Response to call for evidence on ECHA's investigation report on PVC and its additives

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The European Environmental Bureau, ClientEarth and Health Care Without Harm Europe

Over the past years, NGOs have brought ample evidence to the EU institutions of the hazardousness of PVC and its additives, for example in the context of the proposed restriction of lead in PVC. While PVC is one of the most widely used types of plastics, it has also been considered as "the most environmentally damaging of all" (*Greenpeace,"PVC: the poison plastic", 2003*). Continuing to allow the marketing of PVC products would come at odds with the promise of a non-toxic circular economy.

The EEB, ClientEarth and HCWH welcome the opportunity to provide further evidence to ECHA as to the harmfulness of PVC, and of the need to strictly restrict its manufacture and use.

In the context of this consultation, we are sharing information regarding:

1. **The use and release of hazardous chemicals during the manufacture of PVC;**
2. **The hazardousness of PVC polymer;**
3. **The emission of hazardous substances during manufacture and blending of PVC articles:**
   - **3.1. In food contact materials and articles, and**
   - **3.2. In healthcare products (exposure to plasticisers).**
4. **Emissions during combustion of PVC;**
5. **PVC and circular economy.**

We remain at your disposal for further details regarding the information provided.

1. Manufacture of PVC

Highly hazardous chemicals are used, generated and released to the environment during the production of PVC and its feedstocks, including VCM, EDC, chlorine and highly hazardous chlorinated byproducts. This is documented by the EU BREF for the Production of Large Volume Organic Chemicals (*Falcke et al, 2017*), extensive scientific reviews (*Stringer and Johnston, 2001*) and reports (*HCWH, 2020; Thornton, 2002*). These pollutants comprise non-threshold chemicals such as carcinogens, mutagens, endocrine disruptors and PBTs, which pose a high risk to people and the environment.

Under the Industrial Emissions Directive, industrial plants producing PVC and its feedstock chemicals (chlorine, EDC, VCM) are subject to monitoring and reporting obligations in relation to the emissions of several highly toxic chemicals. However, the public data provided through the E-PRTR is considered to underreport emissions to the environment as highlighted by the authors of a recent global inventory of chlorine, VCM and PVC production plants (*Vallete et al, 2018*).

Highly hazardous chemicals related to PVC production include:

- **Asbestos**: used and emitted during the production of chlorine with asbestos diaphragms. This process is still used in the European Union by Dow's complex in Stade - Germany having been allowed to continue using asbestos. Yet the company doesn't report emissions although it is estimated that for each ton of asbestos diaphragm, chlor-alkali production generates between 64 and 160 grams of asbestos' waste (*Vallete et al, 2018, pages 39-40*).

- **Mercury**: used and emitted during the production of chlorine with mercury cells. Although these cells have been phased out all over the EU, two German chlor-alkali plants have an exemption to continue using mercury indefinitely: BASF in Ludwigshafen and Evonik in Lülsdorf. Mercury cell production is also ongoing in Hungary, as well as in two plants in Belgium.

  Industry data provided by EuroChlor and included in the EC BAT for chloro-alkali shows that for each ton of chlorine produced using mercury cell technology, 0,56 grams are emitted into the air, 0.07 grams discharged to water, 0.05 grams become contaminants in products, and 19.42 grams become waste. However, data from a research project, also included in this BREF, measured much higher emissions to air than those reported by EuroChlor. For example, researchers measured emissions of 1,4 to 3,8 gr/t at the Solvay plant in Rosignano (Italy), while EuroChlor reported emissions of 0.41 to 0.67 g/t. The comparison of mercury inputs and outputs in OSOAR countries in 2009 showed a median difference of 2.6 g/t annual chlorine capacity, which was much higher than the total emissions reported by industry, meaning that significant amounts of mercury remain unaccounted for (*Brinkmann et al, 2014*).

- **PFAS**: PFAS are used in resin membranes in the rest of chlorine plants in Europe. Researchers have documented PFAS depletion from use in membrane technology between 4 and 6.7 grams per ton of chlorine capacity. Applying these rates to combined annual chlor-alkali production capacities reveals a substantial potential mass of membrane resins: between 30.7 and 51.5 tons for Europe (*Vallete et al, 2018, page 11*).

- **Chlorine**: the chlorine content of PVC ranges from 56% in homopolymer PVC grades to 56% to 67% in chlorinated polyvinyl chloride (CPVC). In 2012, according to industry estimates, PVC applications used one third (33.3%) of the chlorine in Europe. There is a direct link between the production of chlorine and the manufacture of PVC. Imports of chlorine and PVC from the US Gulf Coast and other low-cost areas are increasing due to the lower energy costs in North America (*Vallete et al, 2018, page 23*).

  Chlor-alkali plants routinely release chlorine gas into the air. The EC BAT for chloro- alkali reports average emissions of chlorine to the air of 0.01-15 g/ t of chlorine produced and 0.001 - 3.8 g/t to water (*Brinkmann et al, 2014*).

- **Ethylene dichloride (EDC)**: 95% of EDC production in the EU is used for manufacturing VCM/PVC. The EU CAK BREF lists 23 EDC and EDC/VCM manufacturing plants in Europe. As this BREF is already 10 years old there may be some changes in the number of plants operating today. EDC and a wide range of chlorinated byproducts are released during the production of EDC as highlighted in the EU BREF for the Production of Large Volume Organic Chemicals. It ranges emissions of EDC from EDC/VCM plants after abatement between 0.0015 and 3.5 (mg/Nm3). Estimated fugitive emissions of EDC range between 0.01 and 93 g/t of VCM produced, with a median of 8g/t VCM (*Falcke et al, 2017*).

- **Vinyl Chloride Monomer (VCM):** 34 PVC and VCM factories reported releasing VCM to the environment from 2012 to 2016 in Europe. Several plants did not report any release. 17 plants reported releasing more than 30 grams of VCM per ton of PVC. Seven of these 17 plants reported releasing over 100 grams of VCM per ton of PVC. The combined emissions of Kem One's plants in Europe add up to 180 tons of VCM per year, or 197.8 grams of VCM per ton of PVC resin capacity. Detailed data for each plant can be found in the Healthy Building Network report (*Vallete et al, 2018*). ECHA can also consult the E-PRTR for updated data.

  Residual amounts of VCM are present in PVC resin. Members of the European Council of Vinyl Manufacturers committed to limit rVCM concentrations in emulsion PVC products to below 1 ppm. For suspension PVC, ECVM limits residuals to 1 gram per ton for food and medical applications, but allows up to 5 ppm in other suspension PVC (*ECVM, 2023*). However no information is available regarding the compliance with this commitment.

- **Other chlorinated substances**: the EU CAK and LVOC BREFs, which are based on information provided by industry, i list highly hazardous chemicals generated as by-products, in particular during the manufacturing of chlorine, EDC and VCM, although no significant data on amounts released is provided.

  The Health Building Network inventory (Vallete et al, 2018) reports aggregated figures for USA plants reporting releases of chlorinated chemicals. The median rates per 1,000 tons of chlorine throughput that have been found are: 117.8 kg EDC, 42.5 kg VCM, 5.8 kg hydrochloric acid, 4.7 kg chloroform, 4.2 kg carbon tetrachloride, 2.3 kg hexachlorobutadiene, 2.26 kg chlorine, 0.002 grams PCBs, 0.001 grams dioxins (Toxicity Equivalent Weight). Chlorinated pollutant release rates (including chlorine, hydrochloric acid, and organochlorine chemicals) do not appear to correlate with technologies used to produce the chlorine (*Vallete et al, 2018, page 43*).

  Carbon Tetrachloride: Chlor-alkali plants release significant amounts of carbon tetrachloride. Although the E-PRTR regulation requires manufacturers to report emissions of 100 kg/y to air, and 1 kg/y to water for CCl_4, European chlorine plants have not reported any carbon tetrachloride releases. Researchers nonetheless estimate that these industrial plants do emit around 0.4 kg per ton of chlorine produced (*Graziosi et al, 2016*). Using this rate of 0.4 kg-per-ton of chlorine produced, plants in Europe (11,069,000 tons of estimated chlorine capacity) might be emitting 4,427 tons of carbon tetrachloride per year (*Vallete et al, 2018, page 45*).

  Dioxins and PCBs: The highest releases of dioxins and polychlorinated biphenyls (PCBs) come from plants that produce EDC and/or VCM. Reported rates of release for these highly potent chlorinated pollutants vary greatly between plants. Releases reported through the European E-PRTR system are extremely low compared to emissions in other regions, suggesting data gaps. The chlorine to PVC resin facility of Ercros in Vila-seca, in Spain, has reported releases of PCBs into water at rates of 400 grams in 2014, 754 grams in 2015, and 850 grams in 2016 (*Vallete et al, 2018; pages 46-47*)

- **Other contaminants:**

  PVC dust and pellets : PVC manufacturing plants routinely release PVC dust and pellets into surrounding communities and waterways (*Vallete et al, 2018)*. PVC microplastics threaten human health and contaminate aquatic ecosystem health:

  → Exposure to PVC particles has been linked to diseases, predominately in occupational settings. For instance, inhalation of airborne PVC dust has been associated with interstitial lung disease, as determined by chest radiographic abnormalities (*Lilis et al, 1976, Soutar et al, 1980*).

→ Recent studies have also highlighted the impacts of PVC microplastics on the aquatic environment. Due to its high content in heavy metals, in particular zinc, leachated PVC microplastics have shown to damage the embryo development of marine invertebrates (*Paganos et al, 2023*). Due to its higher density, compared to other polymers, PVC tends to deposit in the sea floor, where it may persist for longer periods as in sea surface. Researchers have also concluded that the presence of PVC microplastics in the environment may have been underestimated due to analytical challenges (*Fernández-González, 2022*).

2. Hazardousness of PVC polymer

PVC polymer has been ranked as **highly hazardous** by several reviews. Lithner et al. (2011) consider PVC as one of the 5 most hazardous polymers due to the toxicity of its monomer and the additives needed to maintain PVC polymer stability.

In comparison to other high volume polymers, PVC polymer is inherently thermally unstable and heat stabilising additives are required to allow processing without degrading and discolouring the polymer. Large amounts (4 wt%) of heat stabilisers and lubricants are incorporated into the polymer. More heat stabilisers are needed in rigid PVC due to higher processing temperatures. The primary heat stabilisers are lead salts (tribasic lead sulphate,dibasic lead phthalate, dibasic lead phosphate, which are combined with lead stearates), mixed metal stabilisers (barium/zinc or zinc/calcium) and organotin stabilisers (mono and dibutyl, methyl or octyltin isooctyl mercaptoacetates, mono- and dimethyltin 2-mercaptoethyl carboxylate sulfides, and mono- and dibutyltin sulfides. Secondary heat stabilisers are mainly epoxidised oils and esters. Primary heat stabilizers contain lubricating substances such as metallic soaps of lead, barium, calcium and zinc. Lubricants must be added for processing since PVC gets sticky when the temperature increases.

Another categorisation of polymers by Clean Production Action based on the hazardous properties of feedstock, monomers and intermediates used in their production, ranks PVC among the most hazardous polymers *(Blake and Rossi, 2014)*.

3. Manufacture and blending of PVC articles

3.1. (Harmful) PVC chemicals with evidence for presence in food contact materials and articles

Table 1: PVC chemicals with evidence for presence in PVC food contact materials (FCMs) and articles (Annex 1)

For 229 chemicals there is evidence of their presence in finished PVC food contact articles, as shown by their detection in migrates (97 chemicals) and/or extracts (196 chemicals) of PVC food contact plastics (*Geueke et al., 2022*).

All these chemicals shown to migrate from PVC FCMs into food or food simulates and/or be extractable are listed together with their CAS number, the type of experiment, and the data source in Table 1. The data was extracted from the Food Packaging Forum's FCCmigex dashboard.

The "database on migrating and extractable food contact chemicals" (FCCmigex) lists chemicals that have been analyzed by scientific studies for migration into food or food simulants, or that have been extracted from food contact materials and articles. The FCCmigex shows that 2881 food contact chemicals (FCCs) have been detected in FCMs.

Table 2: Chemicals with evidence for presence in PVC food contact materials (FCMs) and articles that are considered harmful according to the EU's Chemicals Strategy (and that are reported for intentional use in the manufacturing of FCMs) (Annex 2)

Among the chemicals with scientific evidence for presence in PVC FCMs, there are chemicals that are considered harmful according to the EU's Chemicals Strategy for Sustainability, meaning they are carcinogenic, mutagenic, or toxic to reproduction (CMRs), or persistent and bioaccumulative, or endocrine disrupting chemicals (EDCs), or are toxic to specific target organs (STOT).

A systematic analysis of chemicals listed for intentional use in FCMs which have these hazard properties and which also have empirical evidence for presence in PVC FCMs (i.e. shown to migrate or to be extractable from FCMs) shows that this is the case for 34 chemicals (*Zimmermann et al., 2022*).

For instance, 25 of these PVC chemicals are known CMRs, and 9 are known EDCs. All these 34 chemicals are listed in Table 2 together with their CAS number, hazard, use, and production volume information. The table also indicates if they have been detected in migration and/or extraction experiments. The data was extracted from the FCCoC list.

The FCCoC list includes chemicals that have been identified by regulatory or industry inventories worldwide as potentially used in the manufacturing of food contact materials and articles and that are of high concern due to hazard properties considered harmful according to the EU Chemicals Strategy for Sustainability (i.e., substances that are known to be carcinogenic, mutagenic and toxic to reproduction (CMRs), endocrine-disrupting chemicals (EDCs), chemicals with persistence-bioaccumulation-related or persistence-mobility-related hazards, and chemicals included in the REACH SVHC list due to their toxicity to specific target organs (STOT).

The FCCoC list only includes chemicals reported for intentional use in the manufacturing of FCMs that have been classified as hazardous by official sources, such as the chemicals on the REACH SVHC list. Thus, many more hazardous chemicals are probably used and present in (PVC) FCMs.

The FCCoC list includes 388 food contact chemicals of concern (FCCoCs).

Of these 388 FCCoCs, 127 have been detected analytically in migrates or extracts of FCMs (i.e., are listed in the FCCmigex database). Of the 127, 34 have been detected in migrates and/or extracts of PVC FCMs.

3.2. Plasticisers Exposure - Healthcare

The 2017 EU Medical Devices Regulation (2017/745) does not prevent manufacturers from using substances of very high concern in medical devices "where justified" (Annex 1, Chapter II, Section 10.4.1). Because it is not yet completely banned (sunset date in 2025), DEHP for instance is still used in plastic medical devices in the Neonatal Intensive Care Unit (NICU) and exposures remain elevated above the tolerable daily intake. Alternative plasticisers might provide interesting opportunities to reduce toxicity, but human data regarding health effects remains limited.

Via parenteral nutrition: the study performed by Panneel et al. in 2022 indicates that premature neonates requiring parenteral nutrition are still exposed to DEHP and a range of alternative plasticisers (ATBC, TOTM, DEHT & DEHA). ATBC leached from infusion circuits, while lipid emulsions were the major source for DEHP, TOTM, DEHT, and DEHA (*Panneel et al., 2021; Bernard et al., 2022; Panneel at al., 2022*).

Torki et al. investigated the endocrine-disrupting activity of three non-phthalate alternatives (DINCH, ATBC, and DEHA), which suggested a potential for thyroid hormone disruption. (*Torki at al., 2022*)

Moreover, recent studies found that the development or progression of uterine fibroids has been associated not only with endocrine disruptors but also with emerging chemicals such as OPEs and alternative plasticisers. Lee at al., found for the first time that several alternative plasticisers were linked to the risks of uterine fibroids in pre-menopausal women. Among APs, metabolites of di-isononyl phthalate (DINP) and di(2-propylheptyl) phthalate (DPrHpP) were detected in >75% of the urine samples (*Lee., at al 2020*).

As documented in a position paper published by HCWH Europe in 2021, healthcare providers have started their actions to phase out PVC, and many countries have set criteria for their procurement (*HCWH, 2021; HCWH, 2007*). HCWH Europe is updating and gathering these efforts in a new report, soon available on its website.

4. Emissions during combustion of PVC

It is well documented that controlled and uncontrolled combustion of PVC leads to the generation of highly hazardous by-products that are emitted together with heavy metals and hazardous ingredients (*Wagner et al, 1991; Costner, 2001; Zhang et al, 2015; Chong et al, 2019*). That includes: heavy metals, dioxins and furans, PCB, PAH, chlorine dioxide, methyl chloride, methylene chloride, allyl chloride, vinyl chloride, ethyl chloride, 1-chlorobutane, tetrachloroethylene, chlorobenzene, hydrogen chloride, benzene, 1,3-butadiene, methyl methacrylate, carbon monoxide, acrolein, and formaldehyde.

While formation for these byproducts can be decreased by incineration at sufficiently high temperatures, a remaining problem is the inherent generation of the highly corrosive hydrochloric acid in the combustion process.

As almost half of the PVC waste ends up in incineration plants, the issues linked to toxic emissions and hazardous waste cannot be ignored. For example, not all the Nordic countries allow incineration of used PVC due to the amount of neutralization waste generated by the purification of the flue gases (Nordic Swan Ecolabel).

In general, modernisation of incineration plants in Europe has reduced the emissions of polyaromatic hydrocarbons (PAH), benzo-a-pyrene, dioxins and furans. But the problem is the way emissions are currently measured - results only represent a tiny snapshot of the incinerator's output, meaning that not all incineration emissions are evaluated. Recent Zero Waste Europe reports from a biomonitoring research around three waste incinerators show an environment under threat by contamination of substances of very high concern in eggs of backyard chicken, pine needles, and mosses (Zero Waste Europe, 2022).

- The analysis of chicken eggs around incinerators shows that the majority of eggs exceed the EU action limits for food safety as regulated in the EU Regulation 2017/644. The EU regulations urge for action on these sampled egg locations to find out the source of POP contamination, in order to eliminate or – at least – do the utmost to reduce dioxins (PCDD/F) to minimum levels. Moreover, a high percentage of eggs exceed the safe level for consumption. If these eggs were intended for the commercial market, they should have been withdrawn from the market.
- The results of the analysis of the vegetation, pine needles and mosses also show high elevation of dioxin levels in the vicinity of the waste incinerators. Although there is no legal obligation to take action, it's a sign of pollution. Moreover, people living in the vicinity of incinerators could be under threat if they grow vegetables for consumption.
- This biomonitoring research gives a warning sign for contamination of the environment with toxic substances such as dioxins (PCDD/F), dioxin-like PCBs, PAHs and PFAS.

A review of PVC waste management practices in the Nordic region (Denmark, Sweden, Norway and Finland), i.e. the region known for high recycling rates and advanced environmental standards, shows that there is still a significant share of incineration (Miliute-Plepiene et al., 2021).

5. PVC and circular economy

PVC does not belong to a healthy circular economy. Hazardous substances contained in PVC articles, including PVC polymer as such and the numerous additives it needs, threaten people's health and the environment, compromise recycling possibilities of other plastics and pose a reputational risk to the companies willing to use recycled materials (*HCWH, 2020*).

A report by the Nordic countries reviewed the content in SVHCs of different plastics and recycling rates. PVC was the plastic with the largest number of SVHCs identified (41) and among the lowest recycling rates. Only rigid PVC (mainly construction material) is reported to have recycling schemes in place in Germany. They consider PVC to be the most problematic construction plastic when recycled due to the high number of hazardous substances it contains. Authors of this review have interviewed building industries in Sweden who stated that they are reluctant to use recycled PVC due to the risk of undermining recycling in the future (*Stenmarck et al, 2017*).

Most of the recycling of clean pre-consumer PVC waste collected in the region takes place abroad with the exception of small on-site recycling capacities in Sweden for clean PVC cable waste. Overall, a large part of PVC waste in Finland, Norway, Sweden and, to a smaller extent, in Denmark, ends up in mixed waste streams and is eventually treated in waste-to-energy plants (Miliute-Plepiene et al., 2021).

VinylPlus, the PVC industry consortium, claims it has reached its voluntarily-set target of recycling 800,000 T of waste per year by 2020 (*VinylPlus, 2022*). However, its definition of recycling combines pre-consumer waste and post-consumer waste, therefore, it is not possible to identify which waste streams are by-products of current production, and which are coming from discarded products. In 2021, 810,775 tonnes of PVC waste were recycled within the VinylPlus framework, of which 63.6% was pre-consumer waste and 36.4% post-consumer waste (*VinylPlus, 2022*). Germany and the UK are responsible for about half of the European recycling. Regardless, the figure of 800,000 T of recycled PVC represents still a small share (10%) of 8.1 million T of PVC products manufactured in the EU every year - and window frames are probably the largest and the only consistently recycled waste stream (mainly down-cycled in fact). We are not aware of any product-to-product high quality PVC recycling.

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