



MARYLAND TECH COUNCIL

TO: The Honorable Brian J. Feldman, Chair
Members, Senate Education, Energy, and the Environment Committee
The Honorable Pamela Beidle

FROM: Andrew G. Vetter
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DATE: March 15, 2023

RE: **OPPOSE** – Senate Bill 916 – *Environment – Ethylene Oxide – Prohibition*

The Maryland Tech Council (MTC) writes in **opposition** to *Senate Bill 916: Environment – Ethylene Oxide – Prohibition*. We are a community of over 700 Maryland member companies that span the full range of the technology sector. Our vision is to propel Maryland to become the number one innovation economy for life sciences and technology in the nation. We bring our members together and build Maryland's innovation economy through advocacy, networking, and education.

Senate Bill 916 prohibits the use, manufacture, sale, offering for sale, or distribution of ethylene oxide (EtO) in the State. EtO is a gas that is commonly used in the sterilization of medical devices. The sterilization of these devices is done in a safe, tightly controlled, and highly regulated manner to ensure medical devices prevent infection and lead to safe surgeries and medical treatments for patients. According to AdvaMed, the Advanced Medical Technology Association, approximately 50% of all medical devices are sterilized with EtO, and for many of those devices it is the only option for sterilization. If EtO could not be used for sterilization purposes, there could be significant disruptions in the medical device supply chain and adverse impacts to Maryland's health care system and patients.

EtO is already highly regulated at the Federal level. The Federal Food and Drug Administration (FDA) has regulations to ensure that manufacturers' sterilization methods are properly validated, and the Environmental Protection Agency (EPA) sets emissions standards for EtO under the National Emission Standards for Hazardous Air Pollutants rule, which applies to commercial sterilization operations. In addition, the Occupational Safety and Health Administration (OSHA) sets permissible EtO exposure limits for workers under the Toxic and Hazardous Substances rule.

Senate Bill 916 proposes a prohibition on EtO – as drafted, it would have a significant impact on several MTC member companies in the "Medtech" industry that manufacture medical devices which must be sterilized to be safely used. As such, the proposed prohibition could have a significant detrimental impact to those companies and their employees. Given that the use of EtO is already strictly regulated by the FDA and emissions controlled by the EPA, we request that the General Assembly take time to complete additional due diligence on this issue before taking the drastic step of imposing a prohibition.

In fact, Maryland would become the first state in the nation to impose such a prohibition. Before taking this step, we believe that additional examination and discussion is warranted. MTC would be pleased to serve as a convener of our MedTech member companies to participate in a substantive discussion of appropriate regulatory steps at the State level moving forward.

For these reasons, MTC respectfully requests an unfavorable report.