organisms) would be significantly reduced, and risk would be significantly reduced. If real-world data was used, e.g. migration, occupational exposure and biomonitoring data were to be used, then estimated exposure would be significantly reduced.

If instead of Assumption 3 (vP), the REACH criteria of PBT and vPvB based on actual data were applied, then many additives would not be considered as non-threshold and would be subject to further risk assessment. Consistent with good scientific practice, not applying PBT and vPvB criteria (which were never intended for polymeric materials) to polymeric materials such as PVC would result in PVC not being considered as vP.

If Assumption 4 was not applied, then a more complex assessment of environmental fate (with physical and biological degradation processes) would apply rather than the simplistic view that an

assumed vP substance is assumed to accumulate in the environment. For some of the substances, higher level fish bioaccumulation studies are available, which appear not to have been taken into account.

If Assumption 5 was not applied and a more complex realistic assessment of the release of different additives and their potential for synergistic effects assessed based on the science, including using a common mode of action as a basis, there would be a more targeted approach to this topic (rather than the broad approach for 63 additives).

Assumption 6 depends upon Assumptions 1 – 5, and in particular Assumptions 1, 3 and 5 according to the ECHA report.

Given the above remarks, VinylPlus strongly believes that assumptions and extrapolations which are not grounded in robust scientific data and evidence should not be the basis for recommending regulatory action on PVC and PVC additives.