October 20, 2023

The Honorable Dr. Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
United States Environmental Protection Agency
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Additional Comments of the North American members of the American Chemistry Council's Polycarbonate/BPA Global Alliance (Alliance) submitted on *Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)* (Proposed Rule) (Docket No. EPA-HQ-OPPT-2020-0465)

Re: Negative Potential Impact of the Proposed Rule Prohibiting Use of Methylene Chloride on the Polycarbonate Industry's Downstream Customers

Dear Administrator Freedhoff:

Thank you again for discussing the Proposed TSCA Risk Management Rule on Methylene Chloride with the Polycarbonate/BPA Global Alliance of the American Chemistry Council (ACC) on September 18, 2023. We appreciate that, at the meeting, the U.S. Environmental Protection Agency (EPA) agreed to allow ACC's Polycarbonate/BPA Global Alliance to supplement its July 3, 2023 comments to the proposed rule with additional details on the crippling impact of the proposed rule on downstream products. We request that you include this additional information in the rulemaking docket.

Polycarbonate goes into hundreds of product applications. The proposed ban of methylene chloride's use in polycarbonate manufacturing would not just effectively eliminate U.S. manufacturing of polycarbonate, it would also trigger an extremely adverse chain reaction on downstream customers including the medical, automotive, and electronics/electrical industries, as well as impact key military applications. These comments explain how the proposed rule would create the need for a large number of downstream customers to recertify a new material or similar imported polycarbonate, a process that, in some cases, would be extremely costly and take years. Moreover, suitable alternatives might not be available for all applications.

The impact on the medical industry alone would be profound. The proposed rule would disrupt supply for over a year on life-saving devices including the 100 million dialyzers used annually by approximately 700,000 U.S. patients. Makers of blood oxygenators, a critical device routinely used during cardiac surgery, would face similar disruption.

1. **Medical Devices**

Interfacial polycarbonate has played a key role in the medical field since the 1960s. It is used to manufacture many medical devices, such as hemodialyzers, anesthesia containers, blood oxygenators, arterial filters, intravenous connectors, vaccine production, syringes, medical personnel PPE, sample bottles, and endoscopic surgical appliances. It is one of the most widely used and tested thermoplastics in use in the medical device industry today. This is based upon its strength, optical clarity, high heat distortion temperature and dimensional stability. Interfacial polycarbonate can be manufactured to withstand radiation and high temperature liquid resistance, or it can be blended with other materials.

Interfacial polycarbonate films are often used for sterile medical packaging. Any change to the manufacturing process, or even manufacturing location, of polycarbonate would impact the availability of these products.

Many polycarbonate grades have FDA Master Files, which include the manufacturing process, composition, and manufacturing location. The Master Files are referenced by customers in their medical device submissions to the Food and Drug Administration (FDA). Any change to the manufacturing process or location, which would be the case with a ban on the use of methylene chloride, requires updates to all affected Master Files and could affect FDA clearance of a customer's medical device. This is another example of the negative chain reaction: changes to the polycarbonate production process would affect the Master Files which in turn would disrupt the supply of medical devices to the U.S. market.

When a change of materials (manufacturing process or composition) is required in medical device manufacturing, companies require a minimum of one year and extensive, expensive testing to manage the transition if the solution for replacement is known. A known replacement would still require biocompatibility and demonstrated effectiveness and safety. It is important to restate that a known replacement for interfacial polycarbonate does *not* exist in the U.S. EPA's proposed rule would trigger a change in materials and this would significantly disrupt product supply to existing patients.

In addition to the one-year minimum time required for minor changes, EPA's proposed ban on the use of methylene chloride would result in product changes that medical manufacturers would consider to be "significant" and with no assurance of being acceptable. A "significant" change in the medical industry includes a change in the solvent used in polycarbonate manufacturing, in polycarbonate process (*i.e.,* melt polycarbonate), in manufacturing location, or to a different material (non-polycarbonate). EPA's proposal would exceed the "significant" threshold, and this would result in industry-wide review of alternatives and changes expected to take well over the one-year minimum. Device manufacturers would not be able to supply the U.S. market with devices until the changes were validated to the satisfaction of U.S. regulators. The same factors apply to exported medical devices. Device manufacturers would not be able to export these devices to other countries until reviewed and approved by international regulators. As mentioned, common medical devices using polycarbonate include dialyzers, IV components, blood oxygenators and drug delivery devices.

Application	Impact
Insulin pumps & continuous glucose monitors	Significant disruption of device supply for the 1.9 million patients living with type 1 diabetes, including about 244,000 children and adolescents in the U.S.
Dialyzers	Significant impact to hemodialysis treatments, used for 700,000 patients within the U.S. affected by chronic kidney disease requiring 100,000,000 dialyzers per year.
IV access components	Most hospitalized patients require IV lines. Polycarbonate is a dominant material for the rigid connectors and IV catheters. Very significant disruption to the IV supply chain would occur.
Surgical Devices	Membrane oxygenators and cardiotomy reservoirs made with polycarbonate are used during invasive surgical procedures, such as open heart surgery. Supply disruption could limit the ability to perform these procedures.

Similarly, all polycarbonate marketed for food contact is manufactured under defined FDA regulations. Any changes to the production process that vary from the relevant FDA regulation would render the polycarbonate unusable for food contact applications.

2. **Automotive Original Equipment Manufacturers (OEMs)**

Many automotive producers have rigorous approval processes for materials used in vehicles and requirements related to the origin of materials. A change in the manufacturing process to make polycarbonate, or changing from domestic to non-domestic manufactured polycarbonate, would necessitate that the material be re-approved by the OEM customers. This would have a massive impact on the supply chain for the automotive OEMs.

EPA's proposed rule would require automotive OEM customers to re-qualify existing parts using U.S.-manufactured polycarbonate. The cost of re-qualifying an alternative material is $10,000 to $100,000 per auto part and the number of auto parts that would have to be re-requalified is in the thousands. Given the enormity of the cost impact on automotive OEMs alone, the negative chain reaction of EPA's ban on the use of methylene chloride would be far-reaching and extremely adverse.

Besides cost, there is also a substantial time element. Some re-qualifications take up to four years, especially if it is a safety-related part (or AMECA[1] listing is needed) as it must go through weathering cycles and performance tests that take years to complete. Human and technical resources are limited at every level in the industry. A re-validation of this magnitude would take up to 10 years to be completed on the current 145+ models and variations that are currently produced in the U.S., as well as the parts

[1] https://ameca.org/list-of-acceptable-plastics/

manufactured for exportation. The automotive industry starts the engineering and design of a car up to four years before its launch, so changes into these considerations would also have to be adjusted for the 45+ new vehicle models that the U.S. launches every year. Safety applications can only be met using polycarbonate and its blends; eliminating the capacity of production in the U.S. would lead to a shortage of polycarbonate, increasing prices and lead times.

Forward lighting headlights depend on the clarity and impact of polycarbonate for driver and pedestrian safety. Interfacial polycarbonate is superior to melt polycarbonate in both these categories and, therefore, melt polycarbonate is not a drop-in replacement for interfacial polycarbonate in this critical safety component of the vehicle. AMECA lists plastics that can meet the Federal Motor Vehicle Safety Standards in 49 C.F.R. § 571.108 for materials used in forward lighting applications to ensure the headlamp assembly maintains impact and clarity over the extended life of the vehicle. There are limited melt polycarbonate products with the AMECA listings needed for these applications and AMECA listing can require multiple months of testing for approval. Performance issues or supply shortages would result from a loss of interfacial capacity in the U.S. and hinder auto industry production of vehicles for an extended time.

Electric vehicles and the infrastructure required to support them have multiple applications using interfacial polycarbonate that would all need to be recertified and qualified. Given some of the unique polycarbonate copolymers that are specified in Electric Vehicle Service equipment, this could require a complete re-design of the unit or compromise on safety margins. Based on these re-designs, re-qualifications could take 3 to 5 years due to long-term testing and weathering cycles.

Application	**Impact**
Forward Lighting	Currently, polycarbonate and its blends are the only materials that meet safety standards. Eliminating capacity of production in the U.S. would lead to significant supply chain disruption.
Interiors	Safety requirements, including "head impact," cannot be met by any other resin.
Glazing	Lightweighting and fuel/battery charge efficiency would decrease, as well as safety for pedestrians and passengers.

3. **Electronics & Electrical Products**

Polycarbonate blends, including interfacial polycarbonate, are used in the following electronic applications: housings for cell phones, tablets, computers, chargers, base stations, servers, etc. Numerous electronic applications must meet industry standards set by Underwriters Laboratories.[2] These standards are set to ensure consumer safety in end-use applications. To redesign a product to meet the standard would take, on average, a minimum of two years; longer, if more than one UL certification is needed. In addition, changes to cell phone applications could disrupt the national 5G

[2] https://www.ul.com/services/combustion-fire-tests-plastics

rollout. There are initiatives associated with solar panel systems and EV charging stations (commercial and residential) that are being launched and developed with UL listed materials based in interfacial polycarbonate in the U.S.

Application	Impact
LED Lighting	Alternative material would have trouble meeting the thickness, flame-retardancy, and transparency requirements.
Notebook Computer	Extremely hard to substitute, requires hydrolytic resistance, high heat, and dimensional stability.
Servers	Would need to totally redesign the product to account for heat.
Appliances	Large cost to redesign using a different material.

4. **Polycarbonate Sheet and Film in Military Applications**

Polycarbonate is used to make polycarbonate sheet. Although polycarbonate sheet does not necessarily require interfacial polycarbonate, it is used in key U.S. military applications. Full dependency on imported material, which would result from a ban, would not be prudent. Military applications include all fighter jet canopies and bullet resistant glazing used in armored vehicles as well as other bullet resistant glazing applications.

5**.** **Aerospace**

Specialty polycarbonate blends are specified in commercial aerospace applications based on a balance of properties, including impact, heat resistance and compliance to the stringent flame, smoke, and heat release requirements of Federal Aviation Administration (FAA) regulations found at 14 CFR § 25.853. In addition, these materials meet major aircraft OEM toxicity requirements. Re-design of components and re-qualification of materials can take 5+ years and re-testing costs could range from $10,000 to $100,000 per component.

A common aircraft component that requires highly flame-retardant polycarbonate is the clear, transparent dust cover to the window. This is the part that one can touch inside the airplane when the shade is open. The application has a unique set of performance requirements including high impact resistance and flame resistance. Polycarbonate has been used for over thirty years and innovation is likely required to develop an alternative. Until such an innovation is developed, this could lead to a reduction in safety that would require FAA regulation changes and risk stoppage of airplane refurbishments and new aircraft manufacture.

6. Conclusion

Overall, the proposed rule's impact on downstream markets would be massive and impact the supply chain, lifesaving medical treatments, and consumer safety and quality of life. In summary, ACC respectfully requests EPA consider the detailed and effective procedures and processes already in place that protect employees from the risks of use of methylene chloride in polycarbonate manufacturing. Robust programs and protective measures are in place today and EPA should change its proposed regulatory action to allow continued use of methylene chloride in polycarbonate manufacturing in compliance with a workplace chemical protection program.

Thank you for your thoughtful consideration of these comments. We are happy to answer any additional questions you may have regarding the information above.

Sincerely,

Samir Hifri
Chairman & President
Covestro LLC

Chris Jahn
President & CEO
American Chemistry Council

Brian J. Powers
President
SABIC Innovative Plastics US LLC