AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

AmCham EU views on proposed German restriction for Bisphenol A and Bisphenols of similar concern

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research

Executive summary

The American Chamber of Commerce to the European Union brings together over 150 companies of US parentage committed to Europe on trade, investment and competitiveness issues. Aggregate US investment in Europe totaled more than €3 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

AmCham EU has been an active stakeholder in REACH since its inception and remains committed to being a constructive partner in sharing industry insights with policy-makers to improve REACH and ensure that it effectively meets its objectives. Our member companies include players across the whole value chain, from developers and producers, to downstream users and service providers. This allows us to represent the views of the entire value chain, bringing a diversified set of experiences to the table when it comes to uses, applications and alternatives to Bisphenol A and other bisphenols. Currently we are very concerned about the recent developments of the restriction proposal, prepared by the German authority Umweltbundesamt (UBA).

For our Members, Bisphenol A and other similar bisphenols are used as a basis for a variety of polymers, mixtures, and additives, which form the basis for a vast number of everyday products as well as for innovation.

Scope of the restriction

The proposal in its current form it would lead to negligible environmental benefit at a significant socio-economic cost. To illustrate: the suggested residual and migration limit values would have a major impact on the manufacturing and use of polycarbonate. Most of its production would be put into question.

In contrast, the socio-economic effects would entail significant loss for the various sectors of the European Industry impacted by the restriction, as these would need to urgently substitute those materials. In addition, BPA and alternative bisphenols are used in the making of polymers that bring added value to society and the environment. Those polymers are essential in developing electric cars, life-saving medical devices or electrical and electronic equipment.

The potential impact of the suggested residual and migration limit values of Bisphenol A (BPA) and other related bisphenols could have wide-ranging effects in these sectors. This would lead to lower quality products, potential harmful environmental and climate impacts and negative socio-economic effects. Any regulatory action leading to a substitution with substances whose effects on human health and the environment have been subject to less research would be driven by reasons other than scientific research and would most likely lead to decrease in safety standards. Once again, it should be reasonable to assume that any limit value imposed in the restriction proposal should take into account the proportionality principles.

Polycarbonates (PC)

BPA-based PC is characterized by a set of unique properties, such as transparency, heat resistance, impact resistance. This is essential inter alia, for electrical and electronic application, building and construction, automotive, medical devices, household appliances, leisure, sports, aerospace and defence.

PCs are a useful material whose properties and use contribute to Europe's sustainability objectives, such as some of those outlined in the European Green Deal, by enabling environmental benefits and more sustainable innovations in several ways. PCs represent a material class that can be used for engineering at low cost and with high efficiency. Some properties of polycarbonate provide specific sustainability benefits across many applications (e.g. lightweight which reduces emissions for transportation and durability, which increases material efficiency and reduces waste and recycling issues).

There is a high degree of technical manufacturing know-how, which is fundamental for the entire global supply chain of products related to PC. The socio-economic footprint of the downstream value chain is many times larger than that of the polycarbonate industry itself. Polycarbonates are used in industries generating billions of turn-over and employing millions of people. Polycarbonates provide vital performance characteristics to products, creating socio-economic value far beyond the direct impact created by the industry itself. Statistics of EUROSTAT point to the fact that the potentially affected companies in the EU amount to up to 50,000 downstream plastics processors[1].

[1] Eurostat: „Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E)", Last update: 30-11-2021, Link.

Polycarbonate is used across numerous medical devices, including injector pens. While PC is used in some applications for transparency purposes, it is primarily used due to its superior properties and performance over other polymers. In addition, the ease of processing is another critical factor that has led to PC being the material of choice.

For some of the applications that depend on the transparency feature, alternatives will probably be more straightforward to implement though they will of course need to be commercially available at the volumes required for a mass switch to a different polymer. However, even in this case if the shrinkage of the other polymers is not like PC or if the processability is not as good as PC, it will lead to significant efforts in terms of molding tooling (equipment) changes. In this case, different shrinkage would mean the parts of the device are out of dimensions and therefore will not fit with the other parts to form the final device, so it is extremely important that shrinkage is managed so there is no impact. Additionally, new molds and in some cases, new designs, may have to be created to make sure the parts fit with each other.

For the more critical applications (load bearing, components needing to sustain high impacts) the PC grade will have been validated after rigorous testing including performance over its shelf life. Reevaluating alternative grades to PC in these applications would mean the new grades have to be rigorously (re)evaluated to ensure satisfactory performance This effort will consume a lot of time (>3-4 years); it may lead to design changes and reauthorizing by the local health regulators (e.g., EMA, FDA)

Epoxy resins

BPA-based epoxy resins are a family of plastic materials used in coatings, adhesives, sealants and matrices for composite materials, such as in the reinforcement of carbon fibers. Mostly used for protection and functioning of reinforcement, epoxy resins are key to the function of electronic appliances, food packaging and many other everyday objects.

Epoxies are high-performance and high-tech materials that allow for long-lasting products that enable today's lifestyle at a reasonable cost. In the energy sector, epoxy resins are used in the manufacturing of wind turbine blades as structural elements, as coatings of generators and other components and as adhesives. They provide the blades with added strength and durability at a lightweight, enabling longer blades. Protective coatings prolong operational lifetimes of both components and turbines, lowering costs. These characteristics together ensure more energy generation at a lower unit cost. In the potential absence of epoxy resins, manufacturers would adopt alternatives where feasible, with adverse effects on longer turbine blades and on operational and maintenance costs of the turbine.

Epoxy resins are also used in electrical and energy distribution systems as sealants, coatings and adhesives, as well as in the manufacturing of primary components such as transformers, insulators and bushings. They are used as protective coatings in large generators and on printed circuit boards. They provide durability and performance in high-voltage systems, contributing to longer lasting and more reliable components and electricity distribution.

In the transportation sector, they are used in internal parts of vehicles, with advantages that include weight reduction (leading to lower emissions), increased durability, mechanical strength and heat resistance. In railways, their use prevents damage from debris, increases service life and helps reduce weight. In boat building, epoxy resin composite materials help to reduce weight and the need for repair, replacement and therefore maintenance costs. In aviation and aerospace, epoxy resins have supported the increased use of lightweight composite components with improved strength and durability of aircraft components, while contributing to reducing weight and improving fuel efficiency (and reducing CO2 emissions).

The aerospace and defence sectors rely on epoxy resins extensively in composites, adhesives, coatings, electronics, and many other uses. Their ability to create lightweight, high-strength structures, weather and chemical resistant coatings, and reliable high-strength adhesive bonds are extensively exploited to provide warfighters with capable, transportable, and affordable systems. Lightweight composites used in newer aircraft positively impact fuel a reduction in fuel consumption and therefore greenhouse gas emissions. There are not currently alternatives available, and their qualification takes longer times than many industries due to the safety concerns and regulatory testing and certification requirements

Medicinal products packaged in cartridges or vials: aluminium seals (cartridge disc seals and vial flip off seals) use an epoxy lacquer (clear or colored) covering the aluminum seals. BPA is a building block for the epoxy lacquer. This lacquer is protecting the aluminum from oxidation, providing an acceptable cosmetic aspect. BPA is mostly consumed within the manufacturing process, however there is a potential for a low amount of BPA to migrate from the cured epoxy. Alternatives to the epoxy such as aluminum anodization or polyester lacquer has been tested by suppliers. To date, no alternative to epoxy was found acceptable. Adhesives also use epoxy chemistry similar to that in the aluminium seals. Alternatives could potentially be offered by suppliers however this would be a significant undertaking including the need for re-evaluation studies.

Epoxy resins are extensively used in commercial construction, providing particularly strong bonding adhesives, sealants and fillers. Often marketed as replacements for mechanical fixings and to repair bridge decks, epoxy resins are suitable for internal and external use given their strength, durability and chemical resistance. Epoxies are also used extensively in flooring, protecting against wear, preventing slippage and providing high chemical and abrasion resistance. As the largest end-user sector examined, accounting for 22% of epoxy resin manufacturer's sales.

In the medical sector, epoxy resins are widely used in surgical instruments, diagnostic equipment and Prosthetics. There are many other sectors in which epoxy resins are used, which include also home, leisure, information and communication technologies, and food and water sector.[2]

[2] See more information on the following link

Fluoroelastomers (FKM)

FKM polymers are used in automotive, aerospace, and industrial applications, where a combination of heat and chemical or oil resistance are needed from a single component, such as a seal or hose. FKM are indeed ideal for applications that require resistance to fuel mixtures and solvents, such as fuel hoses and seals used in the automotive or chemical processing sectors. BPAF is the most widely used crosslinker for FKM. Crosslinking with BPAF gives base polymers elasticity, which is essential for sealing properties. The BPAF is almost entirely converted in to crosslinks with an extremely limited residual part, which would not end up in the environment. For that reason, we see no reason to restrict its use in such applications.

The EU has its own set of emissions standards that all vehicles must meet. Currently, standards are set for all road vehicles, trains, barges, and 'nonroad mobile machinery'. A large part of the seals, tubing and hose in cars are made with BPAF crosslinked FKM, specifically designed to meet the above-mentioned standards. Emission standards set quantitative limits on the permissible amount of specific air pollutants that may be released from specific sources over specific timeframes and BpAF crosslinked FKMs provide the best performance in that regard because they are specifically designed to meet the applicable standards. The main reason is that FKM has excellent heat resistance. FKMs are used so that these pollutants cannot penetrate car part barriers. Hence, without these products, automotive and non-road machinery companies in the EU will be unable to achieve emissions standards such as Commission Regulation (EU) 2016/646 as regards emissions from light passenger and commercial vehicles (Euro 6), the requirements of which determine air pollutants released into the atmosphere.
Restricting the use of BPAF is not technically possible for FKM and their downstream users. There are currently no alternatives to BPAF that provide the necessary performance.