February 19, 2024

REPORT

VINYLPLUS COMMENTS ON THE ECHA INVESTIGATION REPORT ON PVC AND PVC ADDITIVES

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1. Introduction

The investigation of PVC and PVC additives was an intensive exercise for all parties involved, given its wide scope and limited timeframe. VinylPlus® appreciates having had the opportunity to actively contribute data and evidence and acknowledges the significant work done by ECHA. We also appreciate the recognition efforts made by the PVC industry in the context of the VinylPlus sustainability commitment, notably that the industry has taken a proactive role in phasing out certain substances which were identified as posing potential risks (such as lead, cadmium and certain LMW ortho-phthalate plasticisers).

Having carefully read the ECHA investigation report on PVC and PVC additives (hereafter, the ECHA report)[1] and its appendixes, we believe further work is needed to refine the assessment. The purpose of this VinylPlus document is to provide detailed scientific comments with the objective of strengthening the scientific and technical analysis laid out in the ECHA report.

VinylPlus is firmly committed to continue supporting regulators with data and evidence as needed and to help close data gaps. We hope these comments can lead to further scientific dialogue.

The comments outlined in this document follow the specific section of the report.

[1] ECHA (2023), Investigation report on PVC and PVC additives

2. Overall conclusions

Paragraph 4, Lines 1-3 – VinylPlus questions whether it is an accurate statement that *"This investigation identified risks to human health based on conventional realistic worst-case quantitative risk assessment."* According to page 31 of the report such quantitative risk assessments were only done for 7 of the 63 prioritised additives (see also the Table on page 32). The ECHA report states (page 31) that it was not possible to screen risks for other substances due to a lack of DNELs. However, there are DNELs available for more than just these 7 substances on the list of 63 prioritised additives (at least 24 of the 63 substances have DNELs). Therefore, only limited quantitative risk assessments were conducted, and hence, the original European Commission request, i.e. to assess the risks of PVC and its additives, has not been met.

Paragraph 4, Line 1-3 – VinylPlus questions whether it is plausible and justified based on scientific data and evidence to state that "*Risks to the environment (incl. man via the environment) were also found for all prioritised additives based on a pragmatic approach applied in the absence of a more complete set of data.*" We question this statement since it is based on assumptions with respect to hazards, exposure, and environmental fate, and not on scientific data and evidence. There are ongoing REACH processes which are addressing some of these assumptions, whereas, for others, they are not consistent with actual data and assessments. These assumptions are further stated in more detail in sections "3.2. Risks from current PVC additives" including Tables 1, 2 and 3. VinylPlus would also note that this conclusion on "Risks to the environment" is not consistent with other more detailed and in-depth risk assessments on specific additives which ECHA has conducted, nor is it consistent with the assessments in the REACH registration dossiers.

Paragraph 4, Line 5 – VinylPlus recognizes that further research is needed on microplastics and is part of the Plastics Europe major research program on microplastics[2]. VinylPlus is also ready to initiate projects specific to PVC microparticles and to review such projects with ECHA and the European Commission. However, VinylPlus questions the statement that "*Risks due to microparticle exposures in the environment are also expected for PVC itself."* The ECHA report shows that a risk assessment has not been carried out on PVC microplastics and that, therefore, this statement is based on an assumption. Concerns in the ECHA report are based on a study from a single recycling site in the UK, which was not recycling PVC, and which is now no longer in operation. PVC is estimated to represent approximately 3% of total microplastic emissions (UNEP, 2018)[3] and in this regard VinylPlus agrees with the ECHA report statement (Paragraph 4, Line 6) that "*this is not a PVC-specific issue but a general challenge for any plastics which is also recognised in the EU Plastics strategy (EC, 2023c).*" ECHA sees greater additive use in flexible PVC in particular and with specific regard to plasticisers as leading to potential greater exposure in the environment to such additives from PVC. In this regard the following points can be noted:

1) for polyolefins, flame retardants can be present at high levels similar to those for plasticisers in PVC and hence this point is not specific to PVC.

[2] brigid • Plastics Europe
[3] UNEP (2018), Mapping of Global Plastics Value Chain and Plastics Losses to the Environment: With a Particular Focus on Marine Environment

2) the major plasticisers being used in PVC bind tightly with the polymer matrix, have very low water solubilities, and hence are not bioavailable to a significant degree according to an ARCHE study (ARCHE, 2023)[4] results.
3) for the very small amount of plasticiser which can be released the major plasticisers are readily biodegradable by microorganisms based on the required REACH registration dossier testing requirements and
4) consistent with points 2) and 3), recent data obtained by VinylPlus (subsequent to the ECHA report publication) following work with ARCHE has shown that migration of major plasticisers from landfill sites is infinitesimally small (~3x10-7% after 1 year during 91 rain events).

Paragraph 5 – Alternative Materials – The ECHA report does not assess the alternatives to the same degree with regard to performance, safety and sustainability. Lifecycle assessments are based on a limited amount of publicly available Environmental Product Declarations (EPDs), which are all based on different product category rules (PCRs) and estimations (such as service life, maintenance or recycling quotes). VinylPlus believes an in-depth robust equitable assessment of PVC and alternative materials in specific applications is needed, including chemical industrial application, for example in the chlor-alkali sector and metal surface treatment.

Paragraph 6 – Alternative Additives – VinylPlus agrees that alternative non-CLP classified, non-SVHC, safe additives are available to replace additives identified as SVHC and which pose a demonstrated risk. These alternative additives include High Molecular Weight (HMW) ortho-phthalates and other plasticisers, MOTE (organotin) and other organotin compounds, and Ca/Zn stabilisers. These alternatives can readily meet the performance requirements of today's application and have successfully replaced SVHC additives over the last 25 years with major investments. Extensive testing and regulatory assessments have been made on these substitutes. Therefore, VinylPlus does not agree with the grouping of these alternative additives on the list of 63 prioritised (see below for additional information). Proposals to replace these substitutes would result in major issues of technical and economic feasibility, as well as availability with major implications for the entire PVC value chain. The development of additives can involve major investment over several decades, and these costs should be reflected in the socio-economic assessment.

Paragraph 8 and the remaining sub-paragraphs through to page 4 – Need **for regulatory actions –** Given the extensive assumptions in the ECHA report conclusions, VinylPlus questions the justification for the ECHA report recommendations for regulatory action. These recommendations pre-empt the outcome of further and already ongoing REACH regulatory processes which could identify if there is a risk which is not adequately controlled.

Paragraph 8 – sub-paragraph 1 – *"Regulatory action is needed to minimise risks from plasticisers and in particular ortho-phthalates".* The significant commercial ortho-phthalates (DEHP, DBP, BBP and DIBP) which have shown significant reprotoxic effects in animal studies and which are classified as Category 1B Reproductive agents have already been restricted under REACH and other EU regulations (RoHS, Cosmetics, Toys, and medical devices). With regard to structure activity, it should be noted that reproductive effects have been shown to be caused by ortho-phthalates with C3-C6 longest

[4] Arche (2023), Exposure Assessment of the PVC Additive: DNIP end of life Stage - Landfill

straight chain backbones in the alkyl side chains. DIBP – Di-isobutyl phthalate is a C3 longest straight chain backbone with one methyl group; Dibutyl phthalate (DBP) is a linear material with C4 longest straight chain backbone. VinylPlus will, therefore, refer to C3-C6 backbones where appropriate. In addition to the four Low Molecular Weight (LMW) phthalates (C3-C6 straight chain backbones in the alkyl side chains) there are a further 10 LMW phthalates which are included on the Candidate and Authorisation Lists (and which were either never commercialised or have already been decommercialized in recent years). For the High Molecular Weight (HMW) ortho-phthalates (C7 and above backbones in the alkyl side chains with total carbons of C8-C14), extensive data and ECHA RAC assessments have confirmed the lack of adverse reproductive effects and the safety in current applications. With respect to the ECHA report concerns about the possible presence of C3-C6 backbones in HMW phthalates, data has been provided to ECHA RAC during the assessment of DINP with the conclusion of no classification for any adverse reproductive effects (including endocrine-related reproductive endpoints). ECHA RAC also recognised the structure activity relationships for adverse reproductive effects (C3-C6 backbones in the alkyl side chains). VinylPlus is also aware that detailed business confidential information has been provided as part of the REACH registration dossiers for individual producers of HMW ortho-phthalates, demonstrating the lack of presence of C3-C6 backbones in these plasticisers – addressing point (i) in the ECHA report conclusions in this paragraph. In addition, extensive testing and regulatory assessments have confirmed the lack of adverse reproductive (including endocrine related effects) effects for HMW ortho-phthalates – addressing point (ii) in the ECHA report conclusions in this paragraph. With regard to point (iii) read across, this is appropriate for LMW phthalates for which there is no data and has already been used to identify several of LMW phthalates which have then already been included in the Candidate and Authorisation Lists. VinylPlus believes it is not appropriate when extensive data is present and has been evaluated.

Paragraph 8 – sub-paragraph 2 – Ortho-phthalates – *"The need for regulatory action is based on the environmental (and man via the environment) risks assessment which applied a non-threshold case-by-case risk approach."* The Category 1B LMW phthalates (DEHP, DBP, BBP and DIBP) have also been identified as endocrine disruptors (human health), with DEHP also having been identified as an ED for the Environment as well as an ED for human health under REACH (Article 57(f)) and are being further regulated under the REACH Authorisation process as a result. VinylPlus disagrees with assuming that all ortho-phthalates (and all of the 63 prioritised additives) are "very persistent "when they are released within PVC microparticles." It is not clear whether ECHA means that additives would be released from PVC microparticles. If they remain within the PVC microparticles, then, normally, the additives are not bioavailable. This phrase seems to suggest that release of PVC microparticles means in the view of the ECHA report that if a PVC microparticle is released then both the particle and the additives are "very persistent". This is not a logical statement. If the additive is released from the microparticle to the environment, then it will have the properties of the substance not of the PVC microparticle. It is unprecedented to apply a hazard characterization (of vP) to every additive of PVC on the basis that "the additives released within PVC microparticles are expected to behave in the environment as very persistent substances because they are bound in the PVC microparticle matrix." Every additive, including possible alternatives, would be covered by this illogical assumption. P/vP assessment, in conjunction with PB and vB exists in the REACH Regulation to clarify the intrinsic property of the substance under relevant conditions.

In the case of plasticisers, the studies required under REACH have shown that the major ortho-phthalate plasticisers (DINP, DIDP, DPHP, DIUP, DTDP – see REACH dossiers; Danish EPA Substance Evaluations for DIUP[5] and DTDP[6]) used today are biodegradable. In addition, OSPARCOM concluded in 2004 that HMW ortho-phthalates (DINP, DIDP) are not PBT and not vPvB substances[7]. In 2021, the Danish EPA concluded, following a 7-year substance evaluation process, that the two highest molecular weight ortho-phthalates (DIUP, DTDP) are not PBT nor vPvB substances (2022)[8] [9]. These conclusions were based on discussions within the ECHA PBT Expert Group on these substances. Based on the scientific data and formal regulatory assessments, VinylPlus cannot agree that all ortho-phthalates (and all 63 prioritised additives) are "very persistent" simply because they are used in the production of PVC articles and hence are found in PVC microparticles. With respect to PVC, VinylPlus would also note that the PBT/VP designation was never intended for polymeric materials which by definition (whether natural or synthetic polymers) are intended to have durability and hence to be persistent, with the associated performance, resource efficiency and sustainability benefits. Since VinylPlus disagrees with the designation of "very persistent" for all ortho-phthalates (and all 63 prioritised additives), we similarly disagree with the statement in this paragraph that it is "therefore preferable [based on the assumption of being very persistent) not to wait until each of these substances (or subgroups) have gone through the steps of CLH, SVHC or even data generation before a restriction would take place....". Indeed, ECHA has encouraged VinylPlus members to continue to implement the regulatory processes and to fill any data gaps and we are fully in agreement on this point. Not following REACH and CLH legal processes would also remove all regulatory predictability for the (PVC) industry.

Paragraph 8 – Sub-paragraph 3 – Alternative general-purpose plasticisers – The statements in this paragraph are correct to some degree in that "Alternative general-purpose plasticisers" (based on other statements in the report principally DOTP) could replace large volume medium chain ortho-phthalates (depending on the application). This is indeed happening already in a competitive marketplace where DINP and DOTP, for example, are interchangeable in flooring, and the availability of both products helps to ensure competitive pricing. However, as explained in the VinylPlus input to the ECHA Calls for Evidence (CfEs), it is very difficult technically to replace the higher-performing DIDP and DPHP with DOTP (in applications such as wire and cable and synthetic leather for car interiors). DIDP and DPHP are also higher costs (given higher performance and higher production costs) than general-purpose products such as DINP and DOTP. The ECHA report is inaccurate in stating that longer chain ortho-phthalates such as DIDP can replace DINP and DOTP with no additional unit cost – this is not accurate on both performance and cost grounds.

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[5] Hazard Assessment Outcome Document for Diundecyl phthalate, branched and linear (DIUP), (2019)

[6] Hazard Assessment Outcome Document for 1,2-Benzenedicarboxylic acid, di-C11-14 branched alkyl esters, C13-rich (DTDP), (2019)

[7] https://www.ospar.org/work-areas/hasec/hazardous-substances/deselection *"DINP and DIDP are not PBT substances according to OSPAR DYNAMEC or EU-TGD criteria and there is no indication of potential for endocrine disruption".*

[8] Danish EPA (2022), Substance Evaluation Conclusion as required by REACH Article 48 and EVALUATION REPORT for 1,2-Benzenedicarboxylic acid, di-C11-14 branched alkyl esters, C13-rich (DTDP)

[9] Danish EPA (2022), Substance Evaluation Conclusion as required by REACH Article 48 and Evaluation Report for 1-2-benzenedicarboxylic acid, di-C10-12 branched alkyl esters (D1012P) EC No 700-989-5 (Previously registered as diundecyl phthalate (DIUP), branched and linear, EC No 287-401-6, CAS No 85507-79-5)

Paragraph 8 – Sub-paragraph 4 – Transition from shorter chain phthalates to longer chain phthalates in the EU and implications of imports. VinylPlus agrees with the statement that *"it is important to note that there has been a transition to use longer chain (high molecular weight) ortho-phthalates in the EU" and that "shorter chain [low molecular weight] ortho-phthalates are still widely produced and used in other markets, e.g. China, India etc."*. This transition in the EU has involved major investment (over 6 billion EUR) over 25 years. While the ECHA Report states that the above means that *"imported articles are likely to contain shorter chain ortho-phthalates",* this statement appears to ignore the fact that broad REACH restrictions are already in place for the major LMW or shorter chain ortho-phthalates (i.e. DEHP, DBP, BBP and DIBP). Restrictions are also in place for these LMW phthalates under RoHS, Cosmetics, Toys, Food Contact and Medical Device regulations). If EU regulations are being followed by importers of articles and enforced by Member States, then logically there should be no/very limited imports of imported articles containing shorter chain ortho-phthalates. This raises another key issue which is the necessity to ensure imported goods' safety for end consumers. REACH should not be used to compensate for the shortcomings of European market surveillance.

Paragraph 8 – Sub-paragraph 5 – VinylPlus disagrees with the recommendations for regulatory action on ortho-phthalates on the basis of assumptions and similarly disagrees with such an approach for the use of plasticisers in other polymers.

Paragraph 8 – Sub-paragraph 6 – "*Regulatory action is needed to reduce the risks from the organotin substances (other than MOTE with a concentration of DOTE below 0.3%)".* VinylPlus questions whether regulatory action is needed and disagrees with the statement that "*The seemingly most suitable regulatory action is REACH restriction….*".

Paragraph 8 – Sub-paragraph 7 – Risks for workers at recycling plants. Specifically, VinylPlus disagrees with the identification of risks for workers at recycling plants as stated in the report. A significant part of the basis for this conclusion appears to be the potential use of organotin compounds in window profiles. Attributing edge bands (used in furniture) to windows and hence extrapolating the volume of installed tin stabiliser used in Europe to all currently recycled volumes of rigid PVC is incorrect. The presence of tin stabilisers in microparticles is hence also overestimated by several magnitudes This also means that for recycling and landfill the potential exposure to organotin stabilisers is very low. It would then be appropriate to conduct again the quantitative risk assessment with this new information and to determine whether there is a risk. Confirmatory tests on the absence of organotin can also be considered for window profiles. VinylPlus is also supportive of conducting occupational exposure measurements for plasticisers and organotin compounds (subject to a revised risk assessment) in recycling plants, also including dust measurements which would address microplastics exposure via inhalation. There are existing OELs for dust and consistent with occupational health regulations all appropriate measures should be taken to minimise exposures of workers in recycling plants. Based on VinylPlus' knowledge of the recycling industry our understanding is that these occupational health regulations and requirements are being applied. Treat rates for organotin stabilisers are as follows for the main different applications:

- Typical calendered films: 0.9% (pharmaceutical and food packaging)
- Other calendered films: 1.3%

- Extruded sheets: up to 2%
- PVC-piping from industrial installations for chemical fluid handling: below 2% of the weight every piping component. Due to the contamination of the PVC piping with the chemical fluids to be conveyed through them, such piping components need special disposal according to regulations in place.

Paragraph 8 – Sub-paragraph 8 – Use of organotin stabilisers. There are more than indications that MOTE has already been used to substitute DOTE in pharmaceutical packaging. This has been confirmed by producers of pharmaceutical packaging in the EU and this was confirmed in writing to ECHA. Organotin compounds are used for specific performance requirements, such as shelf life of pharmaceuticals and transparency, weathering requirements. Organotin stabilisers are high cost because of the costs of tin metal, and therefore it is not a question of cost with regard to potential replacement by Ca/Zn stabilisers as indicated in the ECHA report. Significant Research and Development costs would be needed to assess whether Ca/Zn could replace organotin compounds with the distinct possibility that the same performance requirements would not be met (e.g. safety and service life of chemical industrial plants). It should be noted that the correct designation for Calcium and Ca/Zn stabilisers is either "calcium based" (no use of zinc) or "Ca/Zn" but not "Zn/Ca." The VinylPlus input explained that calcium based (no zinc) for example are used in pipes. This is not explained in the ECHA report, rather there is repeated reference to Zn/Ca which is inaccurate.

Paragraph 8 – Sub-paragraph 9 – Use of organotin stabilisers outside the EU. as stated in the Report, there continues to be significant use of organotin stabilisers outside the EU including North America where use of such products is based on risk assessments showing safe use and regulatory approvals e.g. National Sanitation Foundation (NSF). VinylPlus suggests that ECHA evaluates risk assessments conducted by experts in the US EPA, FDA and NSF, rather than assuming risk based on a screening level worst case assessment. So far, organotin compounds are the only class of stabilisers permitted in the United States by NSF for potable water supplies. The prior EU Risk Assessments on organotin compounds led to conclusions to restrict certain uses, and to allow the current uses. These conclusions were based on in-depth EU Risk Assessments under the Existing Substances Regulation and so the question arises as to what has changed versus these prior risk assessments. Assumptions regarding microplastics should not be the basis to reject prior risk assessments. It should be noted that are no imports of window profiles from the US made with organotin compounds since EU production meets the needs of the EU market and such imports could have impacts on recycling.

Paragraph 8 – Sub-paragraph 10 – Regulatory action is needed to ensure minimisation of the releases of PVC microparticles and prioritised PVC additives. While VinylPlus supports all appropriate steps to minimize the emissions of plastics microparticles including PVC (~3% of all microplastics) and in particular at recycling and landfill sites, we disagree with the logic of the arguments for recommending regulatory action in the ECHA report. There are existing extensive occupational hygiene and environmental regulations which are related to this matter and full compliance with these regulations should be ensured. Recycling sites are already subject to local permitting requirements, and there is an existing EU Landfill Directive which addresses emissions. The basis for the statement that *"Recycling plants are a significant source of PVC microparticles"* is based on a single study from a single UK recycling plant, which was not recycling PVC, and where the site is now closed and no longer operating. Given this, we believe this statement may be inaccurate. In fact, for DEHP, biomonitoring data does exist for recycling plants – provided as part of Applications for

Authorisation from recyclers – and these data show that exposures to DEHP are within occupational exposure/safe limits. Since the data was part of Authorisation applications it is confidential business information. Given the lack of data, VinylPlus disagrees that *"There is sufficient evidence to consider action at EU level"* but is committed to addressing data gaps.

VinylPlus notes that the ECHA report did not assess the socio-economic impacts of additional mandated emission minimisation technologies. This is an important point to assess before deciding on any regulatory action since recycling facilities are typically SMEs with low profit operations and significant additional investments in new technologies would be challenging for these businesses. VinylPlus also questions the statement that there are major releases of additives at recycling and landfill sites. The additives remain bound to a significant degree within the microparticle matrix and hence are not bioavailable. VinylPlus requests to clarify what is the evidence for release. Moreover, if the additive is released into the environment, then based on scientific data, biodegradation by microorganisms is a key fate for many of the additives (e.g. ortho-phthalate plasticisers). Physico-chemical degradation is another key pathway (e.g. hydrolysis, photodegradation). With respect to landfill sites, recent data obtained by VinylPlus (subsequent to the ECHA report publication) (ARCHE, 2023)[10] has shown that migration of major plasticisers from landfill sites is infinitesimally small (~3x10-7% after 1 year during 91 rain events). With respect to organotin emissions, please see the prior comments above.

Paragraph 8 – Sub-paragraph 11 – Flame retardants. VinylPlus stresses, as is noted elsewhere in the ECHA report, that due to the intrinsic flame retardancy of PVC, there is limited use of flame retardants in PVC applications (e.g. use of chlorinated paraffins in high temperature flexible vinyl cables). Unlike polyolefins and other plastics, brominated flame retardants are not used in PVC.

Paragraph 9 – Data and assessment gaps, priorities for data gathering. VinylPlus is highly supportive of filling relevant data gaps and is interested to learn from the ECHA report that data gaps can be addressed via the EU PARC (Partnership for the Assessment of Risks from Chemicals) project.

3. Summary of Risks

3.1.1. Starting materials in the production of PVC

VinylPlus appreciates that the ECHA report acknowledges industry efforts and progress in several areas, especially for the manufacturing of PVC. This reflects the efforts made by the PVC industry through successive VinylPlus commitments and, in particular, the application of the ECVM Charter.

VinylPlus agrees with the ECHA statement that *"...the levels of residual EDC/VCM in PVC articles seem to be appropriately controlled in Europe."* With regard to the figure of ~90% compliance it should be noted that for the VCM concentration in PVC resin (and hence in PVC articles) was found to be 100% in suspension grades of PVC (the largest volume) and 90% in emulsion grades – and hence much above 90% overall. The ECHA report also recognises that some imported articles may have levels well above 1 ppm of VCM and even as high as 1000 ppm. This underlines the importance of supporting the EU manufacture of PVC and strengthening controls for imported material.

[10] ARCHE (2023), Exposure Assessment of the PVC Additive: DNIP end of life Stage - Landfill.

3.1.2. PCDD/Fs

VinylPlus agrees that the BAT-AELs under the EU Industrial Emissions Directive limit the amount of PCDD/Fs that can be emitted from the EDC/VCM/PVC to the relevant very low limits. VinylPlus also appreciates the acknowledgement of the third-party verification of compliance with the criteria set in the ECVM charter, in addition to controls by permitting authorities.

VinylPlus also agrees that the potential production of PCDD/Fs in incinerators depends upon the furnace types, operating conditions, and the type and efficiency of air pollution controls, that there are several other sources of chlorine than PVC, and that emissions of PCDD/Fs are declining over the years.

3.1.3. PVC Dust

Paragraph 2 – with respect to suggestions that PVC dust might promote pulmonary carcinogenesis and possible associations with pneumoconiosis and interstitial fibrosis, the following comments showing that in practice PVC does not cause these effects, are relevant.

In 2013 the Dutch Health Council (2013)concluded that *"The epidemiological studies available showed no consistent evidence for carcinogenicity of PVC in humans. Some studies show an association between certain cancer types and workers involved in PVC handling, whereas others do not. As these studies have serious methodological limitations (e.g. lacking a reliable exposure assessment of PVC, and limited correction for confounders including co-exposures), the Committee considers the human data insufficient to draw any conclusions on the carcinogenic properties of PVC in humans"*[11]. There are several other studies which do not identify concerns for pulmonary cancer in association with PVC dust exposure (Graham, 2005)[12] (Haiyan Xu E. V., 2004) [13] (Haiyan Xu H. M., 2004) [14].

The ECHA report notes that the exposures to dust in the epidemiological studies were often over 10 mg/m3, which are very high levels, making it very difficult to assess whether such effects are due to "dust" or whether this is related to PVC. Typical exposures are below 5 mg/m3 in the workplace, and hence, such high levels are not typical.

Paragraph 3 – with respect to statements in the ECHA report on potential differences between the toxicity of uncompounded PVC and compounded PVC due to the potential migration of additives, there is no robust scientific evidence to support such leaching for example in the lungs, where if dust is inhaled the mucociliary escalator is an efficient barrier removing such dust from the lungs and potentially leading to ingestion with evidence indicating that the large majority of dust is excreted in the faeces.

[11] Health Council of the Netherlands (2013), Polyvinyl chloride: Evaluation of the carcinogenicity and genotoxicity

[12] M.K. Graham et al (2005), Mortality study of workers at the Hillhouse PVC plant, IOM research report.

[13] H. Xu et al (2004)), Pulmonary toxicity of polyvinyl chloride particles after a single intratracheal instillation in rats, Toxicology and Applied Pharmacology, Volume 194, Issue 2.

[14] H. Xu et al (2004), Pulmonary toxicity of polyvinyl chloride particles after repeated intratracheal instillation in rates, Toxicology and Applied Pharmacology, Volume 194, Issue 2

Paragraph 5 – it is more accurate to state that the occupational limit for PVC dust is 0.3 mg/m3 x the density of PVC (8hr TWA) in Germany for the respirable fraction (this gives a value of 0.435 mg/m3)[15].

VinylPlus appreciates the acknowledgement of the work done by resin producers as part of the ECVM charter and agrees that *"the operational conditions and risk management measures implemented in the VCM/PVC industry are adequate and effective to control the risk from PVC dust in industrial settings."*

VinylPlus would note that there are also dust controls in operation in recycling sites (re: ECHA discussion of PVC microparticles and other microplastics) with similar occupational limits. Further improvements can no doubt be made in recycling operations.

3.2. Risks from current PVC additives

Paragraph 2 – states that the 470 substances identified as being (potentially) used in PVC were prioritized based on *"hazard scoring (severe hazards only)"* and *"release potential (Appendix B)"*. For many substances, the hazards are only potential or suspect hazards which are still subject to confirmation (or not, as the case may be). The use of the Assessment of Regulatory Needs (ARNs) and suspected hazards contradicts formal regulatory processes in some cases and the existing robust scientific data on the substances. Examples here include the RAC opinion on DINP (a major ortho-phthalate plasticiser), which reached a consensus decision in 2018 that classification for adverse reproductive effects is not required for DINP (ECHA, 2013)[16] (ECHA, 2018)[17].

This assessment by RAC included looking at about 10 male reproductive programming studies (i.e. the key endocrine effect related to LMW phthalates such as DEHP), with the conclusion that no adverse endocrine related reproductive effects were observed. The assessment by RAC included the assessment of information on constituents. The ECHA ARNs and the PVC Investigation report, therefore, contradict the formal ECHA RAC Opinion by designating DINP (and related HMW phthalates) as "Reprotoxicity, ED (HH based on constituents, ENV), PBT." Other examples have been provided by VinylPlus in the Calls for Evidence and were first submitted in a letter to Ms Simone Doyle (ECHA) on November 8, 2022.

The argument that the hazard assessment with assumptions that concerns are confirmed and the PLASI model are only "screening tools" does not hold in that these screenings are being used to recommend regulatory action, which is not justified based on the actual scientific data.

In summary, the inclusion of many substances (~51%) on the list of 63 prioritized substances is not warranted as it is based on assumptions without scientific substantiation.

Tables 1, 2 and 3 – Prioritised additives – With respect to Tables 1, 2, and 3 VinylPlus has the following comments:

- Tables 1, 2 and 3 of the report assume severe hazards (Reprotoxicity, ED, PBT, vPvB) for many of the 63 prioritized additives. There are no references for Tables 1, 2 and 3 in the tables so the precise basis is not clear. Based on the text, it would appear that the basis for Tables 1,2 and 3 is the ECHA informal ARNs. The ARNs also include a lot of assumptions and are not

[15] A. Hartwig, MAK Commission (2016), Polyvinylchlorid (PVC), MAK Value Documentation in German language
[16] ECHA (2013), RAC opinion on Evaluation of new scientific evidence concerning DINP and DIDP
[17] ECHA (2018), RAC opinion on proposing harmonised classification and labelling at EU level for DINP

consistent with the REACH registration dossiers, nor with the outcome of formal legal processes under the REACH and CLP regulations. Furthermore, when the original ARNs were questioned, industry was informed that these are informal assessments and will not be used for regulatory action. These ARNs are now being used to support recommendations for regulatory action in the ECHA Investigation Report. Furthermore, the assumptions are not consistent with prior in-depth regulatory risk assessments conducted before REACH and since REACH has come into force. Examples include:

- DINP – formal ECHA RAC process under the CLP for a harmonized classification dossier. After a 3-year process and final published opinion in June 2018, ECHA RAC rejected by consensus the CLH proposal from the Danish EPA for classification of DINP as a reproductive agent. ECHA RAC concluded that there was no evidence of “some” (Category 2), or “clear” (Category 1A / Category 1B) adverse effects based on extensive animal data and human epidemiological data. As part of this assessment, several (~10) male programming window studies (published in the academic literature) were assessed with respect to endocrine-disrupting effects for male reproduction. No significant, consistent effects were identified which could be considered as adverse. ECHA RAC also requested composition information which was provided and included information on constituents (including with respect to the presence of C4-C6 straight chain backbones in the branched alkyl side chains with a total carbon number of C9) as part of their assessment; this information was provided and is included in the Background document to the RAC opinion. In addition, significant updates to REACH registration dossiers have been completed in 2022 by registrants (who are members of VinylPlus) and were not taken into account in the ECHA Investigation Report on PVC and its additives. For these reasons, VinylPlus strongly disagrees with the statement that identifies DINP as “Reprotoxicity, ED (HH based on constituents, ENV), PBT”. VinylPlus also finds that the absence of any reference to the extensive ECHA work in the references[18] list is problematic, especially as the ECHA report directly contradicts the ECHA RAC opinion. There is no significant new information on DINP to change this conclusion, and if such information exists then it should logically be subject to further formal assessment, bearing in mind the major evaluation which RAC undertook.

- ECHA Substance Evaluation Process – CoRAP – for DIUP and DTDP. After a 7-year assessment, the Danish EPA concluded in early December 2021 that DIUP and DTDP are not PBT and are not vPvB, as mentioned above. Yet in mid-December 2021, the ARN for ortho-phthalates was issued showing DIUP and DTDP as PBT substances.

- In Tables 1, 2, and 3, it appears that both actual and potential hazards are identified re: “Leading (potential) hazard”. It is not clear from the table which hazards are already established and which are “potential” and still subject to confirmation. Similar comments apply to the risks – some of which are “potential”, and some are “identified” – depending on the additives. Yet in the “Overall Conclusions” to the report, ECHA states that their findings are “identified risks” (not potential).

- Page 15, Table 3. There is no use identified for Dimolybdenum trizinc nonaoxide – it is a smoke suppressant (information was included in the VinylPlus input to the CfEs).

[18] ECHA report pages 99 to 102; Appendix A and B reference list pages 152-160

- Page 15, Table 3. LCCP is stated as PBT. It should be noted that the formal REACH dossier evaluation has recently just started, and this has not yet concluded with respect to PBT properties. It is also stated that there are "No identified uses" for LCCP. These are included in the REACH registration dossier and include PVC Compounding, PVC furniture and PVC cables.

3.2.1. Hazard Assessment

VinylPlus notes that this section covers the principal assumptions which are then the basis for supporting regulatory action. Please see the VinylPlus Table 1 for detailed comments as to why these are assumptions without a robust scientific basis, as well as proposals for addressing these assumptions, with recommendations for how to confirm whether or not these assumptions are valid, and for filling relevant data gaps. The PVC industry is ready to work with regulators and researchers in order to address data, information and assessment gaps, and the PVC industry would appreciate to dialogue further on this topic.

Additional detailed comments on page 16 are as follows: The ECHA report (page 16 Section 3.2.1., Line 7 Hazard Assessment) states that *"experimental or estimated leaching data are needed for PVC microplastics released and present in the environment. Such data are not available for substances in focus of this report*." In the admitted absence of data, the ECHA report nevertheless states that "*Accumulation of PVC and additives contained therein <u>can be expected</u> in the environment in the similar manner as for vP substances*" (VinylPlus underlining). This is an assumption, and no scientific evidence is provided to support it. ECHA then combines assumptions on persistence (vP) together with assumptions on co-exposures to different additives ("synergistic or additive effects cannot be excluded" – no evidence provided) to make assumptions on "non-threshold" effects related to PVC additives. ECHA formulates this on page 16 as follows: *"In summary, the concern related to PVC additives should be considered of non-threshold character because: The additives released within PVC microplastics are expected to behave in the environment as very persistent substances because they are bound in the PVC microparticle matrix".*

As stated above (see here), this statement is difficult to understand because it is contradictory – it is stated that additives are both "released within PVC particles" and that they are "bound in the PVC microparticle matrix". Additives are either bound in the microparticle or released to the environment and not released within the PVC microplastic. Furthermore, if the additives are bound in the PVC microparticle matrix then they are not biologically available. If they would become biologically available in the environment (data is needed to assess) then the specific properties of the additive will apply - if the substance is biodegradable, then it will biodegrade when it is dissolved in water and bacteria get to work on it (this is certainly the case for many plasticisers including ortho-phthalates). It is not correct to propose that the additive takes on the properties (in this case vP) of PVC just because it is used in the manufacture of the PVC article and can then be found in PVC microparticles. If ECHA is suggesting that the PVC microparticle containing the additives is itself bioavailable and has the potential to cause effects, this is not consistent with current scientific data and understanding.

The ECHA Report then states that *"the use of additives in PVC induces direct human and environmental co-exposures. Synergistic or additive effects cannot be excluded."* There is limited scientific basis for this statement. As pointed out elsewhere in the report, migration and leaching are complex subjects. Additives may leach (data is needed to confirm whether this happens) at very different rates meaning that co-exposures are not necessarily occurring or not in the way foreseen. The first organisms "exposed" in the environment will typically be bacteria and this exposure from microplastics will be at extremely low levels (picograms). Since many additives are biodegradable, the bacteria normally see the different chemicals as a source of nutrients and biodegrade the additives, so co-exposures should not be a concern and with biodegradation, there is significant breakdown and elimination of the chemicals. Regarding heat stabilisers, it should be considered that during PVC processing into products, they are mainly being converted into chemical products which do not share same hazard properties as the original organotin prior to use (Dominik Kirf, 2023)[19]. Given the complexity of assessing combined exposures to different substances, broad generalizations concerning co-exposures cannot be made, otherwise all substances and polymers will be considered as posing risks requiring regulatory action. Instead, tools such as the WHO methodology should be applied (2011)[20].

The ECHA report also states that "*the leading effects of the prioritised additives are severe, many of which are non-threshold*". This is not an accurate statement with respect to the 63 prioritised additives. The statement in the ECHA report is based on assumptions made in the ARNs, which for many substances are not supported by data in the registration dossiers, or by robust read-across where relevant. The few substances identified as EDs for Human Health under REACH include the classified LMW phthalates (DEHP, DBP, BBP, DIBP) which have been determined to be EDs because of adverse reproductive effects seen in animal studies and because they are considered to act via an endocrine mode of action.

An analysis of Tables 1, 2, and 3 has shown that the severe classifications are based on assumptions for 51% of the substances and for many of these there will be data or robust read-across not supporting the assumption. Examples here include the HMW phthalates (see detailed comments under Section 3.2.1.2.). With respect to thresholds, typically, reproductive effects have thresholds. In 2016 the European Commission (2016) confirmed that *"Based on the information provided in the previous sections, it is concluded that it is not appropriate to extend a-priori the scope of Article 60(3) to all substances identified under Article 57(f) as substances with endocrine disrupting properties which have an equivalent level of concern. Consequently, Article 60(3) of REACH will continue to be applicable to those EDs for which it is not possible to determine a threshold. It remains the responsibility of applicants for authorisation to demonstrate that a threshold exists and to determine that threshold in accordance with Annex I to REACH. Even though this might be particularly difficult for EDs, it cannot be excluded on the basis of current knowledge that it will be possible. It is up to RAC to assess the validity of the assessment and ultimately decide on the possible existence or not of this threshold"*[21].

ECHA is not following this approach and is assuming all EDs are non-threshold. Based on the actual data, many of the 63 substances are of low toxicity, not classified under the CLP, are safe for use, and have in fact replaced SVHC additives (e.g. DEHP, DBP, BBP and DBP replaced by HMW phthalates

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[19] Dominik Kirf et al (2023), Simulated gastric hydrolysis and developmental toxicity of dimethyltin bis(2-ethylhexylthioglycolate) in rats, Frontiers in Toxicology

[20] WHO/IPCS (2011), Risk assessment of combined exposure to multiple chemicals: A WHO/IPCS framework, Regulatory Toxicology and Pharmacology, Volume 60, Issue 2, Supplement.

[21] European Commission (2016), Report from the Commission to the European Parliament, the Council and the European Economic And Social Committee in accordance with Article 138(7) of REACH to review if the scope of Article 60(3) should be extended to substances identified under Article 57(f) as having endocrine disrupting properties with an equivalent level of concern to other substances listed as substances of very high concern.

(DINP, DIDP, DPHP) and other plasticisers (DOTP, DINCH). e.g. MOTE (less than 0.3wt% DOTE) which has replaced DOTE where feasible (e.g. pharmaceutical packaging).

VinylPlus finds the following sentence in the ECHA report contradictory: *"substances for which the lead effect has been so far suspected based on screening information (and pending confirmation) data on further effects are largely available to support the hazard profile (need full assessment in the follow-up)."* In our view, either a substance or group of substances are suspected of possible effects, and this is pending confirmation, or data is available and supports the hazard profile. Both should not be true at the same time. ECHA has clarified post-publication that many of the hazards for the additives are subject to confirmation (or not, as the case may be based on the data and assessment) following further testing and assessment. In such cases then such assumptions should not be used as a basis for recommending regulatory action.

With respect to statements on non-threshold the following comments are relevant: Non-threshold is being assumed for many substances without any evidence. In principle hormone like mediated effects are dependent on thresholds. In practice, practical thresholds are often the case – as shown in a study by S. Brescia (Brescia, 2020)[22].

3.2.1.1. Heat Stabilisers

Page 17, Paragraph 1 – As stated in the VinylPlus response to CfE number 2, both calcium-based and calcium/zinc stabilisers are the major stabilisers used. Calcium-based (without zinc) and Ca/Zn are used in PVC pipes; calcium/zinc (Ca/Zn and not "Zn/Ca" as used in the ECHA report) are used in window profile The reference "Zn/Ca" should be replaced with "Calcium based (without zinc) and calcium/zinc stabilisers. It should be noted that Ca/Zn heat stabilisers represent ~83% of the stabilisers in the EU (these are solid stabilisers, liquid mixed metal (LMM) stabilisers are ~11%, and organotin compounds have now been reduced to ~6% of stabiliser use. It is not fully accurate to state that Ca/Zn represent ~94% of stabiliser uses in the EU (see VinylPlus input to the ECHA CfE number 2).

Organotin substances

Page 17, Paragraph 4 – With respect to this paragraph VinylPlus would note that MOTE does have reproductive studies which are included in the REACH registration dossier, and which support the conclusions that classification is not needed for fertility or development effects. In addition, there is now an ongoing EOGRTS study due for completion by October 2024. The way this is worded in the report could be interpreted as suggesting that the registrants are not being responsive to the REACH dossier evaluation re: *"…and the registrants have not responded yet to ECHA's request for testing data."* This is not the case since registrants have initiated the testing with completion due by October 2024 and informed ECHA accordingly.

Page 17, Paragraph 5 – "*several of them*…" This should be specified – only 3 out of 10 have neurotoxicity or immunotoxicity classifications.

Page 17, Paragraph 7 – with respect to the potential for co-exposures and possible additive/ synergistic/ inhibitory effects, it is important to assess common modes of action with actual data. This is also a broad generic topic – i.e. how to effectively assess potential co-exposures. Solid scientific data and a methodology is needed to have a targeted approach rather than to speculate.

[22] S. Brescia (2020), Thresholds of adversity and their applicability to endocrine disrupting chemicals, Critical Reviews in Toxicology

Page 17, Paragraph 9 – Phenyl 1,3-diones – states that these substances *"seem to be used as costabilisers etc"*. Input by VinylPlus into the CfE No. 2 for these substances stated:

"With respect to Calcium based stabilisers and LMM stabilisers certain dione costabilisers are necessary at low levels in the stabiliser formulation for their performance (i.e. to achieve technical performance such that lead stabilisers could be replaced). VinylPlus has previously noted the following in communications with ECHA: Heat Stabilizers – Phenyl 1,3-diones (2 substances) are included on the list of 63 additives in focus – based on robust testing data and assessment one substance is a skin sensitizer (EC no 204-398-9) and one substance is not (EC no 915-316-2). Robust study summaries are included in the REACH registration dossiers for the studies conducted on these substances with a reliability score of 1 (highest possible). Yet both are listed in the group of 63 substances. We would note that there is no ARN document for these substances so the basis for their inclusion is not transparent. The assumption of "Reprotoxicity" in Table 1 (page 11 of ECHA report) is also based on an assumption and not on robust data – data generation is ongoing to address this potential concern. It is positive to note that the PBT assessment was corrected to conclude based on the scientific data that these diones are not PBT."

With respect to organotin compounds, VinylPlus would also highlight again the EU regulatory risk assessments conducted under REACH, which resulted in certain substances being restricted and certain uses allowed. Organotin compounds are also permitted in food contact plastics under EU regulations. VinylPlus asks that ECHA clarifies whether new information has been obtained to cause the previous in-depth organotin risk assessments to be set aside. VinylPlus maintains that until the relevant testing and assessments are completed, assumptions should not be made regarding the outcome of those studies – this is not scientifically or ethically justified.

Further evidence was submitted by VinylPlus as part of the ECHA CfEs, including specific studies (FABES, 2004)[23] (RPA, 2007)[24].

3.2.1.2. Plasticisers

Paragraph 2 – Page 18 – It is not correct to state that *"Different alcohols and different acids lead to…"* since alcohols and acids are not used as plasticisers. Rather, it should be stated that *"Different alcohols and different acids used to make plasticisers will lead to…"*.

Ortho-phthalates

Page 19 – Paragraph 4 – It would be more accurate to state that "Ortho-phthalates can be sub-grouped based on the straight chain alkyl backbone length…", since this is what counts in determining the structure activity for adverse reproductive effects. Such *"longest straight chain alkyl backbones"* may then of course also have methyl, ethyl and in some cases propyl branching making the total carbon number higher. Before the ARN on ortho-phthalates was published, the accepted structure activity was that substances composed of C3-C6 straight chain alkyl backbones in the alkyl side chains (typically two such chains i.e. a diester) result in adverse reproductive effects in laboratory rat reproductive studies (both developmental and fertility effects typically). This structure

[23] FABES (2004), Migration study of organotin compounds from octyl tin stabilized PVC
[24] RPA (2007), Impact Assessment of Potential Restrictions on the Marketing and Use of Certain Organotin Compounds, Final Report

activity understanding dates from the early 2000s, and the commercial products meeting this structure definition included DBP (C4 longest straight chain with no branching) and DEHP (C6 longest straight chain with an ethyl branch in the 2-position). Butyl Benzyl Phthalate (BBP) includes a straight chain C4 alkyl group and an aryl (C6 aromatic) side group (forming a diester). This also shows adverse reproductive effects in laboratory rat studies. Later other substances with C3-C6 backbones were identified as reproductive agents also – this includes DIBP – di-isobutyl phthalate – with a C3 longest straight chain with a methyl branch, Di-pentyl, Di-isopentyl, Di-isohexyl, Di-isoheptyl (includes C6 methyl branched). These phthalates were designated as LMW phthalate (C4-C6 longest straight chain carbon backbone in the alkyl sidechain – and since the testing on DIBP (C3 backbone) more correctly C3-C6).

Testing on ortho-phthalates that do not contain any straight chain C6 backbones results in no evidence of adverse developmental and fertility effects in laboratory rat studies. So, studies on DINP (straight chain alkyl backbone C7 and above), DPHP (straight chain alkyl backbone C7 and above), DIDP (straight chain alkyl backbone C8 and above) do not show adverse reproductive effects. This was confirmed by the ECHA RAC Opinion of March 2018 (see comments above). These phthalates with the longest straight chain alkyl backbones of C7 to C13 (C13 is the limit for plasticisers for PVC because of compatibility and processability) were designated as HMW phthalates. The OECD issued a SIDS (OECD, 2004)[25] document confirming the lack of adverse reproductive effects for C7-C13 straight chain alkyl backbones in the side chains. An additional benefit of such products is that they bind very tightly within the PVC matrix, and with higher molecular weights, they have very low vapour pressures resulting in lower migration and higher performance in PVC applications e.g. wire and cable, interior synthetic leather. To complete the picture, the C1 and C2 ortho-phthalates (not used as plasticisers in PVC) do not show adverse reproductive effects in laboratory animal studies. HMW ortho-phthalates are the major commercial products being used today in flexible vinyl and are the result of the assessment of 30,000 different substances for plasticising properties over the last 70 years by the global plasticiser industry.

ECHA RAC (2018) also made clear comments on the differentiation of LMW and HMW ortho-phthalates with respect to reproductive effects and DIOP (includes C6 backbones in the alkyl side chains). The ECHA RAC Opinion on DIOP[26] states:

"However, more importantly, it is concluded that classification in category 1B for sexual function and fertility is supported by a category approach with C3-C6 ortho-phthalates where the phthalates with a side chain length closest to DIOP are already classified as Repr. 1B for fertility. The phthalates in the category showed similar toxicity on male reproductive organs as was reported for DIOP. Furthermore, mechanistic studies indicate an anti-androgenic MoA that is considered relevant for humans. RAC therefore considers that read across to the C3/C4-C6 orthophthalates category is justified, and that DIOP should be classified as Repr. 1B for sexual function and fertility. In conclusion, RAC considers that classification for DIOP as Repr. 1B, H360F, is justified."

The ECHA RAC statements are consistent with the OECD 2004 SIDS document. This also includes references to work by Saillenfait et al (Anne-Marie Saillenfait A.-C. R.-P., 2011)[27], (Anne-Marie

[25] OECD (2004), SIDS Initial Assessment Profile, High Molecular Weight Phthalate Esters (HMWPE)
[26] ECHA (2018), RAC opinion on proposing harmonised classification and labelling at EU level of DIOP
[27] A-M. Saillenfait et al (2011), Prenatal developmental toxicity studies on di-n-heptyl and di-n-octyl phthalates in Sprague-Dawley rats

Saillenfait A. R.-P.-F., 2011)[28], (Anne-Marie Saillenfait J.-P. S.-C., 2013)[29] which supports this science-based distinction between LMW (C3-C6 backbone (longest straight chain in the alkyl side chains) and HMW (C7 and above backbone (longest straight chain in the alkyl side chains).

Given the above points, industry has questioned why ECHA decided to create a new grouping approach for ortho-phthalates which doesn't follow the established structure activity grouping based on extensive test data of the last 30 years. Without clear explanation for the ARN or for the current report, ECHA has proposed 6 groups in the Assessment of Regulatory Needs document and now proposes 4 groups in the ECHA Investigation Report. In summary:

According to the ARN on ortho-phthalates[30], ECHA proposes the following groups:

1. Sub-Group 1 – Phthalic acid and its salts
2. Sub-Group 2 - Short-chain length (C1-C2 backbone) linear and branched ortho-phthalates
3. Sub-Group 3 - Short-chain length (C3 backbone) linear and branched ortho-phthalates (sat. and unsat.)
4. Sub-Group 4 - Medium-chain length (C4-C6 backbone) linear and branched ortho-phthalates incl. aromatics and cyclics
5. Subgroup 5 - Medium-chain length (predominantly C7-C8 backbone) linear and branched ortho-phthalates
6. Subgroup 6: Long-chain length (predominantly C9-C18 backbone) linear and branched ortho-phthalates

According to the ECHA Investigation Report on PVC and PVC additives – with the carbon numbers referring to backbone – stated at the beginning of the paragraph but not in the grouping, there would be:

1. Short-chain phthalates (backbone chain length lower than C4)
2. Medium-chain phthalates (C4-C6)
3. Medium-chain phthalates (C7-C8)
4. Long chain phthalates (C9-C18)

This compares with the grouping which is consistent with the scientific data, OECD RAC Opinion on DIOP, prior ECHA reports, and academic papers such as Fabjan et al (Evelin Fabjan, 2006)[31] and Saillenfait et al (Anne-Marie Saillenfait J.-P. S.-C., 2013):

1. Very LMW Phthalates (C1-2 longest straight chain backbones in the alkyl side chains) – not used in PVC.
2. LMW Phthalates (C3-C6 longest straight chain backbones in the alkyl side chains)
3. HMW Phthalates (C7-C13 longest straight chain backbones in the alkyl side chains and total number of carbon atoms in the alkyl side chains of C8 or more) – phthalates above C13 are not used in PVC because of compatibility and processability issues.

[28] A-M. Saillenfait et al (2011), Effects of in utero exposure to di-n-hexyl phthalate on testosterone synthesis in fetal rat testis, Reproductive Toxicology, Volume 32, Issue 2, Pages 172-173
[29] A-M. Saillenfait et al (2013) Adverse effects of diisooctyl phthalate on the male rat reproductive development following prenatal exposure, Reproductive Toxicology, Volume 42, Pages 192-202
[30] ECHA (2021), Assessment of Regulatory Needs, Ortho-phthalates
[31] E. Fabjan et al (2006), A Category Approach for Reproductive Effects of Phthalates, Critical Reviews in Toxicology

Page 19 – 7 lines from the bottom – VinylPlus, while questioning the need and scientific basis for the two new sub-groupings, notes that it is not accurate to state that *"none of the short-chain ortho-phthalates and the medium-chain ortho-phthalates have been identified in any use in PVC with the exception of DEHP in medical applications."* DINP is included in the medium chain phthalates (C7-C8 backbone and Subgroup 5) and is a major plasticiser in the EU and globally. Also as stated elsewhere in the report the medium chain phthalates C4-C6 backbones (DBP, DEHP, BBP) are still widely used in PVC outside the EU and North America.

As noted in the ECHA report, of the 28 plasticisers in Table 2, 6 have been identified as SVHC based on adverse reproductive effects (4 of these also identified as EDs under REACH i.e. DEHP, DBP, BBP and DIBP). There are another ~8 LMW ortho-phthalates, (not included in Table 2 in the ECHA Report) which have also been identified as SVHCs (several based on read across and consistent with robust structure activity relationships) and are included on the Candidate List and the Authorisation List – making a total of 14 SVHCs covering all the LMW phthalates which were commercial products in the past in the EU.

Page 19 – last paragraph – with respect to the reproductive toxicity of DINP, VinylPlus, in addition to again highlighting the ECHA RAC Opinion on DINP would refer ECHA to a recent state of the art study comparing DINP and DBP for reproductive and ED related reproductive adverse effects – van den Driesche et al (Sander van den Driesche, 2020)[32].

This state-of-the-art study has not been taken into account in the ECHA Investigation Report. It shows that DINP (HMW phthalate) does not cause the same adverse reproductive and ED effects as DBP (LMW phthalate). For DPHP, VinylPlus would refer ECHA to the REACH registration studies and the state-of-the-art reproductive studies included there. The same applies to DPHP. In Appendix B, ECHA acknowledges that there is an OECD TG 416 study in rats which shows no reproductive or developmental toxicity. No maternal or developmental toxicity was observed in an OECD TG 414 study in rats up to the limit dose. Furthermore, there is an OECD 414 study in rabbits, that also does not show effects, but is not mentioned by ECHA. Given these studies, it is not clear why toxicity to reproduction and ED are considered for DPHP.

The EFSA Opinion on five phthalates (EFSA, 2019)[33] concluded that the current exposure to these five phthalates from food is not a concern for public health, and that dietary exposure to the group of DBP, BBP, DEHP and DINP for average consumers is seven times below the safe level.

With regard to the critical effects of the different phthalates, the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) concluded the following:

"*The CEP Panel derived the same critical effects and individual tolerable daily intakes (TDIs) (mg/kg bw per day) as in 2005 for all the phthalates, i.e. reproductive effects for DBP (0.01), BBP (0.5), DEHP (0.05), <u>and liver effects for DINP and DIDP (0.15 each)</u>*" (VinylPlus underlining). While reference to reversible changes in testosterone were made by EFSA (and also by RAC who concluded these transient changes do not lead to adverse effects) in implementing this opinion the European

[32] S. van den Driesche et al (2020), Systematic comparison of the male reproductive tract in fetal and adult Wistar rats exposed to DBP and DINP in utero during the masculinisation programming window, Toxicology Letters, Volume 335, Pages 37-50.

[33] EFSA (2019), Update of the risk assessment of di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP) and di-isodecylphthalate (DIDP) for use in food contact materials, EFSA journal, Volume 17, Issue 12.

Commission kept the group TDI for the 3 LMW phthalates used in food contact (DEHP, DBP and BBP) quite separate to that of the 2 HMW phthalates (DINP, DIDP) which do not cause reproductive effects[34].

With regard to the further statements in the ECHA report– *"However endocrine disrupting effects cannot be excluded …)",* VinylPlus stresses that concerning possible presence of C4-C6 constituents in DINP (and HMW phthalates), ECHA RAC had the constituent information on DINP and concluded no adverse reproductive effects/no classification required. For the full analytical information ECHA should consult the REACH registration dossiers for the relevant products (which have been updated with additional detailed analytical data). With regard to possible thyroid effects there are extensive 90 day and 2-year studies where thyroid glands were subject to histopathology. It is also well established that high dose oral studies can lead to liver hypertrophy (an adaptive change) with liver enzyme activation, which can then lead to secondary thyroid effects (re: reference to DPHP).

Page 20 – line 6 – DPDP should be corrected to DPHP.

Page20 – Paragraph 2 –For PVC plasticisers, the maximum total carbon alkyl chain is C13 – this is for example represented by Di-isotridecyl phthalate (C11-C14, C13-rich alkyl side chains). The reason that C13 is the main upper limit for total carbons is that higher carbon numbers result in compatibility and processability issues for PVC and, therefore, such substances are simply not used as PVC plasticisers. As such, it is not appropriate to consider C14-C18 (total carbon) substances in the context flexible vinyl (PVC and plasticisers). With regard to data on C9-C13 (total carbon) plasticisers there is significant data on DIDP (C10 total carbon – C9-C11, C10-rich) and DPHP (C10 total carbon).There is extensive data on DIDP which has been subject to in-depth assessment (EU Risk Assessment Report (2006) and ECHA Evaluation of New Data on DIDP and DINP (ECHA, 2013), with conclusions that hazard classification is not required and that products are safe for use in current applications. These data are then being used as the basis for robust scientific read across to DIUP and DTDP (which are very low volume products in comparison with DIDP (<5% of the volume)). Furthermore, there were a series of REACH Substance Evaluations conducted by the Danish EPA between 2014 and 2021 covering DUP, DIUP and DTDP and other HMW Phthalates. These concluded that these substances are not PBTs or vPvBs (in direct contrast to Table 2 in the ECHA report). These Substance Evaluations (2022)[35] did reject the read across proposed by the registrants for DIUP and DTDP and the other substances. Given the fact that these substances are manufactured from the same raw materials in the same manufacturing process as DIDP and DINP it is difficult to understand why such read across was rejected, particularly also given the low volumes of these substances, the very limited applications (e.g. high temperature cables for automotive) and the associated very limited exposure potential. These substances are now subject to further REACH dossier compliance checks with associated extensive animal testing requests.

Page 20 – Paragraph 3 – VinylPlus disagrees with the statement that *"…it is considered as if medium-chain (C7-C8 [backbone]) are likely going to display ED properties."* This statement is contrary to:

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[34] Commission Regulation (EU) 2023/1442 of 11 July 2023 amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as regards changes to substance authorisations and addition of new substances.

[35] Danish Environmental Protection Agency (2022), SUBSTANCE EVALUATION CONCLUSION as required by REACH Article 48 and EVALUATION REPORT for 1,2-Benzenedicarboxylic acid, di-C11-14 branched alkyl esters, C13-rich (DTDP)

1) Actual data on the substances
2) REACH registration dossiers
3) ECHA RAC Opinion on a major medium chain substance (DINP) (see comments above).
4) Detailed constituent information on the relevant substances (in formulating their opinion on DINP, ECHA RAC specifically requested constituent data for DINP, and this information is included in the Background document to the ECHA RAC Opinion).

For long chain (C9-C18 backbones) it is not accurate to state that it is "less likely" that they will display ED properties (compared to medium chain (C7-C8 backbones). Rather all the data including 2-generation reproduction studies and endocrine studies show that substances such as DIDP and DPHP do not have endocrine disrupting properties in rats.

VinylPlus would like to understand why Log K_{OW} is being quoted to support possible PBT effects of medium chain (C7-C8 backbone) ortho-phthalates (this is further developed in Appendix B.4.1.2.4 of the ECHA report). A neat Log K_{OW} consideration is scientifically not appropriate (William M. Meylan, 1999)[36]. The Appendixes of the ECHA report (B.4.1.2.4) also refence QSAR and predicted BCF values with respect to substances such as DINP, whereas there is higher tier data available. There are several higher-level studies including fish feeding studies (P. Patyna, 2000)[37] which have demonstrated the lack of bioaccumulation potential. Furthermore, there is a detailed PBT assessment in the REACH Registration dossiers for the relevant substances concluding on the lack of PBT. OSPARCOM has also evaluated the PBT properties of DINP and DIDP in the past (no references to this in the ECHA report) with conclusions on the lack of PBT properties. The Danish EPA Substance Evaluation Reports also concluded that DIUP and DTDP are not PBT/vPvB. If these longer chains, more branched substances are not PBT then it is difficult to see how the medium-chains (C7-C8 backbone) are PBT (and evaluations have concluded they are not, such as OSPARCOM).

The ECHA report also refers to "flaws" in the data on ready biodegradability but no additional details on what the potential flaws are provided. VinylPlus would appreciate having more details and understanding what ECHA believes are the flaws in this data. Although it is noted that ECHA states the ready biodegradability cannot be "fully supported", even if "partially supported", this would suggest they should not be considered PBT.

Below are regulatory and related assessments on HMW ortho-phthalates:

- OECD report on HMW phthalate (OECD, 2004)
- EU Regulatory Risk Assessments under pre-REACH regulations (2003)[38]
- ECHA Evaluation of New Data on DINP and DIDP (ECHA, Evaluation of new scientific evidence concerning DINP and DIDP, 2013)[39]

[36] Meylan et al. (1999), Improved method for estimating bioconcentration/bioaccumulation factor from octanol/water partition coefficient, Environ. Toxicol. Chem. 18, No. 4, pp. 664–672, 1999.
[37] P. Patyna, K.R. Cooper (2000), Multigeneration reproductive effects of three phthalate esters in Japanese medaka (Oryzias latipes), Marine Environmental Research, Volume 50, Issues 1–5Page 194,
[38] European Chemicals Bureau (2003), European Risk Assessment Report 1,2-benzenedicarboxylic acid, di-C8-10 branched alkyl esters, C9-rich and di-"isononyl" phthalate (DINP).
[39] ECHA (2013), Evaluation of new scientific evidence concerning DINP and DIDP

- ECHA RAC Opinion on DINP (ECHA, 2018)[40]
- With respect to environmental endocrine there are extensive fish studies including reproductive studies showing a lack of any such effects in fish (P.J. Patyna, 2006)[41].-
- DINP, DIDP and DPHP meet the OECD Test Guideline requirements for being readily biodegradable and showed no evidence of bioaccumulation in fish feeding studies. OSPARCOM concluded that DINP and DIDP are not PBT substances[42]

Full details of the above information are included in the REACH Registration dossiers for the relevant substances.

Page 20 – Paragraph 5 – Terephthalates. With respect to DBTP (Dibutyl Terephthalate) VinylPlus notes that thyroid toxicity secondary to liver hypertrophy (and hepatic enzyme activation) is commonly observed in many high dose animal studies. This should not be a basis for assuming endocrine disrupting properties. It is noted that the relevant substance which is being read across to DBTP is under substance evaluation. VinylPlus disagrees with assuming ED properties – the relevant tests should be conducted, and an evaluation made before concluding.

Page 21 – Paragraph 1 – Trimellitates. It is stated that based on the ARN no firm conclusions can be made on reprotoxicity and ED with regard to trimellitates, and that dossier evaluation is ongoing, nevertheless, the ECHA report states that *"for the purpose of this investigation report it is considered as if they are likely to display ED properties*." There is no scientific basis for making such an assumption – in line with the REACH dossier/substance evaluation processes the relevant tests should be conducted and an evaluation made before concluding.

VinylPlus notes that it is stated that PBT is *"also under consideration in dossier evaluation."* This would appear then to contradict the fact that these substances are designated already as PBT in Table 2 of the report.

Page 21 – Paragraph 5 – Benzoates. Benzoate with EC # 421-090-1 has a 2-generation reproduction study which shows no adverse effects (full details included in the REACH registration dossier for this substance[43]). It therefore difficult to understand why this is being further assessed. It would appear to be an example of unjustified read across from Benzoate 447-0101-5 and C12-C15 alkyl benzoates. If robust data is available on a substance, then read across is not warranted. This is a fundamental principle of REACH giving some degree of predictability. VinylPlus disagrees with unclear effects at high doses being used directly without expert scientific interpretation in hazard only approaches. VinylPlus notes that these substances are subject to REACH Dossier Evaluation with the involvement of registrants. Given these ongoing processes it is not justified to already assume the outcome as is done in the ECHA report Table 2.

Appendix B.4 of the ECHA report – VinylPlus has a different interpretation regarding several of the studies (see below)

[40] ECHA (2018), RAC opinion on proposing harmonised classification and labelling at EU level for DINP
[41] P.J. Patyna et al (2006), Hazard evaluation of diisononyl phthalate and diisodecyl phthalate in a Japanese medaka multigenerational assay, Ecotoxicology and Environmental Safety, Volume 65, Issue 1
[42] https://www.ospar.org/work-areas/hasec/hazardous-substances/deselection *"DINP and DIDP are not PBT substances according to OSPAR DYNAMEC or EU-TGD criteria and there is no indication of potential for endocrine disruption".*
[43] ECHA registration dossier Benzoic acid, C9-11, C10-rich, branched alkyl esters

B.4.3.2.3 – Page 63 – *"Based on the information provided in the US EPA ToxCast Screening Library (US EPA, 2023), EC 222-020-0 [TEHTM] was identified as agonist in the ToxCast ER model, which predicts the outcome of the Uterotrophic assay (Browne et al., 2015). This information is consistent with the results published by (Ter Veld et al.). reporting estrogen receptor 1 (ER1) and estrogen receptor 2 (ER2) activity of the substance in a transactivation assay (US EPA, 2023)."*

ECHA uses the outcome of these in vitro results to support the per se inaccurate interpretation of the OECD TG 234 study results (see section "3.3 Scientifically incorrect interpretation of the Fish Sexual Development Test (FSDT)" as being endocrine mediated. ECHA's interpretation relies on only single data points of this study as a trend towards a male-biased sex-ratio and concludes on a trend towards defeminisation/ masculinization based on an estrogen-antagonistic, androgen-agonistic, or steroidogenesis-related activity (p. 9 of draft decision on substance evaluation for TOTM/TEHTM EC 222-020-0 issued by ECHA on 28 June 2023).

However, these effects would not be concordant with a potential agonistic estrogenic mode of action as concluded by ECHA based on the available in silico and in vitro data. The available in vitro and in silico data do neither support an antagonistic activity towards the ER, nor an agonistic activity towards AR, nor any steroidogenesis-related activity. Anyhow, in the absence of an adverse, test item-related effect on the sex ratio, the OECD TG 234 study does not provide any indication of EAS-mediated activity or adversity.

B.4.3.2.3 – page 63 – "*In the same study (I.e. OECD TG 421) with EC 222-020-0 (TEHTM), adverse effects on spermatogenesis and the testis have been detected in P0 males. No reproductive/developmental effects were observed in OECD TG 421 study with TOTM, but in an OECD 408 study a decrease in absolute uterus weight was observed at all tested doses (stat. significant at the low and highest dose). For EC 222-020-0 transient nipple retention and increased weight of seminal vesicles and the epididymis were observed in males of the high dose group in a pre- and postnatal developmental toxicity test (similar or comparable to OECD TG 414)."*

VinylPlus does not agree with this interpretation of the study data and would note the following points: Furr et al. (2014) included in the registration dossier, section 7.9.4 Specific investigations: other studies, describes a methodology termed the Foetal Phthalate Screen (FPS) to detect phthalate esters and other chemicals that may disrupt foetal testosterone synthesis and thus adverse developmental outcomes via disruption of the androgen synthesis pathway. In the study, pregnant rats and rat foetuses were exposed to one of 27 chemicals, including phthalate esters, several phthalate ester alternatives, two pesticides and a potent PPARalpha agonist to determine which chemicals suppressed foetal rat testis testosterone production during the "masculinizing window" of foetal development.

Pregnant Sprague Dawley rats were treated by oral gavage at a dose level of 750 mg/kg bw/d from gestational day 14 to 18 a; er which testis testosterone production (T Prod) was measured ex vivo from three males per litter from three litters. In this model, TOTM did not reduce testosterone production.

These two mechanistic studies assessing specific effects related to testes development could be assigned to Level 3 of the OECD Conceptual Framework, although they are not officially listed in the guidance document. The negative outcome of these two studies, which are included in the registration dossier, has not been taken into account by ECHA in their overall assessment.

Furthermore, a study similar to OECD TG 414 but including a post-natal group of 15 dams that were allowed to litter, has been undertaken in the rat with animals treated, by gavage, at dose levels of

100, 500, 1050 mg/kg body weight/day (Renaut and Whiteley. Reproductive Toxicology 74: 59-69, 2017). No treatment-related effects were observed in maternal, foetal, or offspring body weights, or litter viability. No teratogenic effects were observed. No effects were noted on sexual maturation or development of the reproductive tract in male or female offspring.

There was a slight, statistically significant, increase in the number of areolar regions of male offspring at PND 13, which was not seen any longer at PND 18. In the absence of any other supporting data (e.g. there were no effects on AGD) and due to this being a transient effect, this finding was regarded as being of no toxicological significance.

An apparent increase in the incidence of displaced testis in examined foetuses, renal cavitation in both foetuses and 15-week-old males, and hydroureter in examined foetuses appeared to be related to the low incidence of these findings in the concurrent control group compared to the range of historical control values.

B.4.3.2.3 – page 64 – "*No reproductive toxicity study is available for T810TM. In an OECD TG 408 study, no effects on reproductive organs were observed, but mechanistic data indicate a potential ED mode of action. In addition, foetal toxicity (< litter and foetal weight, delayed ossification, visceral malformations) was observed in an OECD 414 study with this substance*."

VinylPlus would note that the relevant study (Liberati 2010) clearly indicates that "the test item caused a marked maternal toxicity as indicated by the reduction in food consumption, body weight, body weight gain, gravid uterus weight and absolute weight gain. As a consequence of the marked maternal toxicity, at the same dosage, foetal toxicity was present as demonstrated by the reduction in litter weight, foetal weight and delay in the ossification of different parts of the foetal skeleton. Visceral malformations detected in mid- and high dose groups were considered common findings in foetuses, that usually disappear shortly after birth and since the incidence was low and not dose-related, they did not show clear relationship to treatment and therefore were considered incidental."

VinylPlus notes that the report states that data generation is ongoing for several trimellitates and VinylPlus would propose awaiting the outcome of these studies before concluding that trimellitates are assumed to be EDs for the purposes of this study.

B.4.3.2.4 – PBT and vPvB Assessment – "*The only simulation study available is a sediment simulation study (OECD TG 308) on EC 222-020-0 [TEHTM]. This substance is highly adsorptive with a predicted log Koc of 7.83 (KOCWIN v2.00). The substance partitions rapidly to the sediment phase, the half-life in the sediment can reasonably be estimated from the half-life for the total water-sediment system. Bi-phasic kinetics were observed in the study for both sediment samples and bi-phasic models were used to calculate the slow-phase (FOCUS, 2014, p. 117, Figure 7-2)17. For both water-sediment systems the slow-phase DT50 values is > 10 000 days (DFOP) which indicates the substance may be concluded vP.*"

VinylPlus disagrees with the above interpretation and conclusion on vP for TEHTM and would refer to the following prior submission made to ECHA on TEHTM: OECD 308 study report for substance EC number 222-020-0 (TEHTM) submitted to ECHA in 2017 which states that "in conclusion, degradation and dissipation of TOTM has been demonstrated to be bi-phasic within a water sediment system. The dissipation is driven by multiple processes, partition into the water and the sediment phase, initial degradation to DOTM followed by further degradation and formation of CO2. TOTM does not fulfil the persistence criterion according to REACH, Annex XIII for freshwater sediment (degradation half-life for freshwater sediment > 120 days) and would not therefore require classification as persistent (P) or very persistent (vP)."

3.2.1.3. Flame Retardants

VinylPlus notes that the ECHA report correctly identifies the intrinsic flame-retardant properties of PVC and that the use of flame retardants in PVC is quite limited (e.g. in high temperature cables). VinylPlus notes that the ECHA report states that the risks of flame retardants will more likely be associated with plastics other than PVC. With regard to heating flexible vinyl with a flame, this will result in the PVC including the plasticiser being flammable. The paper by Weil et al (Weil ED, 2006)[44] used to support this part of the report goes on to explain how this flammability is overcome by using antimony oxide and phosphate plasticisers to reduce the flammability. So, this is not necessarily a case of plasticisers being "volatile" but rather flammable. Without heat by flame (or any other source of heat) plasticisers, of-course, have exceedingly low vapour pressures (e.g. 0.00006 Pa at 20 degrees C for DINP) and are held within PVC through specific molecular interactions and the crystalline PVC network which prevents migration and exudation. The flammability of plasticisers is only an issue at significantly elevated temperatures, at which all materials will be melting and breaking down. The presence of the chlorine in the polymer molecule makes it difficult for the PVC article to catch fire and ignite, a characteristic enhanced through the addition of flame-retardant and/or fireproof substances. Due to the difficulty to catch fire, and because of its limited contribution in terms of the heat development, PVC is not considered to be among the factors that lead to the propagation of flame[45] (ISO, 2019) [46].

Page 22 – paragraph 7 – Organophosphates. VinylPlus would again question the rush to judgement. As the report indicates the testing is ongoing and the expert interpretation of the data is needed, conclusions should not be made before the assessment is complete.

Page 24 – Halogenated Flame Retardants. With respect to the use of chlorinated flame retardants in PVC. Some MCCPs are still used in PVC, and ECHA has separately carried out a restriction proposal including use in PVC. LCCPs are also used in PVC. VinylPlus would like to clarify that brominated flame retardants have not and are not used in PVC, but chlorinated paraffins have been used.

Page 24, Line 12 – with regard to the ECHA statement that there is an apparent contradiction between the response to CfEs for different projects, VinylPlus would note that many groups inputting to the ECHA CfEs would be referring to rigid PVC where flame retardants are not used and with only some use of flame retardants in flexible vinyl - so it is likely not a contradiction that different calls for evidence may indicate use/non-use of flame retardants in PVC. It should be noted that chlorinated paraffins are used in limited applications for PVC; brominated flame retardants are not used in PVC but are widely used in other polymers. The term "halogenated" of course encompasses both chlorinated and brominated materials. Given there is a separate strategy for flame retardants and other polymer manufacturers have much greater interest VinylPlus concludes its comments on flame retardants here.

3.2.2. Exposure Assessment

VinylPlus is concerned about the assumptions made on severe hazards at a time when studies are still ongoing in many cases. This is especially problematic as these are then used to argue for non-

[44] E.D. Weil et al (2006), Flame and Smoke Retardants in Vinyl Chloride Polymers – Commercial Usage and Current Developments. Journal of Fire Sciences.
[45] PVC4Cables (2023), The production of PVC cables: past and future of the value chain.
[46] ISO (2019), Plastics — Guidance on fire characteristics and fire performance of PVC materials used in building applications, Technical Report ISO/TR20118

threshold and against the need for risk assessment. Only 7 of the 63 substances have had quantitative risk assessments conducted, and even here, the PLASI model, which is not suitable for PVC, has been used to (over)estimate exposure to additives. The PLASI project linked release potential to the % content of additives in the plastics. Since additives are designed and needed to remain in the polymer matrix it is very simplistic to assume release based on content). A more appropriate model for PVC migration is as described in the report by Losher et al (C. Losher, 2023)[47].

On organotins, there are errors with the assumptions made: weathering for outdoor use is not relevant for the industrial uses for which organotin-based PVC piping is required (e.g. Chemical-and Food processing installations). Additionally, migration to skin of organotin heat stabilizers from the PVC-piping components in industrial applications is less probable since factory workers need safe protecting equipment to perform their work in chemical environment.

VinylPlus notes positively that ECHA acknowledges the actual migration data on organotin stabilisers and plasticisers (DEHP, DINP and DIDP) which shows "very low migration and compliance with the relevant legislation". These simulation tests use acetic acid and alcohol solutions which are likely to induce migration more than water alone. Even then the migration is very low and indeed the plasticisers indicated have very low water solubility. The ECHA report then questions whether such data is applicable to the environment and weathering conditions. Food migration tests are also run at high temperatures to assess longer term migration. With respect to saliva tests, these have been done with flexible PVC toys (and are reported in ECHA Evaluation of New Scientific Data on DINP and DIDP, 2013), and similar results to those of food migration have been observed. It is not intended for PVC articles to be placed in the mouth nor ingested. Similarly, given the very low vapour pressures of the plasticisers and stabilisers used, inhalation is not a significant route of exposure. Furthermore, tests under ISO/CEN/National standards specify stringently low criteria for release since such release would affect product performance over time e.g. ISO 16000 series of tests for cable aging. There are new recent data relating to this which can be provided to ECHA (Chunyi Wang, 2023)[48]. VinylPlus would again reiterate that HMW plasticisers, have exceedingly low vapour pressures (e.g. 0.00006 Pa at 20 degrees C for DINP) and are held within PVC through specific molecular interactions and the crystalline PVC network which prevents migration and exudation. High temperature processing of PVC articles (180 degrees C) results in gelation and fusion of the PVC article such that the plasticiser is intimately bound within the PVC matrix.

Page 27 – Biomonitoring – VinylPlus notes that the ECHA report refers to the biomonitoring data but does not provide any of the data, nor does the report interpret this data correctly. The power of biomonitoring is that it measures exposure from all possible sources because specific metabolites of plasticisers are being detected in the urine, which allows back calculations to the actual exposure to the parent substances. For the major products used today biomonitoring shows that exposure from all sources to major plasticisers such as DINP, DIDP, DPHP, DINCH and DOTP is well below safe/tolerable limits, these limits being highly conservative with at least 100-fold safety factors versus doses which do not produce effects in comprehensive animal studies. Such studies also show that, by far, the main route of exposure) is via the food pathway (due to food packaging and food processing equipment including tubing/hoses for example). This has been demonstrated by biomonitoring studies where the level of metabolites from several plasticisers were measured in urine before and after fasting, and also after the restart of food intake. This study showed that

[47] C. Losher et al (2023), Investigation Report Modelling on DINP migration from PVC-p articles into (rain)water, FABES Forschungs-GmbH für Analytik und Bewertung von Stoffübergängen.
[48] C. Wang et al (2023), A rapid micro chamber method to measure SVOC emission and transport model parameters, Environmental Science Processes & Impacts

following fasting the already low levels of exposure reduce significantly and are close to detection limits for HMW phthalate, clearly demonstrating that food is the source of exposure. Instead of focussing on this reassuring information, ECHA highlights what is historical data showing that DEHP exposures were close to safe limits in certain East European countries. More recent data clearly shows DEHP, and other LMW phthalate exposures are decreasing significantly as these products have been replaced by non-classified HMW phthalates and other plasticisers. The way the ECHA report describes the biomonitoring information is that detection of the presence of phthalates means risk, yet a risk assessment comparing exposure to DNELs, as was done by ECHA staff in the 2013 report (ECHA, 2013)and by ECHA RAC (ECHA, 2018) confirms the lack of risk. Such biomonitoring data reduces the need to collect extensive information on release from various applications since it captures exposure from all sources. In the ECHA Evaluation of New Evidence on DINP and DIDP (ECHA, 2013) the biomonitoring data was a key element of the conclusion of "No further risks identified" (neither for adults nor children).

This 2013 report concluded that "*The few available biomonitoring data seem to confirm the low exposure to DINP of the mean or median adult population data. These figures correspond well to the typical exposure assumed for the indoor environment and food (see sections 4.6.6 and 4.6.7)*."

References on biomonitoring were provided by VinylPlus as part of the ECHA CfE number 1. Approximately 25 publications on biomonitoring relating to plasticisers were submitted by VinylPlus as Attachment II – these studies range from 2015 through to 2022.

VinylPlus recommends that ECHA use these human biomonitoring data to a much greater degree as was done in the ECHA report of 2013. VinylPlus would also highlight that there is biomonitoring data for a recycling operation showing exposure is within safe/tolerable limits for DEHP. The ECHA report does reference Wang et al (Wang, 2019)[49] and while this paper supports the ECHA statement that there is *"widespread human exposure"*, Wang et al in their conclusions state that *"Biomonitoring studies clearly demonstrate that human exposures are almost ubiquitous, and, in most cases, children have higher exposures than do adults. The existing studies indicate that the observed associations between phthalate exposure and disease outcomes are exploratory and preliminary, the health effects of phthalate exposure warrant further study. Robust analytical methods exist to measure more than 20 phthalate metabolites in urine, a preferred matrix of choice for biomonitoring studies. Although studies have reported the occurrence of phthalate metabolites in other human specimens, including serum, seminal plasma, and amniotic fluid, the relevance of these matrices in understanding toxic effects needs further investigation."* The researchers are proposing further research since analytical techniques are now so sensitive that almost anything can be detected everywhere. As noted, the current exposure from all sources for LMW phthalates are decreasing and those for HMW phthalates are well within safe, tolerable limits for the major ortho-phthalates used today e.g. DINP, DIDP, DPHP (Nina Vogel, 2023)[50]

ECHA also quotes the HBM4EU (2023) Initiative as demonstrating widespread exposure. As already noted, such exposure may be widespread and demonstrates the power of analytical techniques as well as the widespread use of flexible PVC in all aspects of modern society. However, exposure does not mean risk. The HBM4EU (2023) initiative highlights that there are significant exposures to LMW phthalates such as DEP, DBP, and DEHP. These are the products which have been then substituted by

[49] Y. Wange et al (2019), A Review of Biomonitoring of Phthalate Exposures, Toxics.

[50] N. Vogel et al (2023) Urinary excretion of phthalates and the substitutes DINCH and DEHTP in Danish young men and German young adults between 2000 and 2017 – A time trend analysis, International Journal of Hygiene and Environmental Health, Volume 248

HMW phthalates (DINP, DIDP, DPHP), and the HBM4EU reports (HBM4EU, 2022)[51] itself states that: *"The HBM4EU analyses show decreasing time trends for most regulated phthalates since the 2000s, illustrating the effectiveness of policy action."*

While there may be some minimal increases in exposures to non-SVHC HMW phthalates and other plasticisers, these are still well below safe limits and none of these substitutes are CLP classified nor are they SVHCs.

Lastly, the biomonitoring data show that ortho-phthalates are metabolised in humans and do not accumulate i.e. do not bioaccumulate. Fasting studies conducted by Koch et al (2013) have shown that metabolite levels in urine reduce to levels 5-10 lower very rapidly (within 48 hours) for DINP, DIDP and DEHP. This observation also contradicts the conclusion in the ECHA report of the B (Bioaccumulation) in PBT, with the Table 2 of the ECHA report indicating PBT for the ortho-phthalates (similarly not supported by the ready biodegradation data for the P, and by the toxicity data for the T).

3.2.3. Risk Characterisation

3.2.3.1. Release as a proxy of risk

This section includes several assumptions which are used in the conclusion of the report:

1. Assumption that PVC microparticles and the additives contained within are vP.
2. Assumption that co-exposures are important but that it is not possible to estimate the environmental exposures of individual additives and co-exposures.
3. Assumptions on the available effects data on additives (for 51% of the 63 prioritised additives the hazards are assumed and in contrary to actual data for many substances).
4. Further assumptions are made that release of additives from microparticles are causing an ongoing increase of environmental levels – this neglects actual data on many additives which shows biodegradation and other environmental degradation processes (these data are included in the REACH registration dossiers e.g. DINP, DIDP, DPHP).

The ECHA report, based on these several assumptions, states a further major assumption which is not supported by scientific evidence, and which has broad implications: *"For the purposes of this investigation report it is considered sufficient to assume as a hypothesis that emissions of additives can be taken as a proxy for risk to the environment and man via environment."* Since all microplastics and microparticles can contain additives/other materials this means that any emission from the particles is a risk to the environment and man via environment. This statement has implications for all substances used in association with plastics.

VinylPlus disagrees with using several assumptions to conclude that environmental emissions and release are a proxy for risk. Risk fundamentally is hazard x exposure and not exposure/release on its own nor hazard on its own. Exposure/release is not risk.

3.2.3.2 Environmental risk (total releases)

The approach described in Paragraph 1 is broad and lacks detail. VinylPlus would appreciate further clarification.

Paragraph 2 – the percentage figures for the main contributors to the overall estimated releases of the prioritised additives are misleading without absolute figures. VinylPlus notes the tonnage figures

[51] HBM4EU (2022), Substance report, Phthalates and Hexamoll® DINCH

for releases to the environment in Appendices B (pages 96-97 for organotin compounds; pages 105-108 for plasticisers) and notes that these overestimate such releases by approximately two orders of magnitude see comments above on why the PLASI model is not suitable for PVC, based on the data available to VinylPlus members and included in information used in the REACH regulation. Such an overestimation of the tonnage figures leads to overestimating the potential risk. VinylPlus stresses the low hazards of MOTE (major organotin compound) and the non-classified HMW plasticisers used today. The migration and biomonitoring data demonstrates with scientific evidence that releases are very low since the additives bind tightly within the PVC matrix. This also applies to PVC microparticles and VinylPlus does recognize that further data is needed on the potential impacts of microplastics including the migration of additives from microplastics. Based on the biomonitoring data it has been estimated that the plasticisers remain within flexible vinyl articles to an extent of greater than 99.9% wt of production. This means actual absolute releases of plasticisers (which do biodegrade) is of the order of 500 – 1000 tonnes per year on a total production of 1,300,000 tonnes per year (~0.07%). This covers the entire EU and UK/Switzerland/Norway. The data on estimated releases of DINP from landfills which has recently become available and is referenced elsewhere in the comments further confirm the very small releases of plasticisers from PVC articles (ARCHE, 2023).

Page 28 – Line 2 – It is important to establish whether there is a risk or not from the use of flexible vinyl based on robust scientific data i.e., is exposure within relevant safe, tolerable, DNEL limits or environmental concentrations, and not whether a potential risk from one type of plastic is higher or lower than another is higher than another – if both are within safe limits then there is no risk.

Page 28 – Line 6 – While disagreeing with the ECHA sub-groups for ortho-phthalates, it is not accurate to state that DIDP is a "medium chain (C7-C8 [backbone]) ortho-phthalate (DIDP and DINP)". DIDP is a C9-C11-branched, C10 rich ortho-phthalates diester and as such is in the ECHA grouping of long chain ortho-phthalates (C9-C18 [backbone]). Elsewhere in the ECHA report DIDP is referred to as a long chain ortho-phthalate (C9-C18 [backbone]) including in the Conclusions on page 3 (Paragraph 8, sub-paragraph 3).

Page 28 – Paragraph 3/4 – See above comments where it is noted that the absolute tonnages released are being overestimated by approximately two orders of magnitude (re: use of PLASI model which is not suitable for PVC).

Page 28 – Graphic – The graphic is misleading since there is no information provided here on the absolute amounts. Similar comments for the graphics on page 29. See above comments on Section 3.2.3.2.

Page 30 – Paragraph 2 – Here, the ECHA report states that if the annual volumes of (waste) PVC and additives going to recycling, incineration and landfill do not change then the overall volume of PVC and additives circulating in the economy can be expected to increase. It is then further stated that the volumes of landfilled and incinerated PVC would also increase. However, based on work conducted with Conversio (Conversio, 2018)[52] to analyse waste modelling projections, there is no equal linear relationship between amount of PVC waste and recycling, energy recovery and landfill. Rather, it depends on a multiplicity of factors. Projections made by Conversio show an increase in available PVC waste between 2025 and 2040 of ~16%; during the same period Conversio projects recycling to grow by ~45%, incineration with energy recovery to increase by ~14%, and for landfill to actually decrease by ~8%. VinylPlus can propose updating the work done with Conversio to have up to date projections.

[52] Informal waste modelling assessment by Conversio (2018)

Page 30 – Paragraph 4 – the statement that *"This results in an increase of the environmental stock due to the high persistence of PVC and its additives"* appears to implicitly assume that there are negative effects from PVC and its additives, with the associated assumed high release of microparticles and additives which is not the case based on actual data (see prior comments in Section 3.2.2.)

However, VinylPlus agrees with the ECHA report that *"It would therefore be necessary to investigate the mass balance of various baseline scenarios"* and to do this for different materials by application e.g. use of LCAs in the context of the Eco-design and Sustainability of Products Regulation and the Construction Products Regulation (for example).

3.2.3.3. Risk to workers and consumers

Page 30 – Paragraph 2 – The ECHA report states that "*Results obtained with the default realistic worst case exposure assessment methodology suggest that there are risks from DOTE and DEHP for workers exposed at recycling facilities".* This is not consistent with the exposure data (including biomonitoring) which was used as part of Authorisation for several companies for the recycling of PVC made with DEHP. VinylPlus has already commented above, that organotin compounds are not used in window profiles in the EU and that this then means that exposure in recycling plants is likely being overestimated and that the quantitative risk assessment should be redone with the more appropriate exposure information. ECHA also states that for DMTE and Diantimony trioxide risks to workers in recycling operations are likely. The same comments apply to DMTE as were made for DOTE above – this is likely being overestimated due to a misunderstanding over the use of organotin compounds in window profiles. Diantimony trioxide is a suspect carcinogen and as such will be subject to occupational health controls, including OELs. Several countries have set 8-hour Time weighted average values of 0.5mg/m3 for antimony and antimony compounds. EU and national regulations require compliance with these workplace measures. So, while there are potential risks as in all manufacturing operations, they are subject to adequate control.

Page 31 – Paragraph 2 – OELs for PVC dust and several of the additives are available and should be complied with. The principal potential exposure in such facilities is to plastics dust (including PVC) and further information is needed on the degree to which additives in the microplastics become bioavailable. Biomonitoring studies have shown that DEHP exposures are within safe limits. VinylPlus would also note that there are no imports of window profiles made with organotin stabilisers and limited imports from the US of PVC articles made with organotin stabilisers.

Page 31 – Paragraph 3 – From discussions with the European Automotive Manufacturers (ACEA), VinylPlus understands that organotin stabilisers are not used in car interiors.

Page 31 – VinylPlus confirms that there is no significant use of DOTE in PVC packaging, and hence the RCR is likely well below 1. DOTE only represents 16% of the very small volume of organotin stabilisers still used in the EU (organotin is 6% of total stabilisers). Here is the information communicated by VinylPlus in CfEs:

- With respect to other organotin compounds, as noted in the VinylPlus input to CfE number 3 there are four main organotin compounds being used in the EU – these are shown below with their percentage split by volume:
    - MOTE (EC No 248-227-6) – 48% - used mainly in food and pharmaceutical packaging rigid film.

- DOTE (EC No 239-622-4) – 16% - used mainly in construction panels, roofing profiles, pipes and fittings, edge bends and monofilaments.
- DMTE (EC No 260-829-0) – 29% - used in construction panels, roofing profiles, pipes and fittings, edge bends and monofilaments.
- MMTE (EC No 260-828-5) – 7% - used in construction panels, roofing profiles, pipes and fittings, edge bends and monofilaments.

- European producers of pharmaceutical packaging have moved to MOTE completely for this type of packaging. Food contact packaging is similarly using MOTE.

It should also be noted that DOTE is not used in combination with MOTE. DOTE can be an impurity in MOTE but this has now been limited to an upper limit of 0.3wt% MOTE in DOTE (limit for reproductive classification).

Page 31 – Paragraph 5 – VinylPlus agrees that for EC 421-090-1 that further information should be carefully considered with regard to an RCR slightly higher than 1 and the use of this substance in flooring. This substance has a 2-generation study which shows no significant adverse effects (contrary to “Leading (potential) hazards” in the ECHA report Table 2). Further information was provided to ECHA by ERFMI and European Plasticisers.

Page 31 – Paragraph 6 – VinylPlus is aware that many other additives have DNELs since this is required as part of the REACH registration process; for example, the major plasticisers DINP and DIDP have DNELs as derived by ECHA in its 2013 evaluation (ECHA, 2013). In fact, revised DNELs were provided which will likely have a significant impact on the risk assessment, which should then be redone using the revised DNEL values. As an example, for Benzoate, following a specific request from ECHA, updated worker and consumer DNELs were derived in line with the latest ECHA and ECETOC guidance. VinylPlus would therefore ask why ECHA did not also conduct a quantitative risk assessment for such substances. Such substances do have existing extensive regulatory hazard and risk assessments which have not been taken into account in the ECHA Investigation report.

Page 31 – Paragraph 7 – Regarding potential co-exposures a concern, as noted in previous comments, co-exposures are a topic for all chemicals and not just PVC additives. A robust scientific framework is needed to address this. Plasticisers are mentioned with respect to consumer co-exposures from flooring and automotive interiors, for example. Yet, as mentioned previously, the plasticisers are tightly bound within the PVC matrix. This is confirmed by the human biomonitoring data showing exposures to key plasticisers which are well within safe limits (as stated above).

Page 32 – Table 4/Table 5 –The tables confirm that a quantitative risk assessment has only been conducted for 7 additives from the 63 prioritised. VinylPlus notes that from a total of 42 substance/additive scenarios for workers and consumers, the ECHA report sees a risk for five (12%) and a potential risk for another five (12%). This is a significant contrast with the “Assumptions” based approach for which a risk is identified for all 63 additives, with the possible exception of MOTE, DOTP and Zinc Molybdate. VinylPlus appreciates ECHA’s statement that further information and careful assessment could lead to some of the five risk scenarios and five potential risk scenarios becoming no longer a risk. VinylPlus is prepared to provide further relevant information and to support such careful risk assessments as needed.

With respect to DMTE in this table, VinylPlus notes that the addition rate has been overestimated – 3% is proposed in Appendix B.3.6.1 when in reality 1% is the addition rate. Therefore, exposure is being overestimated for the waste recycling stage. The risk is identified for inhalation, and this is controlled by mechanical measures in combination with Occupational Exposure Limits. This overestimation of exposure will also apply in other applications such as automotive.

Page 32 – four lines from the bottom – The report states that if recycling of soft PVC was to increase compared to that of rigid then this could lead to an increase in concentrations (and presumably exposures) to additives in flexible vinyl. Given the regulatory restrictions on many additives in flexible vinyl (on LMW phthalates, i.e., DEHP, DBP, DIBP, BBP etc, chlorinated paraffins, lead compounds etc) recycling will increase significantly when technology at scale is developed to separate the additives from the PVC. Some sectors such as flooring are actively working on these technologies to support recycling. When the technology is developed then exposure to additives would in fact decrease in recycling facilities (since the additives would first be extracted and contained before mechanical recycling and the associated dust generation). Having said that, it should be noted that existing exposures are controlled by the implementation of existing regulations and occupational exposure limits.

Page 33 – with respect to line 2 and the statement that *"consumer exposures need further exploration",* VinylPlus would again reference the importance of the biomonitoring data, which covers consumers and captures exposure from all sources.

3.2.3.4. Risk Matrix

In this section on page 33 a risk matrix is proposed to support prioritisation. The footnote to the table states that as defined by the ECHA report "medium-chain (C7-C8 [backbone])" ortho-phthalates may contain "medium-chain (C4-C6 [backbone])" ortho-phthalates. VinylPlus stressed again that registration dossiers have been updated by registrants to confirm that key products such as DINP, DIDP, DPHP do not contain any significant levels of C4-C6 backbone phthalates (see comments above).

VinylPlus notes that the ECHA report states that "medium-chain ortho-phthalates (both C4-C6 and C7-C8 [backbones])" are assigned the highest priority for "potential further regulatory work". As stated previously, the commercial C4-C6 backbone ortho-phthalates have already been extensively regulated. In addition, the four main commercial products, DEHP, DBP, DIBP and BBP another 10 LMW ortho-phthalates have been listed on the Candidate and Authorisation lists (most of these substances are not commercial). Recognition should be given to the existing extensive regulation for these LMW Phthalates in the main ECHA report (and not just in Annex F) as this contributes significantly to risk reduction and safety.

3.3 Legacy additives on PVC and alternative materials

With respect to point 2 on page 34, VinylPlus agrees to some degree that current legacy additives do not normally cause a challenge for recyclability of PVC, e.g. cadmium and lead in window profiles. However, in some cases, the recycling of legacy additives can be challenging, both from a regulatory and technical perspective (e.g. lead). For DEHP, even though specific recycling companies were initially authorised to recycle PVC containing DEHP under REACH since either safe use or socio-economic benefits could be demonstrated, the market has now rejected recyclate with DEHP (for example intended for shoe soles and pond linings) due to its SVHC and ED status and this has led to closure of some recycling facilities such as the VinylLoop operation in Ferrara, Italy. Further impacts on flexible vinyl recycling with respect to lead stabilisers and chlorinated paraffins can be anticipated; it is therefore important that technology for the extraction of additives from flexible vinyl is further developed and scaled-up if recycling of flexible vinyl is to be maintained at current levels and increased.

With respect to point 3. the ECHA report repeats the view that concentrations of legacy additives in flexible PVC are likely to be higher compared to legacy additives for other plastics. This is not accurate in that flame retardants including brominated flame retardants can be at similar levels in other plastics as plasticisers in PVC – as high as 20% for the brominated flame retardants in other plastics. This is further outlined in the VinylPlus response to CfE number 3: "*Magnesium dihydrate (MDH) and Aluminium trihydrate (ATH) are used as flame retardants in PVC and other plastics, and in certain polyolefin formulations ATH can be as much as 50wt% of the formulation. With polyolefins, when the ATH content is as high as 50%, other additives such as impact modifiers and lubricants have to be added to reach acceptable mechanical properties and processability. In PVC formulations – thanks to the better anti-ignition property of PVC – less ATH would be needed (e.g. 25%). In passing it should be noted that majority of cross-linked polyethylene (used in cable formulations for example) is not recyclable*."

With respect to point 4. and the statement that *"Substitution of a substance in new products would only have a partial influence on releases over time due to the long lifetime of PVC products."* This statement seems contradictory: the reason that PVC products have a long lifetime is due both to the strength and durability of PVC itself, but also due to the properties of the additives which enable the long lifetime of PVC products by providing weathering resistance, flexibility, heat resistance etc. In order to have this effect the additives have to remain within the PVC which is what happens in practice. Additives are expensive and are not added unless needed for product performance of which durability is a major factor. Replacement of SVHC additives (so called legacy additives) has now taken place (e.g. replacement of cadmium and lead by Ca based and Ca/Zn stabilisers; replacement of SVHC ortho-phthalates by non-SVHC ortho-phthalates and other plasticisers). With respect to the fate of legacy additives for residues of cadmium and lead, ECHA in assessing these substances have concluded that the best risk management option is to recycle and to limit to specific concentration limits, as is specified in the regulations now for these substances (point 4. Line 13). With respect to statements on "(new) legacy additives" due to new restrictions then this should clearly depend upon robust hazard and risk assessments which demonstrate a risk that is not adequately controlled.

With regard to the point made at the bottom of page 34 and the start of page 35, VinylPlus would comment that there is no scientific reason why concentration limits would not work for the environment in addition to human health (PEC and PNECs are the basis for environmental risk assessments and REACH registrants are required to apply this approach).

3.4. Recycling

VinylPlus appreciates the recognition in the ECHA report in this section of the major work on recycling done since 2000, going from very low levels to over 800,000 tonnes of PVC waste being recorded and audited as recycled by Recovinyl in 2022. Actual volumes of recycling may be higher (according to Conversio estimates) but are not captured in the Recovinyl system.

Paragraph 1 it is stated that 2.9 million tonnes of PVC waste is generated annually in Europe. This is based on estimations done by Conversio for VinylPlus. The ECHA report then states that "However, the amount of PVC waste is expected to increase over the years." Directionally this is an accurate statement for PVC and many other materials (i.e. waste is expected to increase over the years). As written above, Conversio have estimated the growth of PVC waste between 2025 and 2040.

Since the Conversio projections date from 2018 they did not take into account the impact of Covid, the economic rebound from Covid, and now the economic slump. But the figures illustrate that there is not an equal linear relationship between amount of PVC waste and recycling, energy recovery and landfill. The projections show a major increase in recycling which in terms of C02 emissions and resource efficiency is a major positive. While potential emissions in recycling of dust/microplastics would be a concern this can be addressed through proper controls. It would be possible to consider updating these projections.

With respect to the figures given at the bottom of page 35 it is not clear to us what the reference is– this is presumably an internal ECHA reference. The figures shown in the last 2 lines are not consistent with the Conversio (Conversio, 2021))[53] data provided by VinylPlus (CfE No. 2). These data rather show for 2021:

- Recycling **35%** of total volumes of waste (1035 kta on total of 2920 kta; 436kta post-industrial and 599 kta of post-consumer)
- Incineration with energy recovery **46%** of total volumes of waste (1331 kta on total of 2920 kta)
- Landfill **19%** of total volumes of waste (554 kta on total of 2920 kta)

If the approach is just applied to post-consumer waste, then these figures are:

- Recycling 24% of total volumes of waste (599 kta post-consumer on total of 2484 kta (total of 2920 kta minus post-industrial of 436 kta)
- Incineration with energy recovery 54% of total volumes of waste (1331 kta on total of 2484 kta)
- Landfill 22% of total volumes of waste (554 kta on total of 2484 kta)

Even taking the Recovinyl figure of 811 kta for 2022 and, which likely underestimates post-consumer recycling (c.f. Conversio data), this would give a percentage of 28% recycling. It is then difficult to understand the figure of 20% recycling given at the bottom of page 35 in the ECHA report (ascribed to post consumer recycling).

On page 37 the ECHA report again makes the statement that "for soft PVC in particular, higher additive concentrations are expected in compounded PVC compared to other plastics." Please see comments above on other plastics and flame retardants). Plasticisers are tightly bound within the PVC matrix following processing at high temperatures (180 degrees C for rigid PVC, 140-150 degrees C for soft PVC) with gelation and fusion taking place. As evidenced by the long life and durability of flexible vinyl (e.g. wire and cable), the plasticisers remain tightly bound within the PVC and are not readily released. Biomonitoring data then confirms that in the workplace and for consumers that exposures are extremely small and well within safe limits. The major plasticisers used in PVC are also biodegradable and are not PBT nor are they vPvB.

Figure 8 (page 37) does not reflect the correct 2022 recycling volume for flooring. The VinyPlus data show some PVC flooring recycling separately and some combined in the category 'flexible PVC'. The actual figure for flooring for 2022 is 141,000 tonnes pre-consumer and 4,000 tonnes post-consumer. This same comment applies to Section A 1.3.1 Appendix A.

3.5. About the role of microplastics

The title of this section and Line 1 – *"PVC microparticle releases have a role as the main carrier of PVC additives releases. Most of the PVC additive releases to the environment occur in particle form (see Appendix B)."* It is recognised that much more information is needed with respect to releases of all unintentional microplastics – with regard to how they are generated, particle sizes (important to know if respirable particle sizes are generated (could vary by type of plastic and conditions of use),

[53] Conversio. (2021). *PVC waste in EU 27+3 countries 2020*.

nature of the particles, toxicity, environmental fate and ecotoxicity, and migration of additives and associated fate (many plasticisers for example are readily biodegradable) and potential toxicity. Data from landfills have shown that migration of plasticisers such as DINP are very small (see comments above). The statement *"most of the PVC additive releases to the environment occur in particle form"* is unclear to VinylPlus. There is first the potential release of the microparticle which for a PVC article (being recycled for example) is a small fragment of that article, and hence is made up of PVC and the relevant additives. The additives themselves are not yet released to the environment, and only become bioavailable if/when released from the PVC microparticle (same principle will apply to all plastics and other material microplastics containing additives). An additive is not a microparticle and additives are not released as "particles". This is a fundamental point which should be clarified in the report in the view of VinylPlus. If/when the additive is released from the microparticle then it will have the properties of the additive and does not have the potential vP properties of the microplastic particle as stated in the ECHA report. VinylPlus requests clarification of this point in the report also. Furthermore, the ECHA report states in Appendix A, Section A.2.2., page 14 that *"It is noted that, for this investigation report, no systematic data search on specific effects of PVC microparticles was carried out."* Hence, further work is needed. Also in Appendix A, Section A.2.3.4 PVC Microplastics on Page 26 the following statement is made: *"It is noted that the data reviewed by ECHA does not highlight specific environmental monitoring findings on PVC, but the findings and conclusions are generic to any microplastics."*

VinylPlus agrees to some degree with this statement and further research is certainly needed to determine whether the cited concerns are generic to any microplastic or not. VinylPlus, however, notes that this statement is inconsistent with Section 2. Conclusions (page 2-4) of the report where specific recommendations are being made for regulatory action on PVC microplastics in recycling operations. VinylPlus therefore asks, since the findings and conclusions are generic to any microplastic, why PVC is being singled out and recommended for regulatory action.

In the final conclusion on microplastics (Appendix A, page 27) the following statement is made: "*Finally, it is noted that PVC microparticles generally contain more additives than other plastics (see section B for further details) and therefore would warrant further studies generating measured data on the levels of PVC microparticles in various environments and on the understanding of PVC microparticles as a carrier of additives (data gap)."* VinylPlus would note that this is not a correct statement for rigid PVC and even for flexible PVC: other polymers can contain brominated flame retardants and other flame retardants at levels similar to those of plasticisers in flexible vinyl. VinylPlus does support generation of further data on microplastics including potential leaching of additives.

At the bottom of page (Appendix A) the following statement is also made in the ECHA report: *"Although PVC is the third most demanded polymer in Europe, the presence of PVC in marine ecosystems is mainly reported in low percentages in the literature where PE, PP and PS are the major contributors[…]There is currently no possibility to compare whether these risks would be more severe from PVC microplastics than other polymer microparticles."* VinylPlus agrees with these observations in the ECHA report and notes the inconsistency with then recommending specific regulatory action on PVC.

Line 2 of this section refers to Appendix B and this is presumably Section B.6.3.2.

Appendix A – Page 17 – states that *"ECHA requested information on microparticle releases during the CfE2 (see Appendix E) but no information was received."* VinylPlus has verified this carefully and can find no request for information on PVC microparticles in any of the CfEs. Based on VinylPlus' understanding the first reference to microplastics was in an ECHA public presentation on the Investigation report on PVC at the PVC Formulation conference in Köln in September 2023[54].

Based on these statements in the public presentation VinylPlus provided information to ECHA on the Plastics Europe Brigid project – a major 5-year project to gather more data and information on microplastics in general (which is supported by VinylPlus members who are members of Plastics Europe).

Page 38 – Paragraph 2 – states that *"PVC uses can be expected to cause environmental releases of PVC microparticles in all lifecycle steps (See Appendix A)."* VinylPlus would note that this statement is an "expectation" and is not based on any data. VinylPlus supports obtaining more actual data in relation to PVC and microparticles. VinylPlus would note that different applications of PVC including flexible vinyl underbody coatings actually protect vehicles from the damaging and potentially corrosive effects of particulates which are present on roads and highways e.g. salt, grit, asphalt particles. Similarly flexible vinyl waterproof membranes used as landfill liners and in other applications actually prevent the release of microparticles into the environment from these sources.

Page 38, Paragraph 2 refers to a recent study on a recycling facility ((Erina Brown, 2023)[55]) from which together with other data on recycling it is estimated in the report that there are 7750 tonnes of "very small PVC microplastics being released to the environment."

This is calculated on the basis of 310,000 tonnes of post -consumer waste being recycled (as reported by the VinylPlus Progress Report 2023 for progress made in 2022). Based on Brown et al (Erina Brown, 2023) a figure of 5% is used for the amount of "very small" microplastics) – 5% of 310,000 tonnes = 15500 tonnes of "very small" PVC microplastics. It is then assumed that 50% of this is going to the environment based on estimates from wastewater treatment plants that 43% of microparticles go to agricultural soil and 7% go to surface water. This then gives the final figure of 7750 tonnes per year.

VinylPlus stresses that the recycling plant referenced in the paper (Erina Brown, 2023) was not recycling PVC and the operation is now closed. The plant cannot be considered representative of PVC recycling in Europe, and hence, these figures and further assessments based on this single non-representative case are questionnable.

Page 38 – Paragraph 2 – includes an illogical statement re: *"Furthermore, the scarce measured environmental data provides evidence of PVC microparticle exposures in the environment."* We would like to understand how is that "scarce measured data" provides evidence of exposure? Normally "scarce measured data" would lead to recommendations for more measured data – VinylPlus would agree with obtaining more data but not with concluding that scarce data is evidence of exposure. At the end of this paragraph, it is *"inferred that PVC uses cause the same risks as caused by the releases of intentionally added synthetic plastics microplastics…"*. This statement makes a very large extrapolation without any detailed knowledge on how PVC microplastics are formed, the particle sizes involved, the quantities, the health and environmental potential toxicity, the environmental fate, the leaching of additives etc. It is therefore difficult to see how this statement is scientifically supported and we are interested in obtaining the underlying evidence from ECHA.

[54] ECHA presentation at the PVC formulation 2023 conference (slides 59 to 80)

[55] E. Brown et al (2023), The potential for a plastic recycling facility to release microplastic pollution and possible filtration remediation effectiveness, Journal of Hazardous Materials Advances, Volume 10.

It is stated that *"4. PVC microparticles rend the additives very persistent"*. Please see comments in this report on Section 3.5 of ECHA report *"About the role of microparticle releases"*.

Appendix B, page 92 references a study by Henkel et al ((Henkel, 2022)[56]). The ECHA report states that the authors concluded that *"PVC microparticles are a long-term source of phthalates in the environment."* In reviewing this paper VinylPlus observes that only limited information is provided on the artificial manufacture of the PVC microparticles containing ortho and terephthalates. Based on the information provided (dissolving PVC in Tetrahydrofuran (THF) and adding plasticiser), it is not clear as to whether such artificially manufactured microplastics bear any relationship to unintentional microplastics which may be generated in real life situations. The latter are formed from PVC articles which have been subject to high temperature (140-150 degrees C) gelation and fusion processes, with additives such as plasticisers binding tightly via hydrogen bonding within the PVC matrix; this is the not the case with the artificially manufactured microplastics referenced by Henkel et al for which the process is solvent dissolution, with no thermal processing of the plastic. If indeed microplastics are formed (from articles subject to thermal processing), then plasticisers with very low water solubilities could leach over time at very low levels; the currently used major non-SVHC plasticisers such as HMW ortho-phthalates and other plasticisers have been shown to be readily biodegradable and are not PBT or vPvB) and so would rapidly biodegrade without any adverse effects.

Further data is though needed – the importance and significance of possible microparticle releases is not yet fully understood and does not allow for the assumption of a severe worst case in the absence of actual data and evidence.

4. Risk Mitigation

This section addresses the impact of substituting additives in PVC as well as the impact of substituting PVC with other materials. VinylPlus notes that the report states that *"The main focus of the impact assessment is on the costs…"*, and while economic feasibility of alternatives and cost impacts of substitution are important elements, the technical performance is also a major element which PVC brings to its many applications whether for uses in construction or uses in medical devices. VinylPlus notes that the ECHA report does not give sufficient attention to the beneficial performance aspects which PVC brings and would refer ECHA to the VinylPlus input to the Ramboll Questionnaire on alternative materials which was submitted by VinylPlus to Ramboll in December 2022 and included in the input to the ECHA CfE Number 2 in January 2023. As stated by ECHA in previous discussions, this is the first time ECHA compared full lifecycle performance of different materials. VinylPlus believes some aspects of the assessment should be improved.

4.1. Substitution of additives

This section starts with the assumption that *"For all the prioritised additives [63 in total], there is a non-threshold potential hazard (very high persistency, ED and/or PBT/vPvB) which release/exposure should be minimised."* This categorical statement is not supported by the data on the substances and is based on assumptions – see VinylPlus Annex 1 for list of assumptions and comments on these. VinylPlus supports further data development as appropriate but does not agree with assumptions as a basis for concluding on the need for regulatory action.

[56] C. Henkel et al (2022), Polyvinyl Chloride Microplastics Leach Phthalates into the Aquatic Environment over Decades, Environmental Science & Technology.

In the same paragraph it is noted that the report states that the additives were categorised based on the assessed level of concern (hazard properties and uncertainty of a potential hazard): the banding used is high, medium, low and currently no concern. This is contradictory to the prior statements in the same paragraph that for all prioritised additives there is a non-threshold potential hazard. The report states that a "*PBT approach should be applied (SEAC 2023)"* because of lack of a dose-response function. Many of the additives are not PBTs based on actual data, many are assumed to be PBTs in ECHA Report Tables 1, 2 and 3 (page 16). They are then assumed also to be vP. This is an approach based on assumptions and not the classifications of the substances based on actual data and assessments.

VinylPlus notes that at the end of this section it is stated that "*The main gap of the impact assessment relates to the supply chain impacts on manufacturers of the chemicals and raw materials (additive producers, suppliers of chemicals etc.), and the possible employment impacts."* This disregards the importance of additives for the production and long life of both rigid and flexible PVC articles. VinylPlus did provide some basic information as part of the input for CfE2 as follows:

- "The total PVC production and conversion industry in Western Europe comprises more than 21,000 companies with more than 500,000 jobs and a turnover of more than 80 billion euros. The industry can be roughly divided into four groups:
  - PVC polymer producers
  - Stabiliser producers
  - Plasticizer producers
  - Other additive producers (flame retardants, lubricants, fillers, impact improvers etc)
  - PVC converters. "

Information on the level of investment to move from SVHC LMW phthalates to non-classified HMW phthalates and other plasticisers was also provided (estimated at 6 billion EUR over 25 years) for this major group of additives which makes flexible vinyl and all the associated beneficial applications.

4.1.1. Benefits of additives substitution in reducing risks

VinylPlus notes that the basic approach being taken is to assume that substitution of an additive will result in reduced exposure and reduced risk, reducing potential for harm to health and the environment. This approach appears to ignore existing risk control and risk management practices which are in place and whether then the actual exposure situation being considered poses a risk or not. The approach is also inconsistent with REACH which requires exposure scenarios for any hazardous substances and then with associated risk control measures where exposure can exceed DNELs. The same comment concerning risk control applies to Paragraph 2, page 41 *"As a result of substituting prioritised additives, negative impacts on human health (via indirect exposure) and the environment might be prevented or they would appear further in the future."* These statements are made in the absence of any quantitative risk assessment, so they are effectively an assumption made without robust evidence or data. In the absence of a quantitative risk assessment, it is assumed that substitution of certain additives will lead to reduced risk.

In addition to not taking into account existing risk control measures for the existing additive, the hazards and risks of the alternatives are also not taken into account and are seemingly assumed to be negligible. This results in a biased assessment for alternatives.

Reference is also made to co-exposures, and that not taking these into account could lead to an underestimation of the potential risks. Even though this is a general point, VinylPlus believes such statement should only be made with concrete evidence in the form of hazard and potential exposure information, reference to specific quantified risks, and taking into account existing risk management measures.

Since risk control is not being taken into account in the investigation report VinylPlus would comment that the current investigation cannot be a basis to conclude that there is a risk that is not adequately controlled and needs to be addressed. Hence the report does not provide a robust basis for recommending regulatory action, as is done in Section 2 of the ECHA Investigation report.

4.1.2. Plasticisers

VinylPlus would like to emphasise that it is not appropriate to simplify a complex market into a substitution scenario with one main substitute plasticiser. Please see the Plasticizer Chemical Economics Handbook (2022) [57] for full information on the socio-economic importance of the flexible PVC sector.

In practice there are over 50 REACH registered plasticisers with 5 major products being used today (DINP, DIDP, DPHP, DOTP and DINCH). This follows the assessment of approximately 30,000 substances over 70 years with respect to their function as plasticisers. Such a highly complex, competitive market with different applications within the market being served by different products or groups of products, with some competing for the same applications (which ensures price competition consistent with competition law), and with high demand for volumes cannot be simplified to substitute the current major products with one product. Such an approach would have major implications for the performance of the many flexible PVC products as well as major cost implications since supply-demand aspects would result in the price of the single substitute multiplying several-fold.

Beyond the price aspects, there is a matter of impact for the PVC industry. The ECHA report foresees only "short term losses" for EU producers if DOTP was imported into the EU and current products were restricted. However, producers in the EU moved away from 2-Ethylhexanol production in the late 1990s /early 2000s because of the classification of DEHP as a Category 1B reproductive agent. Switching to DOTP only would require EU producers to move back to 2-ethylhexanol, requiring significant investment in order to make DOTP in the EU. As such, there could be major long-term impacts for EU producers, and it is likely the EU could become dependent on imports of DOTP in this scenario. While DOTP is a general-purpose product which can be used in applications such as flooring and some limited wire and cable applications, it is not suitable for applications such as high performing wire and cable, interior leather and waterproofing membranes (e.g. roofing, geomembranes). For these latter applications even lower volatility products are required in the shape of DIDP, DPHP, DUP, DIUP and DTDP. Further details on these aspects are provided in the VinylPlus input to the ECHA CfE2.

Page 41 – three paragraphs from the bottom of the page – refers to "packaging" as a use of DINP and DOTP. Typically, these products are not used in packaging, and PVC has been replaced by other plastics in general packaging applications. Rigid PVC is used in rigid packaging for pharmaceutical and food contact applications – since this concerns rigid PVC, plasticisers are not used.

Page 41 – two paragraphs from the bottom of the page – it is stated that *"DINP is replaceable with DOTP."* In the market these two products are interchangeable from a technical standpoint for general purpose applications, and this is a continual dynamic in the marketplace, with the two products, made by different suppliers, competing against each other and as a result prices remain

[57] S&P Global (2022), Plasticizers - Chemical Economics Handbook (CEH).

competitive for downstream users with ultimate cost of living benefits for consumers also. However, DOTP cannot be used in the majority of cable applications since it does not have sufficient resistance to thermal aging and could then pose a potential fire risk. For lower specification cables, DOTP can be used in some limited cable applications, but users continue to prefer DINP due to higher thermal resistance. There is a general market trend towards 90 degree C ratings.

There are also stringent national EU and ISO standards for specification cables which cables made with DOTP and even with DINP would not meet. Examples of these standards are:

- VDE 0472 part 1
- VDE 0207 parts 4&5
- VDE 0207-363-3 and 4-1 (equivalent to DIN EN 50363 (-3 and -4.1)
- VDE 0285 (equivalent to DIN EN 50525)
- VDE 0473-811 (equivalent to DIN EN 60811)
- ISO 16000 series of standards

Page 42 – first line – The report states that DOTP is on average 580 EUR/tonne more expensive than DEHP. This is stated in the context of medical uses. VinylPlus notes that the references for the price of DOTP range from 2006 to 2023; for price information recent data should be used or at least data from the same timeframe for different substances. DOTP and DEHP are made with 2-ethylhexanol and phthalic anhydride (DEHP) and phthalic acid (DOTP) and therefore costs of raw materials and production are similar. For medical applications there are additional costs for the substances in order to cover Good Manufacturing Practice (GMP) requirements throughout the supply chain from production to final use by the medical device manufacturer. Therefore, it is important to compare prices of different substances which apply specifically to medical uses. The price differential is so large here that possibly DEHP for general purpose use has been compared with DOTP for medical use. With respect to medical applications, it is inaccurate to state that DOTP has replaced DEHP "in most medical applications". TEHTM, DINCH, ATBC have also been used in medical applications.

Page 42 – Paragraph 2 – proposes that medium chain ortho-phthalates and trimellitates, on the grounds of medium concern could potentially be replaced by long chain ortho-phthalates (low concern). The example that DPHP could be replaced with DIDP or DUP in cables that require a high resistance is given. It should be noted that both DIDP and DPHP are HMW phthalates with C10 total carbons and are interchangeable with other on technical grounds in high performing applications like wire and cable, waterproofing membranes (e.g. roofing membranes) and synthetic leather. DIDP and DPHP are major products used in these applications because of their even lower vapour pressures than DINP and DOTP, and permanence within PVC (this is important for performance including durability and anti-fogging for example in automotive interiors). The interchangeability of the DIDP and DPHP in the market and supply by different producers means that there is significant competition on price which benefits downstream users and ultimately benefits cost of living for consumers. VinylPlus would also note that specific risks based on quantitative risk assessment have not been identified for medium chain ortho-phthalates (C7/C8 backbone with C9 and C10 total carbons), DPHP, and trimellitates in the current investigation report. Therefore, it is not justified or needed to propose substituting these substances with DOTP or any other plasticiser.

Page 47 – end of paragraph 2 – states that *"Trimelitates are assumed to have the same price as long chain ortho-phthalates."* This is not accurate since prices of branched chain and linear trimellitates are 2-3 times higher than long-chain ortho-phthalates. The publicly available information below was provided to ECHA in April 2023 as part of follow-up discussions to the calls for evidence:

IHS Markit | Plasticizers

Western European list prices for plasticizers	2018		2020		2021[a]	
	Euros per kilogram	Dollars per kilogram[b]	Euros per kilogram	Dollars per kilogram[b]	Euros per kilogram	Dollars per kilogram[b]
General-purpose phthalates (DINP)	1.35–1.45	1.67–1.79	1.10–1.20	1.25–1.37	1.30–1.40	1.57–1.69
C_{10} phthalates	1.60–1.70	1.98–2.10	1.20–1.30	1.37–1.48	1.30–1.40	1.57–1.69
Linear phthalates	1.90–2.30	2.34–1.61	1.90–2.30	2.17–2.28	2.50–3.0	3.03–3.63
Branched trimellitates (TOTM)	2.50–3.00	3.13–3.71	2.40–2.50	2.74–2.85	2.50–3.00	3.03–3.63
Linear trimellitates	3.30–3.50	4.07–4.34	3.30–3.50	3.76–3.99	3.30–3.50	4.00–4.24

Page 42 – paragraph 5 – states that *"If DOTP capacity building would take place in the EU, the profit losses incurred by producers of other additives would eventually be compensated by increases in the profit of DOTP producers*." This would mean that following closure of 2-EH and DEHP production in the late 90s and early 2000s due to DEHP classification, and then major investment (over 6 billion) in HMW alcohols and plasticisers (DINP, DIDP, DPHP), producers would be motivated to now re-invest in 2-EH and to use that for DOTP production. This would be on the basis of assumed risks of DINP for example. Investment pay back periods for such chemicals can be 15-20 years.

Table 7 gives an estimate of the costs to EU companies of moving to plasticisers of lower concern. The plasticisers of lower concern are given in the table as DOTP, Long chain ortho-phthalates, DINCH and Mesamoll. VinylPlus would note that this could mean replacing as much as 700 – 800,000 tonnes per year of capacity. This would require major investment by producers to make the quantity of plasticisers. It would require billions of Euros of investment and not millions as indicated in the table. Please note the costs of the last 25 years to invest in the necessary quantities of HMW plasticisers i.e. over 6 billion EUR. In summary the cost impact in the table is grossly underestimated. Given the lack of regulatory predictability and the mature EU market it is also open to question as whether such investments would be considered at this time.

Table 7 refers to DOTP as an alternative additive to DINP and DIDP in "soft packaging". These substances (DINP, DIDP, DOTP) are not used in soft packaging application such as cling film. The latter has moved to DEHA and polymeric plasticisers many years ago.

It should be noted that wherever DOTP is mentioned in Table 7 then DINCH and other plasticisers can also possibly be used. But each application has to be considered in detail and on its own merits as to whether a specific plasticiser is suitable from a technical and economic perspective.

Table 7 also gives DOTP as a replacement in artificial leather – this is not correct for demanding applications since DOTP cannot meet industry standards e.g. VDA 278 fogging test for car interior leather. DOTP has lower compatibility with PVC causing shorter product lifetime.

<u>4.1.3. Heat Stabilisers</u>

While the majority of the input made by VinylPlus is accurately reflected in this section we would note the following: VinylPlus underlines that an important correction to be implemented is that organotin stabilisers are not used in window profiles.

Organotin stabilisers are not used in window profiles (page 43, paragraph 3, line 5). The fact that it was noted that organotin stabilisers are used in window profiles is due to a misunderstanding. There was a reference in the VinylPlus input to use in "profiles", but this is misleading since this was applying to limited uses in furniture "profiles" and not to "window profiles". Further in-depth assessment by VinylPlus, EPPA and ESPA has confirmed that organotin compounds are not used in window profiles. This includes analyses of window profiles under EPPA which represents more than 90% of window profile producers in the EU (these analyses can be made available as needed). This should then in our view reduce significantly concerns in the ECHA report on potential exposure to organotin stabilisers in recycling and landfill operations (page 3, paragraph 8, sub-paragraph 8). This then means that the potential risk in recycling and the associated recommendation for regulatory action on organotin stabilisers is no longer appropriate in the view of VinylPlus.

As stated in this section of the report *"different organotins bring specific technical performance"* and this is why there are four main organotin compounds being used where organotin is needed i.e. MOTE, DOTE, DMTE and MMTE. The fact also that producers are willing to support the Authorisation of DOTE in line with the REACH Regulation and based on risk assessment and safe use means there is an important role still for DOTE to play in key applications. VinylPlus agrees with the ECHA report that a more complete analysis of the technical and cost benefits of DOTE compared to alternatives will be possible in the Authorisation application and review of the Authorisation.

VinylPlus notes that Table 8 is not fully clear as to whether the costs of moving to stabilisers of lower concern are per company or for all the downstream users. The text is clear (page 44, 5 lines from the bottom) *"…. reaching up to EUR 5 million for a single company."* The table should then be made clearer by changing "Costs to EU companies of moving …. etc" to "Costs per company (EU) of moving…. etc". Such a cost is significant for a single company involved in manufacturing PVC articles, many of which are SME companies. It is also noted that costs for the additive manufacturers are not included in this table given the difficulties of estimating such costs. Based on the costs of replacing lead with calcium based and calcium/zinc stabilisers, the replacement of organotin stabilisers (if viable cost-effective alternatives for the applications can be identified) will be in the tens of millions of Euros for the additive suppliers.

4.2. Substitution of the material (i.e. PVC)

VinylPlus notes that this section summarizes the approach taken for monetising the impact of substituting PVC with alternative materials *"The costs of substituting PVC with alternative materials were monetised...".*

VinylPlus notes that supply chain impacts for the PVC resin and additive producers and the downstream users are not taken into account. Some data was provided by VinylPlus in the CfEs (notably CfE number 2), and more information can be provided as appropriate.

The value chain impact of any major reduction of PVC production and consumption (due to replacement by alternatives caused by regulation of PVC) would have a major impact on the entire value chain. It should be noted that many of the additive and downstream users making PVC articles are SMEs. Since 30% of chlorine production in the EU is used to vinyl chloride/ethylene dichloride manufacture in order to make PVC, there would also be a major potential impact for the chlor-alkali industry, with the potential for significant disruption of the sodium hydroxide and chlorine balance, with the associated economic and employment impacts. Sodium hydroxide is used in paper manufacture, the food industry, and the pharmaceutical industry and chlorine is used in applications other than PVC including critical applications such as chlorinated adhesives for wind turbines. Indeed, the chloro-alkali industry with production of sodium hydroxide, chlorine and hydrogen is a strategic manufacturing process for the EU[58]. Moreover, in addition to the economic and employment impacts, the consequences of PVC substitution pose a chlorine management problem linked to the caustic

[58] See the VinylPlus infographic "PVC, from manufacturing to recycling".

soda production. If caustic soda production increases, solutions need to be developed for managing adequately chlorine that is not used in a specific value chain. PVC is a safe Chlorine sink, enabling the EU to balance caustic soda demand.

4.2.1. Benefits of material substitution in reducing risks

Overall, VinylPlus notes questions the general assumption that there would be benefits to risk reduction by substituting PVC with alternative materials.

Comparing materials including using Lifecycle assessment has so far not been a core competency of ECHA. VinylPlus notes that the relevant sections miss some basic information (e.g. impact for PVC and additive producers) and there is very limited assessment on lifecycle aspects and the positives such as the intrinsic low carbon nature of PVC (57% by weight chlorine) are not recognized.

The statement that there would be benefits for risk reduction by substituting PVC is based on assumptions that there is a risk due to PVC additives, and substitution of flexible PVC with the associated claimed reduction in plasticiser release is specifically cited. No such risk has been demonstrated in the current report based on robust scientific evidence and hence this statement is a hypothesis or assumption. It is again stated that other plastics have less additives than flexible vinyl – as already stated this is not necessarily the case, and that flame retardants and other additives can be present at high levels in other plastics. This section also states that *“It is noted that the safety of additives not used in PVC was not mapped in this project”* – hence it is not known if potential alternative additives pose a risk or not and whether they are no risk, low or high risk – there are then no grounds to state that the risk will be reduced if PVC is replaced by alternative plastics with alternative additives.

VinylPlus agrees that further analyses are needed to determine if alternative plastics have no lower, similar or higher potential risk with respect to microplastics. The report states that only “minor effects on the risks directly related to the plastic microparticle releases can be expected” from the substitution of PVC and that the above further analyses are appropriate. In view of these statements, it is difficult to then understand why recommendations are made for regulating PVC microplastics specifically, and at this time. VinylPlus considers that this further work needs to be done and is prepared to work with regulators to address this topic.

Regarding sections 4.2.2. Pipes to 4.2.10. Artificial leather, VinylPlus did complete a Ramboll questionnaire comparing PVC applications with those of other materials. A key point is that the alternatives have not been assessed to the same degree as PVC with regard to potential risks, sustainability aspects and performance. Therefore, VinylPlus would propose that a logical next step is to do a full and fair comparison of for example a specific application such as window frames, with regard to safety, sustainability, performance, and cost compared to alternative materials.

With regard to the performance, safety, sustainability and cost benefits of PVC compared with alternatives, input was given in the VinylPlus input to CfE number2. With regard to LCA studies on PVC and alternative materials the following information and detailed Sphera report (Sphera, 2022)[59] was also submitted to the CfE number 2.

With respect to cradle to grave LCA data on PVC articles, a review of 124 different papers relating to LCA has been made by Sphera (Sphera, 2022). The Sphera report followed a similar approach to a

[59] Sphera (2022), Update of information in the study “Life Cycle Assessment of PVC and of principal competing materials”, done for VinylPlus.

previous study (Baitz, 2004)[60] and confirms the conclusions of that study, namely that PVC and its additives are neutral to positive with respect to Life Cycle aspects for a number of applications (re: Windows, Flooring, Roofing, Pipes, Pharmaceutical packaging/Medical applications, Cables). The full report was submitted to CfE#2. VinylPlus notes some references to the Sphera report (Sphera, 2022), but this is only for uses of PVC and the results on LCA have not been considered.

With respect to alternatives and as noted above PVC is neutral to positive for LCA aspects – the availability of multiple safe and sustainable materials for the same application is of course beneficial to society and consumers in that it leads to competition including price competitiveness.

4.2.2 Pipes

VinylPlus notes that input from TEPPFA has been used in this section and overall, the section seems to reflect the industry understanding regarding PVC pipes and alternatives.

Under economic impacts it is stated that PVC use is only 3-4% in pipes of the total PVC production in Europe. Input from VinylPlus in CfE number 2 highlighted that *“Pipes, fittings and flexible tubes are significantly higher at 24.2% of total PVC production”*; this would mean the economic impacts are being significantly underestimated.

We would like to draw attention to a niche application: chemical fluid handling. For this application, even though there is no available data on organotin release to the environment at the end of the PVC-piping service life (>25 years), the potential risk is controlled, as regulation on the treatment of hazardous wastes stipulates that these pipes have to be incinerated. Moreover, there are currently no alternative stabiliser to organotin which could meet the stringent performance requirements.

With respect to life cycle impacts and CO2 emissions, VinylPlus submitted input to the Ramboll questionnaire of December 2022.

Specific comments:

4.2.2 Pipes, p48	Typo	Line 21, “*and 10% with PE”*. PE should be replaced with PP
4.2.2 Pipes, p49	Application of PP	In first box of Table 9: PP is not used for mains (water pressure). We suggest deleting PP in the first line.
4.2.2 Pipes, p49	Wrong LCA conclusions	*« If PVC pipes are replaced with alternative material pipes, the CO2 emissions would decrease. »* This is not in accordance with the known LCA analysis. Environmental impact of PVC pipes is at the same level of other plastics materials and also concrete. Please see LCAs Archive - TEPPFA

4.2.3. Cables

VinylPlus notes that crosslinked PE (PE-X) is included as an alternative in this section. Replacement of PVC by PE-X could lead to significant sustainability impacts re: difficulties to recycle whereas PVC

[60] M. Baitz et al (2004), Life Cycle Assessment of PVC and of principal competing materials.

cable waste is mechanically recycled. PE also requires significant amounts of flame retardants including brominated materials.

With respect to Paragraph 3 of this section (page 50) and statements on low smoke zero halogen/halogen free cables, a major issue in fires is the generation of carbon monoxide and not hydrogen chloride. All polymers in fires emit carbon monoxide which are highly toxic. By contrast, PVC is difficult to ignite, burns more slowly and hence emits less carbon monoxide and later than other polymers. With regard to the next paragraph, VinylPlus disagrees that Sarti and Piana (Gianluca Sarti, 2022)[61] supports the statement that PVC has been replaced in cables because of stricter fire safety requirements. It rather supports that PVC is one of the best materials and that acidity as a parameter is being incorrectly used in other assessments.

With respect to Table 10 VinylPlus would note that economic impacts for the producers of PVC resin and the additives are not taken into account. With cables representing 3-5% of PVC resin production in the EU and with major volumes of plasticisers and other additives being used to manufacture cables, this would be a major impact for the resin and additive manufacturers.

With respect to life cycle impacts no reference is provided for the study on comparing PE with PVC and also with PET. The reference should be added to the table. With respect to CO2 footprint VinylPlus would highlight the data provided in responding to the Ramboll Questionnaire of December 2022 (and submitted to CfE number 2) which shows that PVC has a lower carbon footprint than alternative plastics re: statement in the table that "there would likely be fewer negative impacts for the environment" for PE. As already noted, a major concern with cross linked polyethylene (PE-X) is the difficulty of recycling this material.

4.2.4. Flooring

VinylPlus notes that reference is made to input from ERFMI. PVC represents 91% of the resilient flooring market bringing significant benefits to society, including uses for hygienic flooring in hospitals and public buildings as well as sports arena and leisure centre flooring. Reference to the total cost of ownership studies would also seem appropriate (A. Marangoni, 2011)[62].

With regard to LCA impacts in Table 11 there is no robust basis for stating that if linoleum or ceramics were used instead of PVC, environmental impacts would be reduced. PVC flooring represents approximately 6.4% of total PVC production in the EU, and the potential significant impacts of replacing PVC for the resin and additives producers should also be taken into account.

4.2.5 Window frames

VinylPlus notes that input from EPPA has been incorporated into this section. The data provided by VinylPlus into the CfE#2 stated that 1255 kta of PVC is used in window profiles – this is approximately 25% of EU PVC production (annual consumption can of course change depending upon economic conditions – the VinylPlus data is from 2021 and is representative data). VinylPlus considers this is a better figure to use than the broad range in the report re: 0.3-1.9 million tonnes. Given the fact that approximately 25% of PVC production is used for window frames, then there could be economic

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[61] G. Sarti, M. Piana (2022), PVC in cables for building and construction. Can the "European approach" be considered a good example for other countries? Academia Letters

[62] Marangoni, A. et al (2011), PVC products competitiveness. A total cost of ownership approach.

impacts for producers of resins and additives as well obviously as the window profile manufacturers (re: Table 12). This should be addressed in the economic impact for Table 12. Removing a major material from the market would also have significant competitive implications and associated costs of the alternatives due to less competition. With respect to comparisons with alternative materials, the total cost of ownership report (A. Marangoni, 2011) concluded, from a total cost of ownership perspective from purchase throughout the lifespan to recycling/disposal including payback period that, PVC is the best performing material for windows (also for flooring and pipes). A similar outcome could be found in the response to the Ramboll Questionnaire on alternatives sent to Ramboll and in the VinylPlus input to the CfE number2.

The assessment of PVC windows versus alternative materials is flawed: while it is stated that PVC windows have a lifetime of 25-30 years, in reality, PVC windows, when properly maintained, can last 40-75 years[63] in terms of technical condition and functionality. Consequently, the results of the life cycle assessment are in-accurate, as they are based on a Reference Service Life (RSL) of 27.5 years for PVC windows. To use a short lifespan influences the quantitative impacts, therefore all the comparative assessment.

With respect to Table 12 the significant energy requirements, carbon footprint and associated emissions for the mining and production of aluminium (aluminium smelting) do not get sufficient mention in the table, and VinylPlus would propose that this is addressed.

As noted in the VinylPlus input to the Ramboll Questionnaire on alternatives, timber and aluminium are the major alternatives to PVC. There is only limited use of aluminium clad wood.

4.2.6 Packaging

VinylPlus notes that the ECHA report does not accurately reflect the VinylPlus input. The ECHA report states that “400 kta of compounded PVC are used in food and non-food packaging” (Paragraph 1, lines 3-4). In fact, VinylPlus using ECVM data provided input that there is 185 kta of PVC packaging for food contact applications, and 215 kta for pharmaceutical packaging, making a total of 400 kta – these figures are for PVC resin only. Although since this is mainly rigid packaging the compounded PVC will only be a small amount higher in terms of kta. The “non-food packaging” referred to is pharmaceutical packaging.

Page 53 – 2 lines from bottom of the page – VinylPlus does not agree with the ECHA report where it is stated “There appear to be no critical differences between the lifetime or performance of PVC and the alternative materials in packaging.” PVC is still in important food contact and pharmaceutical packaging applications precisely because it brings important shelf-life and cost benefits. In general, PVC packaging has been replaced to a large degree by other plastics but remains in certain food and pharmaceutical applications because it brings benefits for shelf life which other plastics don’t bring.

With regard to “Supply chain impacts” in Table 13 (page 54) there is no assessment of the economic impact on producers of PVC resin and additives. Given the significant volumes of PVC going into these applications (3.7% of total production) this should impact the assessment significantly. With respect to the figures given for profit losses to the PVC packaging producers presumably these are

[63] For example, see this verified Environmental Declaration in the Dutch Nationale Milieu Database showing a lifespan of 75 years for a PVC window profile.

annual figures which are given; they would seem to be on the low side. No reference is given and hence it is not clear what is the source. Additionally, profit figures given no indication of the impact on employment and investment in the industry.

4.2.7. Medical packaging: blister packs

In paragraph 3, line 1 it is stated that "*It appears that the alternative materials perform as well as or better than PVC in most of the aspects, but there are differences in barrier protection and transparency*." VinylPlus would note that these are critical performance parameters where PVC performs very well, and underlines why PVC continues to be used. The statement also contradicts to some degree the statement in the previous section that "*There appear to be no critical differences between PVC […] and the alternative materials in packaging*" – see above where VinylPlus disagrees with this statement.

With respect to the figures given for profit losses to the PVC packaging producers presumably these are annual figures which are given; they would seem to be on the very low side (1-7 million EUR). No reference is given for these figures and it is unclear what is the source. Also profit figures given no indication of the impact for employment and investment in the industry.

With respect to Life cycle impacts it is stated in Table 14 that due to a lack of data it is not possible to compare CO2 emissions. Using publicly available data shows that production of 1 kg of PVC has CO2 emissions which are 2-3 times LOWER than 1 kg of aluminium. A more in-depth LCA assessment to compare PVC and alternatives for specific applications would be appropriate. The CO2 emissions and energy advantages of PVC are due to a significant degree to the integrated nature of the chlor-alkali process involving the electrolysis of salt (an abundant raw material) to make sodium hydroxide and chlorine with the latter being used to make vinyl chloride monomer which in turn is polymerized to make PVC. PVC itself is 57% by weight chlorine and hence intrinsically has a low carbon footprint.

4.2.8. Toys

VinylPlus notes that this section includes reference to our input into the CfE#2.

PVC is used in toys because it is easy to mould and shape, is soft and flexible without sharp edges. As such PVC plays an important role in toy safety. As noted in the ECHA report the particular advantages of PVC is that it is readily paintable (eyes of dolls and plastic figures for example).

PVC is also used to make flotation devices (arm bands which are not toys) which play an important role in child safety when learning to swim. VinylPlus would suggest that these benefits should also be referenced in the ECHA report.

Reference is made in the ECHA report in this section to boats and rafts, and of course larger rubber dinghies which can be used in emergency lifesaving operations are also made of PVC.

It is not clear why reference is made to profit losses to "PVC packaging producers" in Table 15 on the impacts of replacing PVC in toys.

Inflatable bouncing castles are also made with PVC because it is strong and durable and hence contributes to the safety of the bouncing castle.

4.2.9. Medical applications

VinylPlus' is aligned with the ECHA report's recognition of the uncertainty in evaluating whether PVC substitution in medical applications provide enhanced environmental and health advantages and takes note of the potential technical drawbacks and the costly process of substitution for the entire medical sector.

Notably, the ECHA report draws attention to the absence of Life Cycle Assessment (LCA) data, highlighting the lack of solid evidence to affirm that alternatives are environmentally superior to PVC.

Given the extensive use of PVC in medical devices and medical equipment it would appear that Table 16 is significantly underestimating the costs of developing alternatives and also obtaining the necessary reviews from the European Medicines (and Medical Devices) Agency – such reviews can take several years.

No information is given on the impact for PVC and additive manufacturers. PVC used in blood bags is estimated at about 85kta (~2% of production); manufacture of PVC for this application will require critical GMP and medical device specifications to be met.

VinylPlus is committed to closing data gaps and supporting initiatives for circularity in the medical sector. VinylPlus initiated the VinylPlus Med scheme[64] that involves hospitals, waste management companies, recyclers, and social partners and has commissioned a study by a third-party consultancy revealing that recycling PVC medical devices can reduce greenhouse gas emissions by 25% compared to incineration.

VinylPlus is also contributing to the knowledge base on the recyclability of medical, flexible PVC. This research aims to quantify how many thermal cycles medical PVC can undergo without compromising its functional properties. The findings to date indicate successful recycling for at least four cycles.

Beyond VinylPlus initiatives, recycling systems are being developed for medical waste not contaminated by bodily fluids[65].

4.2.10. Artificial leather

VinylPlus notes that the ECHA report recognises the benefits of artificial leather and the pros and cons of different types.

With regard to Table 17 VinylPlus notes that no information is provided for the impacts for resins and additive producers. Reference is again made to PVC packaging manufacturers (presumably this is meant to be artificial leather manufacturers) with very low figures given for profit losses from replacing PVC. No source is given for these figures and VinylPlus would note that they appear to be underestimated. Profit figures can vary significantly depending on the economy and also don't give any indication of potential impacts on employment and investment in the business.

4.2.11. Summary of substitution costs

VinylPlus notes that Table 18 states (in the footnotes) that only material costs and producer surplus losses are assessed, and also no lifetime costs are assessed. As stated earlier in the ECHA report costs

[64] VinylPlus® Med Accelerates Sustainability in Healthcare - VinylPlus

[65] See https://recomed.co.uk

for the producers of PVC resin and additives are not assessed in the report. Given the size and investment costs of the integrated chlor-alkali (chlorine, sodium hydroxide and hydrogen) and PVC production industry in the EU the cost impact here is likely to be much greater than that of downstream users. Table 16 does give some significant cost impacts for the producers of articles, but the some of the cost impact estimates seem very low for key applications. VinylPlus acknowledged that estimating such figures is very difficult, but, for example, pipes are given only 530 million, which seems extremely low, and no reference is given to underpin this figure. A more general comment is that if no significant risk has been identified for PVC articles (and potential risks of additives and microplastics in recycling/landfill are being addressed) what is the purpose of estimating the cost impact of replacing PVC with alternative materials? VinylPlus recognizes that information on alternatives to PVC was specifically requested by the European Commission.

A further recurring theme in these sections on alternatives is the lack of information on lifecycle aspects for the alternatives, in spite of VinylPlus input. It would seem then that a logical next step would be to compare in-depth different materials in the same specific application and to apply life cycle assessment and to conduct a more in-depth comparative assessment. Based on prior LCA studies which show that PVC performs as well or better than alternatives, VinylPlus is confident that PVC would continue to do well in such a comparison.

4.3. Technical release minimisation and applicability

With respect to Paragraph 1, VinylPlus would note that it has now been confirmed that organotin stabilisers are not used in window profiles – there was misunderstanding based on the input made into the CfE number 2 (see comments on section 4.2.5 and section 4.1.3 for details). This means that concerns on potential exposure to organotin stabilisers during recycling (because window profiles are a major component of waste PVC for recycling) should be significantly reduced.

VinylPlus would also note that there is existing biomonitoring data on DEHP in recycling plants which shows exposures within safe limits. This data was used in REACH Authorisation requests for the recycling of PVC made with DEHP and Authorisations were granted to three companies in the past.

This section again makes the argument that releases of additives and microparticles are higher in professional handling in the construction sector (installation and removal) as well as in recycling activities. The statements again assume that there are risks and even that there are no risk control measures (no reference to this in the section). The general statement that reducing releases will reduce exposure and risk, without understanding what the actual exposures and risk control measures are then an assumption which lead to the conclusion for regulatory action on some additives and on PVC microparticles – even though as the report again states microplastics is a broad issue involving all plastics. Further information on the nature and amounts of the microplastics, and the migration of additives is needed so that any required regulatory action can be targeted, effective and cost efficient. To require “minimisation” by technology without this additional information could negatively impact recycling investment and capability. Microplastics from all plastics are likely being formed in recycling operations, but this is precisely because the plastics are being recycled (which is overall a positive development for resource and energy conservation and net zero goals) and appropriate risk control measures should be in place (required under existing health and safety regulations and to be added to where needed and appropriate). The general assumptions are not a valid basis for recommending regulatory action. VinylPlus is ready to work with regulators and other stakeholders on further improving the safety and sustainability of such operations.

Page 58 – paragraph 2 – it is not accurate to state that "all types of PVC are channelled via recycling plants and hence those function as the mixing point of release/exposures for practically all PVC additives." In practice there are plants which collect specifically pre-consumer waste and those that collect post-consumer waste. Some plants focus more on rigid waste (e.g. Window Profile recycling plants), and other recycling initiatives focus on flexible PVC (for example, Roofcollect® by ESWA). Some companies have their own recycling programmes. Therefore, all additives will not be channelled in every recycling plant.

4.4. Life-Cycle considerations of risk reduction measures

4.4.1. Upstream supply chain

VinylPlus notes that the ECHA report does acknowledge the critical role and importance of the chlor-alkali production process upon with PVC depends (re: chlorine to make vinyl chloride monomer used to make PVC). The ECHA report also does note *"At least the following impacts […] lower price of chorine"* if demand is reduced due to reduced demand for PVC (assuming regulation on PVC). Another impact which the report notes is *"increase the price of caustic soda as well"*.

Beyond the supply/demand impacts, the broader impact would be to disrupt the balance of production of the chlor-alkali industry in the EU, with the associated impacts on the profitability and viability of this sector. Profitability of such large-scale operations depends upon running the plants at a high capacity of production (economic divisor effect) in order to be competitive with global competitors. The latter would take advantage of any disruptions in the EU manufacturing chain potentially further exacerbating the challenges of the EU industry.

4.4.2. Impacts of non-recycling of PVC

VinylPlus notes that the first paragraph of this section highlights the significant benefits of PVC recycling, by actually considering the socioeconomic impact of stopping PVC recycling. Reference is also made to the benefits of stopping recycling (*"decrease of environmental emissions, particularly for soft PVC"*). It is clear from the information presented that the overall benefits of recycling of PVC outweigh any possible benefits from stopping recycling PVC.

Nevertheless paragraph 2 of this section then states that *"ECHA has drafted a hypothetical scenario where recycling of PVC would come to a full stop."* VinylPlus has been working actively on the recycling of PVC for 25 years so this is a hard hypothesis for us to understand.

VinylPlus disagrees with the analysis in paragraph 3 of this section. The ECHA report has taken the total post-consumer PVC waste which is available (as estimated by Conversio) and then used the Recovinyl data for recycling of post-consumer waste.

If the Conversio data is taken for the total waste, then it would be logical to also use the Conversio data for post-consumer. This is because the Recovinyl data likely underestimate the post-consumer volumes of PVC waste which are recycled, just as Conversio underestimate the post-industrial amounts of PVC waste which are recycled. Recovinyl is an auditing and registration system for waste recyclers and understandably does not cover the entire post-consumer waste recycling market, whereas Conversio is an estimate looking at the entire post-consumer waste market. So, using the Conversio estimates for total waste and post-consumer waste recycled gives:

- Total post-consumer waste (Conversio, 2021)[66]: 2435 kta
- Post-consumer waste recycled (Conversio, 2021)[67] : 599 kta.
- % post-consumer waste recycled: 24% (and not 12% as given in the ECHA report)

So, using the Conversio data appropriately gives twice as much recycling of post-consumer waste as given in the ECHA report. VinylPlus would also note that the Conversio data shows:

- 35% recycling of PVC waste (post-consumer and post-industrial)
- 46% incineration with energy recovery for PVC waste
- 19% landfilling of PVC waste

As noted in the ECHA report VinylPlus recognises the need for increased recycling particularly of post-consumer waste and is actively working on this via the VinylPlus 2030 Program with oversight of the Monitoring Committee made up of Commission officials, MEPs, academics and industry participants.

The final two paragraphs of this section make the argument that the benefit of stopping recycling of flexible vinyl is higher than the benefit of stopping recycling of rigid PVC – this being because of the higher levels of additives including plasticisers and flame retardants. This does of course depend upon the hazard properties and release potential of the additives and the risk assessment; these aspects are assumed in this report in a generic manner. Specific in-depth risk assessments are needed to determine if the risks of recycling can be adequately controlled or not.

With respect to plasticisers the statement on benefits continues to be based on the view that plasticisers can readily migrate from flexible vinyl and flexible vinyl microparticles. As commented earlier, data is available which shows that the migration of plasticisers in landfill is infinitesimally small, and where it does occur in these very small amounts for the major plasticisers used, they are biodegradable.

5. Regulatory Options

VinylPlus notes that this critical section does not recommend regulatory action but rather discusses the need for more information and possible regulatory options. VinylPlus believes that regulatory options would only become relevant subject to further information becoming available and a robust risk assessment being conducted.

VinylPlus notes that the start of this section lists "three main potential risks for PVC and PVC additives" – these being:

- *"Environmental risk from release of PVC microparticles*
- *Environmental risk from release of prioritised additives, mainly bound to PVC microparticles*

[66] Conversio. (2021). *PVC waste in EU 27+3 countries 2020*.
[67] ibid

- *Potential risk to workers, especially in recycling facilities by (combined) exposure to organotin substances (except MOTE with a concentration of DOTE below 0.3%) and medium-chain (C4-C6 and C7-C8) ortho-phthalates"*

VinylPlus notes the difference in wording – in this section "potential risks" are discussed whereas in the Conclusions (page 2-4) the words *"identified risks"*, "risks to the environment (incl. man via the environment", *"to minimise risks"* are used. As VinylPlus previously stated, the Conclusions are based on assumptions regarding hazards, environmental fate of PVC microplastics and additives, co-exposures and threshold/no threshold (see Annex 1 and other sections). Therefore, while *"potential risks"* requiring further information may be appropriate as used in this section in the body of the ECHA report, *"identified risks"* is not appropriate language. VinylPlus thus disagree with recommending regulatory action on *"potential risks"*, and stresses further information is needed to determine whether or not there are risks to human health and the environment which are not adequately controlled, and which would warrant proposing a restrictions dossier under REACH.

With regard to microplastics, VinylPlus would again note the statement in the ECHA report in Section 4.2.1 Benefits of material substitution in reducing risks where it is stated that that only a *"minor effect on the risks directly related to the plastic microparticle releases can be expected, but it is not known whether that has an overall positive (risk reduction) or negative impact (risk increase)"* from the substitution of PVC and that further analyses are appropriate. Given this statement, VinylPlus does not understand why recommendations are made for regulating PVC microplastics specifically**.**

On page 63, 8 lines from the bottom of the page, it is stated that "A need for broader regulatory risk management instrument to reduce the microparticle releases should be therefore further investigated." VinylPlus would agree with this statement and based on a further assessment, the need for targeted regulation that is effective, efficient and economic can be established.

VinylPlus notes that there was no assessment of the impacts of emission minimisation technologies for microparticles and agrees that a follow-up activity is necessary to gather information at a more detailed level.

<u>5.2. Restrictions on PVC additives</u>

Paragraph 2 – line 9 – "*it is highlighted that it is necessary to carry out further work for especially informing on whether substitution of the identified substances groups in the highest concern and release category in section 3.2.3 would entail a sufficient level of effectiveness in reducing/minimising the risk".* VinylPlus agrees that further work is needed and believe this should be done before any regulatory action can be considered.

Paragraph 3 –the report states that *"A more immediate impact could be achieved in a scenario in which PVC recycling comes to a full stop."* Given the importance and benefits of the circular economy which VinylPlus has been supporting for nearly 25 years with concrete actions, this is a concerning scenario. We do note positively though that this is further qualified by the statement that *"…and notes that the non-recycling scenario is provided for comparison only."*

Paragraph 4 – statements on cables – *"When considering which PVC uses contribute the most to the environmental risk found for prioritised additives, it appears that cables (a soft PVC use) stand out as a single contributor to the prioritised additives releases. As discussed in section 4.2, substitution of*

PVC with alternative materials in cables would be less costly than in other uses and hence for minimising risks of additives a restriction of PVC in cables seems worthwhile further assessment."

In this respect VinylPlus would note that cables have been made for decades now with the non-classified, non-SVHC HMW phthalates (DIDP, DPHP, DIUP, DUP, DTDP) and with replacement of SVHC antioxidants, and use of Ca/Zn stabilisers. These substances have been subject to extensive regulatory registrations and regulatory evaluations confirming low hazards and safe use in this application. While these substances have been now prioritised in the 63 additives in the current investigation report this prioritisation is contrary to the actual data on these substances and contrary to REACH/CLP regulatory evaluations e.g. DINP – RAC decision that it is not reprotoxic (which included assessment of reproductive endocrine studies).

The figures for tonnes of release of key plasticisers, organotin stabilisers and other additives are significantly overestimated in general. They would appear to be based on using the PLASI model (not fully clear in the report) which VinylPlus has already highlighted is not appropriate for PVC. A screening tool which is not suitable for PVC should not then be the basis for recommending regulatory action. VinyPlus therefore believes that for cables, the emissions are likely significantly overestimated and that such figures are not consistent with the long-life and durability of flexible PVC cables (40 years +). With respect to the costs of replacing PVC, VinylPlus disagrees that alternative materials in cables would be less costly than in other uses. VinylPlus has already commented on the incomplete nature of Table 10 (Impacts of replacing PVC with alternative materials in cables) under section 4.2.3 Cable stating that - With respect to Table 10, economic impacts for the producers of PVC resin and the additives are not taken into account. With cables representing 3-5% of PVC resin production in the EU and with major volumes (~23% of EU production) of plasticisers and other additives being used to manufacture cables, this would be a major impact for the resin and additive manufacturers. Many of the cables used in construction and automotive applications are also not accessible (within the wall cavities and under bonnets etc) and hence contact with humans and the environment are minimised. If there was significant release of plasticisers from cables, then their performance would significantly be impacted, and they would not be lasting for over 40 years.

The statement in the table in Section 4.2.3 contradicts the statements in this section re: Table 10 states "*However, with the current knowledge, there is not enough evidence to calculate the environmental impacts of switching from PVC to alternative cable materials.*"

Paragraph 5 – DEHP has already been broadly restricted under REACH in indoor and outdoor applications and also for electrical and electronic goods. DEHP has broadly been restricted together with other LMW phthalates (re: DBP, DIBP and BBP). Several other LMW Phthalates have been withdrawn from the market because of SVHC properties and potential risks. Organotin stabilisers have also been subject to risk assessments in the 2000s and have been restricted in certain applications and allowed for use in others. The medium chain ortho-phthalates (C7-C8 backbone; longest straight chain with total carbons of C9/C10) have also been subject to extensive risk assessments during the last 25 years with conclusions of low hazard and no risks identified in current applications (see prior comments for extensive information). Paragraph 5 in recommending restriction for DEHP, medium chain (C4-C6 and C7-C8 [backbone]) ortho-phthalates seems to indicate that ECHA is not aware of the extensive regulations and assessments which have already been put in place or carried out.

Paragraph 6 – the ECHA report raises the question as to whether substitution would also be necessary for other substances like zinc borates, organophosphates and trimellitates. This question can of course be raised for any chemical substance; VinylPlus would though comment that the understanding of industry was that REACH Registration, Evaluation and Authorisation was intended to support the safe use of substances via the submission of extensive data and an assessment in the form of the Chemical Safety Report (CSR). This was done under the banner of "No data, No market". Restriction could then be applied where needed and where a risk to human health and the environment is identified that is not adequately controlled. REACH was not intended to question whether every substance and material should be substituted. REACH and CLP should be data driven (and not based on assumptions) and for a Restriction dossier it should be considered clearly that a substance "poses a risk to human health or the environment that is not adequately controlled and needs to be addressed." VinylPlus would submit that this has not been demonstrated in this case. VinylPlus would certainly agree that further data, studies and information is needed on microplastics, releases of additives from microplastics, and data on substances in line with REACH and CLP. VinylPlus is ready to work further with regulators on developing this additional data to support the safe and sustainable use of PVC and PVC additives.

Paragraph 7 – reference is again made to the fact that cables represent 67% of the overall estimated releases of additives. This figure would appear to be based on the fact that cables are the major flexible vinyl articles which are recycled and that emissions occur during recycling. VinylPlus would again refer to the comments on the PLASI model i.e. that this is not suitable for PVC given the specific nature of the polymeric matrix of PVC with the presence of the Chlorine atom in the monomer and hence in the polymer chains. The tonnages for releases of plasticisers are therefore grossly overestimated giving an inaccurate picture of the risk associated with flexible vinyl (and even then, the major plasticisers used today have low hazards and no requirement of CLP classification for health or environmental hazards). The concerns as already noted are based on assumptions and need to be assessed further to confirm the concern or not as the case may be.

Paragraph 8 – the following is stated in the context of discussion plasticisers that *"Due to the very high persistence and ongoing accumulation of the additives in the environment it is important to act on risks when identified without delay."* VinylPlus would disagree with the statement that the major plasticisers used today are of *"very high persistence"* and that there is *"ongoing accumulation"*. Tests according to OECD Guidelines as required under REACH have shown that the major HMW ortho-phthalates and other plasticisers used today are "readily biodegradable" and that PBT assessments concluded under REACH registration and by authorities (OSPARCOM, 2004 for DINP and DIDP; Danish EPA under REACH Substance Evaluation 2021 for DIUP and DTDP) have concluded that these substances are not PBT and are not vPvB. It is therefore an egregious disregard of robust scientific data and assessments to state otherwise.

Paragraph 9 – VinylPlus notes that this is then taken further with respect to ortho-phthalates, based on the same disregard of the actual scientific data, that substituting ortho-phthalates used today should be applied in a wider context and considering all uses of the substances. While such a statement may be applied to C4-C6 backbone ortho-phthalates, based on the robust weight of evidence scientific data, and the regulatory evaluations which have been conducted over the last 25 years, it does not apply to HMW ortho-phthalates. If the intention of these latter two paragraphs is to include HMW ortho-phthalates, then VinylPlus can only conclude this is not a statement based on science.

Paragraphs 11 and 12 – state that emission reduction by technological means will not address the entire lifecycle of the PVC articles, and that the risk concept being used (assumptions on persistence and vP etc) is not a novelty and is already being applied to other substances. VinylPlus would comment that this blanket type of approach with broad assumptions does not mean that it constitutes robust weight of evidence science, simply because it has been applied elsewhere.

Paragraph 13 – compares using other regulatory instruments versus using the REACH regulation. In this regard VinylPlus would note that a level playing field assessment between different materials with respect to performance, safety and sustainability for specific applications would be appropriate under some of these other regulations e.g. the Construction Products Regulation and the proposed Eco-design for Sustainable Products Regulation (ESPR).

5.3. Other and complementary regulatory options

This section continues the discussion started in the previous section with regard to complementary regulatory options. In this respect VinylPlus would be supportive of setting harmonized OELs for example for plastic dusts including PVC and setting appropriate limits for additives also. Reference to regulation under water directives is also made and this would then be relevant to all microparticles including microplastics and not just to PVC. The possibility to modify waste regulations where appropriate is also raised and VinylPlus would agree with these statements where the regulation adds value and is consistent with better regulation.

The first paragraph does suggest a "more holistic approach" for PVC because of the diverse number of uses. VinylPlus would comment here that the regulation should be tailored towards any risk which is clearly identified based on robust evidence and where risk control is not adequate for controlling the risk. Based on the assumptions in the current report and the lack of identification of such a risk then VinylPlus concludes that a holistic approach is not supported, and neither is a more specific approach. Further work is needed to determine if such risks requiring regulation are occurring in practice.

6. Assessment and data gathering follow-up priorities

VinylPlus agrees with the further work and data needs identified in the second paragraph of this section (seven items are listed). Please see also the Executive Summary, VinylPlus Annex 2 and the detailed comments for specific areas where VinylPlus supports additional work, in collaboration with regulators. VinylPlus also notes that the ECHA report recommends conducting further work under the PARC initiative. VinylPlus is open to this possibility.

With regard to the items listed for "impact assessment" (i.e. impact assessment of substitution of PVC), VinylPlus would first recommend that the further work and data needs are addressed, and that the information and data arising are used to conduct a robust assessment of the nature and degree of any risk, based on robust evidence and replacing the assumptions in the current investigation report. This also should mean that REACH processes (compliance checks, CLH, Substance Evaluations) are allowed to run their course and for the relevant data and conclusions to be used.

If risks are identified then further impact assessment regarding the substitution of PVC would be appropriate, but to do so before any risks are identified would be an inefficient use of valuable resources.

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