HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

June 26, 2023

Submitted Electronically via https://www.regulations.gov/

U.S. Environmental Protection Agency
EPA Docket Center
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Request for Comments on the Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide [Docket No. EPA-HQ-OPP-2013-0244-0044]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments to the U.S. Environmental Protection Agency (EPA) regarding the proposed interim registration review decision and draft risk assessment addendum for ethylene oxide (EtO).

HSCA represents the nation's leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners of virtually all of America's 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. GPOs lower costs for patients, providers, payers, Medicare and Medicaid, and taxpayers. A recent analysis found that GPOs save the U.S. healthcare system $34.1 billion annually, go up to $456.6 billion over ten years, and up to $116.3 billion in Medicare savings and $90.2 billion in Medicaid savings over the same period. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

Healthcare GPOs are committed to bolstering the resiliency of the healthcare supply chain, ensuring that patients and providers have consistent access to essential drugs, products, and devices. GPOs are committed to ensuring patient and provider safety while simultaneously taking into account important environmental considerations. HSCA and its member GPOs recognize the importance of transparency and communication when determining if ethylene oxide meets the standards to be considered a pesticide pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

EtO is used to sterilize approximately 50% of all medical devices annually. Many medical devices – including pacemakers, heart valves, and breathing tubes – can only be sterilized using EtO and would be deemed unsafe for use if sterilized through other mechanisms. The EPA's Proposed Interim Decision dated March 28, 2023, states there are currently "no viable alternatives for EtO for the sterilization of certain medical devices and equipment," and that, "The absence of EtO for use on medical devices and equipment would cause widespread disruption to the availability of sterile medical devices."

As the Proposed Interim Decision indicates, EtO is "highly valuable because it is a penetrative gas that has a high throughput capacity, is effective at a wide range of temperatures, and is compatible with a broad range of materials." Additionally, EtO is the only disinfectant that can penetrate multiple layers of packaging without degrading certain materials like resin or plastic that are used in catheters and tubes. It is also the preferred sterilant for many devices made from certain plastics, resin, metals, or glass due to

its ability to kill microorganisms at low temperatures, as well as penetrate multiple layers of packaging or hard-to-reach crevices. These factors are important and must be considered in the Proposed Interim Decision for EtO. HSCA is concerned that some of the changes in the Proposed Interim Decision could lead to severe delays in sterilizing healthcare facilities, medical devices, and equipment, and could lead to treatment delays for providers and patients across the country.

Given the unique line of sight of GPOs across the entire healthcare delivery system, HSCA and its members respectfully make the following recommendations:

Take Steps to Minimize Disruption to the Broader Healthcare System When Finalizing the Proposed Interim Decision

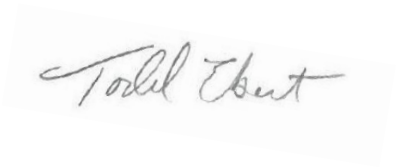
HSCA supports the Agency's mission to protect the environment and public health, and we also recognize the importance of patient safety and access to effective, uninterrupted medical care. As the Agency continues its efforts to reduce exposure to EtO, it is critical that the healthcare sector be able to maintain a high standard of product sterility and that the sterilized products necessary to care for patients remain available. Sterility is critical to reducing the risk of product contamination and negative patient outcomes that can occur as a result of contamination. HSCA member GPOs work to ensure that patients and providers have consistent access to essential drugs, products, and devices. HSCA recommends that the Agency take all possible steps to minimize disruption to the broader healthcare system in the U.S. when finalizing the Proposed Interim Decision.

Increase Transparency, Communication, and Collaboration with Agencies and Supply Chain Stakeholders

The Agency's determination within the Proposed Interim Decision that mitigation of inhalation risk concerns is necessary for EtO to meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for continued registration would require additional, real-time monitoring. Specifically, the Proposed Interim Decision requires facilities to "monitor both processing and non-processing areas, for which the monitoring system would have a visual and audio alarm to alert employees when 10 ppb air concentration is exceeded." While the Occupational Safety and Health Administration (OSHA) requires EtO exposure monitoring, real-time monitoring has the potential to be both expensive and disruptive. If real-time monitoring is ultimately required, HSCA recommends that EPA work with companies that offer real-time EtO monitoring technology to make it more affordable and widely available. HSCA also recommends that EPA work with OSHA to develop EtO levels and exposure monitoring processes with the input of healthcare professionals who can offer perspectives on how to integrate monitoring in a non-disruptive fashion.

We appreciate the opportunity to provide you with our perspective and we look forward to continuing to serve as a resource to our federal partners to maintain a healthy supply chain and protect access to essential drugs and products. Please do not hesitate to contact me directly if HSCA can be a resource on this issue moving forward. I can be reached at (202) 629-5833 and tebert@supplychainassociation.org.

Sincerely,



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