Appendix F – Legacy additives in PVC

This appendix contains a public extract from a report commissioned to Ramboll to assess the impact of the regulatory actions on the use of legacy additives in PVC.

CONTENT

1. Introduction and aim

ECHA received a mandate from the Commission to collect information on the potential risk to human health and the environment posed by PVC additives and PVC itself, the socioeconomic impact of a possible restriction and the need for European Union-wide action. Moreover, it was requested that attention is paid to address the gaps in the recent report "The use of PVC (poly vinyl chloride) in the context of a non-toxic environment: final report" (EC 2022).

ECHA has studied the EC (2022) report carefully and conducted a preliminary gap analysis. This service request should address some of the gaps identified. Already heavily regulated ("legacy") additives in PVC waste have been identified as a challenge for the use of recycled PVC containing such additives.

The ten most important uses of PVC, defined based on criteria related both their risks and socioeconomic importance, were presented in the EC (2022) report. Various topics related to recycling and other waste streams were also discussed.

As one of the tasks under the mandate, ECHA aims to clarify the question on whether there is need for further EU wide regulatory measures for reducing (potential) risks of current occurring legacy additives in PVC. ECHA seeks, with support of this service request, to answer the question. The information and learnings gathered to answer this question also serve the other tasks of the project, e.g., in the question on whether some additives currently used in PVC should be (further) regulated and what would be the consequences of such regulation for waste handling/circularity.

Furthermore, combined effects caused by exposures from the currently used and legacy additives need to be considered for the same purpose.

2. Methodology

The methodology and approach were regularly discussed and coordinated with ECHA, typically in bi-weekly meetings and also emails.

2.1 Baseline assessment

In a first step the baseline information at the time of restriction, as well as the currently applicable restrictions were researched for each substance. The relevant information includes regulatory limit values, H-codes, PVC-relevant products, human biomonitoring data, exposure pathways, releases from waste stage as well as any forecasts of the EU volumes after the restriction comes into force.

For this, relevant background documents about the substance (or substance group, whichever was available) were researched via desktop research. This includes reports from ECHA, EFSA or Member State authorities as well as the Commission. The found reports were analysed and all relevant information extracted into the accompanying excel sheet.

The currently applicable restrictions were extracted from the "regulatory obligations" tab of the substance info card on the ECHA website. All applicable laws were screened for their relevance as to PVC and discussed with ECHA before including them. The results can be found in the sheets "PVC, "PE", "PP", "PE-X" and "PUR" in the respective column for the respective law.

2.2 Current situation PVC

In a second step the current situation of the substance was researched. This included a systematic literature research of recent literature. For this a search string was created and discussed with ECHA. The search string includes all additives, PVC as a material as well as terms specifying that only the presence of the additives in products, articles or waste are relevant:

*("cadmium" OR "arsenic" OR "chromium" OR "tin" OR "phthalate" OR "nickel" OR SCCP OR HBCD) AND additive AND ("PVC" OR "polyvinyl chloride" OR "poly(vinyl chloride)") AND (product OR article OR waste) AND (concentration OR levels OR content) AND Europe**

This search string was then applied in EuropePMC, which yielded 555 sources. The sources were then transferred to a program called DistillerSR in order to analyse them. All sources were checked individually based on their relevance. Relevance criteria included for example the mentioning of a relevant substance, the aim of the study as well as a (potential) reference to PVC. Papers were included if they were published after the restriction date of the substance in questions e.g. (2013 in the case of the phthalates) in order to only have data of the situation after the restriction. Ultimately 31 sources were deemed relevant which were then downloaded. These 31 sources also included 13 review papers.

The papers were analysed, and the relevant information extracted. This includes findings of the substance in relevant products, their found concentrations, and the life stage of the product, biomonitoring data, and answers to the questions whether the presence of a substance in a product poses a problem to the recycling of PVC and whether the presence of a substance in recycled PVC is an issue for the use of the recycled PVC. If a paper also analysed any of the other plastics in focus (PE, PP, PUR and PE-X) then that information was also extracted in the respective excel tab. The sources were also checked for references to other potentially relevant publications, especially the review papers. This way additionally publications were identified. All analysed sources are included in the "Literature" tab of the accompanying excel sheet.

Additionally, a stakeholder consultation was conducted. For this a questionnaire was drafted in close coordination with ECHA, which can be found in Appendix 1. The questionnaire includes all the questions raised above and was sent to selected stakeholders. The stakeholder list was based on the list used in the previous contract *Order Form No. 25 (ECHA/2022/395) "REACH restriction support – Investigation report on PVC and PVC additives",* and further adjusted based on the waste focus of the project. In total 46 stakeholders were contacted. The deadline for the submission of the questionnaire was the 31.03.2023. In total 14 stakeholders sent an answer. Relevant information submitted by the stakeholders is included in the report. Please note that the report therefore contains statements from stakeholders, which might contain biased information.

2.3 Other plastics in focus

In close coordination with ECHA, four other plastic polymers were also in focus of this project namely polyethylene (PE), polypropylene (PP), polyurethane (PUR) and crosslinked polyethylene (PE-X). For these polymers the same methodology as above was applied, however, with an adapted search string as follows:

ABSTRACT:("cadmium" OR "arsen" OR "chrom*" OR "organotin" OR "organo-tin" OR "organo tin" OR "phthalate" OR "nickel" OR SCCP OR HBCD) AND ABSTRACT:(polyethylene OR polyethene OR polythene OR "poly(methylene)" OR polypropylene OR "poly(1-methylethylene)" OR polypropene OR "poly(propene)" OR VPE OR "PE-X" OR PEX OR LXPE OR XPE OR polyurethane OR PUR) AND ABSTRACT:(concentrat* OR level OR content)*

Same as for PVC, EuropePMC was used as a search engine and the same method for assessing the relevance applied. In total 683 papers were found 40 of which were deemed relevant and assessed based on their full text

Questions for the alternative plastics were also included in the questionnaire (see Appendix 1).

2.4 RAPEX

The EU rapid alert system for dangerous non-food products (RAPEX) was screened for relevant products. In this system authorities report non-food related dangerous goods, which are then made publicly available. Apart from hazards such as burning, asphyxiation, electric shock and fire it also includes non-compliance with EU chemicals regulation. As such it can contain project-relevant products.

All non-chemically compliant products, starting from 01.01.2017, were downloaded and screened for relevance. For this the term “PVC” was used to find relevant products in a first instance. In a second step the substance groups (in the case of metals) or the individual substances (for the organic compounds) were searched in the database. Especially in the case of DEHP this resulted in many positive hits, however, the description mostly only refers to “plastic material” without specifying the exact type of plastic polymer. While DEHP (and the other phthalates) have mainly been used in PVC, these hits can be associated with PVC with a high probability. This is, however, not the case for the other additives in focus, which should be kept in mind when analysing the data.

The number of hits is recorded for each substance or substance group and a cursory list was created which includes the country of origin, type of product, year, plastic type as well as the additive in question and its concentration in the product. In the excel file, this data can be found in the tab “RAPEX analysis”. The raw data can be found in the tab “RAPEX”.

3. Results

3.1 Baseline analysis and impacts of the restrictions

3.1.1 PVC

In this chapter the situation regarding the additives in focus in PVC will be discussed, which includes a summary of the baseline situation as well as a comparison with the current situation.

3.1.1.1 Phthalates

Phthalates are and have been used in PVC as plasticisers. As PVC without additives is a rigid polymer, it needs additives in specific applications to become softer. Phthalates have commonly been used for this, most of all DEHP, but also other phthalates such as DBP, BBP and DIBP. These can generally be classified in short, medium, and long chain phthalates (ECHA, 2021b). Short chain phthalates contain sidechains with less than 4 carbons in the backbone. From the additives in focus on DiBP falls in this category.. Medium chain phthalates contain 4-8 carbon atoms in the backbone such as DBP, BBP, DiBP and DEHP but also branched C8-C10 ortho-phthalates (CAS 68515-48-0) fall under this category. Lastly, long chain phthalates such as branched C9-C11 ortho-phthalates (CAS 68515-49-1) have backbones with more than 8 carbon atoms.

Where applicable a difference between these two groups will be made in this report.

3.1.1.1.1 Relevant products, concentration ranges and comparison with concentrations limits

DEHP, DBP, BBP and DiBP were subject to authorisation starting 2013 and restricted in PVC starting 2020. A restriction for all the phthalates in focus (the four aforementioned and the others included in the excel sheet) already existed since 2005, however, this restriction only applies for the use in toys and childcare articles. As such the medium chain (branched C8-C10) and long chain (branched C9-C11) phthalates can still be used in PVC products as they are not otherwise restricted or fall under authorisation.

As phthalates are used as plasticisers almost all flexible PVC products are relevant for this substance group. This includes e.g., cables, roofing tiles, flooring, wallpaper, artificial leather products, hoses, medical products such as blood bags, tarpaulins, shoe soles, toys, shower mats and many more. Medium chain phthalates, especially BBP, DBP and the short chain phthalate DiBP, have also been used in cosmetics and plant protection products. (Anonymous stakeholder) states that legacy phthalates such as DEHP and BBP have been phased out in the early 2000s in PVC flooring in Europe.

It should be mentioned here that while all phthalates are restricted under REACH the degree of restriction varies. Thereby the group mainly consisting of short and medium chain phthalates (DBP, BBP and DiBP) and DEHP is restricted in all plastics excluding silicone rubber and latex, however the other medium and long chain phthalates DiNP, DNP and DIDP are only restricted in childcare articles and toys. The short and medium chain phthalates (BBP, DBP, DiBP and DEHP) are additionally also regulated under RoHS where they currently still have valid exemptions for their use, especially for certain medical devices and cables. As such they are still placed on the market.

All phthalates are also still present in articles, which are restricted as well as in imported articles. For example, Völker et al. (2022) was able to detect DNP (decyl nonyl phthalate), DBP, DEHP, DiNP and DDP (dodecyl phthalate) in store bought floor covering, place mats and pond liners made from PVC, however, the paper did not state any concentrations. The samples were purchased in local retailer stores in Germany. No specific date is given, however, the project team assumes that the samples were purchased around 2018-2019. Given that these phthalates were measured in PVC products it is unlikely that they are present as an unintentional additive. The authors state that the measured PVC products “can be one source of exposure to these [substances]”.

Additionally, Marie et al. (2017) was able to detect DEHP and DiNP in mixed PVC and PVC from medical devices. Concentrations for DEHP ranged from 0.01w%-1.19w% and DiNP was found in concentrations of 36.39w%. However, as stated above, the use of certain phthalates (DBP, BBP, DEHP and DiBP) in medical devices was only recently restricted (2021) and as such it can be assumed that medical devices currently in use in Europe still contain significant amounts of phthalates.

Lastly it should be mentioned that phthalates and especially DEHP are still imported into Europe. In the RAPEX database 29 hits for the presence of DEHP in PVC were found, all of which are above the limit value of 0.1w%. Affected products include dolls, bags, mats, inflatable dolphins, sandals, luggage tags etc. In total 1038 hits for DEHP were found (~3500 products in total), indicating that there are still many products being imported into Europe which do not comply with REACH. The other phthalates in question such as BBP (113 hits), DBP (383 hits), DiBP (82 hits), DiNP (131 hits) and DIDP (24 hits) were also found in imported products. The vast majority of non-compliant products originates from China, however, a few also originate from European countries such as Italy, Portugal and the Netherlands. It is assumed that the majority of product containing these phthalates are made from PVC, however, in most cases only a reference to “plastic material” is made.

While some phthalates have been restricted to be used in PVC, others, not included in the list for this project, have since become more important. McGrath et al. (2021) were able to detect di-2-ethylhexylterephthalate (DEHT) and di-(2-propyl heptyl) phthalate (DPHP) in various PVC products such as yoga mats, inflatable beach balls and pool mats, jump rope, cables and flipflops. 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH) was also detected in some samples, which has been used as a substitute to DEHP (EPEA, 2023).

Additionally, short chain phthalates such as diethyl-phthalate (DEP) have become more popular, especially in cosmetics and personal hygiene articles, as this phthalate is not restricted (Tranfo et al., 2018). The rise in popularity of this phthalate can be seen by the comparatively higher levels in humans (see chapter 3.1.1.1.4) (Schwedler et al., 2020; Tranfo et al., 2018).

3.1.1.1.2 Presence of other legacy substances in the relevant products

While the most commonly used phthalate was DEHP, several sources confirmed that phthalates are used together to achieve the desired mechanical properties of PVC. As a consequence, PVC products can contain multiple phthalates at once.

For example, Völker et al. (2022) was able to detect BBP, DiNP, DNDP and other phthalate-based plasticisers in store bought floor covering. In a place mat DEHP was detected together with several cyclohexane-based plasticisers such as DINCH.

In several other PVC products such as yoga mats, beach balls, jump rope and electrical cables several phthalate-based plasticisers were found together with SCCP and MCCP (McGrath et al., 2021), showing that phthalate-based plasticisers are also used in combination with chlorinated paraffins.

In the inner linings of beer cans in Europe DEHP was found together with DBP and DiBP, however, not in any of the relevant plastic types (Nurlatifah, Nakata, 2021). This example further shows that the phthalates are commonly used together.

The presence of any of the other additives in focus of this study could not be confirmed.

3.1.1.1.3 Predicted volumes and comparison with forecasts

The Annex XV restriction report for three medium chain phthalates (DEHP, BBP, DBP) and one short chain phthalate (DiBP) (ECHA, 2016) contains data and a forecast (starting 2020) for the manufacturing, export and import of the four substances in and out of Europe.

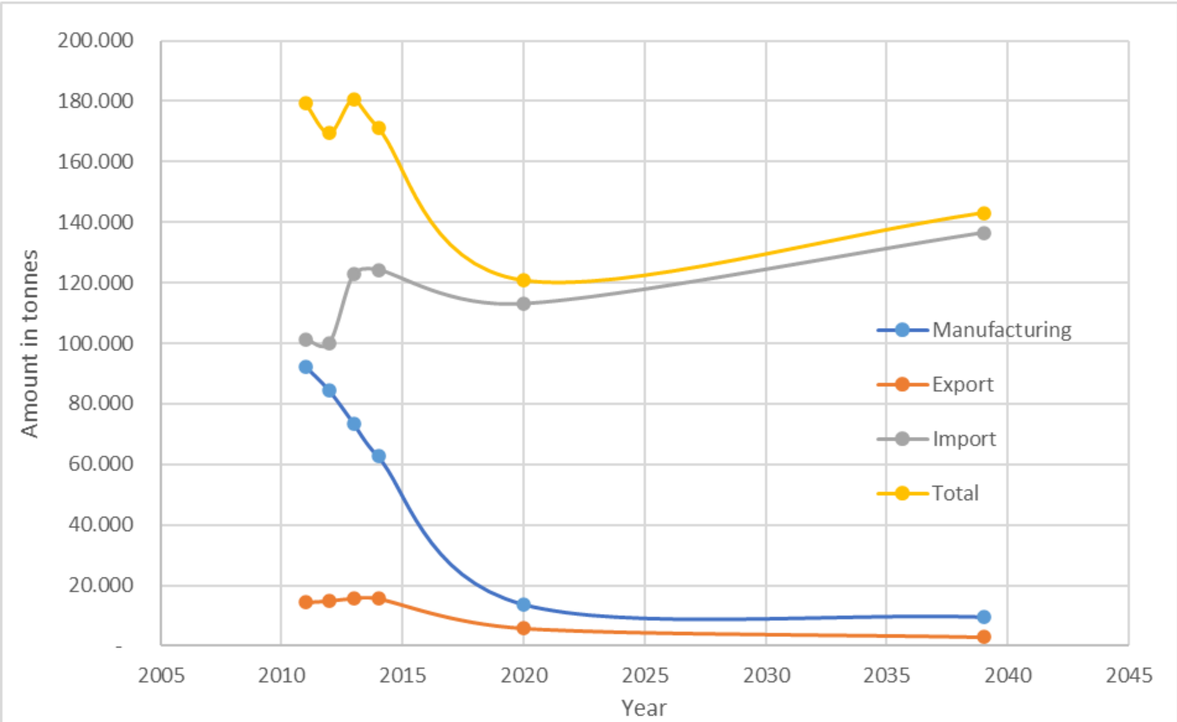

Figure 1: Manufacturing, import and export data as well as forecasest values (starting from 2020) from the restriction dossier for DEHP, BBP, DiBP and DBP (ECHA, 2016)

The data reported in the restriction dossier by ECHA until 2014 are estimates based on manufacturing, import and export statistics on Eurostat (ECHA, 2016). ECHA assumes that DBP, DiBP and BBP will not be used after 21.02.2015 as no authorisation application was submitted by industry at the time (ECHA, 2017). As such the forecasted values starting 2020 only represent DEHP.

ECHA recently released a report detailing the changes of market volume of chemical subject to authorisation, which also includes data on the four phthalates (ECHA, 2022). This data can be compared to the forecasted volumes of the restriction dossier in Figure 1. The following graph is included in the report:

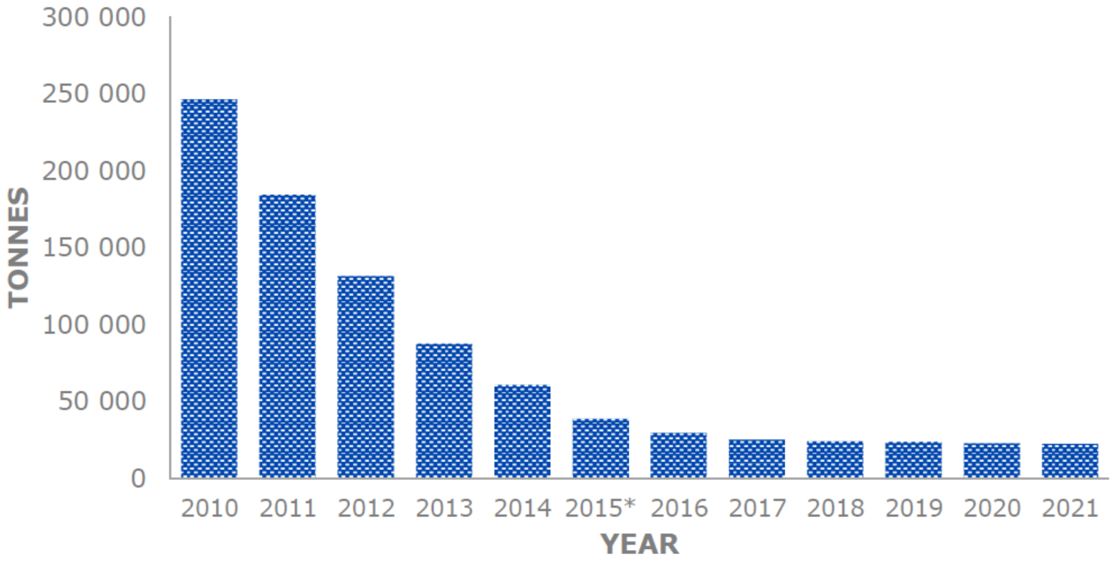

Figure 2: Estimates of volumes of DEHP, DBP, PBP, DIBP and diisopentyl phthalate placed on the EU market, 2010-21, tonnes (ECHA, 2022)

From this data it can be seen that the volumes of the four phthalates (and diisopentyl phthalate) placed on the market in the EU have decreased significantly. While the restriction dossier estimated that by 2020 roughly 120,000 tonnes of the four phthalates will be placed on the market (see Figure 1), this graph (Figure 2) shows that only roughly 30,000 tonnes were placed on the market, which corresponds to only 25% of the forecasted volume. DEHP is currently still used in the manufacturing of blood bags (ECHA, 2022). Additionally, DEZA (2020) mentions that DEHP is still used in the automotive industry (automobiles and spare parts), in manufacturing of pre-press consumables and by a compounder for PVC products (products not further specified). Additionally, some uses are exempt from the authorisation requirement (they do not fall in the amounts shown in Figure 2). These uses include (see REACH Annex XIV Entry Nr. 4-7):

- food contact materials within the scope of Regulation (EC) No 1935/2004;
- immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/ 82/EC, and/or Directive 2001/ 83/EC;
- mixtures containing DEHP at or above 0,1 % and below 0,3 % weight by weight

The data can further be compared to data found in European databases. The PRODCOM database (provided by Eurostat) provides statistics on the production of manufactured goods carried out by enterprises on the national territory of the reporting countries (PRODCOM, 2023). In the following

Figure 3 the physical volume of production sold during the survey period for DEHP, DiBP and DBP is shown. This, however, does **not include data** for BBP:

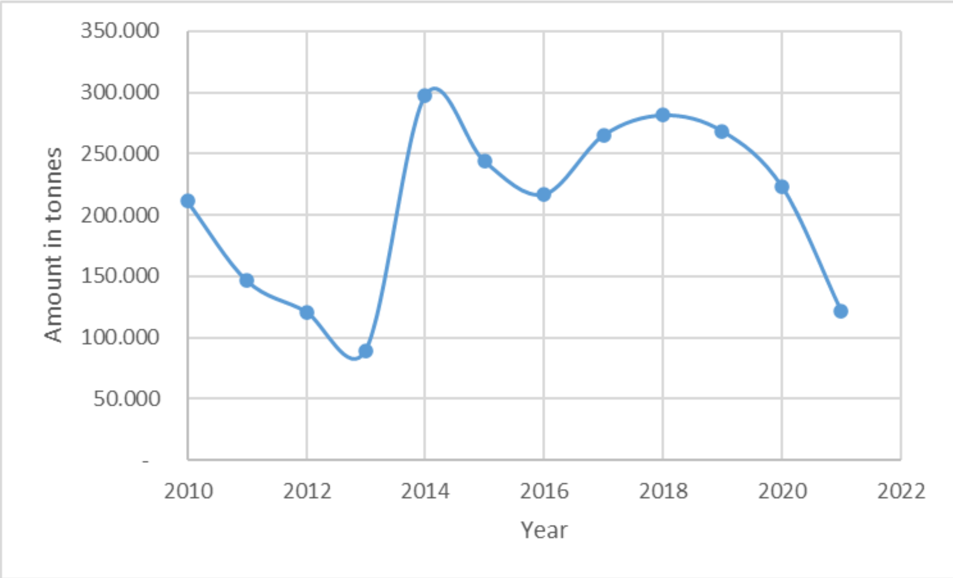

Figure 3: Manufacturing data of DEHP, DiBP and DBP in Europe from the PRODCOM database (PRODCOM, 2023)

The data in from the PRODCOM database differ from the data presented by ECHA in Figure 2. In 2020 223,078 tonnes of DEHP, DiBP and DBP were manufactured in Europe compared to ~30,000 tonnes in Figure 2 according to the PRODCOM database. One explanation might be that the data from the PRODCOM database only refers to “sold” production volume and as such might also include exports. The data presented by ECHA only refers to “placing on the market”.

Lastly, the SPIN-database provides similar data but only for the four Nordic countries Denmark, Sweden, Finland and Norway (SPIN, 2023). In this database manufacturers report their production volumes, however, some data is confidential and exports are subtracted. The following figure shows the data of DEHP, DiBP, DBP and BBP in those four countries from 2000 to 2020:

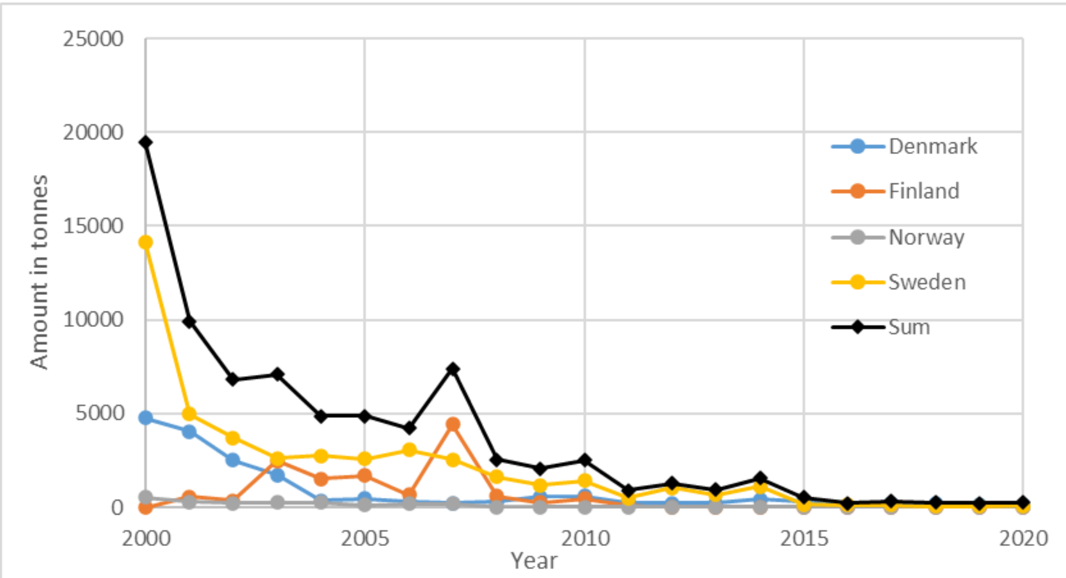

Figure 4: Data for DEHP, DiBP, DBP and BBP from the SPIN-database for Denmark, Sweden, Finland and Norway (SPIN, 2023)

This data is similar to the data presented in Figure 2 and shows a strong decrease of the four phthalates. In 2020 only 256.1 tonnes of the four phthalates were produced down from 2,501 tonnes in 2010.

Lastly, it should not be forgotten, that relevant amounts of the four phthalates, especially DEHP, are still imported in products into Europe. The largest number of imported products containing DEHP stems from China as can be seen in the RAPEX database (see the excel sheet tab "RAPEX analysis" and chapter 3.1.1.1.2). Exact amounts could not be identified.

In summary, it can be said that the authorisation and restriction of the phthalates did influence the production volumes and as such the volume on the market. A strong decrease of the production volumes can be seen in several sources (ECHA, 2022; SPIN, 2023), however, data from the PRODCOM database indicates that a significant amount of DEHP, DiBP and DBP is still produced in Europe. Whether those amounts are also placed on the European market or exported to countries outside of the EU is unknown. Additionally, a certain amount of the four phthalates is still imported in products into the EU mainly from China.

3.1.1.1.4 Change in substance concentrations found in humans

If taken up by humans, the phthalates are usually metabolised. This typically happens via a breaking of the ester group, which results in mono-substituted phthalates (typically named with an "M" instead of a "D" in the substance abbreviation; so a metabolite of DEHP is MEHP). In a secondary step an oxidisation of the aliphatic chain can occur. Due to only one ester bond being broken the metabolites can usually be assigned to a specific phthalate depending on the remaining carbon chain.

In general, the phthalate concentrations of the restricted/authorised phthalates in humans have significantly decreased since the time of restriction/authorisation.

A study from Tranfo et al. (2018) analysed the effect that the REACH Authorisation of DEHP, DBP and BBP (note: DiBP was not included) had on the concentration of the respective metabolites in human urine. For this the authors collected urine from 157 volunteers living in Italy in 2011 and again from 171 volunteers living in the same region in 2016 (the phthalates were subject to authorisation in 2013). Highest concentrations were found for the metabolite of diethyl phthalate (DEP) monoethyl phthalate (MEP), which is currently not restricted and as such might still be present in everyday products. For the other three phthalates they found reduction of up to 100% (for DBP and BBP) in both men and women. For DEHP a reduction of 78% in men and 71% in women, indicating that the authorisation requirement had a significant effect on the exposure of the substance to humans.

Similar results were found by Schwedler et al. (2020). The authors analysed urine samples collected over the course of the German Environment Survey, which periodically analyses environmental samples in Germany. 2256 samples were collected between 2015 and 2017 from children aged 3-17 and subsequently analysed for phthalate metabolites. Relevant phthalates include BBP, DiBP, DnBP, DEHP, DiNP, DiDP and DnOP. Except for DnOP the authors were able to detect the metabolites of all other phthalates with a detection frequency of 97%-100%, with highest concentrations for MiBP (DiBP) of 26.1 µg/L followed by MnBP (DBP) with 20.9 µg/L and cx-MEPP (DEHP) with 11.9 µg/L. High concentrations (25.8 µg/L) were also found for the metabolite MEP (DEP) similar to the findings of (Tranfo et al., 2018). The results were compared to similar studies in other European countries around the same time (2015-2017) and were found to have similar concentration ranges for each metabolite.

The authors also compared the results to samples taken in 2003-2005 and found that current levels are significantly lower. The concentrations of MiBP (DiBP), MnBP (DBP) and the DEHP metabolites amounted to only 29%, 23% and 23% of the levels measured in 2003-2005. The

lowest decrease was found in DiNP with current levels being 57% of those in 2003-2005. The authors state that this decrease may be associated with the bans and restriction of the substances.
Lastly, the measured metabolite levels were compared to health-based guidance values, which revealed, that 0.38% of the participants exceeded these values for MnBP (DBP), 0.08% for the metabolites of DEHP and 0.007% for DiNP, meaning that in a worst-case scenario around 41,500 children still exceed these health-based guidance values, even though these three substances (DEHP, DBP and DiNP) were subject to authorisation.

In summary, it can be stated that the restriction had a significant effect on the levels of the phthalates in humans, showing their effectiveness. Average concentrations decreased by at least 50% compared to 2003-2005, however, a small percentage of the analysed samples still exceed health-based guidance values, indicating that regular exposure to these substances is still occurring.

3.1.1.1.5 Conclusion

All of the listed phthalates have been or still are used in PVC. They can be present in almost any flexible PVC product and are typically used together with other plasticisers (phthalates and chlorinated paraffins). Three medium-chain phthalates (DBP, BBP and DEHP) and one short chain-phthalate (DiBP) have all been restricted in almost all uses, which can also be seen in the declining amount of them being manufactured and present on the market. This is furthermore seen in the reduced concentrations found in humans. Alternative non-restricted plasticisers have since become more popular, including the short chain DEP as well as non-phthalate plasticisers such as DINCH.

3.1.1.2 Arsenic

3.1.1.2.1 Relevant products, concentration ranges and comparison with concentration limits

Contrary to the case of phthalates where a lot of studies was found indicating the presence and continued use in articles, literature screening did not result in any of the studies which confirm or deny the current use of arsenic and arsenic compounds in articles.

According to Norway Annex XV Dossier, 2008, inorganic arsenic compounds were mainly used as pesticides during the mid-1800s and 1900s and in medicine up to the 1970s. More specifically, Turner (2021) mentions the use of diphenoxarsin-10-yl oxide as a fungicide and antimicrobial agent mainly in unplasticized PVC.

During the stakeholder consultation, few responses were received regarding the use and presence of arsenic and arsenic compounds in PVC formulations, mainly for diphenoxarsin-10-yl oxide.

INEOS Inovyn (2023) stated they are not aware of many arsenic compounds used in PVC in Europe, with diphenoxarsin-10-yl oxide (CAS 58-36-6) being the only exception. According to them, diphenoxarsin-10-yl oxide was used as an industrial biocide for flexible PVC applications until the early 1990s and it was sold under the trade name “Vinyzene” by a company called ICI (later Zeneca). Since it was very expensive, it's use was very limited (<0.1% w/w) and generally restricted to applications such as in top and bottom layers of flooring and/or wall covers for bathroom and wet room with high risk of microbial growth. Since the early 1990s numerous non-arsenic biocides have been developed and this substance received a non-approval decision within Product Type 9 under the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012).

The use of diphenoxarsin-10-yl oxide as bactericide/fungicide in PVC was confirmed by another stakeholder as well (Reagens, 2023).

Furthermore, VinylPlus (2023), mentions that arsenic compounds had some limited use in the past in the flexible PVC but are no longer used.

EPEA (2023) stated that arsenic (CAS 7440-38-2) occurs only as impurity of different raw materials such as crush stones used as fillers and there is no indication of intentional addition to any of the applications.

Lastly, (Anonymous stakeholder) measured arsenic in recycled PVC, however was not able to detect the substance (for more info see chapter 3.3.1.2).

3.1.1.2.2 Presence of other legacy additives

Presence of other legacy additives could not be identified during the literature screening nor there was relevant information provided by stakeholders. However, since diphenoxarsin-10-yl oxide was mainly used in floorings and wall coverings, presence of phthalates and other plasticisers is possible.

3.1.1.2.3 Predicted volumes and comparison with forecasts

In a report recently published by ECHA on the changes of market volume of chemical subject to authorisation, estimates of volumes of diarsenic trioxide placed on the EU market are given. In period of 2010-12 there was no annual volume data reported and the quantities reported in the registration dossier are rather low (< 1000 tonnes). As seen in the Figure 5, after the sunset date in 2015, the volume of diarsenic trioxide placed on the market was estimated to have decreased by 20% in 2021. However, we do not expect this substance to play a meaningful role as a PVC additive and as such it should only be seen as an indicator. Data on predicted volumes for the two relevant additives could not be identified.

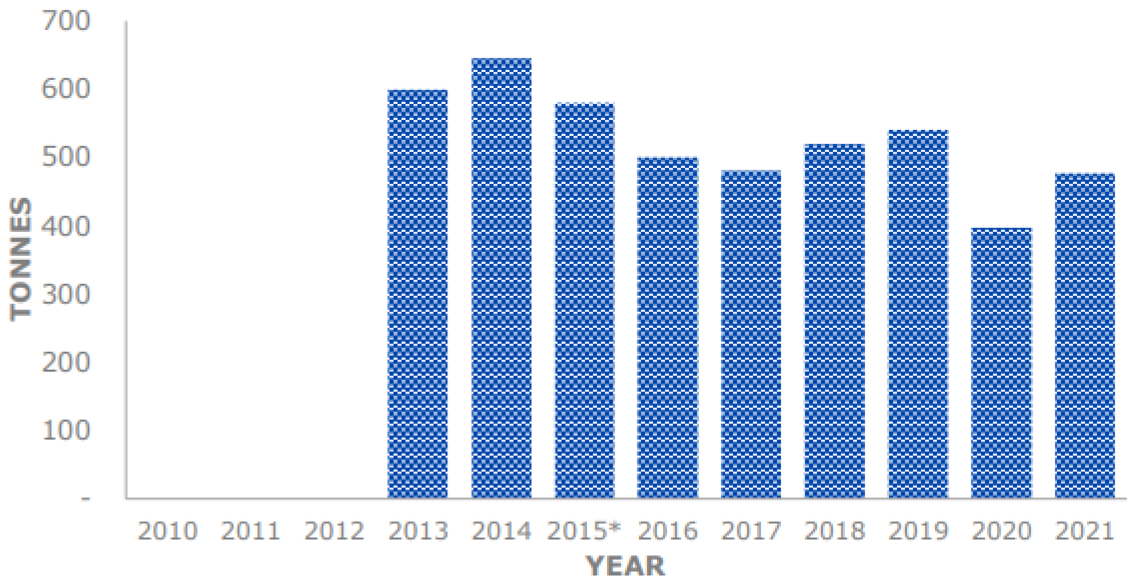

Figure 5. Changes of market volume of chemical diarsenic trioxide subject to authorisation (ECHA, 2022)

Four arsenic compounds are registered under REACH are those are arsenic (CAS 7440-38-2), diarsenic trioxide (1327-53-3), arsenic acid (7778-39-4) and triethyl arsenate (15606-95-8). Arsenic and diarsenic trioxide have a tonnage band indicating the range from ≥ 100 to < 1 000 tonnes per year, while arsenic acid has a lower range from ≥ 1 to < 10 tonnes per year. Triethyl arsenate is registered under REACH but currently is not being manufactured and/or imported to the European Economic Area.

3.1.1.2.4 Change in substance concentrations found in humans

No data on concentrations of arsenic and arsenic compounds in humans could be identified.

Some information was found for the arsenic acid and main routes of exposure. According to ECHA (2011), the main route for the general population is oral exposure, while occupational exposure is mostly happening through inhalation. About 70-90% of soluble inorganic arsenic compounds are rapidly absorbed after oral exposure and 1-6% after inhalation and dermal exposure. Absorbed arsenic reaches different organs in the body mainly concentrating in the nails and hair. With the half-life of about 2 to 3 hours and a three exponential clearance curve most of the arsenic in human blood is rapidly cleared.

3.1.1.2.5 Conclusion

Several stakeholders confirmed that arsenic compounds had some limited use in the past in the flexible PVC mainly referring to the diphenoxarsin-10-yl oxide used as fungicide in floorings and wall coverings in areas with a high risk of microbial growth. Data confirming the health risks for arsenic and arsenic compounds could not be identified.

3.1.1.3 Cadmium

Historically, cadmium compounds were used as stabilizers and as a pigment in both rigid PVC (e.g., pipes and fittings, hoses, gutters, window frames and profiles as well as roof plates) and soft PVC products (e.g., packaging for toys, bags, cases,). When used as stabilisers they were usually added in the range of <1 - >8% by weight of the compound resin, largely depending on the application (RPA, 2009). According to ECHA (2021) the use of cadmium compounds in PVC in Europe stopped in 1996 while the stakeholders indicate the phase out of cadmium in the EU-15 started in 2001 and later expanded on the EU-27 in 2017 through the voluntary industry commitment called Vinyl 2010.

Following five cadmium compounds have been identified by several stakeholders as relevant for PVC (Anonymous stakeholder; Reagens, 2023; VinylPlus, 2023a):

- Pigments:
  - Cadmium sulphide (CAS 1306-23-6)
  - Cadmium zinc sulfide yellow (CAS 8048-07-5)
  - Cadmium sulfoselenide red (CAS 58339-34-7)
- Stabilisers:
  - Cadmium dilaurate (CAS 2605-44-9)
  - Cadmium distearate (CAS 2223-93-0)

However, both cadmium pigments and cadmium stabilisers are no longer used (INEOS Inovyn, 2023; TEPPFA, 2023; VinylPlus, 2023a).

3.1.1.3.1 Relevant products, concentration ranges and comparison with concentration limits

Cadmium is currently regulated by Annex XVII of REACH (entry 23) which prohibits the use of cadmium and its compounds in mixtures and articles produced from polyvinyl chloride (PVC) in concentrations equal or greater than 0,01% (100 ppm) by weight (expressed as Cd metal). The same entry contains a specific derogation for mixtures and articles used in certain applications containing recycled PVC in which case a higher concentration of cadmium is allowed, i.e., 0.1% w/w (1000 ppm) instead of 0.01% w/w. Even though cadmium is restricted in many applications, there are some exemptions which allow the use of cadmium, such as the articles coloured with mixtures containing cadmium for safety reasons.

The presence of cadmium in products that are still in its service life was confirmed by (Turner, 2021b). The year of the samples is unknown but expected to be around 2017. In the study, a total of 92 samples of consumer plastics made from PVC were collected from households, offices, schools, shops, and restaurants in England. Concentrations above the LOD of cadmium was detected in 2 samples in the range of 1580 – 1680 mg/kg which exceeds the concentration limit set by REACH (100 mg/kg). Both samples originated from the construction sector. In addition to that, residual metal concentrations were also investigated. For that purpose, all hits with concentrations lower than 1000 mg/kg were considered as too low to function as additives and are therefore considered as residual metal concentrations. In this case, there was a total of 10 samples with residual concentrations of Cd in the range of 120 – 476 mg/kg, all being above the limit concentration of 100 ppm. The origin of samples with residual concentrations is not given. Even though the study confirms the presence of cadmium as intentionally added in two samples coming from construction use, it should be noted that the year of origin of those samples is not known and due to the long lifespan of certain PVC products (especially in construction sector) it could be that cadmium was added before the restriction came into force.

The RAPEX database confirms that certain products containing cadmium are still imported into the EU. The screening resulted in a total of 12 hits for cadmium in different plastic materials, indicating there are some products not compliant with REACH, i.e., exceeding the concentration limit of 0.01% by weight. Non-compliant products include vinyl tablecloth, inflatable toys, sandals, wallets, etc. and they are mainly originating from China. Even though in most cases only a reference to 'plastic material' is made, it can be assumed that a good portion of those products is made from PVC.

On the presence of cadmium in PVC, one representative of the flooring manufacturing stated cadmium is present in concentrations lower than 0.006% in end-of-life products, mainly in PVC floor covering older than 20 years (Anonymous stakeholder).

According to the stakeholder input, recyclers also measure cadmium (and lead) content in their output on a regular basis to ensure that material is not contaminated with other waste (in case window profile waste was mixed with other waste during collection or transportation). EPPA (2023) collects and consolidates obtained results twice a year. Additionally, (Anonymous stakeholder; TEPPFA, 2023; VinylPlus, 2023a) provided data on the presence of cadmium in rPVC from various sources. Almost all measured samples were below the limit of 1000 ppm of the REACH Regulation (see chapter 3.2.1.2).

3.1.1.3.2 Presence of other legacy additives

Since cadmium stabilizers were used both in soft and rigid PVC, the presence of phthalates which are commonly used as plasticizers in soft PVC is expected. Moreover, it is often the case that multiple phthalates are used at once to achieve desired properties of PVC (see chapter 3.2.1.1.2), therefore, even more phthalates in combination with cadmium can be expected. The presence of phthalates is also confirmed by the RAPEX database where a few products (e.g., inflatable unicorn, towel in PVC bag) contained a combination of cadmium, DEHP, DINP and SCCP.

Furthermore, since stabilization in the past took place with either cadmium or lead, one of the stakeholders indicated that today's rPVC-U may contain a mix of those substances due to the mixing of old profiles during waste collection and the compounding of recyclate (EPPA, 2023).

Other than that, no data could be found that confirms the combined use of cadmium compounds and other legacy additives in the focus of this study.

3.1.1.3.3 Predicted volumes and comparison with forecasts

ECHA (2021b) contains some predictions on the presence of cadmium in recycled PVC.

The cadmium content in PVC waste arising from windows and other profiles was extrapolated based on the average use concentration (3500 ppm) and the stop in use. Here a reference year for stop in use is 1996 contrary to the stakeholder input on the phase-out of cadmium in 2001. In 2020 a concentration of ~1075 ppm of cadmium in window profiles and 600 ppm in other profiles is predicted. In 2030 these concentrations have fallen to 600 ppm and 300 ppm respectively. A concentration of ~0 is reached in ~2050 (see Figure 6).

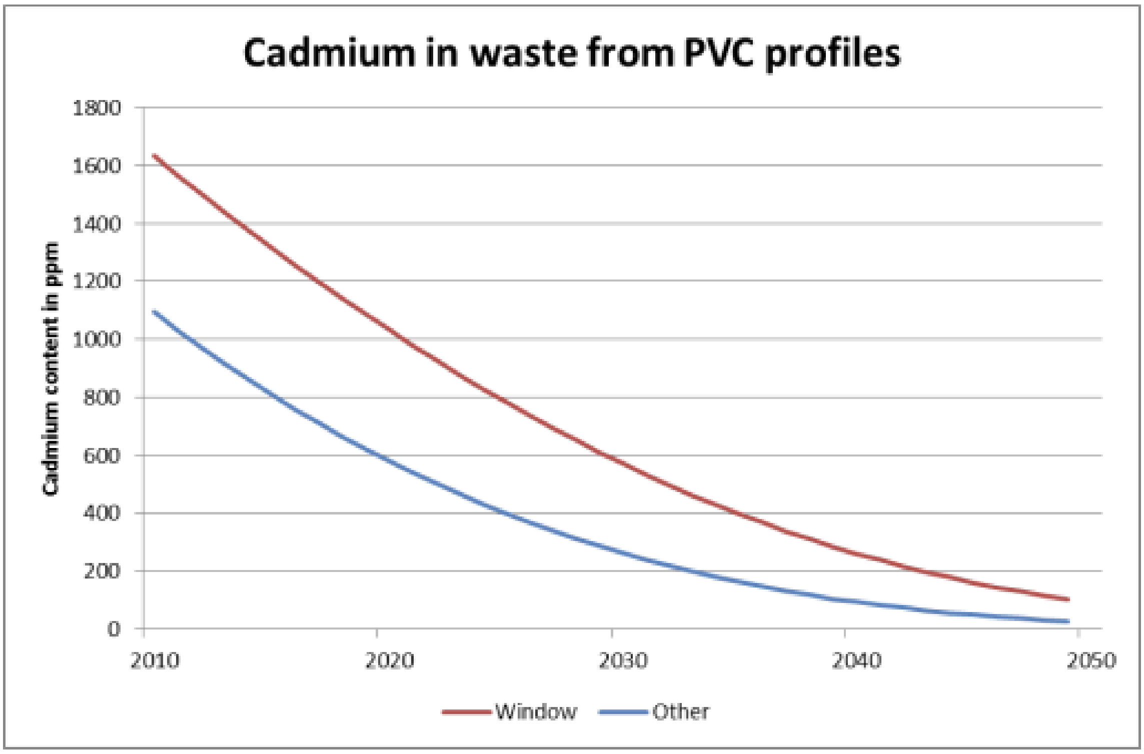

Figure 6. Prediction of cadmium concentration in waste from PVC profiles (2010-2050) ECHA (2021b)

A similar calculation is done for cadmium in window and other profiles containing PVC recyclate (which contains cadmium). The content depends on the amount of recyclate used in the products and ranges in the graph from 3,5%-70%. This results in a maximum Cd concentration of 2500 ppm in 1996, which decreases to ~1450 ppm in 2005, ~839 ppm in 2017, 400 ppm in 2030 and ~0 ppm in 2050. On the low end a concentration of ~120 ppm was calculated, which decreases to ~100 ppm in 2005, 42 ppm in 2017, 20 ppm in 2030 and ~0 ppm in 2050 (Figure 7 and Figure 8).

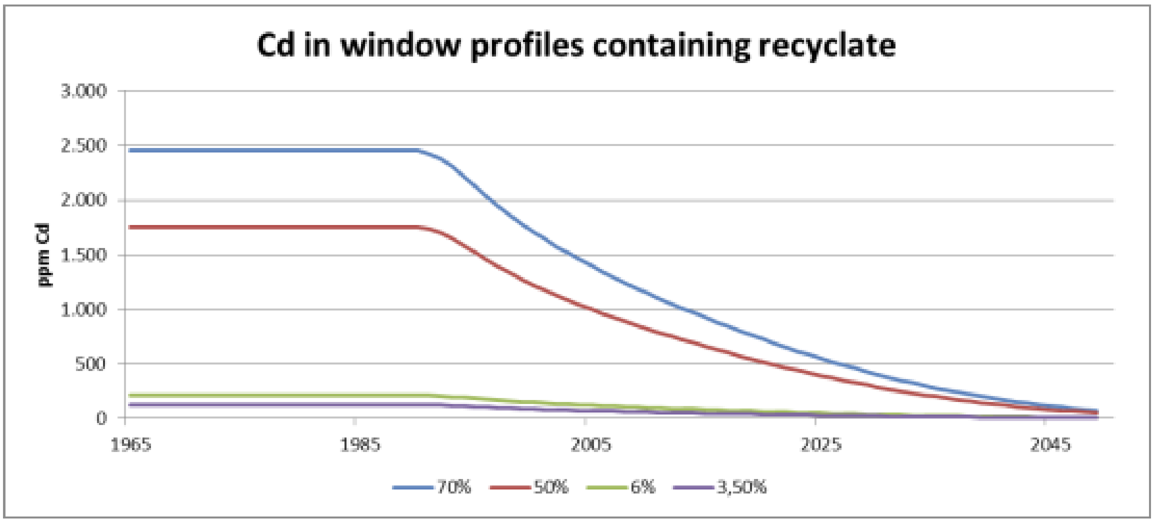

Figure 7. Cadmium concentration in window profiles containing recyclate, based on the use of recyclate of 3.5%, 6%, 50% and 70% (1965-2050) ECHA (2021b)

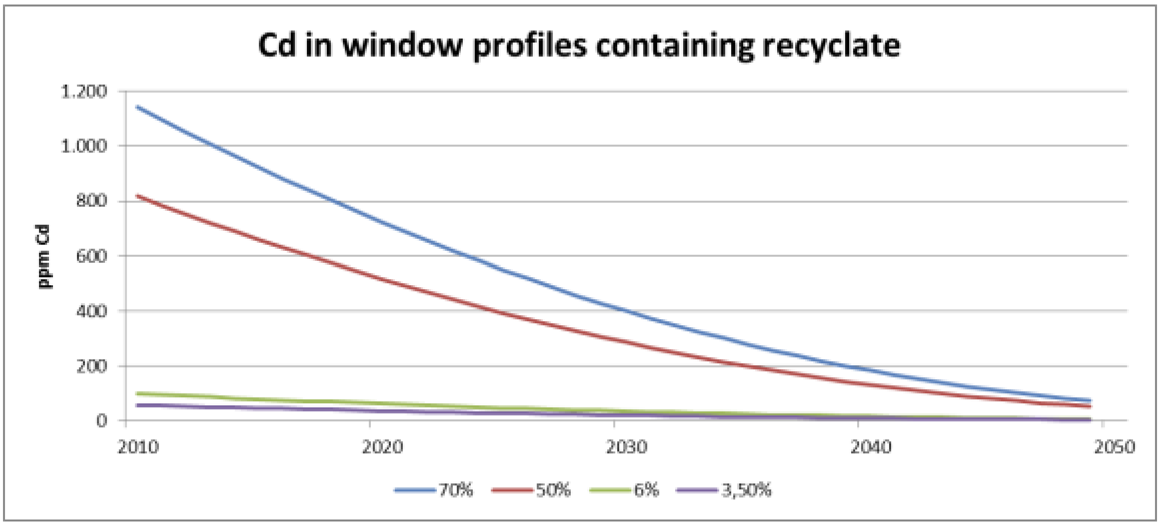

Figure 8. Cadmium concentration in window profiles containing recyclate, based on the use of recyclate of 3.5%, 6%, 50% and 70% (2010-2050) ECHA (2021b)

According to the information provided by EPPA (2023) on the concentration of cadmium in rPVC-U core of window profiles (Figure 18), and the average maximum recyclate content in a window profile of around 50%, the concentration of cadmium in window profiles can be calculated. Based on that, a concentration of cadmium for 2022 equals ~ 100 ppm. Compared with the predictions given for cadmium in window profiles containing 50% of recyclate in 2022 (Figure 8, red line, ~500 ppm) that would mean that current concentrations of cadmium in window profiles containing recyclate are well below the predicted concentrations for 2022.

Similarly the average cadmium concentration in rPVC from windows is ~400 ppm (see Figure 17), which is also below the prediction of ~1000 ppm by ECHA (2021b) (see Figure 6).

In addition to ECHA (2021b), RPA (2010) also contains predictions for cadmium concentrations in new window profiles. Here the predictions were made based on the uptake of 40% and 70% of PVC profile waste recyclate (Figure 9 and Figure 10). Same as in predictions given in ECHAs Annex XV Evaluation report (Figure 8), gradual decrease in concentration of cadmium is expected in the years to come. Based on the concentration of cadmium in window profiles provided by EPPA

2023 (Figure 18), a concentration of cadmium for 2022 can be estimated at roughly 80 and 140 ppm, taking into consideration the uptake of 40% and 70% of PVC recyclate, respectively. Again, compared with the predictions given for cadmium in window profiles containing 40% and 70% of recyclate in 2022 (Figure 9, ~280 ppm and Figure 10 ~500 ppm), current concentrations of cadmium in window profiles are well below the predicted concentrations for 2022.

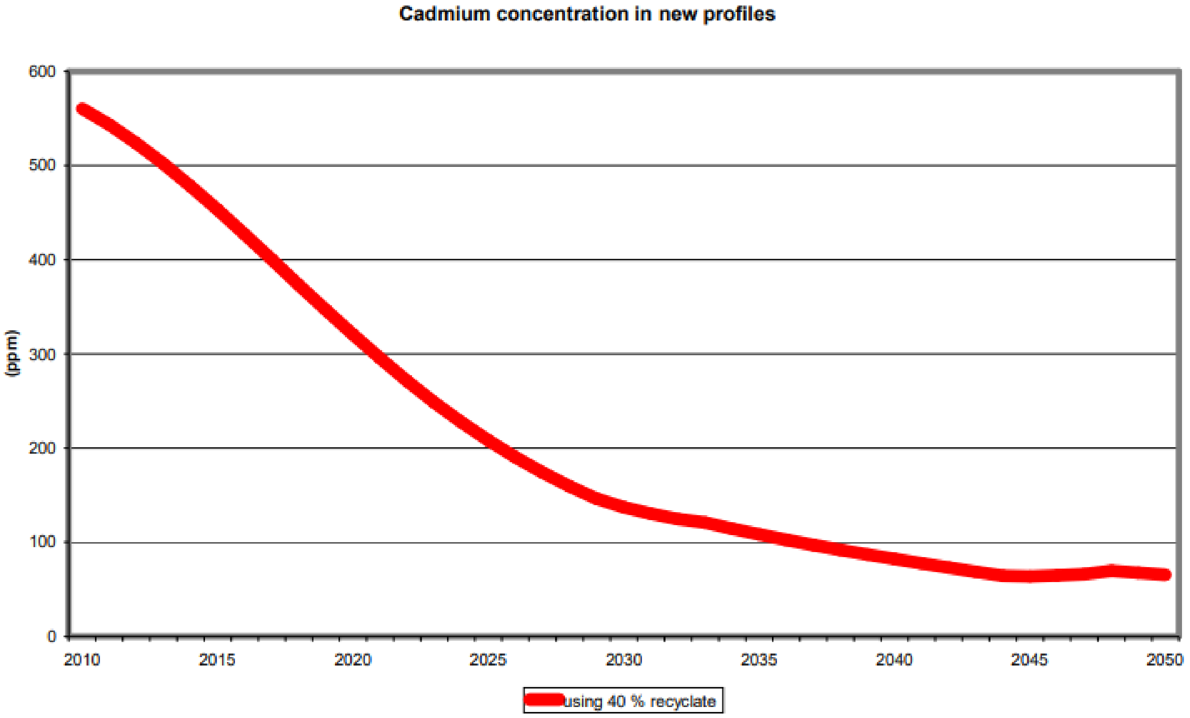

Figure 9. Concentration of cadmium in new window profiles made from recycled PVC in the EU using 40% PVC profile waste recyclate (reproduced from VITO, 2009) (RPA, 2010)

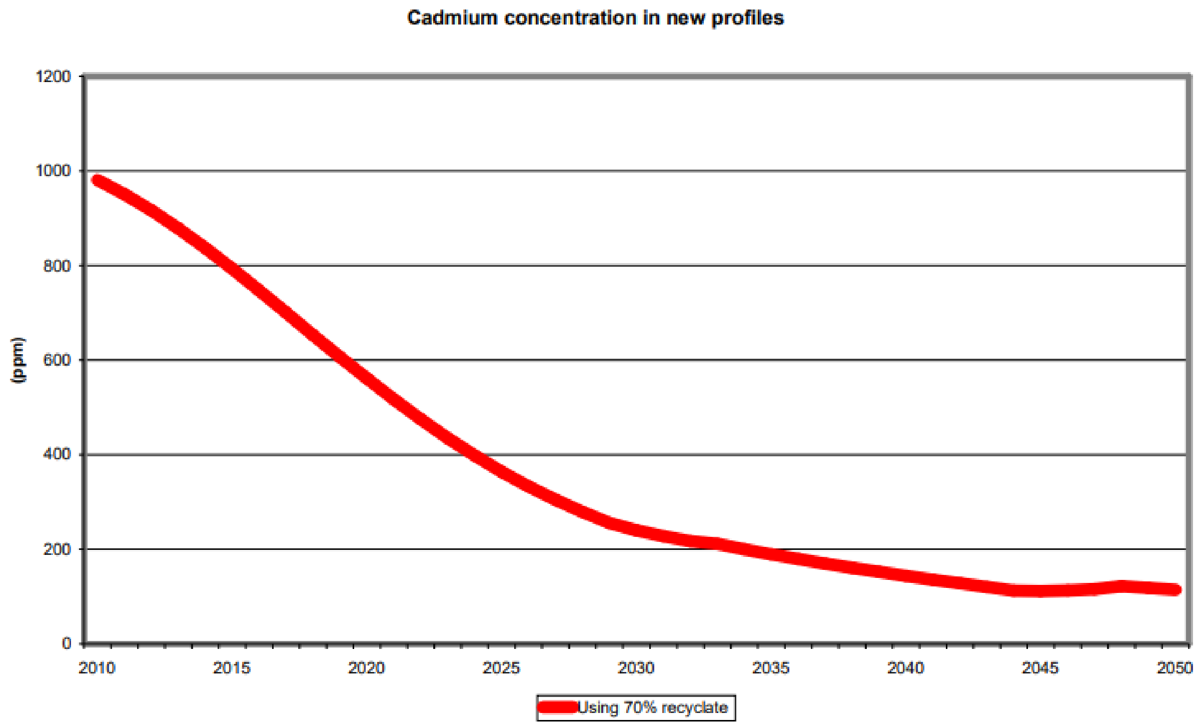

Figure 10. Concentration of cadmium in new window profiles made from recycled PVC in the EU using 70% PVC profile waste recyclate (reproduced from VITO, 2009) (RPA, 2010)

Analogous to the calculation for windows a calculation for pipes was conducted. Based on a recyclate amount of 30% and 50% the Cd concentration in new products containing recycled PVC can be calculated. These range from 1200 ppm in 1990 to ~400 ppm in 2010, 287 ppm in 2017, 118 ppm in 2030 and ~0 ppm in 2050 for a recyclate content of 50%. For 30% a concentration of ~700 ppm in 1990, ~320 ppm in 2010, 132 ppm in 2017, 71 ppm in 2030 and ~0 ppm in 2050 was calculated (Figure 11).

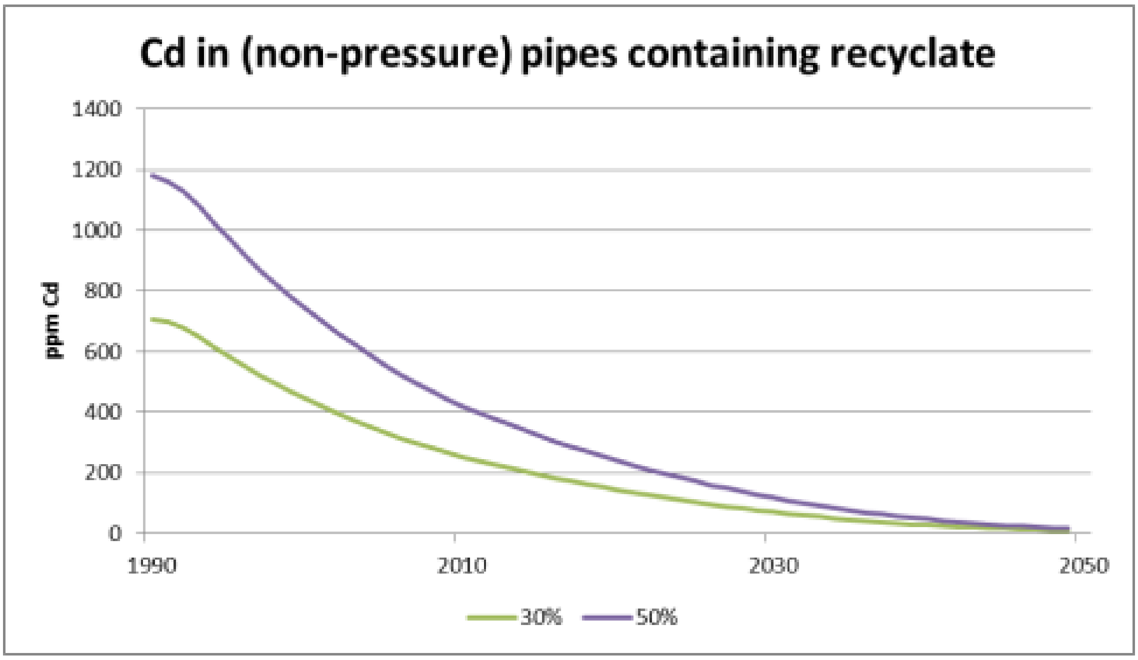

Figure 11. Cadmium concentration in pipes containing recyclate, based on the use of recyclate of 30% and 50% (1990-2050) (ECHA, 2021c)

Data on the current volumes of cadmium in waste was calculated based on the concentrations of cadmium in PVC recyclate provided by the stakeholders and the amounts of recycled PVC from the VinylPlus yearly progress report (see Figure 15 and Figure 16 as well as the excel sheet under “Amount of recycled PVC”).

As seen in Table 1, the amount of cadmium in recycled PVC waste is proportional to the amount of recycled PVC waste. In other words, the higher the amount of PVC waste, the higher the amount of total cadmium in waste. Based on the concentrations provided by stakeholders (Anonymous stakeholder; EPPA, 2023; TEPPFA, 2023), the total amount of cadmium in recycled post-consumer PVC waste can be calculated (Table 1).

The amount of recycled pre-consumer PVC waste is much higher than recycled post-consumer PVC waste. However, since cadmium is no longer added as a stabiliser in new PVC applications it can be considered that the amounts in this case are close to zero.

Table 1. Calculated amounts of cadmium in recycled PVC waste in 2021

Type of application	**Recycled amount of PVC waste, 2021 [t]**		**Average concentration of cadmium in recycled PVC waste [ppm]**	**Total amount of cadmium in recycled PVC waste [t]**	
	Pre-consumer waste	Post-consumer waste		Pre-consumer waste	Post-consumer waste
Windows and window profiles	213,909	141,420	400 (EPPA, 2023)	85.56*	56.57
			170 (Anonymous stakeholder)	36.36*	24.04
Rigid PVC (windows+ pipes)	247,952	151,674	43.5 (TEPPFA, 2023)	10.79*	6.60
Pipes and other PVC	66,108	36,245	30 (Anonymous stakeholder)	1.98*	1.09

*expected to be zero as cadmium is no longer used in PVC

Of the five listed cadmium compound substances, only cadmium sulphide (used as a pigment not just in PVC but other plastics as well) is still registered under REACH and is manufactured in and / or imported to the European Economic Area, at ≥ 10 to < 100 tonnes per year.

3.1.1.3.4 Change in substance concentrations found in humans

Main exposure of general population to cadmium occurs through the consumption of food, drinking water and tobacco, while occupational exposure is mostly related to manufacturing processes where cadmium is used (EU RAR, 2007). It is important to note that these processes are not specifically related to the production of PVC.

Swedish Chemicals Agency (2013) provides results of several studies which measured the concentration of cadmium in the general population. Those are the National Swedish health-related environmental monitoring program (SEM), the Women's Health in the Lund Area Study (WHILA), and the Swedish Mammography Cohort (SMC) study. In the SEM study, sampling of urine took place in the period of 2002-2009 in 4 regions in Sweden. In total 669 women (age 20-29) and 759 women (age 50-59) were sampled. Average concentration of cadmium in women age group 20-29 was 0.12 µg/g creatinine while for the age group 50-59 the average concentration was 0.29 µg/g creatinine. Furthermore, in the WHILA study, both blood and urine were sampled from 820 women aged 54 to 63 in 1999 from rural area of Southern Sweden. Cadmium level in urine was on average 0.52 µg/L (urine density adjusted = 0.67 µg/g creatinine) while in blood average value was 0.83 µg/L. In a third study from the SMC, a total of 2831 urine samples from women 56-69 years of age were taken during 2003 and 2009 in the town of Uppsala. Average value of the cadmium was 0.35 µg/g creatinine. In conclusion, by comparing the results of those three studies, it can be seen that values of cadmium concentration decreased from 1999 to 2009.

In a more recent study from Vogel et al. (2021), concentrations of lead, chromium and cadmium are given for urine and blood samples of children and adolescents in Germany. In this study 2294 urine samples of children aged 3-17 were taken in Germany between 2015 and 2017, together with background information such as diet and typical exposure. Additionally, 720 blood samples were also taken from 2014 to 2017. Cadmium was measured both in blood and urine. Cadmium was detected in 76% of urine samples in an average concentration of 0.096 µg/L (maximum concentration of 1.85 µg/L), or 0.075 µg/g creatinine (maximum concentration of 4.22 µg/g creatinine). While cadmium concentrations were about the same for boys and girls, both in blood and urine samples, cadmium concentrations increased with the age of the children. 14- to 17-year-old adolescents had 71% higher GM (geometric mean) urinary cadmium levels than 3- to 5-year-old children. Active smoking was found to be associated with 28% higher volume-based GM urinary concentrations when operationalized via self-report and 36% higher levels when measured with the urinary cotinine cut-off compared to non-smokers. In blood, higher cadmium levels of smokers compared to non-smokers were reflected by more individuals with quantifiable concentrations (both in self-reported and in urinary cotinine levels), namely twice as many measurements at or above LOQ. Vegetarian diet was related to 35–41% increased average urinary cadmium concentration and about 1.5 times as many blood cadmium measurements at or above LOQ. The authors also compared the results of this study with similar studies in the past (GerES II, 1990–1992 and GerES IV, 2003–2006) which were observed on the same age groups but in different timelines. Cadmium levels were lower by a factor of ~15% with higher disparities found in participants from East Germany (40% in urine and 25% in blood). Obtained results authors also compared with studies that took place in other countries. For example, in the Czech Republic significantly higher cadmium concentrations were found in children age group 5-9, which the authors associated to a higher environmental contamination and differences in the nutrition.

While in general a decrease of cadmium concentration in humans can be obtained, it should be kept in mind that other factors such as differences in the nutrition and daily habits can have an impact on concentrations which makes it harder to compare data over time. A clear link to the exposure to cadmium in PVC was not mentioned in the study.

3.1.1.3.5 Conclusion

Historically, cadmium was used as a pigment and as a stabiliser in both soft and rigid PVC. According to the stakeholder input, the use of cadmium compounds in PVC in Europe was phased out first in the EU-15 in 2001 and later expanded on the EU-27 in 2017 through the voluntary industry commitment called Vinyl 2010. Stakeholders consider five of the six cadmium compounds listed on the legacy additives listed as relevant for PVC, with all five being completely phased out and no longer in use. Studies and stakeholder input show that cadmium is still present in some products made from PVC, however, in many cases only in low concentrations and mainly originating from recycled PVC. Based on the RAPEX database, some amount of cadmium gets imported from China in EU through products such as inflatable toys, sandals, wallets, and bags. Concentrations in humans have decreased since the ban, however, exposure to cadmium is still present from e.g., food and tobacco.

3.1.1.4 Nickel

Nickel has only a minor role as a PVC additive. The main reason nickel was used in any plastic including PVC is as a pigment. The colours range from yellow to orange and black depending on pigment.

Four additives from the list provided by ECHA fall under the category of nickel pigments:

- Reaction mass of melamine and Nickel, 5,5'-azobis-2,4,6(1H,3H,5H)-pyrimidinetrione complexes (alternative name: "C.I. Pigment Yellow 150") (EC: 939-379-0)
- Antimony nickel titanium oxide yellow (CAS: 8007-18-9)
- Nickel iron chromite black spinel (CAS: 71631-15-7)
- Pigment Orange 68 (CAS: 42844-93-9)

3.1.1.4.1 Relevant products, concentration ranges and comparison with concentration limits

No products still containing nickel substances could be identified. Several stakeholders confirmed the use of the four Nickel pigments in PVC (Anonymous stakeholder; Reagens, 2023; VinylPlus, 2023a), however, one producer of PVC is not aware that nickel compounds are used in PVC formulations in Europe (INEOS Inovyn, 2023). (Anonymous stakeholder; VinylPlus, 2023a) both state that the pigments are used in very low concentrations and the nickel contents in PVC waste are typically below the limit of detection (30 mg/kg). EPEA (2023) compared the provided list with their own list of legacy additives and found only Pigment Black 30 (71631-15-7) and Pigment Yellow 53 (8007-18-9) to match with their list. They state that the use of these two pigments is only “anecdotical” as only two instances of use have been recorded in over 20 years of record keeping.

(Anonymous stakeholder) measured nickel in recycled PVC, however, all measured samples had nickel concentrations below the LOD of 30 ppm (see chapter 3.2.1.2).

3.1.1.4.2 Presence of other legacy additives

No information on the presence of other additives could be identified, however, it is not expected that another pigment is used together with nickel pigments. Due to many different PVC articles having a colour, nickel can be present in rigid as well as plasticised PVC articles.

3.1.1.4.3 Predicted volumes and comparison with forecasts

No specific information on the amounts of the pigments still in PVC products could be found. All four pigments are registered under REACH and three have a tonnage band indicated ranging from ≥ 100 to < 1 000 tonnes per year (EC 939-379-0) to ≥ 10 to < 100 tonnes per year (CAS: 42844-93-9) and ≥ 100 tonnes per year (CAS: 71631-15-7).
The additives are used in a wide variety of plastics, not only PVC.

3.1.1.4.4 Change in substance concentrations found in humans

While several studies analysing the presence of nickel in humans were identified, none had a connection to PVC (see for example (Campos et al., 2021; Interdonato et al., 2014; Tavares et al., 2022)). The main route of exposure to nickel is from occupational exposure (e.g. welding) and exposure by living close to industrial areas (e.g. oil refineries).

In general pigments are expected to have a low bioavailability due to their low water solubility (ECHA, 2023a; IMAP, 2020), and a health risk from the use of nickel pigments in PVC is not expected.

3.1.1.4.5 Conclusion

Nickel is only added to PVC in the form of pigments, typically in low concentrations. As such it can be present in both rigid and plasticised PVC articles, however, nickel only plays a small role as an additive in PVC. Significant health concerns from the use of nickel pigments in PVC are not expected due to the low use concentrations and low bioavailability of the pigments.

3.1.1.5 Chromium

Chromium, like nickel, is mainly present in plastics due to its use as pigment. The colours typically range from yellow to red. From the additives list only one chromium additive is a pigment in plastics namely Barium Chromate (CAS 10294-40-3).

3.1.1.5.1 Relevant products, concentration ranges and comparison with concentration limits

No products still containing chromium were found. The use of chromium pigments was phased out around 2000 in Europe. Several stakeholders state that chromium additives were never used in PVC (INEOS Inovyn, 2023; Reagens, 2023; VinylPlus, 2023a). All other stakeholders do not mention chromium in their answers, indicating a low relevance of this additive group.

The chromates in the excel list were mainly used in the leather industry (Anonymous stakeholder; Reagens, 2023).

(Anonymous stakeholder) measured chromium in recycled PVC and it was detected in 25 of the 42 samples. All samples comply with the 0.1% concentration limit of the REACH Regulation (see chapter 3.2.1.2).

3.1.1.5.2 Presence of other legacy additives

Chromium pigments in general are often lead chromates, meaning that the two heavy metals are often detected together (RIVM, 2011). In the report by (Anonymous stakeholder) the presence of tin and cadmium together with chromium was confirmed for window profiles (cadmium), rigid PVC (both) and cables (tin).

3.1.1.5.3 Predicted volumes and comparison with forecasts

No specific information on the additives in the list could be found with the exception of chromium trioxide. Additionally, information on lead chromates used as pigments was available in ECHA (2022). While not in focus of this project the graph shows that the production and use of these types of pigments has stopped in 2022:

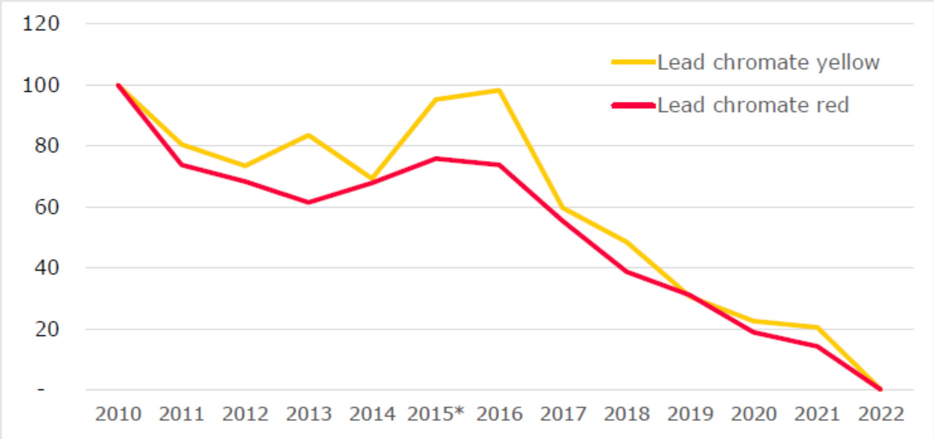

Figure 12: Estimates of volumes of lead chromates placed on the EU market, 2010-22, tonnes (ECHA, 2022)

Data is also available for chromium trioxide, which has been used as a catalyst for the production of PE and PP, however, it has its main application in chrome plating processes and as such the fraction used for the production of PE and PP cannot be estimated. This fraction is however expected to be low:

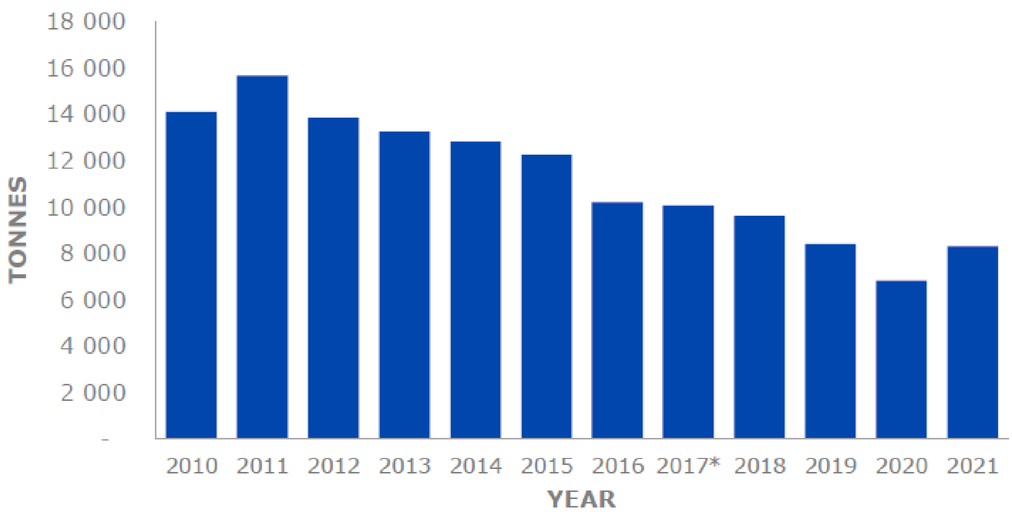

Figure 13: Estimates of volumes of chromium trioxide placed on the EU market, 2010-22, tonnes (ECHA, 2022)

Lastly, based on the data provided by (Anonymous stakeholder) (see chapter 3.2.1.2) the amount of chromium in recycled PVC for specific product types can be calculated. In their study rPVC samples were measured for chromium. Average concentrations were extracted from the graph for rigid PVC samples (roofing, siding, pipes, 55 ppm)), window profiles (50 ppm) and cables (17 ppm) and then multiplied with the amount of recycled PVC published by VinylPlus (2023b) for each application (see Figure 15 and Figure 16. This calculation results in the following amount of chromium in recycled PVC in 2021 (can also be found in the excel sheet under "Amount of recycled PVC"):

- Rigid PVC: 5.63 tonnes

- Windows: 17.77 tonnes
- Cables: 1.44 tonnes

3.1.1.5.4 Change in substance concentrations found in humans

No baseline data on the exposure of humans to chromium used in PVC could be found. As chromium only has a very small role as a PVC additive the exposure to humans is expected to be negligible.

One study from Vogel et al. (2021) analysing chromium in the urine of humans was identified. The authors analysed chromium in the urine of children aged 3-17 in Germany from 2014-2017. Chromium was detected in 91% of samples with an average concentration of 0.45 µg/L and younger children had higher internal exposure than adolescents. The authors state that the exposure to leather products did not affect the concentration of chromium in the urine and neither did the presence of chromium in the tap water. Ultimately the authors could not identify a reason for the higher concentrations of chromium in younger children.

3.1.1.5.5 Conclusion

Chromium additives were used in PVC only as pigments and as such play only a minor role as PVC additive.

As they are used as pigments, chromium additives can be present in flexible and rigid PVC applications. Their use as additives in PVC was stopped in 2000. Significant human exposure from the use in PVC is not expected. Residual amounts of chromium can still be found in recycled PVC from various applications (windows and other profiles, rigid PVC from construction and cables).

3.1.1.6 Short-chain chlorinated paraffins

Short-chain chlorinated paraffins (SCCP) were listed in Annex I of the POP Regulation in 19.06.2012. They have been used in PVC as plasticiser and flame retardant. In the EU the use was stopped in 1994.

3.1.1.6.1 Relevant products, concentration ranges and comparison with concentration limits

As SCCP are used as a plasticiser they can be found in flexible PVC products such as conveyor belts, dam sealants, mats, cables, floors, shoes, bags and garden goods. Several stakeholders also confirmed that SCCP were used in PVC in the past (Anonymous stakeholder; INEOS Inovyn, 2023; VinylPlus, 2023a). They have mainly been substituted by long-chain chlorinated paraffins (LCCP) by now (MCCP have already been phased out by the PVC industry in Europe (VinylPlus, 2023a), probably as they are too volatile to be used in PVC (INEOS Inovyn, 2023)).

McGrath et al. (2021) analysed several PVC products purchased on the Belgian market in 2019. The products include a yoga mat, beach ball, inflatable pool mat, can holder, jump rope, electrical cable and flipflops. SCCP were found in all products with concentrations ranging between 1.2-82 mg/kg (0.082%). As the concentration limit in the POP Regulation is 0.15% all products are compliant with European law. The authors state that the SCCP were not intentionally added but are present as an impurity from the production. This can happen during the transport of the products on conveyor belts or through the contact with mechanical lubricants both of which have benefited from an exemption under the Stockholm Convention (only conveyor belts in POP Regulation).

Additionally, in RAPEX 77 hits were found for SCCP, however, some hits also refer to the use in rubber. Nevertheless, 12 products made from PVC and containing SCCP above the 0.15% concentration limit were identified. Such products include toys, sandals, rain jackets, jump rope and yoga mats. Several other products made from plastic and containing SCCP were also identified, however, it is unclear which plastic the product was made of. The vast majority of products originated from China.

In a report by Ramboll, (2021) several PVC products were analysed as to their SCCP content. All measured concentrations were below 50 mg/kg and as such compliant with the POP-Regulation. Additionally, in cables very high concentrations of 99,000 mg/kg of MCCP were found showing that this substance group was used as a substitute for SCCP in flexible PVC (see also chapter 3.2.1.2).

3.1.1.6.2 Presence of other legacy additives

McGrath et al. (2021) was also able to identify phthalates in the products, however, none in the list provided by ECHA. They also didn't provide any concentrations of the identified phthalates.

In the RAPEX data SCCP are mostly found together with other phthalate-based plasticisers mainly DEHP but also DiNP, DiBP and BBP. In a towel wrapped in a PVC bag the presence of cadmium was also confirmed.

3.1.1.6.3 Predicted volumes and comparison with forecasts

The substance is no longer registered in Europe (ECHA, 2023c). This means that it can only be imported into the European market. This is also confirmed by the RAPEX data. Data on the exact amounts of SCCP imported into Europe could not be identified.

3.1.1.6.4 Change in substance concentrations found in humans

In the risk profile for SCCP under the Stockholm Convention two studies form the UK are cited in which human breast milk was sampled and analysed for SCCP around 2002 and 2006. Concentrations ranged from 4.5-100 µg/kg lipid (2002) to 49-820 µg/kg lipid (2006).
In a study from Sweden in 2012 a mean SCCP concentration of 107 µg/kg lipid in human breast milk was obtained (UNEP/POPS/POPRC.11/10/Add.2, 2015).

A more recent study from Tomasko et al. (2021) analysed the blood serum of policemen from the Czech Republic. Sampled regions include Prague and Ostrava (industrial) as well as Ceske Budejovice (agricultural, control group). Sampling took place in 2019. SCCP were detected in 78% of samples. The concentrations of SCCPs were in the range of <150–2600 µg/kg lw (median 370 µg/kg lw) and <0.9–13.9 µg/kg ww (median 2.2 µg/kg ww), respectively. The median concentrations in Ostrava, Prague and Ceske Budejovice were 890, 350 and 250 µg/kg lw. The authors state that dietary intake is expected to be the main source of SCCP exposure. The results are compared to other studies analysing SCCP in blood serum, mainly from China. The results are the lowest of all the compared studies.

However, as SCCP levels are still above the LOD humans are still exposed to this group of substances.

3.1.1.6.5 Conclusion

SCCP were used in Europe until 1994. As they were used as plasticisers and flame retardants, they are found in soft PVC products, often in combination with other plasticisers such as phthalates. SCCP are not produced in Europe anymore, however, they are still present on the European market from imports. This is also confirmed by recent human biomonitoring in the Czech Republic, which found SCCP in the blood serum of policemen. The main source of exposure is expected to be dietary intake.

3.1.1.7 Hexabromocyclododecane

Hexabromocyclododecane (HBCD) is used as a flame retardant in plastics. It was listed in the POP-Regulation on 22.03.2016.

3.1.1.7.1 Relevant products, concentration ranges and comparison with concentration limits

The use of HBCD in PVC could not be confirmed. Several stakeholders mentioned that HBCD was never used in PVC (Anonymous stakeholder; Reagens, 2023; VinylPlus, 2023a). No PVC products containing HBCD could be identified in this study.

3.1.1.7.2 Presence of other legacy additives

No data found for PVC.

3.1.1.7.3 Predicted volumes and comparison with forecasts

HBCD is registered under REACH however it is not manufactured or imported into Europe (ECHA, 2023b). This is confirmed by the RAPEX data. No entry concerning HBCD could be identified.

3.1.1.7.4 Change in substance concentrations found in humans

Before the listing of HBCD as a POP, the substance has been detected in breast milk from women in Norway. The following median concentrations (pg/ml plasma) were found: α-HBCD 19 (<11-345), β-HBCD 7 (5-343), γ-HBCD 23 (7-317). The detection frequency was above 50% but most samples were close to the LOD (ECHA, 2008).

Typical concentrations in human breast milk samples in populations living in industrialised areas appears to be <1-5 ng/g lw (study form 2009). In Spain high concentrations ranging from 3-188 and 8 -188ng/g lw, with median values of 27 and 26 ng/g lw, respectively were reported (studies from ~2009) (UNEP/POPS/POPRC.6/13/Add.2, 2010).

In a recent study stemming from the Human Biomonitoring for EU (HMB4EU), HBCD was analysed in the blood of children from various European countries (Greece, France and Slovenia). Samples were taken between 2014-2016 (France), 2018 (Slovenia) and 2020-2021 (Greece). α-HBCD had a maximum detection frequency of 27% (Slovenia), while γ-HBCD had a maximum detection frequency of 5% (Slovenia). The LOD was around 0.01 µg/L. Concentrations for samples that contain HBCD above the LOD are not given (Schyff et al., 2023).

3.1.1.7.5 Conclusion

Stakeholders stated that HBCD was never used in PVC. This is confirmed by this study, as no information regarding the presence of HBCD in PVC products was identified. The substance is, however, still present in humans, indicating that exposure from other sources is still relevant.

3.1.1.8 Organotin compounds

According to the stakeholder input from (Anonymous stakeholder; Reagens, 2023) only three organotin compounds from the list of legacy additives (Table 3) are relevant for PVC with two of them used as stabilisers for PVC and one of them used as a catalyst:

- Stabilisers:
  - Methyl (Z,Z)-8,8-dibutyl-3,6,10-trioxo-2,7,9-trioxa-8-stannatrideca-4,11-dien-13-oate (CAS 15546-11-9)
  - Dihydro-2,2-dioctyl-6H-1,3,2-oxathiastannin-6-one (CAS 3033-29-2)
- Catalyst:

- o Dibutyltin dilaurate (CAS 77-58-7)

3.1.1.8.1 Relevant products, concentration ranges and comparison with concentration limits

Di-substituted organotins are used mainly as stabilisers for PVC and to a lesser extent as catalysts in various products such as PVC gloves, PVC sandals, PVC printed T-shirts, PVC food packaging and other PVC and non-PVC products. When used as stabilizers they are added to PVC during the manufacturing process with concentrations up to 2% of the plastic weight with the aim to reduce the decomposition and deterioration of the product when exposed to heating, ultraviolet light, or weathering (RPA, 2007).

As stated above, several stakeholders confirm the use of only three substances in PVC with dibutyltin dilaurate having only a limited use in PVC (Anonymous stakeholder). VinylPlus (2023a) states none of these substances is still used in PVC. (Anonymous stakeholder) states it is not clear whether these substances are still used or not. (INEOS Inovyn, 2023) mentioned the use of dibutyltin maleate, typically used to obtain the high clarity in specific rigid profile applications (such as greenhouses). However, this substance is not in the scope of this project.

The presence of tin in products that are still in its service life was confirmed by Turner (2021a). The year of the samples is unknown but expected to be around 2017. In the study, a total of 92 samples of consumer plastics made from PVC were collected from households, offices, schools, shops, and restaurants in England. Tin was identified in 18 samples in the range of 1020 – 5100 mg/kg (with 2700 mg/kg on average) which exceeds the concentration limit set by REACH (1000 mg/kg). The samples originated from a wide range of applications including electronic (2), food and hygiene (2), clothing accessories (2), office tools (3), storage construction (4), and leisure (5). In addition to that, residual metal concentrations were also investigated. For that purpose, all hits with concentrations lower than 1000 mg/kg were considered as too low to function as additives and are therefore considered as residual metal concentrations. In this case, there was a total of 20 samples with residual concentrations of Sn in the range of 39 – 913 mg/kg (with 300 mg/kg on average), all being below the limit value of 1000 mg/kg. The origin of samples with residual concentrations is not given. Even though the study confirms the presence of tin as intentionally added in 18 samples of consumer plastics, it should be noted that the year of origin of those samples is not known and due to the long lifespan of certain PVC products (especially in construction sector) it could be that tin was added before the restriction came into force. Furthermore, since in the study the authors only measured tin and the exact substance is not specified it cannot be concluded whether tin comes from these legacy additives or from other compounds.

The use of dibutyltin dilaurate was also confirmed by (EPEA, 2023). However, as stated, it occurs only occasionally in the raw materials for coatings at a level below 100 ppm.

According to the RAPEX database certain products containing organotin compounds are still imported into the EU, however, in very low amounts. The screening resulted in a total of 8 hits for organotin in different plastic materials, indicating there are some products not compliant with REACH, i.e., exceeding the concentration limit of 0.1% for dibutyltin and dioctyltin compounds expressed by weight of tin. Non-compliant products mostly include toys, and they are all coming from China. Even though in most cases only a reference to ‘plastic material’ is made, it can be assumed that a good portion of those products is made from PVC.

On the presence of tin in PVC, one representative of the flooring manufacturing stated tin is present in concentrations lower than 0.007% in end-of-life products, mainly in PVC floor covering older than 20 years (Anonymous stakeholder). The stated concentration complies with the 0.1% concentration limit of the REACH Regulation. Two other stakeholders provided data on the presence of tin in rPVC and all measured concentrations were below the REACH limit of 1000 ppm (see also chapter 3.2.1.2) (TEPPFA, 2023).

3.1.1.8.2 Presence of other legacy additives

Since organotin stabilizers were used both in soft and rigid PVC, the presence of phthalates commonly used as plasticizers in soft PVC is expected (see chapter 3.1.1.1.2). That was also confirmed in the RAPEX database where various types of phthalates were detected together with organotin in a lot of imported products.

Furthermore, since stabilization in the past took place with either cadmium or lead, one of the stakeholders indicated that today's rPVC-U may contain a mix of those substances due to the mixing of old profiles during waste collection and the compounding of recyclate (EPPA, 2023).

Additionally, (TEPPFA, 2023) also confirmed the presence of multiple additives such as lead, cadmium, and tin in commercially available PVC recyclate. (Anonymous stakeholder) also confirmed the presence of chromium and cadmium in rPVC samples containing tin.

3.1.1.8.3 Predicted volumes and comparison with forecasts

No specific information on the amounts of the organotin compounds still present in PVC products could be found. However, based on the concentrations of tin in the recyclate provided by (Anonymous stakeholder) (see chapter 3.2.1.2) and the amounts of recycled PVC published by (VinylPlus, 2023b) for each application (see Figure 15 and Figure 16) the amount of tin in recycled PVC from cables (average concentration 45 mg/kg) and rigid PVC (average concentration 145 mg/kg) can be calculated. Calculation resulted in following amounts of tin for 2021:

- Rigid PVC: 5.26 t
- Cables: 3.34 t

(Anonymous stakeholder) also measured tin in the window profile recyclate, however, due to significantly low detection frequency of <5%, the concentrations were not taken into account.

Based on the data provided by (TEPPFA, 2023), who measured tin in rPVC from pipes and window profiles, a total amount of tin in rigid rPVC of 9.07 t can be calculated (average concentration 43.5 mg/kg).

All three compounds that stakeholders listed as relevant are registered under REACH. Dibutyltin dilaurate has a tonnage band of ≥ 100 to < 1 000 tonnes per year, dihydro-2,2-dioctyl-6H-1,3,2-oxathiastannin-6-one ≥ 10 to < 100 tonnes per year while methyl (Z,Z)-8,8-dibutyl-3,6,10-trioxo-2,7,9-trioxa-8-stannatrideca-4,11-dien-13-oate is registered under REACH but is not currently being manufactured in and/or imported to the European Economic Area. According to VinylPlus (2023a), dibutyltin dilaurate is produced by several producers but is not intended for PVC applications.

3.1.1.8.4 Change in substance concentrations found in humans

Main exposure of general population to organotin compounds is via food, indoor air, household dust and dermal contact with different polymer materials (RPA, 2007). In a review paper from Okoro et al. (2011) fish and fish products are stated as the main source of the organotin compounds of the human diet in Finland as they were detected in the whole blood samples of fishermen and their family members, with a high correlation between the levels found and age, gender, and frequent fish consumption.

A review paper from Sousa et al. (2014) provides a summary of organotin levels detected in human biological tissues and fluid on different locations in Europe. As stated, a study from Kanan and Falandysz, 1997 was among the first studies which measured organotin compounds in humans. Back in 1994, targeted population included male adults from Poland. In a total of 9 samples from liver, concentration of measured ∑BTs (sum of butyltins (monobutyltin, dibutyltin and tributyltin)) was in the range of 2.4 – 11.0 ng/g. This was followed by a study from Nielsen and Strand, 2002 in which a total of 18 samples from liver were taken in period of 1999-2000. Again, targeted population included male adults but this time from Denmark. Detected concentration of ∑BTs was in the range of 1.1 – 33.0 ng/g where tributyltin and triphenyltin were below LOD of 0.3 and 3 ng/g, respectively in all samples, and monobutyltin and dibutyltin levels varied between 0.3 – 4.7 ng/g and 0.8 – 28.3 ng/g, respectively. In a subsequent study from Rüdel and Steinhanses, 2001, where organotin compounds were measured in 30 whole blood samples in students from Germany, monobutyltin and dibutyltin could be detected only in 3.3 and 17% of the samples, respectively. Furthermore, a study from Lo et al 2003 detected very low concentrations of organotin compounds in healthy adults from Germany. In a total of 8 samples of human plasma monobutyltin, dibutyltin, tetrabutyltin, monooctyltin and dioctyltin were always below detection limit. However, in this study, tributyltin was detected for the first time, indicating accumulation in the human body. Low concentration of organotin compounds was also detected in a study from Peter 2004 in which a total of 91 samples of whole blood was taken from individuals in the Netherlands. Dibutyltin, monophenyltin, diphenyltin and triphenyltin were always detected below LOD while monooctyltin, dioctyltin, and monobutyltin were detected in 13%, 14%, and 3% respectively. In a study from Rantakokko et al. (2008), a total of 300 samples of whole blood were taken from fishermen and their families in period of 2004 – 2005. Monobutyltin, tributyltin, monophenyltin, monophenyltin, diphenyltin and dioctyltin were below LOD in all samples. Only dibutyltin and triphenyltin were detected, however, in low concentrations, <0.18–0.38 ng/mL and <0.04–0.56 ng/mL. Even though a decreasing trend in concentrations in both liver and whole blood samples can be obtained, it should be kept in mind that the concentrations also vary depending on the diet as well as on the exposure to certain products containing organotin compounds which makes it harder to compare data over time. The high relevance of fish to the presence of organotin compounds in humans is probably due to its past use in anti-fouling paints.

More recent studies that measured the organotin compounds in humans could not be identified. However, since the use of organotins is widespread, not just limited to the use in PVC, exposure from several sources is expected.

3.1.1.8.5 Conclusion

Only three compounds from the list of legacy additives in the scope of this project are relevant for PVC. They are mainly used as stabilisers and to a lesser extent as catalyst. It is not very clear whether organotin compounds are still used today or not. Only one study was identified which confirmed the presence of tin in PVC products still on the market. However, since the authors only measured tin and the exact substance is not specified, it cannot be concluded whether tin comes from these legacy additives or from other compounds. In 18 of the 92 analysed samples, the concentration of tin is above the REACH restriction limit of 0.1%. The presence of tin in rPVC was also confirmed by stakeholders. Some measurements indicate the combined use of cadmium, lead and tin compounds in rigid PVC since all three are/were used as stabilisers. The exposure to organotin compounds largely occurs through food consumption, but also via indoor air, household dust and dermal contact with different polymer materials. More recent studies that measured the organotin compounds in humans and a direct link of the exposure to organotin substances to the use in PVC could not be identified.

3.1.2 Alternative plastics

Over the course of this project four alternative plastic types were looked at:

- Polyethylene (PE)
- Polypropylene (PP)
- Crosslinked Polyethylene (PE-X)
- And Polyurethane (PUR)

These will be discussed together in the following chapter. Differences in the use and occurrence of the additives in focus depending on the type of plastic will be highlighted where applicable.

3.1.2.1 Phthalates

Phthalates are and have been used in PVC as plasticisers, however, they have also been used in other plastics.

3.1.2.1.1 Relevant products, concentration ranges and comparison with concentrations limits

For background information on the phthalates see chapter 3.1.1.1.1.

Similarly, to the use in PVC the phthalates have also been used in PE, PP and PE-X products.

For example Graíño et al. (2018) detected DEHP and DiBP in candy wrapper from Spain. DEHP was detected in 7 and DiBP in 4 of 8 samples, however, the type of plastic is not mentioned in the text. It can be assumed that the wrapping was made form PE or PP as these are the most common types of plastic used for this application. The authors were also able to detect DEP in 7 of the 8 samples.

Similarly, Murat et al. (2020) were able to detect DBP, DiBP and DEHP in cosmetic packaging made from PE/PP/PE-X (presumably purchased in France around 2019). Concentrations are not given. DEP was also detected in some samples.

Lestido-Cardama, Sendón, et al. (2020) were able to prove the presence of DEHP, DiBP and DBP in food packaging from products purchased on the Spanish market. Products include milk, cheese, yogurt, and custard packaging. Packaging was mainly made form PE however some products also contained PP. The three phthalates were detected in all PE sampled and DEHP and DiBP were also detected in a PP sample. The authors were also able to confirm the presence of the short chain phthalate DEP in both PE and PP packaging. Only DEP exceeds the TDI at the 95th percentile, while all other analysed additives do not. Concentrations of the phthalates in the packaging are not given in the study.

In a similar study the same authors also analysed the presence of phthalates in Spanish snack packaging made from PP. DEHP, DBP and the short-chain DiBP and DEP were detected in all samples, however, without concentrations (Lestido-Cardama, de Quirós, et al., 2020).

Zuri et al. (2022) analysed phthalates in PP face masks and were able to detect DBP (2.56 - 21 µg/mask), BBP (5.6 – 13.7 µg/mask), DEHP (2.34 – 4.54 µg/mask) and a C8 phthalate di-n-octy phthalate (3.95 – 5.07 µg/mask) in water after a migration experiment. DEP and DMP were also analysed, however, both were not detected in any samples. The authors state that the amount of leached phthalate per mask 1,000 times lower than the migration limit set for food contact material.

Herrero et al. (2021) detected DBP and BBP in milk samples from Spanish milk packaged in HDPE bottles. They were also able to confirm the leaching of DEP and dimethyl-phthalate (DMP) from HDPE into the milk. Concentrations are not given and the samples are from 2014.

The phthalates were also detected in multiple different microplastic samples collected in Europe. While the exact origin in terms of product and plastic type cannot be determined in the studies, the phthalates were detected in all analysed microplastic studies, most of which had a high weight percentage of PE and PP. It can be assumed that the phthalates were present in the original PE and PP products (Fries et al., 2013; Garcia-Torné et al., 2023; Llorca et al., 2021).

Lastly it should be mentioned that phthalates and especially DEHP are still imported into Europe. In total 1038 hits for DEHP were found (~3500 products in total), indicating that there are still many products being imported into Europe which do not comply with REACH. The other phthalates in question such as BBP (113 hits), DBP (383 hits), DiBP (82 hits), DiNP (131 hits) and DIDP (24 hits) were also found in imported products. The vast majority of non-compliant products originates from China, however, a few also originate from European countries such as Italy, Portugal and the Netherlands. As only a reference to "plastic material" is made it is unclear what plastic the phthalates were found. While it can be assumed that most will be in PVC products, it cannot be excluded that the phthalates are also present in PE, PP and PE-X products.

The use of the phthalates in PUR could not be confirmed in this study.

3.1.2.1.2 Presence of other legacy substances in the relevant products

Similar to the situation in PVC, the phthalates are also used together in the alternative plastics. See chapter 3.1.2.1.1 and (Graíño et al., 2018; Lestido-Cardama, de Quirós, et al., 2020; Lestido-Cardama, Sendón, et al., 2020; Murat et al., 2020; Zuri et al., 2022).

The presence of any of the other additives in focus of this study could not be confirmed.

3.1.2.1.3 Predicted volumes and comparison with forecasts

See chapter 3.1.1.1.3.

3.1.2.1.4 Change in substance concentrations found in humans

See chapter 3.1.1.1.4.

3.1.2.1.5 Conclusion

The presence of the phthalates could be confirmed in various alternative plastic products. Similar to the situation in PVC they have been typically used together. The presence of the phthalate has also been confirmed in PE and PP rich microplastic samples from Europe. Short-chain alternative non-restricted plasticisers have since become more popular, including the short chain DEP as confirmed by various studies.

3.1.2.2 Arsenic

3.1.2.2.1 Relevant products, concentration ranges and comparison with concentration limits

No products made of alternative plastic types (see chapter 3.2.1.2) still containing arsenic or arsenic compounds could be identified. One stakeholder mentions the use of diphenoxarsin-10-yl oxide as bactericide/fungicide in PUR, and other plastics (not specified which ones) (Reagens, 2023). (VinylPlus, 2023a) also mentions that arsenic compounds had some limited use in the past in PUR as well as use in plastics other than the 5 alternative plastics identified as part of this study, however, exact plastic materials are not stated nor are the concentration ranges given.

3.1.2.2.2 Presence of other legacy additives

No information on the presence of other legacy additives could be identified.

3.1.2.2.3 Predicted volumes and comparison with forecasts

See chapter 3.1.1.2.3.

3.1.2.2.4 Change in substance concentrations found in humans

See chapter 3.1.1.2.4

3.1.2.2.5 Conclusion

One stakeholder confirmed use of diphenoxarsin-10-yl oxide in PUR and other types of plastics. Concentration ranges are not given but it can be assumed they were the same as for PVC (<0.1% w/w), due to their high price (see also chapter 3.1.1.2.1). Data confirming the health risks for arsenic and arsenic compounds could not be identified.

3.1.2.3 Cadmium

Historically, cadmium compounds used as heat stabilisers were used not just in PVC but in also in other plastics, however, not in any of the identified alternative materials in the scope of this study. On the other hand, cadmium compounds used as pigments were also used in PE, PP, PE-X, PUR and other plastic materials. Same as in the case with PVC, voluntary phase out by industry started in 2001. Following three cadmium compounds are relevant:

- Cadmium sulphide (CAS 1306-23-6)
- Cadmium zinc sulfide yellow (CAS 8048-07-05)
- Cadmium sulfoselenide red (CAS 58339-34-7)

3.1.2.3.1 Relevant products, concentration ranges and comparison with concentration limits

No relevant data was identified on the presence of cadmium compounds in any of the identified alternative materials in the scope of this study.

Several stakeholders agreed that three cadmium compounds from the legacy list were used as pigments not just in PVC but also in PE, PP, PE-X, PUR (Anonymous stakeholder; Reagens, 2023; VinylPlus, 2023a). Cadmium dilaurate and cadmium stearate were not used in any of the identified alternative materials. Stakeholder also agree that both cadmium pigments and cadmium stabilisers are no longer used and are completely phased out (INEOS Inovyn, 2023; TEPPFA, 2023; VinylPlus, 2023a).

3.1.2.3.2 Presence of other legacy additives

No data could be identified on the combined use of cadmium compounds with other legacy additives from the list in any of the identified alternative materials.

3.1.2.3.3 Predicted volumes and comparison with forecasts

No data was found on the predicted volumes of cadmium compounds in any of the identified alternative materials. However, it can be assumed that same trends are expected as in the case with PVC (see chapter 3.1.1.3.3)

3.1.2.3.4 Change in substance concentrations found in humans

See chapter 3.1.1.3.4.

3.1.2.3.5 Conclusion

Several stakeholders confirmed that only three cadmium compounds from the list of legacy additives are relevant for identified alternative materials. Those are cadmium sulphide, cadmium zinc sulfide yellow and cadmium sulfoselenide red, all historically used as pigments. Since cadmium pigments and stabilisers are firmly bound into the polymer matrix, they are usually not released in the environment. However, releases may occur due to the loss of material, therefore, higher exposure is expected during the later stage of product's service life (Swedish Chemicals Agency, 2013).

3.1.2.4 Nickel

As nickel is mainly used in pigments (see chapter 3.1.1.4) it can also be present in other plastic types.

3.1.2.4.1 Relevant products, concentration ranges and comparison with concentration limits

Similarly, to the situation in PVC no products still containing nickel substances could be identified. One stakeholder mentioned that all 4 nickel pigments can also be used in any of the alternative plastic types (Reagens, 2023). However, another stakeholder production polyolefins stated that they have never used any of the additives in focus (INEOS Inovyn, 2023). The project team expects the use concentrations to be similar to those in PVC (below 30 mg/kg see chapter 3.1.1.4.1).

3.1.2.4.2 Presence of other legacy additives

No information on the presence of other additives could be identified.

3.1.2.4.3 Predicted volumes and comparison with forecasts

See chapter 3.1.1.4.3.

3.1.2.4.4 Change in substance concentrations found in humans

See chapter 3.1.1.4.4.

3.1.2.4.5 Conclusion

Nickel is only added to the alternative plastics in the form of pigments, typically in low concentrations, however, nickel only plays a small role as an additive in these plastics. Significant health concerns from the use of nickel pigments in PVC are not expected due to the low use concentrations and low bioavailability of the pigments.

3.1.2.5 Chromium

Chromium, like nickel, is mainly present in plastics due to its use as pigment. The colours typically range from yellow to red. From the additives list only one chromium additive is a pigment namely Barium Chromate (CAS 10294-40-3). Chromium trioxide has also been used as a catalyst for the production of plastics (PE and PP) and can as such be present in the final product. It was not used as an additive in the plastic itself (Reagens, 2023). The most common use of chromium is in the form of chromium trioxide, which is typically used for hard and decorative plating of products, including plastic parts. However, it is not used as an additive and in principle it is reduced to Cr(0) in the final application.

3.1.2.5.1 Relevant products, concentration ranges and comparison with concentration limits

No products still containing chromium were found. The use of chromium pigments was phased out around 2000 in Europe. For PE and PP chromium trioxide was only used as a catalyst in the production. Studies confirming the presence of chromium trioxide residues in PP and Pe could not be identified. All other stakeholders to not mention chromium in their answers, indicating a low relevance of this additive group.

The chromates in the excel list were mainly used in the leather industry (Reagens, 2023).

3.1.2.5.2 Presence of other legacy additives

See chapter 3.1.1.5.2.

3.1.2.5.3 Predicted volumes and comparison with forecasts

See chapter 3.1.1.5.3.

3.1.2.5.4 Change in substance concentrations found in humans

See chapter 3.1.1.5.4.

3.1.2.5.5 Conclusion

Chromium additives were used only as pigments and as such play only a minor role as additive. Additionally, chromium trioxide was used as a catalyst in the production of PE and PP.

As they are used as pigments, chromium additives can be present in a wide variety of applications. Significant human exposure from the use in PVC is not expected.

3.1.2.6 Short-chain chlorinated paraffins

Short-chain chlorinated paraffins (SCCP) were listed in Annex I of the POP Regulation in 19.06.2012. They have been used in PUR as flame retardant, however, this use has since been discontinued in the EU.

3.1.2.6.1 Relevant products, concentration ranges and comparison with concentration limits

(Anonymous stakeholder; VinylPlus, 2023a) both confirmed that SCCP were used in PUR as a flame retardant. No source confirming the use of SCCP in the other three alternative plastics in focus could be identified.

In a report by Ramboll (2021) plastics from small domestic appliances, end-of-life vehicles and construction waste were analysed for SCCP. SCCP were found in the PE/PP fractions from the small domestic appliances and ELV, however, in concentrations <20 mg/kg. Thus, all samples complied with the provisions of the POP Reregulation.

3.1.2.6.2 Presence of other legacy additives

While the presence of other plasticisers such as phthalates could be confirmed in PVC, no such data was found for the alternative plastics. However, as the alternative plastics are more flexible than PVC it is unlikely that phthalates will be present together with SCCP.

While not in focus of this study, the presence of flame retardants (decaBDE, TBBPA and DBDPE) in PE/PP recycling fractions could be confirmed by Ramboll (2021).

3.1.2.6.3 Predicted volumes and comparison with forecasts

See chapter 3.1.1.6.3.

3.1.2.6.4 Change in substance concentrations found in humans

See chapter 3.1.1.6.4.

3.1.2.6.5 Conclusion

SCCP were used as a flame retardant in PUR in Europe, however, this use has since been phased out. The presence of other plasticiser is less likely in the alternative plastics as these are not as rigid as PVC. SCCP only play a minor role in the alternative plastics.

3.1.2.7 Hexabromocyclododecane

Hexabromocyclododecane (HBCD) was used as a flame retardant in plastics. It was listed in the POP-Regulation on 22.03.2016.

3.1.2.7.1 Relevant products, concentration ranges and comparison with concentration limits

HBCD was mainly (>90%) used in EPS and XPS insulation for construction purposes and in HIPS for electric and electronic appliances, however, it was also used in all of the plastics in focus of this project, as confirmed by various stakeholders (Anonymous stakeholder; Reagens, 2023; VinylPlus, 2023a).

In a report by Ramboll (2021) PP pipes from construction waste were analysed for their HBCD content. A concentration of 89 mg/kg of HBCD was detected confirming the use of HBCD in PP pipes. The study also analysed shredded plastics from end-of-life vehicles as well as large and small domestic appliances. All concentrations were below 10 mg/kg (for more information see chapter 3.2.1.2).

3.1.2.7.2 Presence of other legacy additives

In the report of Ramboll (2021) SCCP were detected in many of the samples containing HBCD at concentrations below 50 mg/kg. While not in focus of this study, the presence of other flame retardants such as decaBDE, TBBPA and BTBPE was also confirmed for the mentioned products.

Furter information could not be identified for the alternative plastics in focus.

3.1.2.7.3 Predicted volumes and comparison with forecasts

See chapter 3.1.1.7.3.

3.1.2.7.4 Change in substance concentrations found in humans

See chapter 3.1.1.7.4.

3.1.2.7.5 Conclusion

HBCD was used in all alternative plastics according to the information from the stakeholders. Its main use was in EPS and XPS insulation in construction and in HIPS for electric and electronic appliances. The presence could be confirmed in PP pipes from construction waste, as well as in various shredder fractions from ELVs and electric appliances. Concentrations are all below the 1,000 ppm limit of the POP Regulation.

3.1.2.8 Organotin compounds

According to the stakeholder input from (Anonymous stakeholder; Reagens, 2023), all three organotin compounds from the list of legacy additives (Table 3) that are relevant for PVC were also used in PUR, with dibutyltin dilaurate also used in PE-X.

3.1.2.8.1 Relevant products, concentration ranges and comparison with concentration limits

The RAPEX database confirmed that certain products containing organotin compounds are still imported into the EU, however, in very low amount. The screening resulted in a total of 8 hits for organotin in different plastic materials, indicating there are some products not compliant with REACH, i.e., exceeding the concentration limit of 0.1%. Non-compliant products mostly include toys, and they are all coming from China. Even though in most cases only a reference to 'plastic material' is made, it can be assumed that some of the products were made from plastic material alternative to PVC falling under the scope of this project.

No other data could be found that confirms the presence of organotin compounds in any of the alternative materials that are under the scope of this project.

3.1.2.8.2 Presence of other legacy additives

While the presence of other plasticisers and metals used as stabilisers confirmed in PVC, no such data was found for the alternative plastics.

3.1.2.8.3 Predicted volumes and comparison with forecasts

According to (VinylPlus, 2023a), dibutyltin dilaurate is still produced by several producers for the use in the alternative materials.

For more information, see also chapter 3.1.1.8.3.

3.1.2.8.4 Change in substance concentrations found in humans

See chapter 3.1.1.8.4.

3.1.2.8.5 Conclusion

Only three organotin compounds were also used in alternative plastic materials, specifically in polyurethane and PE-X. No data other than RAPEX database could be found that confirms the presence of organotin compounds in any of the alternative materials. Data on current volumes is also very scarce.

3.2 Impacts of the legacy additives on the waste phase

In this chapter the influence of additives on the waste handling of PVC and the alternative plastics will be discussed. For the purposes of this study the waste handling ends with the recycled plastic material (typically the output of a recycling process in the form of flakes or pellets etc.).

The use of the recycled plastics (i.e., recompounding or similar) will be discussed in chapter3.3.

3.2.1 PVC

3.2.1.1 Current situation of waste PVC and the impacts of the regulatory measures

Generally, none of the legacy additives hinder the recycling of PVC from a technological standpoint. Rigid and flexible PVC can both be mechanically recycled regardless of the present additives (EPEA, 2023; EPPA, 2023; TEPPFA, 2023). During the mechanical recycling tin and lead stabilisers can react and colour the recycled PVC grey (EPPA, 2023; TEPPFA, 2023), however, this is seen as a non-issue for PVC profiles in Europe as these typically do not contain tin (EPPA, 2023).

The issues with the presence of legacy substances in PVC stems from the regulatory obligations. In general, SVHCs can be present in concentrations up to 0.1w%, before additional obligations apply. As many legacy additives are SVHC, manufacturers avoid having to use SVHC in their products and as such avoid using SVHC containing rPVC in concentrations >0.1w% (Anonymous stakeholder; VinylPlus, 2023a).

Several additives such as cadmium, arsenic, organotin and the phthalates are also restricted under REACH (see excel sheet for full list) and have specific concentration limits (typically 0.1w%) apply to them. Several of the heavy metals and phthalates are also restricted under RoHS also with concentration limits of 0.1w% (except for cadmium which has a limit of 0.01w%).

However, exemptions under REACH exist for cadmium. Cadmium can be used in concentrations up to 0.1w% in rigid rPVC (up from 0.01w% in virgin PVC), in order to not hinder the recycling. While not in focus of this study a similar issue occurred in the proposed restriction on lead additives in PVC (ECHA, 2018).

For most additives the regulatory limits in rPVC can be complied with. This is due to the fact that the PVC industry phased out the use of most of the legacy additives before or around the year 2000. Typically, there is a delay in the regulatory limits applying to the production of new products and the impact on the occurrence of the additives in the waste phase. This is due to the (long) lifetimes of products, which for example means that a window profile produced with cadmium in 1980 will become waste at the end of its lifetime roughly 30 years later e.g. in 2010. This can create issues with the recycling, as the cadmium concentrations in the recyclates can exceed the regulatory limits restricting the placing on the market. However, as most additives have been phased out over 20 years ago the regulatory limits can typically be complied with. This is especially the case for cadmium, chromium, organotin, arsenic and SCCP. If concentrations of the legacy additives in waste PVC are above the concentration limits the waste may be mixed with in-house pre-consumer waste PVC (basically legacy additive free) in order to lower the concentration of the legacy additive (EPPA, 2023).

This issue, however, still persists for the phthalates. Although they have been phased out in PVC flooring around 2000, they have only fallen under the authorisation requirement in 2013. As such their industrial relevant phase out only started roughly 10 years ago (EPEA, 2023).

A direct impact of the authorisation requirement of DEHP could be seen in the closing of the Vinyloop PVC recycling facility in Ferrara Italy. Following the authorisation requirement in 2015 the company applied for authorisation, as their PVC recycling process was not able to sufficiently remove DEHP form the recycled polymer. The authorisation was subsequently granted, however, after criticism from governmental and non-governmental organisations the authorisation was not renewed, and the plant closed in 2018. The plant employed 17 people and was able to produce 10.000 tonnes of recycled PVC per year (VinyLoop, 2018; Wagner, Schlummer, 2020). This example shows that the restriction of substances can also hinder a circular economy by preventing recycling in order to prevent keeping hazardous subsances in circulation.

The authorisation requirement and restriction of the phthalates also affects PVC flooring. As these have a long lifetime and phthalates have high use concentrations (up to ~40%) there are still many flexible PVC products entering the waste stream which have high phthalate concentrations, which hinder recycling. This issue can be seen in the following graph provided by (Anonymous stakeholder):

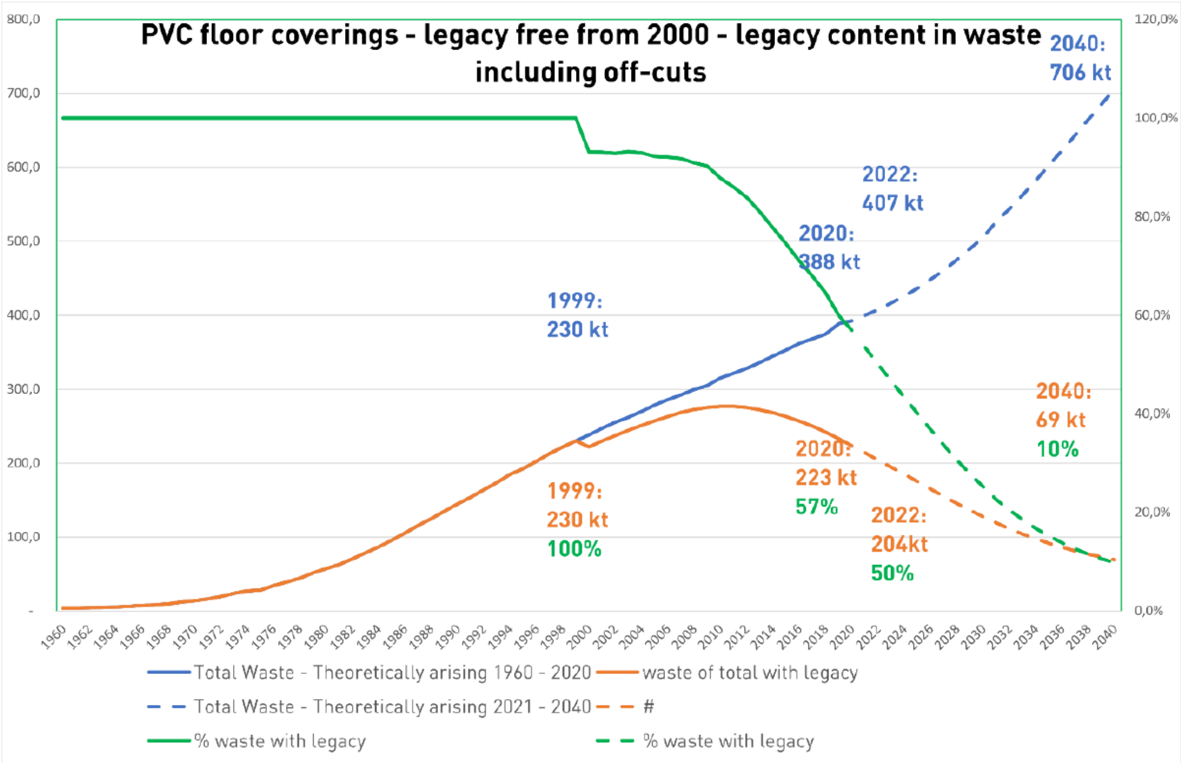

Figure 14: Predicted change in phthalate concentrations in PVC flooring entering the waste stage by (Anonymous stakeholder)

In this figure it can be seen that the phthalates were phased out in the year 2000 (green line), after which the percentage of flooring waste containing legacy phthalates decreases with time. At the same time the total amount of floor waste containing phthalates increases up to roughly 280 kt in 2012. In 2022 204 kt of phthalate containing floor waste was generated. Roughly 50% of the currently generated flooring waste contains legacy phthalates and 50% does not. Extraction of legacy phthalates (or additives) is currently not state of the art, however, several stakeholders are working on new technologies in order to identify, separate and extract legacy additives from PVC waste.

(Anonymous stakeholder) states that it is possible to separate flooring with legacy additives from flooring without legacy additives using commercially available NIR (near-infrared) sorting technologies. The stakeholder succeeded in gaining a stream of material with less than 0.2% of legacy plasticisers in the mix. The same technology is also used in Belgium for PVC waste arising from hospitals, which enables the separation of DEHP-containing PVC waste (VinylPlus, 2023a). Generally, as PVC is extensively used in the medical industry ranging from medical devices to drip chambers, blister packaging and IV-bags, it can be separately collected and recycled, which is extensively done in Australia by the Australian Vinyl Council (Joseph et al., 2021).
For the fraction containing legacy phthalates, dissolution technologies such as the CreaSolv® process have been applied in order to separate the PVC from its additives (Anonymous stakeholder). Typically, this fraction is, however, incinerated.

(INEOS Inovyn, 2023) has initiated a new project targeting the development of new advanced recycling technologies based on three technological routes: dissolution, pyrolysis, and gasification. The preliminary results of the dissolution project show promising results related to the extraction of legacy stabilizers and plasticisers and upscaling from lab to industrial scale is foreseen over the upcoming years. For this dissolution technology, the feedstock is requiring mono PVC applications streams, like window profiles, tubes, flooring, roofing, cables etc. In terms of pyrolysis technology, the company is working on a 2-step technology approach to dehydrochlorinate PVC in a first step and to pyrolyse the dechlorinated material in a second step. The pyrolysis technology allows to work with mixed PVC waste streams. The scope is to recover the chlorine to recycle it in the vinyl production chain and the carbon to produce pyrolysis oil which can be further converted into ethylene. The legacy additives are anticipated to be captured in the fly ash of this process. The stakeholder states that the advanced recycling industrial units should be operational by 2030 with a capacity of 40-60kt per year.

The issues with the recycling of PVC can also be seen in the published PVC recycling data from Vinyl Plus (see Figure 15).

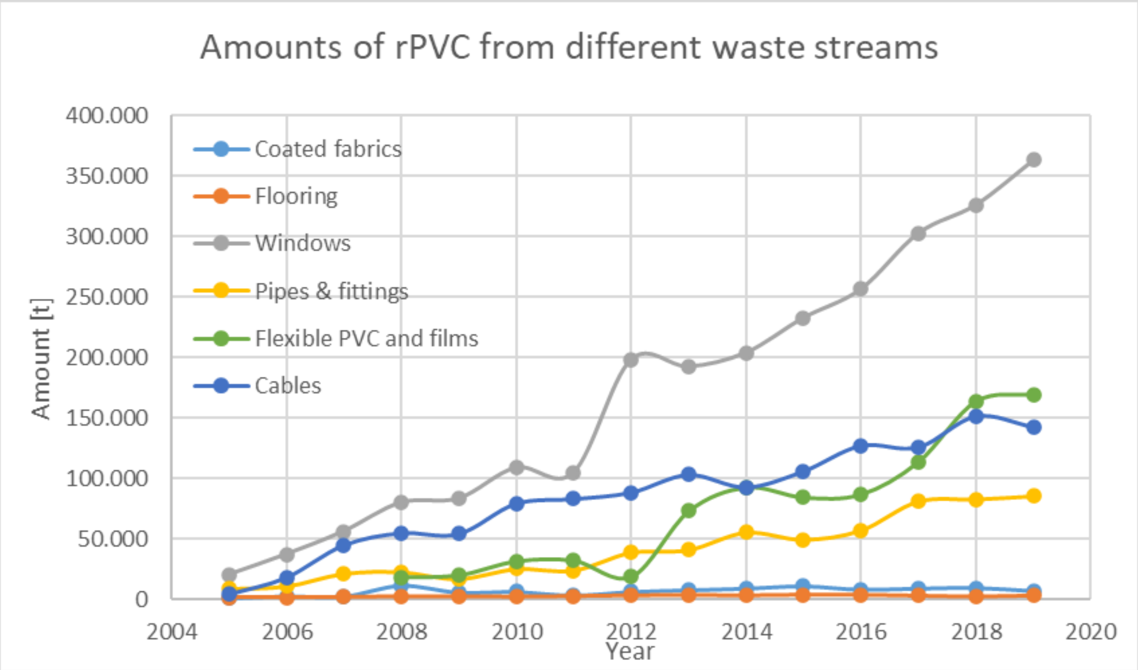

Figure 15: Amount of PVC recycled in Europe by usage (VinylPlus, 2023b).

By far the highest share of rPVC stems from the use in windows and other profiles, followed by flexible PVC & films and cables. PVC from pipes and fittings is also recycled in significant quantities. Flooring and coated fabrics play only a minor role as a source for recycled PVC.

Cables and flexible PVC and films are not as affected by the phthalate authorisation and restriction as these uses have much shorter lifetimes than floorings, for which the occurrence of phthalates in the waste is still an issue.

Apart from the regulatory restrictions, PVC, like other plastics, needs to be separated from the other plastic types in order to enable efficient and high quality mechanical recycling. For PVC this issue is however more important, as other plastics can typically be sorted out later in the recycling process. Typically, plastic fractions are separated via density separation during the recycling process where the lighter polymers such as PE, PP, PS and ABS float to the top and heavier polymers such as PVC or PE containing (brominated) flame retardants sink to the bottom. The heavy fraction is then typically sent to incineration, while the light fraction is further separated and recycled. As such the lighter polymers can still be recovered from mixed plastic waste, however PVC is typically sent to incineration if present in mixed waste. Thus it is important to separate PVC before it is mixed with other plastics. However, advanced sorting technologies for the heavy fraction are currently under development.

As windows are easily separated during demolition work and their composition is well known in the PVC industry, they are a high interest waste stream for recycling (EPPA, 2023). Similarly, cables and pipes can be easily separated and occur as a homogeneous waste stream, which enables efficient recycling.

This can also be seen in literature. For example, Ramboll (2021) analysed PVC pipes and cables from building and construction waste streams as separate samples, as these wastes are typically collected separately. In the case of WEEE (electronic waste) PVC is found in cables, which are also typically separated before the recycling process. As the main PVC fractions (mainly cables) are separated from the other mixed plastics and sent to a separate recycling process before shredding PVC is not a main fraction of the typical shredded plastic mixed obtained from WEEE (Stenvall et al., 2013).

Despite these issues the total amount of recycled PVC in Europe has been steadily increasing for the last 15 years (see Figure 16). However, up until 2020, Vinyplus provided in its yearly reports only the total amounts of recycled PVC which consider both pre-consumer and post-consumer waste. Thus it can only be assumed that the pre-consumer waste contributes more to the overall amount of recycled PVC with steady increases each year.

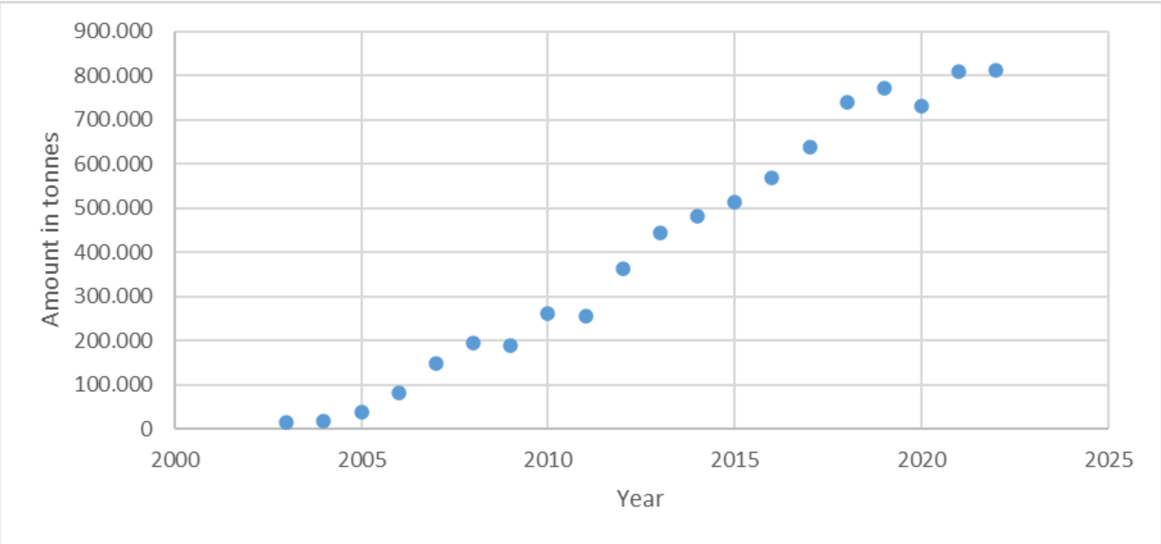

Figure 16: Amount of PVC recycled in Europe (VinylPlus, 2023b).

In total 813.266tonnes of PVC were recycled in Europe in 2022 (see excel sheet tab “Amount of recycled PVC”). While most of the recycled PVC from cables stems from post-consumer waste (~91%), most of the recycled PVC from flexible PVC (including films) and windows profiles is pre-consumer waste (~90% and ~58%, respectively). In general, most of the recycled PVC stems from pre-consumer PVC (~62%) while only ~38% stems from post-consumer waste. 495.749 tonnes of PVC were recycled from rigid and 317.517 tonnes from flexible PVC, indicating that overall plasticisers don’t necessarily hinder the recycling of PVC. When looking only at the flexible PVC in period of 2020-2022 (Table 2), it can be seen that the amounts of recycled PVC coming from pre-consumer waste are in general higher than the amounts coming from post-consumer PVC waste, except for year 2020 where the amount of recycled PVC coming from post-consumer waste was slightly higher than from pre-consumer waste. However, it should be kept in mind that the information provided is for years largely affected by COVID pandemic.

Table 2. Amounts of recycled flexible and rigid PVC for period 2020-2022 (VinylPlus, 2023b)

	2020	2021	2022
Flexible PVC			

	2020	2021	2022
Pre-consumer	145.597	235.485	201.837
Post-consumer	150.077	117.608	115.680
Total amount of flexible PVC	**295.674**	**353.093**	**317.517**
	Rigid PVC		
Pre-consumer	273.713	280.017	305.835
Post-consumer	162.074	177.665	189.914
Total amount of rigid PVC	**435.787**	**457.682**	**495.749**

Generally, if the PVC contains little contamination from additives, then mechanical recycling can still be performed multiple times before the plastics show signs of degradation (Lewandowski, Skórczewska, 2022).

3.2.1.2 Legacy additives in recycled PVC

Several stakeholders provided measurement data on the occurrence of the legacy additives in focus of this project.

Arsenic

Arsenic was measured by (Anonymous stakeholder) in recycled PVC. In total 42 samples were analysed including recycled PVC from 21 windows profiles, 10 rigid PVC construction samples (pipes, siding, roofing) and 11 samples from cables. Arsenic could not be detected via X-Ray Fluorescence in any of the samples (no LOD given in report, typical LOD for XRF between 10-500 mg/kg).

Cadmium

The content of cadmium has been regularly measured by recyclers in rPVC-U pellets of PVC window profiles over the course of 10 years (2012-2022). The results are given in Figure 17 (EPPA, 2023).

As seen in the figure the content of cadmium is mostly below the restriction limit of 0,1w% set by REACH with the first quarter of 2021 being the only exemption. According to the stakeholder input, the higher amount of post-consumer material in the recyclate leads to higher concentrations of cadmium in the recyclate (EPPA, 2023) (compare with the 66% of rPVC originating from windows stemming from pre consumer waste; see excel sheet “Amount of recycled PVC”). For comparison, when cadmium stabilizers were still used, concentrations of cadmium were around 1%, so the current concentrations are lower by a factor of >1.000. Obtained recyclate is then sent to converters who can mix it with in-house pre-consumer waste keeping the cadmium content in the final product below the threshold of 0,1w% in recycled PVC (EPPA, 2023).

The raw data for the graph in Figure 17 can be found in the excel table under “Cadmium rPVC EPPA 2023”. The stakeholder mentioned that they expect the cadmium concentration to rise in the coming years, due to more post-consumer waste being collected, recycled, and reused.

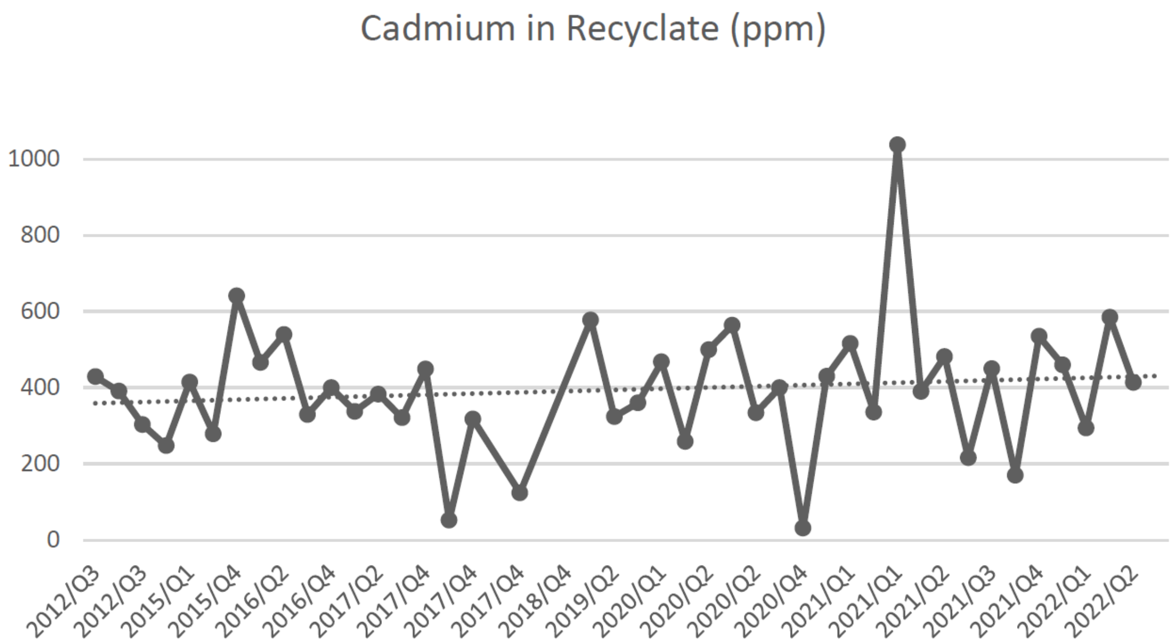

Figure 17. Content of cadmium in PVC windows recyclate measured by recyclers (2012-2022) (EPPA, 2023)

In addition to measurements in PVC recyclate, cadmium content is also measured by converters in the recycled part of PVC window profiles and measurements of the rPVC-U core are given for period 2017-2022 (see Figure 18). Again, the cadmium content is below the threshold of 0.1w% in recycled PVC.

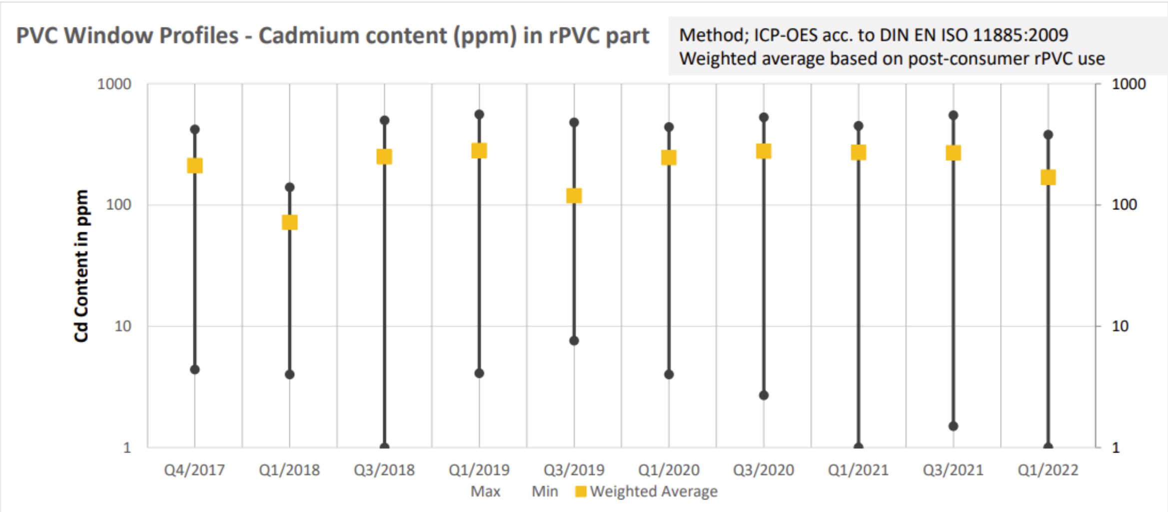

Figure 18. Cadmium content in rPVC part of window profiles measured by converters (2017-2022) (EPPA, 2023)

(Anonymous stakeholder) measured cadmium in recycled PVC. In total 42 samples were analysed including recycled PVC from 21 windows profiles, 10 rigid PVC construction samples (pipes, siding, roofing) and 11 samples from cables. Cadmium was detected in 25 of the 42 samples, with 15 of them coming from window profiles and 10 of them coming from other rigid PVC samples. Cadmium content in window profiles was always above 100 ppm with a maximum concentration of 630 ppm. In other rigid PVC samples, it was detected in lower concentrations, in the range from 47 to 53 ppm. All samples comply with the 0.1w% concentration limit of the REACH Regulation.

(VinylPlus, 2023a) also provided measurements of cadmium in window profiles waste and recyclate showing the status on the presence of cadmium in PVC. A total of 21 samples were taken in the period of 2012 – 2016. The average concentration of cadmium in recyclate is 220 ppm with a maximum concentration of 641 ppm. In all cases, the concentrations are below the restriction limit of 1000 ppm.

(TEPPFA, 2023) is also amongst the stakeholders that regularly measure cadmium, mainly focusing on the recyclate delivered to plastic pipe and fitting manufacturers. The measurements are done on the ad-hoc basis by both suppliers and by pipe producers. In 2022, 54 samples of commercially available recyclate were analysed. Analysis showed low concentration of cadmium with 0.00435w% on average in the range of 0.0011-0.031w%.

For total amounts of cadmium and a comparison with regulatory forecasts please see chapter 3.1.1.3.3.

Nickel

(Anonymous stakeholder) measured nickel in recycled PVC. In total 42 samples were analysed including recycled PVC from 21 windows profiles, 10 rigid PVC construction samples (pipes, siding, roofing) and 11 samples from cables. Nickel was below the LOD in all samples (30 ppm). As such all samples comply with the REACH Regulation.

Chromium

(Anonymous stakeholder) measured chromium in recycled PVC. In total 42 samples were analysed including recycled PVC from 21 windows profiles, 10 rigid PVC construction samples (pipes, siding, roofing) and 11 samples from cables. Chromium was detected in 25 of the 42 samples, mainly in the rigid PVC samples (detected in each rigid rPVC sample). Except for three samples all concentrations were below 100 ppm. A maximum concentration of 420 ppm was reported in a window profile sample. All samples comply with the 0.1% concentration limit of the REACH Regulation.

For total amounts of chromium and a comparison with regulatory forecasts please see chapter 3.1.1.4.3.

Short-chain chlorinated paraffins

In a report by Ramboll (2021) several PVC products were analysed as to their SCCP and MCCP content. Samples included flooring, pipes, and cables. SCCP were detected in every sample, however, all concentrations were all below 50 mg/kg and as such compliant with the POP-Regulation.

Organotin compounds

On the presence of tin in PVC, one representative of the flooring manufacturing stated tin is present in concentrations lower than 0.007% in end-of-life products, mainly in PVC floor covering older than 20 years. The stated concentration complies with the 0.1w% concentration limit of the REACH Regulation (Anonymous stakeholder).

(Anonymous stakeholder) measured tin in recycled PVC. In total 42 samples were analysed including recycled PVC from 21 windows profiles, 10 rigid PVC construction samples (pipes, siding, roofing) and 11 samples from cables. Tin was detected in 22 of the 42 samples, mainly in the rigid PVC samples and cables (detected in each cable and rigid rPVC sample). Tin was identified in only one sample from window profiles with a concentration of ~170 ppm. In rigid samples the concentration was in the range of 140 to 150 ppm and in the cable samples in the range of 30 – 60 ppm. All samples comply with the 0.1% concentration limit of the REACH Regulation.

In 2022, (TEPPFA, 2023) measured Pb, Cd and Sn in 54 samples of commercially available recyclate. The PVC recyclate was a mixture of pipe and window profile waste. Analysis showed concentration of tin with 0.00227w% on average in the range of 0.01-0.079w%. Again, all samples comply with the 0.1% concentration limit of the REACH Regulation for dibutyltin and dioctyltin compounds.

For total amounts of tin and a comparison with regulatory forecasts please see chapter 3.1.1.8.3.

3.2.2 Alternative plastics

As many additives are not relevant for the alternative plastics on focus, not much information could be identified.

In general, all plastics (including PVC) need to be separated from one another for recycling. This is why PVC windows and PET bottles have high recycling rates, as these waste streams are collected separately and do contain other materials only to a certain extent.

The biggest issue for the current polyolefin recycling is the presence of flame retardants especially in the automotive and electric and electronic sectors. While PE and PP are not the main polymers in WEEE and ELV they are still a target for recycling (Stenvall et al., 2013). In general, PE and PP are the two most recycled polymers.

The plastic waste from these two waste streams is typically shredded before it is further separated into the respective plastic types via physical or spectroscopic separation techniques. During this process flame retardants can be separated via density separation. As the halogenated flame retardants are heavier than the plastics, they increase the density and sink to the bottom, while the flame retardant free plastic swim on the top (Ramboll, 2021). PVC also typically falls to the bottom and is then sent to incineration (see chapter 3.2.1.1 for more information).

From the list of legacy additives only HBCD falls in this category. Ramboll (2021) was able to demonstrate that HBCD (and other halogenated flame retardants) can efficiently be separated in modern recycling facilities. In PP pipes HBCD was detected in a concentration of 89 mg/kg, which is far below the limit of 1.000 mg/kg of the POP-Regulation (500 mg/kg proposed by the Commission but not yet implemented).

Low concentrations of SCCP <20 mg/kg were found in the PE/PP shredder fraction of waste stemming from small domestic appliances and ELV. The measured concentrations are also below the limit of the POP-Regulation 10.000 mg/kg (1.500 mg/kg proposed by the Commission but not yet implemented).

Recently, chemical recycling has also been applied to the alternative plastics. The aim is to break the plastics down into smaller molecules, typically their monomers. This is the case for polyester and polyamides, which can be broken into their monomers via hydrolysis. As PE and PP (and PS) so not contain function groups in their backbone, hydrolysis cannot be applied. In this case pyrolysis can be applied, which breaks the molecules into small compounds via heat and a lack of oxygen. The products are various fractions of low and high boiling hydrocarbons which then need to be separated further before they can be used in the synthesis of new materials. The presence of halogens can however potentially lead to the formation of halogenated hydrocarbons and acids which are often hazardous compounds. Charitopoulou et al. (2022) for example found that the presence of tetrabromobisphenol A, a brominated flame retardant, leads to the formation of more phenolic compounds when compared to the absence of a halogenated flame retardant. They were also able to detect large amounts of brominated phenol compounds such as mono- and dibromophenol as well as other brominated compounds such as 1,54-dibromo-tetrapentacontane, indicating that the presence of halogens can lead to different products after pyrolysis.

PE and PP from other sources such as packaging and food contact material are not expected to contain any of the legacy substances in the excel list.

Specific information on the recycling of PUR could not be identified.

Generally, it is expected that the major issues arise from the regulatory obligation concerning the legacy additives, similar to the situation of PVC.

3.3 Use of recyclates

3.3.1 PVC

If the concentration of the restricted additives is below the regulatory limits, then the recycled PVC can be reused.

Stakeholders indicated that rPVC can be used in multiple different applications. Generally, PVC can be reused in the same application again. I.e., PVC from pipes can be reused in pipes and PVC from floors can be reused in floors etc., however, the use in other (lower quality) applications is also possible (Anonymous stakeholder; EPEA, 2023; Facon Srl, 2023; TEPPFA, 2023; VinylPlus, 2023a). The addition of new additives to rPVC is generally not necessary (Anonymous stakeholder; VinylPlus, 2023a).

In general, the use depends on the requirements of the new application and the quality of the recyclate. E.g. the use of rPVC from windows in new window profiles is state of the art. Similarly, rPVC from pipes can easily be reused in pipes (Anonymous stakeholder; EPPA, 2023; TEPPFA, 2023). For these applications it is typical that the rPVC is used in a sandwich structure on the inside of the product and virgin PVC on the outside (EPEA, 2023; Lewandowski, Skórczewska, 2022).

However, generally speaking PVC recycling is characterised by an open-loop recycling process. This means that recycled PVC from one application is also used in other applications. For example, rigid recycled PVC from construction applications (e.g., windows, pipes) can be reused in any other uPVC application in the construction sector (Anonymous stakeholder; EPPA, 2023). Especially rPVC from window profiles has a high quality due to the homogeneity of the waste stream (EPPA, 2023).

(TEPPFA, 2023) provided data on the origin of rPVC used by their members (presumably for the pipe production; not stated in report). In their report the members reported, that ~52k tonnes of rPVC were used, 4.4% of which came from pipes, 1.4% from profiles and 94.1% from mixed pipes/profiles/other (such as bottles, sheets, credit cards).

In contrast, the reuse of plasticised PVC from cables in new cables is typically not possible due to the performance requirements of this application (VinylPlus, 2023a). rPVC from flexible sources is thus typically used in uses with lower requirements such as shoe soles and road furniture (Anonymous stakeholder; VinylPlus, 2023a). Other uses include for example, traffic cones and garden hoses (Joseph et al., 2021).For flooring containing recycled PVC it is common practice to apply a coating on the flooring e.g., in order to prevent migration (EPEA, 2023).

It should be kept in mind that the new lead restriction in PVC will change the landscape of the PVC recycling, as the restriction requires the “closed-loop” recycling of rigid PVC. The new restriction proposal provides a derogation from the general concentration limit of 0.1w% of 1.5w% for several rigid PVC applications in the construction sector and also states that only PVC recovered from those applications can be used for them (EU COM, 2022). This will limit the use of rPVC containing lead after the restriction comes into force (~2026), even though the use of recycled uPVC is possible also outside the construction sector.

As seen with the phthalates, the effects of a restriction on the waste handling often have a delay due to the (long) lifetimes of the products containing the restricted additives/substances. For example, cadmium was phased out in the EU-15 around 2000 (see chapter 3.1.1.3), however as can be seen in Figure 17 and Figure 18 the amount of cadmium since 2012 is already below the regulatory concentration limit of 1000ppm. This indicates that after a timeframe of ~10-15 years the concentrations of the restricted substance in waste can be well below the regulatory concentration limit, even in the case of cadmium in window frames, which typically have a lifetime of up to 30 years. While the exact implications of the lead restriction cannot be determined in this project, a similar or slightly longer timeframe of the phase out can be assumed for PVC products containing lead. Considering that lead was phased out in windows in 2004 (EPPA, 2023) and fully in 2015 (VinylPlus, 2023a), this point in time might already be reached before 2030. However, as lead was typically used in twice the concentration of cadmium (lead typically 2% and cadmium typically 1%) (EPPA, 2023), the phase out might take longer than in the case of cadmium. The requirements of the PVC restriction (closed-loop) will also only be relevant as long as the lead concentrations in waste PVC are above the concentration limit of 0.1w%.

If concentrations of lead in waste PVC are above the concentration limits the waste may be mixed with in-house pre-consumer waste PVC (basically legacy additive free) in order to lower the lead concentration (EPPA, 2023).

A norm for the “controlled recycling” of PVC for window profiles and door is already established (EN 17410:2021) (EPPA, 2023; TEPPFA, 2023).

In conclusion it can be said that rPVC can be used in a wide variety of uses, especially rigid PVC. Flexible PVC is usually used in application with lower requirements. The main barriers for the use of rPVC stem from the regulatory provisions, in particular the proposed restriction for lead in PVC.

3.3.2 Alternative plastics

Similar to PVC, EU legislation restricts the use of recycled plastics, especially in food contact material (see Regulation 2022/1616). As such recycled plastics are typically used in non-food applications such as in construction, agriculture, non-food packaging etc.(PlasticsEurope, 2023). In order to reuse a recycled plastic as food contact material, the recycling process needs to be approved by EFSA.

The open loop situation of the alternative plastics (especially PE and PP) can also be seen in the submission of TEPPFA. The association asked their members from which sources their recycled PE/PP comes from and how much they used (presumably to be used in pipes). The members responded that in total they used 198.932 tonnes in 2021, 0.5% of which comes from other pipes, 8.3% from bottles, 25% from other packaging and 66.2% from other sources.

Plastics Europe also published data every year on the plastic industry in Europe. Their report shows that PE and PP are used in packaging, building and construction, automotive, electronics, agricultural and household goods, indicating that they have a wide variety of uses. PUR is mainly used in building and construction, automotive and electronic applications. For PUR the category “others” is also a main use of PUR, however, no further information on the exact uses is presented (PlasticsEurope, 2022).

Furthermore, the report shows how much recycled plastic is used in the individual sectors. The agriculture, farming and gardening sector has the highest share with 25.4% of all plastics used in new products being recycled plastics, followed by the building and construction sector with 18.1% and the packaging sector with 8.5% (PlasticsEurope, 2022). The report indicates that recycled plastics are used in all sectors, indicating that once recycled the plastics find a wide variety of uses.

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5. Appendix 1

"REACH restriction support – Investigation report on PVC and PVC additives (part 2)"

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Thank you for your participation in this research project.

On behalf of the European Commission, **the European Chemical Agency (ECHA)** is collecting information on the potential risk to human health and the environment posed by PVC additives and PVC itself, the socioeconomic impact of a possible restriction and the need for European Union-wide action.

More specifically, it was requested that attention is paid to address some of the gaps identified by ECHA in the recent report "The use of PVC (poly vinyl chloride) in the context of a non-toxic environment: final report" (EC 2022).

The information gaps in focus of the present information collection are particularly related to the presence and influence of certain legacy additives in PVC and PVC-alternatives:

1) the presence and concentration of those additives in (waste) PVC and PVC recyclate
2) the presence and concentration of those additives in alternative plastics to PVC. Relevant to this are the following 4 polymers
    a. **Polypropylene (PP)**
    b. **Polyethylene (PE)**
    c. **Cross-linked polyethylene (XLPE, PE-X)**
    d. **Polyurethane (PUR)**
3) the relevance of the legacy additives for the recycling of PVC and the relevant alternative materials: both from the point of view of hindering/not hindering the recycling and hindering/not hindering the use of the recycled PVC in certain applications
4) exposure data from service-life releases, waste stage streams, and human biomonitoring data (on workers and general population)

Ramboll, as a contractor is supporting ECHA in this project and therefore has prepared some questions in order to close these gaps from the recent report.

If some questions are not relevant to you, please feel free to skip them.

A list with all relevant additives can be found on the bottom of this document (see table 3).

We would appreciate if you could share any data and information to improve the current data situation. We would ask that you preferably send non-confidential information, however, if you provide relevant confidential information, please mark it accordingly so it can be treated as such.

If you would like to send us additional information or documents, please feel free to send an e-mail to Benjamin Schramm and Klaudija Obajdin: benjamin.schramm@ramboll.com, klaudija.obajdin@ramboll.com

If you have any further questions, please do not hesitate to contact us.

Questionnaire

First and last name:	
Position:	
Organisation:	
E-mail address or telephone number:	
Agrees on publishing the name of the organization	☐Yes, I agree with the publication of the organisation's name in publicly available documents. ☐No, all information provided should be anonymised.

Questions related to the presence of legacy additives in selected polymers.	
Substances that are considered as legacy additives and are in the focus of this study can be found in table 3. **These questions are relevant for all mentioned materials (PVC, PP, PE, PE-X and PUR)** unless stated otherwise.	
1	**Do you measure the presence/concentration levels of the relevant additives in PVC (or in any of the selected alternative materials)? If yes, could you please specify which additives you measure and in which of the relevant materials?** **We are also grateful for any publication that you know of, measuring the presence of the relevant additives in PVC (or in any of the selected alternative materials).**
	Answer:
2	**In which of the product(s) life stage does the measurement take place? During the service-life, end-of-life or in the recycled material etc.?**
	Answer:
3	**Could you provide concentrations or a concentration range in which the additive(s) is/are present in the product(s)?**
	Answer:
4	**Could you specify in which type of product(s) the additive(s) is/are present? Are the use profiles different depending on the application? Are/were certain additives typically used together?**
	Answer:

5	**Do you have any information on the currently remaining EU volumes of the relevant additives still on the market as well as in recycled PVC (and in the selected alternative materials)? An estimation or educated guess is also of use.**
	Answer:
6	**Could you specify for which product(s) made of PVC (or any of the selected alternative materials) the presence of the relevant additive(s) prevents recycling? What are typical concentration limits where this happens and are the limits different depending on the additive?**
	Answer:
7	**Could you specify whether recycled PVC from certain products is used in the same products again? E.g., PVC from old window frames is recycled and then used in the manufacturing of new window frames.** **Or can the recycled PVC be used in other applications (please specify)? Are there products in which recycled PVC cannot be used?**
	Answer:
8	**Do you have any information regarding human exposure to the relevant additives from the service life and/or waste stage of PVC products (or of products made from any of the selected alternatives)?** **Recent human biomonitoring data regarding the relevant additives is also of use.**
	Answer:
9	**Please feel free to share any additional documents/information that you find relevant for the purpose of this request.**
	Answer:

Thank you for your support.

Table 3. A list of substances that are considered as legacy additives in PVC

EC/List No.	CAS No.	Public name	Substance group
605-040-8	15606-95-8	Triethyl arsenate	Arsenic compounds
231-148-6	7440-38-2	Arsenic	
215-116-9	1303-28-2	Diarsenic pentaoxide	
215-481-4	1327-53-3	Diarsenic trioxide	
200-377-3	58-36-6	Diphenoxarsin-10-yl oxide	
231-901-9	7778-39-4	Arsenic acid	
427-700-2	15606-95-8	Triethyl arsenate	
939-379-0		Reaction mass of melamine and Nickel, 5,5'-azobis-2,4,6(1H,3H,5H)-pyrimidinetrione complexes (alternative name: "C.I. Pigment Yellow 150")	
215-147-8	1306-23-6	Cadmium sulphide	Cadmium compounds
232-466-8	8048-07-5	Cadmium zinc sulfide yellow	
261-218-1	58339-34-7	Cadmium sulfoselenide red	
310-077-5	102184-95-2	Silicic acid, zirconium salt, cadmium pigment-encapsulated	
220-017-9	2605-44-9	Cadmium dilaurate	
218-743-6	2223-93-0	Cadmium distearate	
287-476-5	85535-84-8	Alkanes, C10-13 Chloro	Chlorinated paraffins
215-607-8	1333-82-0	Chromium trioxide	Chromium (VI) compounds
231-906-6	7778-50-9	Potassium dichromate	
232-143-1	7789-09-5	Ammonium dichromate	
234-190-3	10588-01-9	Sodium dichromate	
232-140-5	7789-00-6	Potassium chromate	
232-142-6	7789-06-2	Strontium chromate	
246-356-2	24613-89-6	Dichromium tris(chromate)	
231-801-5	7738-94-5	Chromic acid	
231-889-5	7775-11-3	Sodium chromate	
233-660-5	10294-40-3	Barium chromate	
234-329-8	11103-86-9	Potassium zinc chromate hydroxide	
236-881-5	13530-68-2	Dichromic acid	
603-802-4	134237-51-7	(1R,2R,5R,6S,9R,10S)-1,2,5,6,9,10-hexabromocyclododecane	Hexabromo-cyclododecane (HBCD)

EC/List No.	CAS No.	Public name	Substance group
603-804-5	134237-52-8	(1R,2R,5R,6S,9S,10R)-1,2,5,6,9,10-hexabromocyclododecane	
221-695-9	3194-55-6	1,2,5,6,9,10 - hexabromocyclododecane	
247-148-4	25637-99-4	1,2,5,6,9,10 - hexabromocyclododecane	
239-594-3	15546-11-9	Methyl (Z,Z)-8,8-dibutyl-3,6,10-trioxo-2,7,9-trioxa-8-stannatrideca-4,11-dien-13-oate	Organotin compounds
201-039-8	77-58-7	Dibutyltin dilaurate	
221-218-4	3033-29-2	Dihydro-2,2-dioctyl-6H-1,3,2-oxathiastannin-6-one	
232-353-3	8007-18-9	Antimony nickel titanium oxide yellow	Nickel compounds
275-738-1	71631-15-7	Nickel iron chromite black spinel	
255-965-2	42844-93-9	Pigment Orange 68	