Japan Business Council in Europe

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JBCE's views following the call for comments and evidence on PVC and its additives

Being a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE welcomes the opportunity to contribute to the call for comments and evidence on PVC and its additives.

1. Introduction

JBCE strongly supports the objectives of the REACH Regulation to contribute to the protection of human health and the environment. At the same time, JBCE also firmly supports a risk assessment approach with regard to the use of chemical substances. As for the feedback to the call for comments and evidence on PVC and PVC additives, JBCE would like to share its views and insights below.

2. Details

2-1: Uses and technical functions of PVC

PVC has been used in a wide variety of industrial applications for infrastructures such as water supply, sewerage (e.g. drainage pipes, water service pipes), electrical wire (e.g. wire coating), building materials (e.g. window frames and wall sheet), automotive (e.g. automotive interiors and seat covers), consumer applications (e.g. fashion, footwear, food packaging, synthetic leather, chemical-resistant gloves and photographic materials), advanced electronics for semiconductors, agricultural materials (e.g. greenhouses) and medical equipment (e.g. blood storage bags, infusion bags, medical tubes and blister packs for medicines). Applications of PVC products are usually classified as hard PVC, soft PVC, electrical wire and others based on hardness. Long durability with high reliability is PVC's prime property for final products.

Important technical functions of PVC are weather resistance (i.e. PVC products have excellent weather resistance and can be used outside in sunlight (UV), chemical resistance (i.e. excellent chemical resistance to both organic and inorganic chemicals), acid and alkali resistance (i.e. PVC products are resistant to acids and alkalis, slightly damaged by strong acids), water resistance (i.e. excellent water resistance and impervious to water), flame retardant (i.e. highly flame retardant and difficult to burn), physical strength, electrical insulation (i.e. it has excellent electrical insulation and does not conduct electricity), workability (i.e. PVC can be used by both hard and soft materials, embossing is also possible for blister packaging, excellent colourability (i.e. it is also highly printable) and inexpensive.

Although there are many applications and functions of PVC products, it is important to distinguish how these essential functions have been achieved by PVC as a polymer or by functionalization of additives.

2-2: End-of-life information of PVC

Currently, PVC is being recycled by either one of the following methods:

a. Mechanical recycling – This involves mechanically treating the waste (e.g. grinding) to reduce it into smaller particles. The resulting granules, called recyclate, can be melted and remoulded into different products, usually the same product from which it came.
b. Feedstock recycling – Chemical processes such as pyrolysis, hydrolysis and heating are used to convert the waste into its chemical components. The resulting products – sodium chloride, calcium chloride, hydrocarbon products and heavy metals to name a few – are used to produce new PVC, as feed for other manufacturing processes or as fuel for energy recovery.

Challenges:

a. **Post-industrial waste** is relatively pure and comes from PVC production and installation, such as offcuts from laying of cables or scraps from the installation of window frames. These are easily recycled since they can be collected directly from processors or installers or even recycled by producers themselves as raw material to manufacture the same product.
b. **Post-consumer waste** contains mixed materials and has been used for different applications. These are products that have reached the end of their life or have been replaced due to damage, like underground pipes , window frames being replaced for renovation and electric cables recovered from demolition. They require further sorting and cleaning, adding costs to the recycling process. The recyclate produced is usually of a lower quality and consequently of decreased economic value.

An interesting process is to utilise an organic solvent to dissolve PVC composite and separate the PVC from other materials. After filtration, the PVC compound is dried and packaged, while the filtrate is treated, and the solvent is recovered and recycled. The primary energy demand, global warming potential and water consumption to produce one kilogram of such product from the said process are all lower than for the production of the same amount of PVC by the traditional route.

2-3: Uses and technical function of additives in PVC

Heat stabilisers, plasticisers and flame retardants used in PVC products have the following characteristics:

a. Heat stabilisers

At a temperature of 170°C to 180°C, the chlorine and hydrogen are desorbed from PVC resins which results in the generation of hydrogen chloride. Once decomposed, unstable pores are formed in the structure which promote desorption of hydrogen chloride. This leads to a chain reaction of decomposition. Since PVC resin is processed by heating and softening, it is necessary to suppress the generation of hydrogen chloride due with a thermal procedure and suppress decomposition during processing. Heat stabilisers are added during processing to prevent the initial elimination as hydrogen chloride from the PVC resins and to stop the chain reaction of decomposition. Also, while being used as a product, dehydrochlorination is caused by a slight amount of UV or oxygen. In addition, dehydrochlorination is further accelerated by metal chlorides which may cause discolouration and deterioration of physical properties. UV stabilizers and antioxidants are used in parallel with heat stabilisers to suppress these forms of deterioration.

b. Plasticisers

Plasticisers are selected depending on the applications of the PVC products. DEHP, DINP and DEHT are usually used for wire coating. Trimellitic acid esters and polyesters are also used to improve heat resistance and prevent migration to other resins. DEHP is used in medical device applications to suppress blood coagulation. Adipate esters are used in food wrapping films. Citrate esters are used in children's toys. In cases where a single plasticiser cannot be used, it is common to use multiple plasticisers, each with its own properties.

c. Flame retardants

Plastics for which the oxygen index is higher than 27% are not so flammable. These polymers can be called flame retardant resins. An oxygen index of 23 to 27% is self-extinguishing and specific examples are nylon 66, polycarbonate and PVC. Many plastics require the addition of flame retardants. Since PVC is a self-extinguishing material, the amount of flame retardant used can be relatively low. PVC is an important core chemical material made by through reactions with ethylene and chlorine, which is a by-product of the electrolysis in salt production.

In order to show the desired functions mentioned above, substances need to be contained above a certain concentration.

2-4: Hazard information of PVC

A distinction should be made between the hazard and safety information of PVC itself and the effects of its additives . For example,

- Reference (i)[1] states that the in-vitro cytotoxicity and pro-inflammatory potential of PVC-E3 particles were reduced when the additives had been "washed off" (PVC-W3), indicating that PVC-particle associated toxicity is probably related to the residual additives. This means that additive-free PVC showed a reduction in toxicity in in-vitro studies using human cells.
- Reference (ii)[2] states that the addition of microplastics had no significant negative effect on wheat seedling emergence, wheat biomass production, earthworm growth, mortality or avoidance behaviour and nematode mortality or reproduction compared to controls.
- The following reference (iii)[3] states that microplastics most likely do not transfer elevated amounts of environmental pollutants to biota and, therefore, do not pose a specific additional threat to aquatic organisms.

Although the amount of scientific literature on environmental impacts by plastics has been increasing, reference (iv)[4] states the opinions on the specific lack of good science and choice of research methodology. i.e. the plastics tested in much of the literature are evaluated as final products containing impurities such as plasticisers and colourants. There is a lack of research based on fundamental information such as purities. The objects of testing should be chemically characterised before evaluation and validation. "One of the most important and fundamental issues, which are probably intentionally ignored by many, is the lack of the basic polymer chemistry of the plastics chosen for any investigations because there is almost no rudimentary characterization data on the purity, molecular weight, and molecular weight distribution of the plastic prior to any (bio)degradation test conducted." In addition, it says "commercial films contain a range of impurities that are common in these products, including many biodegradable components, e.g., plasticisers. Because of this, a majority of the published results using post-consumption or commercial products assume the products used in their testing are 100% in purity and the molecular weights are uniform completely; both of these assumptions are oversights or shortcomings due to the poor understanding of the polymer chemistry at the beginning." Although this reference is a review of

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[1] Reference (i): Haiyan Xu, David Dinsdale, Benoit Nemery, and Peter H.M. Hoet, Toxicological Sciences, Volume 72, Issue 1, March 2003, Pages 92–102.

[2] Reference (ii): Jonathan D. Judy, Mike Williams, Adrienne Gregg, Danni Oliver, Anu Kumar, Rai Kookana, and Jason K. Kirby, Environmental Pollution Volume 252, Part A, September 2019, Pages 522-531.

[3] Reference (iii): Lisa Hanslik, Sven Huppertsberg, Nadine Kämmer, Thomas P. Knepper, and, Thomas Braunbeck, Science of the Total Environment, Science of The Total Environment Volume 816, 10 April 2022.

[4] Reference (iv): Ji-Dong Gu, Environmental Science and Pollution Research, volume 28 (2021) pages1278–1282

biodegradability rather than toxicity, many reports seem to lack detailed background analysis of plastics.

At present, there seems to be little evidence of whether PVC itself is toxic or the additives are. Some scientific literature also states that there is little data on the effects of microplastics on organisms. Industry will make efforts to properly reduce and replace additives for which there is data on elution and the effects on organisms and the environment in case of contact with water. However, it is almost impossible to investigate precisely the contents of the substances via global and multi-tiered supply chain, if they are not classified as hazardous and not covered under any legal requirements such as listed as SVHC. For this measure, industry needs sufficient information and structure to reach to downstream users. PVC is a non-petroleum polymer which contributes to absorbing a large amount of harmful chlorine gas which is a by-product of electrolysing seawater. The characteristics of PVC itself must not be denied but efforts should be made to find appropriate additives and alternatives. SVHC is expected to encourage the proper collection of data and promote information sharing and substitution for downstream stakeholders.

2-5: Information on exposure

For professional and industrial use, exposure can be reduced with product design, appropriate communication (label, explanation sheet), an appropriate usage environment (fully controlled extraction system, local extraction system) and wearing protective equipment. If the scope of restriction is expanded only based on hazards without risk assessment, some useful products will be restricted even though they are safe to use and exposure to them is properly controlled.

2-6: Additional relevant information

2-6-(ⅰ) Alternatives, cost and transition period

The stakeholders have been studying alternatives of PVC and its additives for industrial applications. For example, in a sealed PVC product which comes into contact with pharmaceuticals, chemicals and biomaterials, there was an attempt to replace polyolefin with other polymer materials for the gas barrier and sealing properties (e.g. PTFE, PVDF, PVA, PVE polyacrylonitrile, etc). However, the desired performance could not be achieved. Even with the feasibility studies carried out for over 10 years, it is extremely difficult to find a combination of materials and additives that can be applied for the wide range of uses of PVC products. PVC provides flame retardancy, gas barrier properties (oxygen, water vapor), chemical stability (acid resistance, alkali resistance, biomaterial (blood) resistance), sealability and physical strength. It is very difficult to find alternative polymers and additives which are as multifunctional as PVC.

With regard to cables, it is mentioned in the final report on "The use of PVC in the context of a non-toxic environment" that "*the analysis of alternatives to PVC in wires and cables has found that a variety of technically feasible alternatives exist which possess acceptable, similar or better material properties to PVC*".[5] However, most of the alternatives being considered as substitutes for PVC are thermoplastic polymers (PE, PP and PUR) or fluoropolymers (ETFE, PTFE and PFA). These alternatives require additives when used in cables. To avoid "*regrettable substitutes*", careful examination of alternatives is necessary.

Importantly, the availability of alternative materials does not mean that real substitutes are available for final use in products.
Even if the equivalent performance of an alternative substance is confirmed at material level, it is necessary to check its performance in the final product and thus the total performance of the final

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[5] European Commission: The use of PVC (Poly Vinyl Chloride) in the context of a non-toxic environment" Final report, January 2022, p.236.

product. After a material is found to be an appropriate alternative, several processes are required before it is integrated into or used together with a final product. For example, manufacturers need to check the specifications of the parts with new material and safety and liability tests after integrating it into the final product.

We therefore suggest a step-by-step restriction. First, restrictions would be introduced for chemicals only and the relevant chemicals will be designated as SVHCs. Then, simple articles such as cables should be restricted. Finally, restrictions on complex articles (final products) integrating simple articles should be introduced. Final products such as EEE have long, complex and worldwide supply chains. The implementation of the restriction throughout the supply chain also requires a certain period of time.

2-6-(ⅱ) Derogation and exclusion

a. Derogation for safety uses of electrical and electronic equipment (EEE)

The safety of EEE should be prioritised above all else. Properties such as durability, flame resistance, electrical insulation, heat resistance and flexibility are necessary to ensure product safety. For such usages, derogations are necessary until the availability of true alternatives is confirmed which can ensure the safe use of final products.

b. Derogation for measuring devices for laboratory use, or parts thereof

Products used in laboratories and their parts must be resistant to chemicals in addition to durable, flame resistant, heat resistance and flexible as well as offering electrical insulation. These products are, for example, used to measure hazardous substances or for research and development which are essential for the protection of human health and the environment.

c. Reference materials should be excluded from the scope

Reference materials and substances used in scientific research and development are necessary for the analysis of PVC and its additives. Without them, precise analysis is not possible. Therefore, reference materials for analysis should be excluded from the scope.

d. Spare parts exemption

JBCE strongly believes that spare parts for EEE placed on the market before the implementation of the restriction should be excluded without an expiry date. If spare parts are not exempted, the lifespan of EEE might be shortened. Consequently, the volume of EEE waste will rapidly increase, which is undesirable from the viewpoint of circular economy.

2-6-(ⅲ) Harmonisation with product specific legislation

Harmonisation of substance restrictions and product-specific legislations is important. For example, current harmonised standards under the Low Voltage Directive (LVD) include 16 standards for the use of PVC. It would be very confusing for manufacturers that LVD harmonised standards allow the use of PVC whilst the REACH Regulation restricts the use of PVC. Therefore, before the introduction of restrictions, new harmonised standards with alternative materials should be available and a specific transition period should be provided for manufacturers to comply with them. Otherwise, some products will not be able to comply with both the LVD and REACH Regulation and consequently some EEE will disappear from the EU market.

Particular attention needs to be paid to the fact that PVC cable standards are cited in the safety standards of EU product-specific legislation. For example, LVD harmonised standards include EN 61010-1, EN 60799, EN 60335-1 and EN 62368-1, whose international standards IEC 61010-1, IEC 60799, IEC 60335-1 and IEC 62368-1 refer to IEC 60227: Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V. Some of these LVD harmonised standards limit the use of rubber or PVC only, and in such cases a large number of devices actually use PVC cables in accordance with IEC 60227.

Similarly for medical devices, EN 60601-1 is one of the harmonised standards for the Medical Device Directive (MDD) whose international standard IEC 60601-1 cites IEC 60227: Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V.

JBCE would also like to draw your attention to the fact that some phthalates used as plasticisers are already restricted under the RoHS Directive 2011/65/EU. To avoid double regulation, these substances should be further restricted under the RoHS Directive, not under the REACH Regulation.

3.Conclusion

JBCE would like to highlight the following points:

- Chemicals should be used appropriately and knowledgeably with the purpose of ensuring a high level of product safety, reliability and functionality. At the same time, the use of chemicals in products should not run counter to the protection of human health and the environment.
- Alternatives should be carefully evaluated to avoid “regrettable substitutes”. Special attention should be paid to the final products: the availability of alternative materials does not mean that real substitutes are available for final products.
- A sufficient transition period should be considered for each product group since long and complex supply chains are involved. Special attention should be paid to products with a long model lifespan (mostly medical devices and analytical devices) in order to avoid a shortage of these devices on EU market.
- Substance restrictions should be harmonised with harmonised standards for product-specific legislation.

About JBCE

Created in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of more than 95 multinational companies of Japanese parentage active in Europe.
Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceuticals, steel, textiles and glass products.
Building a new era of cooperation between the European Union (EU) and Japan is the core of our activities, which we perform under several committees focusing on Corporate Social Responsibility, Digital Innovation, Environment & Energy, Standards and Conformity and Trade.
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