Summary

16 June 2023

VinylPlus' contribution to the ECHA Investigation Report on PVC and its Additives

Executive Summary

The Commission (DG GROW and ENV) mandated ECHA to conduct a comprehensive investigation on the use, exposure, life cycle, and waste management of PVC and its additives. The investigation report aims to gather scientific evidence to assess potential risks to health and the environment from PVC and its additives and whether further regulatory measures beyond those already in place are needed.

As part of the process, ECHA opened three calls for evidence on PVC and its additives and potential alternatives. ECHA collected information on a subset of 63 additives used as heat stabilisers, plasticisers, and flame retardants in PVC, alternative plastics to PVC, and additives used in alternative plastics to PVC. ECHA also tasked Ramboll with parts of the investigative work, and Ramboll conducted two surveys on alternatives to PVC and the socioeconomic impacts of potential replacement of PVC as well as the presence and influence of certain legacy additives in PVC and PVC alternatives.

VinylPlus, the European PVC industry's commitment to sustainable development, which brings together the full value chain, engaged in the ECHA investigation on PVC and its additives proactively and constructively. Throughout the multiple calls for evidence and questionnaires, VinylPlus has provided accurate, updated, and comprehensive information on PVC additives, their alternatives, and potential impacts, submitting over 1800 pages of evidence.

VinylPlus has not only corrected inaccuracies in the initial lists of additives but also submitted extensive data on volumes, uses, migration, and exposure of additives and information on alternative plastics and their additives.

Based on the data collected and submitted to ECHA, VinylPlus draws several conclusions:

- The input submitted by VinylPlus does not show an EU-wide risk that would require further regulatory action; the extensive data on PVC and its additives, as well as the significant progress made in moving to safe additives, supports the overall safe use and increasing sustainability of PVC and its additives.
- Should a concern be demonstrated, the PVC industry has proven that it is willing to tackle issues: VinylPlus proactively substituted lead in PVC ahead of EU regulation. In fact, over the past 30 years, the industry transitioned from SVHC Low Molecular Weight (LMW) phthalates to High Molecular Weight (HMW) phthalates and other plasticisers and shifted away from cadmium and lead-based stabilisers towards calcium-zinc stabilisers.
- PVC is safe:
    - The production of PVC is tightly regulated in the EU, and the PVC production industry, represented by ECVM (European Council of Vinyl Manufacturers), has adopted a voluntary charter that specifically addresses the prevention of dioxin generation during PVC production and waste management practices.
    - Plasticisers do not readily migrate from PVC: they are tightly bound within the PVC polymer.
- PVC is increasingly sustainable and circular:
    - PVC is intrinsically low-carbon: PVC is composed of 57% chlorine and 43% carbon, the latter being primarily derived from oil or gas through the production of ethylene. Due to its substantial chlorine content, PVC production utilises fewer fossil resources compared to other plastics like PE, PP, PET, and PS, which are entirely dependent on oil or gas.
    - PVC has the longest recycling history: It is estimated that 35% of PVC waste produced yearly is recycled. In the Recovinyl system, which brings together 150 recyclers, the audited figure is 27% of PVC waste recycled.
- PVC plays a vital role in European society:
    - The total PVC production and conversion industry comprises over 21,000 companies, providing employment to more than 500,000 people and generating a turnover exceeding 80 billion euros.
    - PVC is the third largest-selling commodity plastic globally and is mainly used in long-term applications. Its unique characteristics, including product and processing versatility, mechanical strength, exceptional durability, recyclability, and cost-effectiveness, make it the preferred material for numerous applications in sectors such as healthcare, IT, transportation, textiles, and, notably, construction, which represents the most prominent application area.

1. ECHA's First Call for Evidence on PVC and Its Additives

June 2022 - September 2022
Objective: Verify the list of additives used in PVC

ECHA shared a list of about 500 additives used in PVC and asked for its verification. ECHA also organised a follow-up meeting with the contributors to the first call for evidence and on the additives list to explain the process, related timelines and the subsequent calls for evidence.

Key points of VinylPlus' submission:

- VinylPlus submitted to ECHA an updated additives database, adding 150 substances to the list and removing about 100 substances that are not used in PVC or are not commercially available.
- In addition to the updated list, VinylPlus also shared an explanatory note with ECHA regarding the questions the Agency raised during the stakeholder meeting. Some of the main points are:
    - Plasticisers will not migrate from flexible PVC unless there is a thermodynamic driver. Such a driver may be high temperatures or contact between the flexible PVC article and another material (e.g., a food contact). Minimal migration has been observed for permitted food contact uses in aqueous or acidic foods, as indicated by the data sent to ECHA. This data is also relevant to situations where PVC articles and waste may come into contact with soil and aqueous media, and it supports the notion of minimal migration into such media.
    - Plasticisers are not ionically or covalently bonded in PVC but rather tightly bound within the PVC polymer matrix through dipole-dipole interactions, which can be measured. Without these interactions, plasticisers would exude from the polymer matrix, as would be the case if plasticisers were used with polyethylene (e.g., LDPE), which is not the case. Therefore, the PLASI model (which uses LDPE as the matrix) is not appropriate for estimating the release of plasticisers from PVC. Instead, other more suitable models (e.g., FABES/Fraunhofer) should be used, along with factual data.
    - Significant plasticiser release requires high temperatures. Some cable specifications require a maximum mass loss of only 1.5 mg/mm2 after exposure to 100°C for seven days, while more advanced specifications require the same at 140°C. These specifications are designed to simulate lifetime use. It is widely known that old cables in buildings and houses do not become more rigid due to plasticiser loss; they continue to function and remain flexible for over 40 years.

2. ECHA's Second Call for Evidence on PVC and Its Additives

November 2022 – January 2023
Objective: gather information on uses, use volumes, life-cycle steps for the 63 additives prioritised by ECHA, and for PVC itself; recycling rates, landfilling and incineration per use

- **ECHA sought detailed and extensive data on volumes and uses of plasticisers, stabilisers and flame retardants** – for the 63 substances prioritised. For PVC resin, the volumes are requested for 87 different specific end uses (by 9 sectors and 15 subsectors).
- **The 63 substances include:**
    - **Heat stabilisers – 21 in total**: 10 organotin compounds/ 7 phosphite derivatives / 2 diones / 1 barium salt / 1 amine
    - **Plasticisers – 30 in total**: 20 ortho-phthalates / 5 trimellitates including TOTM (also known as DEHTM) /2 benzoate co-plasticisers / 1 phosphate / 1 chloro paraffins hydrocarbons / 1 terephthalate (DOTP)
    - **Flame retardants** – 12 in total – 7 organophosphates / 1 brominated phthalate / 2 borates / 1 antimony compound (Di-antimony trioxide) / 1 boron/zinc compound

- **End-of-life volumes for PVC were also requested** –for the 9 sectors/15 subsectors and 87 specific end uses, for amounts being recycled, landfilled, and incinerated.

Key points of VinylPlus' submission:

- In its submission, **VinylPlus shared market and competition-sensitive information with ECHA** for its review. In this summary, we include the key highlights of the main sections without the business confidential information.
- **VinylPlus and key information on the EU PVC industry**
  - In Western Europe, the total PVC production and conversion industry comprises over 21,000 companies, providing employment to more than 500,000 people and generating a turnover exceeding 80 billion euros.
  - PVC is composed of 57% chlorine and 43% carbon, with the carbon primarily derived from oil or gas through the production of ethylene. Due to its substantial chlorine content, PVC production utilises fewer fossil resources compared to other plastics like PE, PP, PET, and PS, which are entirely dependent on oil or gas.
  - Currently, PVC ranks as the third largest-selling commodity plastic globally, following polyethylene and polypropylene. Its unique characteristics, including product and processing versatility, mechanical strength, exceptional durability, recyclability, and cost-effectiveness, make it the preferred material for numerous applications in sectors such as healthcare, IT, transportation, textiles, and, notably, construction, which represents the largest application area.
  - VinylPlus submitted comprehensive details regarding the manufacturing processes of vinyl chloride and PVC, emphasising the significant EU regulations and BREF (Best Available Techniques Reference) documents that govern their production, ensuring their safety and sustainability. Furthermore, the PVC production industry, represented by ECVM (European Council of Vinyl Manufacturers), has adopted a voluntary charter that specifically addresses the prevention of dioxin generation during PVC production and waste management practices. This charter underscores the industry's commitment to minimising any potential environmental impact associated with the production and disposal of PVC.
- **Sales volumes of PVC by applications in the EU 27 + UK + Norway + Switzerland**
  - VinylPlus submission provided information on the sales volumes of PVC resin in the EU 27, UK and Norway by major application. The information has been gathered and compiled by the European Council of Vinyl Manufacturers (ECVM) in strict compliance with competition rules.
    - The specific tonnages are considered Confidential Business Information (CBI) and are not publicly disclosed.
    - The data confirms that approximately 60% of PVC is used in rigid applications, while the remaining 40% is used in flexible applications.
    - A significant proportion, around 70%, is used in critical building and construction applications.
    - Volumes going to sensitive applications, including food contact, medical applications, toys, and childcare articles, are relatively low.
      - In these uses, e.g., in PVC film trays used for food or pharmaceutical packaging, PVC is used only in small quantities to fulfil crucial functions without including plasticisers and follows very stringent EU regulations for food contact materials.
      - The use of pipes for drinking water is also a sensitive end-use, and PVC pipes (like all materials for pipes for drinking water) are subject to rigorous tests for safety and hygiene performance.
- **Volumes of waste and end-of-life (re: recycling/incineration with energy recovery/landfilling). Origin of waste and outlets for recycling:**
  - VinylPlus shared all the available data with ECHA. This data was compiled by Recovinyl and Conversio on the PVC recyclate volumes, origins, and uses, and also provided information on total PVC waste, incineration with energy recovery and landfill.
- **Volumes and uses of additives**
  - **Stabilisers**
    - A relatively low volume of stabilisers is required to achieve stabilisation during the thermal processing of PVC and its additives.
    - Consistent with the replacement of cadmium and lead stabilisers between 2000 and 2015 in the EU, the major stabilisers in use today are low toxicity Calcium Organic Stabilisers (Ca/Zn OBS), representing 83% of Stabiliser use.
  - **Plasticisers**

- The primary commonly used general-purpose plasticisers today are DINP, DIDP, DPHP, DOTP, and DINCH. These plasticisers make up approximately 70% of the total plasticisers utilised and have undergone extensive testing and evaluation by EU regulators for many years. Based on this comprehensive testing and evaluation, none of these substances has been found to require classification for health or environmental hazards, nor do they pose any risks to human health in their current uses. However, it is important to note that DINP and DIDP are restricted in toys and childcare articles.
- These substances have largely replaced the low molecular weight (LMW) phthalates, including DEHP, DBP, BBP, DIBP, and around 11 other LMW phthalates, which have been identified as Substances of Very High Concern (SVHCs) under the REACH regulation. Achieving this transition has required substantial investment of over 6 billion Euros and more than 25 years of effort, considering the large volumes involved in the plasticiser market. Given the numerous substances and diverse applications, it is not feasible to provide detailed data for all uses. However, broader information on their usage was provided to ECHA.

- **Flame retardants**
  - PVC itself brings important flame-retardant properties. Some applications need additional flame retardants (e.g., high-temperature cables), as is also the case for other polymers.

- **Migration and exposure data for additives**
  - Stabilisers: Regarding additives' migration and exposure data, VinylPlus submission enclosed reports on the migration of organotin compounds from PVC and the assessment of potential restrictions on organotin compounds. It also added information on tin salts, explaining that they have been extensively assessed, and certain restrictions have been imposed based on identified risks. In contrast, the safe use of other tin compounds has been demonstrated.
  - Plasticisers: Several data gaps were identified in the Ramboll (2022) report, and the submission explained in detail why there is no migration from flexible PVC by referring to peer-reviewed articles.

3. *Ramboll's First Questionnaire*

2 December –14 December 2022
Objective: Identify potential alternatives to PVC and the socioeconomic impacts of potential replacement of PVC.

Here, VinylPlus highlighted the **performance and cost/benefits of PVC compared to potential alternatives**, as well as **safety, health, environmental and sustainability benefits during production and use**. Detailed reports on the Total Cost of Ownership (TCO) showed the cost advantages of PVC window frames, pipes, flooring and wires/cables when the total lifecycle is considered.

VinylPlus contribution covered:

- The European PVC Industry and the performance, cost and sustainability benefits of PVC
- The importance of the chlor-alkali industry as an integral driver of sustainability
- Flexible vinyl performance and alternatives – based on the Ramboll Denmark Report
- Key comments on Ramboll (2022) report with respect to alternatives to PVC and its additives
- The importance of considering the "Total Cost of Ownership" and not just the purchase price of materials
- Eco profiles for PVC with CO2 per kg of PVC and total energy per kg of PVC

4. *ECHA's Third Call for Evidence on PVC additives in focus*

2 February 2023 - 31 March 2023
Objective: collect information on alternative materials to PVC per use, performance, lifetime, availability and costs, recycling rate and CO2 emissions

ECHA's 3rd Call for Evidence focused on alternative additives to PVC additives and alternative plastics to PVC. ECHA provided a Background Note and four spreadsheets. Two had already been issued under the 2nd Call for Evidence: the total list of additives (457) and the list of 63 "additives in focus". In addition to these, two new spreadsheets are covering:

- In the first part of the 3rd Call for Evidence, ECHA requested information on the availability of alternative additives to the "additives in focus", and on requesting information on the technical performance of the additives – ECHA is listing "Key Performance Criteria" (KPC).
- In the second part, ECHA compiled a "tentative list" of alternative plastics to PVC in a spreadsheet and asked for information on which additives are used in these plastics (not limited to the "additives in focus"). Stakeholders were invited to make additions to ECHAs tentative list of alternative plastics and are also invited to provide information on the additives used in alternative plastics.

Key points of VinylPlus' submission:

- VinylPlus provided comprehensive comments on the list of alternative plastics and their additives, highlighting significant advancements and changes that have occurred in the past 25 years.
- **Plasticisers:**
  - There has been a major transition from Low Molecular Weight (LMW) phthalates which are Substances of Very High Concern (SVHCs), to High Molecular Weight (HMW) phthalates and other plasticisers. The EU market today offers a wide range of plasticisers that have undergone intensive competition and assessment, with approximately 30,000 different substances evaluated for their plasticising properties and only a small part of those which meet technical application requirements and regulatory needs is currently used. EU regulatory developments, including substance assessments and associated regulations, have played a crucial role in shaping the plasticisers available on the market today.
- **Stabilisers:**
  - Over the same period, there has been a significant shift away from cadmium and lead-based stabilisers towards calcium-based stabilisers. The industry has invested over two decades of intensive work in developing better, safer, and more sustainable alternatives to substances classified as SVHC. While the industry has been proactive in replacing additives, regulations have also played a vital role. The phased-out use of lead and cadmium, along with reduced reliance on organotin compounds, demonstrates compliance with stringent EU regulations. Calcium-based Stabilisers (COS) have completely replaced lead and cadmium-based stabilisers.
- **Flame retardants:**
  - PVC inherently possesses flame retardancy and relies on flame retardants only in specific applications, unlike other plastics. The industry has phased out SVHC flame retardants and replaced them with safer alternatives. This progress in flame retardant use aligns with significant advancements in the recycling of rigid and flexible vinyl within the EU.
- In addition, **VinylPlus has actively contributed to the development of sustainability initiatives and tools in the industry**. These include:
  - **Recycling Progress:** There has been major progress in the recycling of both rigid and flexible vinyl in the EU. This achievement reflects the industry's commitment to sustainable practices and the circular economy.
  - **Additives Sustainability Footprint (ASF)**: VinylPlus has developed the ASF tool, which helps assess the sustainability impact of additives used in the production of PVC. This tool enables stakeholders to make informed decisions regarding the environmental aspects of PVC and its additives.
  - **Voluntary Certification Schemes:** VinylPlus has introduced voluntary certification schemes such as the VinylPlus Product Label and VinylPlus Supplier Certificates. These certifications provide assurance to stakeholders that the products and suppliers meet specific sustainability criteria, further promoting responsible practices in the industry.
- In conclusion, the progress made in the recycling of vinyl, the development of sustainability tools like the ASF, and the implementation of voluntary certification schemes indicate a positive trajectory for the safety and sustainability of PVC and its additives. These advancements are spearheaded by the VinylPlus 2030 Sustainability commitment, which emphasises close cooperation with policymakers, regulators, and other stakeholders. It is important to consider that the choice of materials and additives for any application involves a multitude of technical, practical, safety,

environmental, and economic considerations, and many additives used in PVC also find applications in other plastics, ceramics, wood, glass, and metals.

5. *Ramboll's Second Questionnaire*

27 February 2023 - 31 March 2023
Objective: collect information on the presence and influence of certain legacy additives in PVC and PVC alternatives.

Ramboll specifically asked about typical concentration levels of the legacy additives in PVC and PVC alternatives, which products contain which additives, and whether the additives pose a problem to the recycling and reuse of PVC.

The VinylPlus response highlighted that many of the additives on the Ramboll list have never been used in PVC. For key legacy additives such as lead (not included in the Ramboll list) and cadmium-based stabilisers, analytical measurements are systematically conducted to confirm compliance with EU regulations to support safe and sustainable recycling.
VinylPlus also provided supplementary information on the safety of landfill sites with respect to PVC and its additives.