HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

May 5, 2023

By Electronic Submission

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

Subject: Request For 60-Day Comment Period Extension For 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:

The Health Industry Distributors Association (HIDA) submits this letter requesting an extension of the comment period for 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 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, they reliably delivered 51 billion units of PPE "the last mile" to providers.

Sterilized medical products are critical to healthcare. 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] Should regulatory policy or actions limit or abolish the use of EtO as a sterilization agent, the negative effect on healthcare providers and patients would be profound.

Currently, the proposal published in the Federal Register on April 13, 2023, gives 60 days for public comment, closing on June 12, 2023. The EtO Commercial Sterilizer NESHAP includes thousands of pages of documents and requests comments on numerous scientific, operational, and economic issues. A 60-day comment period will not provide adequate time for HIDA to thoroughly evaluate the impact of

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

these proposals and draft thoughtful, responsive comments. We therefore request the comment period be extended by an additional 60 days.

On April 13, the EPA also published in the Federal Register the "Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Notice of Availability" (EtO PID and Draft RA). This proposal also has a direct impact on EtO commercial sterilizers and has the same 60-day comment period as the EtO Commercial Sterilizer NESHAP. This means that those wishing to provide comments on both proposals must do so in the same timeframe, while evaluating how the two major regulatory proposals interact and impact the healthcare supply chain and overall patient care. For that reason, HIDA is concurrently requesting a 60-day extension of the comment period for EPA's EtO PID and Draft RA.

Responding to these proposals requires an approach that considers the impact on the delivery of healthcare nationwide. Any changes to EtO policies must include a realistic and feasible plan to anticipate and address any potential product disruptions and 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. For these reasons, it is important that the original comment period be extended 60 days so that we can provide the most complete response to these proposed regulations.

Thank you for considering HIDA's request to extend the comment period for EPA's 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