APPENDIX C

TO THE INVESTIGATION REPORT

ON

PVC AND PVC ADDITIVES

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TABLES

LIST OF ACRONYMS AND ABBREVIATIONS

Acronym / abbreviation	**Meaning**
ATO	Diantimony trioxide
CfE	Call for evidence
EEE	Electrical and electronic equipment
EoL	End-of-life
EU	European Union
HDPE	High density polyethylene
LDPE	Low density polyethylene
LCA	Life cycle analysis
PE	Polyethylene
PE-X	Crosslinked polyethylene
PP	Polypropylene
PVC	Polyvinyl chloride

APPENDIX

C. Impact assessment

C.1. Approach to impact assessment

PVC is used in various sectors and uses, both in rigid and soft forms. Each use has its specific technical functionality requirements, requiring different formulations of compounded PVC and having different alternative materials. Also, the impacts of possible substitution are use-specific. PVC can be substituted with another material, or some of the additives in PVC can be substituted with alternative additives.

As requested in the mandate from the European Commission, the impact assessment covers both alternative materials to PVC and alternatives to prioritised substances used as additives in PVC, which include some plasticisers, heat stabilisers and flame retardants (see Appendix B for details).[1] The impact assessment focuses on the substitution and end-of-life options, but not on the impacts of other potential risk management options such as product modifications or emission abatement at the end-of-life.

Impacts have been assessed separately for various uses of PVC, including pipes, cables, flooring, window frames, packaging, medical packaging, medical applications, toys and artificial leather. Pipes have been further divided into three sub-uses and packaging into two sub-uses in the assessment in order to account for differences in substitutability. Roofing, wallpapers and miscellaneous consumer items have not been covered in the analysis due to a lack of relevant data. See Table 1 for further information on the coverage of the uses in the analysis undertaken.

The main focus of the impact assessment of this investigation report are the costs of substituting PVC with alternative materials or substituting certain additives in PVC with other substances. Costs are presented by use and additive group (heat stabilisers, plasticisers, flame retardants). In addition, additives have been categorised based on their level of concern into high, medium, low and no concern based on their hazard and weight-of-evidence considerations (see Appendix B). The costs of moving to additives of a lower level of concern have been estimated and are presented in this appendix and in the main report.

Considering that the hazards in PVC additives are mainly non-threshold and most of them lack a dedicated dose-response function that would link exposure to expected health outcomes, a PBT approach should be applied (SEAC, 2023). The impact assessment for PBT (and other persistent) substances consists of calculating the cost per kg or tonne of releases avoided (so-called cost-effectiveness). The cost-effectiveness of release reductions of prioritised additives has not been quantified in the impact assessment of this investigation report (for more details see section C.1.5).

In the absence of a quantitative risk assessment, human health and environmental benefits have not been monetised. Benefits from the substitution of PVC and prioritised

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[1] Additives were prioritised for further analysis in the report based on their hazard scoring and release potential. Several substances currently used were excluded, because they were undergoing the final stages of regulatory decision process towards regulatory risk management.

additives, as well as from technological emission reduction measures, have been described qualitatively in Section C.14.

The impact assessment builds on EC (2022), complemented with additional information on the availability, performance and costs of alternative materials to PVC and alternative substances to PVC additives. The additional data was collected via market surveys, calls for evidence (see Appendix E) and literature reviews.

C.1.1. Impact assessment of alternative materials

The costs of substituting PVC with alternative materials were monetised, at least partly, for all uses covered in this impact assessment report. They include consumer surplus losses due to changes in lifetime costs or prices, and producer surplus losses due to premature retirement of productive tangible or intangible assets.

For the estimation of the consumer surplus loss entailed by substituting PVC in certain uses (pipes, cables, flooring, window frames), article lifetime costs were assessed, including the purchase, installation, replacement, maintenance and dismantling costs. These uses have a long lifetime, often decades. During the lifetime, many of the cost items can differ depending on the specific material used. For example, the choice of the material can have an impact on the installation and maintenance costs, the need for future replacement based on the lifetime of the material and the costs related to the end-of-life treatment. The lifetime costs are expressed as net present value calculated over the lifetime of the material that has the longest lifetime in each use. This allows considering the difference in lifetimes of each material quantitatively. The lifetime costs of a representative article are multiplied with the annual quantity of PVC articles placed on the market in the EU to gauge the annual costs of substituting PVC with an alternative material in the specific use, or the annual change in the consumer surplus for the end-users of the articles.

For some uses (packaging, medical applications, toys, artificial leather), assessment of lifetime costs was not possible due to a lack of information. For these, the costs include the difference in the price of the materials for the total annual sales volume of PVC in the use, as well as some discussion on possible additional costs of substitution. The cost estimates for these uses can be considered as supporting information but are not sufficient for a proper assessment of substitution costs.

Producer surplus losses were estimated for the producers of PVC articles using SEAC’s approach to assessing changes in the producer surplus (SEAC, 2021). The approach is based on assessing producer surplus changes from the premature retirement of productive tangible or intangible assets by estimating the future profits of those assets during their remaining lifetime. This reflects the fact that some of the machinery and know-how related to producing PVC articles would lose its value or require re-investments.

The approach makes a distinction between cases where alternatives are generally available in the EU, and cases where this is not the case. This is due to an assumption that other productive assets in the EU might increase their future profits in the former case and partially offset the loss, while in the latter, no such assets are readily available. Based on the average remaining service life of both tangible and intangible assets, SEAC recommends that by default, 2 years of profit losses should be included in the assessment in the cases where alternatives are generally available. This approach has been used in the assessment, as alternatives to PVC products are available for all uses (SEAC, 2021).

The producer surplus losses are based on the annual trade value of the EU-produced PVC articles for each use and a common assumption of a profit margin of 10 %. No information is available on the profit margins for the sectors, uses and companies using PVC. A more detailed analysis would require sector- or use-specific estimates of the profit margin.

For some of the uses, for example cables, the sector provided aggregate estimates at the EU level of the need for new investment in machinery to produce alternatives. This investment is done to replace the loss in capital related to the production of PVC articles. Although investment cost estimates are reported, the profit losses and the one-off costs related to new machinery cannot be aggregated due to double-counting issues as both approximate the same loss in producer surplus impact.

Supply chain impacts were not quantified due to a lack of data. The main gaps relate to the supply chain impacts for the manufacturers of the chemicals (PVC producers, compounders, additive producers etc.) and the raw materials, and the possible employment impacts in the entire supply chain, starting from the raw material supply all the way to the production of PVC articles. These impacts are dependent on the origin of the chemicals and raw materials for PVC and the alternative materials. If further information is received in the future, SEAC's approaches for quantifying the producer surplus losses and the employment impacts throughout the supply chain will be applied. (SEAC, 2021, SEAC, 2016)

Circular economy aspects and wider environmental impacts of PVC and alternative materials were assessed based on life cycle analysis (LCA) data and literature. These wider impacts include other than chemical pollution related aspects, such as climate change, eutrophication, and resource depletion. When possible, these wider impacts were quantified, and for climate change impacts also monetised, to assess the costs to society. A more complete analysis was made for flooring to exemplify the approach. A similar analysis could be conducted for additional uses that have good LCA data availability, such as pipes, cables and window frames.

There is no quantitative comparison of human health and environmental risks between PVC and alternative materials. A qualitative comparison can be found in Appendix A.

C.1.2. Impact assessment of alternative additives

The impact assessment for additives entailed estimating the costs of substituting prioritised additives with alternatives of lower concern. This is a proxy of the consumer surplus losses, depending on the market conditions. The costs include the difference in the price of the additives. When available, additional one-off costs related to either R&D or machinery have been provided. Additives were categorised based on the assessed level of concern (concern banding) to four categories: high, medium, low and currently no identified concern. Based on the analysis, it is possible to calculate the costs of moving to additives with currently no identified concern or from higher concern category additives to lower concern ones. In cases when there are no alternative additives with currently no identified concern, the cost of replacing additives can be estimated by the costs of substituting PVC with alternative materials.

At this stage, the costs of replacing prioritised additives were estimated for the reduced quantity of the prioritised additive used.

Health and environmental impacts of using alternative additives were monetised. Release estimates are presented in Appendix B. Based on the hazard assessment, the PBT approach should be applied to the risk reduction, independent of the potential (regulatory) risk management options. The PBT approach entails minimisation of releases as the ultimate objective of risk management, as the releases can be considered a proxy of the corresponding risks. The impact assessment consists of the calculation of the cost per kg of releases avoided. However, such an assessment was not done for this report (see Section C.1.5).

Supply chain impacts include producer surplus losses for the EU producers of additives. They were estimated in those cases where the additives currently used are (mainly) produced in the EU, while the alternative additives are (mainly) imported. If additives that are largely produced in the EU are substituted with an alternative additive that is largely imported, it will impact the EU additive producers in terms of capital losses. Again, based on the average remaining service life of both tangible and intangible assets, SEAC recommends that by default, 2 years of profit losses should be included in the assessment in cases where alternatives are generally available in the EU. The impact was calculated with an assumption of a 10 % profit margin of the total trade value of the additive in each use (SEAC, 2021).

The main exclusions from the additive impact assessment are the supply chain impacts for the manufacturers of the chemicals and raw materials (additive producers, suppliers of chemicals etc.), and the possible employment impacts. These impacts are dependent on the origin of both raw materials and the chemicals. If further information is received in the future, SEAC's approaches for quantifying the producer surplus losses and the employment impacts throughout the supply chain will be applied. (SEAC, 2016, SEAC, 2021)

C.1.3. End-of-life impacts

End-of-life impacts have been estimated for two different scenarios: one where recycling of PVC is possible, and one where it is not. The costs related to the no-recycling scenario are proportional to the extent of the decrease in recycling, so that a 50 % decrease in recycling would result in approximately 50 % of impacts in comparison to the no-recycling scenario. The analysis is made separately for rigid and soft PVC. The impacts in the no-recycling scenarios include i) the increase in the price of the PVC articles as virgin PVC is used instead of recycled PVC, ii) additional costs in terms of landfilling and incineration, iii) impacts on the recyclers, and iv) societal costs from the increase in GHG emissions resulting from the increased production of virgin PVC.

C.1.4. Methodological choices

The geographic scope of the impact assessment is the European Union as of 2020 (EU27). The assessment could also apply to the EEA states, but because of a lack of data for Iceland, Liechtenstein and Norway, impacts in these countries were not assessed.

All cost estimates are expressed in 2022 price level, with inflation adjustment based on the Eurostat consumer price index (Eurostat, 2023a). Annual costs are presented whenever possible. The discount rate used is 3 % (EC, 2023).

C.1.5. Follow-up work

The cost-effectiveness of release reductions of prioritised additives has not been calculated in this report, as in the context of substituting PVC additives, this approach is not particularly informative. If a prioritised additive is substituted with an additive of lower concern, the quantity of releases would remain the same, i.e. there is no release reduction. For this reason, instead of quantifying the abatement potential and its costs, the additives are divided into four categories based on their potential concern level, and the compliance cost of moving to a category with lower concern is provided.

This approach builds on the fact that the hazard properties of prioritised additives are known or strongly suspected, and therefore the expected risks are more tangible and at least qualitatively better predictable than for the other additives. Substituting a (group of) prioritised additive(s) with a non-prioritised additive (or an additive of lower concern) will remove (or prevent) the specific concern/effect known for the additive to be substituted. For example, the substitution of short-chain DEHP phthalates with DOTP/DINCH would reduce the likelihood of environmental and human endocrine disrupting effects.

However, a generic approach for quantifying the benefits of potential restriction options has been developed and can be applied in a potential future Restriction Dossier. The substitution priority of the additives can be made in based on the concern scoring, which uses different scores for different levels of (severe) hazards. This is because the potential for persistent substances to damage human health or the environment varies widely across substances. The PBT approach advises that in addition to quantified release estimates, for example the toxicity potential, the environmental fate and the exposure potential be considered (SEAC, 2023). One way to account for differences in the damage potential of multiple persistent substances is weighting of emissions, i.e., by scaling the corresponding release estimates. In the case of prioritised additives in PVC, the release estimates can be weighted using the categorization of prioritised additives based on their level of concern (concern banding). Provided that a weighting scheme for additives is available, it is possible to calculate the cost per kg of releases avoided, taking partly into consideration the damage potential of the releases.

Among the prioritised additives, there are some with established thresholds. For threshold/non-PBT human health impacts the cost of decreasing the exposure to meet the threshold can be estimated. In many cases, this cost is reflected in the cost of substituting a particular substance, since based on the information submitted in the CfEs, the concentration of those substances has already been minimised in such a way that the technical function of the additive is maintained. In addition, if dose-response relationships and monetary values of the relevant health endpoints are available (such as the value of cancer mortality, infertility or IQ loss), it is possible to estimate the monetised benefits of the reduction in the number of cases or to perform a break-even analysis. However, this approach to benefit assessment would be very limited, since only a fraction of societal benefits would be covered.

A more complete analysis of the health and environmental benefits would require input in the form of quantitative risk assessment, including information on the relationship between emissions, exposure/risk, health/environmental impacts and damage costs. Considering the nature of the hazards posed by the additives in scope, this seems infeasible, and thus it is unlikely that the benefits of restricting their use can be systematically monetised.

C.2. Overview of PVC use in the EU

The main sectors using PVC are building and construction (pipes and pipe fittings, cables, flooring, window frames, wallpaper, roofing, other rigid profiles), electrical and electronic equipment (cables), health services (medical applications), plastic products (packaging, toys), textiles, leather and fur (clothing) and vehicles (automotive interiors and cables) (

Table 1).

Volume data has been obtained via ECHA market survey (CfE2, see Appendix E). It is presented as the sales volume of compounded PVC in tonnes per year (tpa), including both virgin and recycled material. Compounded PVC includes both the PVC resin and additives. When the original volume estimate has been provided as uncompounded PVC, compounded volume has been calculated by adding the typical average share of additives in the use to the volume of PVC resin. Exact volume estimates are in many cases known but confidential, and public ranges have been constructed for confidential data.

The annual sales volume of uncompounded PVC totalled 5.2 million tonnes in the EU in 2021 (Eurostat, 2023b), which corresponds to approximately 6.8 million tonnes of compounded PVC. In addition, 0.5 million tonnes of uncompounded PVC are imported annually to the EU and 1.2 million tonnes exported outside of EU (Eurostat 2023b). Approximately 60–70 % of the volume goes to rigid and 30–40 % to soft applications.

The use-specific volume data is in most cases confidential, and thus presented using public ranges (Table 1). The volume data for uses also includes PVC in imported articles, when that information has been available (e.g. pipes, flooring). For some uses, no or very limited import of articles takes place (window frames), and for some uses, the volume of PVC in imported articles is unknown (e.g. cables, toys).

Approximately 70 % of PVC is used by the building and construction sector, including pipes and pipe fittings, cables, flooring, roofing, wallpaper, window frames, and other profiles and sheets (ECVM, 2023a). The largest individual uses are pipes and pipe fittings, flooring, cables and window frames.

In Western Europe, PVC production and conversion industry comprises thousands of companies with several hundred thousand jobs (CfE2, #1601, VinylPlus). The industry includes PVC resin producers, additive producers, compounders (formulating mixtures of PVC resin and additives), converters (article manufacturers) and recyclers. PVC is the third largest-selling commodity plastic in the world, after polyethylene (PE) and polypropylene (PP) (ECVM, 2023a).

The impact assessment covers 70–85 % of the total volume of compounded PVC used in the EU. The type of analysis is either comprehensive (lifetime compliance costs) or partial (only material costs). The other uses have not been assessed due to lack of data at present. A significant share of the total volume (7.5–18.7 %) is allocated to “other” uses, consisting of miscellaneous consumer items. As there is no detailed information on which uses this category consists of, impact assessment is not possible.

Table 1: Overview of uses of PVC

Sector	**Use**	**Sub-use**	**Type of PVC**	**Compounded volume of PVC (tonnes/year)**	**Share of the total volume (%)**	**Typical average share of additives (%)**	**Analysis of compliance costs[1]**
Building and construction	Pipes and fittings	Water mains; water service lines; water piping systems	Rigid	254 000	3.3–7.9	10 %	Comprehensive
		Rain water; sewage	Rigid	682 000	8.9–21.2		Comprehensive
		Irrigation	Rigid	37 000	0.5–1.2		None
		Natural gas; industrial processes	Rigid	40 000	0.5–1.2		Partial
		Flexible tubes	Soft	35 000–44 000	0.6–1.1	49 %	None
	Cables	-	Soft	466 000	6.1–14.5	49 %	Comprehensive
	Flooring		Soft	772 710	10.1–24.0	64 %	Comprehensive
	Roofing	-	Soft	88 000–526 000	2.7–6.8	53 %	None
	Wallpaper	-	Soft	15 000–92 000	0.5–1.2	44 %	None
	Window frames	-	Rigid	274 000–1 900 000	8.5–24.7	19 %	Comprehensive
	Other profiles and sheets	-	Rigid	17 500–105 000	0.5–1.4	NA	None
Medical applications	Blood and infusion bags, medical devices, gloves and medical tubing	-	Both	28 000–170 000	0.9–2.2	57 %	Partial
Plastic products	Packaging	Rigid food and non-food packaging	Rigid	41 000–244 000	1.3–3.2	4 %	Partial
		Flexible food and non-food packaging	Soft	88 000	1.1–2.7	34 %	Partial
		Blister packs	Rigid	47 000–284 000	1.5–3.7	4 %	Partial
	Toys	-	Both	6 000–36 000	0.2–0.5	40 %	Partial
Textiles, leather and fur	Clothing	Artificial leather (not car) / Bags, luggage	Soft	47 000–281 000	1.5–3.7	42 %	Partial
Vehicles	Automotive (interior)	Artificial leather, foamed films	Soft	21 000–127 000	0.7–1.7	50 %	Partial

Sector	**Use**	**Sub-use**	**Type of PVC**	**Compounded volume of PVC (tonnes/year)**	**Share of the total volume (%)**	**Typical average share of additives (%)**	**Analysis of compliance costs[1]**
	Automotive (exterior)	Tarpaulins etc.		9 000–53 000	0.3–0.7	53 %	None
	Automotive	Dashboards, sheets, profiles		8 000–45 000	0.2–0.6	13 %	None
Other	Miscellaneous consumer articles	-	Rigid	54 000–323 000	1.7–4.2	13 %	None
	Miscellaneous consumer articles	-	Soft	186 000–1 117 000	5.8–14.5	57 %	None
Total				6 800 000 (3 216 210–7 686 710)			

Note: [1] Comprehensive analysis: lifetime compliance costs. Partial analysis: only material costs. None: no analysis of compliance costs.

C.3. Pipes

C.3.1. Description of use and performance criteria

PVC is used in many piping sub-categories, including: 1) Water mains, 2) Water service lines, 3) Water piping systems (buildings), 4) Rainwater, 5) Sewage, 6) Drainage waste vents, 7) Irrigation, 8) Natural gas, 9) Industrial processes and 10) Flexible tubes/pipe fittings.

Following the recommendation by TEPPFA (CfE2, #1596, TEPFFA), ECHA will narrow down the list to three more broad applications:

i) Potable/Drinking water (including sub-categories 1, 2 and 3)

ii) Sewage (including sub-categories 4, 5 and 6)

iii) Industry (including sub-categories 8, 9 and industrial pipe fittings).

These three applications account for more than 95 % of the total use of PVC in the pipes. For other uses, sub-category 7 (irrigation) will be left outside of the analysis and for the sub-category 10 (flexible tubes/pipe fittings), ECHA has asked stakeholders to provide data both on alternatives to PVC pipe fittings and alternative additives to currently used prioritised additives in pipe fittings. These are discussed in sections C.3.3. (Alternative materials) and C.3.4. (Alternative additives). Applications i) potable/drinking water and ii) sewage is subject to a more rigorous analysis, as they together account for more than 90% of the total tonnage of PVC used in pipes. Application iii) industry is covered to the extent that ECHA has received data during the CfEs, in particular in section C.3.4. related to alternative heat stabilizers.

By this grouping, the collection of information has been kept at a feasible level considering the project time frame and objective. Under each broader application, a variety of different types of pipes are used. For example, the size of the pipeline, the soil conditions and the water pressure requirements are always taken into account when designing a new water main or service line. The requirements are typically based on the theoretical maximum capacity of the pipe and the estimated water pressure. These considerations, as well as the soil conditions, can also have an impact on the preferred material.

For the applications i) and ii), there are many alternative materials that the water service provided can choose to use. For the industry application, iii), there is evidence that alternatives are widely used, but it is possible, that there can be niche uses where PVC would be hard to replace with an alternative.

C.3.2. Baseline

ECHA compiled volume data on the use of PVC as a pipe material in the CfE2. The most accurate information was submitted by TEPPFA (CfE2, #1596, TEPPFA). The market information was dated at year 2017.

The highest volume of PVC is used and imported in application ii) Sewage. The annual volume of PVC pipes for sewage was around 682 000 tonnes in 2017. For the application i) Potable water/Drinking Water, approximately 254 000 tonnes was used and imported. The application iii) Industry has an annual tonnage of approximately 88 000 tonnes. Other uses include irrigation, flexible tubes, and pipe fittings, have a volume of around 80 000 tonnes in total.

The total volume of PVC pipes placed in the market in EU is then around 1 100 000 tonnes.

For the calculations, ECHA has converted these tonnages into a functional unit of a DN200 [2]PVC pipe. While the weight of such a pipe is around 7.5kg – 10kg per meter, the amount of pipes, measured in functional units are approximately 20 000 – 34 000km for application i) Potable Water/Drinking Water, 54 000km – 91 000km for the application ii) Sewage, and 7 000km – 12 000km for application iii) Industry.

Table 2 provides an overview of PVC use in pipes.

Table 2: Use of PVC pipes

Use	**Pipes**
Description	i) Potable water/Drinking Water ii) Sewage iii) Industry Other uses, including irrigation, flexible tubes, and pipe fittings.
Main performance criteria	Lifetime -related: Durability, chemical resistance, crack propagation, resistance of bacterial formation Performance -related: i) Potable water/Drinking water: Water corrosion resistance; Ability to withstand pressure; flow capacity; temperature resistance; sanitary and non-toxic; flexibility ii) Sewage: Water corrosion resistance; chemical resistance to alcohols, fats, oils and petrol; flow capacity; ability to withstand pressure iii) Industry: Chemical resistance to corrosive agents, ability to withstand pressure, fire resistance
PVC market share in pipes	The market share of PVC in different pipe applications is not known or reported in the CfEs. However, in the section C.3.3. ECHA will present the findings from a market study made by Aqua Publica Europa (at the request of ECHA) on the current use of pipe materials in applications i) and ii).
Compounded volume of PVC placed in the market per year in EU27	TEPPFA, Market study 2017 (CfE2, #1596, TEPFFA): i) 254 000 tonnes compounded ii) 682 000 tonnes compounded iii) 88 000 tonnes compounded
Type of PVC	Rigid
Share of additives in typical compounding	1-2 % heat stabilisers; 2-15 % fillers, pigments, impact modifiers; 0 % plasticisers
Prioritised substances used as additives	Heat stabilisers: Organotins (see section C.3.4).

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[2]

Sources: CfE2, #1601, VinylPlus; CfE2, #1596, TEPPFA, ECHA Market Survey 2023

C.3.3. Alternative materials

For all the pipe applications, many different materials are used. Some pipe materials might also require an inside or outside coating, dependent on the intended use or external conditions such as soil type. The choice of the material of the pipes is not only based on the requirements of the use, but based on the stakeholder responses, there are large differences between European countries which materials are favoured over the other (Aqua Publica Europea (APE) market study, 2023). Even within a country, some water companies might have different recommended materials for a same type of a use in their planning guides (HSY, Personal communication, 2022).

The main alternatives to PVC for each application are listed in Table 3.

Table 3: Alternative pipe materials

Application	Alternative materials to PVC
Potable water/ Drinking water	Water mains and water service lines: PE (medium and high density), Ductile iron, concrete, steel, copper, PE-X, Carbon steel Water piping for distribution in buildings: PP, glass fibre reinforced polypropylene composite pipes, PE-X, polybutylene (PB), galvanised steel, stainless steel, cast iron
Sewage	ABS, galvanised steel, cast iron, ductile iron, PE (low, medium and high density), concrete, clay, steel, PP, Stoneware
Industry	PE (medium and high density), PE-X, polyamide/nylon, stainless steel, copper, ductile iron, aluminium, PP

Sources: ECHA Market survey, 2023; APE Market study, 2023

For a more detailed overview of the use of different materials ECHA asked APE (The European association of public water operations), to conduct a market study with the European water companies (regional & municipal). The market study included a questionnaire about the recommended pipe materials for application i) and ii) and the associated costs attributed to different pipe materials (both acquisition cost and the installation). Costs related to installation were not given separately for different alternative materials – the reason being that most of the costs are related to digging costs. However, where possible, water companies related qualitative information in case there were significant differences between the materials in their associated installation costs. Responses were received from 10 different water companies: Hungary (Budapest region), Italy (Apuli region & Milan area & Turin area & Province of Lecco), Ireland, Austria (Vienna), Switzerland (Geneva region), Belgium (Brussels area) and France (Alsace-Moselle region). In addition to these responses, ECHA interviewed Helsinki water company (HSY, personal communication, 2022) with a similar questioning prior to the market study. The answers are summarised in Table 4. In the second column, each plus sign indicates a recommendation for the material for the intended use from one of the water companies (for example, ++ means a recommendation from two water companies). Regions are referred by the country in the table.

Similar questions were asked about sewage pipes. The results are summarised in Table 5.

Table 4: Potable water/Drinking water, recommended pipe materials and cost of purchase

Application: Potable water/Drinking water			
Size (inside diameter in mm)	**Recommended material**	**Reasons for the recommendation**	**Cost of purchase €/m**
50, 90	PE (++++++++++)	PE: Ease of implementation; flexibility; chemical stability and leak-free system; highly impervious; safety of the potable water; resistance to corrosion; long-term reliability; lightweight; easy to transport and install	50mm: PE: €2.5-5/m 90mm: PE: €6-14/m
<150	PE (++++++), PVC (+), Carbon steel (+), Steel (++)	See above for PE. Ductile iron: robustness, ease of implementation	150mm: PVC: €15/m PE: €18-26/m Ductile iron: €35/m
150-300	Ductile iron (+++++), PE (++), PVC (+), Carbon Steel (+), Steel (++)	See above for PE and Ductile iron.	200mm: PVC: €24/m PE: €28-43/m Ductile iron: €46/m
>300	Ductile iron (+++++), Carbon Steel (+)		400mm: Ductile iron: €222/m
The share of PVC used in (new) Potable water/Drinking water lines (Water mains and water distribution lines): 0 % in other regions, except 25% in Water mains and 10% water distribution lines (France) PE: Water distribution lines: 90-100 % (all regions) Water mains: 2% (France), 65 % (Hungary), 100 % (Italy), 15 % (Switzerland), 90 % (Ireland), 50 % (Italy), 40 % (Italy) Ductile iron: Water mains: 39 % (France), 3 % (Italy), 85 % (Switzerland), 20 % (Italy), 30-90 % (Hungary), 10 % (Ireland), 30 % (Belgium), 30 % (Italy) Conclusion: PVC is the cheapest pipe material for application i) based on the market study. PE pipes are at			

<table>
<tr><th colspan="4">Application: Potable water/Drinking water</th></tr>
<tr><th>Size (inside diameter in mm)</th><th>Recommended material</th><th>Reasons for the recommendation</th><th>Cost of purchase €/m</th></tr>
<tr><td colspan="4">least 20 % more expensive (and 80 % at most) compared to PVC pipes. Ductile iron pipes are at least 90 % more expensive (and 130 % at most) compared to PVC pipes.
The figures are well aligned with earlier estimates from Marangoni and Garbarino (2011), where PE pipes were 20 % more expensive and ductile iron 100 % more expensive compared to PVC pipes.
While the difference in the purchase cost is high, the purchase cost itself is a minor cost component in comparison to the installation costs (5-10 % of the total cost for other regions, <5 % in Finland), and thus often the price of the pipe itself is not a deciding factor when choosing the material.
PVC is still used for application i) Drinking Water/Potable water in the EU while more common materials are PE and Ductile iron.
The main alternatives for PVC for application i) are PE (estimated 70 % replacement), and Ductile Iron (20 %). PVC is also used as a water service pipe within buildings. Here, the main alternative reported was PP (estimated 10 % replacement).</td></tr>
</table>

Source: ECHA Market survey, 2023; APE market study, 2023

Table 5: Sewage, recommended pipe materials and cost of purchase

<table>
<tr><th colspan="4">Application: Sewage</th></tr>
<tr><th>Size (inside diameter in mm)</th><th>Recommended material</th><th>Reasons for the recommendation</th><th>Cost of purchase €/m</th></tr>
<tr><td>150 – 300</td><td>PP (++), Stoneware (+++), PVC (++++++), PE (+++)</td><td>Stoneware pipes:
Resistance to corrosion; suitability for carrying polluted water; good flow capacity due to smooth surface; strong in compression; highly impervious and durable in time.
One water company pointed out that stoneware pipes are much harder to install (small length elements, very heavy, specific joints).
PVC:
Used mainly for sewage lines that connect private utilities to storm drains to the main conduit and for non-pressurised (gravity) sewage. The main advantages are cheap cost, ease of installation and smooth surface.
PE:
Mainly for pressurised sewage. Surface not smooth enough (typically) for non-pressurised sewage.
PP:
New designs are also smooth in surface.</td><td>160mm (gravity):
PVC:
€8-14/m
PE:
€18/m
200mm (gravity):
PVC:
€15-22/m
Stoneware:
€40/m
PP:
0-20 % more compared to PVC pipes (Pipelife, personal communication, 2023).
200mm (pressurised):</td></tr>
</table>

Application: Sewage			
		More durable than PVC (against physical blows, low temperatures, and chemicals). Slightly more time needed for the installation.	PVC: €55/m PE: €54/m
>300	Concrete (+++++), Stoneware (++), PRFV (+), PP(+), Ductile iron (+)	Reinforced concrete pipes with internal epoxy coating are preferred for medium and large conduits by half of the water companies. Widely available in wide range of size; ease of installation; made to desired strength, resistant to corrosion and abrasion.	No comparable price information due to PVC not preferred in this pipe category.
The share of PVC used in application ii) Sewage (new lines): Small diameters: 100 % (France), 100 % (Italy), 0 % (Switzerland), 0 % (Italy), 0 % (Austria), 50 % (Hungary), 100 % (Italy), 100 % (Italy); used but no exact information: Ireland Large diameters: Only the water company in Hungary stated that PVC is used for larger diameter sewage pipes. PE: 0 % (France), 0-10 % (Italy), 0 % (Switzerland), 30 % (sewage user connection, Italy), 0 % (Austria), 75 % (pressurised sewage, small diameter, Hungary); used but no exact information: Ireland Stoneware: 4 % (France), 5 % (Italy), 0 % (Switzerland), 70-100 % (Italy), 0 % (Hungary), 0 % (Austria) Concrete: 100 % for large diameters in France, Italy, Hungary, 0 % other regions; used but no exact information: Ireland PP: 100 % Switzerland, 100 % Austria, The water company in Finland is considering switching their recommendation to PP (HSY, personal communication, 2023). Conclusion: PVC is the cheapest available material for application ii) Sewage based on the market study. For small diameter sewage pipes common alternative to PVC are PP, PE and stoneware. In those regions, where a combination of different materials is used (e.g. Hungary), PVC is mainly used for gravity non-pressurised systems. PE is 30-100 % more expensive compared to PVC (gravity lines), and stoneware is 190-400 % more expensive compared to PVC. It is also likely that stoneware is more expensive to install. The main alternative for gravity pipes, PP, is around 0-20 % more expensive compared to PVC. (Pipelife, personal communication, 2023). For large diameter sewage pipes, PVC is used to a lesser extent. The main materials are Concrete, Stoneware and PP. Based on the information, it is expected that the main alternative for PVC sewage pipes are PP (replacement 75 %), and PE (replacement 25 %). Concrete and stoneware are mainly used for sewage pipes larger than those PVC is used for.			

Source: ECHA Market survey, 2023; APE market study, 2023

All the materials listed as alternatives for pipes fulfil the key characteristics. However, there are differences in their performance: for example, in the ease of detecting leaks, flow capacity and lifetime. The largest use for PVC is in the category of small diameter pipes in gravity sewage in application ii) Sewage. Based on the market study (APE, 2023) and the interviews (HSY, personal communication, 2022 & 2023) PVC is easier to install than PE pipes since it does not need to be welded and it has a smoother surface than PE pipes, making it less likely for the pipe to get stuck. PE can also be used as a gravity sewage pipe but will need a protective tube to keep its shape.

PP pipes do not require welding and have a smooth surface and are therefore the main alternative for PVC sewage pipes. Two water companies responding in the study indicated that they use only PP for sewage pipes. One of the companies is currently considering switching from PVC to PP. For the same technical reasons, PP is also a likely alternative for PVC pipes that are used in buildings and is already the main material in many countries for such a use. (Pipelife, personal communication, 2023).

The lifetime of the different materials is taken into account when determining the discounted lifetime cost of each pipe. ECHA has compiled lifetime data for pipes of different materials from literature and from stakeholder consultations. Table 6 summarises the information.

Table 6: Overview of the lifetime information of PVC and the main alternatives for applications i) Potable Water/Drinking Water and ii) Sewage

Material	**Aksela (2021)**	**Vinylplus (ECHA Market Survey 2023)**	**OECD (2019)**	**EC (2000)**	**AWWA (2012)**
PVC	70	100	50	>20	55-100
PE	70	100	50	>20	
PP	70		50	>20	
Ductile iron	60	11-14			50-60

C.3.3.1. Economic impacts

The economic cost (Table 7) is calculated based on the annual replacement cost of PVC pipes according to replacement shares for the application i) and ii), reported in Table 4 and Table 5. The calculation does take into account the difference in lifetimes by using a required lifetime of 100 years for a pipe installation and calculating the net present value of the future replacement cost. Installation costs are assumed to be the same for different materials, while there is qualitative evidence that the alternative materials can be more labour intensive to install. Since this is not accounted in the figures due to lack of quantitative estimates, the replacement cost represents a minimum of the true replacement costs.

Table 7: Cost of replacing PVC pipes with alternative pipe materials

Data	**PVC**	**PE**	**Ductile iron**	**PP**
Purchase cost (€/DN200 pipe)	22.7 (10.7 – 34.6),	28.4 (14.2 – 42.6)	45.6 (31.7 – 59.4)	24.9 (10.7 – 41.5)
Total cost over lifetime (excluding installation, possible maintenance) (€/200DN pipe, 100	23.5 (11.1 – 35.9)	29.5 (14.8 – 44.3)	48.7 (33.9 – 63.4)	25.9 (11.1 – 43.1)

Data	PVC	PE	Ductile iron	PP
years)				
Annual sales volume (km of 200DN pipe)	25 100 km for i) Potable Water/Drinking Water 67 500 km for ii) Sewage			
Difference to PVC in annual costs (€ millions) for the total sales volume of PVC pipes for application i) Potable water/Drinking water		151 (73 – 283)	634 (455 – 933)	59 (0 – 243)
Difference to PVC in annual costs (€ millions) for the total sales volume of PVC pipes for application i) Sewage		403.4 (196.2 – 759.7)	Not relevant	158 (0 – 652.9)
Difference to PVC in annual costs, for the total sales volume of PVC pipes for i) Potable Water/Drinking water, weighted by the approximate shares (€million, mean, min, max)		105.7 (51.1 – 198.1)	189.8 (136.6 – 279.9)	5.9 (0 – 24.3)
Difference to PVC in annual costs, for the total sales volume of PVC pipes for ii) Sewage, weighted by the approximate shares (€million, min and mean)		101 (49 – 190)	Not relevant	119 (0 – 490)
Total	The total cost of replacing PVC pipes for the applications i) Potable Water/Drinking and ii) Sewage, would be in the magnitude of €520 million per year in the EU. The application iii) Industry is not included in the calculation, however, it represents only 3-4 % of the total PVC tonnage in the Use. Moreover, according to TEPPFA (ECHA Market survey, 2023), pipe manufacturers would have to invest at least €840 million for new machinery if they were to switch producing only alternative materials. In addition, some of the alternatives might be slightly more expensive to install.			

Sources: ECHA Market survey, 2023; Aqua Publica Europea market study, 2023

Nearly all the main pipe producers in the EU have a portfolio consisting of pipes made of different pipe materials. The capability to produce PE and PP pipes within EU is comparable to that of producing PVC pipes. However, according to TEPPFA (ECHA market survey, 2023), pipe manufacturers in the EU would have to invest at least €840 million for new machinery if they were to switch producing only alternative materials.

Based on the purchase price of a PVC pipes and sales volume, the total sales value of PVC pipes for categories i) and ii) in the EU is €1.9 billion per year. Since the volume refers to the total placing on the market in the EU, Eurostat statistics were used to estimate the share of imports. In 2021, the amount of imports was very small compared to the total volume (3 %) (Eurostat, 2023b). With a profit margin of 10 %, the profits for the EU producers would be around €190 million per year.

According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the PVC pipe producers would be around €13 million.

C.3.3.2. Life cycle impacts

C.3.3.2.1. Qualitative description of impacts at different lifecycle stages

Circular economy aspects and wider environmental impacts of PVC and alternative materials have been assessed based on life cycle analysis (LCA) literature. These wider impacts include other than chemical pollution related aspects, such as climate change, eutrophication potential, and resource depletion potential. The starting point of the life cycle impact assessment was the review study by (Baitz et al., 2005). According to the study, the highest environmental impacts come from the production of the pipe itself. No conclusion was found which of the analysed materials (PVC, HDPE, PP, concrete, fibre-cement, clay, cast iron and stoneware) is preferrable from the environmental point of view.

Table 8 presents an overview of reviewed life cycle analysis studies for pipes. Sanjuan-Delmás et al. (2014) compared various materials (PVC, PE (high density), ductile iron, glass fibre reinforced polyester) for water mains and water supply lines in a cradle-to-gate study. For the small pipes (90mm), only different plastics were compared. PVC and PE performed very similarly. For the larger pipes (200mm) PVC and PE outperformed ductile iron and reinforced polyester. A study with quite a similar scope, but with the geographical location of Teheran, found that PVC is the best material in terms of least negative environmental impacts, closely followed by PE, whereas ductile iron and steel have more negative environmental impacts. (Hajibabaei et al., 2018). Zhao et al. (2016) compared PVC with PP, PE and galvanised steel in a cradle-to-gate study. With five impact categories (excluding for example energy consumption), the PVC was concluded to be the least preferable material, and PE the best.

Petit-Boix et al. (2014) performed a cradle-to-grave study for sewage systems in medium-to-small cities in the Southern Europe. The study also included a comparison of materials. The use-phase was partially captured by taking into account the lifetimes of the different materials, but no other possible differences during the use stage. Materials included in the comparison were PVC, PE (high density), concrete and fibre-cement. PE was found to be the least favourable option both for small and large diameter pipes. Concrete and fibre-cement outperformed plastics, but this finding is attributable by the difference in the expected lifetimes (concrete 100 years, plastics 50 years). However, in a later study, the same authors conclude that for small sewage pipes, plastic pipes (both PE and PVC) outperform concrete. (Petit-Boix et al., 2016).

Vahidi et al. (2015) performed two cradle-to-grave studies for alternative materials in sewage systems in the United States. The first study compared the following materials:

fibre reinforced polymer, PVC, ductile iron and concrete. Ductile iron performed the worst in 9 out of 11 impact categories, while the PVC had the lowest environmental impacts in all but 2 impact categories (climate change and fossil fuel use). The second study also analysed how the choice of material affects the energy use to pump the sewage. Inclusion of energy use was shown to improve the relative attractiveness of materials with a low friction coefficient. In the second study, ductile iron and reinforced polymer performed the worst and concrete the best.

In a cradle-to-grave study by Morera Carbonell et al. (2016), also impacts related to work in the construction phase, installation and renovation were included. The study compared the following materials: PVC, PE (high density), pre-cast and reinforced concrete. Also the end-of-life stage was included – plastic pipes were expected to be incinerated after the use and concrete pipes to be landfilled. This study ranks pre-cast concrete and PE to have the least environmental impacts, and reinforced concrete and PVC the most. It should be noted that a relative short lifetime was assumed for PVC pipes (25±5 years, in contrast to PE 40±10 and concrete 70±20).

Based on the current evidence, it cannot be concluded if PVC performs better or worse than other materials. While none of the LCA studies took into account the risks related to additives in plastics, ECHA has no information that plasticisers, flame retardants or heat stabilisers would be used in PVC pipes. The exception is the PVC pipe fittings with heat stabilisers. However, none of the LCA studies analysed pipe fittings specifically.

It should be noted also that the end-of-life phase of the pipes was particularly poorly covered in the studies.

Table 8: Overview of LCA studies for pipes

Author & year	Type	Application	Alternative materials assessed	Dimen-sions	Geogr. focus	System boundaries	Impact categories	Material prefera-bility ranking
Petit-Boix et al. (2014)	Journal Article	Sewer construction	PVC, HDPE, concrete, fibrocement	ENV	EU (ES)	Cradle to Gate	ADP, AP, EP, GWP, HTP, ODP, POCP	concrete ≈ fibrocement > PVC > HDPE
Petit-Boix et al. (2016)	Journal Article	Trench-pipe system for sewage	PVC, Concrete, HDPE	ENV	n.a.	Cradle to Gate + EoL	ADP, AP, EP, GWP, HTP, ODP, POCP, CED	?
Vahidi et al. (2015)	Journal Article	Wastewater Piping Systems	PVC, composite FRP, ductile iron, concrete	ENV	USA	Cradle to Gate + Use	ADP (minerals, fossil fuels), AP/EP, CC, ET, HTP canc., land use, radiation, resp. inorganics, resp. organics, ODP	PVC > Concrete > FRP > DI

Vahidi et al. (2016)	Journal Article	Sewer system	PVC, composite FRP, HDPE, DI, vitrified clay, reinforced concrete	ENV	USA	Cradle to Gate + Use	AP, EP, ET, FD, GWP, HTP canc., HTP non-canc., ODP, resp. effects, smog	Concrete > others (incl. PVC) > vitrified clay > DI
Morera et al. (2016)	Journal Article	Sewer system	PVC, Concrete, HDPE	ENV & ECON	EU (ES)	Cradle to Gate + EoL	CC, FD, HT, PM	Concrete > HDPE > PVC

Abbreviations: ADP = Abiotic depletion potential, AP = Acidification potential, ALU = Aluminium, CC = Climate change, CED = Cumulated energy demand, ECON = Economic, ENV = Environment, EoL = end-of-life, EP = Eutrophication potential, ET= ecotoxicity, EU = European Union, FD = Fossil fuel depletion, FE = Freshwater eutrophication, FET = Freshwater ecotoxicity, FGL = Fiberglass, GWP = Global warming potential, HTP = Human toxicity potential, IR = Ionising radiation, LU = Land use, ME = Marine eutrophication, ODP = Ozone depletion potential, PM = Particulate matter, POCP = Photochemical ozone creation potential, POF = Photochemical ozone formation, PVC = Polyvinyl chloride, RD = Resource depletion, TA = Terrestrial acidification, TE = Terrestrial eutrophication

C.3.3.2.2. Quantitative description of impacts at different lifecycle stages

There is indicative screening level data available on the climate change impacts of different pipe materials (in kgCO2eq) (ECHA market survey, 2023).

The emissions were calculated with the embodied energy approach. The embodied energy is defined as “the quantity of energy required by all the activities associated with a production process, including the relative proportions consumed in all activities upstream to the acquisition of natural resources and the share of energy used in making equipment and in other supporting functions i.e., direct energy plus indirect energy” (Piratla et al., 2012). The calculation was done first by selecting a nominal diameter (DN200), then obtaining the wall thickness (mm) of pipes from literature and datasheets of pipes, then specifying parameters (e.g. material density) of pipes from literature and datasheets of pipes; and pipe weight is calculated and referred to environmental emissions per linear meter of pipe by using European electricity grid mix emissions in kgCO2.

Emissions associated to the production stage of pipes are (per meter of pipe DN200): 121 kgCO2/m for PVC pipes, 119-129 kgCO2/m for PE, 131 kgCO2/m for ductile iron pipes and 90 kgCO2/m for PP pipes.

Table 9 presents the CO_2 emissions for PVC, PE, Ductile iron and PP and their differences for the production stage. The social cost of carbon emissions has been estimated based on the average price of the EU ETS carbon permit in 2022 (€80.82/tonne).

Table 9: CO_2 emissions and social cost of carbon emissions for PVC and alternative materials for pipes from the production stage

Material	**PVC**	**PE**	**Ductile iron**	**PP**
CO2 emissions (kgCO2eq/1m of DN200 pipe)	121	124 (119-129)	131	90
Annual sales volume (km of DN200D pipe) i) Potable water/Drinking water; ii) Sewage	25 100 km (i) 67 500 km (ii)			

Difference to PVC in total emissions on average, weighted by the likely replacement rate (million kgCO2eq/year)		+0.1	+0.1	-1.6
Difference to PVC in the social cost of carbon emissions on average (million €/year)		8.4	4.1	-133
	If PVC pipes are replaced with alternative material pipes, the CO2 emissions would decrease. This is attributable to lower CO2 emissions of PP compared to PVC. With the social cost of carbon approach, the value of the decrease would be around €120 million per year.			

Sources: CO2 emissions: ECHA market survey 2023; cost of carbon: EU ETS permit price in 2022 (ICAP 2023)

C.3.4. Alternative additives

C.3.4.1. Plasticisers

Pipes are typically rigid material and ECHA has no information that plasticisers would be used to a large extent in the sector. However, a small tonnage of PVC is used per year to produce flexible tubes, where plasticisers are used. ECHA has no further information on the specific plasticisers used to produce flexible tubes.

C.3.4.2. Heat stabilisers

The PVC pipe industry in the EU used a little less than 150 tonnes of organotins in 2021. The majority (80 % of the total) being DOTE and DMTE (other organotins: MMTE, DOTTG, MOTE). (CfE3, #1652, TEPPFA.) Table 10 presents the currently used prioritised heat stabilisers and their alternatives in pipes.

The main applications using organotins are pressure fittings & valves for all end-use applications i), ii) and iii) (81 %), pressure pipes for iii) Industry (14 %), pressure pipes for i) Potable water/Drinking water (4 %). A small share, around 1 % is for used irrigation pipe fittings/pressure pipes.

Due to regulatory pressure, TEPPFA (CfE3, #1652) states that industry is conducting research and testing programmes to assess the performance of alternatives, which might include further use of mixed metal stabilisers (Zn/Ca) and organic-based stabilisers.

TEPPFA (Cf3, #1652) assessed the costs of switching to alternative heat stabilisers. They broke down the analysis between a) pressure pipes, fittings & valves for chemical processes, and b) pressure fittings for applications i) potable water/drinking water and ii) sewage.

For the first identified use of organotins, the switch to alternatives (Zn/Ca, organic-based stabilisers) seems to be more difficult. The use covers critical and demanding industrial applications using harsh chemical media and safety considerations under severe operational conditions (pressure up to 16 bar and up-to 90-100 degrees Celsius). TEPPFA (CfE3, #1652) specify the required qualification tests, which include material specific test methods, for example on tensile properties, hydrostatic strength testing (exceeding 1 year testing period) and type testing including long-term internal pressure tests. Finally, the whole piping system must be subject to chemical resistance testing. TEPPFA has estimated that the total capital and operational costs are estimated above €10 million per product range (the exact amount of product ranges is unknown to ECHA), with possible decrease in performance. A transitional period of at least 5 years might be needed according to TEPPFA.

For the pressure pipe fittings for applications i) and ii), the switch to alternatives (Zn/Ca and organic-based stabilisers) would likely involve modification of the machinery, short scale lab-tests, production trials and industrial trials. Again, TEPPFA argues for a 5-year transitional period.

Assuming the switch to Zn/Ca is possible, at least within a 5-year transitional period, the total cost of the substitution can be estimated. The price of organotin additives is on average €9 000–12 000/tonne, while Zn/Ca stabiliser costs €5 000–7 000/tonne (ESPA, email communication, 18/05/2023). However, a 1-3 times larger quantity of calcium-based stabiliser is needed (ESPA, email communication, 18/05/2023). Assuming the average price and taking into account the larger quantity of Zn/Ca stabilisers needed, Zn/Ca stabiliser would be approximately €1 500/tonne more expensive. For the total volume of organotins in pipes (136 tonnes/year), the cost of moving to Zn/Ca stabilisers would be €0.2 million per year.

It should be noted that at least for the pressure pipe fittings, alternatives exist in other materials. Both the pipe manufacturers interviewed (Pipelife, personal communication, 12.4.2023) and the water companies (Aqua Publica market survey, 2023) indicated that there is the possibility to use, for example, PE fittings (and other alternatives) even for PVC pipes.

Table 10: Currently used prioritised and alternative heat stabilisers in pipes (pressure fittings)

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used heat stabilisers (estimated volume in tonnes)	DOTE (50 tonnes/year), DMTE (65 tonnes/year)	MMTE (1 tonnes/year), DOTTG (2 tonnes/year)		MOTE (15 tonnes/year)
Likely alternative heat stabilisers				Zn/Ca* OBS*

*Notes: * These substances are also currently used in pipes in significant volumes and were not prioritised (Appendix B)*

C.3.4.3. Flame retardants

ECHA has no information that flame retardants would be used in pipes.

C.3.4.4. Supply chain impacts

The main impacts on the supply chain of chemical providers would occur from replacing additives with ones with lower concern. Both DOTE and MOTE are mainly manufactured in the EU (DOTE 80 %, MOTE 65 %), as well as is ‘reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione’ (72 %). Almost all DMTE and DOT-MalEt is imported (6–7 % manufactured in the EU) and MMTE is fully imported.

Import of Zn/Ca stabilisers to the EU is negligible, except from Turkey (ESPA, email communication, 18/05/2023). Thus, no significant negative supply chain impacts in the EU are expected from replacing organotins with mixed metal stabilisers.

C.4. Cables

C.4.1. Description of use and performance criteria

Cable is an assembly of one or more wires to transmit electrical power or data. There are many different types of cables, and even one company can produce over 2000 different types of cables. (Aupetit, 2021).

The conductor of the cable is most often copper or aluminium. The next layer in a typical cable is the insulation, which protects the conductor from coming into contact with other conductors and preserves the conductor against environmental threats and resists electrical leakage. Insulation is made out of non-conducting material, such as plastic, rubber or fluoropolymer materials. The most common material used for insulation is PVC. The top of the cable is called the jacket or the sheath of the cable. Again, the same material choices apply, the most common ones being PVC and polyolefins. For many cables, there is also a layer called armour between the insulation and the jacket, most often made of steel. (Aupetit, 2021).

Cables are used in many sectors. The main sectors are buildings and construction, electrical and electronic equipment (EEE), and vehicles (in which the automotive sector is the main sub-sector).

C.4.2. Baseline

Approximately 466 000 tonnes of compounded PVC is used to produce cables annually in the EU. This amounts to approximately 270 000 tonnes of uncompounded PVC. This figure includes the cables used in the building and construction sector, in EEE, and in vehicles (mainly cars). (CfE2, #1564, Europacable). However, Europacable (CfE2, #1564, Europacable) points out that this does not include imported cables, and the actual tonnage of PVC in cables placed on the market in the EU can be significantly higher. According to KEMI (2015), 80-90% of EEE is imported to the EU, and thus the actual tonnage of PVC cables in particular for the EEE sector is deflated in the reported figures. However, more cars are exported from the EU than imported to EU (ACEA, 2023), partially balancing the mismatch. Soft PVC is used to produce cables, and of the additives in focus, many plasticisers are used in cables.

Table 11 presents an overview of PVC use in cables.

Table 11: Use of PVC in cables

Use	**Cables**
Description	PVC used in cables as an insulation or sheath material
Main performance criteria	Electrical insulation and voltage rating, Fire properties, Flexibility, Temperature range, Resistance to hydrocarbons, chemical resistance, UV resistance, durability
Share of PVC of cables placed in the market in the EU (2021)	35-40%
Compounded volume of PVC used per year in EU27 (tonnes)	466 000 (corresponding to 270 000 tonnes of uncompounded PVC) Building and construction: 68 000 – 406 000 tonnes per

	year EEE: 34 000 – 203 000 tonnes per year Vehicles (mainly automotive): 16 000 – 94 000 tonnes per year
Type of PVC	Soft
Share of additives in typical average compounding	2 % stabilisers and lubricants; 20 % fillers, pigments, impact modifiers; 27 % plasticisers
Prioritised substances used as additives	Plasticisers: Many medium and high molecular weight phthalates Heat stabilisers: No prioritised heat stabilisers. Flame retardants: Many phosphates Brominated phthalates Antimony compounds Borates

Sources: ECHA market survey; CfE2, #1601, VinylPlus; #1564, Europacable; PVC4cables websites, 2023

C.4.3. Alternative materials

Overall, the following list of alternative materials was submitted in the ECHA Market Survey (2023) by VinylPlus:

- Polyethylene (PE)
- Chlorinated polyethylene (CPE)
- Polypropylene (PP)
- Polyurethane (PU)
- Thermoplastic elastomers (TPE)
- Modified polyphenylene ether (mPPE)
- Fluorinated ethylene propylene (FEP)
- Ethylene tetrafluoroethylene (ETFE)
- Polytetrafluoroethylene (PTFE)
- Perfluoro alkoxy alkanes (PFA)
- Crosslinked polyethylene (PE-X)
- Chloroprene (CP)
- Ethylene propylene diene monomer (EPDM)
- Ethylene-vinyl acetate (EVA)
- Silicone rubber.

In the cables placed on the market in the EU, PVC has the highest market share of around 35-40%. PE (including low/medium/high density PE and PE-X) cables have a market share of around 33-38 %, low smoke zero halogen/halogen-free flame-retardant (LS0H/HFFR "halogen free cables" – main resins polyolefins mixed with EVA) have a market share of around 18 % and others, such as silicone rubber cables, represent the remaining market share (PVC4Cables websites, 2023).

Mainly due to a stricter fire safety requirement for buildings materials the overall market share of PVC cables has decreased significantly (from around 65 % in 2000 to around 35 % in 2023) (Aupetit, 2021, Sarti and Piana, 2022). Most cables used in the construction sector are in the scope of the Regulation (EU) No 305/2011 (Construction Products Regulation, CPR) (EU, 2011) and need to follow harmonised standards. The relevant standard to assess the fire performance of cables is EN Standard 50575 which sets the fire reaction requirements, test methods and cable evaluation and defines performance requirements (Euroclasses) linked to the acidity of gases released during combustion. Since PVC cables are classified into worst class for acidity (a3), they are, according to the standard, not suitable to be used in locations where the classes a1 or a2 are required (such as most public buildings). However, standard PVC cables can still be used, for example, in residential buildings. Despite the efforts by the PVC compounders in the cable industry to reach the classes a1 and a2 (Sarti and Piana, 2022), it is estimated that the share of halogen-free cables will further increase in the future at the expense of PVC cables (Aupetit, 2021).

In the standard applications in the building and construction sector (not requiring high fire prating; class *Eca*[3] in Euro-class rating) PE cables are mainly used as an alternative to PVC cables, but also increasingly completely halogen-free cables. A more typical use of halogen-free cables are applications where low smoke/high fire resistance products are needed, such as in public buildings. Flame retardants in halogen-free cables are typically alumina trihydrate or magnesium hydroxide. Where high voltage, high temperature resistance or high data transfer capacity is needed, PE-X cables are typically used. (Reka cables, personal communication, 2023). For example, a standard automotive cable is PVC (called general purpose thermoplastic wire or GPT), but when higher temperature resistance or higher voltage is required, a PE-X cable can be used (single conductor primary wire with cross-linked polyethylene (PE-X) insulation called SXL cable). e SXL has higher performance ratings (e.g. higher temperature rating of -40 °C to 125 °C for SXL, -40 °C to 85°C GPT), but is less flexible than a standard PVC cable.

EEE also uses PVC as a cable material. Kemi (2015) reports that most of the products in the consumer electronics sector are supplied with PVC cables. The ROHS Annex II Dossier for Diantimony trioxide (ATO) (OEKO, 2019) studied the alternatives to ATO in EEE. They concluded that it is more likely that ATO would be substituted with halogen-free solutions (PVC-free) rather than with replacing only ATO as a synergist[4]. They produced a list of halogen-free flame retardants that can be used with various other polymers, such as PE. The list includes, for example, aluminium hydroxide and magnesium hydroxide. Another mentioned solution are alternative technologies, such as metal enclosures/housing for IT products e.g. aluminium. Alternative polymers, such as TPE, but also other materials, such as silicone or rubber, can also be used in EEE.

Computer manufacturers, including Apple, Asus, Dell, HP and Samsung, have made voluntary pledges to phase-out PVC in their products. However, it is not always clear which alternative is used for which sub-applications, or what is the added cost of such solutions (ROHS Annex II Dossier for Diantimony trioxide (ATO)). Apple states in their 2016

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[3] The Euroclass cable rating has 7 classes with additional classification for smoke production, flaming droplets and smoke acidity. The first 5 classes (*Aca, B1ca, B2ca, Cca, Dca*) are typically used in installation commercial locations and offices; *Eca* can be used in residencies, shops and small offices, while *Fca* is used in outdoor applications.

[4] Synergism means that the overall flame retardancy effect is higher than the sum of the single components' effects.

Environmental Responsibility Report that it took the company four years to remove PVC from the power cords and headphone cables. After testing dozens of formulations, Apple found a right blend in the non-chlorinated and non-brominated thermoplastic elastomers that are used as replacements (Apple, 2016). A comment in CfE3 (CfE3, #1653, Japan Electronics and Information Technology Industries) also stated that for the EEE, at least 4 years is needed to find alternatives for such complex products, and even 10 years for industrial equipment.

ECHA has no information on the costs related to the R&D to make such a switch.

C.4.3.1. Economic impacts

The economic impacts of substitution are calculated for the end-users of the cables, who pay the purchase of the cable, either in the price of the cable itself, or as a component in a more complex product. In the case of cables, evaluation of the costs for use and maintenance are not relevant: Cables do not need ordinary maintenance and the costs of use (for example in the form of loss of electric power) are not significant if cables are correctly installed. The technical life for all cables is estimated at 30 years, regardless of the material, and there is no need to differentiate between different materials (Marangoni (2019), via ECHA Market Survey 2023).

C.4.3.1.1. Building and construction

One meter of a standard three-conductor 3 x 1.5 mm building and construction cable has an approximate weight of 0.81kg in the insulation and jacket material (ECHA market survey, 2023). ECHA conducted interviews with cable producers (Reka cables, personal communication 2023; Anonymous, personal communication, 2023). While PVC is still largely used as a standard wire in many applications, PE and halogen-free alternatives could be used as well. For example, in residential buildings, a typical cable is a PVC 3 x 1.5 mm cable with a fire classification of *Eca*. However, halogen-free cable with a higher fire classification could be used as well. In the interviews, the price difference was estimated between 10-15 % in favour of the PVC cable. From a cable warehouse (Verkkokauppa, 2023), 1 meter of insulated and sheathed PVC cable has a cost of €1.5/m, while a halogen free has a cost of €1.7/m. The price difference falls within the range indicated in the interviews. Depending on the manufacturer, country and the brand, the prices can vary. The average price difference of 13 % is used in the calculations, so that the price range of a PVC cable is €1-1.5/m and the halogen-free cable has a price range of €1.13-1.7/m.

C.4.3.1.2. Vehicles

As stated, in those situations where temperature requirements are higher (e.g. in the motor compartment), a typical alternative for PVC is a cable made out of PE-X. For example, in the automotive sector, PVC is used for typical cable applications, but for more demanding applications (industrial vehicles, race cars, performance cars) PE-X cables are used. It should be pointed out that PVC can be also compounded to have high heat resistance capabilities (up to 105 °C) – compounds typically include high molecular weight phthalates such as DIDP, DPHP, linear (C9-11) or DTPT or trimellitates, and flame retardants or a synergist (such as ATO that works as a synergist for the chlorine). (Cfe3, #1683, Japan Measuring Instruments Federation; Cfe3, #1708, VinylPlus). PE-X cables are typically more expensive (10-20 %) and less flexible compared to PVC cables (ECHA Market survey, 2023; Reka cables, personal communication, 2023). We use the price difference of 15 % for PE-X cables and assume that PE-X would replace the share of PVC that is used in the vehicles, mainly in cars, as it is already widely available, suitable in terms of KPCs, and less expensive compared to some potential alternatives (e.g., TPE).

C.4.3.1.3. EEE

For the EEE, it is not immediately clear which material would be the main alternative for PVC. RoHS Annex II Dossier for ATO states that the two most promising steps forward concerning the substitution of a commonly used synergist (ATO) to achieve flame retardancy, for example in PVC, are the co-substitution of the halogenated flame retardant with which ATO is applied as synergist, and the option of alternative technologies which basically means a substitution of the polymeric host material. As stated in the RoHS Annex II Dossier, literature provides these alternatives, but the actual application in products recently placed on the market cannot be confirmed properly.

ECHA did not receive enough information for this in the Calls for Evidence. For those who have substituted, such as Apple, the R&D took several years. For illustrative purposes, for the tonnage of PVC used to produce cables for EEE, the calculation will be based on the price difference between TPE and PVC, based on the successful and proven large-scale substitution by Apple.

Table 12 shows the result of these calculations for all three sectors. Since the volume and share of PVC used in the different sectors is confidential, the calculation has been broken down by sector using public ranges of the volume estimates.

Table 12: Costs of replacing PVC in cables in the EU

Material	**PVC**	**Halogen-free**	**PE-X**	**TPE**
Sector		Building and construction	Vehicles	EEE
Difference to PVC in costs	Not relevant	10-15 %	10-20 %	152 % (market price of PVC €1 808/t, TPE €4 560/t)
Tonnage to replace PVC (min max, public range, based on confidential shares of use of PVC per sector)	(Total tonnage of PVC: 466 000)	68 000 – 406 000	16 000 – 94 000	34 000 – 203 000
Annual cost per alternative € million (min max, public range, based on confidential shares of use of PVC per sector)	Not relevant	13 – 81	4 – 22	79 – 473
Total	If total volume of PVC would be replaced with the main alternatives, the cost would be at minimum €384 million per year. However, it is likely that there would be large R&D costs for both the cable manufacturers and the manufacturers of EEE and vehicles.			

Source: costs: ECHA Market Survey, 2023; Reka cables, personal communication, 2023; Anonymous, personal communication, 2023; volumes: CfE2, #1601, VinylPlus; #1564, Europacable

Nearly all the main cable producers in the EU have a portfolio consisting of different types of cables made of different cable materials. However, as pointed out by a comment in CfE3 (CfE3, #1656, Federazione ANIE) the one-time costs of replacing machinery used to produce PVC cables could be in order of magnitude €10 – 20 million for each cable producing company in the EU. In the Medium-chain chlorinated paraffins (MCCP) Restriction Dossier (ECHA, 2022), it was assumed that there would be around 400 cable producers in the EU that could be affected by the restriction. By using this estimate of the number of companies, one-off costs related to machinery could then amount to €4-8 billion. While an average lifespan of a 40 years is indicated for such machinery (CfE3, #1656, Fenerazione ANIE), on average, the current machinery has a remaining lifespan of 20 years. The annualised costs would then be around €270 – 540 million.

Eurocapable (CfE2, #1564, Europacable) estimated that a large share of EEE is imported and might be outside of the scope of the tonnage figures, and Kemi (2015) estimated that approximately 80-90% of EEE is imported. In the EEE sector, this would mean that a large share of the R&D costs associated with fitting EEE with alternative cables could take place outside the EU.

In the vehicles, especially in the automotive sector, EU has a positive trade balance and much more cars are exported than imported. Approximately 10 million cars are manufactured in the EU per year, out of which 5.7 million are exported. Approximately 3 million cars are imported. (ACEA, 2022). For the automotive sector, the R&D costs could be then skewed towards the EU manufacturers. ECHA has not received information from the sector to estimate these costs.

For the building and construction sector, the halogen-free cables and the PVC cables are to a large degree interchangeable, and the main costs are related to more expensive price of the halogen-free cables, already included in the estimated costs.

Based on the purchase price of a PVC cables and sales volume, the total sales value of PVC cables in the EU is €0.7 billion per year. As explained, the volume information quoted above includes only EU production. With a 100 % production in the EU and a profit margin of 10 %, the profits for the EU producers would be around €70 million per year.

According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the PVC cable producers would be around €5 million. (SEAC, 2021)

C.4.3.2. Life cycle impacts

C.4.3.2.1. Qualitative description of impacts at different lifecycle stages

The review by Baitz et al. (2004) did not reveal any definite ranking between different materials in cables from the LCA viewpoint.

ECHA screened the LCA literature of studies with a comparison of PVC to other materials in cables. Only one study was identified performing such a comparison. Table 13 presents an overview of reviewed life cycle analysis studies for cables. The study by Ozelkan and Stephens (2021) compared PVC to PET and PE (high density). The study was made in the U.S. and for the telecommunication cables only.

Impact categories included were ozone depletion, global warming, smog, acidification, eutrophication, eco-toxicity, carcinogenic, non-carcinogenic and respiratory effects.

PE outperformed PVC in all but one of the assessed impact categories. On the other hand, PVC outperformed PET in all other impact categories with the exception of acidification. The ranking of materials for the total (standardised across impact categories) environmental impacts was quite clear, as PE was the favoured material, PVC the second, and PET performed the worst.

Table 13: Overview of LCA studies for cables

Author & year	Type	Application	Alternative materials assessed	Dimen-sions	Geogr. focus	System bounda-ries	Impact categories	Material preferability ranking
Ozelkan & Stephens (2021)	Journal article	Fibre optic cable	PVC, PET, HDPE	ENV & ECON	USA	Cradle-to-grave	ozone depletion, global warming, smog, acidification, eutrophication, eco-toxicity, carcinogenic, non-carcinogenic and respiratory effects	PE > PVC > PET

C.4.3.2.2. Quantitative description of impacts at different lifecycle stages

In the ECHA market survey (2023), one meter of PVC cable produced 8.2kg CO2/m, while for PE (high density) and PE-X the similar figures were around 5kg CO2/m. For TPE cable the estimate was 6.9 kg CO2/m; and for EVA, 5.7 kg CO2/m. However, the CO2 emission calculation was only based on the production of the virgin material for the cable. ECHA has received comments (ECHA market survey, 2023; CfE3 #1656, Federazione ANIE) that other polymers demand more energy for processing due to lower extrusion speed when pulled into cables. Also, many of the materials need a relatively higher amount of flame retardants, such as alumina trihydrate or magnesium hydroxide with the life cycle impacts of their own (CfE3, #1680, anonymous). On the use-stage, there can be large differences in the energy loss between the cable materials (ECHA market survey, PVC4Cables), with PVC4cable (ECHA market survey) submitting a (non-peer reviewed) study showing a clear advantage of PVC in terms of lower energy losses compared to PE and PE-X cables.

Consequently, with the current knowledge, there is not enough evidence to calculate the environmental impacts of switching from PVC to alternative cable materials.

C.4.4. Alternative additives

C.4.4.1. Plasticisers

Table 14 presents currently used plasticisers in cables. DINP and DOTP can be used as an alternative for standard cables in the building and construction sector. (ECHA Market Survey, 2023; Personal communication, Reka cables, 2023; Vinylplus e-mail, 16.05.2023). A typical fire rating for such cables is less than 70 degrees Celsius. (Vinylplus e-mail, 16.05.2023).

For the more demanding applications, with a high temperature rating (i.e. up to 80 degrees Celsius), high molecular weight phthalates, such as DIDP and DPHP are preferred, due to their lower vapour pressure (CfE3, #1708, Vinylplus). Vinylplus (Cf3, #1708) states that the alternatives for DIDP and DPHP could be other high molecular weight phthalates such as DUP, DIUP and DTDP.

If an even higher temperature rating is required (i.e. up to 105 degrees Celsius, one comment states that test temperature can be even 130 degrees Celsius), such as for some cables in the automotive sector (the exact use not specified in the comments), trimellitates are often applied, as in addition to the plasticising effect, they have also heat resistant properties (CfE3, #1708, Vinylplus; CfE3, #1683, Japan Measuring Instruments Federation).

As a conclusion, none of the identified safer alternatives, such as DOTP or DINCH, can be considered as an alternative for such cable applications where high temperature resistance is needed. This is because both high molecular weight phthalates and trimellitates have a low vapour pressure, which means that they are less likely to leach out of the PVC matrix even at high temperatures. This means that long chain (C9-C18) ortho-phthalates are, given the current scientific understanding, the least risky plasticisers that could be used in PVC cables that require high temperature rating. Medium-chain ortho-phthalates, such as DPHP, could be replaced DIDP or with higher-chain ortho-phthalates, such as DUP or DIUP (a move from orange to yellow category), but with a premium on the price. For the standard cables, DINP could be replaced with DOTP (a move from medium concern to currently no identified concern).

In 2020-2022, DOTP has been on average €50/tonne more expensive than DINP and DIDP (Chemorbis, 2022b). The additional cost from using DOTP would be €2 million per year for the total volume of DINP used in cables (44 000 tonnes/year).

For DPHP and DIDP, ECHA assumes that the price is equal, and the move from DPHP to DIDP for example would in practise mainly entail reformulation costs. However, ECHA assumes, based on anecdotical evidence, that the price of the even longer molecular chain ortho-phthalates is double of that of DINP, DIDP and DPHP. Assuming half of the medium-chain ortho-phthalates (excluding DINP) are replaced with DIDP and half with long-chain ortho-phthalates, the additional cost would be €14 million per year for the remaining medium-chain ortho-phthalates. The trimellitates are assumed to be replaced with long-chain ortho-phthalates, but assuming the same price, at no extra material cost.

Table 14: Currently used prioritised and alternative plasticisers in cables

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used plasticisers (estimated volume in tonnes)		Medium-chain ortho-phthalates (C7-C8): DINP (44 360 tonnes) DPHP (15 840 tonnes)	Long-chain ortho-phthalates (C9-C18) DUP (115 tonnes) D911P (685 tonnes)	DOTP (21 315 tonnes)

		D810P (2 260 tonnes) Trimellitates: T911M (145) T810TM (2 945) TOTM (785 tonnes) TINTM (205) TIDTM (485) tBuTPP (2 265 tonnes)	D114P (835 tonnes) DIDP (16 180 tonnes) DDP and DDDP (1 120 tonnes) D1012P (825 tonnes)	
Likely alternative plasticisers			Medium-chain ortho-phthalates to long-chain ortho-phthalates (for example DPHP -> DIDP or DPHP -> DUP)	DINP -> DOTP

C.4.4.2. Heat stabilisers

Zn/Ca stabilisers are used in cables, and they are not included on the list of prioritised additives. None of the prioritised additives are used as heat stabilisers in cables.

C.4.4.3. Flame retardants

PVC compounds for standard cables do not require any flame retardant (ECHA Market survey, 2023; Personal information, Reka cables, 2023). This includes mainly cables with a temperature rating below 70 degrees of Celsius. However, many different flame retardants are used in high temperature wire and cable applications (Table 15).

A common finding from the CfE3 was that ATO, an inorganic synergist to enhance the flame retardancy of halogens such as chlorine, is one of the most commonly used flame retardants in PVC (e.g. CfE3, #1653; #1683; #1704; 1708). One comment (CfE3, #1704, Campine NV) mentions that even when the price of ATO tripled in 2012, no substitute was found by the industry to provide the needed fire resistance properties. It was also mentioned that when ATO is applied as a synergist to plasticized PVC, no other halogenated flame retardants are necessary.

In the ROHS Annex II Dossier on ATO, it was concluded that there are two most promising steps towards substitution of ATO:

1) The co-substitution of the halogenated flame retardant (chlorine in the case of PVC) with which ATO is applied as synergist, and;

2) The option of completely alternative technologies (such as metal enclosures)

It should also be noted that ROHS Annex II Dossier concluded on ATO that if it would be restricted, there would be a high risk of regrettable substitution since an increased amount of halogenated flame retardants would be expected to be used. No restriction was proposed on ATO, but instead a recommendation to carry out a joint assessment, with high priority, of the system of halogenated flame retardants and ATO synergists.

Not much information has been submitted to ECHA in regard to other prioritised flame retardants used in PVC. On the other hand, when asked about additives that cannot be replaced in PVC, only ATO came up.

Also, there was not much information submitted on alternative flame retardants for PVC. Vinylplus (CfE3, #1708, Vinylplus) mentioned magnesium dihydrate and aluminium trihydrate as alternatives. PVC4Cables (2023b, through Vinylplus e-mail, 16.05.2023) states that there is growing interest towards all those natural minerals that have the properties of flame retardants, as for example mixtures of calcium and magnesium carbonates and magnesium hydrates. These mineral mixtures, in the presence of heat, decompose with an endothermic reaction and have substantially the same behaviour as the other flame retardants. A comment (Cf3, #1620, anonymous) mentioned that zinc stannate can replace ATO, however at a cost of effectivity. Vinylplus (e-mail, 16.05.2023) stated that due to CPR regulation and the potential concerns related to many currently used flame retardants, new low toxicity flame retardants and smoke suppressants are under market development, but the exact chemistry is proprietary and undergoing patent filling.

As a conclusion, it seems that many of the flame retardants used in cables could be replaced by ATO (a move from high concern and medium concern to low concern), and ATO could possibly be replaced by mineral mixtures (a move from low concern to currently no identified concern). ECHA has not been submitted cost information related to such substitution.

Table 15: Currently used prioritised and alternative flame retardants in cables

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used heat stabilisers (estimated volume in tonnes)	Bis(2-ethylhexyl) tetrabromo-phthalate (no information on tonnes)	Phenol, isopropylated, phosphate (3:1) (1 355 tonnes/year) Reaction mass of 3-methylphenyl diphenyl phosphate (4 580 tonnes/year) Tris(methylphenyl)phosphate (1 665 tonnes/year) Tert-butylphenyldiphenyl phosphate (tBuTPP) (555 tonnes/year) Tris-(2-ethylhexyl) phosphate (5 330 tonnes/year) Zinc borate (100 tonnes/year) Hexaboron dizinc undecaoxide (10 400 tonnes/year)	Diantimony trioxide (ATO) (10 500 tonnes/year)	
Likely alternative heat stabilisers				Magnesium dihydrate* Aluminium trihydrate* Zinc stannate*

*Notes: * These substances are also currently possibly used in cables and were not prioritised (Appendix B)*

C.4.4.4. Supply chain impacts

The main impacts for the supply chain of chemical providers would happen if DINP would be replaced with DOTP. Almost all other plasticisers listed above have much higher EU production rate compared to DOTP.

DINP is produced mainly in the EU, and very little is imported (99 % EU production rate), while for the DOTP, around 67 % of the EU consumption is imported, with the main import countries having been South-Korea and Turkey (Chemorbis, 2022b).

The total value of the DINP production for the production of cables is around, with the mean price and mean of volume range, in the EU is around €67 million per year. ECHA has no information on the profit margin of the plasticiser manufacturers, but with an assumed 10% profit margin, the loss in profit for the DINP producers would then be around €7 million per year. According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the DINP producers would be around €1 million.

There has been capacity building in the EU towards domestic production of DOPT as well. (Businesswire, 2018), when a new DOTP production facility, capable of producing 60 000 tonnes per year, was planned to be built in Germany in 2019. If DOTP manufacturing capacity would increase in Europe, the loss in the profit of DINP producers would be eventually replaced by the increase in the profit of DOTP producers. However, in Vinylplus (e-mail, 16.05.2023) stated that the planned increase in production might have stalled.

For the cable manufacturers, the move from DINP to DOTP, and from DPHP to DIDP or other long-chain ortho-phthalates would also entail reformulation costs.

In the MCCP and other Chloroalkanes CA:C14-17 Restriction Dossier, it was evaluated that 400 cable producing companies in EU would be affected by a restriction that would force them to change their formulation, and the reformulation costs were estimated at €300 000 per company (including testing and revalidation). The total one-off costs for the EU cable providers was estimated then at €120 million. We assume that similar costs could take place in case companies would have to change their plasticiser formulation.

C.5. Flooring

C.5.1. Description of use and performance criteria

Flooring falls under the building and construction sector, which is the largest sector using PVC. There are different types of PVC flooring. Homogenous PVC flooring refers to floor covering with one or more layers of the same composition and colour and are available in both sheets and tiles. Heterogenous PVC floor coverings consists of a wear layer and other layers, and are available in sheets, tiles and planks. Tiles and planks can be sold as Luxury Vinyl Tiles, which can be further divided into glued down tiles or tiles and planks with a mechanical locking system. Foamed heterogenous PVC floor coverings have a heterogenous structure with one or more foamed layers and are available as sheets and tiles. Heterogenous floor coverings represent the majority of the PVC floorings. (ERFMI, e-mail, 13.04.2023)

PVC flooring is in the market segment of resilient flooring that consist of materials that can withstand heavy use, are easy to maintain, hygienic, and comfortable underfoot. Other materials in the resilient flooring market segment are linoleum, other polymers, rubber, and cork. (ERFMI, 2023). However, the products within the resilient market segment also compete with products in the flooring market in general. There are certain standards that apply to all floor covering in general, of which the EN 685 is often cited as the most important. The classification identified classes for:

- Domestic: light (21), moderate (22), heavy (23)
- Commercial: moderate (31), general (32), heavy (33), very heavy (34)
- Industrial: moderate (41), general (42), heavy (43)

Other EN classifications specify, for example, sound reduction properties, slip resistance, fungi and bacteria resistance, fire classification and numerous other properties that might be important, depending on the intended use.

The classification is shown to highlight the fact that also many other flooring materials other than resilient flooring (e.g. stone, ceramics, even some parquet and laminate) can, based on the design, be classified into very heavy (34) to industrial classes (41-43).

ECHA has compiled some general key performance criteria for the flooring. However, as stated by the stakeholders (ECHA Market survey, 2023), the required criteria are sometimes very use specific (sound insulation, thermal conductivity/heat retention, water/moisture repellence) or are reflected in the lifetime costs of the material (durability, ease of installation, maintenance and cleaning, flexibility and weight).

The analysis related to alternatives will be done based on the comparison of the lifetime costs of different flooring materials. Two different replacement scenarios will be tested: 1) The PVC would be replaced based on the market share of flooring materials in the EU, and 2) The PVC would be replaced by other resilient flooring materials, based on the market share of resilient flooring materials in the EU.

C.5.2. Baseline

In 2021, estimated 773 000 tonnes of compounded PVC was imported and used for flooring (60 % imported, 40 % EU production), which with a typical compounding, amounts to 278 000 tonnes of uncompounded PVC. This figure includes all PVC flooring placed in the market in the EU, both the articles produced in the EU and the ones imported. The tonnage equates to roughly 200 million square meters of flooring. (ERFMI, e-mail, 02.06.2023).

If one compares the volume of PVC to the resilient flooring market, PVC is the dominant material in this market with a share of approximately 91 % of this market.

However, if one compares the volume to the overall flooring market in the EU, with an estimated 3 billion square meters of flooring sold every year in the EU, the PVC has a total market share of less than 10 %. The largest market shares belong to the ceramics, carpet, and laminate (BlueWeave Consulting, 2023). There are also large differences between different countries in the EU on the preferability of the flooring material: In 2009, almost 75 % of the total flooring market was covered by ceramics in Italy (4 % PVC), while the share of ceramic flooring was less than 20 % in Germany (13 % PVC).

Table 16 gives an overview of PVC use in flooring.

Table 16: Use of PVC in flooring

Use	**Flooring**
Description	PVC using in flooring
Main performance criteria	Life-cycle cost related: durability, ease of implementation, maintenance and cleaning, flexibility, weight Performance related: Sound insulation, thermal conductivity/heat retention, flame retardancy, water/moisture repellence
Share of PVC of the total flooring market / resilient flooring market	<10 % of the total flooring market (main materials: ceramics, carpet, stone, laminate, wood) 91 % of the resilient flooring market
Compounded volume of PVC placed in the market per year in EU27 (tonnes)	Approximately 773 000 tonnes (corresponding to approximately 278 000 uncompounded) of PVC placed in the market (including also imported flooring) Other estimates: 188 000 – 1 139 000 tonnes per year (CfE3, #1601, Vinylplus)
Type of PVC	Soft
Share of additives in typical average compounding	1-2 % stabilisers and lubricants; 25-60 % fillers, pigments, impact modifiers; 13-27 % plasticisers
Prioritised substances used as additives	Plasticisers: DINP, DOTP (primary plasticisers in flooring) Other plasticisers: DIDP (400 tonnes per year); Dibutyl terephthalate (2500 tonnes per year); Benzoic acid, C9-11, C10-rich, branched alkyl esters (300 tonnes per year) Heat stabilisers: 1,3-diphenylpropane-1,3-dione, Organotin compounds are also used for some digital print layers (films) for Luxury Vinyl Tile flooring Flame retardants: Diantimony trioxide, Zinc borate

Sources: ECHA market survey 2023; CfE2, #1601, VinylPlus; ERFMI, e-mail, 13.04.2023; 02.06.2023

C.5.3. Alternative materials

Other materials in the resilient flooring market segment are linoleum, other polymers, rubber, and cork. (EFRMI websites, 2023). Other important flooring materials in terms of use volume in the EU are wood (hardwood, parquet), laminate, ceramic and stone, and carpet.

As stated, when deciding the floorcovering for a given building, multiple factors affect the choice, such as the level of traffic, sound insulation, resistance to chemicals, slip resistance and so on. Thus, not all of the listed materials can be considered as an alternative to PVC flooring in all possible uses.

The cost of each material needs to be also taken into account. In the case of flooring, the cost is often divided into the cost of the material itself, the installation cost and the maintenance cost. Depending on the materials, the maintenance cost can be up to 50% of the total lifetime cost of the flooring (Minne and Crittenden, 2015). The lifetime of the flooring materials varies between materials and the level of traffic and intensity of use. For example, a correctly chosen PVC material in a heavy traffic area (commercial, very heavy use class 34) is estimated to have a lifetime of a 20 years, while in a low traffic area (domestic, moderate use class 22) the lifetime is estimated at 40 years. For a stone or a (correctly chosen) ceramic flooring, the lifetime is estimated at a minimum of 50 years (Rakennustieto, 2023). Some materials are quicker and easier to install, and there are large differences in the installation costs of different flooring materials. For example, the RT product information database (2023) estimates that an average time of installing a square meter of vinyl sheet is 0.17 hours, while for a floating wood or laminate floor it takes 0.81 hours. For the stone and ceramic floors, the amount of work (and pre-work) is even higher.

Table 17 below depicts some of the characteristics of different types of floorings. The lifetime estimates are for a heavy traffic area with high intensity of use, due to PVC being mostly used in applications demanding resilient flooring

Table 17: PVC and alternative materials for flooring

Material	**PVC**	**Cork**	**Other polymers (e.g. PP)**	**Rubber**	**Laminate**	**Wood**	**Stone /ceramic**	**Linoleum**	**Carpet**
Lifetime	20	15	15	20	10	20	>50	20	10
KPCs (Positive/ negative)		Lower water, wear and bacteria resistance	Comparable to PVC	Less flame retardant, worse bacteria resistance, very comfortable underfoot	Lower water resistance, less flame retardant, Lower sound insulation/absorption, more slippery	Lower water resistance, lower sound insulation/absorption, more slippery	Non-flammable, ability to store heat/cool building, poor sound insulation/sound absorption, more	Lower wear and water resistance, good antistatic properties and bacteria resistance	Can stain in use, less flame retardant, good sound insulation/absorption, very comfortable underfoot

							slippery, falling can cause damage		
Cost €/sqm	5-40	25-100	10-65	30-120	10-85	35-170	Ceramic: 13-165 Stone: 35-100	18-60	6-58
Time required to install /sqm	0.17 (sheets) 0.81 (tiles)	0.81	0.17	0.17	0.81	0.81	1.62	0.81	0.17
Time required to renew /sqm	0.32 (sheets) 0.72 (tiles	0.72	0.32	0.32	0.72	0.72	1.44	0.72	0.32
Maintenance cost/total cost	29 %	49 %[1]	29 %	29 %[2]	29 %[2]	49 %	10 %	30 %	30 %

Sources: Lifetime (RT product information database, 2023; KPC (ECHA market survey, 2023; Other polymers (CfE3, #1627, #1689) Material cost (EFRMI, 2023b; Marangoni and Garbarino (2011); ECHA market analysis; Time required to install (RT Product information database, 2023; Time required to renew (RT product information database, 2023); Maintenance costs (Minne and Crittender, 2015)

[1] *Assumed to be in the same order as wood.*

[2] *Assumed to be in the same order was plastics.*

Given that many alternative materials exist, PVC represents in total a small share of the overall flooring market (<10%), and an alternative material can be found for almost every use, ECHA does not see the technical feasibility of the alternatives as a significant problem. PVC is used in some very specific industries, such as hospital environment, which might add further requirements on the hygienic properties. (ECHA Market survey, 2023). Based on the analysed KPCs, other polymers and linoleum flooring could be under such requirements.

If only the market of resilient flooring is considered, PVC is the most significant material in terms of volume (>90%). In the short-term, there could be shortage of materials such as cork, linoleum, and alternative plastic floorings (such as PP flooring), should the use of PVC be restricted. It is however also reasonable to assume, that in many cases, the substitute could be one of the other flooring materials, for example carpet in an office building.

ECHA notes that PVC tends to be less costly compared to alternative materials. The low cost is the result of low material cost, ease of installation and ease of maintenance, and better durability compared to some materials (i.e. carpet and laminate).

C.5.3.1. Economic impacts

The economic impacts are calculated for the end-user of the flooring material who will eventually pay the price for the material, installation and the maintenance. The type of analysis is referred as the total cost of ownership (Marangoni and Garbarino, 2011). Costs are presented per square meter of a flooring material, and the range for the price is provided. The installation costs are calculated by the time required for installation times the mean salary in the EU. Maintenance costs are estimated based on the Minne and Crittender (2015), who estimated the share of maintenance cost of the total cost during a lifetime of 60 years.

The main comparison is made to other resilient flooring materials, most similar to PVC in terms of properties: Other polymers (for example PP), linoleum and rubber. Table 19 depicts the total annual cost over a lifetime of 60 years, €2020 per square meter, the difference to PVC, the share of sales in the resilient flooring market segment, the total annual costs if all PVC flooring is replaced by a given alternative, the difference per the share of the market, and finally the total cost. The total cost of substitution is the lowest if all PVC flooring is replaced by an alternative polymer material, such as PP. This minimum cost would be €2.4 billion annually. However, due to the limited availability of such materials, a more realistic figure is obtained by assuming that the replacement is done by equal shares compared to the current market volumes in the resilient flooring market (Table 18). The minimum replacement cost would be then around €10 billion per year, and the mean replacement cost €15 billion per year.

Given the limited supply of alternative resilient flooring materials, it would be likely that some of the replacement would consist of alternative flooring materials in general.

Assuming 30% of PVC volume would be replaced by ceramics, 30% by carpet, 15% laminate, 15% by wood and 10% by linoleum would result in a flooring mix that would not have drastic changes in the supply of materials. The total replacement cost would in this case be €12 billion to €24 billion per year in the EU.

Table 18: Scenario 1). Annual costs of replacing 200 million square meters of PVC in the EU with the (general) flooring materials based on their market share.

Data	PVC	Ceramics	Carpet	Laminate	Wood	Linoleum
Total annual cost over lifetime of 60 years (€/sqm, min and mean)	52 – 79	78 – 154	62 – 147	176 – 297	231 - 356	104 - 143
Difference to PVC in annual costs (€/sqm, min and mean)		26 – 75	10 – 68	124 – 218	179 – 277	52 - 64
Approximate share of sales in flooring market (excluding PVC)		30 %	30 %	15 %	15 %	10 %
Total annual costs, for the total sales volume of PVC flooring (€billion, min and mean)	10.4 – 15.5	15.5 – 30.8	12.5 – 29.3	35.2 – 59.5	46.2 – 71.3	20.9 – 28.7
Difference to PVC in annual costs, for the total sales volume of PVC flooring (billion €, min and mean)		5.1 – 15.3	2.1 – 13.8	24.8 – 44	35.8 – 55.8	10.5 – 13.2
Difference to PVC in annual costs, for the total sales		1.5 – 4.6	0.6 – 4.1	3.7 – 13.2	5.4 – 8.4	1.1 – 1.3

volume of PVC flooring weighted by the share of sales (billion €, min and mean)						
Total	If PVC is replaced with other flooring materials according to their market shares in the EU flooring market, the total cost would be in minimum €13 billion per year and calculated with the mean prices €39 billion per year. The minimum figure is probably more likely, since alternatives such as wood and laminate are very costly in heave use due to the need for multiple replacements during the lifecycle of 60 years, and materials such as carpet, linoleum and ceramics are thus more likely alternatives for PVC.					

Table 19: Scenario 2). Annual costs of replacing 200 million square meters of PVC in the EU with other resilient floorings, based on their market share in the segment.

Data	**PVC**	**Other polymers**	**Linoleum**	**Rubber**
Total annual cost over lifetime of 60 years (€/sqm, min and mean)	52 – 79	64 – 144	104 – 143	102 - 186
Difference to PVC in annual costs (€/sqm, min and mean)		12 – 65	52 – 64	50 – 107
Approximate share of sales in flooring market (excluding PVC)		6 %	77 %	18 %
Total annual costs, for the total sales volume of PVC flooring (€ billion, min and mean)	10.4 – 15.5	12.8 – 28.8	20.9 – 28.7	20.4 – 37.1
Difference to PVC in annual costs, for the total sales volume of PVC flooring (€ billion, min and mean)		2.4 – 13.3	10.5 – 13.4	10 – 21.6
Difference to PVC in annual costs, for the total sales volume of PVC flooring weighted by the share of sales (billion €, min and mean)		0.1 – 0.8	8.1 – 10.3	1.8 – 3.9
Total	If the total volume of PVC would be replaced with the cheapest alternative polymer, the total cost would be in minimum €2.4 billion per year. If PVC is replaced with other resilient flooring materials according to their market shares in the market segment, the total cost would be in minimum €10 billion per year and calculated with the mean prices €15 billion per year.			

The total trade value of PVC flooring in EU per year is around 4 billion €. Out of this, EU production is around 40 % and imports around 60 %. Assuming a profit margin of 10 %, the profits for the EU producers would be around €160 million per year.

According to SEAC’s approach to assessing changes in producer surplus, the profit losses of 2 years are taken into account to account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. A typical assessment period in REACH restrictions is 20 years. By annualising two-year losses with a 3 % and an assessment period of 20 years, the annual profit losses would be around €22 million. (SEAC, 2021)

C.5.3.2. Life cycle impacts

C.5.3.2.1. Qualitative description of impacts at different lifecycle stages

The starting point of the life cycle impact assessment was an earlier review study by Baitz et al. (2004). The study was commissioned by the EU Commission to make a literature review of the existing knowledge of LCA of PVC and principal competing materials. In the case of flooring, Baitz et al. (2004) concluded that no general recommendation can be given on the ranking between flooring materials (expect that of singling out carpet as the worst-performing alternative), but instead gave some general comments on the importance of different life stages and impacts. They pointed out that the impacts from the use stage can be even more important than those of the production phase, and for a complete picture, cradle-to-grave assessments are needed instead of cradle-to-gate.

Since 2004, some LCA studies have been published that compare PVC to other flooring materials, and at least two that have assessed the lifecycle from cradle to grave (Table 20).

Minne and Crittender (2015) compared PVC to carpet, solid hardwood, linoleum, and ceramics in the U.S. Particular attention was paid to the use phase, where a comprehensive data collection was done from trade association studies and recommendations from the manufacturers. Impact categories included were climate change, acidification, eutrophication, resource depletion, ozone depletion, ozone formation, particulate matter formation, water depletion and land occupation. Ros-Dosdá et al. (2019) compared PVC to stone, ceramics, carpet, wood and laminate in the EU. The analysis was done based on approximately 150 Environmental Product Declarations (EDPs). Impact categories included in the study were climate change, acidification, eutrophication, resource depletion, ozone depletion and ozone formation.

The replacement of PVC with ceramic reduced the impacts in most of the impact categories and resulted in total emission reduction by around half, irrespective of the maintenance scenario considered, according to both studies. Replacing PVC with natural stone or ceramic flooring reduced the overall impact by almost half. Wood performed worse than PVC, which can be partially explained by the assumption of Ros-Dosdá et al. (2019) that in high traffic uses the lifetime of wood flooring is only 15 years, and thus in high traffic use, four installations are needed during the assessment period of 50 years.

Minne and Crittenden (2015) used a lifetime of 42 years in their assessment for wood flooring which explains the better relative performance of wood in their assessment. Minne and Crittender (2015) found that linoleum performed better than PVC in most impact categories. Since the material is not assessed in the Ros-Dosdá et al. (2019) study, a verification of the results in the EU context is not possible. In both studies, carpet performed in the overall preferability worst and more than doubled the total impacts compared to PVC, especially for depletion of non-fossil resources, eutrophication, climate change and ozone depletion. Ros-Dosda et al. (2019) found that laminate and PVC compared fairly equally, and the normalised overall impacts were on the same magnitude when compared to PVC. The total normalised values ranged from slightly reduced impacts (-10 %) to a small increase (~20 %) depending on the assumptions of parameters subject to sensitivity analysis.

Table 20: Overview of LCA studies for flooring

Author & year	**Type**	**Alternative materials assessed**	**Dimen-sions**	**Geogr. focus**	**System bounda-ries**	**Impact categories**	**Material preferability ranking**
Minne & Crittenden (2015)	Journal article	PVC (vinyl composition tile), carpet, solid hardwood, linoleum, ceramic tile with recycled glass	ENV & ECON	USA	Cradle-to-grave	climate change, acidification, eutrophication, resource depletion, ozone depletion, ozone formation, particulate matter formation, water depletion and land occupation.	linoleum ≈ PVC > wood ≈ ceramics > carpet
Ros-Dosdá et al. (2019)	Journal article	PVC, ceramic, natural stone, carpet (polymer), wood laminate, wood parquet	ENV	EU (ES)	Cradle-to-grave	climate change, acidification, eutrophication, resource depletion, ozone depletion and ozone formation	ceramics ≈ stone > laminate ≈ PVC >≈ wood > carpet

C.5.3.2.2. Quantitative description of impacts at different lifecycle stages

Ros-Dosdá et al. (2019) study presents the absolute values of each impact for the assessed categories per functional unit of a flooring material for 50 years. Since the results are derived in the context of the EU, with a wide range of EDPs assessed for different flooring products, the absolute impact values can be used as an indication of the magnitude of impacts of replacing PVC with other materials. The study is missing the assessment of linoleum, which is one of the most likely alternatives to PVC. Thus, the results of Minne and Crittender (2015) are used to extrapolate the impacts to those categories which both studies assessed in common: fossil depletion, climate change and eutrophication. Since the assumptions and the methods differed between the two studies, the results of the Minne and Crittender (2015) study are transferred in percentage terms to the absolute values of the Ros-Dosda et al. (2019) study (for example, a 75 % reduction of climate impacts when replacing PVC with linoleum found in Minne and Crittender (2015) means reducing the absolute impact of PVC in the Ros-Dosda et al. (2019) by 75 %).

Assuming again, as in the calculation of economic impacts in the scenario 1), that 30 % of PVC volume would be replaced by ceramics, 30 % by carpet, 15 % laminate, 15 % by wood and 10 % by linoleum, the total environmental impacts can be calculated for seven impact categories: Climate change (kg CO_2 eq.), acidification (kg SO_2 eq.), eutrophication (kg PO4-3-eq.), ozone layer depletion (kg CFC-11 eq.), photochemical ozone creation (kg C2H4 eq.), depletion of non-fossil resources (kg Sb eq.) and depletion of fossil resources (MJ).

In total, the results show that only for the depletion of fossil resources, positive impacts could be expected should PVC be replaced with the currently used alternatives (Table 21). However, it needs to be noted that not all impact categories are represented in the study, and most importantly, the ecotoxicological impacts related to additives are not included in the LCAs and are left to the risk assessment of this study.

Out of the impact categories, climate change impacts can also be quantified in monetary terms. The social cost of carbon emissions has been estimated based on the average price of the EU ETS carbon permit in 2022 (€80.82/tonne). The total cost of the estimated increase in CO_2 eq. emissions is around €89 million per year.

Much of the negative impacts are attributable to carpet that performs worst in many of the impact categories. For example, if all of the PVC replaced by carpet in the most likely scenario would be replaced by either ceramics or linoleum, negative environmental impacts would be reduced or even reversed in most categories.

Table 21: Quantitative analysis of environmental impacts if PVC is replaced with alternative materials according to scenario 1)

Impact category	**Total impact for the current use of PVC (200 million m2 per year)**	**Total impact with replacement of PVC in million tonnes per year**	**Difference in total impacts in million tonnes per year**
Climate change (million tonnes CO_2 eq.)	9.54	10.65	+1.1
Acidification (million tonnes SO_2 eq.)	0.024	0.028	+0.004
Eutrophication (million tonnes PO_4^{3-}eq.)	0.0068	0.0091	+0.0023
ozone layer depletion (million tonnes CFC-11 eq.)	6.6E-08	1.35E-07	+6.84E-08
photochemical ozone creation (million tonnes C_2H_4 eq.)	0.0056	0.0070	0.0014
depletion of non-fossil resources (million tonnes kg Sb eq.)	1.96E-05	5.68E-05	+3.72E-05
depletion of fossil resources (MJ).	145	132	-12.9

C.5.4. Alternative additives

C.5.4.1. Plasticisers

Floor coverings are one of the largest applications using plasticisers in terms of total volume (Table 22). As DEHP was phased out in flooring, DINP became the most used plasticisers in flooring in the EU. Based on information from CFE2 (CfE2, #1603, ERFMI), the use of DINP has declined as the use of DOTP has increased. Based on 2021 data, the use of DOTP was already almost 50 % higher compared to DINP. In a recent market analysis by ERFMI, DOTP was already almost twice the amount of DINP (ERFMI, e-mail, 01.06.2023). DOTP and DINP 70 % of the total plasticiser use in flooring. Another general-purpose plasticiser, DINCH, covers 25% of the market. DINCH is not on the ECHA's prioritised additives list and is considered as an additive with no currently identified concern. Other plasticisers include DBTP, DIDP, D810P, and "Benzoic acid, C9-11, C10-rich, branched alkyl esters".

The DOTP has been gradually replacing DINP in the EU (Bywall and Cederlund, 2020). The two most important factors have been the industry's commercial interest to move away from orthophthalates, and the low difference in the price between DINP and DOTP. The availability of DOTP in the world market has pushed down the prices to be comparable to DINP (Chemorbis, 2022a). In comparison, in the U.S, due to legislative action on phthalates in flooring 2015, DOTP has already almost completely replaced DINP in the flooring, and DINP can only be found in recyclate streams. (Bywall & Cederlund, 2020; Malveda et al. (2018)). A comment (CfE3, #1708, VinylPlus) from the EU plastic industry also stated that DINP is replaceable with DOTP and confirmed that the main cost for the industry would be in terms of the possible price difference between the two plasticisers. Another general-purpose plasticiser DINCH is also used in flooring, but the availability of DINCH (>10 ,000 tonnes) is more limited compared to DINP (100 000 – 1 000 000 tonnes) and DOPT (100 000 – 1 000 000 tonnes) (CfE3, #1708, VinylPlus).

We use the most updated information by ERFMI (01.06.2023), where DINP covers around 20 % (27 000 tonnes per year) of the current market volume of plasticisers used in flooring and focus in the main analysis on the cost of replacing DINP with DOTP.

In 2020-2022, DOTP has been on average €50/tonne more expensive than DINP and DIDP (Chemorbis, 2022). The total replacement cost for the annual tonnage of 27 000 of DINP with DOTP would then be around €1.4 million or 5 cents per kg.

Table 22: Currently used prioritised and alternative plasticisers in flooring

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used plasticisers (estimated volume in tonnes)		Medium-chain ortho-phthalates (C7-C8): DINP (27 000 tonnes) D810P (250 tonnes) Trimellitates: Benzoic acid, C9-11, C10-rich, branched alkyl esters (400 tonnes)	Long-chain ortho-phthalates (C9-C18): DIDP (540 tonnes) DBTP (3100)	DOTP (52 000)
Likely alternative				DINP -> DOTP

plasticisers				DINP -> (DINCH)*

*Notes: * These substances are also currently used in flooring in significant volumes and were not prioritised (Appendix B)*

C.5.4.2. Heat stabilisers

Heat stabilisers are used in low quantities in PVC flooring (Table 23). Based on a comment in CfE2 (CfE2, #1603, Vinylplus), 1,3-diphenylpropane-1,3-dione is used in flooring. However, the quantities are small in comparison to the use of plasticisers (<0.01% in comparison to DINP for example).

Organotin compounds are, possibly, used in Luxury Vinyl Tiles in the flooring sector in small quantities (CFE3, #1708, Vinylplus). This information was contested in a meeting with the resilient flooring sector (ERFMI, meeting, 19/05/2023).

Table 23: Currently used prioritised and alternative heat stabilisers in flooring

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used heat stabilisers (estimated volume in tonnes)	DOTE (possibly, small quantities in Luxury vinyl tiles)	1,3-diphenylpropane-1,3-dione (14 tonnes)		MOTE (possibly, small quantities in Luxury vinyl tiles)
Likely alternative heat stabilisers				Zn/Ca*

*Notes: * These substances are also currently used in flooring in significant volumes and were not prioritised (Appendix C)*

C.5.4.3. Flame retardants

ECHA has information that flame retardants are used in low quantities in comparison to plasticiser in PVC flooring (Table 24). Based on a comment in CfE2 (#1603), Diantimony trioxide (<0.01% in comparison to DINP) and Zinc borate (0.001% in comparison to DINP) are used in flooring. ATO is used exclusively for the sealant in flooring. ECHA has no information on the alternatives for these flame retardants, but in case of flooring, none of them were listed in the non-replaceable additives list.

Table 24: Currently used prioritised and alternative flame retardants in flooring

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used heat stabilisers (estimated volume in tonnes)		Zinc borate (20 tonnes)	Diantimony trioxide (ATO) (280 tonnes)	
Likely alternative heat stabilisers				

C.5.4.4. Supply chain impacts

The main impacts for the supply chain of chemical provides would happen if DINP would be replaced with DOTP. Almost all other plasticisers listed above have much higher EU production rate compared to DOTP.

DINP is produced mainly in the EU, and very little is imported (99 % EU production rate), while for the DOTP, around 67 % of the EU consumption is imported, with the main import countries having been South-Korea and Turkey (Chemorbis, 2023).

The total value of the DINP production for flooring, with the mean price and mean of volume range, in the EU is around €40 million per year. ECHA has no information on the profit margin of the plasticiser manufacturers, but with an assumed 10% profit margin, the loss in profit for the DINP producers would then be around €4 million per year. According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the DINP producers would be around 0.5€ million.

There has been capacity building in the EU towards domestic production of DOPT as well. (Businesswire, 2018), when a new DOTP production facility, capable of producing 60 000 tonnes per year, was planned to be built in Germany in 2019. If DOTP manufacturing capacity would increase in Europe, the loss in the profit of DINP producers would be eventually replaced by the increase in the profit of DOTP producers. However, in Vinylplus (e-mail, 16.05.2023) stated that the planned increase in production might have stalled.

C.6. Window frames

C.6.1. Description of use and performance criteria

Windows are essential building components that consist of a glass unit fitted in a frame. PVC is one of the materials commonly used for window frames, alongside wood, aluminium and fiberglass. Rigid PVC is used for the frames, and the use falls under the building and construction sector, which is the largest sector using PVC (CfE2; (ECVM, 2023a)).

General performance properties for window frames include durability, waterproofing, resistance to pressure and warping, resistance to fire, energy efficiency (good thermal performance), light weight, low maintenance and ease of cleaning.

The standard window size is 1.23m x 1.48m (1.82 m^2) (ISO 10077-1, 2017). The impact assessment has been performed using the standard window as the unit rather than for the volume of PVC used for window frames, as costs estimates have been available for window units. All cost information has been converted into costs per the standard window unit (1.82m^2). A standard PVC window frame weighs approximately 15 kg (ECHA, 2016).

C.6.2. Baseline

Approximately 0.3–1.9 million tonnes of compounded PVC is used for window frames annually in the EU, which is approximately half of the rigid PVC used in the building and construction sector (CfE2, #1601, VinylPlus; #1587, EuPC). This amounts to approximately 0.2–1.6 tonnes of uncompounded PVC, considering that in the typical average compounding, PVC window frame contain 19 % of additives (CfE2, #1587, EuPC). Of the prioritised additives in PVC, only heat stabilisers are used in window frames (CfE2, #1587, EuPC).

In total 56.6 – 78.5 million windows are sold in the EU annually, depending on the source data (Fenster and Fassade, 2017, Fenster and Fassade, 2023, Ceresana, 2020). The market share of PVC in window frames in the EU is 50.1 %, aluminium 21.5 %, wood 22.0 % and aluminium-clad wood 6.4 %, based on 2015 data (VFF 2017). The market share of fiberglass is below 1 % in Europe (ECHA market survey 2023, EPPA). The use of frame materials varies across countries, the most common material being the following (VFF 2017):

- PVC in Austria, Belgium, Bulgaria, Croatia, Czechia, Estonia, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxemburg, the Netherlands, Poland, Romania, Slovakia, and Slovenia;
- aluminium in Greece, Malta, Portugal and Spain;
- wood in Denmark, Finland and Sweden;
- aluminium and wood equally common in Italy.

In addition to window frames, rigid profiles for building applications include doors. In total 45 million doors are sold in the EU annually, with wood used in 74.6 %, PVC in 8.6 % and some other material in 16.8 % (Ceresana 2020). Due to lack of technical performance and cost information for doors, the analysis presented here focuses on window frames. Further work is needed to assess the relevance of the current analysis to PVC for other rigid profiles, including doors, and to obtain a more complete picture of the economic impacts related to their substitution.

Table 25 provides an overview of PVC use in window frames.

Table 25: Use of PVC in window frames

Use	**Window frames**
Description	PVC is used as a frame material
Main performance criteria	durability, waterproofness, resistance to pressure and warping, resistance to fire, energy efficiency, lightweight, and low maintenance / ease of cleaning
Share of PVC of total window sales in the EU (2015)	50.1 % (28.3 – 39.3 million windows, 1.82m^2 as the standard window unit)
Compounded volume of PVC used per year in EU (tonnes)	274 000 – 1 900 000 (corresponding to 222 000 – 1 600 000 tonnes of uncompounded PVC)
Type of PVC	Rigid
Share of additives in typical average compounding	3 % stabilisers and lubricants; 16 % fillers, pigments and impact modifiers; 0 % plasticisers
Prioritised substances used as additives	Heat stabilisers: Organotins (DOTE, MOTE, DMTE, MMTE, DOT-MalEt), Phenyl 1,3-diones No prioritised plasticisers No prioritised flame retardants

Sources: ECHA market survey; CfE2, #1601, VinylPlus; #1587, EuPC

C.6.3. Alternative materials

Wood, aluminium and aluminium-clad wood are commonly used in window frames in the EU besides PVC. All of these materials are commercially available (EC 2022). Although fiberglass is often mentioned as an alternative to PVC and its share is expected to grow (Saadatian et al. 2021a), it has been excluded from the analysis due to its small market share in Europe (less than 1 %) and lack of lifetime cost information (ECHA market survey 2023, EPPA).

Table 26 depicts the lifetime, performance and cost characteristics of different window frame materials. Although some sources note that the state-of-the-art service life of a window of any material is 40 years (ECHA market survey 2023, EPPA), there appear to be some differences in the lifetime of window frame materials. Information on service life varies, but the common understanding is that PVC windows have the shortest lifetime (25-30 years) and aluminium the longest (45 years), with wood and aluminium-clad wood somewhere in between (e.g. Asif et al. (2005), Carlisle and Friedlander (2016)). This is the basis of the lifetime estimates.

According to data in EC (2022) and additional data compiled for this report (ECHA market survey 2023), all window frame materials have relatively similar technical performance. A similar level of thermal insulation can be achieved with all frame materials (Saadatian et al., 2021a). Some differences can be found for wood, which requires surface treatment to achieve weather resistance and more frequent maintenance than the other materials (ECHA market survey 2023, EPPA, VinylPlus). Wood can also be somewhat less resistant to pressure and warping and heavier than the other materials (ECHA market survey 2023). However, there seem to be no critical differences in the technical performance of the window materials, when they are properly treated and maintained.

The costs of window frames include purchase, installation, maintenance and end-of-life management costs (Marangoni and Garbarino, 2011). Costs are presented in 2022 euros per standard window. The purchase cost of aluminium, wood and aluminium-clad wood window frames is higher than the cost of PVC frames. Maintenance costs are higher for wood frames compared to the other materials, as they require more frequent treatment.

Table 26: PVC and alternative materials for window frames

	PVC	**Aluminium**	**Wood**	**Aluminium-clad wood**
Lifetime	27.5	45	40	42.5
Negative/ Positive impacts on performance compared to PVC	-	Higher durability, prone to condensation (waterproofness)	Needs to be treated for waterproofness, lower resistance to pressure and warping, higher weight, more maintenance needed	Higher durability
Purchase cost (€/window, 1.82 m^2)	321	646	478	562
Installation and dismantling cost (€/window, 1.82 m^2)	136	136	136	136
Maintenance cost for the lifetime of the window (€/window, 1.82 m^2)	145	192	362	187

Sources: lifetime: Asif et al. (2005), Carlisle and Friedlander (2016); technical performance: ECHA market survey 2023; costs: Marangoni and Garbarino 2011

C.6.3.1. Economic impacts

The economic impacts are calculated for the end-user of the windows, who pays the purchase, installation, maintenance and dismantling costs (total cost of ownership). Costs are presented for the standard window (1.82 m^2) and in total for the window market. The assessment period of 45 years corresponds to the lifetime of the longest lasting window type (aluminium).

The substitution costs vary between €66 and €144 per window per year and between €1.9 and €5.7 billion per year for the total volume of PVC window frames sold in the EU, depending on the alternative material used (Table 27). With substitution taking place according to the current market shares of the alternative materials, the total annual cost of substituting PVC in window frames would be €3.3–4.6 billion per year.

The current share of PVC window frames in the EU is approximately 50 % (VFF 2017). Thus, substituting all PVC frames with alternative materials could be challenging in the short term, although all other materials are commercially available in significant quantities (EC 2022). It is likely that the companies making PVC window frames cannot easily switch to aluminium or wood. In particular, production of wood frames requires different skills (ECHA market survey 2023, EPPA). Availability of the alternative materials in sufficient quantities to totally replace PVC was also questioned by stakeholders, as there are several competing uses (ECHA market survey 2023, EPPA). However, both wood and aluminium are largely available and already used to a considerable extent in window frames.

Table 27: Costs of replacing PVC in window frames in the EU

	PVC	**Aluminium**	**Wood**	**Aluminium-clad wood**
Total cost per year over 45 years (€/window, 1.82 m^2, mean cost)	869	974	1 013	935
Difference to PVC in costs per year over lifetime of 45 years (€/window, 1.82 m^2, mean cost)	-	105	144	66
Annual sales volume (million windows, 1.82 m^2)	28.3–39.3	12.2–16.9	12.5–17.3	3.6–5.0
Share of the total sales volume (%)	50.1	21.5	22.0	6.4
Difference to PVC in costs per year, for the total sales volume of PVC window frames (million €)	-	2 979–4 138	4 084–5 672	1 877–2 606
Total	If total volume of PVC would be replaced with the cheapest alternative (aluminium-clad wood), the total cost would be €1 877 – 2 026 million per year. With substitution taking place according to the current market shares of the alternative materials, the total annual cost of substituting PVC in window frames would be approximately €3 322 – 4 614 million per year.			

Sources: costs: Marangoni and Garbarino 2011, Saadatian et al. 2021b; sales volumes: Fenster and Fassade (2017) and Ceresana (2020)

Import and export of rigid profiles (including window frames, doors and other rigid profiles) takes place between the EU and Turkey and Ukraine to cover the European demand (CfE2, #1602, EPPA). Profiles are also exported to India and the United States. There is no import of PVC windows from outside of EU (CfE2, #1602, EPPA). According to Eurostat, import of plastic window frames and doors has been on average 6 % of the total consumption in 2012-2021 (Eurostat, 2023b).

The number of employees in the PVC window frame value chain (PVC profile manufacturers, window manufacturers, recyclers) is estimated to be around 25 000 people in the EU. In the supply chain, 11 PVC window profile producers represent around 90 % of EU market production, and there are thousands of window manufacturers in the EU that build windows from the profiles produced by these 11 companies. However, majority of windows are produced by about 100–150 largest companies. (CfE2, #1602, EPPA.).

Similar information on the market structures is not available for the alternative materials. However, import of wooden and aluminium window frames to the EU is likewise limited (on average 3 % and 9 %, respectively, of total EU consumption in 2012-2021) (Eurostat, 2023b).

Based on the purchase price of a PVC window frame and sales volume, the total sales value of PVC window frames in the EU is €9–13 billion per year. This is predominantly EU production, and the share of imports is less than 10 %. Assuming a 100 % production in the EU and a profit margin of 10 %, the profits for the EU producers would be around €900–1300 million per year.

According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the PVC window frame producers would be around €120–170 million. (SEAC, 2021)

C.6.3.2. Life cycle impacts

C.6.3.2.1. Qualitative description of impacts at different lifecycle stages

From the life-cycle perspective, the production, use and end-of-life stages are important for determining the broader environmental impacts of window frames. Compared to other applications, the use phase is particularly relevant for the life cycle impacts, as the lifetime of windows is quite long and has an influence on the energy demand of buildings via heat loss (Saadatian et al., 2021b, Souviron et al., 2019).

Table 28 presents an overview of reviewed life cycle analysis studies for window frames. The findings on the preferability of different window frame materials throughout the life cycle are mixed (Baitz et al., 2004, Souviron et al., 2019). Some studies find PVC to have larger environmental impacts than other materials through the assessed life cycle stages (Owsianiak et al., 2018, Souviron et al., 2019), while others consider the impacts of aluminium to be the highest and wood lowest, with PVC in the middle (Saadatian et al., 2021a, Saadatian et al., 2021b). One reason for PVC to have higher impacts than the other materials is the shorter lifetime of PVC windows. The studies highlight the importance of considering the use phase and heat losses for a robust assessment, as it has high influence on the life cycle impacts (Souviron et al. 2019, Saadatian et al. 2021b). However, the existing studies allow no conclusion on the preferable window frame material throughout all life cycle stages and impact categories.

Table 28: Overview of LCA studies for window frames

Author & year	Type	Alternative materials assessed	Dimen-sions	Geogr. focus	System boundaries	Impact Categories	Material preferability ranking
Owsianiak, et al. (2018)	Book chapter	PVC, W/ALU, W/C, Wood	ENV	EU (DK)	Cradle to Grave	CC, FEP, FETP, HT cancer, HT non-cancer, IR, LU, ME, ODP, PM, POF, RD (mineral, fossil), TA, TE	W/C > W = W/ALU > PVC
Souviron et al. (2019)	Journal article (review)	n.a.	ENV	EU (ES)	n.a.	n.a.	n.a.
Saadatian et al. (2021a)	Journal article	PVC, ALU, Fiberglass (FGL), Wood	ENV	EU (PT)	Cradle to Gate	AP, CED, EP, GWP, ODP	Wood > PVC & FGL > ALU
Saadatian et al. (2021b)	Journal article	PVC, ALU, FGL, Wood	ENV & ECON	EU	Cradle to Gate + Use	AP, CED, EP, GWP, ODP	Wood > others > ALU

Notes: ALU = Aluminium, CC = Climate change, CED = Cumulated energy demand, DK = Denmark, ECON = Economic, ENV = Environment, EP = Eutrophication potential, EU = European Union, FE = Freshwater eutrophication, FET = Freshwater ecotoxicity, FGL = Fiberglass, GWP = Global warming potential, HT = Human toxicity, IR = Ionising radiation, LU = Land use, ME = Marine eutrophication, ODP = Ozone depletion potential, PM = Particulate matter, POF = Photochemical ozone formation, PT = Portugal, PVC = Polyvinyl chloride, RD = Resource depletion, TA = Terrestrial acidification, TE = Terrestrial eutrophication, W/ALU = wood/ALU, W/C = wood/composite

C.6.3.2.2. Quantitative description of impacts at different lifecycle stages

There is indicative screening level data available on the climate change impacts of different window frame materials (in $kgCO_2eq$) (ECHA market survey 2023). Emissions associated to the production stage of windows frames are (per meter of window profile): 26–107 $kgCO_2$ for PVC frames, 3–17 $kgCO_2$ for wood and 25–77 $kgCO_2$ for aluminium-clad wood frames. It could be argued that CO_2 emissions from the production of wooden frames are in the lower range, followed by clad-wood frames, and that emissions from PVC frames are in the higher range of emissions. Estimates of the emissions from use and the end-of-life treatment of window frames are rather few and highly uncertain, and thus not reported here.

Table 29 presents the CO_2 emissions for PVC, wood and aluminium-clad wood frames and their differences for the production stage. The social cost of carbon emissions has been estimated based on the average price of the EU ETS carbon permit in 2022 (€80.82/tonne) (ICAP, 2023). The production of PVC window frames results in higher CO_2 emissions compared to wood and aluminium-clad wood, and thus the social costs from CO_2 emissions from PVC in the production phase are also higher.

The use phase is important for CO_2 emission from windows, as they impact the energy demand of buildings via heat loss. The most important factor for heat loss (thermal transmittance) of windows is the number of glass layers, and similar thermal insulation can be achieved with all frame materials (Saadatian et al., 2021a). This indicates that there would be no significant differences in heat loss (and CO_2 emissions) in the use phase of windows across frame materials.

Table 29: CO_2 emissions and social cost of carbon emissions for PVC and alternative materials from the production stage. The standard window has approximately 5.4 m of frame material.

	PVC	Wood	Aluminium-clad wood
CO2 emissions ($kgCO_2eq$/ window, 1.82m2)	140–577	16–92	135–416
Difference to PVC in emissions ($kgCO_2eg$/window, 1.82m2)	-	-(124–486)	-(5–162)
Total units of window frames (million windows/year)	28.3–39.3		
Difference to PVC in total emissions on average (million $kgCO_2eq$/year)	-	-11 000	-3 000
Difference to PVC in the social cost of carbon emissions on average (million €/year)		-913	-263

Sources: CO2 emissions: ECHA market survey 2023; cost of carbon: EU ETS permit price in 2022 (ICAP, 2023)

C.6.4. Alternative additives

Of the prioritised additives, no plasticisers or flame retardants are used in window frames.

C.6.4.1. Heat stabilisers

In the typical average compounding, PVC frames contain 19 % additives. Altogether, 3 % of the total volume of the frame are stabilisers and lubricants. Stabilisers used in window frames are largely mixed metal stabilisers (mainly Zn/Ca). Of the prioritised additives, only heat stabilisers (organotins and phenyl 1,3-diones) are used in window frames with 0.06 % of the total volume of the PVC frame (Table 30). Organotins are only used in edge bends (CfE3, #1708, VinylPlus).

Out of the organotins used, DOTE and DMTE are classified as high concern additives (Table 30). MMTE and DOT-MalEt are medium concern and there is currently no identified concern for MOTE. Organotins are more costly than other heat stabilisers and are thus used specifically for their performance-enhancing properties (CfE3, #1708, VinylPlus). Organotins contribute to the long-term heat stability and durability of the product, provide colour retention and good processability with high through put (CfE3, #1708, VinylPlus). Although mixed metal stabilisers are largely used in window frames, they have a lower performance in terms of long-term heat stability and durability (CfE3, #1708, VinylPlus).

The price of organotin additives is on average €9 000–12 000/tonne, while Zn/Ca stabiliser costs €5 000–7 000/tonne (ESPA, email communication, 18/05/2023). However, a 1-3 times larger quantity of the Zn/Ca stabiliser is needed (ESPA, email communication, 18/05/2023). Assuming the average price and taking into account the larger quantity of stabilisers needed, Zn/Ca stabiliser would be approximately €1 500/tonne more expensive than organotins. For the total volume of organotins in window frames (600 tonnes/year), the cost of moving to Zn/Ca stabilisers would be €0.9 million per year.

Lower heat stability with mixed metal stabilisers may also reduce the processing time window for converters, increasing downtime and generating more scrap, as well as increase the energy consumption in manufacturing, lead to increased risk of damage to machinery and reduce the recyclability of PVC (CfE3, #1625, Swish Building Products; #1675, BENVIC SAS).

MOTE and MMTE would have lower concern than DOTE and DMTE, but according to industry, DOTE has already been substituted by MOTE to the extent possible, and it is not possible to fully replace DOTE with MOTE and DMTE with MMTE. Different organotins bring specific technical performance properties, and hence cannot simply replace each other (CfE3, #1708, VinylPlus). More complete analysis of replacing DOTE will be possible when information is available from applications for authorisation on the technical performance and costs of alternatives for DOTE, starting from Q3 of 2023.

As no alternative additives to organotins with similar performance are currently available, eliminating their use would require replacing them with lower-performing additives, such as mixed metal stabilisers, developing novel additives that perform similarly, or replacing PVC window frames with alternative materials (see section C.6.3 for cost estimates).

Stabilisers are relatively small volume products (e.g. compared with plasticisers) and often made in batch reactors (CfE3, #1708, VinylPlus). Thus, the replacement costs are not as high as for plasticisers (CfE3, #1708, VinylPlus). However, the development of new stabilisers are expected to incur significant costs, including R&D costs associated with the adjustment for formulations and testing of key properties for compounders, evaluation of formulations and alignment with application requirements for converters, conformity with norms or quality labels either for the compounders or converters, as well as investments to build new plants and machinery (CfE3, #1657, BENVIC SAS, #1708, VinylPlus). Precise cost estimates of developing novel heat stabilisers to replace organotins are not available, but earlier substitution costs could give potential indication of their magnitude. For example, costs of replacing lead-based stabilisers over a period of 15 years were of the order of €100–250 million (CfE3, #1708, VinylPlus). Additionally, reformulation, R&D and requalification cost at converters may be significant, reaching up to €5 million for a single company (CfE3, #1708, VinylPlus).

Table 30: Currently used prioritised and alternative heat stabilisers in window frames

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used heat stabilisers (estimated volume in tonnes)	Organotins: DOTE (50–335 tonnes/year), DMTE (85–575 tonnes/year)	Organotins: MMTE (15–95 tonnes/year), DOT-MalEt (7–50 tonnes/year) DOTTG (1–6 tonnes/year) Phenyl 1,3-diones: 'Reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione' (915-316-2) (110–760 tonnes/year)		Organotins: MOTE (10–85 tonnes/year)
Likely alternative heat stabilisers				Mixed metal stabilisers (Zn/Ca)*

*Notes: * These substances are also currently used in window frames in significant volumes and were not prioritised (Appendix B)*

C.6.4.2. Supply chain impacts

The main impacts on the supply chain of chemical providers would occur from replacing additives with ones with lower concern. Both DOTE and MOTE are mainly manufactured in the EU (DOTE 80 %, MOTE 65 %), as well as is 'reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione' (72 %). Almost all DMTE and DOT-MalEt is imported (6–7 % manufactured in the EU) and MMTE is fully imported.

Import of Zn/Ca stabilisers to the EU is negligible, except from Turkey (ESPA, email communication, 18/05/2023). Thus, no significant negative supply chain impacts in the EU are expected from replacing organotins with mixed metal stabilisers.

C.7. Packaging

C.7.1. Description of use and performance criteria

In packaging, PVC is used in food packs and trays (rigid disposable boxes), shrink foils (also called shrink wraps or films, plastic wraps which shrink to fit around a product when exposed to heat), cling films, closures (PVC polymer-based coating in enclosed containers), labels, transparent gift films, and blister packs (rigid plastic sheets formed into blisters which hold individual products or pharmaceutical doses) (EC (2022); CfE2, #1552, Plastics Recyclers Europe). The volume of PVC used in bottles is currently close to zero (CfE2, #1601, VinylPlus; CfE2, #1552, Plastics Recyclers Europe). Blister packs are discussed in their own section (section C.8), as they are used as medical packaging and use-specific information is available.

Performance criteria for PVC in packaging include durability (incl. impact tolerance), transparency, barrier protection, temperature resistance and in some cases flexibility (ECHA market survey 2023).

C.7.2. Baseline

Overall, the use of PVC in other than medical packaging is limited compared to other plastics. In food packaging, PVC is used in niche application with specific performance requirements (VinylPlus, email communication, 09/10/2023). In non-food packaging (excluding medical packaging), PVC has already been largely replaced with PE, PP, PET and PS (VinylPlus, email communication, 09/10/2023). However, more than 400 000 tonnes of compounded PVC is used in food and non-food packaging across Europe each year (ECVM, 2023b). The major packaging applications are rigid film (about 80 %), flexible film, such as cling film (15 %), and closures (3 %). A major share of rigid film is used in pharmaceutical packaging (blister packs, see section C.8). Table 31Table 31 shows the volumes used for packaging applications, excluding pharmaceutical packaging (i.e. blister packs).

Table 31: Use of PVC in food and non-food packaging (excluding blister packs)

Use	**Packaging for food and non-food**	**Rigid food and non-food packaging**	**Flexible film, such as cling film**	**Closures**	**Other**
Description	Rigid and soft food and non-food packaging, excluding pharmaceutical packaging (blister packs)				
Main performance criteria	durability (incl. impact tolerance), transparency, barrier protection, temperature resistance, for soft applications flexibility				
Compounded volume of PVC used per year in EU (tonnes) (207)	129 000–332 000	41 000–244 000	66 000	13 000	9 000
Type of PVC	Both	Rigid	Soft	Soft	Soft
Share of additives in typical average compounding	-	1 % stabilisers and lubricants; 3 % fillers, pigments, impact modifiers; 0 % plasticisers	No information on typical compounding, so the following assumptions are made: 1 % stabilisers and lubricants; 3 % fillers, pigments, impact modifiers; 30 % plasticisers		

Prioritised substances used as additives		Heat stabilisers: Organotins (DOTE, MOTE, DMTE, MMTE)	Plasticisers: DINP, DIDP

Sources: CfE2, #1601, VinylPlus; #1587, EuPC

C.7.3. Alternative materials

There are several alternative materials to PVC in packaging, including both plastics and other types of materials:

- Polyethylene terephthalate (PET)
- Polyethylene (HDPE/LDPE/LLDPE)
- Polypropylene (PP), including BOPP (biaxially oriented PP)
- Polystyrene (PS)
- Polyamide (PA) (BOPA - biaxially oriented nylon)
- Polychlorotrifluoroethylene (PCTFE)
- Ethylene vinyl alcohol (EVOH) – only used in combination with PVC or other materials in multilayer applications
- Polyvinylidene chloride (PVDC) - only used in combination with PVC or other materials in multilayer applications
- Bioplastics
- Aluminium
- Paper
- Ceramics
- Glass.

Availability and feasibility of alternatives to PVC depends on the packaging application. For example, LDPE would be a suitable replacement for PVC in cling film (CfE2, #1552, Plastics Recyclers Europe), and PVC labels can be replaced with PE or PP (CfE2, #1593, Zero Waste Europe). Overall, it seems that more alternatives are available for other rigid PVC food and non-food packaging than blister packs (ECHA market survey 2023).

Packaging is single-use, and lifetime is relevant in the sense that the material should ensure sufficient shelf-life. Stakeholder consultation indicates that the lifetime of PVC alternatives in packaging is not one of the key performance criteria categories of concern (ECHA market survey 2023), and thus there appear to be no substantial differences between the lifetime of PVC and the alternative materials in packaging.

The alternative materials, including PET, PE, PP, PS, PA, bioplastics, aluminium, paper, ceramics and glass, are all produced in considerable quantities.

Comparison of key functionalities of PVC and alternative materials for packaging is presented in

Table 32. There are some differences across materials e.g. in impact tolerance, transparency and barrier protection, but no immediate critical differences to PVC. Furthermore, discussions with Flexible Packaging Europe (2023) revealed that all alternatives for PVC in packaging perform the same if not better than PVC (ECHA market survey 2023).

Table 32: PVC and alternative materials for packaging

Material	**Negative / Positive impacts on performance compared to PVC**	**Examples of uses in packaging**
PVC	-	Food packs/ trays, cling film, closures
Polyethylene terephthalate (PET)	-	Bottles, food and personal care packaging
Polyethylene (HDPE/LDPE/LLDPE)	Lower chemical and wear resistance, lower barrier resistance (HDPE), not transparent (translucent)	Consumer bags, frozen food trays, films (HDPE) Squeezable tubes and bottles, wrappers and bags, frozen food containers, coating material for bottle cartons (LDPE)
Polypropylene (PP), including BOPP	Better fatigue and chemical resistance	Closures, boil-in-bag food packages, containers exposed to high levels of thermal and chemical stress
Polystyrene (PS)	Lower impact tolerance	Vending cups, yogurt containers, packaging of fragile products
Polyamide (PA) (BOPA - biaxially oriented nylon)	-	Flexible films and foils for food packaging and shrink bags for e.g. meat and cheese (Tyuftin and Kerry, 2020)
Ethylene vinyl alcohol (EVOH) (only used in combination with PVC or other materials in multilayer applications)	Better gas barrier protection	Multilayer packaging to improve gas barrier (IMPACT, 2018) in rigid and semi-rigid food packaging (Packagingbest, 2021)
Polyvinylidene chloride (PVDC) (only used in combination with PVC or other materials in multilayer applications)	Better gas and water barrier protection	Multilayer packaging of food (e.g. meat, cheese, snack foods, tea, coffee and confectioneries) (Goswami and Mangaraj, 2011), cosmetics (Farmer, 2013)
Polychlorotrifluoro-ethylene (PCTFE)	-	Films in food packaging (ERIKS, 2023)
Bioplastics	Various, depending on the exact bioplastic	Bags, films, containers, bottles, wrappings, coatings (Shlush and Davidovich-Pinhas, 2022)
Aluminium	Lower impact tolerance, better barrier protection, not transparent	Food and closures, beverage packaging (cans) (ECONOMIST, 2022), cosmetics (Metalpackagingeurope, 2023)
Paper	Lower impact tolerance, not transparent	Food cartons and containers (Metalpackagingeurope, 2023), non-food packaging (e.g. personal care, electronics, toys) (UPM, 2023)
Ceramics	Lower impact tolerance, not transparent, not flexible	Electronic packaging (SAMaterials, 2023)
Glass	Lower impact tolerance, not flexible	Bottles and jars (Agnusdei et al., 2022)

Notes: Sources: technical performance and uses: ECHA market survey 2023, Hahladakis and Iacovidou (2018). NA = not available

C.7.3.1. Economic impacts

The economic impacts of substitution include possible changes in material costs, investment costs and costs related to testing and validation of the new material. Only information on material costs is available.

The amount of the material itself, as well as other materials/substances needed for a product can differ across alternatives. Thus, a simple comparison of material costs per tonne is not sufficient to capture all impacts from changing the material. In addition to material costs, replacing PVC with non-polymer alternatives and also other polymers may require different technology to process the materials and changes to packaging lines, entailing investment costs (ECHA market survey 2023, Flexible Packaging Europe).

Table 33 presents a comparison of the market price of PVC and alternative materials per tonne of material and for the total sales volume of PVC. These include only the price of the material and no other costs. There is no information on lifetime costs or costs of final products. Thus, these can be considered only as supportive information.

The costs of the materials indicate that PP, bioplastics and aluminium would be more expensive and many other materials cheaper than PVC. EVOH and PVDC, which are only used in combination with PVC or other materials in multilayer applications, are considerably more expensive. However, calculations of cost differences assume that the same amount of material is needed for the product as PVC, which does not capture the full cost of changing the material. Based on information from stakeholders, the costs per square meter of material are the lowest for PVC, followed by PET, PO, COC/PO and aluminium (ECHA market survey 2023, Flexible Packaging Europe). Further, investment costs related to material changes, as well as costs of investigation, stability testing, and product verification are excluded due to lack of estimates.

Many alternative plastics and other materials to PVC are already used in packaging. Therefore, there are already experiences of using these in packaging and development of novel alternatives would not be needed, considering that various alternatives are available and no significant issues with performance have been identified. As there are several potential alternative materials for packaging, availability issues are not expected to be significant.

Table 33: Cost differences between PVC and alternative materials used for food and non-food packaging, excluding pharmaceutical packaging.

Material	**Market price of material (€/tonne)**	**Difference to PVC in material costs (€/tonne)**	**Difference in annual costs, for the total sales volume of PVC in packaging (rigid and soft, excluding pharmaceutical packaging) (million €)**
PVC	1 808	-	-
Polyethylene terephthalate (PET)	1 652	-156	-(20–52)
Polyethylene (HDPE/LDPE/ LLDPE)	1 716	-92	-(12–30)
Polypropylene (PP), including BOPP	2 064	256	33–85
Polystyrene (PS)	1 587	-221	-(28–73)
Polyamide (PA) (BOPA - biaxially oriented nylon)	1 356	-452	-(58–150)
Ethylene vinyl alcohol (EVOH) (only used in combination with PVC or other materials in multilayer applications)	6 299	4 491	577–1 489
Polyvinylidene chloride (PVDC) (only used in combination with PVC or other materials in	3 563	1 755	226–582

multilayer applications)			
Polychlorotrifluoroethylene (PCTFE)	1 140	-668	-(86–221)
Bioplastics	4 275	2467	317–818
Aluminium	2 286	478	61–158
Paper	897	-911	-(117–302)
Ceramics	NA	NA	
Glass	432	-1 376	-(177–456)

Notes: Sources: costs: Chemanalyst (2022) (PVC, PET, PE, PP, PS, EVOH), Made-in-China (2023b) (PVDC, PCTFE), Procurement Resource (2022) (PA, glass), Sparkoncept (2023) (bioplastics), Markets Insider (2022) (aluminium). Annual sales volume of PVC in packaging (rigid and soft, excludes blister packs): 129 000 – 332 000 tonnes.
NA = not available

Based on the price of the material and sales volume of PVC, the total sales value of PVC packaging in the EU is €230–600 million per year. This is a minimum value based on the value of the material, and information on the purchase price of the final products is not currently available. Considering that 100 % of that production volume takes place in the EU and assuming a profit margin of 10 %, the profits for the EU producers would be around €23–60 million per year.

According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the PVC packaging producers would be around €3–8 million. (SEAC, 2021)

C.7.3.2. Life cycle impacts

C.7.3.2.1. Qualitative description of impacts at different lifecycle stages

Main life cycle impacts of packaging come from the production, feedstock (raw material supply) and transportation phases (Baitz et al., 2004). The use phase is not very relevant due to the short lifetime of the products. The weight of the material (mass ratio packaging/product) plays a key role in the transportation impacts. Overall, plastics appear rather preferable for non-reusable packaging in terms of impacts over the total life cycle, but there is no consensus which plastic is overall the most favourable (Baitz et al. 2004). No recent LCA studies on packaging were found in the study screening.

It is not possible to compare the CO_2 emissions between packaging materials, due to the large number of packaging types and subsequent lack of comparable data, as well as lack of CO_2 emission data for some materials from literature, environmental product declarations or stakeholders (ECHA market survey 2023).

C.7.4. Alternative additives

Plasticisers that are on the list of prioritised additives are used in soft packaging and organotins in rigid packaging.

C.7.4.1. Plasticisers

Soft packaging contains approximately 30 % of plasticisers of the total compounded volume (CfE2, #1601, VinylPlus). These are mainly substances that do not have an identified concern currently or are not in the list of prioritised additives (DOTP, DICH, ATBC and DEHA), but also some DINP and DIDP are used (Table 34).

Medium and low concern plasticisers (DINP, DIDP) could also potentially be replaced with no identified concern plasticisers (DOTP) that are already used in packaging. In 2020-2022, DOTP has been on average €50/tonne more expensive than DINP and DIDP (Chemorbis, 2022b). The additional cost from using DOTP would be €0.13 million per year for the total volume of DINP and DIDP used in soft packaging (2 575 tonnes/year).

Table 34: Currently used prioritised plasticisers in soft PVC food and non-food packaging (excluding blister packs)

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used plasticisers (estimated volume in tonnes)	None	DINP (1 255 tonnes/year) D810P (65 tonnes/year)	DIDP (1 320 tonnes/year)	DOTP (5 940 tonnes/year)
Likely alternative plasticisers				DINP, DIDP => DOTP

C.7.4.2. Heat stabilisers

Organotins (DOTE, MOTE, DMTE, MMTE) are used in rigid food packaging to meet performance requirements, including colour retention, transparency, clarity, good shelf-life and long-term heat stability (CfE3, #1708, VinylPlus). They are more costly than other heat stabilisers and are thus used specifically for their performance-enhancing properties (CfE3, #1708, VinylPlus). Use of organotins in rigid food contact packaging is permitted by the EU food contact regulations based on the EU risk assessment. All heat stabilisers used in rigid food packaging are organotins, and they make up 1 % of the total compounded PVC volume (Table 35). Stakeholder indicated initially that in rigid packaging, 60 % of MOTE, 11 % of DOTE and 29 % of DMTE and MMTE in total would be used (CfE3, #1708, VinylPlus).

According to stakeholders, without organotin stabilisers, rigid PVC food packaging applications could no longer be produced due to lower performance of alternative stabilisers (CfE3, #1708, VinylPlus). No currently used alternative substances to organotins (DOTE, MOTE, DMTE, MMTE) in rigid food packaging with similar performance have been identified.

MOTE and MMTE would be of lower concern than DOTE and DMTE, but there is contradictory information on their interchangeability from stakeholders. According to industry, DOTE has already been substituted by MOTE to the extent possible, and it is not in general possible to fully replace DOTE with MOTE and DMTE with MMTE, as different organotins bring specific technical performance properties and hence cannot simply replace each other (CfE3, #1708, VinylPlus). However, this may not be true for packaging. In pharmaceutical packaging, DOTE has already been replaced with MOTE, and there are indications that DOTE and MOTE are easily exchangeable in all packaging (pharmaceutical packaging representative, personal communication, 29/09/2023). Similarly, there has been a major move away from DOTE to MOTE in food packaging since 2018 (VinylPlus, email communication, 09/10/2023). Thus, it appears that specifically in packaging, MOTE can replace DOTE without any major consequences on performance or costs. More complete analysis of replacing DOTE will be possible when information is available from applications for authorisation on the technical performance and costs of alternatives for DOTE, starting from Q3 of 2023.

Although mixed metal stabilisers (mainly Zn/Ca) are already used in packaging and they are cheaper than organotins, they have a lower performance (CfE2, #1601, VinylPlus; CfE3, #1708, VinylPlus). The price of organotin additives is on average €9 000–12 000/tonne, while Zn/Ca stabilisers cost €5 000–7 000/tonne (ESPA, email communication, 18/05/2023). However, a 1-3 times larger quantity of Zn/Ca stabiliser is needed (REF). Assuming the average price and taking into account the larger quantity of stabilisers needed, Zn/Ca stabiliser would be approximately €1 500/tonne more expensive. For the total volume of organotins in packaging (1 425 tonnes/year), the cost of moving to Zn/Ca stabilisers would be €2.1 million per year.

Lower heat stability with mixed metal stabilisers may also reduce the processing time window for converters, increasing downtime and generating more scrap, as well as increase the energy consumption in manufacturing, increase the risk of damage to machinery and reduce the recyclability of PVC (CfE3, #1625, Swish Building Products; #1675, BENVIC SAS).

Table 35: Currently used prioritised and alternative heat stabilisers in rigid PVC food and non-food packaging (excluding blister packs)

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used heat stabilisers (estimated volume in tonnes)	DOTE (45–270 tonnes/year), DMTE (60–355 tonnes/year)	MMTE (60–355 tonnes/year)		MOTE (245–1 465 tonnes/year)
Likely alternative heat stabilisers				MOTE Mixed metal stabilisers (Zn/Ca)*

*Notes: * These substances are also currently used in packaging in significant volumes and were not prioritised (Appendix B)*

Considering that mixed metal heat stabilisers would mean lower performance than organotins, rigid PVC food packaging applications could be replaced with alternative materials (see section C.7.3).

Alternatively, novel stabilisers could be developed. Stabilisers are relatively small volume products (e.g., compared with plasticisers) and often made in batch reactors (CfE3, #1708, VinylPlus). Thus, the replacement costs are not as high as for plasticisers (CfE3, #1708, VinylPlus). However, development of new stabilisers are expected to incur significant costs, including R&D costs associated with the adjustment for formulations and testing of key properties for compounders, evaluation of formulations and alignment with application requirements for converters, conformity with norms or quality labels either for the compounders or converters, as well as investments to build new plants and machinery (CfE3, #1657, BENVIC SAS, #1708, VinylPlus). Precise cost estimates of developing novel heat stabilisers to replace organotins are not available, but earlier substitution costs could give potential indication of their magnitude. For example, costs of replacing lead-based stabilisers over a period of 15 years were of the order of €100 million – 250 million (CfE3, #1708, VinylPlus). Additionally, reformulation, R&D and requalification cost at converters may be significant, reaching up to €5 million for a single company (CfE3, #1708, VinylPlus).

C.7.4.3. Supply chain impacts

The main impacts on the supply chain of chemical providers would occur from replacing additives with ones that have lower concern.

Regarding plasticisers, DINP and DIDP are almost entirely produced in Europe, while 67 % of DOTP is imported, mainly from South Korea, US, China and Turkey (Chemorbis 2023; CfE3, #1708, VinylPlus). Thus, moving to DOTP would mean losses in profit for European plasticisers producers.

The total value of the DINP and DIDP production for soft packaging in the EU, with the mean price of €1530/tonne and mean volume of 2640 tonnes of DINP and DIDP per year, is around €4 million per year. There is no information on the profit margin of plasticiser manufacturers, but with an assumed 10 % profit margin, the profits for the EU producers would be around €0.4 million per year.

According to SEAC’s approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the EU producers from moving from DINP and DIDP to DOTP in soft packaging would be around €50 000. (SEAC, 2021)

If DOTP manufacturing capacity would increase in Europe, the loss in the profit for the other additive producers would be eventually replaced by the increase in the profit of DOTP producers.

For heat stabilisers, DOTE and MOTE are mainly manufactured in the EU (DOTE 80 %, MOTE 65 %), while almost all of DMTE and all of MMTE is imported. Import of Zn/Ca stabilisers to the EU is negligible, except for Turkey (ESPA, email communication, 18/05/2023). Thus, no significant negative supply chain impacts in the EU are expected from replacing organotins with mixed metal stabilisers.

C.8. Medical packaging: Blister packs

C.8.1. Description of use and performance criteria

Blister packs are rigid sheets formed into blisters which hold individual products, sealed with a lidding foil. They are largely used for pharmaceutical (medicine) and nutraceutical (such as dietary supplements and functional foods) purposes, but also for packaging other individual products.

Blister packs have a mouldable base film with cavities and a lidding foil. The lidding foil is typically aluminium. The base film is usually plastics (PVC, PP or PET, sometimes combined with PVDC, PCTFE or COC for multilayer films), but it can also be made of aluminium (de Oliveira et al., 2021). The majority of base films in blisters on the market are either 'thermoformed' (single or multi-layer plastic) or 'cold formed' (aluminium or multi-layer laminate of aluminium and plastic). Both of these types primarily use PVC for the plastic component (CfE2, #1588, EFPIA). The product determines if a single or multi-layer blister is used (CfE2, #1588, EFPIA). A single layer of plastic is often used when the product is robust and low barrier protection is required. Multi-layer of plastics provides more barrier protection. Some blister packs are also manufactured entirely from aluminium, referred to as push-through-packs (Sphera, 2022).

Overall performance criteria for PVC in packaging include durability (incl. impact tolerance), transparency, barrier protection and in some cases flexibility (ECHA market survey 2023). For blister packs, the critical criterion appears to be barrier resistance.

C.8.2. Baseline

Of all packaging applications, PVC is used the most commonly in pharmaceutical or nutraceutical blister packs (ECHA market survey 2023, Flexible Packaging Europe). PVC is the dominant material for the base film for pharmaceutical blister packs (Sphera 2022). Blisters can contain 30–100 % of PVC (CfE2, #1588, EFPIA). PVC used for blister packs does not contain plasticisers, and is thus rigid (CfE2, #1588, EFPIA).

Table 36 presents the basic information on use of PVC in blister packs.

Table 36: Use of PVC in blister packs

Use	Blister packs
Description	PVC is used in the mouldable base film, often together with some other plastics or aluminium
Main performance criteria	Durability (incl. impact tolerance), transparency, barrier protection, in some cases flexibility
Volume of compounded PVC used in medical packaging (mainly blister packs) in the EU in 2021 (tonnes/year)	47 000 – 284 000 tonnes/year
Type of PVC	Rigid
Share of additives in typical average compounding	1% stabilisers and lubricants; 3% fillers, pigments, impact modifiers; 0% plasticisers

Prioritised substances used as additives	Heat stabilisers: Organotins (DOTE, MOTE, DMTE, MMTE and DOT-MalEt) No prioritised plasticisers No prioritised flame retardants

Sources: ECHA market survey 2023; CfE2, #1601, VinylPlus; CfE2, #1587, EuPC

C.8.3. Alternative materials

Alternative materials to PVC in blister packs include other plastics and aluminium. Some of the general alternatives for PVC packaging are not considered suitable for blister packs, including PS, BOPA, EVOH, bioplastics, paper, ceramics and glass (ECHA market survey 2023). Some novel alternatives are also being investigated, such as CoPET (copolyester), PETG, PE and recyclable polyolefin laminate (CfE2, #1588, EFPIA; Sphera 2022).

Alternatives to PVC in blister packs include:
- Aluminium
- Polyethylene terephthalate (PET)
- Polypropylene (PP), including BOPP (biaxially oriented PP)
- Polychlorotrifluoroethylene (PCTFE)
- Cyclic olefin copolymer (COC/PO) – only used in combination with PVC or other materials in multilayer applications
- Ethylene vinyl alcohol (EVOH) – only used in combination with PVC or other materials in multilayer applications
- Polyvinylidene chloride (PVDC) - only used in combination with PVC or other materials in multilayer applications

Packaging is single-use, and lifetime is relevant in the sense that the material should ensure sufficient shelf-life. The expected lifetime in pharmaceutical packaging lies between 5-10 years (ECHA market survey 2023, Flexible Packaging Europe).

All alternative materials are produced in considerable quantities. However, they have other competing uses.

Pharmaceutical blister packs are primary packaging, meaning that they come into direct contact with the product and affect shelf-life. There must be no interaction between the medicinal product and packaging material, and packaging must protect the products against external influences (CfE2, #1588, EFPIA). For pharmaceutical blister packs, barrier protection (in particular water barrier) is the most critical factor, as it ensures drug stability and affects shelf-life (ECHA market survey 2023, Flexible Packaging Europe, anonymous). In addition, in the marketing authorisation, the company has to demonstrate the integrity and stability of the medicine in its packaging for the entire shelf-life. For other types of products (nutraceuticals, other products), barrier characteristics may not be as important.

Comparison of PVC and alternative materials for blister packs is presented in Table 37Table 37. Based on the available data, it appears that the alternative materials perform as well as or better than PVC in most of the aspects. Only differences in barrier protection and transparency can be discerned. PVC itself has a low barrier protection, but it can be coated with PVDC or PCTFE in multilayer blisters to improve the barrier (de Oliveira et al., 2021). COC/PO, PCTFE, aluminium and PP have a higher water barrier than PVC and could in that sense be suitable alternatives to PVC in blister packs requiring a high barrier (de Oliveira et al. 2021; ECHA market survey 2023).

The potential alternatives also have some disadvantages. PP is not transparent. It also has a lower light barrier (without additives) and a high shrinkage rate, making it difficult to mould (de Oliveira et al., 2021, PEREIRA and FERREIRA, 2017). Aluminium has an excellent light, oxygen and water barrier (de Oliveira et al. 2021), but it is not transparent. It is often combined with PVC or oriented polyamide (OPA/nylon) to improve structural characteristics (de Oliveira et al. 2021). COC provides good resistance and has a higher water barrier than PVC (de Oliveira et al. 2021). PET has a lower water barrier, which could impact shelf-life (ECHA market survey 2023).

Multilayer blisters that combine several materials are common, so these could also present alternative to PVC and multilayer PVC blister packs.

Table 37: PVC and alternative materials for blister packs

Material	**Negative/ positive impacts on performance compared to PVC**
PVC	-
Aluminium	Lower impact tolerance (fragile to high impact), better barrier protection, not transparent
Polyethylene terephthalate (PET)	-
Polypropylene (PP), including BOPP	Better water barrier, not transparent
Polychlorotrifluoroethylene (PCTFE)	Better barrier protection
Cyclic olefin copolymer (COC/PO), only used in combination with PVC or other materials in multilayer applications	-
Ethylene vinyl alcohol (EVOH), only used in combination with PVC or other materials in multilayer applications	Better barrier protection
Polyvinylidene chloride (PVDC), only used in combination with PVC or other materials in multilayer applications	Better barrier protection

Sources: technical performance: ECHA market survey 2023, de Oliveira et al. 2021; costs: Chemanalyst (2022) (PVC, PET, PP, EVOH), Made-in-China (2023b) (PCTFE, PVDC), (Alibaba) (COC/PO), Markets Insider (2022) (aluminium)

C.8.3.1. Economic impacts

The economic impacts of substitution include possible changes in material costs, investment costs and costs related to testing, validation and approval of the new material for pharmaceutical packaging. There are estimates of the material costs, and some information on the investment and validation costs required for the alternative materials.

The amount of the material itself, as well as other materials/substances needed for a product can differ across alternatives, and thus a simple comparison of material cost per tonne is not sufficient to capture all impacts from changing the material. For example, cold-formed aluminium base films for pharmaceutical packaging need larger cavities and therefore consume more material for the same amount of product than PVC (de Oliveira et al. 2021).

In addition to material costs, replacing PVC with other polymers may require different technology to process the materials and changes to packaging lines, entailing investment costs (ECHA market survey 2023, Flexible Packaging Europe; CfE2 #1588, EFPIA).

Any change to the materials used in blister packs takes several years with significant labour and non-labour costs (CfE2 #1588, EFPIA). Early investigations include examining downstream impacts through the supply chain and technical performance of the material. Execution of the change requires verification testing for product function (at shelf life), sterility, etc. In addition, it can also potentially trigger marketing authorisation/registration activities, depending on local health authority requirements. For pharmaceutical products, there is existing authorisation for the use of PVC (ECHA market survey 2023, Flexible Packaging Europe), and any change in the packaging composition requires an update of the pharmaceutical application per distinct type of item, as well as new stability and sterilisation tests, which entail costs (ECHA market survey 2023, Flexible Packaging Europe). The costs will vary significantly depending on whether the new formulation is compatible with existing manufacturing assets, the number of assets impacted, and the number of products impacted.

According to a recent example, a primary packaging material change which required marketing authorisation / registrations amendments on a global scale (product was manufactured and packaged in the EU but also for a global market) resulted in costs of up to 3 million euros per product with a 5-year timeline (CfE2 #1588, EFPIA). For this specific example, the scope of work included early investigation, stability testing and product verification, but no asset amendments. It is unclear to what extent this information is representative for other products and how many products would be affected, and thus the total costs of material changes cannot be estimated.

Table 38 presents costs of PVC and alternative materials. These include only the price of the material per tonne and no other costs. There is no information on lifetime costs or costs of final products. Thus, these can be considered only as supportive information.

The costs of the materials indicate that aluminium and PP would be more expensive and PET, PCTFE and COC cheaper than PVC. EVOH and PVDC, which are only used in combination with PVC or other materials in multilayer applications, are considerably more expensive than the other materials. However, calculations of cost differences assume that the same amount of material is needed for the product as PVC, which does not capture the full cost of changing the material. Based on information from stakeholders, the costs per square meter of material are the lowest for PVC, followed by PET, PO, COC/PO and aluminium (ECHA market survey 2023, Flexible Packaging Europe).

Investment costs related to material changes, as well as costs of investigation, stability testing, product verification and potential approval are not presented due to lack of estimates.

Table 38: Cost differences between PVC and alternative materials used for blister packs.

Material	**Market price of material (€/tonne) in Q4/2022**	**Difference to PVC in material costs (€/tonne)**	**Difference in annual costs, for the total sales volume of PVC blister packs (million €)**
PVC	1 808	-	
Aluminium	2 286	478	23–136
Polyethylene terephthalate (PET)	1 652	-156	-(7–44)
Polypropylene (PP), including BOPP	2 064	256	12–73
Polychlorotrifluoroethylene (PCTFE)	1 140	-668	-(32–190)

Cyclic olefin copolymer (COC/PO)	903	-905	-(43–257)
Ethylene vinyl alcohol (EVOH)	6 299	4491	213–1278
Polyvinylidene chloride (PVDC)	3 563	1755	83–499

Notes: Sources: ECHA market survey 2023, Market Insider (aluminium); Chemanalyst (PVC, PET, PP); Made-in-China (PCTFE); Alibaba (COC). The annual sales volume of PVC in blister packs is 47 000 – 284 000 tonnes.

According to stakeholders, there may be supply issues for pharmaceutical products, as availability of compliant alternative materials and products can become a bottleneck (ECHA market survey 2023, Flexible Packaging Europe, anonymous). Validation and approval of new materials might take more than 3 years (ECHA market survey 2023, Flexible Packaging Europe, anonymous). There are fewer alternative materials to PVC available for blister packs than other types of packaging.

Based on the price of the material and sales volume of PVC, the total sales value of PVC blister packs in the EU is €90–510 million per year. This is a minimum value based on the value of the material, and information on the purchase price of the final products is not currently available. Considering that 100 % production takes place in the EU and assuming a profit margin of 10 %, the profits for the EU producers would be around €9–51 million per year.

According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the PVC blister pack producers would be around €1–7 million. (SEAC, 2021)

C.8.3.2. Life cycle impacts

C.8.3.2.1. Qualitative description of impacts at different lifecycle stages

There are only few life cycle studies on blister packs. Table 39As for the other types of packaging, it is not possible to compare the CO_2 emissions between packaging materials due to lack of comparable data from the literature, environmental product declarations or stakeholders (ECHA market survey 2023). However, aluminium has higher CO2 emissions during its production (de Oliveira et al. 2021).

Table 39 presents an overview of reviewed life cycle analysis studies for blister packs. The findings indicate that, in terms of life cycle impacts, PVC is preferable to aluminium and to the combination of PVC/PVDC or OPA/aluminium/PVC as the base film material (Bassani et al., 2022, Raju et al., 2016). However, the existing studies cover only part of the lifecycle (from resource extraction to the factory gate) and few alternative materials, and thus allow no conclusion on the preferable material throughout the entire life cycle and all potential alternative materials.

As for the other types of packaging, it is not possible to compare the CO_2 emissions between packaging materials due to lack of comparable data from the literature, environmental product declarations or stakeholders (ECHA market survey 2023). However, aluminium has higher CO2 emissions during its production (de Oliveira et al. 2021).

Table 39: Overview of LCA studies for blister packs

Author & year	**Type**	**Alternative materials assessed**	**Dimen-sions**	**Geogr. focus**	**System boundaries**	**Impact Categories**	**Material preferability ranking**
Raju et al. (2016)	Journal article	PVC-ALU, ALU-ALU	ENV	n.a.	Cradle to Gate	ADP elem., ADP fossil, AP, CED, EP, FAETP, GWP, HTP, MAETP, ODP, POCP, TETP, Water depletion	PVC > ALU
Bassani et al. (2022)	Journal article	PVC, PVC/PVDC, OPA/ALU/PVC	ENV	EU (PT)	Cradle to Gate	ADP fossil, AP, EP, GWP, ODP	PVC > PVC/PVDC > OPA/ALU/PVC

Notes: ADP = Abiotic depletion potential, ALU = Aluminium, AP = Acidification Potential, CED = Cumulated energy demand, ENV = Environment, EP = Eutrophication potential, EU = European Union, FAETP = Freshwater aquatic ecotoxicity potential, GWP = Global warming potential, HTP = Human toxicity potential, MAETP = Marine aquatic ecotoxicity potential, ODP = Ozone depletion potential, OPA = ortho-phthalaldehyde, PT = Portugal, PVC = Polyvinyl chloride, PVDC = Polyvinylidene chloride, TETP = Terrestrial ecotoxicity potential

C.8.4. Alternative additives

No plasticisers or flame retardants that are on the list of prioritised additives are used in blister packs.

C.8.4.1. Heat stabilisers

Organotins (DOTE, MOTE, DMTE, MMTE) are used in pharmaceutical packaging (blister packs), in applications that require colour retention, transparency and clarity, providing also long-term heat stability for a long shelf-life (CfE3, #1708, VinylPlus). 90 % of heat stabilisers used in rigid pharmaceutical packaging are organotins, and 10 % are mixed metal stabilisers (mainly Zn/Ca). MOTE is the main organotin used (60 % share of organotins), followed by DMTE and MMTE (together 29 %) and DOTE (11 %) (CfE3, #1708, VinylPlus) (Table 40). Organotins (DOTE, MOTE, DMTE, MMTE and DOT-MalEt) represent 0.9 % of the total compounded PVC volume used for blister packs.

Organotins are needed to meet performance requirements in packaging, including transparency, clarity and improved shelf-life (CfE3, #1708, VinylPlus). Without organotin stabilisers, stakeholders indicate that rigid pharmaceutical packaging applications could no longer be produced (CfE3, #1708, VinylPlus).

In pharmaceutical packaging, information indicates that DOTE has already been replaced with MOTE, and that DOTE and MOTE are easily exchangeable in all packaging (personal communication, pharmaceutical packaging representative, 29/09/2023). This would represent a switch to a substance of lower concern, while the use of organotins would continue.

Although mixed metal stabilisers (mainly Zn/Ca) are already used in packaging and they are cheaper than organotins, they have a lower performance (CfE2, #1601, VinylPlus; CfE3, #1708, VinylPlus). The price of organotin additives is on average €9 000–12 000/tonne, while Zn/Ca stabilisers cost €5 000–7 000/tonne (ESPA, email communication, 18/05/2023). However, a 1-3 times larger quantity of Zn/Ca stabiliser is needed (ESPA, email communication, 18/05/2023). Assuming the average price and taking into account the larger quantity of stabilisers needed, Zn/Ca stabiliser would be approximately €1 500/tonne more expensive. For the total volume of organotins in packaging (1 500 tonnes/year), the cost of moving to Zn/Ca stabilisers would be €2.2 million per year.

No currently used alternative substances to organotins in rigid pharmaceutical packaging with similar performance have been identified. Achieving similar performance as with the current heat stabilisers in blister packs would require the replacement PVC with alternative materials or development of novel additives. Cost estimates of replacing PVC with alternative materials are presented in section C.8.3.

Stabilisers are relatively small volume products (e.g., compared with plasticisers) and often made in batch reactors (CfE3, #1708, VinylPlus). However, in general the development of new stabilisers is expected to incur significant costs, including R&D costs associated with the adjustment for formulations and testing of key properties for compounders, evaluation of formulations and alignment with application requirements for converters who provide PVC components or products for pharmaceutical companies, and conformity with norms or quality labels either for the compounders or converters (CfE3, #1708, VinylPlus; #1588, EFPIA). The costs will vary significantly depending on whether the new formulation is compatible with existing manufacturing assets, the number of assets impacted, and the number of products impacted (CfE2 #1588, EFPIA).

Precise cost estimates of developing novel heat stabilisers to replace organotins are not available, but earlier substitution costs could give potential indication of their magnitude. For example, costs of replacing lead-based stabilisers over a period of 15 years were of the order of €100 million – 250 million (CfE3, #1708, VinylPlus). Additionally, reformulation, R&D and requalification cost at converters may be significant, reaching up to €5 million for a single company (CfE3, #1708, VinylPlus).

More complete analysis of replacing DOTE will be possible when information is available from applications for authorisation on the technical performance and costs of alternatives for DOTE, starting from Q3 of 2023.

Table 40: Currently used prioritised and alternative heat stabilisers in blister packs

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used heat stabilisers (estimated volume in tonnes)	DOTE (45–280 tonnes/year), DMTE (60–370 tonnes/year)	MMTE (60–370 tonnes/year)		MOTE (255–1 535 tonnes/year)
Likely alternative heat stabilisers				MOTE Mixed metal stabilisers (Zn/Ca)*

*Notes: * These substances are also currently used in blister packs and were not prioritised (Appendix B)*

C.8.4.2. Supply chain impacts

The main impacts on the supply chain of chemical provides would occur from replacing additives with safer ones. Both DOTE and MOTE are mainly manufactured in the EU (DOTE

80 %, MOTE 65 %). Almost all DMTE is imported (6–7 % manufactured in the EU) and MMTE is fully imported.

Import of Zn/Ca stabilisers to the EU is negligible, except for Turkey (ESPA, email communication, 18/05/2023). Thus, no significant negative supply chain impacts in the EU are expected from replacing organotins with mixed metal stabilisers.

C.9. Medical applications

C.9.1. Description of use and performance criteria

PVC is widely used in medical devices, including sterile disposable tubing, catheters and cannulas; connectors; medical bags, such as blood, intra-venous (IV), dialysis and urine bags; oxygen and anaesthetic masks; and exam and surgical gloves (CfE2, #1588, EFPIA; CfE2, #1600, VinylPlus Deutschland e.V.; CfE2, #1601 VinylPlus). Most of these applications are flexible (soft PVC), including the tubing, IV/blood bags and gloves, while connectors can also be rigid (CfE2, #1588, EFPIA). Further, PVC is used in both soft and rigid pharmaceutical packaging (see Sections C.7 and C.8 for more information of using PVC in packaging).

Overall performance criteria in medical applications include biocompatibility, elasticity and flexibility (with good tensile strength), safe storage of contents, heat resistance, chemical resistance, water resistance, sterilizability, transparency, surface properties (abrasion resistance, surface friction), dimension control, kink resistance and recovery, solvent bondability, printability, manufacturability (cutting, welding, bonding and moulding) and avoidance of latex allergies (ECHA market survey 2023; CfE3, #1629, MedTech Europe; CfE3, #1693). Biocompatibility is the minimum criterion for a material to be considered for use (CfE3, #1628, MedTech Europe).

C.9.2. Baseline

PVC is the single most commonly used polymer in medical devices in Europe, with 27 % of the total volume of polymers for medical devices (Global-Market-Insights, 2021). PVC is particularly important in medical bags, with approximately 80 % of bags being made of PVC in Europe (Global Market Insights 2021). In flexible medical tubing, PVC is the primary material with a share of approximately 30 % in Europe (CfE2, #1588, EFPIA; Global-Market-Insights (2021)). PVC gloves for medical use are nowadays made to a large extent outside the EU (mainly in Asia) and imported into the EU as finished articles (CfE2, #1601, VinylPlus).

Table 41 presents the basics of the use of PVC in medical applications

Table 41: Use of PVC in medical applications

Use	Medical applications
Description	Medical tubing, connectors, bags, masks, gloves
Main performance criteria	Biocompatibility, elasticity and flexibility (with good tensile strength), safe storage of contents, heat resistance, chemical resistance, water resistance, sterilizability, transparency, surface properties (abrasion resistance, surface friction), dimension control, kink resistance and recovery, solvent bondability, printability, manufacturability (cutting, welding, bonding and moulding), avoidance of latex allergies
Compounded volume of PVC used per year in the EU in 2021 (tonnes)	28 000 – 170 000
Type of PVC	Mainly soft (tubing, bags, masks, gloves), small portion rigid (connectors)

Share of additives in typical average compounding	No information on typical compounding, so the following assumptions are made: 2 % stabilisers; 25 % fillers, pigments, impact modifiers; 30 % plasticisers
Prioritised substances used as additives	Plasticisers (DEHP, TOTM, DOTP) No prioritised heat stabilisers No prioritised flame retardants

C.9.3. Alternative materials

Several alternatives to soft PVC in medical applications are on the market or in development (CfE2, #1588, EFPIA; CfE3, #1694; Sphera (2022); Global-Market-Insights (2021)), including

- Polyurethane (PU)
- Ethylene-vinyl acetate (EVA)
- Polypropylene (PP)
- Polyethylene (PE)
- Polyethylene terephthalate (PET)
- Poly(ethylene-co-ethyl acrylate) (EAA)
- Polystyrene (PS)
- Acrylonitrile butadiene styrene (ABS)
- Styrene-butadiene-styrene (SBS)
- Thermoplastic elastomers (TPE)
- Rubber latex
- Polyester (PE) and polyolefin (PO) blends
- Polyurethane (PU) and polyester (PE) blends
- Non-phtalate/non-DEHP plasticised PVC.

Whilst various potential substitutes do exist, publicly available research on their performance and properties is sparse (Sphera 2022). The alternative materials depend on the specific medical application. Besides PVC, polymers commonly used in medical tubing and masks include PP, PE and PS, rubber latex and SBC (Global-Market-Insights, 2021). Also silicone and TPE are already used for many medical tubing products (CfE2 #1588, EFPIA). For medical bags, alternative polymers to PVC include PU, EVA and PP (CfE2 #1588, EFPIA).

Stakeholder input indicates that a single alternative material would not be suitable to replace PVC in all medical uses, and that there may be challenges in finding suitable alternatives to PVC for some uses (CfE2, #1611, MedTech Europe; CfE3, #1628, MedTech Europe).

PU, EVA and TPE have been mentioned by stakeholders as potential viable alternatives to PVC (CfE3, #1628, MedTech Europe). PU has higher coil tension properties than PVC, resulting in potential challenges for the design (CfE2, #1588, EFPIA). Coiled tubing ensures kink resistance and allows for smaller packages to be used, allowing easier storage at hospitals and easier set up (CfE2 #1588, EFPIA).

Rigid plastic alternatives are not suitable for coiled medical tubing applications that demand flexibility and clarity (CfE2, #1588, EFPIA). PE and PP are used for certain semi-rigid applications within medical devices but would not be suitable to replace PVC in all medical applications (CfE3, #1628, MedTech Europe).

In medical bags, stakeholders indicate storage problems with alternative materials (EVA and polyolefins), such as issues with shape retainment and leaking when frozen/thawed (CfE3, #1693).

Based on the available information, it seems there are alternatives to all uses of PVC in medical applications. However, these may imply changes to the performance of the product. The lack of comparable data prevents presenting detailed data on functionalities. The evident disadvantage of rubber latex is that it may cause allergic reactions to some people.

Most medical applications are single-use items or have a limited lifetime, and thus the importance of lifetime appears smaller than in other uses of PVC. At present, there is no reliable information on the lifetime of the different materials.

The alternatives are largely available. However, all of these have competing uses.

C.9.3.1. Economic impacts

The economic impacts of substitution include possible changes in material costs, investment costs and costs related to testing, validation and approval of the new material for medical applications. There are estimates of the material costs for some of the alternatives, and some information on the investment and validation costs.

Cost information for the different materials is in market prices per metric tonne (missing for some materials). There is no information on lifetime costs or costs of final products (see Table 42Table 42). The amount of material needed for a product can differ across alternatives, and thus a simple comparison of material cost per tonne is not sufficient to capture all impacts from changing the material. Thus, the costs can be considered only as supportive information.

In addition to material costs, replacing PVC with other polymers may require technological redesign and even complete redesign of the product, entailing investment costs (CfE2, #1611, MedTech Europe). However, several alternative materials are already being used in the same medical applications as PVC, and thus these alternative designs are already available. For example, EVA, TPE, and TPU would be viable, but would require investment in new extrusion lines by the device manufacturer (CfE3, #1628, MedTech Europe).

Medical devices and IVDs are regulated by the Medical Devices Regulation (MDR, Regulation (EU) 2017/745) (EU, 2017a) and the In Vitro Diagnostic Medical Devices Regulation (IVDR, Regulation (EU) 2017/746) (EU, 2017b). A change in the material of a medical device that could impact the device's safety, effectiveness or reliability may trigger its evaluation as a new device (CfE2, #1611, MedTech Europe). This requires time for testing and re-validation as well as re-registration of individual products. Material/formula changes can take several years with significant labour and non-labour costs (CfE2 #1588, EFPIA). Early investigations include examining downstream impacts through the supply chain and functional performance of the material. Changes require verification testing for product function (at shelf life), sterility and biocompatibility, among others. In addition, they can also trigger marketing authorisation/registration activities depending on local health authority requirements. The costs will vary significantly depending on whether the new formulation is compatible with existing manufacturing assets, and the number of assets and products impacted.

According to a recent example, a minor reformulation qualification project resulted in non-labour costs exceeding €650 000 with a 5-year timeline (CfE2 #1588, EFPIA). For this specific example, the scope of work included early investigation, supplier asset qualification, product verification, and biocompatibility studies, but no asset modification or regulatory impacts. It is unclear to what extent this information is representative for other products and how many products would be affected, and thus the total costs of material changes cannot be estimated.

Another estimate indicates that a material change could cost approximately €900 000 in total per product that is sold worldwide, including e.g. raw materials, new manufacturing equipment, and regulatory approval costs (CfE3, #1628, MedTech Europe). New material introduction (a non-plasticized polymer resin) has historically required 2-5 years for non-implant medical devices (CfE3, #1628, MedTech Europe).

Table 42 presents costs of PVC and alternative materials. These include only the price of the raw material and no other costs. PVC is considered to be a low-cost material in medical applications (CfE2, #1611, MedTech Europe). Based on costs per tonne of raw material, it seems that PE would be less expensive per tonne, but the other alternatives more expensive (Table 42). However, calculations of cost differences assume that the same amount of material is needed for the product as PVC, which does not capture the full cost of changing the material. Further, investment costs related to material changes, as well as costs of testing and validation are not presented due to lack of data.

Table 42: Costs of selected alternative materials used for medical applications.

Material	**Market price of material (€/tonne)**	**Difference to PVC in material costs (€/tonne)**	**Difference in annual costs, for the total sales volume of PVC medical applications (million €)**
PVC	1808	-	-
Polyethylene (HDPE)	1474	-334	-(8–47)
Polypropylene (PP)	2064	256	6–36
Polyurethane (PU)	2787	979	23–138
Silicone rubber	8018	6210	146–873
Nitrile	3506	1698	40–239
Ethylene-vinyl acetate (EVA)	3228	1420	33–200

Source: Chemanalyst (2022), Q4/2022

Note: The annual sales volume of PVC in medical applications is 28 000 – 170 000 tonnes.

Considering the extensive use of PVC in medical applications, in particular medical bags, supply issues for alternative materials and products are possible.

Based on the price of the material and sales volume of PVC, the total sales value of PVC medical applications in the EU is €50–310 million per year. This is a minimum value based on the value of the material, and information on the purchase price of the final products is not currently available. Considering that 100 % production takes place in the EU and assuming a profit margin of 10 %, the profits for the EU producers would be around €5–31 million per year.

According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the PVC medical application producers would be around €1–4 million. (SEAC, 2021)

C.9.3.2. Life cycle impacts

C.9.3.2.1. Qualitative description of impacts at different lifecycle stages

The number of robust good-quality LCA studies on medical applications is limited (Sousa et al., 2021, Sphera, 2022). Individual LCA studies comparing PVC and other materials exist on catheters (Stripple et al., 2008), masks (Eckelman et al., 2012), and blood bags (Carlson, 2012, Sjons and Wendin, 2017), most of which seem to indicate that other materials (such as PE, PP, rubber and silicone) would perform better in terms of broader life cycle impacts than PVC. However, due to lack of comparable studies, no robust conclusion on the performance of PVC compared to alternative materials from the life cycle perspective can be made.

The same applies to CO_2 emissions from alternative materials for medical applications, which cannot be consistently compared due to lack of primary data on environmental emissions for the various types of medical applications (ECHA market survey 2023).

C.9.4. Alternative additives

No heat stabilisers or flame retardants that are on the list of prioritised additives are used in medical applications.

C.9.4.1. Plasticisers

Five plasticisers are permitted to be used in PVC for medical applications in the EU: DINCH, DOTP, TOTM, BTHC and DEHP (European Pharmacopoeia). DOTP is used in most medical applications, including masks, tubing and IV bags, and DEHP in specific applications, including blood bags (CfE3, #1708, VinylPlus). Also DINCH, TOTM and BTHC are already used in several medical applications, and using ATBC is also possible (CfE3, #1708, VinylPlus). Of these, only DEHP and TOTM are on the prioritised list of additives (Table 43).

DEHP is used in blood bags specifically for its distinct performance properties (CfE3, #1708, VinylPlus). DEHP contributes to the long shelf life for blood bags, which is a critical parameter for maintaining blood supplies in healthcare (CfE3, #1708, VinylPlus, #1680

Shin-Etsu PVC b.v.). Stakeholders indicate that any alternatives should meet this critical performance criterion (CfE3, #1708, VinylPlus).

DEHP is a SVHC (reprotoxic cat. 1B and for its endocrine disrupting properties for human health and environment) subject to authorisation. The sunset date for the use of DEHP in medical devices is 1 July 2030. After the sunset date, an authorisation is needed to continue the use of DEHP. Thus, companies are likely already assessing suitability of alternatives to substitute DEHP, and further information on substitutes and substitution costs will be available from the applications for authorisation as of 1 January 2029 (current Latest Application Date for these uses).

Several studies show that DEHP can be replaced in all medical applications by one of the four alternatives (CfE3, #1708, VinylPlus). DOTP has already replaced DEHP in most medical applications (CfE3, #1708, VinylPlus). Some companies have also successfully replaced DEHP using ATBC or DINCH (CfE3, #1628, MedTech Europe).

The assessment of economic impacts focuses on substituting DEHP in medical applications, as it is in the high concern category. DEHP has already been replaced as a general-purpose plasticiser. For the development of DOTP as an alternative to DEHP, the price premium has been of the order of 15–20 %, after initial introduction of products and with larger scale production being put in place (CfE3, #1708, VinylPlus). The average price of DOTP had been €1580/tonne in 2020-2022 (Chemorbis, 2022b), and DEHP €800–1200 per tonne (ECHA, 2006, Maag et al., 2010, Intratec, 2023). These estimates have been used to assess the costs of replacing DEHP in medical applications with DOTP.

Costs of replacing DEHP with DOTP are in the range of €1.0–5.9 million per year for the total volume of DEHP use (1680–10 200 tonnes/year), considering only the differences in the price of the additives. Large-scale use of DOTP already takes place (with volume of 100 000 – 1 million tonnes/year), so additional costs are not expected.

TOTM is also used as a plasticiser in medical applications and could potentially be replaced with DOTP, but there is no detailed information on the purpose it is used and its replaceability. TOTM is more costly than DOTP or DEHP, and it seems to have already been replaced in those uses where possible (ESPA, email communication, 18/05/2023).

As alternative additives to DEHP in medical applications are already in use, they are likely substitutes. In case novel plasticisers would need to be developed, previous experience in R&D indicates a minimum of €50 million is needed for a single company to scale-up production of a potential new plasticiser from the laboratory to small pilot plant scale, to produce sufficient quantities for customers to assess plasticising properties in their application and run toxicology tests required under REACH (CfE3, #1708, VinylPlus). Additionally, reformulation, R&D and requalification cost at converters may be significant depending on which plasticisers are involved, may reach up to €5 million for a single company (CfE3, #1708, VinylPlus). Introduction of new additives will require extensive testing, biocompatible, biostability, and characterization prior to regulatory submission (CfE3, #1628, MedTech Europe). Additive substitution (i.e. plasticisers) has historically required approximately 2 years (CfE3, #1628, MedTech Europe).

According to another estimate, the approximate minimum costs of switching to alternative additives can be annually €0.25 million for a single company, component and device (CfE3, #1628, MedTech Europe). The cost depends on the additive, function, product and region where the device is sold, and the estimate includes costs related to R&D activities, logistics, the additive itself, and manufacturing.

According to stakeholders, replacement of currently used plasticisers with alternatives would require 5-8 years transition period (CfE3, #1628, MedTech Europe; #1588, EFPIA). This time is needed to 1) conduct functional performance and shelf-life studies, 2) determine loading ratios depending on the product requirements, 3) comply with regulatory requirements and 4) assess exudation/ leaching under stress (in case of high loading of plasticiser) (CfE3, #1628, MedTech Europe).

Table 43. Currently used prioritised and alternative plasticisers in medical applications

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used plasticisers (estimated volume in tonnes)	DEHP (1 680–10 200 tonnes /year)	TOTM (1 680–10 200 tonnes/year)		DOTP (1 680–10 200 tonnes/year), DINCH, BTHC
Likely alternative plasticisers				DEHP => DOTP, DINCH*, BTHC*

*Notes: * These substances are also currently used in medical applications and were not prioritised (Appendix B)*

C.9.4.2. Supply chain impacts

DEHP is largely manufactured in Europe, and only approximately 9 % is imported. For DOTP the situation is different, as two-thirds is imported (67 %). The price of DEHP has been approximately €800–1200 per tonne (ECHA, 2006, Maag et al., 2010, Intratec, 2023).

The total value of the DEHP production in the EU for medical applications, with the mean price of €1000/tonne and mean volume of 5920 tonnes/year, is around €5.9 million per year. There is no information on the profit margin of the plasticiser manufacturers, but with an assumed 10 % profit margin, the profits for the DEHP producers in the EU would be around €0.6 million per year. According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the EU producers from moving from DEHP to DOTP in medical applications would be around €80 000. (SEAC, 2021)

If DOTP manufacturing capacity would increase in Europe, the loss in the profit for the other additive producers would be eventually replaced by the increase in the profit of DOTP producers.

C.10. Toys

C.10.1. Description of use and performance criteria

PVC is used in various toys, including dolls, bath ducks, snorkels, inflatable beach toys, balls and paddling pools, rubber boats and rafts, modelling clay, trampolines, building blocks, and toy figures ((Baitz et al., 2005, Sphera, 2022) and CfE3). Both soft and rigid PVC is used in toys. Dolls, bath ducks, snorkels, inflatable toys, balls and paddling pools, rubber boats and rafts, modelling clay and trampolines are soft PVC, while building blocks and toy figures are rigid PVC. Of the various toy types, PVC appears to be used the most in inflatable toys, boats and rafts (Baitz et al. 2004, Sphera 2022).

Performance criteria for toys include flexibility, water resistance, high strength to weight ratio, durability, resistance to flexing, ease of decorating and moulding possibilities.

C.10.2. Baseline

The use of PVC in toys in the EU is minor compared to the total volume of PVC used, and its share of plastics used in toys is also small. The total volume of PVC used in toys and childcare articles in the EU is estimated to be 6 000–36 000 tonnes per year (CfE2, #1601, VinylPlus). Information on PVC use from four individual companies operating in the sector is consistent with this estimate (CfE2, #1539, #1546, #1579, #1604). However, the estimates from the companies cover only part of the toy types included, and for example, no estimates of PVC used in inflatable toys or boats and rafts are available.

The manufacture of toys and childcare articles has largely moved outside the EU (CfE2, #1601, VinylPlus), and the EU is a net importer of toys from the rest of the world. In total €7.1 billion worth of toys were imported from extra-EU countries and €2.4 billion exported to extra-EU countries in 2021 (Eurostat, 2022). Most of the toys come from China (83 % in 2021) (Eurostat 2022).

Table 44 presents an overview of the use of PVC in toys.

Table 44: Use of PVC in toys

Use	Toys
Description	Dolls, bath ducks, snorkels, inflatable beach toys, balls and paddling pools, rubber boats and rafts, building blocks, toy figures
Main performance criteria	Flexibility, water resistance, high strength to weight ratio, durability and resistance to flexing, ease of painting, decorating ang gluing, moulding possibilities
Compounded volume of PVC used per year in the EU in 2021 (tonnes)	6 000–36 000
Type of PVC	Soft and rigid (mainly soft)
Share of additives in typical average compounding	1 % stabilisers and lubricants 7 % fillers, pigments, impact modifiers 32 % plasticisers
Prioritised substances used as	Heat stabilisers: Phenyl 1,3-diones

additives	Plasticisers: DOTP No prioritised flame retardants

Sources: ECHA market survey 2023; CfE3, #1614, #1615, #1664

C.10.3. Alternative materials

Potential alternatives to PVC in toys include:

- polyolefins, such as PP, PE (various PVC applications, e.g. dolls, batch ducks, snorkels, inflatable beach toys, balls, paddling pools, building blocks, play figures)
- thermoplastic elastomers (TPE) (e.g. doll parts, play figures, possibly inflatable toys)
- ethylene vinyl acetate (EVA) (e.g. inflatable toys, possibly doll parts)
- polyurethane (PU) (e.g. rubber boats, rafts)
- polystyrene (e.g. building blocks, play figures)
- silicone
- rubber (e.g. rubber boats, rafts)
- wood (e.g. dolls, building blocks).

Based on data available on the properties of the materials, there appear to be no evident differences in their durability, flexibility and strength, and in some cases the alternatives can perform better than PVC (ECHA market survey 2023, EC 2022, Tickner (1999)).

Selected alternative materials for soft PVC in toys have been examined by Tickner (1999). TPEs can be processed to various flexibilities and strength properties. EVA can be used to achieve a broad range of toy properties, including flexibility, toughness and resilience, and it has a good stress cracking resistance for toys. Polyolefins (PP, PE) are also versatile, and can be better than PVC in terms of stress cracking resistance and toughness. Stakeholders have indicated that TPE and PP are potential substitutes in some specific applications (CfE3, #1638, #1631).

The advantages of PVC in toys are that it is easy to paint, decorate and glue, and components, such as eyes and hair, can be easily inserted (CfE3, #1615, #1664). In addition, injection and roto-moulding as well as undercut moulding are possible (CfE3, #1615, #1638, #1664). According to stakeholders, alternative materials are not able to provide similar performance (CfE3, #1614, #1615, #1664). For example, painting, decoration and gluing of TPE and EVA is considered difficult, and roto-moulding or moulding undercuts is not possible for TPE, EVA, PE and PP. PP and PE are considered too hard for some soft toy applications, such as dolls (CfE3, #1638).

No information on the lifetime of the materials in toys is available. Lifetime likely differs considerably across toy types, and proper comparison would require information on the lifetime of PVC compared to its alternatives for specific toy types. Toys may be reused several times if their condition allows, and thus the lifetime of some plastic toys may be years or even decades, while some may last only months.

All the alternative materials are commercially available and are already used in toys.

C.10.3.1. Economic impacts

The economic impacts of substitution include possible changes in material costs and investment costs. Only estimates of the prices of different materials for some of the alternative materials are available.

Cost information for the different materials is in market prices per metric tonne (missing for some materials). There is no information on lifetime costs or costs of final products (see Table 45Table 42). Thus, these can be considered only as supportive information.

The material costs do not represent the full costs of substitution, as the amount of the material itself and other substances needed for a product can differ across alternatives, and investment and other possible cost estimates are missing. Thus a simple comparison of material cost per tonne is not sufficient to capture all impacts from changing the material.

Table 45: Costs of selected alternative materials used for toys.

Material	Market price of material (€/tonne)	Difference to PVC in material costs (€/tonne)	Difference in annual costs, for the total sales volume of PVC in toys (million €)
PVC	1 808	-	-
Thermoplastic elastomers (TPE)	4 560	2 752	16–98
Ethylene vinyl acetate (EVA)	3 228	1 420	8–51
Polyethylene (PE)	1 716	-93	-(1–3)
Polypropylene (PP)	2 064	256	2–9
Polyurethane (PU)	2 787	979	6–35

Sources: ECHA market survey 2023; Chemanalyst (2022)

Note: The annual sales volume of PVC in toys is 6 000–36 000 tonnes.

Considering the limited amount of PVC used for toys and the fact that toys are largely imported to the EU, supply chain impacts of limiting the use of PVC are considered to be minor.

Based on the price of the material and sales volume of PVC, the total sales value of PVC toys in the EU is €10–60 million per year. This is a minimum value based on the value of the material, and information on the purchase price of the final products is not currently available. Considering that 100 % production takes place in the EU and assuming a profit margin of 10 %, the profits for the EU producers would be around €1–6 million per year.

According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the PVC toy producers would be around €0.1–0.9 million. (SEAC, 2021)

C.10.3.2. Life cycle impacts

C.10.3.2.1. Qualitative description of impacts at different lifecycle stages

Estimation of wider environmental and life cycle impacts is complicated as there are various types of toys with different lifespans and target customers. Toys can also contain several different materials, and PVC be used only for a specific part. LCA studies comparing alternative materials for the same toy type or part are largely missing (Baitz et al. 2004, ECHA market survey 2023). Thus, the comparison of life cycle impacts of PVC and alternative materials for toys is not possible due to lack of comparable data from scientific literature, environmental product declarations (EPD) or stakeholders (ECHA market survey 2023).

The comparison of CO_2 emissions of toys across materials is not possible due to lack of sufficient publications investigating emissions of toys (ECHA market survey 2023). Further research is required to assess emissions of toys and their materials for each life cycle stage.

C.10.4. Alternative additives

Prioritised heat stabilisers and plasticisers are used in toys.

There is uncertainty regarding the additives for articles that are imported to the EU. Imported articles should comply with the relevant EU regulations, including the restrictions on low molecular weight (LMW) phthalates in all toys and childcare articles, and DINP and DIDP for toys and childcare articles that can be placed in the mouth. All toys manufactured inside or outside the EU are subject to the EU Toy Safety Directive (2009/48/EC) (EU, 2009), which bans the presence of CMR substances. Information from stakeholders indicates that outside Europe, diantimony trioxide (flame retardant) is used in inflatable beach toys, balls, and paddling pools (CfE3, #1703).

C.10.4.1. Plasticisers

Stakeholders indicate that potential plasticisers used in toys are DINCH, DOTP, ATBC, and DEHA (CfE2, #1601, VinylPlus; CfE3, #1708, VinylPlus; #1664). DINCH, ATBC and DEHA are not in the list of prioritised additives and DOTP has no identified concern currently. DINP and DIDP are restricted in toys and childcare articles which can be placed in the mouth.

There is only information on alternative plasticisers to replace DOTP in toys. DOTP in dolls, batch ducks and snorkels could be replaced with DINCH and potentially other additives, such as citrates, 1,2-cyclohexane dicarboxylic acids and dicarboxylic acid esters (CfE3, #1638, #1664). Time required for substitution is estimated to take 1-3 years. No costs are expected from replacing DOTP with DINCH, but quality and delivery time problems are possible (CfE3, #1638). For the other alternatives, costs include higher raw material costs and costs of re-qualification and re-tooling, as applicable. These alternatives imply some reduction in the performance of the additives, in terms of compatibility at the conjunction with other plastics, viscosity and moulding. (CfE3, #1664.)

However, at present there is no identified concern associated with DOTP, and thus no assessment of the economic impacts of its substitution has been made.

C.10.4.2. Heat stabilisers

Of heat stabilisers, mixed metal stabilisers (mainly Zn/Ca) are largely used (CfE2, #1601, VinylPlus), and liquid mixed metal stabilisers are used in soft PVC toy applications (CfE3, #1708, VinylPlus). The only prioritised heat stabiliser use is 1,3-diphenylpropane-1,3-dione is used (CfE2, #1539, #1546) (Table 46). There is no specific information on the performance enhancing properties of 1,3-diphenylpropane-1,3-dione and potential alternatives. Mixed metal stabilisers could potentially be used to replace it, but there is no information on the potential impacts on costs and performance.

Table 46: Currently used prioritised and alternative heat stabilisers in toys

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used heat stabilisers (estimated volume in tonnes)		1,3-diphenylpropane-1,3-dione (2–15 tonnes/year)		
Likely alternative heat stabilisers				Mixed metal stabilisers (Zn/Ca)*

*Notes: * These substances are also currently used in toys and were not prioritised (Appendix B)*

C.10.4.3. Supply chain impacts

As the use of prioritised additives in toys is limited, no significant negative supply chain impacts are expected from replacing them with ones that have lower concern.

C.11. Artificial leather

C.11.1. Description of use and performance criteria

Coated fabrics are fabrics that have undergone a chemical finishing to gain additional functional or decorative properties, such as waterproofing. One specific type of coated fabrics is artificial (synthetic) leather, which is a substitute for leather in upholstery, automotive interiors, clothing, accessories, footwear and other uses. Artificial leather consists normally of polyester textiles coated with PVC or PU (Meyer et al., 2021). Soft PVC is commonly used in artificial leather both in clothing and automotive interiors. PVC provides wear-resistance, while the textile gives strength and tear resistance (Wilkes et al., 2005).

The main functionalities required from artificial leather include durability, water resistance, flame resistance, UV radiation resistance, cold resistance, insulation, comfort, aesthetic factors, lightweight, staining, and cleanability (ECHA market survey 2023; Bywall and Cederlund (2020); CfE3, #1697, EURATEX).

The focus of the impact assessment for the clothing and automotive sectors is on artificial leather, due to its large share of the PVC volume used in these sectors and data availability. Other uses of PVC in clothing include wellingtons, ski boots and shoe soles/bottoms. In automotive, the use of soft PVC includes underbody protection and tarpaulins, and rigid PVC dashboards, sheets and profiles. These other uses besides artificial leather are excluded from the impact assessment due to lack of data. Cables in cars are assessed in section C.4.

C.11.2. Baseline

The volume of compounded PVC used in artificial leather is 47 000–281 000 tonnes/year in clothing and 21 000–127 000 tonnes/year in automotive uses (CfE2, #1601, VinylPlus; #1587, EuPC).

In clothing, artificial leather is used, for example, in jackets, pants, bags and shoes. In automotive interiors, PVC is used in instrument panel skins, seat upholstery, door panels and trim parts. Also foamed PVC can be used for a cushioning effect. (Bywall and Cederlund 2020.)

According to the typical average compounding, 42–49 % of the PVC in artificial leather is additives, mainly plasticisers (CfE2, #1587, EuPC).

Table 47 presents an overview of the use of PVC in artificial leather.

Table 47. Use of PVC in artificial leather

Use	**Artificial leather**
Description	PVC is used to coat the base textile
Main performance criteria	Durability, water resistance, flame resistance, UV radiation resistance, cold resistance, insulation, comfort, aesthetic factors, lightweight, staining, cleanability
Compounded volume of PVC used per year in EU (tonnes)	Clothing: 47 000–281 000 (corresponds to 33 000 – 200 000 tonnes of uncompounded PVC) Automotive: 21 000–127 000 (corresponds to 14 000 –

	86 000 tonnes of uncompounded PVC)
Type of PVC	Soft
Share of additives in typical average compounding	Clothing: 1.3 % stabilisers and lubricants; 7.3 % fillers, pigments, impact modifiers; 33 % plasticisers Automotive: 2.2 % stabilisers and lubricants; 10 % fillers, pigments, impact modifiers; 37% plasticisers
Prioritised substances used as additives	Potentially used plasticisers: DINP, DPHP, D810P, DUP, D911P, D1114P, DIDP, D1618P, D1012P, DDP/DDDP, DBTP, DOTP, T911TM, T810TM, TOTM, TINTM, TIDTM Flame retardants: Diantimony trioxide, zinc borate, hexaboron dizinc undecaoxide No prioritised heat stabilisers

C.11.3. Alternative materials

Alternative materials to artificial leather include leather, cotton, silk, wool, latex, polyester, PU, and PA (ECHA market survey 2023). Not all of these alternatives are suited to all uses. These materials can either replace artificial leather altogether or only the PVC component in artificial leather.

PU leather is the most common type of artificial leather. There are also various bio-based artificial leathers, where the PVC or PU coating is partly replaced, or fossil-based raw-materials are fully replaced, with bio-based materials (Meyer et al. 2021). Bio-based materials used in artificial leather are often natural fibres, for example, flax or cotton mixed with palm, soybean, and corn; fungi-based material; apple pomace; cactus leaves; and pineapple leaves (Meyer et al. 2021).

Compared to leather, PVC artificial leather is considered to be less durable and comfortable in terms of breathability and flexibility, but it provides a better water and staining resistance and cleanability. Compared to PU artificial leather, PVC is more durable, has a higher weather resistance, and has a lower risk of staining, but is less comfortable (less breathable and flexible). PU leather is thought to resemble real leather better, as it wrinkles and remains soft throughout its life.

Table 48 shows the performance of PVC and alternative materials. Stakeholders indicate that alternative materials would be more expensive and less durable (CfE2, #1595, European Automobile Manufacturers’ Association; CfE3, #1697, EURATEX).

Information on lifetimes of the different materials is lacking. However, durability correlates with lifetime, and thus leather can be expected to have a longer and PU artificial leather shorter lifetime than PVC artificial leather.

Table 48: PVC and main alternative materials for artificial leather

Material	**Negative / positive impacts on performance compared to PVC**
Leather	More durable, lower water resistance, more breathable, more flexible, higher risk of staining, lower cleanability
Cotton	NA

Silk	Much lower durability, higher risk of staining, lower cleanability
Wool	NA
Latex	NA
Polyester	NA
PA (nylon)	Lower UV resistance, more breathable
PU (as an alternative to PVC in artificial leather)	Less durable, lower weather resistance, more breathable, more flexible, higher risk of staining, resembles real leather more
Bio-based artificial leather	NA

Notes: Sources: Sewport (2023): ECHA market survey 2023. NA = not available

C.11.3.1. Economic impacts

The economic impacts of substitution include possible changes in material costs and investment costs. Only information on material costs is available.

The amount of the material itself, as well as other materials/substances needed for a product can differ across alternatives, and thus a simple comparison of material cost per tonne is not sufficient to capture all impacts from changing the material. In addition to material costs, replacing PVC with other materials may require different technology to process the materials and changes to production lines, entailing investment costs (ECHA market survey 2023).

Table 49 presents a comparison of the market price of PVC and alternative materials for artificial leather. These include only the price of the material per tonne and no other costs, and investment costs related to material changes are excluded due to lack of estimates. There is no information on lifetime costs or costs of final products. Thus, the costs can be considered only as supportive information.

The costs of the materials per tonne indicate that leather would be considerably more expensive than PVC artificial leather, and PU artificial leather would be somewhat more expensive than PVC. PA (nylon) would be cheaper than PVC. Calculations of cost differences assume that the same amount of material is needed for the product as PVC, which does not capture the full cost of changing the material. In the final material, PVC and PU is combined with another material, often polyester. Thus, the share of PVC and PU is lower in the final product than leather.

Comparison of final material prices per meter indicates that PVC leather is the cheapest, PU leather somewhat more expensive and real leather considerably more expensive, consistent with the material prices per tonne (Vegan Foundry (2022), Made-in-China (2023a), Leatherhouse (2023)).

There are several alternatives to PVC artificial leather, both as other materials and alternative polymers (PU) used in artificial leather. PU leather is already more common than PVC leather, but it is more expensive. Development of novel alternatives would likely not be needed, and supply issues are not expected, considering that alternatives are already available and in use.

Table 49: Cost differences between PVC and alternative materials to artificial leather in clothing and automotive interiors.

Material	Market price of material (€/tonne) in Q4/2022	Difference to PVC in material costs (€/tonne)	Difference in annual costs, for the total sales volume of PVC in clothing (million €)	Difference in annual costs, for the total sales volume of PVC in automotive interiors (million €)
PVC	1 808	-	-	
PA (nylon)	1 356	-452	-(21–127)	-(10–58)
Leather	6 590	4 782	224–1341	101–609
PU (as an alternative to PVC in artificial leather)	2 787	979	46–275	21–125

Notes: Sources: costs: (Chemanalyst, 2023a, Chemanalyst, 2023b) (PVC, PU), (Procurement Resource, 2023) (PA), IndexBox 2022 (leather). The annual sales volume of PVC is 47 000–281 000 tonnes in clothing and 21 000–127 000 tonnes in automotive.

China is the largest textile producer and exporter in the world. Asia Pacific region is the largest producer of artificial leather, with China in the lead (Marketsandmarkets, 2023).

China (25 %) and Brazil (10 %) are the world's largest producers of leather (BizVibe, 2022). The largest exporters of leather are Italy, USA and China (Bizvibe 2022). China accounts for a third of global production of PU (Vantage Market Research, 2022).

Based on the price of the material and sales volume of PVC, the total sales value of PVC artificial leather in the EU is €80–510 million per year in clothing and €40–230 million per year in automotive interiors. This is a minimum value based on the value of the material, and information on the purchase price of the final products is not currently available. Considering that 100 % production takes place in the EU and assuming a profit margin of 10 %, the profits for the EU producers would be around €8–51 million in clothing and €4–23 million in automotive interiors per year.

According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the PVC artificial leather producers would be around €1–7 million in clothing and €1–3 million in automotive interiors. (SEAC, 2021)

C.11.3.2. Life cycle impacts

C.11.3.2.1. Qualitative description of impacts at different lifecycle stages

Very limited information on the wider environmental impacts related to use of PVC and alternative materials in artificial leather in clothing and automotive uses exists, and thus comparison of life cycle impacts is not possible (ECHA market survey).

There is a lack of comparable data on CO_2 emissions in the scientific literature, EPDs and stakeholders for artificial leather and its alternatives in clothing or automotive interiors. Thus, a comparison of CO_2 emissions is not possible, and no statement can be made the performance of the different materials.

C.11.4. Alternative additives

Of the prioritised additives, diantimony trioxide and borates are used as flame retardants in artificial leather. Although there is no detailed data on the specific plasticisers used in artificial leather, various plasticisers in the list of prioritised additives are potentially used.

C.11.4.1. Plasticisers

There is no detailed data on the specific plasticisers used in artificial leather, but various plasticisers in the list of prioritised additives are potentially used, including orthophthalates, terephthalates and trimellitates. There is information that at least DINP, DPHP, DIDP, DUP and DOTP are commonly used (Bywall and Cederlund 2020). There are indications that the use of DOTP has increased at the expense of DINP and DPHP, although DOTP is not considered to perform as well as ortho-phthalates in the end product (Bywall and Cederlund 2020). The estimated use volumes of these plasticisers, excluding DUP, are the highest (Table 50). Specifically in automotive interiors, there is a move towards non-phthalate and bio-based plasticisers (Bywall and Cederlund 2020).

Potential alternatives to the currently used plasticisers are DINCH and mesamoll (phenyl ester of sulfonic acids, EC 701-257-8) (CfE3, #1715, Gesamtverband Textil und Mode e.V.). In artificial leather for automotive uses, a non-aromatic plasticiser could also be an alternative to the currently used ones (CfE3, #1697, EURATEX; #1715, Gesamtverband Textil und Mode e.V.).

Stakeholders indicate that a switch to DINCH would not increase the costs of additives and the time required for the change would be less than one year (#1715, Gesamtverband Textil und Mode e.V.). However, R&D costs of €5 million are expected per company.

It is estimated that changing to mesamoll would increase additive costs by €700/tonne, and by 20 % per kg of final compound or end product (#1715, Gesamtverband Textil und Mode e.V.). Thus, the costs from moving from the low and medium concern plasticisers to mesamoll would be €9–56 million per year for the total volume of these additives used in artificial leather in clothing and automotive interiors (13 000–80 000 tonnes/year).

DINP and DIDP could also potentially be replaced with no identified concern plasticisers that are already used in artificial leather (i.e. DOTP). The main cost for the industry would be in terms of the possible price difference between DOTP and the other plasticisers (CfE3, #1708, VinylPlus). In 2020-2022, DOTP has been on average €50/tonne more expensive than DINP and DIDP (Chemorbis, 2022b). The cost of replacing DINP and DIDP with DOTP would be €0.5–2.8 million per year for the total volume of these plasticisers used in artificial leather in clothing and automotive interiors (9 300–55 900 tonnes per year). However, if the use of DOTP would increase considerably, price increases are expected. In addition, there will be costs from increasing the production capacity. In the case of substitution of DEHP with DINP, the total costs of increasing the production volume were estimated to be €6 billion (CfE3, #1708, VinylPlus).

Of the medium chain ortho-phthalates, DPHP (medium concern) could be replaced with DIDP (low concern). The price of these plasticisers is assumed to be equal, and thus the move from DPHP to DIDP would mainly entail reformulation costs. D810P (medium concern) could potentially be replaced with long chain ortho-phthalates (low concern).

ECHA assumes, based on anecdotical evidence, that the price of long chain ortho-phthalates is double of that of D810P, and that D810P has the same price as DINP (€1 530 per tonne). Thus, the replacement costs would be €0.8–5 million per year for the total volume of D810P used in artificial leather in clothing and automotive interiors (290–1 700 tonnes per year).

Trimellitates (medium concern) could potentially be replaced with long chain ortho-phthalates (low concern), assuming the same price, at no extra material cost.

It is uncertain whether the other long chain ortho-phthalates than DIDP could be replaced with safer alternatives.

Stakeholders indicate that alternative plasticisers would provide worse performance and that DPHP, DIDP, DINP and DOTP could not be replaced in PVC artificial leather due to high certification efforts needed (CfE3, #1697, EURATEX). In Europe, EFSA certification is often asked for by fashion producers since the products are in close contact with skin (Bywall and Cederlund 2020). However, considering that various plasticisers, including DOTP, are already being used, certification efforts are expected to have already taken place.

According to stakeholders, use of alternative plasticisers outside the currently used ones would increase the costs per end product considerably, for both the clothing and automotive uses (CfE3, #1697, EURATEX).

Table 50: Currently used prioritised plasticisers in artificial leather (clothing and automotive)

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used plasticisers (estimated volume in tonnes/year)	None	Medium chain ortho-phthalates DINP (6 820–40 950 tonnes/year) DPHP (2 425–14 560 tonnes/year) D810P (290–1 740 tonnes/year) Trimellitates T911TM (20–130 tonnes/year) T810TM (450–2 700 tonnes/year) TOTM 120–720 tonnes/year) TINTM (30–190 tonnes/year) TIDTM (70–445 tonnes/year)	Long chain ortho-phthalates DIDP (2 485–14 935 tonnes/year) DUP (15–100 tonnes/year) D911P (105–630 tonnes/year) D1114P (125–770 tonnes/year) D1618P (25–165 tonnes/year) D1012P (80–495 tonnes/year) DDP/DDDP (110–675 tonnes/year) Terephthalates DBTP (50–300 tonnes/year)	Terephthalates DOTP (3 205–19 260 tonnes/year)
Likely alternative plasticisers			DPHP => DIDP D810P, trimellitates => long chain orthophthalates	DINCH*, mesamoll* DINP, DIDP => DOTP

*Notes: * These substances are also currently used in artificial leather and were not prioritised (Appendix B)*

C.11.4.2. Flame retardants

Of the prioritised additives, diantimony trioxide and borates (zinc borate, hexaboron dizinc undecaoxide) are used as flame retardants in artificial leather in automotive interiors (Table 51). Stakeholders indicate that none of these could be easily replaced (CfE3, #1697, EURATEX).

Potential alternative to the prioritised flame retardants is zinc stannate, but stakeholders raise the issue that zinc is a conflict mineral and there is only limited availability (CfE3, #1697, EURATEX). Stakeholders also indicate that alternatives would compromise flame retardancy and are more expensive than diantimony trioxide (CfE3, #1697, EURATEX).

However, research indicates that zinc stannate can be a highly efficient flame retardant and smoke suppressant in soft PVC, but other flame retardants are often needed to achieve optimal efficiency (Pan et al., 2022, Xu et al., 2005). Thus, zinc stannate could potentially be used to partly replace substances with identified concern.

In general, also mineral mixtures (such as magnesium dihydrate and aluminium trihydrate) have been mentioned as potential alternative flame retardants (CfE3, #1708, VinylPlus), but there no information on the costs of such substitution is currently available.

Table 51: Currently used prioritised and alternative flame retardants in artificial leather (automotive)

	High concern	**Medium concern**	**Low concern**	**Currently no identified concern**
Currently used flame retardants (estimated volume in tonnes/year)	None	Zinc borate (4–25 tonnes/year) Hexaboron dizinc undecaoxide (415–2 515 tonnes/year)	Diantimony trioxide (420–2 540 tonnes/year)	
Potential alternatives				Zinc stannate* Magnesium dihydrate* Aluminium trihydrate*

*Notes: * These substances are also currently used in artificial leather and were not prioritised (Appendix B)*

C.11.4.3. Supply chain impacts

Many medium and low concern plasticisers are mostly produced in Europe, except for DUP (100 % imported) and DBTP (90 % imported). DOTP is mainly imported (67 %), primarily from South Korea, US, China and Turkey (Chemorbis 2023; CfE3, #1708, VinylPlus). Thus, moving to DOTP would mean losses in profit for European plasticisers producers.

For the largest quantity plasticisers used in artificial leather, DINP and DIDP, the total value of the production in the EU, with the mean price of €1 530/tonne and mean volume of 33 000 tonnes of DINP and DIDP per year, is around €50 million per year. There is no information on the profit margin of plasticiser manufacturers, but with an assumed 10 % profit margin, the profits for the EU producers would be around €5 million per year. According to SEAC's approach to assessing changes in producer surplus, two-year profit losses account for the producer surplus losses during the entire assessment period when alternatives are generally available in the EU. Assuming a 20-year assessment period and using a discount rate of 3 %, the annual profit losses to the EU producers from moving from DINP and DIDP to DOTP in artificial leather would be around €0.7 million. (SEAC, 2021)

If DOTP manufacturing capacity would increase in Europe, the loss in the profit for the other additive producers would be eventually replaced by the increase in the profit of DOTP producers.

C.12. Wider impacts on the upstream supply chain

Chlorine and ethylene are the two main inputs for the production of PVC. Ethylene is used in a wider scale (for example, to produce polyethylene). However, in the case of chlorine, almost a third of all chlorine in the EU is used to produce PVC. Thus, for upstream supply chain impacts, we focus on the chlorine.

Chlorine is produced by electrolysis of brine, also called the chlor-alkali process. The main outputs of the chlor-alkali process are chlorine, caustic soda and hydrogen. Around 32 % of chlorine is used for the production of PVC. (Euro Chlor, 2023)

Approximately 99.5 % of all caustic soda is produced by the chlor-alkali process (Kumar et al., 2021). Main uses of caustic soda are alumina, paper & pulp, chemical industry (both organic and inorganic), soaps and detergents, and textile industry (Orbichem, 2022). There are some foreseen capacity issues related to the production of caustic soda, which are tied to its increased production costs, especially in the EU, with the main drivers being high energy prices in the EU (Tecnon OrbiChem, 2022). Stakeholders have commented that if there would be a restriction that would decrease/cease the use of PVC, and thus have a large impact on the demand for chlorine, there would also be wider impacts for the chlor-alkali chain affecting the supply of caustic soda (VinylPlus, 2022).

Hydrogen is another by-product of the chlor-alkali process. There is an increasing demand for hydrogen, both from traditional uses in refining and industry, but an increase in demand has also been observed for new applications (IEA, 2022). However, the chlor-alkali process accounts for a relatively small share of the hydrogen output, and the impacts on the hydrogen market from changes in the chlor-alkali chain are likely to be minor.

One of the main points from the PVC industry is that if chlorine could not be used for PVC anymore, or would be used to a lesser extent, there would be a significant decrease in the demand for chlorine. This would then also impact the market of the other outputs of the chlor-alkali process, most importantly caustic soda (VinylPlus, 2022). (CfE3, #1643, Vinyl Environmental Council) This seems likely. NGOs (CfE2, #1593, EEB), on the other hand, have commented that there is a direct link between the production of chlorine and the manufacture of PVC, and the demand of PVC is a driver in the production of chlorine. While this is true, if the chlor-alkali chain would be less profitable and less chlorine would be produced, this would also affect the supply of caustic soda.

At least the following impacts would occur if a restriction would alter the production of PVC:

- If there is a 30 % decrease in the demand of chlorine, the market price of chlorine would decrease. The demand function for chlorine is unknown, particularly in the case of large-scale changes in the demand. It is not known if the market price of chlorine would stay positive, or if the industry would need other ways to treat the excess chlorine. In the case of smaller changes in the demand of chlorine from the PVC industry, the main impact would be a lower price of chlorine.

- If the price of chlorine decreases, it would make the chlor-alkali process less profitable and would increase the price of caustic soda as well, since caustic soda is produced 99.5 % out of this process.
- There would likely be no direct impact on the price of hydrogen, as there are various sources of hydrogen, and the price is driven by the energy market price.

C.13. Impacts of non-recycling of PVC

This section discusses and quantifies the impacts of a possible future restriction on the end-of-life (EoL) treatment of PVC articles. Based on evidence of impacts of past restrictions and stakeholder comments, the most significant impacts of a possible future restriction on the EoL treatment would be on recycling. The socio-economic impacts, due to changes in the recycling volumes of PVC, are monetised for a hypothetical no-recycling scenario.

C.13.1. Examples of impacts of restrictions on EoL of PVC articles

During the preparation of the lead stabilisers in PVC restriction dossier (Lead in PVC), PVC recyclers and compounders highlighted that in order to comply with the proposed 0.1 % limit for lead in PVC, only 10 % of an article could be made from recycled PVC. This in turn would render recycling of lead containing PVC economically unviable. The Dossier Submitter (ECHA) concluded that for those uses where lead stabilisers had been widely used, PVC recycling would not be possible with a 0.1 % limit. PVC articles at the end of their service life would then be disposed via incineration and landfilling, which would have both socio-economic and negative ecotoxicological impacts. The negative ecotoxicological impacts were largely attributed to lead releases in case of increased incineration and landfilling of PVC (ECHA, 2016).

Commission decided a derogation for recycled rigid PVC with a higher limit of 1.5 % to allow the circular use of PVC. However, to prevent the possible leaching of lead and the formation of lead-containing dust, recovered rigid PVC in certain derogated articles (e.g., window frames, rigid sheets and pipes) needs to be entirely enclosed within a layer of virgin PVC, recovered PVC or other material, that contains less than 0.1 % lead, unless the article is inaccessible during normal use. Moreover, enforcing a closed loop, the Commission decision states that rigid PVC containing more than 0.1 % of lead should only be used to produce new articles for the same application (EU, 2023).

If risk management measures were targeted to any of the widely used prioritised additives in PVC, similar concerns as in lead in PVC restriction apply. From a technical point of view, neither legacy additives nor any additives restricted in the future hinder the recycling of PVC. Rigid and soft PVC can be mechanically recycled, regardless of the presence of additives. Many uses of PVC have long lifecycles. Currently, for example, many of the legacy additives, with the exception of lead, do not pose a problem because regulatory limits in recycled PVC can be met. However, the same is not true for the (already) restricted phthalates. There are still many soft PVC products that enter the waste stream which have high restricted phthalate concentrations, which hinders recycling. Currently, for example, around 50 % of the flooring waste constraints legacy phthalates. Extraction of these on a large-scale is not possible at present, while the flooring industry is developing technologies in order to identify, separate and extract legacy additives from the PVC waste.

Some potential regulatory risk management measures on PVC additives could lead to either decreased recycling, or even halting PVC recycling for a time. To analyse the impacts, ECHA has drafted a hypothetical scenario where recycling of PVC would come to a full stop. The assessment has been implemented separately for rigid and soft PVC, since there is a large difference in terms of the use volumes of the prioritised additives between the rigid and soft PVC.

In the rigid PVC, the use of prioritised additives is largely related to organotin substances. They are used as heat stabilisers in uses that have high performance requirements or where transparency is needed. It is likely that future risk management measures would not completely stop the recycling of rigid PVC but could just slightly decrease it. An example can be provided for organotin substances. Out of the post-consumer rigid PVC waste around 90 % is from window frames. The concentration of organotins in PVC window frames is at most 0.06 % (w/w). A limit value above 0.1 % for organotins would then have no impact on the recycling of PVC window frames. For rigid packaging applications, the concentration of organotins is around 1 % (w/w). A limit value of 0.1 % (w/w) would then impact also the recycling of rigid PVC packaging (which is also currently very limited). The example shows that the limit values in any risk management measures can have a large impact on the (decrease of) recycling of PVC. The assessment for the rigid PVC can also be applied to a less drastic decrease in recycling of rigid PVC in a proportional manner.

All of the soft PVC in different uses contains at least some of the prioritised additives. While substitution of prioritised additives seems possible for many of the uses, for example from DINP to DOTP (or DINCH), the waste streams would have a high content (i.e. higher than any foreseeable limit value) of the prioritised plasticisers for a long time. Moreover, stakeholders have indicated (see e.g. Section C.4.3.) that for many of the uses, there are no viable alternatives for some of the prioritised additives (for example medium or long chain orthophthalates or trimellitates in high temperature cable applications). In addition to prioritised plasticisers, the same applications also often require the use of flame retardants that are difficult to replace.

The second large difference in terms of recycling of soft and rigid PVC is that rigid PVC recyclate is often used in the same use at the second cycle (“closed loop”) – and it is required to do so by the EC decision for many of the uses. For the soft PVC, most often recovered from cables, the recyclate is of poorer quality due to impurities and cannot be used for the same use in the second cycle. Typical uses where lower quality recycled PVC can be used are road furniture, tarpaulins etc.

The third difference is that rigid PVC can be encapsulated within a layer of virgin PVC, so that the hazardous substances, such as lead, are covered under a protective layer. This is not possible for the soft PVC recyclate.

Further, based on the information received in the calls for evidence, the current analytical techniques in the recycling facilities are mainly based on X-ray fluorescence (XRF), which is particularly effective for identifying metals, and near-infrared spectroscopy (NIRS), which could be more effective for detecting organic substances. However, neither of them would be able to identify a specific substance but only a group of substances. For instance, XRF will be able to identify if a metal is present, e.g. Sn, but not the specific substances. NIRS would be able to identify, for instance, if there is an orthophthalate but not which specific one. In addition, while these analytical techniques could theoretically be used to scan individual waste PVC articles, in practice this would not be done because it would be economically not viable considering the amount of resources needed. Therefore, it is currently unlikely that PVC waste would be sorted into a fraction containing specific hazardous substances and a fraction without them (CfE2,#1552).

C.13.2. Baseline

In total, around 813 000 tonnes of PVC (rigid and soft combined) was recycled in Europe in 2022 (Vinylplus, 2023b). The figure includes both *pre-consumer* and *post-consumer* recycling. Pre-consumer waste consists of waste generated during the production of final and intermediate products in which the materials are normally homogeneous, and the additives are known. Post-consumer waste consists of waste produced by end consumers or commerce in which materials are likely not homogeneous and the additives are less known. This pre-consumer stream of waste is practically the same material content-wise as the virgin material used in the respective applications, and thus not included in this assessment.

The amount of recycled post-consumer waste was around 310 000 tonnes in 2022, with 120 000 tonnes being soft and 190 000 tonne rigid PVC waste. The total amount of post-consumer waste of PVC is around 2 500 000 tonnes per year, and thus around 12 % is recycled. Stakeholders expect progress in the future to increase the share of PVC waste that is recycled with technological development (mechanical & chemical recycling) and social innovation ("designed for recycling", market incentives for collection) (VinylPlus, 2023).

Most of the post-consumer recyclate comes from applications where PVC articles can easily be separated from other articles, the waste stream is homogenous and easily recyclable. These types of articles are window frames, which are easily separated during demolition work. Similarly, cables and (above-ground) pipes can be easily obtained in the demolition phase. Due to digging and cleaning costs, underground pipes are typically left in the ground after the lifecycle. For the cables, there are high economic incentives for recycling so that the conductor material (e.g. copper) can be recovered (VinylPlus, 2023).

Out of the rigid PVC post-consumer recyclate, around 90 % is recovered from old PVC windows. Another 5 % is from pipes, and the remaining fraction is from the other rigid uses. Out of the soft PVC post-consumer recyclate, around 80 % is from cables and the rest is from non-defined soft PVC uses, such as "flexible PVC and films".

C.13.3. No-recycling scenario

This section describes the socio-economic impacts of a hypothetical no-recycling scenario. The following socio-economic impacts are included quantitatively:

i) Impacts on the price of PVC articles currently using recycled PVC, with a likely increase in the price of PVC due to more expensive virgin PVC being used

ii) Additional costs in terms of landfilling and incineration

iii) Impacts for the recyclers (loss of revenue, unemployment)

iv) Societal costs from the increase in CO_2 emission from the increased production of PVC

In addition to the quantitatively estimated impacts, there are also other environmental aspects related to reduction in recycling, such an increase in raw materials consumptions.

The analysis is largely similar to the lead in PVC restriction dossier, with some additional information and analysis available for items iii) and iv).

C.13.3.1. Rigid PVC

i) Increase in the price of articles using recycled PVC

In the lead in PVC restriction dossier, a price difference of €350 per tonne was estimated between recycled PVC and virgin PVC.

Applying the price difference for the 190 000 tonnes of recycled rigid PVC, the total cost for the end-user, in terms of higher prices, would be €67 million per year. Given that majority of the recycled PVC is obtained from window frames, and the lead in PVC restriction will change the landscape of the PVC recycling, requiring a “closed loop” for the recycling of rigid PVC, the costs will mainly fall to the window sector in terms of more expensive window frames.[5]

ii) Increase in the incineration/landfilling costs and EU incineration capacity

The gate fees from the lead in PVC restriction (€125 per tonne for landfilling; €150 for incineration) are very close to the estimates submitted to ECHA for this report (Marangoni, 2022). Using the gate fees and the incineration (70 %) and landfilling (30 %) shares for the building and construction sector (CfE2, #1601, VinylPlus), the total additional cost of incineration and landfilling would be €27 million per year.

The waste incineration capacity in the EU is around 85 million tonnes/year for energy recovery, and around 6 million tonnes/year for co-incineration in cement plants (Lighea Speziale). The energy recovery plants burn PVC in a mixture of other waste, and the PVC waste can only account 1-2 % of the mixture (Lighea Speziale). This is due to HCl releases from burning of PVC which have a negative impact on the machinery of the plant, and thus the maintenance costs. If rigid PVC recycling would cease, around 60 000 tonnes more of rigid PVC waste would have to be burned annually. In terms of capacity, this could require additional waste incineration capacity between 3 to 6 million tonnes/year in the EU. Based on an interview with an industry expert, the total capacity would not be the main problem in terms of such an increase, but the unequal geographical distribution of the capacity in the Europe (higher capacity in the north compared to south). The capacity would need to be either increased in the southern Europe, or the PVC would need to be transported to the northern Europe.

iii) Impacts for the recyclers

According to the input from the European recyclers in the lead in PVC restriction dossier, the following impacts would take place if there was no derogation with a higher limit for recycled articles (in Lead in PVC; the discussed limits were 0.1 % and 1 %):

a) Closing down of 130 recycling companies

b) Loss of 800 jobs at the recycling companies

c) A loss of more than €7 billion as added value from 2015 to 2020

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[5] If the restriction on Lead in PVC, even given the limited derogation on the rigid PVC recyclate, would decrease the amount of rigid PVC recycled compared to the baseline, part of the costs in this section would be attributable to that restriction.

Based on the assessment in the lead in PVC dossier, the aggregate impacts to the recyclers are difficult to estimate. It was not clear if ceasing of PVC recycling would result in a total or partial shutdown of the individual companies. For the losses to the industry, lost profits are a more appropriate indicator instead of total value.

Monetary losses to the recyclers can be estimated with a standard assumption of a 10 % profit margin. With the estimated virgin PVC price of €1 808 per tonne and €1 458 for recycled PVC, the total trade value of the rigid recycled PVC is around €277 million per year. With a profit margin of 10 %, the annual producer surplus losses would be around €28 million per year. As there is an alternative available, 2 years of profit losses are included in the calculation, with an annual loss in producer surplus of around €4 million.

iv) Societal costs from the increase in CO_2 emissions

The increase in CO_2 emissions is estimated for two sectors for which information is available. These are pipes and window frames, which are also the sectors with highest volumes of rigid PVC recycled.

Pipes

Around 5 % of rigid recycled PVC is from pipes, or around 10 000 tonnes per year. The approach to assessing the CO_2 emissions from the production, recycling, landfilling and incineration, is based on the information presented in section C.3.3.2.2.

The emissions from the production of DN200 pipes of virgin PVC are estimated at 121 $kgCO_2/m$. The weight of one meter of a DN200 pipe is estimated at 15 kg. Dividing the former with the latter results in an estimate of 8.1 tonnes of CO_2 emissions per tonne of PVC pipes.

Using a similar method, recycling PVC produces 0.46 tonnes of CO_2 per tonne of PVC, landfilling 0.081 tonnes of CO_2 per tonne of PVC, and incineration 2.3 tonnes of CO_2 per tonne of PVC.

Following the Product Environmental Footprint method (JRC, 2023) and the avoided burdens approach, we attribute 50 % of the full production process of a virgin PVC pipe to the actual production of the pipe (e.g. injection moulding, additional materials used to manufacture the product).

The total change in the CO_2 emissions is the amount of CO_2 from the production of additional 10 000 tonnes of virgin PVC for the production of pipes, plus the additional emissions from the incineration (70 %) and landfilling (30 %), minus the CO_2 emissions from the recycling of PVC and production of a pipe from recycled PVC. The total increase of CO_2 emissions is approximately 0.06 tonnes per year. The social cost of carbon emissions has been estimated based on the average price of the EU ETS carbon permit in 2022 (€80.82/tonne).

The annual cost of the increase in CO_2 emissions is around €5 million per year.

Window frames

Most of the recyclate from rigid PVC (90 % of rigid post-consumer waste) is from window frames, or around 170 000 tonnes per year.

The summary of the results of the literature review and stakeholder consultation (ECHA market survey 2023) shows that environmental emissions from the production stage of windows frames are 26–107 kgCO_2/m for PVC frames and 2–5 kgCO_2/m for recycled PVC frames per meter of window profile. For the end-of-life CO_2 emissions, the range is 0.02–11 kgCO_2/m. There are no separate estimates for the emissions from incineration and landfilling.

PVC window (1.82 m^2) with a frame size of 1.23 m x 1.48 m has a total of 5.42 m of frame. One meter of PVC frame has an approximate weight of 15 kg/5.42=2.77 kg.

The production of one tonne of PVC window frames results in CO_2 emissions of 9–39 tonnes of CO_2 and recycling 0.7-1.9 tonnes of CO_2. Landfilling is assumed to be in the lower range of the end-of-life emissions, with emissions of 0.007 tonnes of CO_2 per tonne of PVC and incineration in the higher range, with emissions of 4 tonnes of CO_2 per tonne of PVC.

Following the Product Environmental Footprint method (JRC, 2023) and the avoided burdens approach, we attribute 50 % of the full production process of a virgin PVC window frame to the actual production of the pipe (e.g. injection moulding, additional materials used to manufacture the product).

Using these figures, the range for the annual increase of CO_2 emissions is 1.3–3,7 million CO_2 tonnes, in monetary terms €107 to €297 million.

C.13.3.1.1. Summary of socio-economic impacts

Summary of the socioeconomic impacts for non-recycling scenario of rigid PVC is presented in Table 52.

Table 52: Summary of socioeconomic impacts for non-recycling scenario of rigid PVC

Impact	**Estimate (€ million per year)**
Increase in the price	67
Increase of incineration/landfilling fees	27 + capacity problems
Impacts for the recyclers	Loss of profit 4 + employment impacts
Increase in CO_2 emissions	112–302
Total cost	210–400 + capacity problems for incineration plants + employment impacts

C.13.3.1.2. Human health and environmental benefits

Environmental impacts of not recycling the 190 000 tonnes/year rigid PVC waste but rerouting it to incineration (70 %) and landfilling (30 %), assuming the shares from (CfE2, #1601, Vinylplus; (VinylPlus, 2023), will result in a 7.6 % increase of both the PCDD/F releases from incineration and leaching of the additives.

The increase of the PCDD/F releases from incineration may, however, be an over- or an underestimation, because the relationship of the release to the increase of the feedstock waste volume is not necessarily linear due to the chlorine content. As the PCDD/F emissions from incineration are well managed at present (see discussion in Appendix A), it is very likely that the increase is lower than the 7.6 % or even negligible. The releases of priority additives will not increase after the increase of the amount of PVC waste incinerated, as these additives are organic and can be assumed to be under the best available practices to completely degrade. This is different to the lead in PVC case, as lead does not degrade when incinerated (ECHA, 2018).

For the additives, the increase in landfill waste stock amounts to an increase of approximately 7 tonnes/year release of leachate from landfills. No significant particle PVC releases are expected from landfills. On the benefit side, the PVC particle releases and hence the additive releases from the recycling activity decrease to zero when ceasing recycling of rigid PVC. For additive releases, this means a reduction of 0.3 % of the total environmental releases. Please note, that these are approximations assuming a linear relationship.

Risks have been identified for workers in recycling plants to a part of the short-listed organotin substances used as heat stabilisers in some rigid PVC uses (see Appendix B). Re-routing of the rigid PVC waste from recycling to incineration and landfill reduces these risks to zero.

To summarise, for the PCDD/F releases a net damage potential is likely but very low if not negligible, and for the additives releases there is a small gross environmental benefit. For human health impacts, a partial benefit (reduction of worker exposure at recycling sites) is induced, but the risks would not be reduced to zero. Worker exposure at landfills and incineration plants has not been assessed in this project.

C.13.3.2. Soft PVC

The same cost items as for rigid PVC are included for the impacts of no-recycling of soft PVC.

i) Increase of the price of articles using recycled PVC

The total tonnage of recycled soft PVC was approximately 120 000 tonnes in 2022.

With the same assumption of a €350 price difference between recycled and virgin PVC, the total cost in terms of consumer surplus due to higher prices would be around €42 million per year.

A large share of the soft PVC from cables is not usable for cables in the second cycle (or forward). Depending on the quality of the recyclate, the PVC can be used, for example, for road furniture or soft PVC sheets. As the cheap recyclate would not be available anymore, other materials, such as virgin PVC would have to be used.

ii) Increase in the incineration/landfilling costs and EU incineration capacity

Using the same gate fee estimates of €125 landfilling and €150 incineration, and the same assumption of landfilling (30 %) and incineration (70 %) shares, the total cost in terms of increased cost of incineration/landfilling would be €18 million per year.

Similar to the case of rigid PVC, incineration capacity needs to be considered and the same type of analysis applies. The waste incineration capacity in the EU is around 85 million tonnes/year for energy recovery, and around 6 million tonnes/year for co-incineration in cement plants. The energy recovery plants burn PVC in a mixture of other waste, and the PVC waste can only account 1-2 % of the mixture. This is due to HCl releases from burning of PVC which has a negative impact on the machinery of the plant, and thus the maintenance costs. If soft PVC recycling would cease, around 40 000 tonnes more of soft

PVC waste would have to be burned annually. In terms of capacity, this could require additional waste incineration capacity between 2 to 4 million tonnes/year in the EU. Based on an interview with an industry expert, the total capacity would not be the main problem in terms of such an increase, but the unequal geographical distribution of the capacity in the Europe (higher capacity in the north compared to south). The capacity would need to be either increased in the southern Europe, or the PVC waste would need to be transported to the northern Europe.

iii) Impacts to the recyclers

With the estimated PVC prices of €1 808 per tonne for virgin PVC and €1 458 for recycled PVC, the total trade value of the recycled PVC is around €175 million per year. With a profit margin of 10 %, the annual profit losses would be around €17.5 million per year. As there is an alternative available, 2 years of profit losses are applied in the calculation, with annual loss in producer surplus of around €3 million.

iv) Societal costs from the increase in CO_2 emissions

Around 80 % of the soft PVC post-consumer recyclate or 92 000 tonnes comes from the cables. The rest is from the generic categories “soft PVC” and “soft PVC films”.

We use the CO_2 emissions from the production of PVC for cables from virgin PVC as a proxy for the total soft PVC post-consumer recyclate of 120 000 tonnes.

In the ECHA market survey (2023) the following CO_2 emissions were estimated: 8.2 kgCO_2/m; 0.53 kgCO_2/m recycling; 1.95 kgCO_2/m incineration and (practically) 0 for landfilling. With the weight of 0.8 kg/m, the emissions per tonne of PVC cable compound can be estimated: 10.3 tonnes of CO_2 for virgin PVC production; 0.7 tonnes of CO_2 for recycling and 1.95 tonnes of CO_2 for incineration.

Following the Product Environmental Footprint method (JRC, 2023) and the avoided burdens approach, we attribute 50 % of the full production process of a virgin PVC cable to the actual production of the cable.

The total increase of CO_2 emissions is then around 0.8 million tonnes of CO_2 for the total mass of recycled soft PVC. The annual cost of the increase in CO_2 emissions is then around €62 million.

C.13.3.2.1. Summary of socioeconomic impacts

Summary of socioeconomic impacts of non-recycling scenario for soft PVC is presented in Table 53.

Table 53: Summary of socioeconomic impacts of non-recycling scenario for soft PVC

Impact	**Estimate (€ million per year)**
Increase in the price	42
Increase of incineration/landfilling fees	18 + capacity problems
Impacts for the recyclers	Loss of profit 3 + employment impacts
Increase in CO_2 emissions	62

Total cost	125 + capacity problems for incineration plants + employment impacts

C.13.3.2.2. Human health and environmental benefits

Environmental impacts of not recycling the 120 000 tpa soft PVC waste but rerouting it to incineration (70 %) and landfill (30 %), assuming the shares from (CfE2, #1601, Vinylplus; (VinylPlus, 2023)), will result in ca. 5 % increase of both the PCDD/F releases from incineration and leaching of the additives.

The increase of PCDD/F release from incineration may, however, be an over- or an underestimation, because the relationship of the release to the increase of the feedstock waste volume is not necessarily linear due to the chlorine content. As the PCDD/F emissions from incineration are today well managed (see discussion in Appendix A) it is very likely that the increase is lower than the 5 % or even negligible. The releases of priority additives will not increase after the increase of the amount of PVC waste incinerated, as these additives are organic and can be assumed to be under the best available practices to completely degrade. This is different to the lead in PVC -case (ECHA, 2018), as lead does not degrade when incinerated.

For the additives, the increase in landfill waste stock amounts to an increase of approximately 250 tonnes/year release of leachate in total from landfills. No significant particle PVC releases are expected from landfills. On the benefit side, the PVC particle releases and hence the additive releases from the recycling activity decrease to zero when ceasing recycling of soft PVC. This means a reduction of 29 % of the total environmental releases of additives. Please, note that these are approximations assuming a linear relationship. In addition, recycled soft PVC comes mostly from cables, which are recycled mainly for the metal content. Hence, shredding of the cables would happen even if the recycling of soft PVC stops. Further, the result of the shredding is the production of very small pieces/particles of PVC, which increases the surface area and the potential release of additives. Therefore, the reduction of 29 % of the total environmental releases of additives highlighted above might be grossly overestimated.

Risks identified for workers in recycling plants from the plasticiser DEHP and flame retardant diantimony trioxide would nevertheless still prevail, as they are linked to the recycling of soft PVC.

To summarise, for the PCDD/F releases there is some damage potential, but it can be expected to be low if not negligible (not quantified). For the additive releases, there is some environmental benefit in this scenario. The benefit is higher than for the non-recycling scenario of rigid PVC, despite of the lower volume of soft PVC considered for rerouting from recycling to incineration and landfilling. This is because soft PVC contains more additives than rigid PVC (plasticisers and flame retardants), and in particular because they are present in significantly higher concentrations than stabilisers used in rigid PVC. The total risk reduction of additives in this scenario is hence somewhat higher than in the non-recycling of rigid PVC scenario. For this analysis, release reduction of any of the relevant prioritised additives is considered equally beneficial. For human health, this scenario results in some benefit as the worker exposure at recycling sites reduces to zero for plasticisers and flame retardants. Overall, it seems that the benefit (risk reduction) of non-recycling of soft PVC is higher compared to non-recycling of rigid PVC.

C.14. Environmental and human health benefits

The benefits to the environment and human health have been looked at qualitatively for separate risk management areas, namely emission reduction by technological means and by substitution of PVC as a material and substitution of prioritised additives in PVC. The benefits can also be divided into benefits which are specific to the risk management of PVC only (PVC-specific benefits) and benefits which result from risk management of PVC and any other plastic material (non-PVC-specific benefits). In all these situations, the benefits can be measured quantitatively only by release reduction amount, due to the non-threshold risk approach taken. However, a qualitative description of the benefits is provided below. It is also possible to roughly describe the relative benefits.

C.14.1. Benefits of release reduction and additives substitution to the environment - end of life stage

C.14.1.1. Recycling sites

Recycling plants are a common life-cycle stage for all PVC uses (with very few exceptions only). Although the various PVC uses/life-cycle stages may have specificities related to the additives used, 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. Furthermore, recycling plants can be expected to be the most significant common source of releases of PVC microparticles where all uses contribute to the releases.

Recycling plants contribute significantly (31 %) to the overall prioritised additives releases. The release reduction at recycling plants would consequently effectively reduce a significant proportion of the additive releases. As the additives can be assumed to be almost fully released within the PVC microparticles from this activity (to air and wastewater), technical means of reducing PVC microparticles (e.g., prevention of microparticle formation on site, end-of-pipe techniques) are key in the release mitigation of the PVC additives.

The benefits from the additives **release reduction by technological means** are an attenuation of the increase of the environmental stock and exposures (including man via environment exposures) of the PVC additives. This benefit can be expected to be proportionally higher for the release reduction of PVC at recycling plants than for the release reduction of an equal volume of other recycled plastics. Although additives are used also in other plastics, PVC, and in particular soft PVC, requires in total more additives (in the number of additives, functions and their concentration in PVC) than other plastics. The emergence of the known (or potential) severe long-term effects from the prioritised additives is delayed or prevented. Furthermore, the likelihood of synergistic and/or cumulative effects caused by the whole additives spectrum arriving at (and released from) recycling are attenuated in the environment (and man via environment). This means the prevention/attenuation of effects related to human health (reproduction, immunological effects, neurotoxic effects, effects on endocrine system, other) and effects to the populations in nature (endocrine effects, chronic other effects). The benefits from attenuating the risks due to microparticles, only, are listed at the end of the section.

To conclude, release reduction by technological means at recycling plants is considered specifically beneficial for the attenuation/prevention of long-term effects of the prioritised PVC additives with the already known severe hazardous properties. However, benefits would also encompass the less known and even less predictable effects of PVC additives at large, as well as reduce the co-exposures.

Substitution of some or all of the prioritised PVC additives with other PVC additives as a sole risk management measure would result only in a partial benefit for the environment and man via the environment compared to the above described two-fold benefits from release reduction by technological means. The main effect of substitution at recycling sites would be the prevention of the increase of the volume of substituted additive(s) in circular economy and hence prevention of the increase of the releases and, secondary, a gradual reduction of the volume of the prioritised additives processed over time in the circular economy (note: mass balance not carried out in this project). This would lead to a reduction of releases of the substituted additives over a very long time-span. The existing volume of substituted additives remains in the circular economy after the substitution, and hence, is further released from the various life-cycle steps, incineration and (a theoretical) full containment during the uses being the only means to reduce the overall release potential for additives over a long time-span. The temporal progress of the reduction of the amount of the handled (and released) substituted additives would depend also on the legacy concentrations in products made of recycled PVC and on the amount of legacy PVC products in use and their service lifetime. The mechanism of release reduction over time is not straightforward, as illustrated with cadmium in PVC (see Appendix F) and lead in PVC (ECHA, 2018).

Substitution of one or more of the prioritised additives would lead to a relatively similar amount of releases of the alternative additives to the environment, if no additional technological release reduction measures are implemented on sites and no changes in end-of-life routing are taken. The difference in the released amount of the alternative additive(s) is mainly dependent on the total volume and concentration of the alternative additive in PVC compared to the additive substituted based on the applied exposure assessment approaches as described in Appendix B. It is noted that a potential change in the recycling rate of PVC as a result of substitution may also have an impact on the temporal development of the releases of the substituted and alternative additives.

The main uses contributing to the volume of recycled PVC are window frames (about 50 % of the total recycled volume), cables (12 %), pipes and fittings (6 %), and other undefined soft PVC uses (see Appendix A). Soft PVC products contain higher amount of prioritised PVC additives than rigid PVC. The contribution of cables to the releases from recycling plants is therefore the highest of all uses.

The benefit of the substitution for environmental risks can be due to the outcomes described above expected to depend mainly on the difference in the (eco)toxicity profile between the prioritised additive and its alternative. As the substituted additives have more severe hazards than their alternatives, substitution would attenuate or prevent environmental (and man via environment) risks arising in the long-term from the known effects of the substituted additives. In the worst case, effects in general might be expected in a longer term only or they would be less severe as a result of substitution. In order to reflect the relative toxicity in the impact assessment, the additives were divided into four groups based on the identified concern. In order to better quantify the expected benefits of the additive substitution as the only risk management measure, a more detailed analysis would be necessary in particular related to the mass balance and resulting releases of the substituted and alternative additives over a long (20 year) timespan (data and analysis gap).

C.14.1.2. Landfills

Also landfills, similar to recycling plants, are sources of releases which reflect the use of PVC additives at large. They contribute by ca. 11 % to the overall additive releases. Release reduction by technological measures in landfills can therefore be assumed to be a relevant contributor to the positive benefits related to the additives release reduction as described above for recycling plants. The contribution of the landfills to the overall PVC microparticle releases is less clear (see Appendix A) and the form of the releases or additives is not provided in ECHA Guidance. Hence the link between the additives releases and microparticle releases is less straightforward than in the recycling plants. Thus, the contribution of technical release reduction measures at landfills to the overall microparticle release reduction and subsequent additives release reduction is less clear in quantitative terms, although evident.

The main uses contributing to landfilled releases are flooring (32 %),cables (29 %), automotive interiors (13 %), artificial leather (13 %) and medical applications (7 %), with the rest of the uses contributing in minor amounts of 2 % or lower.

The benefits of substitution of prioritised PVC additives by alternative additives can be expected to be analogous to the benefits described for recycling plants.

C.14.2. Benefits of release reduction and substitution - other life-cycle stages than EoL

The other life cycle stages than end-of-life, including the production and service-life stages of PVC articles, have sector and use-specific characteristics. The additives used in PVC are product-specific (see Appendix B). Release reduction by technical means in professional handling of articles, especially for soft PVC used in the construction sector (cables, flooring), has among these life cycle stages the widest benefit potential from reducing additive releases as these releases contribute very significantly (ca. 45 %) to the overall releases of the prioritised additives. Also here the link between the additive releases and PVC microparticle releases is significant. The benefit of technical release reduction measures would be analogous to the benefits in the recycling plants: prevention of the increase of the releases and the gradual attenuation of the releases of a wide set of additives (and PVC microparticles) over a long time span. Although all other life cycle stages and uses (compounding, conversion, industrial and consumer uses) also contribute to the overall releases, the benefits of the release reduction by technological means can be expected to be proportionally less pronounced for individual life cycle stages and uses. However, release mitigation also in these life-cycle stages would contribute to the overall positive benefit of the gradual release reduction.

Substitution of the prioritised additives used in cables and flooring (e.g., medium chain ortho-phthalates, borates, trimellitates) would lead to an equal amount of releases of the alternative additives. The picture of the benefits of substitution is expected to be similar as at the recycling plants but less pronounced, as targeted only to the specific prioritised additives handled by professionals in these uses.

C.14.3. Benefits of reducing risks from direct human exposure to additives

C.14.3.1. Recycling facilities

As mentioned before, PVC post-consumer waste from different sources is processed in recycling plants. Therefore, recycling plants are a point of exposure for all PVC additives. Consequently, workers are expected to be exposed simultaneously to all PVC additives. Among them are organotins (DOTE, DMTE and MMTE), DEHP and diantimony trioxide. Developmental reproductive toxicity is a common hazard across the organotin substances, in addition to immunotoxicity (DOTE and DMTE) and neurotoxicity (DMTE). DEHP has also developmental and fertility reproductive toxicity mediated by endocrine disruptive properties, which in this project are considered as non-threshold effects[6]. For diantimony trioxide, hazard properties are related to carcinogenesis.

The likelihood of neurological, immunological and especially reproductive effects among the workers are expected to be low after the exposure to those substances is reduced (in the case of DEHP minimised).

Regarding the reproductive toxicity, the benefit of reducing the exposure would be in a better quality of life expressed on less difficulties during pregnancies and less developmental impairment of foetuses and breast-fed babies. Reducing the exposure will also result in a reduction of neurotoxicity and immunotoxicity related impairment in workers. It is noted that the specific adverse outcomes and related DNELs and/or dose-responses would need to be assessed and/or refined and identified as a follow-up activity.

The reduction of the worker related identified risks from to the specific prioritised additives (see Appendix B, section B.6.13) are by the highest certainty reached by **substitution** of those additives.

An additional substitution of the prioritised additives for which no risks were identified, or for which no risk assessment was carried out due to lack of DNELs (assessment gap), is also likely to have a further benefit with regard to the co-exposure. The likelihood of dose-additivity at least within the groups of similar additives (e.g., ortho-phthalates) is high and synergistic effects cannot be fully excluded between the prioritised additive groups. In order to understand this potential benefit, the co-exposure related risks would need to be assessed (assessment gap).

Technical exposure reduction of PVC microparticles at recycling plants can be expected to contribute significantly to the exposure reduction of DEHP in particular (very low volatility), but also of the other prioritised additives for which risks were identified. Furthermore, it is noted that further benefits can be expected from PVC microparticle exposure reduction, as this results in an overall a reduction of co-exposures to all PVC additives (additives worker exposures partly mediated by PVC microparticles).

Overall, at recycling plants, positive benefits on reproductive health and in terms of prevention of neurotoxic and immunotoxic (and potentially also carcinogenic) effects can be expected to be reached in particular by substitution of the specific additives for which risks were quantified. However, a wider positive benefit can be reached by a combination of the substitution and exposure reduction of PVC microparticles and potentially even by extending the substitution to the prioritised additives for which risks were not identified or not assessed. Recycling plants are the workplaces where exposure to the whole spectrum of PVC additives is occurring.

C.14.3.2. Consumer exposure during article service life

Potential risks were identified for consumers during article service-life caused by organotin substances via inhalation route (DOTE in packaging and DOTE, DMTE and MMTE in automotive interiors) and benzoate EC 421-090-1 in flooring via dermal route. Developmental reproductive toxicity is a common hazard across the organotin substances and benzoate EC 421-090-1 was also identified as a potential reprotoxicant. Based on

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[6] Due to a lack of knowledge whether the current DNELs are sufficiently protective (ECHA 2021).

further information provided on these substances, the risk should be perceived as 'potential' only, as the concern may be removed after a closer scrutiny.

A reduction of exposure to these substances may result in a benefit regarding the quality of life by preventing the impaired reproduction. Considering the uses (flooring and automotive sector), the benefit will apply to a large number of people.

C.14.4. Benefits of substituting targeted substances/substance groups – general discussion

According to the working approach taken in this investigation report, any additive releases may be expected to constitute a risk to the environment by known or unknown effects taking place in a closer or more distant future, while at that point of time the difficulty to reverse the exposures causes challenges in handling the outcomes. In this approach, releases are considered as a proxy of risk and correspondingly, direct benefits to the environment and man via environment can only be related to the avoided releases compared to the baseline (in the baseline situation releases to the environment would increase (see main report). For the prioritised additives, severe toxicity (and in some cases severe potential severe toxicity) are known and therefore the expected risks are more tangible and at least qualitatively easier to describe than for the other, non-prioritised PVC additives. Environmental risks cannot be further quantified in this approach, although relative comparisons may be possible. See also the description for the environmental benefits, recycling plants above for further discussion. A benefit of substitution of a prioritised additive (group) with a non-prioritised additive can be exemplified by preventing or reducing the specific known effects for the additive to be substituted. E.g., substitution of DEHP with DOTP would reduce the likelihood for the environmental effects (and man via environment effects) related to the relevant endocrine endpoints active in DEHP (all of these have not been assessed by today) to take place in the near future as the increase of releases is prevented, whereas for the distant future the effects might yet arise (releases and increase of the DEHP mass in the environment continued until an equilibrium is reached in a distant future). For human endocrine effects due to worker exposure substitution of DEHP would likely result reduction of risk over time but it would be dependent on the development of the legacy concentrations of DEHP in recycled PVC (the legacy volume of DEHP in the economy would only very gradually reduce).

C.14.5. Benefits of substituting PVC with other plastics – general discussion

Substitution of PVC with **other plastics** has three elements to take into account. Firstly, in terms of the sole risks due to the microparticle releases (without the additives impact), it is expected that substitution with other plastics would likely not change the situation significantly, although some minor differences (benefits or impacts) could be seen. The microparticle releases would, based on the current level of knowledge, remain at the same level, hence, there would be no benefit, assuming that the volumes of end-of-life material would not differ significantly between PVC and other plastics and assuming that the recycling rates would not be different (these elements would need to be further analysed).

Secondly, there would be a benefit in the form of reduced overall additives releases into the environment if PVC would be replaced widely in the various products with other plastics. This is due to the fact that the overall concentrations of additives used in PVC are generally higher than in other plastics. Contribution of soft PVC substitution with other plastics to this benefit may be expected to be higher compared to substitution of rigid PVC with other plastics (for rigid PVC the relative benefit should be more closely analysed; assessment gap). However, the current information available in the project for the additives in alternative plastics does not allow a precise benefit analysis.

Thirdly, the other than microparticle related concerns of the alternative materials were briefly screened but not fully assessed (see Appendix A). For this comparison no firm conclusion can be currently made. The potential concerns specifically related to the PVC material only, and not to alternative plastics, seem to be under control (e.g., PCDD/PFDD formation, hazardous monomers; see Appendix A).

Risks related to direct worker exposure (DEHP, DOTE, DMTE) as identified in Appendix B would likely be reduced. However, the benefit on worker exposure at recycling sites (assuming virgin PVC would be substituted but recycling of PVC would continue) would be significantly dependent on the rate of PVC recycling and especially on the concentration of legacy substances in the recycled PVC. Benefit of substituting PVC with other plastics is, however not clear for worker risks from diantimony trioxide, because the substance is used in various plastics. Hence the worker exposure when used in other plastics would need to be assessed. For consumers, the benefits can be expected to be related to the benefits of reducing the risks identified from organotins. For the consumer risk found for EC 421-090-1 a benefit of material substitution is not clear, but its use in other plastics would need to be explored and assessed, if relevant. It is also noted that consumer risks of additives solely used in alternative plastics were not assessed (assessment gap).

C.14.6. Benefits of substituting PVC with other materials than plastics – general discussion

This substitution would have two-fold environmental and human health benefits. Firstly, increase of the plastic microparticle releases would be prevented and the releases would gradually be reduced. This would lead to an attenuation of the increase of the microparticle levels in the environment roughly proportionate to the volume of PVC versus volume of other plastics (assuming the use of other plastics would continue). It is, however, noted that this benefit is not specific to PVC but the same benefit would result from replacing other plastics with non-plastic materials.

Secondly, additive releases would be reduced. The scale of the release reduction of both type of risks would be dependent on the rate of recycling, landfilling and incineration of PVC and on the effectiveness of site-specific release reduction measures (future development of the volume of PVC in the economy after substitution of PVC was not assessed; assessment gap). This benefit can be expected to be from the overall additive release -perspective proportionately higher when substituting PVC than substituting other plastics with non-plastic materials due to the higher additive amounts used in PVC generally compared to other plastics (exceptions for specific uses may however apply and would need to be investigated). In particular, this benefit would apply to the substitution of soft PVC uses, whereas the relative benefits might be lower for rigid PVC (assessment not carried out). In other words, there are specific benefits to substituting PVC, in particular the soft PVC. However, the current information available for the alternative plastics or other materials does not allow a precise benefit analysis.

Benefits related to the identified risks from direct worker and consumer exposure to specific additives (see Appendix B) may be expected to be similar as in the substitution of PVC with alternative plastics as described above. It should be, however, mentioned that this project did not assess the risks of alternative materials to workers and consumers and hence the overall benefit or impact of this type of substitution is currently unknown.

C.14.7. Benefits of release reduction of PVC microparticles (specific to microparticles only)

Environmental risks due to exposures to microparticles have a non-threshold character and the benefits can be directly quantified only as the avoided releases compared to the baseline. This understanding follows the approach taken by ECHA (2020).

C.14.8. Uncertainties of the benefits screening

The uncertainties related to the risk assessment also apply to the benefits screening (see Appendix A and B). Further data gaps have been identified above.

It is noted that no in-depth assessment of environmental or toxicological risks of alternative materials was carried out. Therefore, no quantitative comparison of the benefits and impacts of moving to alternative materials could be made in this project.

C.15. Key uncertainties and data gaps

Key uncertainties and data gaps in the impact assessment are presented in Table 54. These are mainly related to data gaps or issues with data quality. The impact assessment has not been carried out for all uses due to lack of data, and in other cases the data issues reduce the certainty of the estimated impacts.

Table 54: Main uncertainties and analysis or data gaps related to the impact assessment

Relevant section of the assessment	Identified uncertainties					
	No.	Description of uncertainty	Specific information on uncertainty	Input	Metho-dology	Analysis not carried out
Section C.X.2. Baseline	1	Lack of detailed data on the volume of PVC placed on the market in the EU for some uses.	Cables: No information on imported PVC cables. Blister packs: Unclear if volume covers other than pharmaceutical blister packs or if they are included in the general packaging volume. No information on the share of different types of blister packs (pharmaceutical, nutraceutical, other). Medical applications: No volume information per product type. Toys: No volume information per product type. Clothing: No volume information on other uses than artificial leather.	X		
Section C.X.3. Alternative materials	2	Lack or poor quality of data on the alternatives to PVC and their performance for some uses.	Cables: Poor information on alternatives for the vehicles and EEE sectors. Pipes: Poor information on alternatives for industrial use. Blister packs: Poor information on the performance requirements of other than pharmaceutical blister packs. Toys: Poor information on alternatives and their performance. Artificial leather: Poor information on alternatives and their performance.	X		
Section C.X.3. Alternative materials	3	Lack of evidence of the most likely alternative to PVC.	Cables: Poor evidence that TPE could be one of the main alternatives to PVC in EEE. Pipes: No information related to most likely alternatives for industrial use.	X		

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis not carried out**
			Flooring: Lack of information on the most likely alternative for some specific sub-uses, such as use within the health care sector. Packaging: Poor information on the most suitable alternatives for various types of packaging.			
Section C.X.3.1. Economic impacts	4	Lack or poor quality of data on the price of the alternatives to PVC for some uses.	Cables: For TPE cables (most likely alternative for EEE), only information on the price of the raw material is available. Pipes: No information on the prices related to the alternatives for industrial use. Only qualitative information related to the differences in the installation costs between different pipe materials for potable water/drinking Water. No information on the installation costs for industrial use. Flooring: Wide range of products available under each material with a wide range of prices. Packaging, medical packaging (blister packs), medical applications, toys and artificial leather: Data on the price of final articles lacking, and assessment is based only on prices of the raw material.	X		
Section C.X.3.1. Economic impacts	5	Lack or poor quality of data on data on full/lifetime substitution costs.	Packaging, medical packaging (blister packs), medical applications, toys and artificial leather: Only material costs have been included. R&D costs, investments costs and other potential costs (such as authorisation costs) not estimated.	X		X
Section C.X.3.2. Supply chain	6	Lack of evidence on the impacts to	Cables, packaging, blister packs, medical applications, toys, artificial leather: While majority of the PVC resin is produced in the EU, there is varying quality of data related to the imports and	X		x

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis not carried out**
impacts		the supply chain.	exports of PVC articles under different uses and sub-uses. There is also little evidence related to the origin of the alternative raw materials.			
Section C.X.3.2. Supply chain impacts	7	Lack of data on producer surplus losses.	Producer surplus losses to the producers of PVC articles have been estimated with a uniform assumption of the profit margin of 10 %.		X	
Section C.X.3.2. Supply chain impacts	8	Approach applied to assess producer surplus losses.	SEAC's approach on assessing changes in producer surplus in cases where alternatives are typically available is to account two-year producer surplus losses for the entire assessment period. It is not certain if the two-year assumption is valid in the case of entire sectors.		X	
Section C.X.3.3. Life cycle impacts	9	Limited scientific literature and other information on the qualitative life cycle impacts of replacing PVC.	All uses: Qualitative description of impacts at different lifecycle stages is based on limited scientific literature and stakeholder provided evidence. Cables: The description is based on one article, with results not directly transferable to the EU. Pipes: The description is based on five articles, with no clear conclusion on the preferability of the materials in terms of lifecycle environmental impacts. Flooring: The description is based on two articles. However, the articles are directly related to the comparison of alternative flooring materials, and some conclusions on the likely impacts of replacing PVC with other materials can be drawn. Window frames: The description is based on four articles, and no	X	X	

Relevant section of the assessment	Identified uncertainties					
	No.	Description of uncertainty	Specific information on uncertainty	Input	Metho-dology	Analysis not carried out
			conclusion on the preferable material for all life cycle stages and impact categories can be made. Blister packs: The description is based on two articles, and no conclusion on the preferable material for all life cycle stages and impact categories can be made. Packaging, medical applications, toys, artificial leather: No or limited qualitative information on life cycle impacts.			
Section C.X.3.3. Life cycle impacts	10	Limited scientific literature and other information on the quantitative life cycle impacts of replacing PVC.	All uses: The quantitative description of impacts at different lifecycle stages is based on limited scientific literature and stakeholder provided figures. Cables: CO_2 emissions related to the production of soft PVC are quantified. However, multiple stakeholders commented that other lifecycle stages (such as production of the cable itself) are relatively more important in terms of the CO_2 emissions, but no quantitative estimates (per unit of produced cable) were provided. Pipes: The quantitative CO_2 emission estimates were calculated using the embodied energy approach. While there was a good quantity of data, there are uncertainties related to the approach itself (e.g., omits the use and end of life phases). Flooring: The quantitative LCA impacts can be calculated for seven impact categories based on estimates of two high quality studies. It is not possibly to quantify the uncertainty (variation) related to the impacts. Window frames: Only CO2 emissions for the production phase are quantified and monetised.	X	X	X

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis not carried out**
			Packaging, medical packaging, medical applications, toys, artificial leather: No quantitative information on life cycle impacts.			
Section C.X.4. Alternative additives	11	Lack of data on the use and volume of additives per use.	Cables: Plasticisers: No detailed information on plasticisers used and their volumes; Flame retardants: No information on which additives are used and their volumes. Pipes: Plasticisers: No information on the use of additives in flexible tubes. Packaging: Typical average compounding missing for soft packaging. Medical applications: Typical average compounding missing. Uncertainty about additives used in medical applications. Uncertainty about the volume of plasticisers. Toys: Uncertainty about additives (plasticisers and heat stabilisers) used in toys. Artificial leather: Lack of data on plasticisers used. Uncertainty about the use of flame retardants.	X		
Section C.X.4. Alternative additives	12	Lack of data on the alternatives to currently used prioritised additives in PVC.	Cables: Plasticisers: Poor information on the replaceability of medium chain orthophthalates and trimellitates. Flame retardants: Information about R&D related to alternative flame retardants, no information on potential alternatives. Pipes: Plasticisers: No information on alternative plasticisers for flexible tubes. Heat stabilisers: Uncertainty if substitution is possible. Flooring: Uncertainty related to the use of organotins as heat	X		

Relevant section of the assessment	**Identified uncertainties**					
	No.	**Description of uncertainty**	**Specific information on uncertainty**	**Input**	**Metho-dology**	**Analysis not carried out**
			stabilisers in luxury vinyl tiles. Lack of information on alternative flame retardants. Heat stabilisers in window frames, packaging (rigid), blister packs: Uncertainty if substitution is possible. Artificial leather: Lack of information on alternative flame retardants.			
Section C.X.4. Alternative additives	13	Lack of data on the market prices of some additives.	Cables, flooring, artificial leather: Assumptions on the prices of plasticisers made for long-chain ortho-phthalates compared to medium-chain ortho-phthalates and trimellitates. Pipes: Heat stabilisers: Information on the substitution cost per product line, but the number of product lines is missing (total costs cannot be calculated). Cables, flooring, artificial leather: Lack of price information and substitution costs for flame retardants.	X		
Appendix C	14	No cost-effectiveness analysis conducted for the prioritised additives in terms of costs per avoided releases.	All uses. Cost-effectiveness analysis for additives can be conducted later, with the PBT-approach, where releases are a proxy of the risk and the cost/kg of avoided releases can be calculated (both total C/E ratios, and incremental C/E ratios for different concern categories from high concern to currently no identified concern).	X		X
Appendix C	15	No cost-effectiveness analysis conducted for PVC and	All uses. Impact assessment lacks the comparison of the ecotoxicological risks between PVC and other materials. The PBT approach does	X		X

Relevant section of the assessment	Identified uncertainties					
	No.	Description of uncertainty	Specific information on uncertainty	Input	Metho-dology	Analysis not carried out
		alternative materials in terms of costs per avoided releases.	not seem particularly relevant for such a comparison, due to uncertainty which releases should be included in such a comparison.			
Appendix C	16	Lack of data to conduct impact assessment for some uses of PVC.	Building and construction: Roofing, wallpaper, other profiles and sheets Clothing: Other uses than artificial leather Vehicles: Other uses than artificial leather, e.g. automotive parts Other, miscellaneous consumer articles	X		
Appendix C	17	Lack of information on the risks of imported PVC articles.	All other uses except flooring: Uncertainty regarding the additives in articles that are imported to the EU.	X		
Appendix C	18	No estimation of impacts of other risk reduction measures than substitution.	All uses. Only impacts of substituting PVC with alternative materials, substituting prioritised additives with alternative additives and no-recycling scenarios were estimated. The impacts of other potential risk reduction measures, such as end-of-pipe measures and product-related measures were not covered.	X		X

C.16. Conclusions

The main conclusions from the impact assessment per use are presented in Table 55. It is highlighted that the impact assessment covered substitution and some end-of-life scenarios. Impacts of potential other risk reduction measures (such as, release reduction measures at source) have not been assessed. Benefits have been described qualitatively.

Alternative materials to PVC are available for all uses covered in the impact assessment. In some cases, the performance of the alternative materials differs from PVC. For example, PE-X cables for vehicles are less flexible, but have a higher heat resistance. Since all uses have multiple key performance criteria, it is often impossible to fully compare the overall performance of the materials. Availability may also be an issue for some uses, at least in the short term, when the share of PVC products is large (e.g. window frames, resilient flooring, standard cables, sewage pipes) or certification / authorisation is needed (e.g. medical applications). Thus, in a hypothetical scenario where PVC itself would be restricted, transitional period(s) may be required for uses with large share of PVC used and/or with certification/authorisation requirements.

Replacing PVC with alternative materials is costly for many of the uses, as PVC is often a low-cost option. There are large differences between the uses with regard to the magnitude of the costs entailed. For flooring and window frames, the annual costs are in the order of billions of euros in terms of consumer surplus losses due to higher prices, should PVC be replaced. These stand out as the most expensive uses to replace. For some uses, the impact assessment covers only the material costs and nothing else. In these cases the cost estimates can be considered as providing only indicative information, and full replacement costs are not available at the moment.

There are also environmental impacts from the replacement of PVC with other materials. For flooring, the inclusion of multiple environmental impact categories in the analysis shows that whether the (negative) environmental impacts increase or decrease is strongly dependent on the materials that replace PVC. With the current flooring mix, it is estimated that there would be an increase of negative environmental impacts, which is largely explained by the poor performance of carpet flooring in terms of environmental burden. For the other uses, CO_2 emissions are included in the analysis whenever feasible.

For the prioritised additives, the releases are considered a proxy of risks. The larger the overall release of prioritised additives from a use are, the more that use is expected to cause risks. To further aid the impact assessment, additives were categorised into high concern, medium concern, low concern and currently no identified concern bands. Alternative additives with currently no identified concern or with lower level of concern are available for plasticisers and heat stabilisers.

In the case of plasticisers, there are two general purpose plasticisers available with currently no identified concern, DOTP and DINCH. DOTP is largely imported while DINCH is produced in the EU. In many of the uses, these two plasticisers could replace the currently used plasticisers with identified risks. However, when high temperature resistance or low fogging (car indoor air quality) are needed, DOTP and DINCH cannot be considered as suitable alternatives for long-chain ortho-phthalates or trimellitates. This is because both high molecular weight phthalates and trimellitates have a low vapour pressure, which means that they are less likely to leach out of the PVC matrix even at high temperatures.

Over 90 % of the heat stabilisers used in the EU are mixed metal stabilisers, mostly Zn/Ca carboxylates, which have currently no identified concern. However, organotins (DOTE, DMTE, MOTE and MMTE) are needed for their performance-enhancing properties in specific uses (rigid packaging, blister packs, pipes and window frames). Substituting organotins with mixed metal stabilisers would impact technical performance, and industry has stated that PVC articles could not be produced with these additives due to their lower performance, e.g. in terms of long-term heat stability and transparency. Both organotins and Zn/Ca stabilisers are largely produced in the EU.

Information on alternative flame retardants and their associated substitution costs is largely lacking. Industry has claimed that alternative mineral-based flame retardants are being developed, but more detailed information is confidential.

In some cases, alternatives with currently no identified risk are not available, and then substitution to a lower (but potential) risk is possible. This is, for example, the case with trimellitates. It is assumed that trimellitates could be replaced with long-chain orthophthalates, which would mean a transition from medium risk to low risk. However, going further down in the risk category does not seem possible, for example, for such cables that require high heat resistance properties.

For some uses, there is indication that PVC articles could not be produced using alternative additives due to their lower performance (e.g. organotins in rigid packaging, window frames and pipes). In these cases, replacing PVC may be more feasible than replacing the additives with potential risk in PVC, as alternative additives with similar performance are not always readily available. For example, high resistance cables made with alternative materials are available both for the building and construction sector (halogen-free cables) and for vehicles (PE-X cables), and there are various alternative packaging materials that could be used instead of PVC.

Alternative additives are sometimes more costly, but not always. Costs are mainly based on the price differences between the currently used and alternative substances. Thus, costs of replacing additives are underestimated, as some cost estimates are not available (e.g. reformulation costs). Substitution to alternative additives may result in the need to import the additive instead of relying on manufacturing in the EU, at least in the short term (e.g. replacing DINP with DOTP). Thus, supply chain impacts from switching to alternative additives are possible.

Based on past restrictions and stakeholder comments, the most significant impacts of a possible future restriction on the end-of-life (EoL) treatment of PVC would be on recycling. Rigid and soft PVC differ both in terms of the magnitude of the socio-economic impacts of a hypothetical restriction and changes in risks from reduced recycling of PVC. This is due to rigid PVC having typically less prioritised additives in the compound, being recycled in a closed loop, and the possibility to encapsulate the rigid recyclate with a layer of virgin PVC.

In a hypothetical scenario where the recycling of PVC would cease, there would be socio-economic impacts for the end-users of the product made of PVC recyclate, profit losses for the recyclers, increased cost of EoL treatment of PVC, likely employment impacts, and increase of CO_2 emissions from the production of virgin PVC and incineration of material that cannot be recycled anymore.

Most of the rigid PVC recyclate is used in window frames. Out of the impact categories, the monetised impacts are largest for the increase of CO_2 emissions. The total annual cost from stopping the recycling of rigid PVC would be around €210-400 million, plus possible capacity problems for incineration plants and employment impacts for the recyclers. The environmental and health benefits (for the workers) are expected to be low.

Most of the soft PVC recyclate is from cables. Soft PVC recyclate is not used for the same use after recycling, but, for example, for different types of road- or agricultural furniture. Also for the soft PVC, out of the impact categories, the monetised impacts are largest for the increase of CO_2 emissions. The total annual cost from stopping the recycling of soft PVC would be around €125 million, plus possible capacity problems for incineration plants and employment impacts for the recyclers.

The benefits from non-recycling of soft PVC are higher than for the rigid PVC, despite of the lower volume of soft PVC rerouted from recycling to incineration and landfilling. This is because soft PVC contains more additives than rigid PVC that are present in significantly higher concentrations than heat stabilisers used in rigid PVC. For human health, this scenario results in some benefits as the worker exposure at recycling sites reduces to zero for plasticisers and flame retardants. Overall, it seems that the benefit (risk reduction) of stopping the recycling of soft PVC is higher compared to non-recycling of rigid PVC.

Table 55: Main conclusions from the impact assessment

Use	Sub-use	Use of PVC	Alternative materials to PVC	Costs of alternative materials to PVC	Producer surplus losses for alternative materials	Costs of alternative additives in PVC	Supply chain impacts for alternative additives	Life cycle impacts
Pipes and fittings	Potable water/ Drinking water	Mainly used for water service distribution lines and water distribution in buildings	Several alternative materials exist Most likely alternatives: PE (most commonly used), Ductile iron, PP (for water distribution in buildings)	Lifetime costs of alternative materials assessed. Replacing PVC with alternative materials costs €300 million per year	Producer surplus losses in the EU €13 million per year	Only prioritised additives are heat stabilisers (organotins) – used for pressure pipes, fittings & valves for Industry; and pressure fittings for Potable water and Sewage.	Replacing organotins with Zn/Ca stabilisers costs €0.2 million per year and R&D costs, according to industry, €10 million per product line. 5-year transitional period may be needed. No significant negative supply chain impacts for chemical producers.	Production phase particularly relevant Several studies available with mixed results No conclusion possible on the preferable material Replacing PVC with alternative materials would reduce CO_2 emissions from the production stage and lower the social cost of carbon on average by €133 million per year. CO_2 emissions from PE and ductile iron are similar to emissions from PVC, and the estimated reduction is attributed to PP.
	Sewage	Mainly used for non-pressure sewage lines, where it is very likely the most common material used in the EU	Alternative materials exist Most likely alternatives: PE, PP (most commonly used alternative for non-pressure sewage)	Lifetime costs of alternative materials assessed. Replacing PVC with alternative materials costs €220 million per year				
	Industry	Includes piping application of natural gas, industrial processes and industrial pipe fittings.	Alternative materials exist and may imply deterioration or improvement in performance	No assessment.				
Cables	Building and construction cables	Cables are used for cable insulation and jacket/sheathing.	Alternative materials exist Most likely alternatives:	Unit costs of articles of alternative materials	Producer surplus losses in the EU €5 million per year	For standard cables (<70 °C) DINP could be replaced with DOTP. The cost of moving from medium	Similar one-off reformulation costs for the EU as estimated in the MCCP restriction	Very limited literature available. Based on stakeholder

Use	Sub-use	Use of PVC	Alternative materials to PVC	Costs of alternative materials to PVC	Producer surplus losses for alternative materials	Costs of alternative additives in PVC	Supply chain impacts for alternative additives	Life cycle impacts
			Halogen-free cables (polyolefins, EVA, mineral based flame retardants); PE	assessed. Replacing PVC with alternative materials costs €13-81 million per year		concern to currently no identified concern is around €2 million per year. For higher temperature rating (<80 °C) DPHP could be replaced with DIDP, DUP or with even longer-chain ortho-phthalates. The cost of moving from medium concern to low concern is around €14 million per year. For even higher temperature rating (105 °C) it is assumed that trimellitates could be replaced with long-chain ortho-phthalates with no additional cost. Cables with a higher temperature rating require flame retardants. ATO, a synergist to PVC, seems currently hard to replace. Industry is developing new flame retardants, but costs are not known.	Dossier, €120 million, could take place in case companies would have to change their plasticiser formulation. Profit losses from moving from DINP to DOTP around €1 million per year in the EU. Likely capacity issues related to EU production of DOTP.	comments, the energy demand during pulling of cables seems an important stage in terms of overall contribution. No conclusion possible on the preferable material. Not possible to compare the CO_2 emissions between materials.
	Vehicle cables		Alternative materials exist Most likely alternative: PE-X	Unit costs of articles of alternative materials assessed. Replacing PVC with alternative materials costs €4-22 million per year				
	EEE cables		Alternative materials exist	Only material costs of alternative materials assessed				
Flooring	Sheets, tiles and planks	PVC flooring is in the market segment of	Alternative materials exist and may imply	Lifetime costs of alternative materials	Producer surplus losses in the EU €22 million per	Mainly plasticisers (mainly DINP) are used of the prioritised	Profit losses from moving from DINP to DOTP around €4	Use stage relevant for life cycle impacts, more

Use	Sub-use	Use of PVC	Alternative materials to PVC	Costs of alternative materials to PVC	Producer surplus losses for alternative materials	Costs of alternative additives in PVC	Supply chain impacts for alternative additives	Life cycle impacts
		resilient flooring that consists of materials that can withstand heavy use, are easy to maintain, hygienic, and comfortable underfoot. Share of PVC flooring: 91 % resilient flooring market <10 % of total flooring market	deterioration or improvement in performance Resilient flooring: Linoleum, other polymers, rubber, cork Other flooring materials: Wood, laminate, ceramic and stone, carpet	assessed. Replacing PVC with the cheapest alternative costs €2.4 billion per year. Replacing PVC with resilient flooring materials costs €10–15 billion per year Replacing PVC with other flooring materials costs €13–39 billion per year	year	additives. The replacement of DINP is already taking place in the EU with DOTP and DINCH. Replacing remaining volume of DINP (27 000 tonnes) would cost €1.4 million per year. Some prioritised heat stabilisers and flame retardants are used in low volumes. None were listed as non-replaceable. The costs have not been assessed.	million per year in the EU. Likely capacity issues related to EU production of DOTP.	important than the production stage. Carpet performs the worst, laminate and linoleum perform fairly equally to PVC. Replacing PVC with other materials based on their current market shares would increase life cycle impacts except for the depletion of fossil resources. This result is driven by carpet that performs the worst in many of the impact categories.
Window frames	-	Share of PVC window frames in the EU is 50 %	Alternative materials exist and have no evident performance differences to PVC	Lifetime costs of alternative materials assessed Replacing PVC with alternative materials costs €1.9–2.0 billion per year	Producer surplus losses in the EU €120–170 million per year	Only prioritised additives are heat stabilisers (organotins) Replacing organotins with Zn/Ca stabilisers costs €0.9 million per year and impacts performance	No significant negative supply chain impacts for heat stabilisers	Use stage relevant for life cycle impacts. No conclusion possible on the preferable window frame material throughout the life cycle and impact categories. Replacing PVC with wood and aluminium-clad wood would reduce CO_2 emissions from

Use	**Sub-use**	**Use of PVC**	**Alternative materials to PVC**	**Costs of alternative materials to PVC**	**Producer surplus losses for alternative materials**	**Costs of alternative additives in PVC**	**Supply chain impacts for alternative additives**	**Life cycle impacts**
								the production stage and lower the social cost of carbon on average by 263–913 million € per year.
Packaging	Rigid food and non-food packaging	Main PVC use is rigid film (80 % of food and non-food packaging volume)	Several alternative materials exist (both plastics and other types of materials) and have no significant impacts on performance	Only material costs of alternative materials assessed No assessment of lifetime replacing costs	Producer surplus losses in the EU €3–8 million per year	Only prioritised additives are heat stabilisers (organotins) Replacing organotins with Zn/Ca stabilisers costs €2.1 million per year and impacts performance	No significant negative supply chain impacts for heat stabilisers	Main life cycle impacts of packaging come from production, feedstock, and transportation phases. No conclusion possible on the preferable material. Not possible to compare the CO_2 emissions between materials.
	Soft food and non-food packaging	Main PVC uses are flexible film, such as cling film (15 % of packaging volume), and closures (3 % of packaging volume)	Several alternative materials exist (both plastics and other types of materials) and have no significant impacts on performance	Only material costs of alternative materials assessed No assessment of lifetime replacing costs		Only prioritised additives are plasticisers Replacing DINP and DIDP with DOTP costs €0.13 million per year	Profit losses from moving from DINP and DIDP to DOTP around €50 000 per year in the EU	
	Blister packs	Plastic in the mouldable base film (i.e. blisters) is primarily PVC, and particularly common in pharmaceutical blister packs	Alternative materials exist and may imply deterioration or improvement in performance	Only material costs of alternative materials assessed No assessment of lifetime replacing costs	Producer surplus losses in the EU €1–7 million per year	Only prioritised additives are heat stabilisers (organotins) Replacing organotins with Zn/Ca stabilisers costs €2.2 million per year and impacts performance	No significant negative supply chain impacts for heat stabilisers	

Use	**Sub-use**	**Use of PVC**	**Alternative materials to PVC**	**Costs of alternative materials to PVC**	**Producer surplus losses for alternative materials**	**Costs of alternative additives in PVC**	**Supply chain impacts for alternative additives**	**Life cycle impacts**
Medical applications (blood and infusion bags, medical devices, gloves and medical tubing)	-	PVC is the most common polymer in medical devices in Europe (27 % of the total volume of polymers)	Alternative materials exist but may imply changes in performance	Only material costs of alternative materials assessed No assessment of lifetime replacement costs	Producer surplus losses in the EU €1–4 million per year	Only prioritised additives are plasticisers (orthophthalates and trimellitates) Replacing DEHP with DOTP costs €1.0–5.9 million per year	Profit losses from moving from DEHP to DOTP around €80 000 per year in the EU	No conclusion possible on the preferable material. Not possible to compare the CO_2 emissions between materials.
Toys	-	PVC is used in various toys, most used in inflatable toys, boats and rafts PVC share of plastics used in toys is small	Several alternative materials exist but may imply changes in performance	Only material costs of alternative materials assessed No assessment of lifetime replacing costs	Producer surplus losses in the EU €0.1–0.9 million per year	Only prioritised plasticiser is DOTP, which has currently no identified concern Only prioritised heat stabiliser is 1,3-diphenylpropane-1,3-dione, but there is no information on replacement costs	No significant negative supply chain impacts	No conclusion possible on the preferable material. Not possible to compare the CO_2 emissions between materials.
Clothing	Artificial leather (not car) / Bags, luggage	PVC is used as a substitute for leather in clothing, accessories, footwear and other uses	Alternative materials exist (both plastics and other types of materials) but may imply changes in performance	Only material costs of alternative materials assessed No assessment of lifetime replacing costs	Producer surplus losses in the EU €1–7 million per year	Various prioritised plasticisers are potentially used. Replacing DINP and DIDP with DOTP costs €0.5–2.8 million per year. Replacing DPHP (medium concern) with DIDP (low concern) has no extra material costs. Replacing D810P (medium concern) with long chain ortho-	Profit losses from moving from DINP and DIDP to DOTP around €0.7 million per year in the EU	No conclusion possible on the preferable material. Not possible to compare the CO_2 emissions between materials.
Automotive (interior)	Artificial leather, foamed films	PVC is used as a substitute for leather in automotive interiors (seat covers)	Alternative materials exist (both plastics and other types of materials) but may imply changes in	Only material costs of alternative materials assessed No assessment of lifetime replacing	Producer surplus losses in the EU €1–3 million per year			

Use	Sub-use	Use of PVC	Alternative materials to PVC	Costs of alternative materials to PVC	Producer surplus losses for alternative materials	Costs of alternative additives in PVC	Supply chain impacts for alternative additives	Life cycle impacts
			performance	costs		phthalates (low concern) costs €0.8–5 million per year. Replacing trimellitates (medium concern) with long chain ortho-phthalates (low concern) has no extra material costs. Prioritised flame retardants are used, but there is no information on replacement costs.		

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