HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

June 27, 2023

By Electronic Submission

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments On The Proposed Rulemaking, "National Emission Standards For Hazardous Air Pollutants: Ethylene Oxide Emissions Standards For Sterilization Facilities Residual Risk And Technology Review" (DOCKET ID NO. EPA-HQ-OAR-2019-0178)

Dear Administrator Regan:

On behalf of the Health Industry Distributors Association (HIDA), I write to submit comments in response to the Environmental Protection Agency's (EPA's) proposed rulemaking, "National Emission Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide (EtO) Emissions Standards for Sterilization Facilities Residual Risk and Technology Review" (EtO Commercial Sterilizer NESHAP).

HIDA is the industry trade association representing 118 medical product distribution companies operating 500+ medical distribution centers across the care continuum nationwide. HIDA members deliver medical products and supplies, manage logistics, and offer customer services to virtually every healthcare provider. In 2020 and 2021, they reliably delivered over 90 billion units of PPE "the last mile" to providers.

HIDA appreciates EPA's commitment to addressing EtO risk using the best science and regulatory tools available under the law to protect community members and employees. Healthcare distributors also want to protect public health, and to do so they must be able to deliver sterile critical medical products to providers without interruption in the supply chain. Regulatory policies that limit or abolish the use of EtO as a sterilization agent would have a profound negative effect on healthcare providers and patients.

Sterilized medical products are critical to healthcare. Medical devices are composed of many different types of materials that can be damaged if exposed to the wrong type of sterilization. For example, radiation can make plastics brittle, steam can damage electronics, and heat can melt acrylics. Poor or incomplete sterilization can lead to transmission of infectious diseases or compromised patient health. EPA stated in the Federal Register, "Commercial sterilization facilities play a vital role in maintaining an

adequate supply of medical devices," and about 50% of all medical devices are sterilized with EtO.[1] This amounts to more than 20 billion devices annually.

For many medical devices, EtO is the only sterilization method that does not damage a device during the sterilization process. It is often the most effective sterilizing agent for devices that have many packaging layers or hard-to-reach areas. An open-heart surgery kit has 200 components of different types of medical products. Life-saving items commonly used to treat patients across all care settings made with materials as diverse as polyurethane and gels for hydrocolloid wound care dressings, stents for heart surgery, catheters for delivering or draining fluids, and custom procedure packs such as for emergency cesarean sections.

HIDA would like to offer comments on the proposed EtO Commercial Sterilizer NESHAP rulemaking that will address the following:

1. Availability of sterile product
2. Expansion of Title V Permit requirements
3. Fenceline monitoring
4. Emissions limits
5. Emissions rate requirements
6. Compliance timeframe

Availability Of Sterile Product

Due to our healthcare system's need for sterile medical products and devices for safe patient care, EtO sterilization is currently at capacity. This means that regulations that would have the effect of limiting or restricting commercial sterilization would be catastrophic to the healthcare supply chain, resulting in a public health crisis. EtO sterilizes 95% of all surgical kits. As previously mentioned, it is also the only safe, effective method of sterilization for about 20 billion medical products a year.

According to the U.S. Food and Drug Administration (FDA), any reductions in the capacity of the commercial EtO sterilization industry would increase the possibility of medical device shortages. At a Congressional hearing last month, FDA Commissioner Robert M. Califf M.D. stated that domestic medical product sterilization capacity is critical to protecting Americans and that a restriction of sterilization due to the EPA actions would create a problem. Additionally, Dr. Califf said that there is not an alternative to EtO at this time.

Commercial sterilization facilities sterilize different products in different quantities. You cannot simply shift operations to another facility. If sterilization facilities close or reduce their production, the healthcare supply chain would be negatively impacted because the revalidation of a single product can take months before the product can be moved to another sterilization site.

[1] 88 Fed. Reg. at 22793/1.

HIDA Recommends

- Continue researching alternatives to EtO while allowing commercial sterilizers to continue operations under existing Clean Air Act standards.

Expansion Of Title V Permit Requirements

Title V is a federal program designed to standardize air quality permits and the permitting process for major sources of emissions across the United States. The proposed EtO Commercial Sterilizer NESHAP formalizes community involvement in the authorization of commercial sterilizers. This level of community review is unnecessary and overly burdensome when Clean Air Act regulations already exist. In addition, as commercial sterilizers were considered part of the critical infrastructure to the healthcare supply chain early in the pandemic it is important that permitting requirements be as streamlined as possible.

HIDA Recommends

- That Title V permit requirements not be expanded.

Fenceline Monitoring

Fenceline (or perimeter) monitoring is the use of monitoring technology to measure the ambient air concentration of a specific chemical at the property line of a manufacturing site. It should be noted that the EPA's proposal does not consider background levels of EtO. EtO is a naturally occurring gas, and comes from other sources such as buses, charcoal grills, and lawn mowers. As a result, EtO has been measured in places that are nowhere near a commercial sterilization facility. It is for this reason that establishing a baseline threshold is problematic.

HIDA Recommends

- EPA not include fenceline monitoring in any proposed EtO emissions standards.

Emissions Limits

The emissions requirements proposed by EPA must be achievable. If the new standards cannot be attained, there will be substantially decreased sterilization capacity resulting in medical product shortages across the country. EPA's proposed emissions rates exceed the limits of current treatment technology. Attempting to achieve and maintain these new requirements would be both challenging and expensive, and would have little benefit since EtO levels in these facilities are well controlled at present.

HIDA Recommends

- EPA provide more flexibility in how facilities achieve new emissions limits as the proposed standards are nearly unattainable. Individual sterilization facilities should be allowed to choose the measurement method that is most appropriate for their facility.

Emissions Rate Requirements
In the proposed rule changes to the EtO NESHAP, there is mention of the EPA seeking to adopt a standardized maximum allowable mass emissions rate for two EtO usage categories: <.000025 lb/hr for facilities consuming less than 1 ton annually, and <.000021 lb/hr for facilities consuming between 1 and 10 tons annually, in an effort to reduce overall EtO emissions to the atmosphere. HIDA, however, is aware of alternative EtO sterilization processes that use considerably lower EtO volumes compared to traditional commercial sterilization.

HIDA Recommends

- EPA allow compliance for control efficiency or mass emissions rate standard that takes consumption into account.

Compliance Timeframe
The proposed compliance timeframe of only 18 months to implement NESHAP requirements is too short, especially compared to the more standard timeframe of 36 months. The entire healthcare industry is still recovering from the COVID-19 pandemic. The proposal's stringent technical requirements combined with an aggressive timeline for implementation make successful compliance difficult if not impossible. This proposal will result in upgrade-related shutdowns and appropriate time is necessary to minimize negative impact on the healthcare supply chain and ensure communities do not experience shortages of critical medical products.

HIDA Recommends

- A compliance timeframe of four years, which is the maximal permissible time under EPA's authority, to implement any new EtO Commercial Sterilizer NESHAP requirements. EPA's accelerated timeline for sterilizer facilities to meet new emission and operating requirements is not achievable. As proposed, commercial sterilizers would be required to install pollution controls within 18 months of the final rule and compliance reporting within 60 days after the final rule's effective date.

Conclusion
Given the proposed EtO Commercial Sterilizer NESHAP requirements, the resources necessary for compliance, and the tight if not impossible timeline to comply, commercial sterilization facilities that use EtO will have to either:

- Reduce production, which would result in backorders of essential medical products, while they install the required EtO controls;
- Move sterilization operations overseas, increasing uncertainty in the availability of medical products; or
- Permanently shut down, further impairing the healthcare supply chain that is still recovering from the pandemic.

Any changes to EtO policies must include a realistic and feasible plan to anticipate and address any potential product disruptions and impact on patient care. Disruption at even a single sterilization

facility can have a magnified impact across the country as devices sterilized in one facility support patient care in all 50 states.

Thank you for considering HIDA's comments for EPA's proposed EtO Commercial Sterilizer NESHAP. If you have any questions, I can be reached at rouse@hida.org.

Sincerely,

Linda Rouse O'Neill
Senior Vice President, Supply Chain Policy
Health Industry Distributors Association