

Introduction

EPA's proposed regulation of methylene chloride (88 F.R. 28284) would prohibit its use in the manufacturing of polycarbonate and would offshore, most likely to China, all U.S. manufacturing of polycarbonate and put at risk the security of a supply chain that was deemed critical during the COVID shutdown. It would also severely disrupt key value chains for medical devices, transportation, electrical and electronics, security, and military applications. Importantly, the Proposed Rule is not necessary to protect employee health and safety because the polycarbonate industry has used this chemical safely for decades. In comments to the Proposed Rule, the U.S. polycarbonate industry demonstrated its ability to meet the EPA's proposed Workplace Chemical Protection Program (WCPP) for methylene chloride. We ask that the final rule remove the prohibition on methylene chloride use in the "industrial and commercial use for plastic and rubber products manufacturing" and "industrial and commercial use as a processing aid" conditions of use. Instead, the final rule should adopt the primary alternative regulatory action for these uses, that is, allow these uses to follow the WCPP.

Economic Impact and Supply Chain Security

There is no feasible alternative to using methylene chloride in polycarbonate manufacturing. Prohibiting the use of methylene chloride would effectively shut down all domestic manufacturing of polycarbonate, eliminating thousands of jobs for U.S. workers. Further, the economic ripple effects of this shutdown would be significant, because the domestic polycarbonate manufacturing industry supports jobs for both upstream and downstream users.

Prohibiting the use of methylene chloride in polycarbonate manufacturing would disrupt essential supply chains. U.S. producers of polycarbonates and their co-polymers use interfacial polymerization to create a unique high-performing products. These materials are critical to numerous applications and markets, including health care, consumer electronics, aerospace, mobility, military, infrastructure, and personal protective wear. Foreign producers of polycarbonates primarily use a different polymerization process, resulting in materials that cannot meet the performance demands required in these applications. Patients must be able to rely on medical devices that are durable and long-lasting. Drivers must be able to rely on cars that drive safely. The U.S. government must be able to rely on military capabilities that meet national security needs.

Even if foreign sources of acceptable polycarbonates could be found, interruption risks exist, and the prices of foreign polycarbonate would be significantly inflated due the increased demand on top of the ongoing supply chain and inflation issues.

Demonstrated Ability to Meet the Proposed Rule's WCPP

Methylene chloride is used in the manufacturing of polycarbonate in a closed system and there is no exposure during normal operations. Moreover, the integrity of these closed systems is monitored by Leak Detection and Repair programs. Situations where exposures could exceed acceptable limits, such as unscheduled maintenance, are managed with administrative controls,

engineering controls, and PPE based on the hierarchy of controls, job safety analyses and safe operating procedures. This is the same approach as in the WCPP.

The polycarbonate industry has a long history of compliance of safe use of the chemical. Even though the Proposed Rule's WCPP for methylene chloride is more conservative than the OSHA safety standard, the polycarbonate industry has demonstrated to EPA that existing exposure control plans already meet the WCPP. In support, the polycarbonate industry has provided to EPA exposure data including general area samples, personal full-shift samples, personal short-term samples, and fence line samples.

Impact on Medical Device Value Chain

The Proposed Rule would significantly disrupt the medical device value chain. Interfacial polycarbonates are essential components of a multitude of medical devices, including hemodialyzers, anesthesia containers, blood oxygenators, arterial filters, intravenous connectors, vaccine production materials, syringes, medical personnel PPE, sample bottles, and endoscopic surgical appliances. Devices like these are critical in everyday life and especially in a medical emergency such as the COVID-19 pandemic. The interfacial polycarbonate produced in the U.S. provides the needed strength, optical clarity, high heat distortion temperature and dimensional stability for these demanding settings. Polycarbonates produced without methylene chloride cannot perform as needed and would compromise the health and safety of U.S. citizens. Further, medical device supply chains are highly regulated. Any changes to materials used in medical device manufacturing is subject to significant regulatory review that would cause supply chain delays or gaps.

Impact on Electrical and Electronics Value Chain

The Proposed Rule would significantly disrupt the electronics value chain. Consumer electronics depend on the use of interfacial polycarbonates to provide the strength and durability needed for computer components, charging stations, cell phone housing, and servers to perform as required. Using non-interfacial polycarbonate materials in these products would result in lower-quality electronics that cost consumers more due to supply disruptions and delays due to regulatory oversight.

Impact on Automotive/Aerospace/Transportation Value Chains

The Proposed Rule would significantly disrupt the transportation value chain. In the automotive industry, interfacial polycarbonates are used to make headlights with the clarity and durability needed for driver and pedestrian safety. They are needed to comply with numerous safety standards, including "head impact." They are used to create safer and more efficient electric vehicle batteries. In the aerospace industry, interfacial polycarbonates are the only materials that can withstand the high-performance demands of the aerospace setting while meeting the critical challenge of reducing weight to conserve fuel and lower emissions.

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, or changing from domestic to imported polycarbonate, would necessitate that the material be re-

qualified by the Original Equipment Manufacturers. 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 requalified is in the thousands. 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. A re-validation of this magnitude would take up to 10 years to complete on the current 145+ models and variations that are currently produced in the U.S., as well as the parts manufactured for exportation.

In addition, specialty polycarbonate blends are specified in commercial aerospace applications and must meet Federal Aviation Administration regulations. Re-design of components and re-qualification of materials can take over 5 years and re-testing costs could range from \$10,000 to \$100,000 per component. Given the enormity of the cost and time impact on both industries, the negative chain reaction of EPA's ban on the use of methylene chloride would be far-reaching and extremely adverse.

Impact on Military/Security/Safety Value Chains

The Proposed Rule would significantly disrupt the military and security value chain. Interfacial polycarbonate is used to manufacture items including bulletproof glass for military vehicle and prison windows, portable shields and helmets, visors, riot gear, and fighter jet canopies. These devices must perform in high-demand environments – the lives of our military personnel and those they defend depend on it. Only the interfacial polycarbonates made in the U.S. can produce materials with the needed strength, clarity, and stability.

Conclusion

In summary, we ask that the Proposed Rule prohibiting the use of methylene chloride in “industrial and commercial use for plastic and rubber products manufacturing” and in “industrial and commercial use as processing aid” be changed to the primary alternative regulatory action of the WCPP. This would be a win-win-win. EPA would be able to protect workers to its new standard, the U.S. economy would be able to continue to benefit from the manufacture and use of polycarbonate, and the Administration would be able to protect a critical supply chain.