EOSA **The Ethylene Oxide Sterilization Association, Inc.**
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March 14, 2023

Senator Brian J. Feldman
Chair
Senate Committee on Education, Energy and the Environment
Miller Senate Office Building, 2 West Wing
11 Bladen Street
Annapolis, MD 21401

Re: **SB 0916 – Environment – Ethylene Oxide – Prohibition**

Dear Chair Feldman and Members of the Committee:

On behalf of its members, the Ethylene Oxide Sterilization Association, Inc. (EOSA) is submitting this letter to request for an **UNFAVORABLE** report on Senate Bill 0916. Senate Bill 0916 has the potential to devastate the medical device sterilization capacity and spice treatment/pathogen reduction capacity in Maryland and the United States. Given these serious negative impacts, it is imperative that the Senate Bill be stopped to avoid creating a crisis with respect to availability of medical devices and spices. This is also very important given that the data and science do not support the underlying basis for this Bill.

EOSA members represent a broad spectrum of the U.S. ethylene oxide (EtO) sterilization industry. EOSA is a nonprofit organization that represents EtO suppliers, spice processors, contract sterilizers, sterilization equipment manufacturers, medical device manufacturers, analytical equipment and systems suppliers, and laboratories. EOSA members work diligently to assist in providing life-saving sterile healthcare products around the world, over 50% of which are sterilized using EtO, and assist in providing safe and wholesome spices for consumers. EOSA works to educate industry, regulators, and the public on the essential uses and benefits of EtO sterilization, for which no direct replacement is currently, and not for the foreseeable future, available. EOSA also works to improve safety standards, foster industry communication, and provide a forum for many subjects related to EtO sterilization.

EOSA and its members believe that the safety of surrounding communities and workers in the EtO sterilization industry is critically important. The EtO sterilization industry has historically undertaken, and will continue to undertake, significant efforts to reduce the emissions and potential worker exposure of EtO utilizing the best available technologies and practices. EOSA is providing these comments to ensure that regulatory decisions reflect accurate facts, the best available science, and proven technologies and practices.

Some of the critical facts and information are:

- The critical and essential need for EtO sterilization capacity to ensure available and safe medical devices for the U.S. healthcare system, and the importance of this availability to public health must be carefully considered to ensure no adverse impacts to public health, including potential loss of life resulting from lack of availability of sterile medical devices. The loss of medical device sterilization capacity at even one facility creates a potential risk for medical device shortages due to the limited available capacity of other sterilization facilities to assume sterilization of the medical devices that were sterilized at a closed facility, in addition to lengthy sterilization process validation and regulatory approvals that would be required.

- Approximately 50% of medical products sterilized (U.S. ~20 billion/year) are sterilized using EtO, and currently there are no alternative methods that can replace it. Alternatives to industrial EtO sterilization are limited in material compatibility, penetration, and scalability. Use of other proven industrial sterilization methods, such as radiation and steam, are not compatible with the majority of products currently sterilized by EtO. Novel methods, such as vaporized hydrogen peroxide (VHP), chlorine dioxide (ClO_2), nitrogen dioxide (NO_2) and others, are very limited in terms of applicability. Even if viable alternatives could be developed in the future, it will take years, if not decades, to develop and acquire the required U.S. Food and Drug Administration (FDA) approval. The development of new life-saving, life-sustaining, and life-enhancing products, which could include new materials, new devices, combination devices, etc., can often only be accomplished using EtO as the sterilization modality.

- There are not currently any viable fumigation alternatives for spice products, and where alternatives exist for a limited number of products, there are serious limitations. Alternatives, including steam and irradiation, are limited by their capacity, quality, and/or degradation. EtO remains an essential and necessary tool for the spice industry to comply with food safety requirements and to ensure a supply of clean and safe spices.

- The U.S. Environmental Protection Agency's (EPA) 2016 Integrated Risk Information System (IRIS) value is scientifically flawed and should not be used in EtO risk assessment or regulatory decision making. Alternate risk values have been developed by credible regulatory bodies, such as the

Texas Commission on Environmental Quality (TCEQ), and the disparity between these assessments and the 2016 IRIS value (>2,000 fold) warrants significant concern in relying upon IRIS for a decision of this magnitude. According to IRIS, normal background concentrations of EtO (from automobile exhaust, decay of plant matter, etc.), as well as endogenous EtO (from naturally generated within our bodies and normal biological functions), would cause unacceptable bystander risk for everyone.

Thank you for your consideration of these comments. It is critical that federal and state agencies consider the information presented above since it is of paramount importance not to overestimate the potential risk of EtO from its critical sterilization use. EOSA urgently requests for an **UNFAVORABLE** report on Senate Bill 0916.

Sincerely,

Meibao Zhuang
Senior Manager
The Ethylene Oxide Sterilization Association, Inc.