Japan Business Council in Europe

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JBCE's views following the call for evidence on ECHA's investigation report 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 evidence on ECHA's investigation report on PVC and its additives.

1. Introduction

JBCE strongly supports the objectives of 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 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 pipe, water service pipe), electric wires (e.g. wire coating), building materials (e.g. window frames and wall sheet), automotives (e.g. automotive interiors and seat coverings), consumer applications (e.g. fashion, footwear, food packaging, synthetic leather, chemical-resistant glove and photographic materials), advanced electronics for semiconductors, agricultural materials (e.g. greenhouses) and medical equipment (e.g. blood storage bag, infusion bag, medical tube and, blister pack for medicine). Applications of PVC products are usually classified into hard PVC, soft PVC, electric wires and others based on hardness. Long durability with high reliability is the very important feature of PVC for final products.

Important technical functions of PVC are: weather resistance (i.e. PVC products have excellent weather resistance and can be used outside under sunlight (UV), chemical resistance (i.e. excellent chemical resistance for 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 colorability (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 remolded 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 cut offs 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 material and has been used for different applications. These are products that have reached end of life or are replaced due to damage, like pipes from underground, window frames being replaced for renovation and electric cables recovered from demolition. These would require further sorting and cleaning, adding cost to the recycling process. The recyclate produced is usually of 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 compared to the production of the same amount of PVC from 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

In case of a temperature from 170 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 promotes 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 to thermal procedure and to 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 discoloration and deterioration of physical properties. For the purpose of suppressing these deteriorations, UV stabilizers and antioxidants are used in parallel with heat stabilisers.

b. Plasticisers

Plasticisers are properly selected according to the applications of PVC products. DEHP and DINP 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 ester are used in food wrapping films. Citrate ester is used in infant toys. In cases where a single plasticiser cannot be used, it is common to use multiple plasticisers, each with their own characteristics.

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 to be added on flame retardants. Since PVC is a self-extinguishing material, the amount of flame retardant used can be relatively reduced. PVC is an important core chemical material made by reaction with ethylene and chlorine which is a by-product of the electrolysis of salt production.

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

2-4: Information on exposure

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

2-5: Additional relevant information

2-5-(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 contact with pharmaceuticals, chemicals and biomaterials, there was an attempt to replace polyolefin with other polymer materials for gas barrier and sealing properties (e.g. PTFE, PVDF, PVA, PVE polyacrylonitirle, etc). However, the desired performance could not be achieved. Even with the feasiblity studies carried out for over 10 years, it is extremely difficult to find a combination of materials and additives that can be applied for 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.

Regarding 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 alternative 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*”.[1] 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 for final use in products are available.

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

Even though if the equivalent performance of an alternative substance is confirmed at the material level, it is necessary to check its performance in the final product and thus the total performance of the final product. After a material is found to be an appropriate alternative, several processes are required before it is integrated into/used together with a final product. The manufacturers need, for example, to check the specifications of the parts with new material and safety and liability tests after integrating into the final product.

Therefore, we suggest a step-by-step restriction: First, restrictions would be introduced for chemicals only. 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 chain. The implementation of the restriction in whole supply chain also requires a certain period of time.

2-5-(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 part thereof

Products used in laboratories and their parts must be resistant to chemicals in addition to durability, flame resistance, electrical insulation, heat resistance and flexibility. These products are for example used for the measurement of hazardous substances or research and development which are inevitable for the protection of human health and 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 these, precise analysis is not possible. Therefore, reference materials for its 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 expiry date. If spare parts are not exempted, the lifetime of EEE might be shortened. Consequently, the volume of EEE waste will rapidly increase, which is undesirable from the viewpoint of circular economy.

2-5-(ⅲ) Harmonisation with product specific legislation

The harmonisation of substance restrictions and product specific legislations is important. For example, current Harmonised Standards for Low Voltage Directive (LVD) include 16 standards for PVC use. It would be very confusing for manufacturers that LVD Harmonised Standards allows the use of PVC on the one hand though REACH Regulation restricts the use of PVC on the other hand. Therefore, before the introduction of restrictions, new Harmonised Standards with alternative materials should be available and a certain transition period should be provided to manufacturers to comply with them. Otherwise, some products will not be able to comply with both 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 legislations. 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 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 call your attention that some phthalates 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 properly and to ensure a high level of product safety, reliability and functionality. At the same time, the use of chemicals in products should not run counter 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 for final products are available.
- Sufficient transition period for each product groups should be considered since long and complex supply chains are involved. Special attention should be paid for the products with long model lifetime (mostly medical devices and analytical devices) in order to avoid the shortage of these devices on EU market.
- Harmonisation of substance restriction with Harmonised Standards for product-specific legislations is necessary.

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, pharmaceutical, 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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